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SELECTED SHELLFISH SANITATION REGULATIONS

for

A synthesis of requirements of various sectors of governments and industry relating to microalgal toxins and their sanitary issues

EV/HAB/02/01 – BENGUELA CURRENT LARGE MARINE ECOSYSTEM:

Harmonization of Regulations for Microalgal Toxins for Application in Countries bordering the Benguela Current Large Marine Ecosystem

LIST OF ANNEXES

Annex I

South African Molluscan Shellfish Monitoring and Control Program

DEPARTMENT OF ENVIRONMENTAL AFFAIRS AND TOURISM
Branch: Marine & Coastal Management

SOUTH AFRICAN MOLLUSCAN SHELLFISH

MONITORING AND CONTROL PROGRAMME

CONTENTS

BACKGROUND

Food safety laws throughout the world give special consideration to molluscan shellfish for a number of reasons (summarized below).

Some of them are filter feeding shellfish that accumulate hazardous levels of biotoxins and other toxins and pathogenic micro-organisms (viruses, protozoa, bacteria and helminths) in their flesh causing them to become naturally contaminated.

While filter feeding bivalve molluscs pose by far the greater public health threat from biotoxins, predatory, grazing and scavenging gastropods may accumulate toxins from their prey (e.g. toxic bivalve molluscs), food or if they grow in sea water containing toxin-producing phytoplankton. Often the source of intoxication is not clear for gastropods.

In many cases no thermal process is applied to shellfish prior to sale to eliminate pathogens and therefore, further microbiological multiplication is likely to occur. The presence of marine biotoxins is also not eliminated by cooking.

Raw molluscan shellfish receive the second highest hazard rating for all foods by the ICMSF.

An increasing number of studies worldwide are showing the presence of pathogens in near shore waters and shellfish when faecal coliforms are either absent or present in low numbers. Pathogenic viruses and vibrio's may be present suggesting that the risk of disease may sometimes be underestimated by relying on densities of faecal coliforms alone. In addition, the distribution of biotoxin producing phytoplankton appears to be spreading worldwide either as a result of increased monitoring efforts or new introductions. For these reasons shellfish quality assurance programmes should be reviewed whenever new information becomes available

This Manual has been prepared by Marine & Coastal Management (M&CM) and the Department of Food and Associated Industries of the South African Bureau of Standards (SABS), with the purpose of developing an official manual for South African operators which will provide the necessary guarantees to foreign buyers and Governments as well as to local consumers that the risk of disease and poisoning through consuming molluscan shellfish is adequately managed and minimised.

1 SCOPE AND AUTHORIZATION

1.1 This manual addresses the public health concerns of live molluscan shellfish harvested from mariculture production areas and intended for immediate human consumption or for further processing before consumption. (NOTE: The system of controls and sanitary checks covered in this manual can be extended to include wild-harvested shellfish in the future).

1.2 Hatcheries and nurseries are not subject to public health requirements provided the product is more than 6 months from minimum market size.

1.3 The manual applies to molluscan shellfish as defined under Section 12.

1.4 The manual addresses all activities related to the commercial farming of molluscan shellfish prior to placing on the market, including the growing, harvesting, wet storage, relaying, depuration, packaging, dispatch, processing, transporting, labelling and storing of shellfish.

1.5 The manual includes the monitoring activities required for audit of growing areas and establishments in the interests of public health. These activities will be managed and controlled by M&CM (under the Marine Living Resources Act No. 18 of 1998) and the Department of Health (under the Health Act No 63 of 1977 – to be replaced by the National Health Act) in cooperation with the SABS (the appointed body for administering the various Compulsory Standard Specifications for fishery products in South Africa and the recognised competent authority by certain countries for the trade and export of fisheries products).

1.6 The manual addresses the requirements for the certification and/or issue of permits for the growing, harvesting, relaying, wet storage, depuration, transport and handling of live molluscan shellfish.

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DEPUTY DIRECTOR GENERAL
MARINE AND COASTAL MANAGEMENT

_____

DATE

2. DOCUMENT CONTROL

2.1 This manual was complied by M&CM in cooperation with the SABS and the molluscan shellfish farming industry. The manual will be reviewed as pertinent new information becomes available. The review process will involve consultation with representatives from M&CM, SABS, industry, and the Dept of Health who collectively shall comprise the Shellfish Management Committee.

2.2 Suggestions for alterations that would significantly improve the document are welcomed. These should be forwarded to the co-ordinator of this document, explaining the reasons for the suggested changes.

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Cape Town
South Africa

2.3 A detailed record of all amendments shall be maintained and amended pages dated accordingly.

2.3 The latest version will be made available on the M&CM website or at SABS libraries.

2.4 To update this manual when amendments are received, remove the appropriate outdated pages and replace with pages from the new issue. Sign and date this page in the table below.

Issue No.	Date	Sign	Issue No.	Date	Sign
1			11		
2			12		
3			13		
4			14		
5			15		
6			16		
7			17		
8			18		
9			19		
10			20		

3. RULES

3.1 The definitions in Section 12 apply in this manual unless the context requires otherwise.

3.2 M&CM is the Regulatory Authority authorising the mariculture, harvesting, transport of molluscan shellfish for wholesale trading in terms of the Marine Living Resources Act No. 18 of 1998 and Regulations. Authorisations are administered through the issue of a mariculture right and permit. Associated activities such as relaying, depuration and wet storage will require special authorisation from M&CM in conjunction with the local health authority as relevant. Land-based wet storage facilities and depuration plants must obtain a Certificate of Acceptability for food premises from the local authority as required by regulations (R. 918) under the Health Act, No. 63 of 1977.

3.3 Establishments packing or processing molluscs must also be licensed by M&CM in cooperation with the SABS (canned or frozen products) and/or local health authorities (live and chilled products) as is relevant. Such establishments will be licensed only when the operator can produce a certificate of approval for the establishment, issued by the SABS, and which is not older than 3 months. Each establishment must be licensed annually.

3.4 M&CM may appoint official inspectors (e.g. SABS inspectors, M&CM control officers, environmental health practitioners) or other appropriately trained personnel to assist with the official survey and sampling activities, and for the inspection of compliance of operators with the requirements of this manual. A written appointment is required also defining the responsibilities of the inspector/officer so appointed.

3.5 Where inter-government guarantees are sought (health certificate), the competent authority (e.g. the SABS or Department of Health) must have free access to records kept by M&CM.

3.6 To enable proper liaison between M&CM and other governmental departments in regard to 3.2 - 3.4 above, a Memorandum of Understanding must be prepared and signed by all parties.

3.7 M&CM shall keep and maintain a central file containing copies of the records and documents required by this manual including:

Copies of permits and other approvals.

Official laboratory evaluation records.

Individual growing area reports (e.g. maps of growing areas, surveillance records, sanitary surveys, management plans, transport, closure, harvesting criteria adjustments, reclassification of areas and annual evaluation reports).

Details regarding mariculture operations including reconstruction and remodelling plans.

Summaries of shellfish food-borne illness reports, where available (from Department of Health).

Marine biotoxin monitoring data and notices.

Enforcement action reports;

Evaluation reports generated by foreign governments or local authorities.

All data, criteria and protocols relating to the operation of a restricted area such as relaying reports, depuration reports, harvesting permits and harvesting control records.

All data procedures and reports on wet storage.

All approved documentation for licensing of dispatch and processing establishments.

3.8 The official approved inspector servicing an establishment where molluscan shellfish are landed for relaying, wet storage, depuration, preparation, processing and final packaging or repacking must also keep a file containing copies of the relevant records, documents and reports described in paragraph 3.7.

3.9 Industry shall keep complete, accurate and legible shellfish transaction records for at least 1 year in a permanently bound ledger book (or other approved method). This pertains to each authorised marine farmer including relayer, depuration plant, wet storage unit and establishment packing and/or processing shellfish. Such records shall include:

All information necessary to trace all purchases and sales of cultivated molluscan shellfish back to their growing area source;

Dates of harvesting of molluscan shellfish and of their arrival at the licensed premises for the intended process, including dates of shucking, packing and dispatch.

Results of laboratory analyses instigated by industry.

Permanent records of relaying and depuration activities where applicable.

3.10 Permits to cultivate and harvest shellfish for direct human consumption or further processing shall be issued by M&CM subject to a satisfactory classification of the growing or relaying area following a sanitary survey. An area shall be classified as suitable for growing and harvesting shellfish if it meets the requirements for approved or controlled areas as specified in Paragraphs 4.3 and 4.4.

3.11 It is M&CM policy to promote the development of new mariculture operations in waters meeting the approved criteria. In view of the extra demands for the management and control and the greater risk of contamination for shellfish products originating from waters of lesser microbiological status than approved areas, cultivating shellfish in such areas is discouraged. Approval for cultivation in waters with limited microbial pollution will require detailed motivation.

3.12 Once a growing area has been shown to conform to the approved area requirements (Paragraph 4.3) or that it may be utilized under certain conditions (Paragraph 4.4), a permit may be issued to the operator stating the conditions for operation, harvesting, transport, relaying and marketing as may be applicable. All mariculture facilities must provide access and assistance to official staff for monitoring purposes as specified in Section 5.

3.13 Harvesting, handling and transport of molluscan shellfish by licensed operators shall be regulated as given in Section 6.

3.14 Relaying and depuration are intended to reduce the number of pathogenic organisms that may be present in shellfish from moderately polluted waters and, in the case of relaying, to reduce biotoxins to safe levels. These different purification approaches are not intended for heavily microbiologically contaminated shellfish or to reduce the levels of other accumulated toxic substances.

3.15 Purification of shellfish in relaying areas or in depuration plants may only take place with a permit obtained from M&CM. The permit shall be specific for the particular depuration plant or relaying area. The requirements for the relaying of shellfish are given in Section 7. The layout and water quality required of depuration facilities must comply with the requirements given in Section 8.

3.16 Each nearshore wet storage site for shellfish shall be approved as above (Paragraph 3.10). The general requirements for wet storage, both nearshore and land-based are given in Section 9.

3.17 Requirements for dispatch centres and processing establishments are given in Sections 10 and 11, respectively.

4. CLASSIFICATION OF SHELLFISH CULTIVATION AREAS.

4.1 Compliance

Compliance with classification objectives shall satisfy the conditions listed below.

4.1.1 A sanitary survey shall be made of each new growing area prior to its approval as a source of shellfish for direct human consumption or for shellfish to be used in a relaying or depuration facility. The sanitary survey shall be completed according to the guidelines given in Appendix II.

4.1.2 The requirements for a sanitary survey apply to both near-shore and shore-based mariculture operations.

4.1.3 Existing growing areas that have not been classified will be assessed on the basis of existing data on water quality and related public health information. Based on this review M&CM shall decide on the sanitary classification of a growing area.

4.1.4 Stretches of water are classified primarily according to their microbiological quality, though other health risks such as contamination by heavy metals and pesticides, and occurrence of biotoxin producing algae, shall be considered. Monitoring actions must take into account the risks that were established for a particular area and species.

4.1.5 Shellfish shall not be harvested for the market from a growing area until the sanitary survey has been completed and the sanitary survey report containing the recommended classification and harvesting criteria has been established officially. Results of microbiological testing of water samples taken during a period of one year from stations (indicated on a map or plan of the growing area) are used for the classification and reclassification of growing areas.

4.1.6 The sanitary classification status of production areas shall be reviewed annually taking into account new potential pollution sources and other developments.

4.2 Sanitary Survey.

The sanitary survey is of critical importance in distinguishing acceptable and unacceptable areas for shellfish production. This section sets forth the survey procedures, the classification scheme, and standards to be applied to those waters suitable for harvest for direct human consumption, those waters containing shellfish that require purification or further processing, and those waters where harvesting is prohibited.

4.2.1 Establishing sampling stations:

Officials as specified in Paragraph 3.4 may be appointed by M&CM to assist with sampling activities.

4.2.1.1 Shore-based mariculture systems.

Water samples are to be taken from the source coastal waters at the position of the proposed intake and 500m on either side this point parallel to the coastline. Water taken in for onshore mariculture must comply with the requirements for an approved area (Paragraph 4.3). If water is to be treated to conform to these requirements the microbial quality of source water, prior to disinfection, and recirculated water shall meet, at a minimum, the restricted growing area standards (Paragraph 4.4.2). Water that is excessively contaminated may not be used for mariculture.

4.2.1.2 Cultivating/growing areas in the open:

The growing area survey in open waters shall take into account the proposed positioning of cultivation structures and potential pollution sources in accordance with the following directive.

a) Possible point sources (pollution points) established:

Include a sampling station on the boundary of the growing area nearest to such a point taking the predominant circulation patterns into account. All such possible points must be fixed on the map. Other points not considered pollution points are fixed on the map as in (b). Pollution points must be numbered with the prefix "PP".

b) Other sampling points for monitoring:

Such points are established as follows and also numbered with the prefix "NP" (non pollution point or non-point).

It is recommended that one microbiological sampling station is fixed for every 10 ha of production area though factors such as the local hydrodynamics will be taken into account.

4.2.1.3 Biotoxins and other hazardous substances.

Water sampling positions for phytoplankton identification must take local hydrodynamics into account. A single key station may suffice for a particular growing area.

Shellfish flesh may be composited from a number of sampling points for analysis of other toxic and hazardous substances.

4.2.3 Frequency of Sampling Required.

4.2.3.1 A sample or sampling batch for a particular growing area is considered to include all points (PP's or NP's) which were established as sampling stations by M&CM for the monitoring action required to classify the growing area or tank establishment. All points are to be included during one sampling operation.

4.2.3.2 A minimum of 20 samples from each sampling station shall be required for microbiological classification of new production areas. The samples are to be taken by M&CM sanctioned personnel (Paragraph 3.4). Samples shall be taken at a fixed frequency (determined by M&CM) under sufficiently broad environmental conditions to identify possible adverse scenarios. It is expected the collection of this information will cover a period of at least 12 months for full classification of an area. An initial period of 3 months shall be used for provisional classification following which farm infrastructure may set up. However, the farmer must accept the risk that the production area may ultimately prove to be of unsatisfactory sanitary quality for harvest for human consumption. Harvesting for the market will only be permitted once the full annual survey is completed and the results indicate water of acceptable quality.

4.2.3.3 If samples cannot be taken on a fixed date (e.g. due to bad weather conditions, problems in getting samples to the laboratory within the prescribed time, etc.), they must be taken as close as possible to the stated date. The reason for shifting the date must be depicted in the sampler's report.

4.2.3.4 Microbiological samples shall be taken bi-weekly from each sampling point for both provisional and full classification of a growing area.

4.2.3.5 If at any stage during the sampling regime the test results fall outside specifications, weekly sampling shall either be initiated or continued until such time as the problem is identified.

4.2.3.6 Where possible, microbiological classification of growing areas is based on analyses of shellfish flesh. Where the culture species or a suitable alternative (as determined by M&CM) is not available in a new growing area water samples are analysed for microbial contamination. In the case of bivalves, it may be necessary to place bags containing the culture species in the growing area to provide flesh for additional testing.

4.2.3.7 Shellfish flesh shall be sampled twice during the classification period for analyses of heavy metals and other hazardous substances. One sample shall be taken for radionuclides during this period. Where the culture species is absent from the production area under investigation, an alternative indicator species may be used as recommended by M&CM.

4.2.3.8 Water samples for phytoplankton identification by M&CM personnel are taken at least bi-weekly.

4.2.4 Sampling protocol for microbiological parameters of production waters and products

4.2.4.1 Water must be sampled as described in the latest version of SABS 241 and submitted to an accredited or officially approved microbiology laboratory. The five-tube, three-dilution MPN test for faecal coliforms as per Annex 2B of the Bacteriological Procedures of the "Canadian Shellfish Sanitation Programme" of 31/03/1992 is to be employed.

4.2.4.2 Live shellstock, including intravalvular fluids is sampled from each station and prepared as per paragraphs 2B.2 and 2B.7.3 of Annex 2B of the Bacteriological Procedures of the "Canadian Shellfish Sanitation Programme" of 31/03/1992 and tested for their faecal coliform count per 100g with the standard five-tube, three-dilution MPN method.

4.2.4.3 Sampling procedures are summarised in Appendix I.

4.3 **Approved areas**:

4.3.3 An approved area shall not be contaminated with faecal coliforms exceeding the limits given below and shall not contain hazardous concentrations of toxic substances or biotoxins.

Faecal coliform median MPN not to exceed 14/100ml growing waters.
Not more than 10% shall exceed an MPN of 43/100ml growing waters.

4.3.3 As a water sampling scheme may miss occasionally excessively polluted events, it is preferable for shellfish (culture species or alternative, see Paragraph 4.2.3.6) to be sampled and tested.

The tolerance levels for the flesh including intravalvular fluids are:

300 faecal coliforms/100g shellfish flesh.
Total absence of *Salmonella* in 25g flesh.

4.3.3 Harvesting may take place at any time in an approved area provided a temporary closure is not in effect due to e.g. oil spills, biotoxin contamination.

4.4 Controlled areas (conditionally approved or restricted):

4.4.1 A conditionally approved area is one subject to intermittent and predictable pollution events but meets the approved area standards for a reasonable length of time.

4.4.2 Harvesting from conditionally approved areas for direct human consumption may only occur when it meets the approved area requirements. During harvesting from conditionally approved areas, samples for microbiological analyses are to be taken at least once a week to prove the conformance of the water.

4.4.3 A management plan shall be developed for conditionally approved areas that addresses the predictability of the pollution events (See Appendix II, Paragraph 7).

4.4.4 A restricted area is one in which the sanitary survey indicates a limited degree of microbial pollution. A conditionally approved area may also be classified as restricted during unfavourable conditions.

Limited pollution for seawater is defined as:

Faecal coliform median MPN of the water not to exceed 88/100ml.
Not more than 10% shall exceed a MPN of 260/100ml.

Limited pollution for shellfish meats are given as:

Faecal coliform median MPN of less than 6000/100g shellfish flesh

4.4.5 No shellfish may be harvested for immediate human consumption from restricted areas at any time. Shellfish from restricted areas can only be harvested for depuration or relaying. However, M&CM may consider the issuing of a special permit to harvest shellfish of which the faecal coliform count of the flesh and inter-valvular fluids are below 6000/100g flesh, on condition that it is canned or cooked and frozen in compliance with Section 11.

4.5 **Prohibited areas**

4.5.1 Shellfish shall not be harvested from prohibited areas for either immediate human consumption or depuration /relaying. An area will be classified as prohibited when any of the following conditions exist:

There is no current sanitary survey or annual evaluation report.

The sanitary survey indicates levels of microbial pollution exceeding those given in Paragraphs 4.4.2

The sanitary survey or other data indicate excessive contamination of shellfish with biotoxins, heavy metals, radionuclides, pesticides or other hazardous chemicals. Petrochemical contamination is also considered a food hazard.

Pollution sources may unpredictably contaminate the shellfish.

4.5.2 Areas adjacent to sewage outfalls and other waste discharges of public health significance shall be classified as prohibited. The size of the prohibited zone shall take account of the pollution source loading, dispersion characteristics of the receiving waters and decay (die-off) rate of the pollutant.

4.5.3 Seed may be taken for on-growing from prohibited areas provided it is cultured in an approved or restricted area for a minimum of 6 months prior to harvesting for human consumption or relaying/depuration.

4.6 Toxic and hazardous substance parameters for shellfish products

4.6.1 Limits for environmental toxins

The limits for toxins such as heavy metals, radio-active substances (Caesium 134 and 137), polychlorinated biphenyls and pesticides will be those described in terms of the current Foodstuffs Cosmetics and Disinfectants Act No. 54 of 1972 and Regulations. These limits apply to the fresh weight, edible portion of the shellfish:

4.6.2 Limits for biotoxins

The recommended methods for shellfish toxicity tests are given in Appendix III. No shellfish shall be harvested for direct human consumption if the following regulatory limits are exceeded:

Paralytic shellfish poisoning (PSP)	800 μg STX eq./kg edible flesh.
Diarrhetic shellfish poisoning (DSP)	Not detectable using the mouse bioassay.
Amnesic shellfish poisoning (ASP)	20 mg domoic acid/kg edible flesh.

4.6.3 Limits for veterinary drugs

The limits for veterinary medicines are given in the current Foodstuffs Cosmetics and Disinfectants Act No. 54 of 1972 and Regulations.

5 MONITORING OF SHELLFISH PRODUCTION AREAS

5.1 Background

5.1.1 A system of sanitary checks will be initiated under the guidance of M&CM for each approved and controlled growing area (including both natural and artificial areas used for mariculture or relaying and depuration) to promote public safety in both local and international markets. The functions of this programme are to:

Establish compliance with the requirements of this manual concerning microbiological quality (Paragraph 4.3 and 4.4), toxic and hazardous substances (Paragraph 4.6.1) and biotoxins (Paragraph 4.6.2) in shellfish intended for direct human consumption or for further processing prior to consumption.

Provide data for the annual review of the classification status of the production area, i.e. approved, controlled etc.

Provide an early warning system for biotoxin control, where relevant, in the interests of public health (and shellfish health and survival in certain cases).

5.1.2 Trained and approved personnel shall assist with sample collection and delivery to relevant accredited laboratories for analyses. A system of sample coding will be implemented such that the laboratories are not aware of the provenance of the samples.

5.1.3 It will be the responsibility of M&CM to co-ordinate the monitoring actions, provide a system of record keeping for the monitoring data, and enforce closures/dictate re-opening of harvesting areas subject to public health considerations.

5.2 Microbiological monitoring

5.2.1 Sampling will be dictated to a certain extent by the findings of the sanitary survey. For instance, sampling should take into account any meteorological, hydrological or other conditions that may result in a greater risk of faecal and pathogen contamination. Future developments in the area that may impact on water quality should be addressed as the need arises.

5.2.2 Shellfish grown in controlled areas shall be tested at least weekly for microbial contamination during harvesting, though the management plan for conditionally approved areas may require more frequent testing. If the sanitary survey indicates a growing area is affected by point sources of pollution, a number of fixed sampling points shall be established including both pollution point and non pollution point (Paragraph 4.2.2.2) stations.

5.2.3 Approved growing areas shall be tested at least monthly for microbial contamination. A composite sample of shellstock intended for next harvest shall be taken.

5.2.4 A minimum of 12 samples must be collected from each station over a 12 month period in approved areas, including both shellfish tissue and growing water where required. More frequent testing is required in controlled areas (Paragraph 4.4). These results will be evaluated by adding the samples to the pre-existing bacteriological results that accurately reflect the current situation. The annual evaluation shall address at least the last 20 samples for approved areas and 30 samples for controlled areas.

4.4.5 When an epidemiologically confirmed shellfish-borne illness is reported involving two or more persons and implicating a shellfish growing area, the Health official (Environmental health practitioner, Health Officer) responsible for the particular area shall, in consultation with M&CM, promptly:

Place a ban on harvest from the area

Detain and recall any remaining shellfish from the area that are in the distribution system.

Review the classification of the growing area and re-classify if necessary.

If it is determined that the growing area is not the source of the outbreak (e.g. problem caused in handling or distribution) the ban on harvest is removed and original classification status re-instated.

5.2.6 Where a growing area at any time does not comply with the sanitary requirements of its designated classification (Paragraph 4.3 or 4.4) the following actions must be undertaken by

M&CM in collaboration with the relevant Health authorities and/or the SABS (see flow diagram, Appendix IV):

Review all necessary documentation to trace and recall potentially contaminated shellfish products that are in the distribution system.

A temporary closure to harvest from that area shall come into immediate effect and that particular sampling point or points must be re-sampled with additional sampling points included.

If, at any instance, a re-test sample fails or a positive *Salmonella* presence is indicated or limits exceeded for other human pathogens as specified by a national or international authority, the growing area is closed to harvesting for direct human consumption and contaminated products are recalled.

The growing area will remain closed to harvest until the bacteriological counts show compliance (a minimum of 1 week after re-test sample failure).

Review the classification assigned to the growing area when sampling indicates an area continues to exceed its current classification limits.

5.2.7 Where an end of the line product fails to satisfy the microbiological criteria for human consumption, the following actions must be taken (see flow diagram, Appendix IV):

The relevant Health authority must investigate the possibility of a problem with handling, distribution and labelling and instigate appropriate corrective actions as required.

If the problem is not identified as related to handling, distribution and labelling, the course of actions given in Paragraph 5.2.6 come into effect for the implicated growing area.

5.2.8 Microbiologically contaminated products may also be canned or cooked and frozen as per requirements in Section 11, provided the faecal coliform count is lower than 6000/100g flesh and *Salmonella* is absent. Shellfish not conforming to the 300/100g flesh limit but which are lower than 6000/100g flesh, may be harvested for relaying or purification in a depuration plant until the animals show compliance with the 300/100g flesh limit. This option may only be exercised in accordance with special permit conditions issued by M&CM.

5.3 Monitoring of toxic and hazardous substances

5.3.1 Sampling will address variation within a production area and will be conducted annually for heavy metals, PCBs, radionuclides and pesticides on shellfish flesh only. Sampling for specific contaminants is recommended only when the sanitary survey reveals a potential problem, or if there is concern due to a paucity of data.

5.3.2 Non compliance at any sampling point will require retesting. If the retest fails, sampling should be expanded to trace the source of contamination. Growing areas face long-term or permanent closure if the situation cannot be restored.

5.4 Biotoxin monitoring

5.4.1 Biotoxins and biotoxin-producing algae shall be monitored in each growing area in accordance with a Biotoxin Management Plan. The management plan serves to clearly identify the agencies responsible for and the procedures necessary to undertake the actions listed below:

Monitor toxin producing plankton and the geographical distribution thereof on a routine basis. For the plankton component to act as an early warning system of impending shellfish toxicity, it is essential that a database be constructed relating toxic organism concentration or thresholds to shellfish toxicity. For this reason it is desirable to perform shellfish toxicity tests in conjunction with plankton monitoring, at least until there is sufficient confidence in using plankton as a proxy.

Develop a contingency plan that provides an emergency response when a potential problem is detected. The plan defines those administrative procedures and resources necessary to:

Initiate emergency shellfish and water sampling.

Close areas and embargo shellfish.

Prevent commercial harvesting from closed areas.

Recall shellfish.

Define criteria for re-opening closed areas.

Provide assurance that certain shellfish species, or products, can be safely excluded from the contingency plan. This will require collection of sufficient supporting data and will be reviewed on an annual basis by the Shellfish Management Committee comprising representatives of M&CM, the SABS, the Department of Health, the shellfish industry and relevant analytical laboratories.

5.4.2 Biotoxin Management Plan (See Appendix V)

Each growing area management plan shall include a map showing the sampling positions which are to be determined on the basis of "key stations" and "critical species". Historical data collected by M&CM around the South African coastline indicate that harmful algal blooms, some of which may be toxic, are clearly more prevalent in the west coast upwelling system with relatively few events recorded east of Cape Agulhas. The most likely candidate toxic species are *Alexandrium catenella* (PSP) on the west coast and the DSP-causing species, *Dinophysis acuminata* and *D. fortii* around the coastline. *Alexandrium catenella* has not been recorded east of Cape Point but *Alexandrium tamiyavanichii* has recently been isolated from the Western Agulhas Bank. However, substantial blooms have not been observed and the cell toxin quota is low; thus it does not appear to render shellfish toxic. In both *Dinophysis* species, cell toxin quota data indicate that they are only moderately toxic with okadaic acid the primary toxin. *Pseudonitzschia* spp are frequently encountered, in particular, *Pseudonitzschia australis*. Although a known producer of domoic acid from other parts of the world, preliminary results indicate that blooms of *P. australis* on the west coast of South Africa are not associated with ASP events. A number of *Karenia* spp (formerly *Gymnodinium* spp) are found around the coast though none have been implicated in shellfish poisoning to date. One species, *Karenia cristata*, appears to release an aerosol toxin responsible for skin and respiratory disorders of bathers. (NOTE: Considering the apparent global trend of expanding distributions of toxic algal species, M&CM personnel are actively involved in research on phytoplankton distribution and ecology and attempt to investigate all reported incidences of blooms).

Sampling shall be conducted at differing levels of intensity as determined by the shellfish species of concern, the history of contamination with the biotoxin under consideration, and the geographical area under consideration.

Toxin levels in the edible portions of shellfish provide the present basis for regulatory action. This shall constitute the whole animal except for scallops when the final product is the adductor muscle (with or without roe) and abalone that are cleaned and eviscerated prior to placing on the market.

5.4.2.1 a/ Routine monitoring phase. To be conducted year round.

In open water systems, a composite sample of the upper water column will be taken daily and promptly delivered to M&CM for phytoplankton identification and enumeration.

In land-based systems a water sample representative of intake water will be used for phytoplankton analyses.

These water samples will be composited on weekly basis for microscope counting. Should the presence of toxic algae be indicated in the water or in shellfish flesh, the individual daily samples around the event will be counted.

Shellfish samples for bioassay will be collected in accordance with Table I. A composite sample of shellstock currently being harvested or intended for next harvest is to be taken.

The sampling schedule given in Table I provides the minimum sampling requirements for shellfish flesh. Certain growing areas regarded as high risk may be required to test for biotoxins more frequently than specified.

Table I. Maximum allowable time between biotoxin test and shellfish harvesting.

	West of Cape Point		East of Cape Point	
	Filter feeders	Non-filter feeders	Filter feeders	Non-filter feeders
PSP	48h or twice a week for multiple harvesting	2 weeks	1 month	1 month
DSP	1 week	1 month	2 weeks	1 month
ASP	1 month	1 month	1 month	1month

5.4.2.2 b/ Intensive sampling phase. To be initiated following detection of biotoxins in shellfish meats, though still below regulatory limits (Paragraph 4.6.2). Intensive sampling does not apply to areas with a history of low-level contamination with specific biotoxins. Intensive sampling may also be initiated when toxic phytoplankton are present in the absence of shellfish intoxication. This will be based on the detection of biotoxin-producing phytoplankton in filter-feeder growing waters or the occurrence of toxic blooms in non-filter feeder production waters. (NOTE: With experience it may prove feasible to apply a critical concentration for a particular toxic species as the criterion for initiation of intensive sampling).

Daily testing of filter-feeder shellfish meats and weekly testing of non-filter feeder meats for the relevant biotoxin(s) will be initiated at an increased number of sampling points.

Phytoplankton samples will be analysed on a daily basis.

Routine sampling will be re-established when biotoxin levels are undetectable for 3 consecutive samples.

5.4.2.3 c/ Quarantine phase. To be brought into effect immediately following detection of biotoxin in shellfish meats at levels sufficient to cause a public health hazard. The limits for PSP, DSP and ASP are given in Paragraph 4.6.2.

M&CM will place a ban on harvesting in the area.

The closed status of the area will be communicated to Industry, the SABS, the relevant Health authority and other affected parties.

Contaminated products will be recalled, embargoed and destroyed under the supervision of an Environmental health practitioner or SABS inspector responsible for the area.

M&CM inspectors will ensure the embargo is maintained.

The frequency of testing of shellfish meats will be at the farm managers' discretion in consultation with M&CM. A maximum of one sample per day may be submitted for testing.

5.4.2.4 d/ Re-opening phase. A shellfish growing area closed due to biotoxins will only be re-opened to harvesting when M&CM has determined that the criteria justifying this action are met. Areas will only be re-opened when biotoxin levels are below the regulatory limit for 3 consecutive samples. Information regarding detoxification curves will assist in adjusting these criteria in the future.

The re-opened status will be communicated to all relevant parties.

Sampling intensity following re-opening to harvest will be dictated by toxic algal presence. This may involve intensive sampling in the continued presence of toxic species or biotoxins in the flesh even though the shellfish have attained sub-quarantine levels of biotoxins.

Routine sampling will be re-instated once the biotoxin concentration has returned to non-detectable levels for 3 consecutive samples.

6. REQUIREMENTS FOR HARVESTING AND TRANSPORT OF LIVE SHELLFISH TO A DISPATCH CENTRE, PURIFICATION FACILITY OR AREA, OR PROCESSING PLANT

6.1 Harvesting requirements

6.1.1 No person shall harvest, handle or transport shellfish for human consumption except according to the requirements of this manual under conditions stated in an official permit issued by M&CM.

6.1.2 Harvesting techniques must not cause excessive damage to the shells or tissues of live shellfish.

6.1.3 Shellfish harvested and transported on a vessel for more than 6 hours must be shaded from the sun or sprayed with clean seawater or chilled with clean ice or covered with clean wet sacks.

6.1.4 Shellfish not intended for relaying, wet storage or depuration shall be placed under temperature control at 7°C or less within 20 hours of harvesting. Clean ice may be used for this purpose. Temperature control shall be continuously maintained until final sale of the product to the consumer or until processing. (Except for a maximum period of 2 hours at points of transfer).

6.1.4 Where necessary, shellstock shall be washed using clean seawater or potable water under pressure to remove mud, bottom sediments or seaweed as soon as practicable after harvesting. Wash water may not be recycled.

6.1.5 Containers for the transport or storage of shellstock must be clean and made from impervious easily cleanable materials.

6.1.6 Bags or sacks may not be reused for shellfish unless they are made from impervious material that can be washed and disinfected prior to reuse.

6.2 Transport and Vessels

6.2.1 Decks and storage areas on vessels shall be designed and constructed to prevent bilge water or polluted water from coming into contact with shellfish.

6.2.2 Where the vessel or vehicle deck is not channelled, graded or adequately drained, the shellstock shall be stored at a minimum height of 100mm off the deck.

6.2.3 Where toilets are provided on a harvest vessel, hand-washing basins must also be provided. Toilets and hand-washing facilities shall be designed, located and operated to prevent the contamination of growing areas and adjacent waters and be of the type approved by the official inspector.

6.2.4 Human body wastes shall not be discharged from harvest vessels while in, or adjacent to, growing areas.

6.2.5 All land and water transport vehicles used for shellstock transport shall be constructed, operated, cleaned and maintained so as to prevent contamination, deterioration or decomposition of the shellstock transported and the transporter must be in possession of a valid permit enabling it to transport shellstock.

6.2.6 Refrigerated and frozen transport units must have calibrated thermostats and accurate indicating thermometers. Refrigerated units must be capable of holding the temp at 7°C or less.

6.2.7 All harvesting vessels and road transport vehicles must be inspected at least once annually and approved by the SABS or relevant Health authority.

6.3 Documentation and records

6.3.1 A movement document issued by M&CM shall accompany each batch of live shellfish during transport from the production area to a dispatch centre, processing plant, relaying area, depuration plant or wet storage facility. The movement document must contain the following information:

Document number.

Identity of harvester and signature.

Date of harvesting.

Harvest site and official registration number of production area.

Shellfish identity (common and scientific names) and quantity.

Destination and, if applicable, approval number.

Date and place of receipt.

6.3.2 If harvesting is carried out by the same staff that operate the dispatch centre, processing plant, relaying area, depuration plant or wet storage facility of destination, M&CM may if satisfied that the requirements concerning gathering and handling, are complied with, issue a permanent authorization absolving the harvester from the requirement to use movement documents.

6.3.3 The facility receiving a movement document must keep it available for inspection for a period of at least 12 months.

6.3.4 The harvester must keep a copy on file of all movement documents issued recording all the information contained in the document for a period of not less than 12 months.

6.3.5 M&CM shall keep a copy on file of all completed movement documents issued for a minimum of 2 years.

7. REQUIREMENTS FOR RELAYING OF SHELLFISH

At present no growing areas are being utilized for relaying shellfish in South African coastal waters. The guidelines presented below are recommendations for the management and control of relaying operations and are based on international experience.

7.1 Conditions

7.1.1 Relaying refers to the transfer of shellfish with limited levels of pollution to approved areas for biological purification. Relaying may be applied to reduce microbial and biotoxin contamination to acceptable levels. Relaying is not recommended for the reduction of other toxic or hazardous substances.

7.1.2 Relaying operations must be supervised by an M&CM inspector or duly authorised official.

7.1.3 Relaying areas must be authorised by M&CM as for a mariculture operation. Harvesting of shellfish for relaying may only be undertaken with authorisation from M&CM. Permits shall be valid for 1 year.

7.1.4 Permits for relaying shall be subject to the development of an approved operating procedure.

7.1.5 Relaying areas shall be monitored as for other approved growing areas.

7.1.6 Caution must be exercised in relaying of shellfish from mariculture operations to prevent the potential spread of animal diseases. Assurance of an acceptable disease status may be required.

7.2 Source of shellfish

7.2.1 No shellfish that exceed the contaminant levels for restricted areas (Paragraph 4.4.2) may be relayed. Shellfish must not be contaminated with biotoxins to the extent that safe levels cannot be achieved at the end of the relaying period.

7.2.2 Live shellfish must be gathered and transported in accordance with Section 6.

7.2.3 Shellfish intended for relaying must be accompanied by a movement document (Paragraph 6.3.1). The conditions of Paragraph 6.3.2 apply.

7.3 Relaying areas

7.3.1 Relayed shellfish shall be held in the approved or conditionally approved areas (when open) for sufficient time under suitable environmental conditions to complete purification.

7.3.2 Sites within a relaying area must be well marked and separated to prevent mixing of batches.

7.4 Operating procedures

7.4.1 Each relayer must develop written operating procedures in consultation with M&CM, to provide assurance of end-product safety. The procedures shall specify the following:

Source and species of shellfish.

Contaminant levels of source shellfish and after purification.

Methods of transport to the relaying site.

Relevant information regarding the use of a conditionally approved area for relaying.

Information on the water quality and quality of shellfish indigenous to the relaying area.

Method of holding shellfish at the relaying site and maintaining identity of individual source lots.

7.4.2 Studies shall be undertaken by the relayer to determine the effectiveness of contaminant reduction with due consideration to species and initial shellfish quality. Water temperature and other critical parameters for effective purification should be determined for each species where possible. These environmental variables should be recorded by the relayer when it is known that limiting values may be approached.

7.4.3 The microbiological concentrations in the shellfish shall meet the approved criteria (Paragraph 4.3), and biotoxins less than the limits given in Paragraph 4.6.2, at the end of the relaying process.

7.4.4 A minimum period of 14 days is recommended when conditions are suitable at the relay site.

7.4.5 The harvester of relayed shellfish shall sign a declaration of compliance with operating procedures prior to harvesting, specifying details pertaining to permits, source growing area, relay area and relay operations.

7.4.6 Batches of live shellfish harvested in a relaying area must be accompanied by a movement document (Paragraph 6.3.1) during transport to a dispatch centre or processing plant.

7.5 Records

7.5.1 Relayers shall be required to keep complete and accurate records for inspection by M&CM. This should include the following:

Results of microbial and/or biotoxicity tests of each lot of shellfish before and after relaying

The date of harvest and source/quantity of shellfish harvested.

The period of relay.

Records of temperature and other critical parameters during relaying.

The purchaser and quantity purchased.

7.5.2 M&CM shall maintain records of the following:

The sanitary survey reports and monitoring data for the relaying area.

Approved procedures for operation of the relaying area.

Results of product sampling and environmental monitoring by the relayer

8. DEPURATION

At present there are no shellfish purification centres in South Africa. The guidelines presented below are recommendations for the management and control of purification centres and are based on international experience.

8.1 Conditions

8.1.1 Depuration is the process whereby filter-feeding shellfish are naturally cleansed in a purified and controlled seawater environment. Depuration is intended to reduce the number of pathogenic organisms that may be present in shellfish from moderately polluted areas. Depuration is neither intended to reduce contamination in shellfish from heavily polluted areas nor to reduce the levels of accumulated toxic substances.

8.1.2 All operations harvesting shellfish for delivery to a depuration plant must be issued with a separate permit by M&CM.

8.1.3 Each depuration plant shall be certified by the local authority as for food premises in terms of Regulation 918 of the Health Act No. 63 of 1977. Certification of depuration plants shall require:

Approval of plant design, construction and operation including remodelling.

Verification of the depuration process by the operator.

8.1.4 Certified depuration plants are to be inspected at least monthly to assure compliance of operating procedures.

8.1.5 M&CM shall analyse plant processing data and other records at least monthly to verify the process and controls are sufficient to meet the end product criteria.

8.2 Process verification

8.2.1 Each depuration plant shall develop an approved depuration process (ADP), drawing on outside expertise as necessary, prior to certification. A comprehensive set of trials shall be conducted on the effectiveness of plant operations. The development of the ADP shall take the following critical variables into account:

Shellfish species and source.

Maximum pre-depuration level of faecal contamination to ensure that end point criteria are consistently achieved during normal operations (not to exceed limits given in paragraph 4.4.2).

Design construction and operation of the plant with regard to flow rates, loading rates, tank dimensions and spacing of shellfish

Water quality variables such as temperature, salinity, dissolved oxygen and turbidity. Any seasonal effect must be addressed.

Depuration times.

End point criteria.

Process monitoring.

Plant sanitation.

8.3 Source of shellfish

8.3.1 Only shellfish that meet the requirements for restricted areas (paragraph 4.4.2), at a minimum, may be harvested for depuration. The acceptable pre-purification levels of faecal contamination shall be established as part of the ADP.

8.3.2 Shellfish must be protected from contamination and physiological stress during harvesting and storage.

8.3.3 The identity of each harvest lot must be maintained and tagged to indicate it is from a restricted area.

8.3.4 Shellfish intended for depuration must be accompanied by a movement document (Paragraph 6.3.1) unless the conditions of Paragraph 6.3.2 apply.

8.3.5 Where necessary, shellfish should be washed with clean seawater or potable water prior to depuration.

8.4 Structural requirements

8.4.1 The construction of floors, walls, ceilings (where provided) and installation of lighting, plumbing and sewage disposal systems must comply with the provisions of the Standards and Requirements for Food Premises in terms of Regulation 918 of the Health Act No.63 of 1977.

8.4.2 Effective barriers shall be provided to prevent the entry of vermin, animals and birds into the area and above the storage tanks.

8.4.3 Storage tanks and related plumbing shall be fabricated of non-toxic materials and shall be easily cleanable. The construction of tanks shall allow for easy access for cleaning and inspection and for self-drainage. The design and installation of plumbing shall allow for regular cleaning and sanitising to prevent contamination of the tanks and water.

8.4.4 Shellfish containers (where used) shall have an impervious mesh-type construction that allows adequate flow of water to all shellfish in the containers. They must be placed in tanks in such a manner that sufficient clearance is provided between the shellfish containers and bottoms and sides of the tanks.

8.4.5 The site, facility and plant shall be evaluated and approved annually by M&CM in conjunction with the SABS and relevant Health authority, taking into account the records of water officially tested.

8.5 Process water quality and operation

8.5.1 Process water must meet the requirements for sanitary quality and normal physiological activity of the shellfish species. Critical parameters are given below:

Treated water on entry to a depuration unit shall contain no detectable faecal coliforms. Pre-treated water must not exceed 88 faecal coliforms/100ml and not more than 10% exceed 260/100ml. Water treatment must not leave residues that will interfere with the depuration process or product quality.

pH must be in the range 7.0 - 8.4.

Temperature, salinity, turbidity and dissolved oxygen limits for normal physiology of the particular species are to be established for the ADP. Dissolved oxygen must always be greater than 50% saturation and turbidity less than 20 nephelometric turbidity units.

8.5.2 Operational procedures shall promote water quality uniformity within depuration units. Consideration must be given to flow rates, tank loading rates and shellfish spacing as established in the process verification study. A minimum flow rate of $107 m^3/m^3$ of shellfish is recommended.

8.5.3 The minimum depuration time is 48 hours.

8.5.4 Different lots of shellfish must not be mixed in order to preserve identity and integrity.

8.5.5 After completion of purification, the shells of the live shellfish must be washed with clean seawater or potable water and damaged individuals culled.

8.6 Sanitation of systems

8.6.1 Adequate facilities must be provided for the proper washing, cleaning and sanitising of equipment, utensils and the building.

8.6.2 All equipment and utensils used in the plant must be maintained in a clean condition.

8.6.3 All shellfish and sea water contacting surfaces must be cleaned and sanitised after each use as indicated below:

Process units, trays, containers and racks shall be cleaned, sanitised and rinsed before each depuration operation.

The process unit including the system piping network shall be cleaned, and where possible, sanitised after each batch.

The seawater storage tanks shall be cleaned and sanitised on a regular basis.

The washing, culling, sorting and pre-process storage areas shall be thoroughly washed and sanitised after each use.

8.7 Quality assurance

8.7.1 Depuration plants must have their own laboratories or secure the services of an approved outside laboratory to assess the effectiveness of the process and to establish that the end product meets the approved criteria.

8.7.2 Shellfish from single process batches may not be released to market unless laboratory results confirm that the end product meets the faecal coliform standards for approved areas (Paragraph 4.3).

8.7.3 When water treatment systems are being used, samples should be taken frequently to monitor effectiveness of the treatment units.

8.7.4 In the event of a process batch failing to meet the release criteria, the operator shall notify M&CM and an investigation shall be conducted into the cause for failure. The following actions may be required through consultation with the local health authority or the SABS as relevant:

Destruction of the shellfish.

Non-food use of the shellfish.

An additional depuration cycle.

Modification of the ADP.

8.7.5 Every package of purified shellfish must be provided with a label certifying all of its contents have been depurated. The following minimal information shall be included:

Identity of depuration plant operator.

Depuration cycle number and date.

Identity of harvest area.

Type and quantity of shellfish.

8.8 Records

8.8.1 Operators shall be required to keep the following complete and accurate records:

Information that will allow a package of depurated shellstock to be traced back to the process batch, harvest area, harvest date and harvester and corresponding movement document numbers.

Results of product sampling and critical parameters (maintained for at least 2 years).

Current copy of the plant operating procedures.

Dispatch details of consignments after purification.

8.8.2 M&CM shall maintain records of the items listed below:

The sanitary survey reports and data for the harvest areas.

The pre-certification depuration process verification data.

The monthly sanitary inspection reports for the plant.

The monthly analyses of the process data.

An evaluation report verifying that the operators records have been reviewed and the process been evaluated.

9. WET STORAGE

9.1 Conditions

9.1.1 Wet storage refers to the temporary storage of shellfish in near-shore waters or onshore tanks prior to processing for sale. Wet storage is not intended for purification therefore all controls pertaining to shellfish for direct human consumption should be applied.

9.1.2 Wet storage premises must be certified by the local authority as for food premises in terms of Regulation 918 of the Health Act No. 63 of 1977. Wet storage sites or facilities must undergo an annual evaluation by the relevant Health authority in co-operation with M&CM. This evaluation shall consider the following:

The sanitary survey of the nearshore site and monitoring records.

The design and operating procedures for the onshore storage facility including the quality of source water and details of any water treatment system.

Plans for remodelling.

9.1.3 Caution must be exercised in wet storing shellfish from mariculture operations to prevent the potential spread of animal diseases. Assurance of an acceptable disease status may be required.

9.2 Source of shellfish

9.2.1 Shellfish for wet storage shall be harvested only from approved or conditionally approved growing areas or taken from a certified depuration plant.

9.2.2 Shellfish delivered to a wet storage facility must have been handled, transported and held in such a manner as to prevent deterioration and contamination.

9.2.3 Shellfish from different harvest areas shall be wet stored separately.

9.2.4 Shellfish intended for wet storage must be accompanied by a movement document (Paragraph 6.3.1) unless the conditions of 6.3.2 apply.

9.3 Structural and design requirements

As for depuration (Paragraph 8.4).

9.4 Water quality

9.4.1 Shellfish shall be washed with clean seawater or potable water and culled if necessary prior to wet storage.

9.4.2 Near-shore areas for wet storage must meet the approved or conditionally approved criteria (Paragraphs 4.3 or 4.4).

9.4.3 Process water in onshore systems must not negatively affect the sanitary quality of the stored shellfish or result in physiological stress that may lead to death.

9.4.4 Water of approved growing area status may be used in an onshore facility without disinfection provided the system operates on a continuous flow-through basis and the near shore source water meets the approved area bacterial criteria at all times shellfish are being held for direct marketing.

9.4.5 In-water or land-based wet storage facilities must conduct monthly microbiological testing or secure the services of an outside laboratory to provide confirmation of approved water status. Faecal coliforms in the source waters must conform to the approved limits (Paragraph 4.3)

9.4.5 Re-circulating systems or systems using water of a quality inferior to the approved water criteria must be treated. Source seawater prior to treatment may not exceed a median of 88 faecal coliforms/100ml and not more than 10% exceeding 260/100ml for any sample point.

9.4.6 Treated water entering wet storage tanks shall have no detectable levels of faecal coliform bacteria.

9.4.7 The operator of the facility shall conduct a study on the effectiveness of the disinfection process as assurance that the system will consistently supply water free of faecal coliform bacteria under normal operation. Samples of treated water entering the storage system shall be taken at a minimum frequency of 3/day over a period of 5 days. Additional samples (1/day) shall be taken

of untreated source water. Any positive sample for faecal coliforms in treated water shall require corrective procedures and re-evaluation of treatment effectiveness.

9.4.8 The treatment process shall not leave any residues that are not Generally Recognised As Safe or that may interfere with the process.

9.4.9 The operator shall have routine microbial testing conducted at least weekly for systems using treated water. In the event that a single sample contains detectable faecal coliforms, daily testing shall be immediately initiated until the problem is identified and rectified.

9.4.10 Turbidity shall not exceed 20 nephelometric turbidity units where UV light is used for disinfection. Treatment effectiveness shall be confirmed whenever new UV lamps are installed.

9.4.11 Salt added to increase salinity or produce synthetic seawater must be food-grade salt.

9.5 Records

9.5.1 The following records shall be maintained by the operator:

Information that will enable each lot of shellstock to be traced to the wet storage facility and classified growing area;

Records of water sampling and other tests as may be required (minimum of 2 years).

9.5.2 Live shellfish shall be labelled as described in Paragraph 10.2.1 during transport and distribution until retail sale.

10. REQUIREMENTS FOR DISPATCH CENTRES

10.1 Receiving and storage.

10.1.1 Dispatch centres must be certified according to Regulation 918 of the Health Act No.63 of 1977 and must be inspected at least once annually and approved by an SABS inspector or relevant Health official.

10.1.2 The premises and hygienic standards must comply with the Standards and Requirements for Food Premises in terms of Regulation 918 of the Health Act No. 63 of 1977.

10.1.3 Only batches of live shellfish accompanied by a movement document (Paragraph 6.3.1) shall be accepted at a dispatch centre unless the conditions of Paragraph 6.3.2 apply. Shellfish must have been harvested and transported according to the requirements of this manual (Section 6).

10.1.4 In any sorting or storage area, live shellfish must be kept at a temperature that does not adversely affect their quality and viability. Live shellfish intended for the market in a live chilled state must be stored and transported at a temperature of 7°C or colder. Temperature control must be put in place within 20 hours of harvest.

10.1.5 The room must be vermin proof, have vermin proof doors and have impermeable structures to prevent the shellstock from coming into direct contact with the floor.

10.1.6 No chemicals that may contaminate the live shellfish may be present in the room used for sorting or storing.

10.1.7 Shellfish from different production areas must be kept sorted and packed separately so as not to loose identity.

10.2 Marking of consignments and records.

10.2.1 All parcels in a consignment of live shellfish shall bear a label so that the original dispatch centre may be identified at all times during transport and distribution until retail sale. The label shall contain the following information in addition to other labelling requirements specified in the Foodstuffs, Cosmetics and Disinfectants Act No. 54 of 1972, Trade Metrology Act No77 of 1973, Compulsory Technical Standards as applied in terms of the Standards Act No 29 of 1993, or importing country regulations:

Dispatch establishment number, name and address.

Date of harvest (day, month year)

Date of packaging (day, month, year) and batch code reflecting origin of product.

Production method, commercial designation and species name (e.g. Cultivated abalone – *Haliotus midae*).

Requirements for storage prior to use by consumer (on main panel) and the warning: These animals must be alive when sold (or date of durability).

Net mass in kilograms.

Product of the Republic of South Africa.

10.2.2 The label must be durable and waterproof and the information presented must be legible and indelible.

10.2.3 A person operating the dispatch centre must keep a record of each consignment for a period of not less than 1 year to enable products to be traced and recalled if necessary.

10.2.4 If shellfish are unwrapped and subsequently re-wrapped, handled or further processed in another establishment, the latter establishment must apply its own label to the product and maintain adequate records of origin and destination for 1 year. The label must include, in addition to that set out in Paragraph 10.2.1, details of the original dispatch centre and re-packaging details.

10.3 Transport from a dispatch centre

10.3.1 Consignments of live shellfish intended for human consumption must be transported wrapped in sealed parcels until offered for sale to the consumer or retailer.

10.3.2 Live shellfish must be transported and distributed using closed vehicles or containers which maintain the product at a temperature which does not adversely affect quality and viability. Live shellfish intended for

the market in a live, chilled state must be brought to a temperature of 7°C or less before leaving the centre. This temperature shall be maintained during transport and storage.

10.3.3 Packages containing live shellfish must not come into direct contact with the vehicle floor and must not be transported with other products that might contaminate them.

10.3.4 Ice used for temperature control must have been made from potable water or clean seawater.

11 CANNING OR COOKING AND FREEZING

11.1 Requirements for processing establishments

11.1.1 Processing may only be conducted in establishments issued with a permit by M&CM in terms of the Marine Living Resources Act No. 18 of 1998. Permits are subject to prior certification by the local Health authority or the SABS.

11.1.2 Where any processing is conducted (such as shucking, cooking, freezing, canning, etc.), the premises must comply with the requirements in terms of the SABS Compulsory Standard Specification for the frozen or canned product and the Standards and Requirements for Food Premises in terms of Regulation 918 of the Health Act No.63 of 1977.

11.1.2 Only batches of live shellfish accompanied by a movement document (Paragraph 6.3.1) shall be accepted at a processing establishment unless the conditions given in Paragraph 6.3.2 apply. Shellfish must have been harvested and transported according to the requirements of this manual.

11.1.3 Shellfish shall be protected from heat and contamination and kept alive, where possible, during transport to a processing establishment. Shellfish must have been harvested and transported according to the requirements of this manual (Section 6).

11.1.4 Where shellfish, other than abalone, cannot be kept alive, they shall either be frozen or kept on ice for no longer than 2 days prior to processing.

11.1.5 Abalone shall be kept alive until immediately before processing.

11.2 Canning in hermetically sealed containers:

Shellfish may be subjected to sterilisation in hermetically sealed containers at a canning factory approved by SABS and under supervision of inspectors of the SABS. Each batch so processed must be identifiable as to the harvester and harvesting area. The end product must comply with the requirements in terms of the Compulsory Specification for the Manufacture, Production, Processing and Treatment of Canned Fish and Canned Marine Molluscs.

11.3 Cooking, cooling, packing and freezing.

11.3.1 The handling of the raw material and its preparation, cleaning, cooking, shucking, packing, freezing and storage must be conducted in premises complying with the requirements of the Compulsory Specification for Frozen Fish and Frozen Marine Molluscs and Frozen Products Derived Therefrom. Shellfish not from approved areas but for which the faecal coliform count is less than 6000/100g flesh must be cooked prior to packing and freezing. The following heat treatments are required:

When immersed in boiling water, the internal core temperature of the flesh of the mollusc must be maintained for 90 seconds at a temperature of no less than 90°C.

Cooking may be conducted at a temperature of 120 - 160°C at a pressure between 196 kPa and 490 kPa for the time necessary to comply with the requirements given above.

11.3.2 After cooking the shellfish must be cooled to below 10°C as soon as possible and to below 4°C within 3 hours of cooking. Where ice or water is used for cooling, the ice or water must comply with the requirements for potable water specified in the latest version of SABS 241. The fish must be frozen to a core temperature below -20°C after packaging at the minimum freezing speed required in terms of the Compulsory Specification.

11.5 The product shall comply with the microbiological standards for cooked frozen marine molluscs specified in the Compulsory Specification.

12. DEFINITIONS

Acceptable:

Acceptable to the competent authority for the approval and licensing of molluscan shellfish growing and harvesting waters and for the competent authority inspecting and certifying such product for export.

Adverse pollution conditions:

Conditions determined by changes in meteorological, hydrographic, seasonal and point source pollution conditions that have been historically demonstrated to unfavourably impact on a particular growing area. Examples are unusual climatic conditions, long periods without rain, unusually hot temperatures, consecutive days of light rainfall, heavy rainfall, tidal effects, salinity and wind effects.

Approved areas:

The classification by M&CM of a growing area where shellfish may be harvested for direct sale at any time outside of temporary closures. The classification of an approved area is determined through a sanitary survey conducted by an official, authorised by M&CM in accordance with paragraph 4.2. An approved area may be temporarily closed to harvesting, e.g. when a flood, storm or marine biotoxin event occurs.

\ **Central file:**

The file system maintained by the persons responsible for management of this programme at M&CM.

Clean ice:

Ice made from potable water or clean seawater and that has been stored hygienically prior to use.

Clean seawater:

Water that meets the approved area microbial requirements and does not contain toxic or objectionable substances at levels that pose a public health risk or impair the taste of the shellfish.

Closed area:

A growing area where the harvesting of shellfish is temporarily or permanently not permitted.

Conditionally approved area:

The classification by M&CM of a growing area that meets the approved area criteria for a predictable period. The period is conditional upon established performance standards specified in a management plan.

Controlled area:

A growing area where there is a temporal control over shellfish harvesting (conditionally approved areas) or a purification or processing requirement of the harvested shellfish (restricted areas).

Depuration:

The process of using a controlled clean sea water system to reduce to levels of microbial contaminants in live shellfish.

Depuration plant:

A licensed establishment for purifying shellfish according to an approved depuration process. It comprises one or more depuration units. A depuration unit is a tank or series of tanks fed by a single process water system.

Dispatch centre:

Any installation for the reception, washing, cleaning, grading and packaging of live shellfish fit for human consumption.

Establishment number:

Refers to the official approval number for a growing or harvesting area and packaging or processing facility. This number may also refer to a permit number issued by M&CM for a specific cultivation area, relaying area, depuration plant or harvester. The establishment number for packaging and processing is obtained from the Food Standards Division of the SABS in Cape Town

Growing area (cultivating or production areas):

An artificial or natural seawater or estuarine system that supports or could support the propagation of live shellfish.

Harvester:

A person who takes shellfish by any means from a growing area.

Inspector:

Any control officer, inspector, environmental health practitioner or health officer appointed in terms of the Marine Living Resources Act No. 18 of 1998, Standards Act No. 29 of 1993 or Health Act No.63 of 1977 (to be replaced by National Health Act) and regulations promulgated thereunder.

Lot of shellfish (or batch):

Shellstock harvested from a particular identifiable area at a particular time (i.e. no more than one day).

Mariculture:

For the purposes of this manual mariculture refers to the controlled production of molluscan shellfish in natural and artificial seawater systems destined for the market as a foodstuff.

Marine biotoxins:

Poisonous compounds accumulated by shellfish feeding on toxin-producing dinoflagellates or diatoms, or on seawater containing toxins produced by such organisms.

Molluscan Shellfish:

For the purposes of this manual, applies to all bivalve molluscs and including Pectinidae and marine gastropods but excluding octopus and squid. (Where the word "shellfish" appears in the text, molluscan shellfish is meant).

Person:

An individual, partnership, corporation, association or other legal entity.

Point source (of pollution):

A discernible single source such as any pipe, ditch, channel, tunnel or conduit that carries pollution.

Process batch:

A quantity of shellfish used to fill each separate depuration unit.

Process water:

Seawater in depuration tanks during the time that the shellfish is being depurated, or the water used in a tank system where molluscan shellfish are cultivated or the water in wet storage tanks during the time the shellfish is being wet stored.

Processor:

A person who physically or chemically treats, or shucks, packs or repacks shellfish.

Prohibited area:

A growing area where there is no current sanitary survey or where the sanitary survey or other monitoring programme indicates that faecal material, pathogens or toxic substances may reach the area in excessive concentrations. Any taking of shellfish for human consumption from such area is prohibited.

Relaying

The transfer of live molluscs to a growing area of approved status to facilitate the natural biological cleansing of microbiological contaminants and/or biotoxins. The transfer of shellfish to a different area for further growth or fattening is not included.

Restricted area:

A growing area classified by M&CM as an area from which shellfish may be harvested only by special permit. Shellfish from restricted areas may be subjected to an approved purification process such as relaying or depuration.

Sampling Officer:

A person appointed by M&CM to take water and shellfish samples and submit them to an accredited laboratory (approved by the Competent Authority) for testing according to the requirements of this manual.

Sanitary Survey:

The evaluation, in accordance with the requirements of Paragraph 4.2 of this manual, by an M&CM approved party, of all actual and potential pollution sources and environmental factors that may affect shellfish growing water quality.

Shellfish Management Committee:

The board of management of the M&CM, in co-operation with the Department of Health, SABS, and Industry, whose primary role it is to review the management actions proposed in this manual with regard to public health on an annual or more frequent basis.

Shellstock:

Shellfish in the shell.

Shoreline Survey:

A survey of the shoreline of the growing area catchment conducted by an officer authorised by M&CM according to requirements in Appendix I.

Transaction Record:

A form used to document each purchase or sale of shellfish at the wholesale level.

Treated water:

Seawater used in a depuration or wet storage facility that has been disinfected by either UV, ozone, chlorine/hypochlorite, or iodophor treatment. Treated water must contain no detectable coliforms after treatment.

Wet Storage:

The temporary storage of shellfish harvested from approved production areas.

13. REFERENCES

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2 AOAC 1991. Domoic acid in mussels, liquid chromatographic method, first action 1991. Official Methods of Analysis. Sec 991.26. Association of Official Analytical Chemists, Arlington, Virginia, USA.

3 Canadian Shellfish Sanitation Program. Manual of Operations. 1992.

4 Council Directive 91/492 EEC Health Conditions for the Production and Placing on the Market of Live Bivalve Molluscs.

5 Commission Decision of 11 December 1992. Approving certain treatments to inhibit the development of pathogenic micro-organisms in bivalve molluscs and marine gastropods (93/25/EEC).

6 Commission Decision of 3 May 1996 Establishing health certification of live bivalve molluscs, echinoderms, tunicates and marine gastropods from third countries which are not covered by a specific decision (96/333/EC).

7 Commission Proposal. Document 500PC0438. Proposal for a regulation of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin.

8 Commission Regulation (EC) No 2065/2001. Laying down detailed rules for the application of Council Regulation (EC) No 104/2000 as regards informing consumers about fishery and aquaculture products.

9 Food Safety (fishery Products and Live Shellfish) (Hygiene) Regulations 1998. Statutory Instrument 1998 No. 994.

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11 Issue 1 of the New Zealand Fishing Industry Agreed Implementation Standards IAIA 001,1 : Shellfish Quality Assurance Circular 1995.

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17 Yasumoto, T., Oshima, Y. and M. Yamaguchi. 1978. Occurrence of a new type of shellfish poisoning in the Tohoku district. Bull. Jap. Soc. Scient. Fish. 44:1249-1255.

South African Legislation:

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Health Act No. 63 of 1977

Foodstuffs, Disinfectants and Cosmetics Act No. 54 of 1972

Standards Act No. 29 of 1993

Trade Metrology Act No. 77 of 1973

APPENDIX I – SAMPLING OF SHELLFISH AND WATER

In situations where a localized production area in open waters (e.g. Small Bay, Saldanha) is utilized for harvest by a number of different permit holders, some monitoring (sampling) efforts may be combined as advised by M &CM.

Shellfish samples for faecal coliforms and biotoxin analyses should comprise stock close to market size.

1 Shore-based mariculture systems:

1.1 Filter feeders - samples for microbiological examination are to be taken of:

shellstock within the grow-out units.

1.2 Non-filter feeders - samples for microbiological examination are to be taken of:

shellstock within the grow-out units, as well as,

the intake water to the farm.

1.3 The daily seawater samples for algal identification are to be taken from a position representative of the intake water.

1.4 A composite shellfish sample from the grow-out tanks/ponds will be required for tests on other hazardous and deleterious substances.

2 Cultivation areas in the near-shore environment:

2.1 Filter feeders - samples for microbiological examination are to be taken from shell stock within the growing area.

2.2 Non-filter feeders - samples for microbiological examination are to be taken of:

shellstock within the growing area, as well as,

ambient water.

2.3 Water samples for algal identification shall be taken from positions that provide adequate early warning of the presence of harmful algal species. M&CM will advise on sample station positioning and method of collection.

2.4 A composite shellfish sample will be required for tests on other hazardous and deleterious substances. Where contamination may be expected from an identifiable point source, an additional sample or samples shall be taken in proximity to the source.

3 Shellfish samples:

3.1 A representative and sufficient sample of shell stock including intravalvular fluids and free of open or cracked shells is collected. The following sample sizes are recommended:

Mussels	15 - 30
Oysters and clams	10 - 15
Abalone and scallops	5 – 10

3.2 Shell stock is collected in clean, sterile, waterproof, puncture resistant containers.

3.3 Separate samples are to be collected for analysis of faecal coliforms and for analysis of biotoxins.

3.4 The sample is labelled with the collector's name, type of shell stock, the source or harvest area code, time and date.

3.5 Samples for microbial testing are maintained in dry storage between 0° and 10°C until examined - as soon as possible after collection but not exceeding 24 hours. Samples should not be frozen.

3.6 Samples for biotoxin testing should be kept chilled during same-day delivery to the analytical laboratory. Shell stock should be frozen for longer-term storage.

3.7 Samples for analysis of radionuclides and metals are to be frozen for delivery to the laboratory.

1. Seawater samples for microbial examination:

4.1 Samples are collected in clean, sterile, watertight glass or polypropylene containers of sufficient size to hold a minimum of 100 ml with a head-space for shaking.

4.2 Samples are identified with the collector's name, source or harvest area code, time and date of collection.

4.3 Samples shall be maintained at 0° - 10°C until examined - as soon as possible after collection but not exceeding 24 hours.

2. Seawater samples for algal identification:

5.1 Samples are collected in clean, watertight containers of sufficient size to hold 100 ml with a headspace for shaking.

5.2 Samples are identified with the collector's name, harvest area, time and date.

5.3 Samples are preserved with buffered formalin to a final concentration of 1%.

APPENDIX II: MINIMUM REQUIREMENTS OF THE SANITARY SURVEY REPORT

The following provides an outline of the many factors to be considered in performing and reporting on the sanitary survey as required in Section 4.2. These guidelines act as a checklist and provide a model for the structure of the report.

1. Summary.

Provide a synopsis of the results of the sanitary survey and recommendations for the particular growing area under investigation.

2. Background information

2.1 Motivation for the study.

2.2 General description of growing area - including maps and, where available, aerial photographs.

2.3 Resources to be harvested - specifying shellfish species, location within the growing area and abundances.

2.4 Harvest practices - methods, seasonality, landings (previous and projected) and intended use of harvested shellstock, i.e. immediate human consumption, processing, purification or wet storage.

2.5 History of growing area classification:

Summary of sanitary survey history

Previous classification - including maps and photographs.

3. Pollution source (shore line) survey

3.1 Personnel and procedures - description of plan for shoreline pollution source survey and methods of data collection.

3.2 Summary of pollution sources and location - including maps of major sources of actual or potential pollution.

3.3 Identification and evaluation of pollution sources. All actual sources of pollution must be classified as either a direct impact (discharges directly into growing area) or indirect impact (discharge which is advected or mixed into the growing area from a distant source). The volumes of the different discharges should be quantified where possible.

Domestic wastes - include maps and discussion on use of septic tanks in the catchment area and sewage treatment facilities and outfalls.

Stormwater - information on the nature (combined) and conduiting (drainage ditches, pipes and runoff).

Agricultural waste from farms, feedlots and slaughterhouses.

Industrial wastes.

Wildlife areas - unfenced access of animals to growing areas.

Radionuclides.

Marinas.

Minor sources such as boats birds and seals.

4. Hydrographic and meteorological characteristics.

4.1 Physiography - physical description of water body including chart of depth contours.

4.2 Tides - full description of type, range and tidal exchange rates.

4.3 Currents - type of currents (tidal, wind driven etc.) and dispersion characteristics.

4.4 Waves - heights, frequency of storms and role in sediment re-suspension.

4.5 Rainfall - provide a summary of last 5 - 10 years rainfall figures, showing seasonal variation and frequency of significant rainfalls.

4.6 Winds - provide summary wind data for the last 5 - 10 years on strength, direction and seasonality.

4.7 River discharges - volumes and seasonality

4.8 Summary discussion on actual or potential effects of transport (water borne or air borne) of pollutants to the growing area. Include discussion on physical dispersion and dilution of pollutants.

5. Water quality studies.

5.1 Sampling plan, taking potential pollution sources into account.

5.2 Map showing sampling stations specifying whether sampling is for water and/or shellfish.

5,3 Description of sample collection and analytical procedures.

5.4 Microbial data analysis and presentation. Present data and statistical analyses in table form indicating compliance with criteria given in Section 4 and classification of individual sample stations.

5.5 Assessment of levels of toxic and hazardous substances in shellfish.

5.6 Assessment of risk imposed by biotoxin producing phytoplankton.

5.7 Inter-relationship with physical forcing factors. Discuss how meteorological and hydrodynamic conditions affect actual or potential pollution sources and their impact on water quality. The discussion must address the following:

Effects of meteorological and hydrodynamical factors on pollution sources.

Causes of adverse pollution conditions.

Potential pollution associated with seasonal events such as holidays, festivals etc.

Explanation for the variability in the data.

6. Recommended classification.

Classification of the growing area indicated on a chart/map showing closure lines and separation of various classifications where applicable.

7. Management plans.

Management plans for areas classified as conditionally approved shall be included in the sanitary survey.

7.1 The plan shall include a description of predictable pollution events that cause closure. Information on wastewater treatment, environmental effects and other events shall be included as relevant:

7.1.1 Wastewater treatment facility. The performance standard is based on:

Peak effluent flow.

Bacteriological, chemical and physical quality of the effluent.

Bypasses.

Design, construction and maintenance to minimise mechanical failure or overloading.

Monitoring of wastewater treatment efficacy and feedback system in the case of inadequate treatment.

7.1.2 Meteorological and hydrodynamical events - discussion of the specific events that cause closure, their predictability and frequency of occurrence.

7.1.3 Other events such as marina openings and closures, bird migrations, holiday seasons etc.

7.2 Implementation of conditional area closures.

7.2.1 Notification of management plan violations. Identify agency or agencies responsible for notifying an inspector of such violations, the procedures for prompt notification, and response time between violation and notification.

7.2.2 Implementation of a closure. Identify the response time between notification of a management plan violation and legal closure. Detail means by which Industry and surveillance personnel are notified.

7.2.3 Enforcement of closure. Identify agency responsible and response time between legal closure and patrol agency notification.

7.3 Criteria for reopening a conditional area after a pollution event. M&CM shall establish the following control elements to define reopening criteria:

Procedures to determine that the pollution event has ended.

Physical flushing time, i.e., time for area to exchange a sufficient volume of water to disperse/assimilate the pollutant load.

Shellfish feeding activity is sufficient to promote natural cleansing.

Time after flushing required for shellfish to naturally cleanse themselves.

7.4 Synopsis of the effectiveness of closure and policing procedures and details of the co-operation between different agencies.

8. Recommendations.

8.1 Details of monitoring schedule for microbial indicators and toxic and hazardous substances that will be used in the annual reassessment of growing area classification.

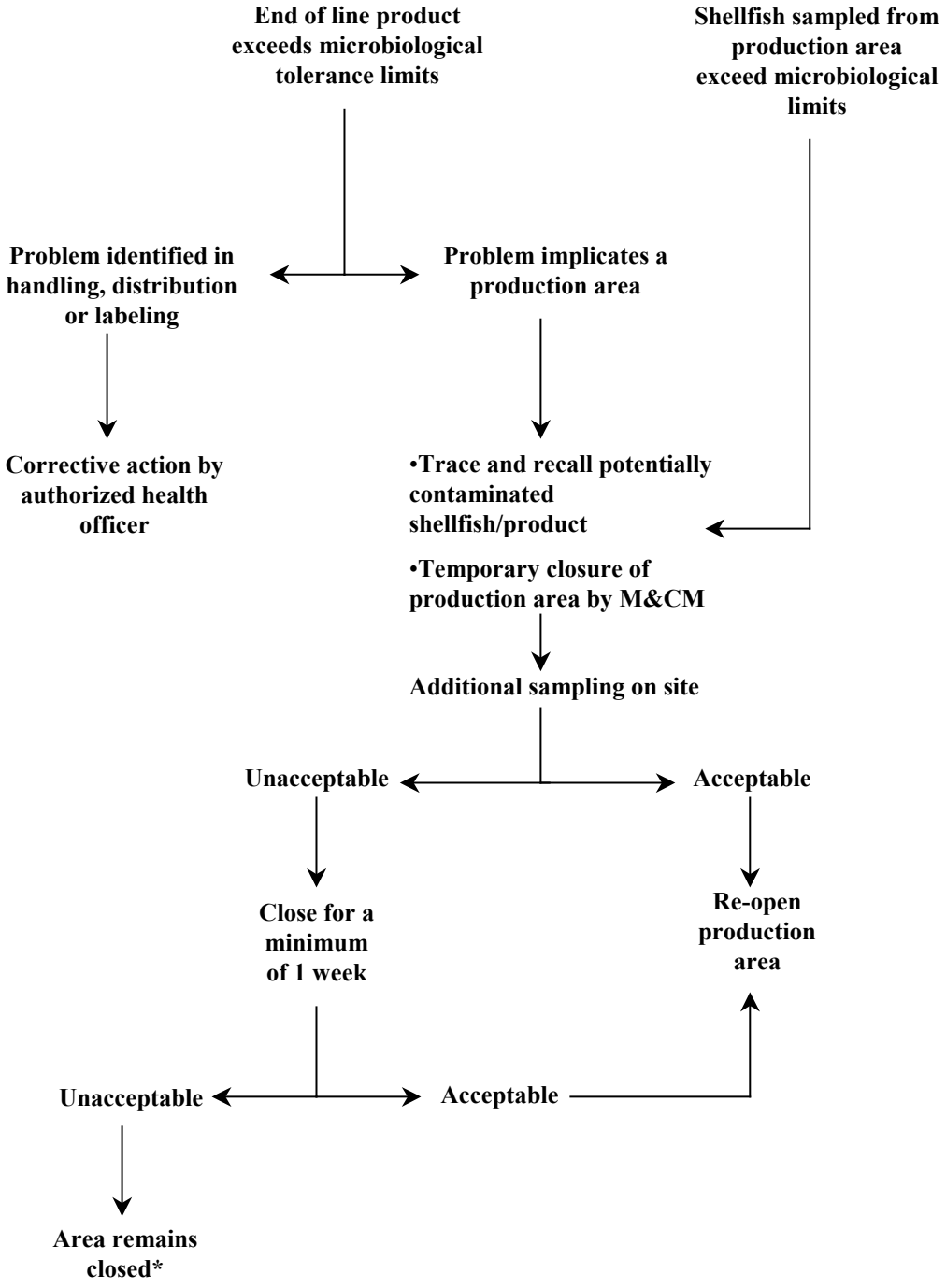
8.2 Monitoring actions for biotoxins.

8.3 Provide suggestions for future work.

APPENDIX III: RECOMMENDED METHODS FOR THE ANALYSES OF BIOTOXINS IN SHELLFISH MEATS

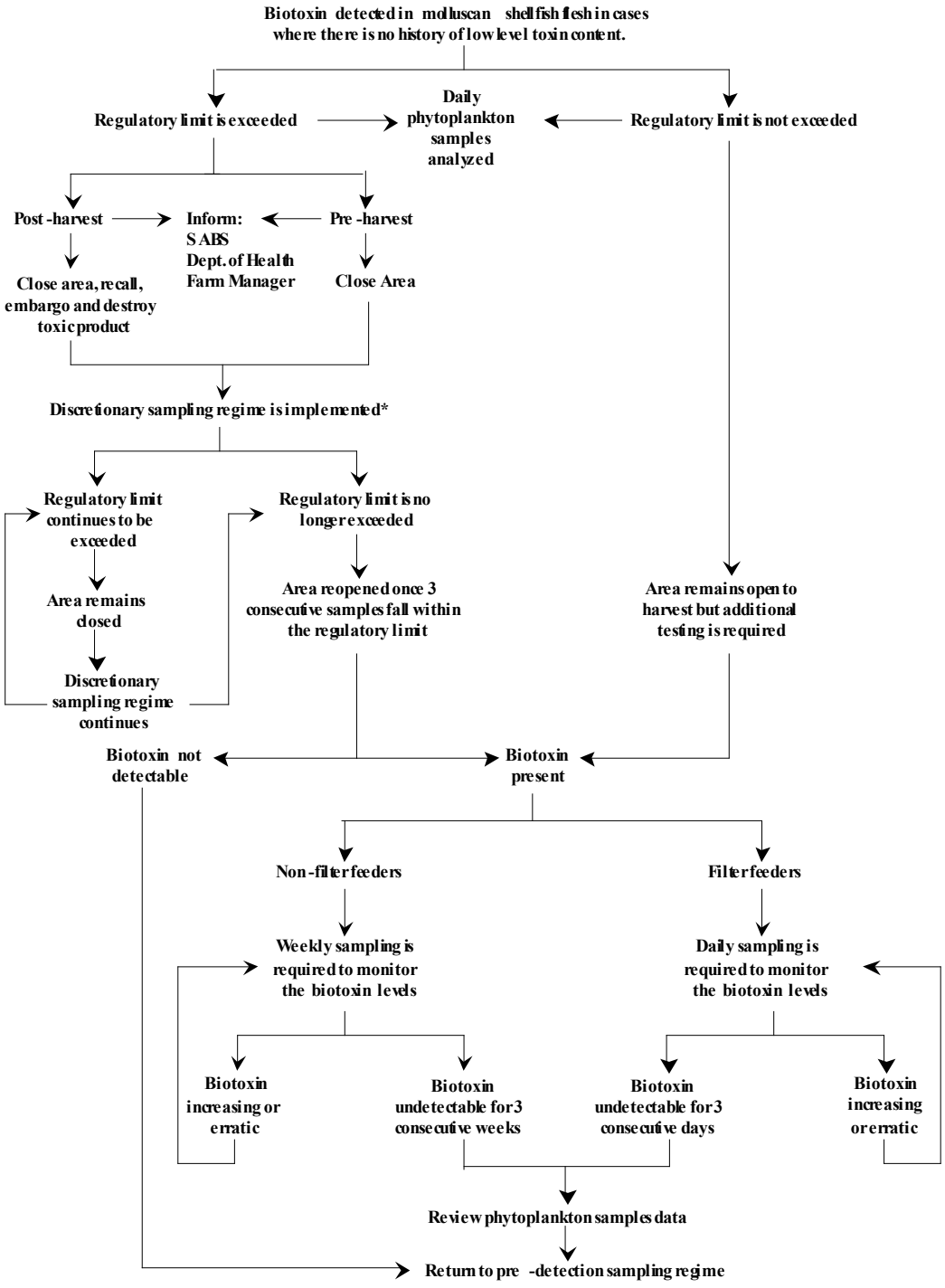
BIOTOXIN	TEST METHOD	STANDARDS
Paralytic Shellfish Poisoning (PSP)	Mouse bioassay according to AOAC, 1990	<0.8 mg total PSP/ kg edible flesh.
Diarrhetic Shellfish Poisoning (DSP)	Yasumoto *et al.,* 1978. (A broad range detection method regarded by the EU as providing the highest level of sanitary protection).	Mouse mortality (EU): 5 hours or less - high toxicity. 5 - 24 hours - less toxic. Reject if any positive findings within 24 hours
Amnesic Shellfish Poisoning (ASP).	Canadian HPLC-UV method for domoic acid (AOAC, 1991)	<20 mg/ kg edible flesh

APPENDIX IV: PLAN OF ACTION FOLLOWING NON-COMPLIANCE WITH MICROBIOLOGICAL LIMITS FOR SHELLFISH



** Re-classify area in the case of continued failure to meet microbiological limits.*

APPENDIX V: PLAN OF ACTION WHEN BIOTOXINS ARE DETECTED IN SHELLFISH



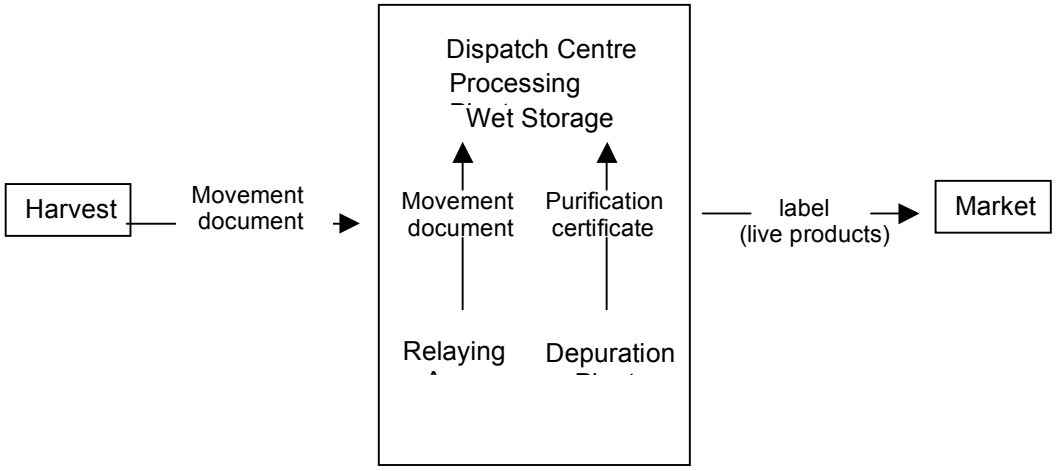
**Frequency of sampling is at farm manager's discretion, but no more than one sample may be submitted per day. Multiple samples on the same day will be considered one sample.*

APPENDIX VI - SUMMARY OF DOCUMENTATION/LABELLING REQUIREMENTS DURING TRANSPORT OF LIVE MOLLUSCAN SHELLFISH

1 A movement document (Paragraph 6.3.1) must accompany batches of live shellfish transported prior to placing on the market unless the same staff operates the facility/relaying site of destination (Paragraph 6.3.2). A movement document identifies the production area where the shellfish were harvested.

2 A label (Paragraph 10.2.1) is required for all batches of live shellfish where the destination is a retailer or consumer. This label allows the dispatch centre of origin to be identified.

3 Depurated shellfish must be provided with a label certifying that all live shellfish have been purified (Paragraph 1.8.7.5).



4 When exporting live shellfish the requirement for supporting documentation can be extensive (e.g. air waybill, certificate of origin, commercial invoice, shippers export declaration, shippers certification for live animals (IATA), insurance certificate, veterinary certificate and CITES certificate). From a public health perspective, some countries (e.g. Commission Decision 96/333/EC) may require that each shipment of seafood products is accompanied by a numbered sanitary/health certificate certifying the product meets certain standards. Such requirements generally exist where a specific decision has not yet been adopted by the destination country. A single certificate may be issued for several containers of the same product considered to be a single lot.

Annex II

The National Shellfish Sanitation Program

A Protocol for International Participation

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
February 6, 2001

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
February 6, 2001

The National Shellfish Sanitation Program

A Protocol for International Participation

This protocol is intended for the use of fishery officials engaged in developing a program to export molluscan shellfish to the United States. This protocol reviews the objectives of National Shellfish Sanitation Program (NSSP) and lists the responsibilities associated with participation in the program. Finally, a procedure for initiating a formal international agreement between the U.S. Food and Drug Administration (FDA) and the exporting nation is presented.

Molluscan shellfish imports must meet both Federal and state requirements to gain free access to U.S. markets. Fresh and frozen oysters, clams, mussels, whole and roe-on scallops are required to meet the federal sanitation and labeling requirements applicable for all foods in the U.S. In addition, fresh and fresh frozen molluscan shellfish products must meet the specific temperature, microbiological, and identification standards contained in the NSSP. The NSSP standards have adopted into state law and enforced by both federal and state officials. The NSSP standards apply equally to both domestic and imported fresh and frozen shellfish.

The National Shellfish Sanitation Program

The NSSP is designed to prevent human illness associated with the consumption of fresh and frozen shellfish (oysters, clams, and mussels) through the establishment of sanitary controls over all phases of the growing, harvesting, shucking, packing and distribution of fresh and frozen shellfish. Simply stated, the quality of the product must be assured during each stage of production.

The NSSP is a voluntary, tripartite program composed of state officials, the shellfish industry, and Federal agencies. FDA coordinates and administers the NSSP. In each participating state, one or more regulatory agencies manage the sanitation programs for domestic and imported shellfish. A foreign country may export molluscan shellfish to the

U.S. by agreeing to abide by the NSSP. This agreement takes the form of a bilateral agreement or Memorandum of Understanding between the FDA and the foreign country. The Memoranda of Understanding on Shellfish Sanitation (MOU) stipulates the respective responsibilities of the exporting country and FDA in assuring that all provisions of the NSSP are met. After an MOU is signed, FDA conducts periodic program evaluations of the foreign country's program using the same criteria applied to state shellfish control programs.

Under the NSSP, the definition of shellfish is limited to molluscan bivalves - oysters, clams, mussels and whole or roe-on scallops. Thermally processed, hermetically sealed and cooked products are not regulated under the NSSP. However, all other oyster, clam, and mussel products which are not shelf stable at room temperature are covered by the NSSP.

Each participating state and country classifies its shellfish growing waters, inspects shellfish packing/shucking facilities and issues certificates (certifies) to individual shellfish dealers that meet NSSP control criteria. FDA evaluates state and foreign shellfish sanitation programs, insures standardization of laboratory procedures and coordinates shellfish research.

FDA publishes monthly the Interstate Certified Shellfish Shippers List (ICSSL) which consist of certified shellfish dealers. The NSSP member states require that only shellfish products from dealers listed in FDA's ICSSL be accepted. Individual state requirements under the Food Code, require that shellfish products be from a certified "source of origin." Proof of origin is dealer listing in the ICSSL. Products are rejected by states if they do not originate from a dealer listed in the ICSSL. In most cases, rejection does not require product testing. Once dealer certification is documented, product testing by FDA does not normally occur. However additional rejections may occur based on quality and safety monitoring performed by the receiving jurisdictions.

Obtaining a Molluscan Shellfish MOU with FDA

Obtaining program acceptance that results with the formal signing of an MOU is a lengthy process. Steps leading to the signing of a MOU include: officials of the applicant nation developing a letter of intent with FDA; technical training of foreign shellfish sanitation officials in the U.S.; the applicant's request for and successful receipt of clearance from National Marine Fisheries Service (NMFS), National Oceanic and Atmosphere Administration, U.S. Department of Commerce, to import live or shells-on shellfish; FDA on-site evaluation of microbiological laboratories; and participation in triennial on-site program audits conducted by FDA that verify the effectiveness of the applicant's program by visiting and evaluating both the shellfish growing areas and firms certified to ship shellfish.
Environmental concerns are addressed by the National Marine Fisheries Service (NMFS). These concerns relate to the introduction and transfer of exotic species, aquatic disease organisms, and parasites that have the potential to adversely affect our domestic fisheries. The literature is replete with examples of introduced species and/or pathogenic agents,

that in the absence of biological controls, have the ability devastate domestic fishery stocks either by producing epizootic outbreak of disease or through simple competition. Therefore, MOUs on shellfish sanitation require statements on environmental risks associated with the introduction of live and shells-on shellfish. Information on NMFS requirements should be directed to the following address:

Assistant Administrator for Fisheries
National Marine Fisheries Service
1335 East-West Highway
Silver Spring, MD 20910

FDA will only negotiate the development of a MOU with authorized officials representing the government of the exporting nation. Generally these governmental officials operate through a ministry of health, agriculture, or fisheries.

Obtaining Listing in the ICSSL

Foreign programs must be evaluated by FDA to assure that they fully meet NSSP certification criteria before shellfish dealers are listed in the ICSSL. Like state programs, foreign programs must meet the NSSP standards for classification of growing waters and certification of firms. The effectiveness of the NSSP sanitation controls are dependent upon the quality of the shellfish when they are harvested. The quality of bivalve molluscan shellfish is dependent upon the quality of the waters where they are grown. The fundamental principles governing shellfish sanitation are 1) that shellfish must be produced in areas shown to be safe and free of direct fecal contamination, and marine biotoxins; 2) that only shellfish from properly classified growing waters may be harvested; 3) that sanitary practices are maintained from time of harvest until retail sale; and 4) that shellfish are properly identified (labeled) to include date and place of harvest.

Product safety is primarily based on the sanitary evaluation of the production area and not on microbiological quality of shellfish meats. This is an important distinction. The assessment of product safety based on water quality at the time of harvest is predicated on numerous assumptions and historical findings, including:

- Some viruses and bacteria are human pathogens potentially transmitted by shellfish.
- Many or these pathogens have unknown survival rates in seawater and uptake and discharge by shellfish.
- The ratios of viral and bacterial pathogens to indicator organisms (fecal coliforms) are not quantified and vary considerably depending on local conditions.
- In the absence of even small quantities of direct fecal pollution, harvesting areas having a fecal coliform count of 14 or less per 100 ml have historically produced shellfish which are safe for direct harvest and raw consumption.
- The elimination of indicator organisms during chlorine disinfection of treated wastewater effluents is not necessarily proportional to the destruction of pathogens.

Water quality then, is determined by an ongoing program of bacteriological monitoring using indicators of fecal pollution. In addition, each shellfish growing area evaluation must include a pollution source survey of the shoreline and other areas adjacent to the shellfish growing waters. This inventory of potential shoreline pollution sources is designed to reveal that the area is not subject to direct contamination with small amounts of fresh sewage which would not ordinarily be revealed by the bacteriological examination." The pollution source survey, followed by routine microbiological testing at times of adverse pollution conditions represent the primary evaluation measures. The results of these surveys are then combined with hydrographic studies to detail how the pollution sources affect the water quality at the specific harvesting site.
The minimum satisfactory compliance criteria, guidelines, and public health explanations for the classification of shellfish growing waters are contained in the NSSP Guide for the Control of Molluscan Shellfish.

The NSSP also provides procedures that allow a participating nation to certify firms handling shellfish products that comply with NSSP criteria. This certification assures U.S. health officials both at the Federal and state levels, that shellfish products from a certified dealer have been grown, harvested, transported, processed, and shipped in accordance with NSSP criteria.

Simply stated, the NSSP certification system requires that all fresh and fresh frozen oysters, clams, and mussels in interstate commerce be tagged by a certified dealer. The certified dealer must hold, pack, and handle the product in accordance with NSSP sanitation controls at all times. The certified dealer must also maintain a file identifying the source of each lot of shellfish shipped in interstate commerce. This certification and record keeping provides sanitary controls and product traceability from harvest to sale. For the certification process to be effective, certified dealers must fully comply with these requirements.

Only those shellfish firms that meet the guidelines are eligible for certification and listing in FDA's monthly publication, the ICSSL. The ICSSL is a compilation of both domestic and foreign certified sources of molluscan shellfish that satisfactorily meet NSSP criteria. A summary of the activities requiring governmental examination and shellfish shipper certification for listing in the ICSSL are:

- Harvesting of shellfish that originate in estuarine and marine waters or the culture and subsequent harvest of shellfish from artificial environments.
- Purchasing shellstock directly from harvesters, tagging and packing the shellstock, and shipping this product in interstate commerce.
- Shucking and packing of shellfish where one or both shells are removed in accordance with NSSP guidelines.
- Wet storage of shellstock either in near shore floats or in tanks.

Reshipping. This term refers to the purchase of shucked shellfish or shellstock from another certified dealer and selling the product without repacking or relabeling to other

certified dealers, wholesalers, or retailers. The use of the reshipper classification is however, left to the option of the participating shellfish control authority.

Interstate Shellfish Sanitation Conference

The Interstate Shellfish Sanitation Conference (ISSC) is an organization of state shellfish control agencies, the shellfish industry, and Federal agencies. The primary goal of the ISSC is to promote the adoption of uniform standards, rules, regulations, and procedures by state shellfish control agencies. Participation in the ISSC is voluntary, but it is supported by state shellfish control officials, participating nations, the shellfish industry, FDA, and the National Marine Fisheries Service.

Requirements for NSSP Participation

The FDA Office of Seafood and the Division of Cooperative Programs, Office of Field Programs coordinates the assignment of FDA shellfish specialists who conduct annual program audits of participating international shellfish sanitation programs. Specific areas for evaluation include: 1) administrative and legal authority, 2) laboratory facilities, 3) plant sanitation and processing, 4) growing area classification, and 5) enforcement of harvesting controls. The points covered in the field program audit are summarized in Table 1, and are explained below.

Table 1

NSSP Shellfish Sanitation

Program Audits

Administrative & Legal Authority	Laboratory	Plant Sanitation	Growing Water Classification and Patrol
Effective State Laws and Regulations Seizure/Embargo Powers Maintain Central Files Perform Internal Program Reviews Annually	Follows APHA Procedures or Other NSSP Accepted Procedures Bacteriological/Toxicological Proficiency Participates in FDA Quality Control Programs Qualified State Laboratory Evaluation Officer	Certify and Inspect Interstate Shippers Participates in Joint Inspections with FDA Regulates Shipping and Labeling Provides Effective Supervision of Depuration and Wet Storage Facilities	Water Sampling and Classification Program Operates Effective Marine Biotoxin Monitoring Program Effective Patrol of Closed Areas Necessary Measures are Taken To Make Classifications Known to the harvesters Provides Controls to Ensure that Only Shellfish Originating From Approved Waters Are Exported to U.S.

Administrative and Legal Authority

NSSP participants are required to provide an adequate legal basis for all phases of the program. This legal authority must enable the shellfish control authority to regulate and supervise the source, shipment, labeling, and storage of shellfish; if applicable, the operation of controlled purification and wet storage facilities; and the shucking, packing, and repacking of shellfish. The control authority shall be empowered to certify and decertify interstate shellfish shippers; to conduct laboratory examinations of shellfish water and shellfish; to prevent the sale of unsafe or uncertified shellfish by such means as detention, monetary fines, seizure, embargo, and destruction; and to suspend interstate shipper certificates in public health emergencies.

Laboratory

American Public Health Association (APHA) laboratory procedures shall be followed for the collection, transportation, and laboratory examination of shellfish and shellfish waters. The appointment of an FDA certified shellfish laboratory evaluation officer is

encouraged to evaluate supporting laboratories within the participating nation's shellfish sanitation program.

Plant Sanitation and Processing

The shellfish control agency shall conduct inspections and maintain records of those inspections with such frequency as to ensure that sanitary conditions of operation are maintained. Dealers that do not meet and maintain the minimal sanitation requirements shall not be eligible for listing in the Interstate Certified Shellfish Shippers List (ICSSL). Dealer listing in the ICSSL requires:

1. a current MOU;
2. the successful completion of an FDA program audit that confirms that the program is in conformity with the criteria of the NSSP. Changes in program status are automatic grounds for removing the names of that nation's shellfish shippers from the ICSSL.

FDA, in cooperation with the ISSC, developed a program to standardize the inspection and certification of shellfish dealers. The purpose of standardization is to train FDA and participating program shellfish plant inspectors in uniform inspection techniques. The prospective international participant should be aware that mandatory participation in the standardization training and testing program is a program requirement.

Growing Area Classification

Each growing area shall be correctly designated with one of the classifications described in NSSP Guide for the Control of Molluscan Shellfish. Growing areas shall be classified on the basis of sanitary and marine biotoxin survey information. Shellfish that do not originate from properly classified waters are effectively excluded from export to the U.S.

Historically, the shellfish sanitation program has found the coliform group of indicator organisms to be the most suitable medium for use when classifying shellfish growing waters. Bacteriological analyses however, must always be evaluated in the context of background information relating to the findings of a sanitary inspection of the surrounding shoreline. The minimum criteria for evaluating bacteriological sampling results includes the consideration of a series of samples collected over a period of time. Additionally, in order to validate the wholesomeness of the shellfish products, in shellfish growing areas affected by point sources of pollution samples must be collected under adverse conditions. Adverse conditions are defined as those meteorological, hydrographic, seasonal and pollution conditions that have been historically demonstrated to unfavorably influence a particular body of water. Therefore, in areas affected by point sources of pollution, the field monitoring program is required to 1) determine if adverse conditions exist that may significantly influence the growing area; and 2) if so, the classification decision is determined using only water sampling results that are collected during the adverse condition. In order to effectively establish the adverse condition and collect the minimum series of water samples, the conscientious environmental water

sampling program usually operates during four (4) consecutive seasons (1 year) before the initial data analysis is completed. In shellfish growing areas which are not affected by point sources of pollution, a systematic random sampling (SRS) strategy may be substituted for the adverse monitoring strategy. SRS must meet the specific requirements outlined in the NSSP Guide for the Control of Molluscan Shellfish.

Marine Biotoxin

The Shellfish Control Agency shall develop and adopt a marine biotoxin contingency plan for all marine and estuarine waters. The plan shall establish effective monitoring programs which provide information on the presence of marine biotoxins as well as effective administrative controls to quickly stop shellfish harvesting when marine biotoxins are present. Each growing area shall be continuously monitored for the presence of marine biotoxins.

FDA Support

The FDA Division of Cooperative Programs, Shellfish Safety Team provides technical assistance, consultation, training and research services for NSSP participants. These support services (subject to prior commitments) are available at no cost in the United States. The FDA Division of Cooperative Programs, Shellfish Safety Team has developed training materials and courses for all facets of the NSSP.

An FDA shellfish specialist will be assigned to your program to facilitate inquiries about participation in the NSSP. The FDA shellfish specialist can answer questions pertaining to all aspects of the program, from administrative to field topics. The shellfish specialist can aid a prospective NSSP participant by acquainting him/her with the appropriate NSSP guidelines and will facilitate the development of regulations and procedures. Also, the shellfish specialist is the primary FDA contact for state technical/training requests.

Procedure for Initiation

The development of an MOU with the FDA is initiated by submitting a formal "letter of intent." This letter must include a commitment that the applicant will provide the funding and personnel needed to develop and operate an ongoing comprehensive shellfish sanitation program. In addition, the letter should define the governmental agency or agencies that will participate in the MOU development. The inclusion of a table of organization (organogram) and a brief narrative report describing the various levels of government, their responsibilities, and how they will interact will facilitate the FDA understanding of the proposed shellfish sanitation program.

The letter of intent should be addressed to:

U.S. Food and Drug Administration
Office of Constituent Operations
International Activities

200 'C' Street SW. (HFS-585)
Washington, D.C. 20204

FDA will aid in the development and formally respond to the letter of intent to develop the bilateral agreement. The letter of intent must contain the commitment to initiate and operate the shellfish sanitation program, fund the travel and per diem of the applicant's program staffers in the U.S.; discuss the available funding sources for the travel and per diem of FDA technical specialists conducting on-site training in the applicant's country; and share the in-country travel expenses for FDA personnel conducting annual field audits after the applicant's shellfish sanitation program is accredited (Table 1). Please note, depending on the scope and breadth of the proposed shellfish sanitation program, training and evaluation arrangements, in addition to those shown on table 1, may be required.

FDA will formally respond to the letter of intent and will provide NSSP guideline and standards to the foreign country.

Depending on FDA's budgetary and staffing commitments, FDA will then proceed with training the applicant's personnel. Arrangements can then be initiated for the training of laboratory and water quality survey personnel (English speakers preferred) at FDA's facility. The training is provided free of charge, however, travel and per diem expenses will be the responsibility of the applicant. Training should be reserved for those program officials that will actually carry out the day-to-day operations of the applicant nation's shellfish sanitation program. (English speaking program personnel preferred, but not necessary when the services of a translator are available.) The training course agenda customarily requires 5 - 10 days of classroom and field study in the U.S. Laboratory and field monitoring training generally will not occur simultaneously. The classroom laboratory training and an on-site laboratory evaluation must be successfully completed before the bacteriological water quality monitoring for the classification of shellfish growing areas can begin.

Following a period for assimilation and trial of the NSSP accepted health controls, an FDA team will be scheduled for an on-site training and overview visit of the applicant nation. In the interim, the administrative controls should be developed via correspondence with the assigned FDA shellfish specialist. Initial development of the MOU may also begin during this period. The governmental public health authority should initiate the NSSP controls before the on-site training and overview visit. The on-site training and overview visit will identify any program weaknesses or deficiencies before the program operations are finalized.

Following the operation of the applicant's shellfish growing water monitoring program and acquisition of a data series meeting NSSP minimum criteria (generally one year) the tabulation and analysis of the sampling and sanitary reconnaissance data are compiled into a comprehensive survey sanitary report establishing the classification of the growing area(s). The completed sanitary survey reports are submitted to the assigned FDA Shellfish Specialist for evaluation prior to the scheduling of the pre-evaluation audit.

FDA will evaluate the comprehensive report and if necessary, make recommendations to improve the operation of the program.

Upon confirmation that the newly developed shellfish sanitation program is ready to be evaluated, a second FDA team will be scheduled to appraise the program. FDA must conduct a through program audit and the applicant nation must successfully demonstrate that it possesses the administrative and technical capabilities to operate a comparable shellfish sanitation program. Only following the successful demonstration of its ability to run a shellfish sanitation program will the MOU be finalized.

Upon successful completion of this evaluation, the FDA Division of Cooperative Programs, Shellfish Safety Team will accept certifications of shellfish shipping firms to be included on the ICSSL. The time frame for completion of the process will vary according to the complexity of the applicant nation's program and availability of FDA technical assistance personnel.

Annex III

United States National Shellfish Sanitation Program Model Ordinance

I. PURPOSE

PURPOSE OF THE
NATIONAL SHELLFISH SANITATION PROGRAM

The National Shellfish Sanitation Program (NSSP) is the federal/state cooperative program recognized by the U. S. Food and Drug Administration (FDA) and the Interstate Shellfish Sanitation Conference (ISSC) for the sanitary control of shellfish produced and sold for human consumption. The purpose of the NSSP is to promote and improve the sanitation of shellfish (oysters, clams, mussels and scallops) moving in interstate commerce through federal/state cooperation and uniformity of State shellfish programs. Participants in the NSSP include agencies from shellfish producing States, FDA, and the shellfish industry. Under international agreements with FDA, foreign governments also participate in the NSSP. Other components of the NSSP include program guidelines, State growing area classification and dealer certification programs, and FDA evaluation of State program elements.

In 1984, the FDA entered into a Memorandum of Understanding (MOU) with the Interstate Shellfish Sanitation Conference recognizing the ISSC as the primary voluntary national organization of State shellfish regulatory officials that provide guidance and counsel on matters for the sanitary control of shellfish. The purpose of the ISSC is to provide a formal structure for State regulatory authorities to participate in establishing updated regulatory guidelines and procedures for uniform state application of the Program. The ISSC has adopted formal procedures for state representatives to review shellfish sanitation issues and develop regulatory guidelines. Following FDA concurrence, these guidelines are published in revisions of the NSSP Model Ordinance.

The NSSP Guide for the Control of Molluscan Shellfish consists of a Model Ordinance, supporting guidance documents, recommended forms, and other related materials associated with the Program. The Model Ordinance includes guidelines to ensure that the shellfish produced in States in compliance with the guidelines are safe and sanitary. The Model Ordinance provides readily adoptable standards and administrative practices necessary for the sanitary control of molluscan shellfish.

Interstate Shellfish Sanitation Conference
209-2 Dawson Road
Columbia, SC 29223
Phone: 803-788-7559
Fax: 803-788-7576
Email: issc@issc.org

M E M O R A N D U M

TO: ISSC Members

FROM: Ken B. Moore, Executive Director

DATE: September 24, 2004

RE: Model Ordinance Changes Adopted by Executive Board

During the March 2004 Board meeting the ISSC Executive Board was made aware that changes were needed to address confusion associated with the handling and labeling of post harvest processed shellfish. A committee was appointed and recommendations developed for Board consideration at the August Executive Board meeting. The Board approved several changes to the NSSP Model Ordinance that are included in the attached document. These changes will be submitted to Task Force II for consideration at the 2005 ISSC Biennial Meeting.

Although these changes have immediate effective dates, the Executive Board recognizes the financial impact associated with tagging and labeling changes. The Executive Board requests states to establish reasonable implementation schedules to allow the shellfish industry to incorporate these changes into their tagging and labeling programs. Included in the Model Ordinance changes adopted by the Executive Board is language in *Chapter X. General Requirements for Dealers .05 Shellstock Identification B. Tags*, which allows for inclusion of language associated with USDA requirements for Country of Origin Labeling (COOL). The new Model Ordinance language does not require Country of Origin labeling but does allow dealers to include this information on tags and labels.

/nsd
Attachment

NSSP Guide for the Control of Molluscan Shellfish

Section II Model Ordinance
Definitions

NEW **Post Harvest Processing** means processing of shellfish for the purpose of added safety or quality that involve hazards not addressed by controls in NSSP Model Ordinance Chapters XI. through XIV.

NEW **Raw** means shellfish that have not been thermally processed:
(a) to an internal temperature of 145°F or greater for 15 seconds (or equivalent); or
(b) altering the organoleptic characteristics.

AMENDED **Shellfish** means all species of:
(a) Oysters, clams or mussels, whether:
(i) Shucked or in the shell;
(ii) Raw, including post harvest processed;
(iii) Frozen or unfrozen;
(iii) Whole or in part; and
(b) Scallops in any form, except when the final product form is the adductor muscle only.

Section II Model Ordinance
Chapter IX Transportation

Requirements for the Authority
@ .02 Shipment Acceptability
A. Shipments are properly identified with tags and/or labels and shipping documents;
B. Shellstock is alive…
C. Shucked or post harvest processed shellfish are ~~is~~ cooled to a temperature of 45° Fahrenheit (7.2° Centigrade) or less; and
D. The time-temperature…
E. All other conditions…

Section II Model Ordinance
Chapter X General Requirements for Dealers

.05 Shellstock Identification
B. Tags
(5) The statement "Keep Refrigerated" or an equivalent statement must be included on the tag.

(6) Country of origin information (USDA 2004) may be included on the delaer tag.

.06 Shucked Shellfish Labeling

A. Shellfish Labeling

(5) The dealer shall assure that:

(a) The shucker-packer's or repacker's certification number is on the label of each package of fresh or frozen shellfish;

(b) The statement “Keep Refrigerated” or an equivalent statement appears on the label;

(c) Packages containing less than 64 fluid ounces have:

(i) A "SELL BY DATE" which is a reasonable subsequent shelf-life or the words "BEST IF USED BY" followed by a date when the product would be expected to reach the end of its shelf-life; and

(ii) The date as a month and day of the month.

(d) Packages containing 64 fluid ounces or more have on the lid and sidewall or bottom the "DATE SHUCKED" indicated as the number of the day of the year or the month and day of the month.

.07 Post Harvest Process Labeling

A. If a dealer elects to post harvest process shellfish and the final product form is live, the dealer shall label in accordance with Chapter X. .05.

B. If a dealer elects to post harvest process shellfish and the final product form is not live, the dealer shall label in accordance with Chapter X. .06 and include the following, or equivalent statement: These shellfish have been post harvest processed.

NOTE: The Consumer Advisory shall be required for both A and B.

.08 Shipping Documents and Records.

.09 Wet Storage in Artificial Bodies of Water.

Section II Model Ordinance
Chapter XVI Post Harvest Processing ~~Treatment~~

All references in Chapter XVI to post harvest treatment will be changed to post harvest processing.

II. MODEL ORDINANCE

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MOLLUSCAN SHELLFISH MODEL ORDINANCE

Purpose.

This Ordinance established the minimum requirements necessary to regulate the interstate commerce of molluscan shellfish and to establish a program to protect the public health of consumers by assuring the sale or distribution of shellfish from safe sources and assuring shellfish have not been adulterated during cultivating, harvesting, processing, shipping, or handling.

Definitions.

A. General. The definitions provided below are consistent in intent with the National Shellfish Sanitation Program.

B. Definition of Terms.

(1) **Adverse pollution condition** means a state or situation caused by meteorological, hydrological or seasonal events or point source discharges that has historically resulted in elevated fecal coliform levels in a particular growing area. [In States using total coliform standard, insert "total coliform" for "fecal coliform".]

(2) **Air gap** means the unobstructed vertical distance through the free atmosphere between the lowest opening from any pipe or faucet supplying water to a tank, plumbing fixture or other device and the flood level rim of that receptacle.

(3) **AOAC** means the Association of Official Analytical Chemists.

(4) **APHA** means the American Public Health Association.

(5) **Approved** means a classification used to identify a growing area where harvest for direct marketing is allowed.

(6) **Aquaculture** means the cultivation of seed in natural or artificial growing areas, or the cultivation of shellstock other than seed in growing areas.

(7) **Authority** means the State or local shellfish control authority or authorities or its designated agents, which are responsible for the enforcement of this Code.

(8) **Assure** means to make best efforts within the reasonable limits of manpower and resources to fulfill the objectives of this Ordinance.

(9) **Backflow** means the flow of water or other liquids, mixtures or substances into the distribution pipes of a potable water supply from any source or sources other than the intended source.

(10) **Back siphonage** means the flowing back of used, contaminated or polluted water from a plumbing fixture, vessel or other source into potable water supply pipes because of negative pressure in the water supply pipes.

(11) **Blower** means a receptacle for washing shucked shellfish which uses forced air as a means of agitation.

(12) **Broker** means any person who is not a dealer but who arranges the packaging, shipping, sale, or distribution of molluscan shellfish without taking ownership or physical custody of the shellfish.

(13) **Certification or certify** means the issuance of a numbered certificate to a person for a particular activity or group of activities that indicates:
(a) Permission from the Authority to conduct the activity; and
(b) Compliance with the requirements of this Code.

(14) **Certification number** means the unique identification number issued by the Authority to each dealer for each location. Each certification number shall consist of a one to five digit Arabic number preceded by the two letter State abbreviation and followed by a two letter abbreviation for the type of activity or activities the dealer is qualified to perform in accordance with this Ordinance using the following terms:
(a) Shellstock shipper (SS);
(b) Shucker-packer (SP);
(c) Repacker (RP);
(d) Reshipper (RS); and
(e) Depuration processor (DP).

(15) **Coliform group** means all of the aerobic and facultative anaerobic, gram negative, nonspore forming, rod shaped bacilli which ferment lactose broth with gas formation within 48 hours at 95 Fahrenheit (35 + 0.5 ◦ Centigrade).

(16) **Commingle or Commingling** means the act of combining different lots of shellstock or shucked shellfish.

(17) **Compliance schedule** means a written schedule that provides a correction time period to eliminate Key and Other deficiencies.

(18) **Conditionally approved** means a classification used to identify a growing area which meets the criteria for the approved classification except under certain conditions described in a management plan.

(19) **Conditionally restricted** means a classification used to identify a growing area that meets the criteria for the restricted classification except under certain conditions described in a management plan.

(20) **Container** means any bag, sack, tote, conveyance or other receptacle used for containing shellfish for holding or transporting.

(21) **Corrosion resistant materials** means materials that maintain their original surface characteristics under normal exposure to the foods being contacted, normal use of cleaning compounds and bactericidal solutions, and other conditions of use.

(22) **Critical Control Point (CCP)** means a point, step or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated or reduced to acceptable levels.

(23) **Critical deficiency** means a condition or practice which:
(a) Results in the production of a product that is unwholesome; or
(b) Presents a threat to the health or safety of the consumer.

(24) **Critical limit** means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate or reduce to an acceptable level the occurrence of the identified food safety hazard.

(25) **Critical Nonconformity** means a deviation of a laboratory requirement which has the highest likelihood of adversely affecting the quality of the analytical results if out of conformance.

(26) **Cross connection** means an unprotected actual or potential connection between a potable water system and any source or system containing unapproved water or a substance that is not or cannot be approved as safe and potable. Examples are bypass arrangements, jumper connection, removable sections, swivel or change over devices, or other devices through which backflow could occur.

(27) **Cull** means to remove dead or unsafe shellstock from a lot of shellstock.

(28) **Dealer** means a person to whom certification is issued for the activities of shellstock shipper, shucker-packer, repacker, reshipper, or depuration processor.

(29) **Depletion** means the removal, under the direct control of the Authority, of shellstock from a growing area classified as prohibited.

(30) **Depuration** or **depurate** means the process of reducing the pathogenic organisms that may be present in shellstock by using a controlled aquatic environment as the treatment process.

(31) **Depuration Processor (DP)** means a person who harvests or receives shellstock from growing areas in the approved or conditionally approved, restricted, or conditionally restricted classification and submits such shellstock to an approved depuration process.

(32) **Direct marketing** means the sale for human consumption of shellfish which:
(a) Does not require depuration or relaying prior to sale; or
(b) Has been subjected to depuration or relaying activities.

(33) **Dry storage** means the storage of shellstock out of water.

(34) **Easily cleanable** means a surface which is:
(a) Readily accessible; and
(b) Is made of such materials, has a finish, and is so fabricated that residues may be effectively removed by normal cleaning methods.

(35) **EPA** means the United States Environmental Protection Agency.

(36) **Facility** means a structure. For other connotations, use person or activity.

(37) **Fecal coliform** means that portion of the coliform group which will produce gas from lactose in an EC or A-1 multiple tube procedure liquid medium within 24 (+ 2) hours in a water bath maintained at 112 ^{O}Fahrenheit (44.5 ± 0.2 ^{O}Centigrade).

(38) **FDA** means the United States Food and Drug Administration.

(39) **Food contact surface** means an equipment surface or utensil which normally comes into direct or indirect contact with shucked shellfish.

(40) **Food Safety Hazard** means any biological, chemical or physical property that may cause a food to be unsafe for human consumption.

(41) **Geometric Mean** means the antilog (base 10) of the arithmetic mean of the sample result logarithm (base 10).

(42**)** **Growing area** means any site which supports or could support the propagation of shellstock by natural or artificial means.

(43) **HACCP** is an acronym that stands for Hazard Analysis Critical Control Point, a systematic, science-based approach used in food production as a means to assure food safety. The concept is built upon the seven principles identified by the National Advisory Committee on Microbiological Criteria for Foods (1992).

(44) **HACCP Plan** means a written document that delineates the formal procedures that a dealer follows to implement the HACCP requirements set forth in 21 CFR 123.6 as adopted by the Interstate Shellfish Sanitation Conference.

(45) **Harvest** means the act of removing shellstock from growing areas and its placement on or in a manmade conveyance or other means of transport.

(46) **Harvest area** means an area that contains commercial quantities of shellstock and may include aquaculture sites and facilities.

(47) **Harvester** means a person who takes shellstock by any means from a growing area.

(48) **Heat shock** means the process of subjecting shellstock to any form of heat treatment prior to shucking, including steam, hot water or dry heat, to facilitate removal of the meat from the shell without substantially altering the physical or organoleptic characteristics of the shellfish.

(49) **Importer** means any dealer who introduces molluscan shellfish into domestic commerce. An importer has ownership of the shellfish, but need not take physical custody of the shellfish.

(50) **Includes or including** means includes or including by way of illustration and not by way of limitation.

(51) **Inspection item** means one of the standard criteria listed in the NSSP Plant Inspection Form under which single or multiple observations of specific critical , key or other deficiencies can be debited. [Note: term "item" appears several places in the Ordinance with a larger connotation than this definition. In the section addressing the use of the inspection form, however, the Ordinance uses the term "inspection item" hence that is provided here as the defined term.]

(52) **Interstate Certified Shellfish Shippers List (ICSSL)** means a FDA publication of shellfish dealers, domestic and foreign, who have been certified by a state or foreign Authority as meeting the public health control measures specified in this Ordinance.

(53) **Interstate Shellfish Sanitation Conference (ISSC)** means the organization which consists of agencies from shellfish producing and receiving States, FDA, the shellfish industry, the National Marine Fisheries Service of the U.S. Department of Commerce, and the U.S. Environmental Protection Agency. The ISSC provides the formal structure wherein State regulatory authorities, with FDA concurrence, can establish updated guidelines and procedures for sanitary control of the shellfish industry.

(54) **Key deficiency** means a condition or practice which may result in adulterated, decomposed, misbranded or unwholesome product.

(55) **Key Nonconformity** means a deviation of a laboratory requirement has a significant potential to adversely affect the quality of the analytical results if out of conformance.

(56) **Label** means any written, printed or graphic matter affixed to or appearing upon any package containing shellfish.

(57) **License** means the document issued by the Authority to a person to harvest or transport shellstock for commercial sale. [In those States issuing permits as opposed to licenses, the term license would be replaced with the term "permit" which would be defined the same as "license".]

(58) **Lot of shellstock** means a single type of bulk shellstock or containers of shellstock of no more than one day's harvest from a single defined growing area gathered by one or more harvesters.

(59) **Lot of shellstock for depuration** means shellstock harvested from a particular area during a single day's harvest and delivered to one depuration plant.

(60) **Lot of shucked shellfish** means a collection of containers of no more than one day's shucked shellfish product produced under conditions as nearly uniform as possible, and designated by a common container code or marking.

(61) **Marina** means any water area with a structure (docks, basin, floating docks, etc.) which is:
(a) Used for docking or otherwise mooring vessels; and
(b) Constructed to provide temporary or permanent docking space for more than ten boats.

(62) **Marine biotoxin** means any poisonous compound produced by marine microorganisms and accumulated by shellstock. Examples include *Alexandrium spp.* [*Protogonyaulax* species], and *Karenia brevis*.

(63) **May** means discretionary and is not mandatory or required.

(64) **Milliliter** (ml) means a unit of measurement equal to the 0.001 portion of a liter.

(65) **Monoculture** means the culture of a single bivalve species.

(66) **MPN (Most Probable Number)** means a statistical estimate of the number of bacteria per unit volume and is determined from the number of positive results in a series of fermentation tubes.

(67) **National Shellfish Sanitation Program (NSSP)** means the cooperative state-FDA-Industry program for the sanitary control of shellfish that is adequate to insure that the shellfish produced in accordance with these guidelines will be safe and sanitary.

(68) **Open water aquaculture** means the cultivation of bivalve shellfish in natural shellfish growing areas.

(69) **Other deficiency** means a condition or practice that is not defined as critical or key and is not in accordance with the requirements of this Model Ordinance.

(70) **Other Nonconformity** means a deviation of a laboratory requirement which does not normally compromise the quality of the analytical results, but generally serve to enhance the overall operation of the laboratory.

(71) **Person** means any individual, receiver, trustee, guardian, personal representative, fiduciary, or representative of any kind, and any partnership, association, corporation or other entity. Person includes the federal government, the State, and any other public or private entity.

(72) **Point source** means any discernible, confined and discrete conveyance including any pipe, ditch, channel, tunnel or conduit that carries pollution.

(73) **Poisonous or deleterious substance** means a toxic substance occurring naturally or added to the environment for which a regulatory tolerance limit or action level has been established in shellfish to protect public health.

(74) **Polyculture** means the cultivation of:
(a) Two or more species of shellfish; or
(b) Shellfish with other species in a common environment.

(75) **Potable water** means a water supply, which meets the requirements of the Safe Drinking Water Act, as, administered by the EPA, and any applicable state or local requirements.

(76) **Principal display panel** means that part of a label that is most likely to be displayed, presented, shown or examined under customary conditions of retail sale.

(77) **Process batch** means a quantity of shellstock used to fill each separate tank or a series of tanks supplied by a single process water system for a specified depuration cycle in a depuration activity.

(78) **Process water** means the water used in the scheduled depuration process.

(79) **Prohibited** means a classification used to identify a growing area where the harvest of shellstock for any purpose, except depletion or gathering of seed for aquaculture, is not permitted.

(80) **Relay** means to transfer shellstock from a growing area classified as restricted or conditionally restricted to a growing area classified as approved or conditionally approved for the purpose of reducing pathogens as measured by the coliform indicator group or poisonous or deleterious substances that may be present in the shellstock by using the ambient environment as the treatment process.

(81) **Remote status** means a designation applied to a shellfish growing area that has no human habitation and is not impacted by any actual or potential pollution sources.

(82) **Repacker (RP)** means any person, other than the original certified shucker-packer, who repackages shucked shellfish into other containers.

(83) **Repacking Shellstock** means the practice of removing shellstock from containers and placing it into other containers.

(84) **Replicate** is defined as two (2) filters for tdh analysis from the same homogenate at the same dilution.

(85) **Reshipper (RS)** means a person who purchases shucked shellfish or shellstock from dealers and sells the product without repacking or relabeling to other dealers, wholesalers, or retailers.

(86) **Restricted** means a classification used to identify a growing area where harvesting shall be by special license and the shellstock, following harvest, is subjected to a suitable and effective treatment process through relaying or depuration.

(87) **Safe materials** means articles manufactured from or composed of materials that may not reasonably be expected to, directly or indirectly, become a component of or otherwise adversely affect the characteristics of any food.

(88) **Sanitation control record** means records that document the monitoring of sanitation practices and conditions during processing.

(89) **Sanitary survey** means the written evaluation report of all environmental factors, including actual and potential pollution sources, which have a bearing on the water quality in a shellfish growing area.

(90) **Sanitize** means to adequately treat food contact surfaces by a process that is effective in:

(a) Destroying vegetative cells of microorganisms of public health significance;
(b) Substantially reducing the numbers of other undesirable microorganisms; and
(c) Not adversely affecting the product or its safety for the consumer.

(91) **Seed** means shellstock which is less than market size.

(92) **Shall** means mandatory and required.

(93) **Shellfish** means all species of:
(a) Oysters, clams or mussels, whether:
(i) Shucked or in the shell;
(ii) Fresh or fresh frozen; and
(iii) Whole or in part; and
(b) Scallops in any form, except when the final product form is the adductor muscle only.

(94) **Shellstock** means live molluscan shellfish in the shell.

(95) **Shellstock packing** means the process of placing shellstock into containers for introduction into commerce.

(96) **Shellstock Shipper (SS)** means a dealer who grows, harvests, buys, or repacks and sells shellstock. They are not authorized to shuck shellfish nor to repack shucked shellfish. A shellstock shipper may also ship shucked shellfish.

(97) **Should** means recommended but is not required.

(98) **Shucker-Packer (SP)** means a person who shucks and packs shellfish. A shucker-packer may act as a shellstock shipper or reshipper or may repack shellfish originating from other certified dealers.

(99) **Standardization** means a process in which applicable staffs from the FDA and the Authority conduct evaluations using standard criteria in a uniform manner.

(100) **State shellfish standardization inspector** means a person that has successfully completed the FDA standardization training course (or one deemed acceptable by the FDA) and the field evaluation phase of shellfish plant inspection with either an FDA standardization officer or a state standardization officer.

(101) **State shellfish standardization officer** means a person that has successfully completed the FDA standardization training course and the field evaluation phase of shellfish plant inspection with an FDA standardization officer.

(102) **Swing deficiency** means a deficiency noted on the NSSP Standardized Shellfish Processing Plant Inspection Form which, depending upon the severity and circumstances, can be either a “Critical” or a “Key” deficiency.

(103) **Transaction record** means the form or forms used to document each purchase or sale of shellfish at the wholesale level, and includes shellfish harvest and sales records, ledgers, purchase records, invoices and bills of lading.

(104) **Wet storage** means the temporary storage, by a dealer, of shellstock from growing areas in the approved classification or in the open status of the conditionally approved classification in containers or floats in natural bodies of water or in tanks containing natural or synthetic seawater.

I. SHELLFISH SANITATION PROGRAM

Requirements for the Authority.

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this section in regulation.]

Additional Guidance
Page 227

@.01 Administration.

A. Scope. The Authority shall establish a statewide shellfish safety and sanitation program to regulate:
   (1) The classification of shellfish growing areas;
   (2) The harvesting of shellfish;
   (3) Shellfish processing procedures and facilities;
   (4) Product labeling;
   (5) Storage, handling and packing;
   (6) Shellfish shipment in interstate commerce;
   (7) Shellfish dealers; and
   (8) Bivalve aquaculture.

B. Records. The Authority shall maintain records to demonstrate the effective administration of a statewide shellfish safety and sanitation program. These records shall be maintained in a central file and made available to any interested person upon request, consistent with appropriate state and federal law.

C. Shared Responsibilities. If more than one agency is involved in the administration of the statewide shellfish safety and sanitation program, memoranda of agreement shall be developed between the agencies to define each agency's responsibilities.

D. Administrative Procedures. The Authority shall have administrative procedures sufficient to:
   (1) Regulate shellfish harvesting, sale, or shipment; and
   (2) Ensure that all shellfish shipped in interstate commerce originate from a dealer located within the state from which the shellstock are harvested or landed, unless the Authority has a memorandum of understanding with the Authority in another State to allow dealers from its state to purchase the shellstock.
   (3) Detain, condemn, seize, and embargo shellfish.
   (4) Assure compliance with Shellfish Plant Inspection Standardization.

E. Epidemiologically Implicated Outbreaks of Shellfish-Related Illness. The Authority shall have procedures for investigating incidents of shellfish borne disease.

F. Commingling.

(1) Except for any shellstock included in the Authority's commingling plan, the Authority shall not permit the commingling of shellstock.

(2) If the Authority permits shellstock commingling, the Authority shall develop a commingling management plan. The plan shall:

(a) Minimize the commingling dates of harvest and growing areas;

(b) Define a primary dealer;

(c) Limit the practice of commingling to primary dealers;

(d) Limit commingling to shellstock harvested from specific growing areas within the State as identified by the Authority and purchased directly from harvesters; and

(e) Define how the commingled shellstock will be identified.

@.02 Dealer Certification.

Additional Guidance
Pages 379, 400

A. General

(1) A person requesting certification shall be subject to a comprehensive, onsite inspection and meet the criteria in §B. or §C., as appropriate. The plant inspection shall be conducted by the state shellfish standardization inspector, using the appropriate inspection form, within the 120-day period immediately prior to the issuance or renewal of the certification.

(2) Certification shall be given only to persons who meet the established requirements established for certification.

(3) All certifications shall expire annually. The month selected for certification expiration shall be at the discretion of the Authority.

(4) The Authority shall issue only one certification number to a dealer for a location. A person or dealer may obtain more than one certification if each business is:

(a) Maintained as a separate entity; and

(b) Is not found at the same location.

(5) The Authority may permit separate certified dealers to share a facility.

(6) The certification number issued to each dealer by the Authority shall be unique.

(7) Adequate records documenting each dealer's compliance with certification requirements shall be maintained for at least three years. These records shall include:

(a) Inspection reports of dealers;

(b) Notification letters and enforcement actions;

(c) Shellfish sample results and follow-up actions taken;

(d) Records of complaints or inquiries and follow-up actions taken; and

(e) Administrative hearing transcripts and records.

B. Initial Certification.
(1) Initial certification shall be given only to persons who meet the following requirements:
(a) HACCP requirements:
(i) A HACCP plan accepted by the Authority;
(ii) No critical deficiencies;
(iii) Not more than 2 key deficiencies;
(iv) Not more than 2 other deficiencies.
(b) Sanitation and additional Model Ordinance Requirements
(i) No critical deficiencies;
(ii) Not more than 2 key deficiencies;
(iii) Not more than 3 other deficiencies.

(2) The initial certification shall include a compliance schedule to correct any deficiencies not corrected by the dealer during the inspection.

C. Renewal of Certification.
(1) A dealer shall make application for certification renewal annually at the time specified by the Authority. The Authority shall not renew the certification for any dealer until the dealer:
(a) Meets the requirements of §B.1(a) and §B.1(b). The number of deficiencies allowed under §B.1(a) and §B.1(b) shall include carry over deficiencies from an existing compliance schedule approved by the Authority and new deficiencies identified during the certification renewal inspection; and
(b) Agrees to a compliance schedule to address any new deficiencies not corrected by the dealer during the inspection.

D. Revocation or Suspension of Certification.
(1) The Authority shall not allow any dealer whose certification has been suspended or revoked under §H. to deal in shellfish.
(2) The Authority shall not issue certification to a dealer whose certification has been suspended or revoked to deal in shellfish until the dealer meets the requirements for initial certification.

E. Interstate Certified Shellfish Shippers List (ICSSL).
(1) When the Authority certifies a person to become a dealer, the Authority shall notify the FDA for the purpose of having the dealer listed in the ICSSL. The notice shall be in the format of FDA Form 3038.
(2) The Authority shall notify the FDA for the purpose of having the dealer removed from the ICSSL whenever a dealer's certificate is:
(a) Suspended; or
(b) Revoked.

F. Inspections.

(1) After any person is certified, the Authority shall make unannounced inspections of the dealer's facilities:

(a) During periods of activity; and

(b) At the following minimum frequencies:

(i) Within 30 days of beginning activities if the dealer was certified on the basis of a pre-operational inspection;

(ii) At least monthly for dealer facilities certified as depuration processors;

(iii) At least quarterly for dealer's activities certified as shucker-packer or repacker; and

(iv) At least semiannually for other dealer activities.

(2) The Authority shall provide a copy of the completed inspection form to the person in-charge at the dealer's operation at the time of inspection. The inspection form shall contain a listing of deficiencies by area in the operation and inspection item with corresponding citations to this Model Ordinance.

G. Performance Based Inspection Program (PIP).

(1) A performance based inspection program may be instituted by the Authority for any dealer who meets the requirements of this section.

(2) The minimum frequency of inspection under a PIP shall be no less than one inspection per certification period. The recertification inspection may qualify as the required minimum inspection frequency.

(3) To be eligible for a PIP, the dealer shall have demonstrated a history of satisfactory compliance for the previous three-year period. The three-year demonstration shall include:

(a) Full compliance with the minimum inspection frequency shown under §F.;

(b) Recertification of the dealer by the Authority;

(c) Verification that no critical deficiencies, no more than one key deficiency and no more than two other deficiencies have occurred in any one inspection;

(d) Correction of all identified deficiencies in accordance with the compliance schedule approved by the Authority; and

(e) No repetition of the identified deficiencies.

H. Enforcement.

(1) General.

(a) The Authority shall use any combination of administrative hearings, fines, certification cancellations, temporary suspension of operating licenses, embargoes, product condemnations or product seizures to accomplish the implementation of this Ordinance.

(b) When a dealer has failed to meet the compliance schedule, the Authority shall:

(i) Consider whether it is appropriate to revise the compliance schedule, suspend or revoke the dealer's certification, or seek other administrative remedies; and
(ii) Document why an option was selected.

(2) Actions Triggered by Inspections.

(a) When any inspection detects a critical deficiency:
(i) The deficiency shall be corrected during that inspection; or
(ii) The dealer must cease production affected by the deficiency.

(b) When the dealer fails to comply with (a) above, the Authority shall immediately begin actions to suspend or revoke the dealer's certification.

(c) Product affected by a critical deficiency shall be controlled to prevent contaminated or adulterated product from reaching consumers. When necessary the Authority shall:
(i) Detain or seize any undistributed lots of shellfish that may have been adulterated;
(ii) Initiate a recall of any distributed shellfish; and
(iii) Immediately notify the enforcement officials for FDA and any other Authorities where the product was distributed.

(d) When any inspection detects any key or other deficiencies not already covered in a compliance schedule, the Authority, working with the dealer, shall develop a compliance schedule to correct the new key or other deficiencies.

(e) When any inspection detects four or more new key deficiencies, the Authority shall consider the following options and document the reasons for the selection of a particular option:
(i) Revise the existing compliance schedule;
(ii) Suspend or revoke the dealer's certification; or
(iv) Seek other administrative remedies.

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II. RISK ASSESSMENT AND RISK MANAGEMENT

Requirements for the Authority

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this section in regulation.]

@.01 Outbreaks of Shellfish-Related Illness.

A. When shellfish are implicated in an illness outbreak involving two (2) or more persons not from the same household (or one or more persons in the case of paralytic shellfish poisoning [PSP]), the Authority shall determine whether an epidemiological association exists between the illness and the shellfish consumption by reviewing:
   (1) Each consumer's food history;
   (2) Shellfish handling practices by the consumer and/or retailer;
   (3) Whether the disease has the potential or is known to be transmitted by shellfish; and
   (4) Whether the symptoms and incubation period of the illnesses are consistent with the suspected etiologic agent.

NOTE: For additional guidance refer to the International Association of Milk, Food, and Environmental Sanitarians' *Procedures to Investigate Food Borne Illness*.

B. When the Authority has determined an epidemiological association between an illness outbreak and shellfish consumption, the Authority shall conduct an investigation of the illness outbreak within 24 hours to determine whether the illness is growing area related or is the result of post-harvest contamination or mishandling.

C. When the investigation outlined in §.02B. does not indicate a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall:
   (1) Immediately place the implicated portion(s) of the harvest area(s) in the closed status;
   (2) Notify receiving states and the FDA that a potential health risk is associated with shellfish harvested from the implicated growing area;
   (3) As soon as determined by the Authority, transmit to the FDA and receiving states information identifying the dealers shipping the implicated shellfish; and
   (4) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 Code of Federal Regulations Part 7.

D. When the investigation outlined in §.02B demonstrates that the illnesses are related to post-harvesting contamination or mishandling, growing area closure is not required. However, the Authority shall:
   (1) Notify receiving states of the problem; and
   (2) Promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 Code of Federal Regulations Part 7.

E. When the investigation outlined in §.02B. cannot be completed within 24 hours, the Authority shall:
   (1) Follow the closure procedure outlined in § 01C; and if the investigation does not indicate a growing area problem, the area shall be immediately reopened and product recall terminated.

F. Upon closing an implicated area for problems other than natural occurring pathogens and/or biotoxins, the Authority shall review the growing area classification and determine if a growing area classification problem exists. The review shall include at a minimum:
   (1) A review of the growing area classification file records;
   (2) A field review of existing pollution sources;
   (3) A review of actual and potential intermittent pollution sources, such as vessel waste discharge and wastewater discharge from treatment plant collection systems; and
   (4) Examination of water quality subsequent to the illness outbreak.

G. Upon closing an implicated portion(s) of the harvest area(s) for naturally occurring pathogens and/or biotoxins, the Authority shall:
   (1) Follow an existing marine biotoxin contingency plan, if appropriate.
   (2) Collect and analyze samples relevant to the investigation, if appropriate.
   (3) Keep the area closed until it has been determined that levels of naturally occurring pathogens and/or biotoxins are not a public health concern.

H. When the growing area is determined the problem, the Authority shall:
   (1) Place the growing area in the closed status until:
      (a) The Authority verifies that the area is properly classified, using current data, in compliance with the NSSP Model Ordinance; or
      (b) Shellfish from the growing area are confirmed as the cause of illness but it has been determined that the event which caused the contamination no longer exists;
   (2) Keep the area closed for a minimum of 21 days if the illness is consistent with viral etiology; and
   (3) Develop a written report summarizing the findings of the investigation and actions taken.

I. Whenever an Authority or dealer initiates a recall of shellfish products because of public health concerns, the Authority will monitor the progress and success of the recall. The Authority will immediately notify the FDA and the Authorities in other states involved in the recall. Each Authority involved in a recall will implement actions to ensure removal of recalled product from the market and issue public warnings if necessary to protect public health. FDA will decide whether to audit or issue public warnings after consultation with the Authority(s), and after taking into account the scope of the product distribution and other related factors. If the FDA determines that the Authority in any state involved in the recall fails to implement effective actions to protect public health, the FDA may classify, publish and audit the recall, including issuance of public warnings when appropriate.

J. The Authority shall assess annually *Vibrio parahaemolyticus* illnesses associated with the consumption of molluscan shellfish. The assessment will include a record of all *V. parahaemolyticus* shellfish-associated illnesses reported within the state and from receiving states, the numbers of illnesses per event, actions taken by the Authority in response to the illnesses, and a summary description of the state's shellfish illness reporting procedures, from patient presentation through laboratory diagnosis of food vehicle and etiological agent, to final public health documentation and reporting of specific illnesses to CDC. The initial assessment should be made for the most recent three calendar years and completed by March 1, 2002.

Additional Guidance Page 424

@. 02 Presence of Human Pathogens in Shellfish Meats.

Additional Guidance Pages 331, 332

A. Finding. Upon determination that human pathogens are present in shellfish meats, the Authority shall investigate the harvesting, the distribution, and the processing of the shellfish.

B. Growing Area Investigation.
   (1) The Authority shall review the following factors:
      (a) The documentation to trace the shellfish to its source;
      (b) The classification assigned to the growing area and whether the sanitary survey data supporting that classification is current; and
      (c) The probability of illegal harvesting from areas classified as restricted or prohibited, or in the closed status.
   (2) The Authority shall take no further action when the Authority determines that:
      (a) The growing area is properly classified;
      (b) No illegal harvesting is taking place; and
      (c) There is no reason to believe that the growing area is the source of the pathogens.

(3) When the Authority determines that the growing area is not properly classified, the Authority shall take immediate action to:
   (a) Change the existing classification to the correct classification; or
   (b) Close the growing area until the correct classification can be determined.

C. Distribution and Processing Investigation.
   (1) The Authority shall evaluate the distribution and processing of the shellfish. This investigation may include collection of additional meat samples.
   (2) The Authority shall take no further action when the Authority determines that there is no reason to believe a problem exists in the distribution or processing of the shellfish.
   (3) When the Authority determines that a problem exists in the distribution or processing of the shellfish, the Authority shall take immediate steps to correct the problem.

D. Risk Management and Tolerance Levels.
   (1) Pathogen Present. When a growing area continues to demonstrate the presence of human pathogen isolates in shellfish meats in the absence of illness, the Authority shall perform a risk assessment to determine the correct classification for an area.
   (2) Established Tolerance Levels.

Additional Guidance
Pages 259, 260

      (a) When the established tolerance level for a particular pathogen isolate is not exceeded, the Authority:
         (i) Shall maintain a written summary of its finding and the data supporting its finding in its central file; and
         (ii) May leave the growing area in its present classification.
      (b) When the established tolerance level for a particular pathogen isolate is known and there are no known outbreaks of shellfish associated disease caused by that pathogen in a particular growing area, the Authority shall:
         (i) Leave the area in the open status of its classification when the tolerance level is not exceeded; and
         (ii) Place the area in the closed status of its classification when the tolerance level is exceeded.
      (c) When the tolerance level is exceeded, the Authority may:
         (i) Maintain the growing area in the closed status of its current classification;
         (ii) Reclassify the growing area to the restricted or prohibited classification; or

(iii) Reclassify the growing area to the conditionally restricted classification and establish a management plan.

(d) Any management plan based on shellstock exceeding established tolerance levels shall:

(i) Meet all appropriate requirements for a management plan for the conditionally approved or conditionally restricted classification;

(ii) Specify the additional criteria associated with the particular pathogen isolate that the growing area must meet to be in the open status of its classification;

(iii) Document the scientific basis for the additional criteria;

(iv) Provide for periodic retesting of the shellfish meats; and

(v) Provide for the growing area to be placed in the closed status if the criteria are exceeded.

(3) Established Tolerance Levels Not Known.

(a) When an established tolerance level does not exist for the particular pathogen isolated, the Authority shall assess the public health significance of the levels of the pathogen found in the growing area shellfish meats. The Authority may consider FDA recommended action levels or levels of concern in this determination. When the Authority determines that:

(i) The levels are acceptable, the growing area shall remain in the open status of its classification; or

(ii) The levels are unacceptable, the growing area shall be placed in the closed status of its classification.

(b) If a growing area is placed in the closed status, the Authority may elect to:

(i) Maintain that status indefinitely;

(ii) Reclassify the area to the restricted or prohibited classification; or

(iii) Reclassify the area to the conditionally restricted classification and establish a management plan. The management plan shall meet the requirements of §D.(2)(d).

@.03 Presence of Toxic Substances in Shellfish Meats.

Additional Guidance
Pages 259, 260

A. Upon determination that toxic substances, including heavy metals, chlorinated hydrocarbons, and natural toxins are present in levels of public health significance in shellfish meats, the Authority shall investigate the harvesting, distribution, and processing of shellfish and take necessary corrective action in accordance with the procedures described in §.02.

B. When a growing area continues to demonstrate the presence of toxic substances in the absence of illness, the Authority shall perform a risk

assessment to determine the correct classification of the area. The risk assessment and subsequent risk management shall follow the procedures outlined in §.02D., Risk Management and Tolerance Levels.

@.04 *Vibrio vulnificus* Risk Management for Oysters.

Additional Guidance
Pages 419, 420

A. For states having 2 or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state (Source State), the Authority shall develop and implement *a Vibrio vulnificus* management plan.

B. The Source State's *Vibrio vulnificus* management_plan shall define the administrative procedures and resources necessary to accomplish (i.e. establish and maintain) involvement by the state in a collective illness reduction program. The goal of the *Vibrio vulnificus* Management Plan will be to reduce the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses reported collectively by California, Florida, Louisiana, Texas, from the consumption of commercially harvested raw or undercooked oysters by 40 percent, for years 2005 and 2006 (average) and by 60 percent for years 2007 and 2008 (average) from the average illness rate for the years 1995 - 1999 of 0.306/million. The list of states (California, Florida, Louisiana, Texas) used to calculate rate reduction may be adjusted if after a thorough review, epidemiological and statistical data demonstrates that it would be appropriate. The illness rate shall be calculated as the number of illnesses per unit of population. The goal may be reevaluated prior to the year 2006 and adjusted in the event that new science, data, or information becomes available.

C. The Source State's *Vibrio vulnificus* management plan shall include, at a minimum:

(1) The ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* illnesses;

(2) A process to collected standardized information for each *Vibrio vulnificus* illness: including underlying medical conditions; knowledge of disease status; prior counseling on avoidance of high risk foods, including raw oysters; existence of consumer advisories at point of purchase or consumption; and, if possible, whether consumer was aware and understood the advisories;

(3) A standardized process for tracking products implicated in *Vibrio vulnificus* illnesses;

(4) Identification and preparation for achieving a goal of post-harvest treatment capacity of 25 percent of all oysters intended for the raw, half-shell market during the months of May through September

harvested from a Source State by the end of the third year (December 31, 2004). The percentage of post harvest treatment will include the capacity of all operational plants and the capacity of plants under construction;

(5) Identification and preparation for implementation of required post harvest treatment capacity of 50% of all oysters intended for the raw, half-shell market during the months of May through September, harvested from a Source State, which shall be implemented should the 40 percent illness reduction goal not be achieved by December 31, 2006. The percentage of post harvest treatment will include the capacity of all operational plants and the capacity of plants under construction. In the alternative, the state may utilize the control measures, or equivalent control measures, listed in .04, (C), (6) (a), (b), (c), and (d) below for such periods of time which, in combination with post harvest treatment, will provide equivalent outcomes. This portion of the plan shall be completed no later than December 31, 2005; and

(6) Identification and preparation for implementation of one or more of the following controls, or equivalent controls, which shall be implemented should the 60 percent rate of illness reduction goal not be achieved collectively by 2008. The control measures identified in the plan shall be appropriate to the state and reflect that state's contribution to the number of Vv illnesses and the controls that have been implemented by each state. This portion of the plan shall be completed no later than December 2007. The temperature and month-of the-year parameters identified in the following controls may be adjusted by the ISSC Executive Board as recommended by the Vibrio Management Committee (VMC) on a state by state basis, as needed to achieve the established illness reduction goal. The adjustment to the State's plan can take into account the illness rate reduction that has occurred since the last review of the plan.

(a) Labeling all oysters, "For shucking by a certified dealer", when the Average Monthly Maximum Water Temperature exceeds 75°F;

(b) Subjecting all oysters intended for the raw, half-shell market to an Authority-approved post-harvest treatment that reduces the *Vibrio vulnificus* levels to 3MPN/g or less," when the Average Monthly Maximum Water Temperature exceeds 75°F;

(c) Closing shellfish growing areas for the purpose of harvest of oysters intended for the raw, half-shell market when the Average Monthly Maximum Water Temperature exceeds 75°F;

(d) Labeling all oysters, "For shucking by a certified dealer", during the months of May through September, inclusive;

(e) Subjecting all oysters intended for the raw, half-shell market to a post-harvest treatment that is both approved by the Authority

and reduces the *Vibrio vulnificus* levels to 3MPN/g or less during the months of May through September, inclusive; and

(f) Closing shellfish growing areas for the purpose of harvesting oysters intended for the raw, half-shell market during the months of May through September, inclusive.

III. LABORATORY

Requirements for the Authority

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this chapter in regulation.]

Additional Guidance
Page 302

@.01 Quality Assurance.

A. NSSP Conformance Required. All laboratory analyses shall be performed by a laboratory found to conform or provisionally conform by the FDA or FDA certified State Shellfish Laboratory Evaluation Officer (LEO) in accordance with the requirements established under the NSSP.

B. State Program Requirements. The Authority shall assure that all samples are collected, maintained, transported, and analyzed in a manner that assures the validity of the analytical results. The Authority shall:

(1) Require laboratories to develop a written quality assurance plan that:

(a) Describes the organization and management structure of the laboratory;

(b) Describes the laboratory staff training program ensuring that all laboratory personnel are qualified, properly trained, and supervised;

(c) Describes all procedures and methods used to collect, maintain, transport and analyze samples;

(d) Describes quality control measures, their frequency and tolerance limits, for determining equipment performance;

(e) Requires maintenance of records of analytical performance, quality control results, and equipment maintenance and calibration; and

(f) Provides a quality assessment program to demonstrate laboratory and analyst competence. At a minimum this program must include triennial onsite laboratory evaluations conducted by either FDA laboratory evaluation officers or FDA certified state laboratory evaluation officers, and annual internal laboratory audits. For microbiological laboratories, participation in the annual FDA sponsored proficiency test programs is also required; and

(g) Requires corrective action for any deficiencies found in the laboratory quality assurance program.

(2) Require laboratories to implement their quality assurance plan;

(3) Ensure that the laboratory has appropriate facilities and resources to effectively manage the workload;

(4) Require triennial or more frequent evaluations of all laboratories which conduct both microbial and marine biotoxin and analyses used to officially support the state shellfish program; and

(5) Require a laboratory to be re-evaluated when any major changes in personnel, workload, or facilities occur and when a laboratory is found in nonconformance.

C. An FDA certified State Shellfish Laboratory Officer may evaluate laboratories in a different State under a memorandum of understanding agreement between the States and FDA. The agreement shall be consistent with NSSP requirements.

D. Laboratory Evaluation.

(1) Laboratory Status. Continued acceptance of analytical data in support of the NSSP by the Authority from any operating laboratory is contingent upon the laboratory being found to conform or provisionally conform to NSSP requirements as determined in their most recent laboratory evaluation using the NSSP standardized laboratory evaluation criteria listed in Section IV Guidance Documents A.12.

(a) Conforms. In order to achieve or maintain its conforms status, a laboratory shall meet the following requirements under the NSSP standardized laboratory evaluation criteria:

(i) No critical nonconformities have been identified;

(ii) Not more than 12 key nonconformities for microbiological or 5 for paralytic shellfish poisoning component have been identified;

(iii) Not more than 17 critical, key, and other nonconformities in total or 9 for paralytic shellfish poisoning component have been identified (not to exceed the critical and key criteria); and

(iv) No repeat key nonconformities have been identified in consecutive evaluations.

(b) Provisionally Conforms. In order to achieve provisionally conforming status, a laboratory shall meet the following requirements under the NSSP standardized microbiological laboratory evaluation criteria:

(i) Not more than 3 critical nonconformities for the microbiological or 2 for paralytic shellfish poisoning component have been identified;

(ii) Not more than 12 key nonconformities for the microbiological or 5 for paralytic shellfish poisoning component have been identified; and

(iii) Not more than one repeat Key nonconformity has been identified in consecutive evaluations.

(c) Nonconformance. When a laboratory exceeds the following criteria, the laboratory shall be determined to be in nonconformance:

(i) More than 3 critical nonconformities for the microbiological or 2 for paralytic shellfish poisoning component have been identified;

(ii) More than 12 key nonconformities for the microbiological or 5 for paralytic shellfish poisoning component have been identified;

(iii) More than 17 critical, key, and other nonconformities for microbiological or 9 for paralytic shellfish poisoning component have been identified; or

(iv) One or more repeat critical or two or more key nonconformities have been identified in consecutive evaluations.

E. Time Limit on Laboratory Status.

(1) Conforming Status. A laboratory in conforming status may operate for up to 90 days during which the laboratory must be actively working on an FDA or FDA certified State Shellfish LEO approved action plan to maintain its conforming status. After this period, the laboratory shall be assigned a nonconforming status if all key deficiencies have not been successfully corrected.

(2) Provisionally Conforming Status. A laboratory in the provisionally conforming status may operate for up to 60 days during which the laboratory must be actively working on a FDA approved action plan that will bring the laboratory into the NSSP conforms status. After this period, the laboratory shall be assigned a status as:

(a) Conforms if all the critical and key nonconformities have been successfully corrected; or

(b) Nonconforming if any critical or key nonconformities have not been successfully corrected.

(3) Nonconformance. Upon determination of nonconforming status, data generated from the laboratory shall not be used in support of the NSSP. If the laboratory wishes to attain conforming status, the laboratory must immediately implement an FDA or FDA certified State Shellfish LEO approved action plan and has up to 30 days to demonstrate successful correction of all critical and key deficiencies. After this period, an onsite re-evaluation should be conducted. Upon re-evaluation, only a status of conforming shall allow data to be accepted in support of the NSSP.

F. Laboratory Services for Depuration Processors. For any laboratory providing services for the quality assurance program (e.g. water quality) including end- product testing of any depuration processor, the Authority shall:
   (1) Require the annual inspection of the laboratory in accordance with 01 and 02 of this Chapter; and
   (2) Require the laboratory to retain its records for a minimum of the previous two years.

@.02 Methods.

A. Microbiological. Methods, practices, and procedures for the analyses of shellfish and shellfish growing or harvest waters shall be the methods required by the National Shellfish Sanitation Program.

Additional Guidance
Page 293

B. Chemical and Physical.
   (1) Methods for the analysis of shellfish and shellfish growing or harvest waters shall:
      (a) Be the current AOAC or APHA method for all physical and chemical measurements; and
      (b) Express results of all chemical and physical measurements in standard units, and not instrument readings.
   (2) When an AOAC or APHA method is not available, EPA methods may be used.

C. Biotoxin. Methods for the analyses of shellfish and shellfish harvest waters shall be:
   (1) The current AOAC and APHA methods used in bioassay for paralytic shellfish poisoning toxins; and
   (2) The current APHA method used in bioassay for *Karemia breve* toxins.

IV. SHELLSTOCK GROWING AREAS.

Requirements for the Authority.

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this chapter in regulation.]

@.01 Sanitary Survey.

Additional Guidance
Pages 243, 263, 278

A General.

(1) The sanitary survey is the written evaluation report of all environmental factors, including actual and potential pollution sources, which have a bearing on water quality in a shellfish growing area. The sanitary survey shall include the data and results of:

(a) A shoreline survey;

(b) A survey of the bacteriological quality of the water;

(c) An evaluation of the effect of any meteorological, hydrodynamic, and geographic characteristics on the growing area;

(d) An analysis of the data from the shoreline survey, the bacteriological survey, and the hydrodynamic, meteorological and geographic evaluations; and

(e) A determination of the appropriate growing area classification.

(2) The sanitary survey shall be periodically updated through the triennial reevaluation and the annual review in accordance with §C. to assure that data is current and that conditions are unchanged.

(3) The documentation supporting each sanitary survey shall be maintained by the Authority. For each growing area, the central file shall include all data, results, and analyses from:

(a) The sanitary survey;

(b) The triennial reevaluation; and

(c) The annual review.

(4) Wherever possible, the Authority shall provide the necessary information to Federal, State, or local agencies which have the responsibility to minimize or eliminate pollution sources identified in the sanitary survey.

(5) The Authority shall maintain a current comprehensive, itemized list of all growing areas, including maps showing the boundaries and classification of each shellstock growing area.

B. Sanitary Survey Required.

(1) A sanitary survey shall not be required to classify growing areas as prohibited. The findings of a sanitary survey, however, may result in a growing area being classified as prohibited.

(2) A sanitary survey, including the triennial reevaluation, when available, of each growing area shall be required prior to:

(a) The harvest of shellstock for human consumption; and

(b) The classification of a growing area as approved, conditionally approved, restricted, or conditionally restricted.

C. Sanitary Survey Performance.

(1) A sanitary survey of each growing area shall be performed at least once every twelve years and shall include the components in §A. (1).

(2) When a written sanitary survey report is not completed, the area shall be placed in the closed status.

(3) The growing area classification and the supporting data from the sanitary survey shall be reviewed at least every three years.

(a) This triennial reevaluation shall include:

(i) A review in accordance with §C. (5) and (6) of the water quality samples;

(ii) Documentation of any new pollution sources and an evaluation of their effect on the growing area;

(iii) Reevaluation of all pollution sources, including the sources previously identified in the sanitary survey, as necessary to fully evaluate any changes in the sanitary conditions of the growing area. The reevaluation may or may not include a site visit;

(iv) A comprehensive report which analyzes the sanitary survey data and makes a determination that the existing growing area classification is correct or needs to be revised; and

(v) If the triennial reevaluation determines that conditions have changed based on the information and data collected during the triennial review and that the growing area classification is incorrect, immediate action shall be initiated to reclassify the area. If it is determined that an emergency condition or situation exists, then the growing area will be immediately (within 24 hours) placed in the closed status.

(b) When a written triennial reevaluation report is not completed, the Authority shall place the growing area in the closed status.

(4) The triennial reevaluation may include:

(a) Inspection of wastewater treatment plants or collection of additional effluent samples to determine their impact on the growing area;

(b) Hydrodynamic studies;

(c) Additional field work to determine the actual impact of pollution sources; and

(d) Collection of additional water samples.

(5) On an annual basis, the sanitary survey shall be updated to reflect changes in the conditions in the growing area. The annual reevaluation shall include:

(a) A field observation of the pollution sources which may include:

(i) A drive-through survey;

(ii) Observations made during sample collection; and

(iii) Information from other sources.

(b) Review, at a minimum, of the past year's water quality sample results by adding the year's sample results to the data base collected in accordance with the requirements for the bacteriological standards and sample collection required in §.02;

(c) Review of available inspection reports and effluent samples collected from pollution sources;

(d) Review of available performance standards for various types of discharges that impact the growing area; and

(e) A brief report which documents the findings of the annual reevaluation.

(6) If the annual reevaluation determines that conditions have changed based on the information and data collected during the annual review and that the growing area classification is incorrect, immediate action shall be initiated to reclassify the area. If it is determined that an emergency condition or situation exists, then the growing area will be immediately (within 24 hours) placed in the closed status.

D. Shoreline Survey Requirements.

(1) In the shoreline survey for each growing area, the Authority shall:

(a) Identify and evaluate all actual and potential sources of pollution which may affect the growing area;

(b) Determine the distance from the pollution sources to the growing area and the impact of each source on the growing area;

(c) Assess the reliability and effectiveness of sewage or other waste treatment systems;

(d) Determine if poisonous or deleterious substances adversely affect the growing area; and

(e) Consider the presence of domestic, wild animal or resident and migrating bird populations for possible adverse effects on growing areas.

(2) The Authority shall assure that the shoreline survey meets the following minimum requirements:

(a) The boundaries, based on the area topography, of each shoreline survey area are determined by an in-field investigation which identifies only the properties with the potential to impact the shellfish waters;

(b) Each shoreline survey area is identified by a unique designation which results in identification of all data associated with each shoreline survey by the unique designation;

(c) Each shoreline survey area is investigated and pollution sources evaluated by qualified, trained personnel; and

(d) Documentation for each pollution source identified by the Authority as affecting a growing area includes:

(i) The location of the site on a comprehensive map of the survey area; and

(ii) The determination that the pollution source has a direct or indirect impact on shellfish waters: and

(e) A written summary of the survey findings.

Additional Guidance
Page 236

@.02 Bacteriological Standards.

Note: The NSSP allows for a growing area to be classified using either a total or fecal coliform standard. The NSSP further allows the application of either standard to different water bodies within the state. The NSSP also allows for two sample collection strategies for the application of the total or fecal coliform standard: adverse pollution condition and systematic random sampling. The 1992 Task Force II recommended that this portion of the Ordinance be codified in two ways: a total coliform strategy and a fecal coliform strategy so that the state may choose sampling plans on a growing area basis. Within each strategy, provisions would appear for use of both systematic and adverse pollution condition sample collection. The Ordinance has been recodified in this manner. For maximum flexibility, a state may wish to adopt the use of both standards and both sampling strategies for each standard. This codification represents the fecal coliform standards. The total coliform standards are outlined in the NSSP Guidance Document, Page 206.

A. General. Either the total coliform or fecal coliform standard shall be applied to a growing area.

B. Water Sample Stations. The Authority shall assure that the number and location of sampling stations is adequate to effectively evaluate all pollution sources.

C. Exceptions.

(1) Except for growing areas classified as prohibited, in growing areas where there are pollution sources having an impact on the water quality, a minimum of 30 samples, collected under various environmental conditions, shall be required to classify any growing area not previously classified under §.03.

(2) Except for growing areas classified as prohibited or when the systematic random sampling standard is applied, in growing areas where there are no pollution sources having an impact on the water quality, a minimum of 15 samples shall be required to classify any growing area not previously classified under §.03.

D. Standard for the Approved Classification of Growing Areas in the Remote Status.

(1) Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard below.

(2) Fecal Coliform Standard for the Remote Status. The fecal coliform median or geometric mean MPN of the water sample results shall not exceed 14 per 100 ml, and not more than 10 percent of the samples shall exceed an MPN of:

(a) 43 MPN per 100 ml for a five tube decimal dilution test; or
(b) 49 MPN per 100 ml for a three-tube decimal dilution test.

(3) Required Sample Collection.
(a) A minimum of two samples shall be collected annually.
(b) A minimum of the most recent 15 samples collected shall be used to calculate the median or geometric mean and percentage to determine compliance with the standard established for the approved classification of remote growing areas.

E. Standard for the Approved Classification of Growing Areas Affected By Point Sources.

(1) Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in §E. (2).

(2) Fecal Coliform Standard for Adverse Pollution Conditions. The fecal coliform median or geometric mean MPN of the water sample results shall not exceed 14 per 100 ml, and not more than 10 percent of the samples shall exceed an MPN of:
(a) 43 MPN per 100 ml for a five tube decimal dilution test; or
(b) 49 MPN per 100 ml for a three-tube decimal dilution test.

(3) Required Sample Collection.
(a) A minimum of five samples shall be collected annually under adverse pollution conditions from each sample station in the growing area.
(b) A minimum of the most recent 15 samples collected under adverse pollution conditions from each sample station shall be used to calculate the median or geometric mean and percentage to determine compliance with this standard.
(c) Sample station locations shall be adjacent to actual or potential sources of pollution.

F. Standard for the Approved Classification of Growing Areas Affected by Nonpoint Sources.

(1) Exception. If the tidal stage increases the fecal coliform concentration, the authority shall use sample results collected during that tidal stage to classify the area.

(2) Pollution Sources. Growing areas shall be:
(a) Impacted only by randomly occurring, intermittent events; and
(b) Not impacted by discharges from sewage treatment facilities or combined sewer overflows.

(3) Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in §E.(2) or §F.(4).

(4) Fecal Coliform Standard for Systematic Random Sampling. The fecal coliform median (or geometric mean MPN of the water sample results shall not exceed 14 per 100 ml and the estimated 90th percentile shall not exceed an MPN of:
(a) 43 MPN per 100 ml for a five tube decimal dilution test; or

(b) 49 MPN per 100 ml for a three-tube decimal dilution test.

(5) Estimated 90th Percentile. The estimated 90th percentile shall be calculated by:

(a) Calculating the arithmetic mean and standard deviation of the sample result logarithms (base 10);

(b) Multiplying the standard deviation in (a) by 1.28;

(c) Adding the product from (b) to the arithmetic mean;

(d) Taking the antilog (base 10) of the results in (c) to get the estimated 90th percentile; and

(e) The MPN values that signify the upper or lower range of sensitivity of the MPN tests in the 90th percentile calculation shall be increased or decreased by one significant number.

(6) Required Sample Collection.

(a) Adverse Pollution Condition Standard. The Authority shall collect samples in the same intensity and frequency as described in §E. (3) for application of the standard under §E.(2).

(b) Systematic Random Sampling Standard. The requirement for systematic random sample collection shall be met when:

(i) Sample station locations are adequate to produce the data to effectively evaluate all nonpoint sources of pollution;

(ii) Sample collection is scheduled sufficiently far in advance to support random collection with respect to environmental conditions. Compliance requires that, prior to implementation, the schedule for random sampling shall be documented in the master file for the growing area, and if conditions at the time of scheduled sample collection are believed to be hazardous to the safety of the individuals assigned to collect samples, sample collection shall be rescheduled at a later date as soon as practical;

(iii) A minimum of six random samples shall be collected annually from each sample station in the growing area;

(iv) A minimum of two random samples shall be collected annually from each sample station in the growing area while in the inactive status. The sample collection frequency of six random samples per station per year specified under @.02F(6)(b)(iii) must resume at least six months before an area is reactivated; and

(v) A minimum of the 30 most recent randomly collected samples from each sample station shall be used to calculate the median or geometric mean and 90th percentile to determine compliance with this standard.

(c) Transition from Adverse Pollution Condition Standard to Systematic Random Sampling Standard. If the Authority:

(i) Does not have 30 recent randomly collected sample results from each station, then the previous 15 samples collected under adverse pollution

conditions may be used with the most recent random samples to meet the minimum 30 sample requirement for a transition period not to exceed three years; and

(ii) Uses the transition period described in (i), as additional random samples are collected; the random samples shall replace chronologically the samples collected under adverse pollution conditions (e.g. sample 31 replaces sample 1).

G. Standard for the Restricted Classification of Growing Areas Affected by Point Sources and Used as a Shellstock Source for Shellstock Depuration.

(1) Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in §G. (2).

(2) Fecal Coliform Standard for Adverse Pollution Conditions. The fecal coliform median or geometric mean MPN of the water sample results shall not exceed 88 per 100 ml and not more than 10 percent of the samples shall exceed an MPN of: (a) 260 MPN per 100 ml for a five tube decimal dilution test; or (b) 300 MPN per 100 ml for a three tube decimal dilution test.

(3) Required Sample Collection. Samples shall be collected in accordance with §E. (3).

H. Standard for the Restricted Classification of Growing Areas Affected by Nonpoint Sources and Used as a Shellstock Source for Shellstock Depuration.

(1) Exception. If the tidal stage increases the fecal coliform concentration, the Authority shall use samples collected under that tidal stage to classify the area.

(2) Pollution Sources. Growing areas shall meet the requirements in §F. (2).

(3) Water Quality. The bacteriological quality of every sample station in the growing area shall meet the fecal coliform standard in §G. (2) or §H. (4).

(4) Fecal Coliform Standard for Systematic Random Sampling. The fecal coliform median or geometric mean MPN of the water sample results shall not exceed 88 per 100 ml and the estimated 90th percentile shall not exceed a MPN of:

(a) 260 MPN per 100 ml for a five tube decimal dilution test; or

(b) 300 MPN per 100 ml for a three-tube decimal dilution test.

(5) Estimated 90th Percentile. The estimated 90th percentile shall be calculated by the same method described in §F. (5).

(6) Required Sample Collection.

(a) Adverse Pollution Condition Standard. The Authority shall collect samples in the same intensity and frequency as described in §E. (3) for application of the standard under §G. (2).

(b) Systematic Random Sampling Standard. The Authority shall collect samples in the same intensity and frequency, and shall apply the sample results in the manner described in §F. (6) for the application of the standard under §H. (4).

@. 03 Growing Area Classification.

A. General. Each growing area shall be correctly classified as approved, conditionally approved, restricted, conditionally restricted, or prohibited, as provided by this Ordinance.

(1) Emergency Conditions. A growing area shall be placed in the closed status under §.03A(5) when pollution conditions exist which were not included in the database used to classify the area.

(2) Classification of All Growing Areas. All growing areas which:

(a) Are not subjected to a sanitary survey every twelve years shall be classified as prohibited;

(b) Have a sewage treatment plant outfall or other point source outfall of public health significance within or adjacent to the growing area shall have an area in the prohibited classification established adjacent to the outfall in accordance with §E. Prohibited Classification; and

(c) Are subjected to a sanitary survey shall be correctly classified based on the twelve year sanitary survey, and its most recent triennial or annual reevaluation when available, as only one of the following:

(i) Approved;
(ii) Conditionally Approved;
(iii) Restricted;
(iv) Conditionally Restricted; or
(v) Prohibited.

(3) Boundaries. The boundaries of each classified growing area shall be delineated on charts which are:

(a) Of sufficient scale and detail so as to adequately describe the boundaries; and

(b) Maintained in the central file by the Authority.

(4) Revision of Classifications.

(a) Any upward revision of a growing area classification shall be supported by an adequate sanitary survey.

(b) The appropriate FDA regional office shall be notified of any revision in growing area classification.

(5) Status of Growing Areas. The status of a growing area is separate and distinct from its classification and may be open, closed or inactive for the harvesting of shellstock.

(a) Open Status. Except for an area in the prohibited classification, any correctly classified growing area, is normally open for the purposes of harvesting shellstock, subject to the limitations of its classification.

(b) Closed Status. Any classified growing area may be closed for a limited or temporary period because of:

(i) An emergency condition or situation;

(ii) The presence of biotoxins in concentrations of public health significance; or

(iii) Conditions stipulated in the management plan of conditionally approved or conditionally restricted areas; or

(iv) Failure of the Authority to complete a written sanitary survey or triennial review evaluation report.

(c) Reopened Status. A growing area temporarily placed in the closed status as provided in (b) above, shall be returned to the open status only when:

(i) The emergency situation or condition has returned to normal and sufficient time has elapsed to allow the shellstock to reduce pathogens or poisonous or deleterious substances that may be present in the shellstock to acceptable levels. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of contaminant levels in the shellstock to pre-closure levels. In addressing pathogen concerns, the study may establish criteria for reopening based on colifiorm levels in the water; or

(ii) The requirements for biotoxins or conditional area management plans as established in §.04 and §.03, respectively, are met; and

(iii) Supporting information is documented by a written record in the central file.

(d) Inactive Status. The authority may place an approved or restricted growing area affected by non-point sources in the inactive status for up to five years when shellstock harvest is suspended or no longer occurring. Shellstock harvesting shall be closed while an area is in the inactive status. The inactive status must continue for a minimum of one year.

(i) While in inactive status, the required bacteriological sample collection under @.02F (6)(b)(iii) may be reduced to two water samples per station per year collected under the systematic random sample collection strategy. Sanitary survey reports, triennial reevaluations, and annual updates must be completed as required under @.01C.

(ii) The sample collection frequency of six random samples per station per year specified under @.02F (6)(b)(iii) must resume at least six months before an area is reactivated.

(iii) Before an area is reactivated, the results of the most recent 30 samples must be reviewed and comply with the requirements under @. 02F.

(e) Remote Status. A growing area may be placed in the remote status if:

(i) A sanitary survey determines that the area has no human habitation, and is not impacted by any actual or potential pollution sources; and
(ii) The area is in the approved classification.

(f) Seasonally Remote/Approved Status. A growing area may be placed in a seasonally remote/approved status requiring two water samples per year if the following criteria are met:
(i) The area is initially classified as approved;
(ii) The closure time period is defined; and
(iii) At least one sample be taken upon reopening the area.

B. Approved Classification. Growing areas shall be classified as approved when the following criteria are met.

(1) Survey Required. A sanitary survey finds that the area is:
(a) Safe for the direct marketing of shellfish;
(b) Not subject to contamination from human or animal fecal matter at levels that, in the judgement of the Authority, presents an actual or potential public health hazard; and
(c) Not contaminated with:
(i) Pathogenic organisms;
(ii) Poisonous or deleterious substances;
(iii) Marine biotoxins; or
(iv) Bacteria concentrations exceeding the bacteriological standards for a growing area in this classification.

(2) Water Quality. The water quality in the growing area shall meet the bacteriological standards for an approved classification in §.02.

C. Conditional Classifications. Growing areas may be classified as conditional when the following criteria are met:

(1) Survey Required. The sanitary survey meets the following criteria:
(a) The area will be in the open status of the conditional classification for a reasonable period of time. The factors determining this period are known, are predictable, and are not so complex as to preclude a reasonable management approach;
(b) Each potential source of pollution that may adversely affect the growing area is evaluated;
(c) Bacteriological water quality correlates with environmental conditions or other factors affecting the distribution of pollutants into the growing area.

(2) Management Plan Required. For each growing area, a written management plan shall be developed and shall include:
(a) For management plans based on wastewater treatment plant function, performance standards that include:
(i) Peak effluent flow, average flow, and infiltration flow;
(ii) Bacteriological quality of the effluent;
(iii) Physical and chemical quality of the effluent;

(iv) Conditions which cause plant failure;
(v) Plant or collection system bypasses;
(vi) Design, construction, and maintenance to minimize mechanical failure, or overloading;
(vii) Provisions for monitoring and inspecting the waste water treatment plant; and
(viii) Establishment of an area in the prohibited classification adjacent to a wastewater treatment plant outfall in accordance with §E. Prohibited Classification;

(b) For management plans based on pollution sources other than waste water treatment plants:
(i) Performance standards that reliably predict when criteria for conditional classification are met; and
(ii) Discussion and data supporting the performance standards.

(c) For management plans based on wastewater treatment plant function or pollution sources other than wastewater treatment plants, criteria that reliably predict when an area that was placed in the closed status because of failure to comply with its conditional management plan can be returned to the open status. The minimum criteria are:
(i) Performance standards of the plan are fully met;
(ii) Sufficient time has elapsed to allow the water quality in the growing area to return to acceptable levels;
(iii) Sufficient time has elapsed to allow the shellstock to reduce pathogens that might be present to acceptable levels. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of coliform levels in the shellstock to pre-closure levels. The study may establish criteria for reopening based on coliform levels in the water; and
(iv) Shellstock feeding activity is sufficient to achieve coliform reduction.

(d) For management plans based on a risk assessment made in accordance with Chapter II, Risk Assessment and Risk Management, criteria that reliably determine when the growing area may be placed in the open status and shellfish may be harvested;

(e) For management systems based on marine biotoxins, the procedures and criteria that reliably determine when the growing area may be placed in the open status;

(f) Procedures for immediate notification to the Authority when performance standards or criteria are not met;

(g) Provisions for patrol to prevent illegal harvest; and

(h) Procedures to immediately place the growing area in the closed status in 24 hours or less when the criteria established in the management plan are not met.

(3) Reevaluation of Conditional Classification.

(a) The classification shall be reevaluated at least once each year. The reevaluation shall include:

(i) Evaluation of compliance with the management plan;

(ii) Determination of adequacy of reporting of failure to meet performance standards;

(iii) Review of the cooperation of the persons involved;

(iv) Evaluation of water quality in the growing area with respect to the bacteriological standards for its classification;

(v) Field inspection of critical pollution sources, where necessary; and

(vi) Written findings, evaluations and recommendations.

(b) Water Sample Collection.

(i) When the conditional management plan is based on the absence of pollution from marinas for certain times of the year, monthly water samples are not required when the growing area is in the open status of its conditional classification provided that at least three of the water samples collected to satisfy the bacteriological standard for the open status are collected when the growing area is in the open status.

(ii) When the conditional management plan is based on the operation and performance of a wastewater treatment plant(s); combined sewer overflow(s); or other point sources of pollution, monthly water samples are required when the growing area is in the open status of its conditional classification.

(iii) If a monthly sample cannot be collected due to environmental constraints, the monthly sampling requirement will be satisfied if an additional water sampling run is conducted the following month.

(iv) When the conditional management plan is based on the effects of non-point sources of pollution, such as rainfall events, stormwater runoff, and seasonal variations, a minimum of five (5) sets of water samples (when the Adverse Pollution Condition sampling regimen is used) or six (6) sets of water samples (when the Systematic Random Sampling regimen is used) are required. The samples shall be collected when the growing area is in the open status.

(4) Understanding of and Agreement With the Purpose of the Conditional Classification and Conditions of Its Management Plan by All Parties Involved.

(a) The management plan shall be developed by the Authority in coordination with:

(i) The local shellfish industry;

(ii) The individuals responsible for the operation of any wastewater treatment plants involved; and
(iii) Any local or State agencies; and

(b) Failure of any one party to agree shall constitute sufficient justification to deny the application of the conditional classification to a growing area.

(5) Conditional Area Types. There are two types of conditional areas:
(a) Conditionally approved; and
(b) Conditionally restricted.

(6) Conditionally Approved Classification. Any growing area in the conditionally approved classification shall:
(a) Meet the requirements for:
(i) An approved area classification when the conditionally approved classification is in the open status; and
(ii) A restricted or prohibited classification when the conditionally approved classification is in the closed status; and
(b) If the closed status meets the criteria for the restricted classification, designate in its management plan whether the shellstock may be harvested for relaying or depuration.

(7) Conditionally Restricted Classification. Any growing area in the conditionally restricted classification shall:
(a) Meet the requirements for:
(i) A restricted classification when the conditionally restricted classification is in the open status; and
(ii) A prohibited classification when the conditionally restricted classification is in the closed status; and
(b) Designate in its management plan whether the harvested shellstock are to be relayed or depurated.

D. Restricted Classification.
(1) General.
(a) A growing area may be classified as restricted when:
(i) A sanitary survey indicates a limited degree of pollution; and
(ii) Levels of fecal pollution, human pathogens, or poisonous or deleterious substances are at such levels that shellstock can be made safe for human consumption by either relaying, depuration or low acid-canned food processing.
(b) The Authority shall have effective controls to assure that shellfish are harvested from restricted areas only:
(i) By special license; and
(ii) Under the supervision of the Authority.

(2) Water Quality. Water quality in the growing area shall meet the bacteriological standards in §.02 for a growing area in the restricted classification if the growing area is used for depuration.

(3) Shellstock Quality Criteria. The Authority shall establish shellstock quality criteria for use in placing an area in the restricted classification. Depending on the treatment process to be applied to the shellstock, the criteria shall be established in accordance with:
(a) Chapter V. Shellstock Relaying; or
(b) Chapter XV. Depuration.

E. Prohibited Classification.
(1) Exception. The prohibited classification is not required for harvest waters within or adjacent to marinas. The Authority, however, may use the prohibited classification for these waters.
(2) General. Except for the harvest of shellstock for the gathering of seed for aquaculture or the depletion of the areas classified as prohibited, the Authority shall:
(a) Not permit the harvest of shellstock from any area classified as prohibited; and
(b) Ensure that shellstock removed from any growing area classified as prohibited is effectively excluded from human consumption.
(3) Sanitary Survey. A growing area shall be classified as prohibited if:
(a) No current sanitary survey exists;
(b) A sanitary survey determines:
(i) The growing area is adjacent to a sewage treatment plant outfall or other point source outfall with public health significance;
(ii) Pollution sources may unpredictably contaminate the growing area;
(iii) The growing area is contaminated with fecal waste so that the shellfish may be vectors for disease microorganisms;
(iv) The concentration of biotoxin is sufficient to cause a public health risk as identified in §.04. or
(v) The area is contaminated with poisonous or deleterious substances causing the shellfish to be adulterated.
(4) Risk Assessment. A growing area shall be classified as prohibited if a risk assessment performed in accordance with Chapter II, Risk Assessment and Risk Management indicates the shellstock are not safe for human consumption.
(5) Wastewater Discharges.
(a) An area classified as prohibited shall be established adjacent to each sewage treatment plant outfall or any other point source outfall of public health significance.
(b) The determination of the size of the area to be classified as prohibited adjacent to each outfall shall include the following minimum criteria:
(i) The volume flow rate, location of discharge, performance of the wastewater treatment plant and the bacteriological quality of the effluent;

(ii) The decay rate of the contaminants of public health significance in the wastewater discharged;
(iii) The wastewater's dispersion and dilution, and the time of waste transport to the area where shellstock may be harvested; and
(iv) The location of the shellfish resources, classification of adjacent waters and identifiable landmarks or boundaries.

@.04 Marine Biotoxin Control.

Additional Guidance
Page 246

A. Contingency Plan.
(1) The Authority shall develop and adopt a marine biotoxin contingency plan for all marine and estuarine shellfish growing areas.
(2) The plan shall define the administrative procedures and resources necessary to accomplish the following:
(a) Initiate an emergency shellfish sampling and assay program;
(b) Close growing areas and embargo shellfish;
(c) Prevent harvesting of contaminated species;
(d) Provide for product recall;
(e) Disseminate information on the occurrences of toxic algal blooms and/or toxicity in shellfish meats to adjacent states, shellfish industry, and local health agencies; and
(f) Coordinate control actions taken by Authorities and federal agencies.
(3) Except that the Authority shall classify as prohibited any growing areas where shellfish are so highly or frequently affected by marine biotoxins that the situation cannot be safety managed, the presence of marine biotoxins shall not affect the classification of the shellfish growing area under §.03. The Authority may use the conditionally approved classification for areas affected by marine biotoxins.
(4) The plan may include agreements or memoranda of understanding, between the Authority and individual shellfish harvesters, to allow harvesting in designated parts of a growing area while other parts of the growing area are placed in the closed status. Such controlled harvesting shall be conducted with strict assurances of safety, such as by batch release of shellfish lots only after samples of each lot are tested and found to be below the action levels specified in §C.

B. Marine Biotoxin Monitoring. In those areas where marine biotoxins are likely to occur in shellfish, representative samples of shellfish shall be collected during all harvest periods. Samples shall be collected from indicator stations at intervals determined by the Authority, and assayed for the presence of toxins in accordance with §C.

C. Closed Status of Growing Areas.

(1) A growing area, or portion(s) thereof as provided in §A.(4), shall be placed in the closed status for the taking of shellstock when the Authority determines that the level of biotoxin present in shellfish meats is sufficient to cause a health risk. The closed status shall be established based on the following criteria:

(a) The concentration of paralytic shellfish poison (PSP) equals or exceeds 80 micrograms per 100 grams of edible portion of raw shellfish; or

(b) For neurotoxic shellfish poisoning (NSP), the harvesting of shellstock shall not be allowed when:

(i) Any NSP toxin is found in shellfish meats; or

(ii) The cell counts for *Karenia brevis* organisms in the water column exceed 5,000 per liter; or

(c) For domoic acid, the toxin concentration shall not be equal to or exceed 20 ppm in the edible portion of raw shellfish.

(2) For any marine biotoxin producing organism for which criteria have not been established under this Ordinance, either cell counts in the water column or biotoxin meat concentrations may be used by the Authority as the criteria for not allowing the harvest of shellstock.

(3) When sufficient data exist to establish that certain shellfish species can be safely exempted from the marine biotoxin contingency plan, the closed status for harvesting may be applied selectively to some shellfish species and not others.

(4) The closed status shall remain in effect until the Authority has data to show that the toxin content of the shellfish in the growing area is below the level established for closing the area.

(5) The determination to return a growing area to the open status shall consider whether toxin levels in the shellfish from adjacent areas are declining.

(6) The analysis upon which a decision to return a growing area to the open status is based shall be adequately documented.

D. Heat Processing. If heat processing is practiced, a control procedure shall be developed. This procedure shall define the following:

(1) Toxicity limits for processing;
(2) Controls for harvesting and transporting the shellstock to processor;
(3) Special marking for unprocessed shellstock;
(4) Scheduled processes; and
(5) End product controls on the processed shellfish.

E. Records. The Authority shall maintain a copy of all of the following records:

(1) All information, including monitoring data, relating to the levels of marine biotoxins in the shellfish growing areas;
(2) Copies of notices placing growing areas in the closed status;
(3) Evaluation reports; and

(4) Copies of notices returning growing areas to the open status.

@.05 Marinas.

A. Marina Proper. The area within any marina which is in or adjacent to a shellstock growing area shall be classified as:
(1) Conditionally approved;
(2) Conditionally restricted; or
(3) Prohibited.

B. Adjacent Waters. Waters adjacent to marina waters classified under §A. may be impacted by pollution associated with the marina.
(1) A dilution analysis shall be used to determine if there is any impact to adjacent waters.
(2) The dilution analysis shall be based on the volume of water in the vicinity of the marina.
(3) The dilution analysis shall incorporate the following:
(a) A slip occupancy rate for the marina;
(b) An actual or assumed rate of boats which will discharge untreated waste;
(c) An occupancy per boat rate (i.e., number of persons per boat);
(d) A fecal coliform discharge rate of 2 x 10 fecal coliform per ninth power per day; and
(e) The assumption that the wastes are completely mixed in the volume of water in and around the marina.
(4) If the dilution analysis predicts a theoretical fecal coliform loading greater than 14 fecal coliform MPN per 100 ml, the waters adjacent to the marina shall be classified as:
(a) Conditionally approved;
(b) Restricted;
(c) Conditionally restricted; or
(d) Prohibited.
(5) If the dilution analyses predicts a theoretical fecal coliform loading less than or equal to 14 fecal coliform MPN per 100 ml, the waters adjacent to the marina may be classified as:
(a) Approved; or
(b) Conditionally approved.
(6) If the Authority chooses not to determine a specific occupancy per boat rate by investigation in specific areas or sites, the Authority shall assume a minimum occupancy rate of two persons per boat.

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V. SHELLSTOCK RELAYING.

Additional Guidance
Page 272

Requirements for the Authority.

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this section in regulation.]

@.01 General. The Authority shall assure that:

A. The shellstock used in relaying activities is harvested from growing areas classified as conditionally approved, restricted, or conditionally restricted;

B. The level of contamination in the shellstock can be reduced to levels safe for human consumption;

C. The contaminated shellstock are held in growing areas classified as approved or conditionally approved for a sufficient time under adequate environmental conditions so as to allow reduction of pathogens as measured by the coliform group of indicator organisms in the water, or poisonous or deleterious substances that may be present in shellstock to occur; and

D. If shellstock are relayed in containers:
   (1) The containers are:
      (a) Designed and constructed so that they allow free flow of water to the shellstock; and
      (b) Located so as to assure the contaminant reduction required in §C.; and
   (2) The shellstock are washed and culled prior to placement in the containers.

@.02 Contaminant Reduction.

A. The Authority shall establish species-specific critical values for water temperature, salinity, and other environmental factors which may affect the natural treatment process in the growing area to which shellstock will be relayed. The growing area to be used for the treatment process shall be monitored with sufficient frequency to identify when limiting critical values may be approached.

B. The effectiveness of species-specific contaminant reduction shall be determined based on a study. The Authority shall retain the written study report indefinitely. The study report shall demonstrate that, after the completion of the relay activity;

(1) The bacteriological quality of each shellfish species, is the same bacteriological quality as that of the same species already present in the approved or conditionally approved area; or
(2) Contaminant levels of poisonous or deleterious substances in shellstock do not exceed FDA tolerance levels.

C. The authority may waive the requirements for a contaminant reduction study if:
(1) Only microbial contaminants need to be reduced; and
(2) The shellstock are relayed from a conditionally approved, restricted, or conditionally restricted area meeting the bacteriological water quality for restricted areas used for shellstock depuration per IV@.02.G and IV@.02H; and
(3) The treatment period exceeds 60 days.

D. The time period shall be at least 14 consecutive days when environmental conditions are suitable for shellfish feeding and cleansing unless shorter time periods are demonstrated to be adequate.

E. When container relaying is used and the Authority allows a treatment time of less than 14 days, the Authority shall require more intensive sampling including:
(1) Product sampling before and after relay, and
(2) Monitoring of critical environmental parameters such as temperature and salinity.

F. The Authority shall establish the time period during the year when relaying may be conducted.

@.03 Licenses to Relay Shellstock or to Harvest Shellstock for Delivery to a Low Acid Canned Food Processing Facility.

A. The Authority shall require that each harvester that relays or harvests shellstock for delivery to a low acid canned food processing facility from growing areas in the conditionally approved (in the closed status), restricted or conditionally restricted classification possesses a valid harvester or relay license.

B. The license conditions shall not be transferable.

C. A license shall be valid only when issued for:
(1) A specific relay or harvest activity; and
(2) Not more than 365 days.

D. The license conditions shall include:
(1) The source, destination, and species to be relayed or harvested for low acid canned food processing;

(2) The relayed or harvested for low acid canned food processing shellstock deposition method;
(3) The method used to maintain adequate separation between different lots of shellfish;
(4) A requirement for the licensee to keep records which:
  (a) Specify the dates on which the shellstock is harvested, deposited for treatment and harvested again, or delivered to a low acid canned food processing facility;
  (b) Identify the buyer and quantity of shellstock harvested for relaying or delivery to a low acid canned food processing facility; and
  (c) Are submitted to the Authority at a specified frequency, if required by the Authority, or made available to the Authority upon request; and
(5) A provision for additional information at the discretion of the Authority.

E. If the relay harvester or harvester for low acid canned food processing fails to comply with the conditions of the license, the Authority shall revoke the license.

@.04 Management of Relaying Shellstock or the Harvesting for Delivery to a Low Acid Canned Food Processing Facility Activities.

A. The Authority shall be authorized and equipped to enforce the State's procedures for relay and low acid canned food processing. The Authority shall develop and maintain an effective program to control the harvest, transport, replanting, and security of the shellstock until the end of the complete relay activity to prevent shellstock from being illegally diverted to direct marketing.

B. In the event that the control of relaying or harvesting for low acid canning activities is shared among two or more agencies, the Authority shall develop written operating procedures for joint use among the agencies. These procedures shall provide for the achievement of all requirements specified in this Chapter, and shall be reviewed annually and updated as necessary.

C. If shellstock from growing areas classified as conditionally approved or restricted are to be relayed or harvested for low acid canned food processing across State boundaries, a memorandum of understanding outlining the procedures to be used shall be developed between the appropriate Authorities in each State.

D. If a growing area in the conditionally approved classification meets the criteria or the restricted classification when the growing area is in the

closed status, the Authority may permit shellstock to be harvested for relaying or low acid canned food processing during the period the area is in its closed status, provided that these activities are addressed in the management plan for the growing area classified as conditionally approved, and all other conditions of this Chapter are met.

E. Locations designated to receive relayed shellstock within growing areas which are classified as approved or conditionally approved shall:
   (1) Be placed in the closed status until the period of treatment is complete and the Authority returns the area to the open status; and
   (2) Be marked so that these areas are easily identified by harvesters transporting the relayed shellstock and by the Authority. These areas shall:
      (a) Be marked prior to the placing of any shellstock;
      (b) Remain marked until the Authority reopens the area and gives written permission to harvest shellstock; and
      (c) Be adequately separated from the shellstock in adjacent waters to prevent cross-contamination and commingling.

Requirement for Harvesters.

.01 Harvester License Required.

A. Any person who wants to relay shellstock or to harvest shellstock from a growing area classified as conditionally approved, restricted, or conditionally restricted shall make application to the Authority for a valid license to relay or to harvest shellstock.

B. No person shall relay shellstock or shall harvest shellstock for low acid canned food processing without a valid harvester license from the Authority.

VI. SHELLFISH AQUACULTURE

Requirements for the Authority

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this section in regulation.]

@.01 General.

A. The Authority shall maintain the following records while the aquaculture activity continues:
   (1) Construction and remodeling plans for any permitted aquaculture facility;
   (2) Aquacultural operational plans; and
   (3) Aquaculture permits.

B. The Authority shall inspect land based and polyculture aquaculture systems at least every six months.

@.02 Seed Shellstock.

A. The Authority shall establish the submarket size for each species of shellfish in accordance with §.01B. and §.01C.

B. All sources of seed shall be sanctioned by the Authority.

@.03 Land Based Aquaculture

A. Inspection. The Authority shall inspect land-based sites at least every six months.

B. The Authority shall approve the written operational plan for any land based aquaculture facility prior to its implementation.

Requirements for the Harvester/Dealer

.01 Exceptions. The following activities are exempted from these requirements:

A. Hatcheries;

B. Nursery products which do not exceed 10 percent of the market weight; and

C. Nursery products which are 6 months or more growing time from market size.

.02 General.

A. Aquaculture encompasses both open water and land based monoculture and polyculture.

B. Any person who performs open water aquaculture or operates an aquaculture facility to raise shellfish for human consumption shall obtain:
(1) A permit from the Authority for the activity or for construction and functioning of his facility;
(2) A harvester's license; and
(3) Certification as a dealer, where necessary.

C. Shellfish aquaculture shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the aquaculture activity. Authorization shall be based on the aquaculturist's written operational plan.

D. Prior to beginning his activity, an aquaculturist shall obtain the permission of the Authority for use of his site and any construction.

E. Water quality at any site used for open water or land based aquaculture shall meet the criteria for the approved, conditionally approved, restricted or conditionally restricted classification.

F. Shellfish cultured in any open water or land based system meeting the criteria for the approved classification of a growing area throughout the culture period may be immediately marketed.

G. Any shellfish raised in aquaculture shall be subjected to relaying or depuration prior to direct marketing if the culture area or facility is located in or using water which is in:
(1) The closed status of the conditionally approved classification;
(2) The restricted classification; or
(3) The open status of the conditionally restricted classification.

H. Only drugs sanctioned by the FDA shall be used for shellfish treatment.

I. Harvesting, processing, storage, and shipping requirements for shellfish raised in aquaculture shall be the same as the requirements for wild shellfish specified in Chapters V, VII, VIII, IX, X, XI, XII, XIII and XIV.

J. Complete and accurate records shall be maintained for at least two (2) years by the aquaculturist and shall include the:
(1) Source of shellfish, including seed if the seed is from growing areas which are not in the approved classification;
(2) Dates of transplanting and harvest; and

(3) Water source, its treatment method, if necessary, and its quality in land based systems.

.03 Seed Shellstock.

A. Seed may come from any growing area, or from any growing area in any classification, provided that:
   (1) The source of the seed is sanctioned by the Authority.
   (2) Seed from growing areas or growing areas in the restricted or prohibited classification have acceptable levels of poisonous or deleterious substances; and
   (3) Seed from growing areas or growing areas in the prohibited classification are cultured for a minimum of 6 months.

.04 Open Water Aquaculture.

Any open water aquaculture activity shall be in compliance when it meets the requirements of §.01, §.02, and §.03, as appropriate.

.05 Land Based Aquaculture.

A. Operational Plan. Each land based aquaculture facility shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include:
   (1) A description of the design and activities of the culture facility;
   (2) The specific site and boundaries in which shellfish culture activities will be conducted;
   (3) The types and locations of any structures, including rafts, pens, cages, nets, tanks, ponds, or floats which will be placed in the waters;
   (4) The species of shellfish to be cultured and harvested;
   (5) If appropriate, the source and species of other organisms to be cultured in any polyculture systems;
   (6) Procedures to assure that no poisonous or deleterious substances are introduced into the activities;
   (7) A program of sanitation, maintenance, and supervision to prevent contamination of the final shellfish products;
   (8) A description of the water source, including the details of any water treatment process or method, if necessary;
   (9) A program to maintain water quality, which includes collection of microbial water samples and their method of analysis and routine temperature and salinity monitoring. The bacterial indicator monitored shall be the same as used for monitoring growing areas;
   (10) Collection of information on the microbial and chemical quality of shellfish harvested from the aquaculture site;
   (11) Collection of data concerning the quality of food production (algae or other) used in the artificial harvest system;

(12) Maintenance of the required records; and
(13) How shellstock will be harvested, processed if applicable, and sold.

B. Water Systems.
(1) If the aquaculture system is of continuous flow through design, water from a growing area classified as approved, or in the open status of the conditionally approved classification at all times shellfish are held, may be used without treatment.
(2) Water used in land-based aquaculture incorporating a closed or recirculating system shall:
(a) Not contaminate shellfish with residues that are not Generally Recognized As Safe (GRAS);
(b) Come from a source meeting the restricted classification criteria at a minimum;
(c) Be maintained, at a minimum, at the bacteriological quality of the restricted classification; and
(d) Be measured at least five times per year.
(3) If the water in the closed or recirculating system meets the criteria for the conditionally approved classification, the operational plan, prior to shellstock harvest, shall require, at a minimum:
(a) Collection of three water samples from the tank at least three days apart over a 14 day period; and
(b) A fecal coliform of less than 14 MPN per 100 ml in each water sample from the holding tank.

C. Shellstock Quality.
(1) Shellstock cultured in any system meeting the criteria for the approved classification throughout the culture period may be used in direct marketing.
(2) If the water in a closed or recirculating system is classified as conditionally approved and in the open status, and if the water quality meets a fecal coliform level of less than 14 MPN per 100 ml in each sample collected in the 14 days prior to harvest, the shellstock may be used in direct marketing.
(3) Shellstock cultured in a closed or recirculating system which does not meet the requirements of §D. (1) or §D. (2) shall be relayed or depurated prior to direct marketing.

.06 Polyculture Systems.

A polyculture system shall:

A. Meet all requirements in §. 05 Land Based Systems;
B. Provide information concerning all sources of and species of all organisms to be cultivated, cultured, and harvested;
C. Include in its operational plan requirements to:

(1) Monitor for human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances that might be associated with polyculture activities; and

(2) Subject all harvested shellstock to relaying or depuration if human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances exist at levels of public health significance.

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VII. WET STORAGE IN APPROVED AND CONDITIONALLY APPROVED GROWING AREAS.

Requirements for the Dealer.

.01 Source of Shellstock.

A. The dealer shall wet store shellstock harvested only from areas classified as approved, conditionally approved, or taken from a certified depuration facility following successful completion of the depuration process.

B. Shellstock shall be harvested, identified and shipped to the wet storage operation in accordance with the requirements of Chapters VIII and IX.

.02 General.

A. Wet storage may be used to store, condition, remove sand or to add salt to shellstock.

B. Wet storage of depurated product shall occur only within the facility in which it was depurated.

C. Wet storage shall be practiced only by a dealer in strict compliance with the provisions in the written approval for the wet storage activity given by the Authority.

D. While awaiting placement in a wet storage operation, shellstock shall be protected from physical, chemical or thermal conditions which may compromise the shellstock's survival, quality or activity during wet storage.

E. Conditions and water quality during wet storage shall be sufficient to minimize the potential for compromising the sanitary quality of the shellstock during storage.

F. For the purpose of certification, each wet storage site or operation shall be evaluated annually. The evaluation shall include an inspection of the near shore storage site and floats, or the wet storage operation.

G. Shellstock from a wet storage operation shall be harvested, identified and shipped according to the requirements of Chapters VIII, IX and X. Any dealer who wet stores shellstock from another state and ships the shellstock as a product of the state where the shellstock was wet stored shall be required to:

(1) Have an operational plan approved by the Authority which describes how this labeling change will be employed in assuring that shellstock can be traced to its source; and
(2) Meet the requirements of Chapter IX.

H. When the product from wet storage was depurated prior to wet storage, the shellstock shall:
(1) Be packed and labeled according to the requirements in Chapter XV.; and
(2) Include the dates of wet storage on the labels or tags.

I. The wet storage operator shall keep complete and accurate records to enable a lot of shellstock to be traced back to the wet storage location. The records shall be maintained for at least:
(1) 90 days from the date of removal of the shellstock from wet storage; and
(2) 120 days from the date of removal of the shellstock from wet storage where the state of origin labeling is changed under §G.2.

.03 Wet Storage Sites.

A. Near shore waters used for wet storage in containers and floats shall meet the requirements for classification as approved or conditionally approved while shellstock is being held in storage. Areas classified as conditionally approved may be used only when in the open status. When an area classified as conditionally approved is placed in a status other than its open status, any shellstock in wet storage in that area shall be:
(1) Subjected to relaying or depuration prior to human consumption; or
(2) Held in the wet storage site until the area is returned to the open status.

B. The near shore site evaluation shall include:
(1) The sanitary survey of the near shore storage site, with special consideration of potential intermittent sources of pollution;
(2) The location of near shore storage sites and floats; and
(3) The examination of the construction of shellstock containers, if used, to ensure the free flow of water to all shellstock.

C. Different lots of shellstock shall not be commingled in wet storage. If more than one lot of shellstock is held in wet storage at the same time, the identity of each lot of shellstock shall be maintained.

VIII. CONTROL OF SHELLFISH HARVESTING.

Requirements for the Authority.

Additional Guidance
Pages 285, 291

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this section in regulation.]

@.01 Control of Shellstock Growing Areas.

A. General
   (1) The Authority shall maintain an effective program to control shellstock growing areas and to assure that shellstock are harvested only:
      (a) From areas in an open status; and
      (b) With approval from areas classified as restricted, conditionally restricted, or prohibited, or in the closed status of the approved or conditionally approved classification.
   (2) This program shall include:
      (a) The patrol of growing areas;
      (b) The licensing of harvesters;
      (c) Enforceable legal penalties sufficient to encourage compliance; and
      (d) Appropriate identification of harvest areas where shellstock harvest is not allowed.
   (3) At the time of issuance or renewal of a harvester's license or a dealer's certification, or an annual mailout to all licensed oyster harvesters, the Authority shall provide each harvester or dealer with:
      (a) Information which explains the public health risk associated with illegal harvesting shellstock in areas classified as restricted, conditionally restricted, or prohibited or in the closed status; and
      (b) When requested, a current, comprehensive, itemized listing of all harvest areas including their geographic boundaries and their classification.

B. Patrol of Growing Areas.
   (1) The Authority shall assure that shellstock are harvested only as provided in this Chapter.
   (2) The Authority shall patrol harvest areas classified as restricted, conditionally restricted, or prohibited, or conditionally approved and approved when in the closed status at sufficient intervals to deter illegal harvesting. This patrol activity shall include consideration of the need for night, weekend, and holiday patrols. At a minimum, these growing areas shall be patrolled at the following frequencies, except as provided in B.(3), in order to ensure effective control:

RISK CATEGORY	MINIMUM FREQUENCY OF PATROL
LOW	Four (4) times per 30 harvestable days
MEDIUM	Eight (8) times per 30 harvestable days
HIGH	Sixteen (16) times per 30 harvestable days

A patrol is accomplished when the majority of an area is monitored. No more than two patrols can be counted in a 24-hour period, and each must be a separate deliberate effort. A harvestable day refers to a day during which tidal, weather and other conditions make it possible to harvest shellfish. When tidal, weather, or other conditions prohibit harvesting on a particular day, that day is not included in the 30-day period.

(3) Exceptions.

(a) Patrol is not required under the following conditions:

(i) There is no shellfish productivity, as demonstrated by one of the following methods:

a. pH, salinity, temperature, or turbidity are not favorable to the growth of shellfish; or

b. The water bottom does not support shellfish growth; or

c. The area has been depleted of shellfish by dredging, disease, or other means;

(ii) Harvest from the area is not economically feasible (i.e., the cost of harvesting exceeds the market value of the product)

(iii) The area meets all of the following conditions:

a. The area is unclassified;

b. Historically there has not been interest in commercial harvesting;

c. Known points of pollution do not exist; and

d. The Authority has current evidence that commercial harvesting does not occur. This can be accomplished by information gathered from periodic patrols or reliable non-patrol sources.

(b) Where natural sets resulting in commercially harvestable quantities of shellfish do not exist and advanced aquaculture methods (e.g. racks, bags, lantern nets, long lines and/or floats) are used in the area: The area shall be patrolled at the frequencies specified in §B. (2) unless the authority develops and implements a Risk Management Plan for the area for the prevention of illegal harvesting of shellfish. The Risk Management Plan shall include monitoring and control of surveillance activities that supplement the minimum required patrol frequency of one (1) time per 30

harvestable days. The Risk Management Plan at least should include the following:

a. Description of the area;
b. Classification of the area;
c. Description of adjacent growing areas;
d. Procedure used to prevent shellfish from prohibited or closed waters to be commingled with shellfish from an aquaculture area; and
e. If, the patrol agency receives assistance from other state, federal, or tribal agencies, a memorandum of agreement must be developed describing responsibilities of each agency. A copy of such MOA must be kept in a central file.

c. If the area is geographically remote, sparsely populated and has limited access (e.g., no or very poor roads) such that the potential for marketing the shellfish is severely restricted:

(i) The area shall be patrolled at the frequencies specified in § B. (2) unless the authority develops and implements a Risk Management Plan for the area for the prevention of illegal harvesting of shellfish. The Risk Management Plan shall include monitoring and control of surveillance activities (e.g. airport, dock, border, or truck surveillance) that will be used in lieu of traditional patrol activities, and the area should be patrolled at least one (1) time per 30 harvestable days. The Risk Management Plan shall describe the administrative procedures and resources necessary to prevent illegal harvesting and/ or the illegal commingling of the product and include at least the following:

a. Description of the area;
b. Classification of the area;
c. Description of adjacent growing areas; and
d. If the patrol agency receives assistance from other state, federal, or tribal agencies, a memorandum of agreement must be developed describing responsibilities from each agency. A copy of such MOA must be kept in a central file.

(ii) If the Authority has current evidence that commercial illegal harvesting is occurring, the Management Risk Plan should be reevaluated.

(d) Where the entire state is closed to harvesting during traditional non-harvesting seasons:

(i) The area shall be patrolled at the frequencies specified in § B. (2) unless the authority develops and implements a Risk Management Plan for the area for the prevention of illegal harvesting of shellfish. The Risk Management Plan shall

include monitoring and control of surveillance activities (e.g. airport, dock, border, or truck surveillance) that will be used in lieu of traditional patrol activities. The Risk Management Plan shall describe the administrative procedures and resources necessary to prevent illegal harvesting and/ or the illegal commingling of the product and include at least the following:

a. Description of the area;
b. Classification of the area;
c. Description of adjacent growing areas; and
d. If the patrol agency receives assistance from other state, federal, or tribal agencies, a memorandum of agreement must be developed describing responsibilities from each agency. A copy of such MOA must be kept in a central file.

(ii) The area shall be patrolled in low risk areas at least once (1) per 30 harvestable days, for medium risk areas at least twice (2) per 30 harvestable days, and for high-risk areas at least four (4) times per 30 harvestable days.

(iii) If the Authority has current evidence that commercial illegal harvesting is occurring, the state agency shall resume patrol at the frequency specified in B. (2).

(4) The Risk Category for an area shall be determined as follows:

(a) Shellfish Productivity. Estimate the abundance of shellfish based on density studies, historical information, and environmental conditions described in B.(3)(a). Consider only commercially marketable species. The descriptions below refer to the range of productivity within the state. The area shall be rated based on the highest density in any portion of the growing area.

Low Production.....1

Medium Productivity 3

High Productivity.....5

(b) Ease of Harvest. Determine the method used to harvest the shellfish. If multiple harvest techniques are used in an area, select the one with the highest score.

Highly mechanized requiring expensive equipment, deep water, difficult harvest.....1

Restricted access aquaculture
relative shallow water dredging 2

Scuba diving, tonging, bullraking 3

Hand collection from a boat 4

Hand collection, no special tools or boat 5

(c) Difficulty of Patrol. Determine the difficulty of patrol. If the difficulty varies in an area, select the description with the highest score.

Resource within sight of population and
a normal patrol route. Patrol Officer can observe
illegal harvesting from the patrol vehicle 1

Resource is near a shore and easily visible 2

Moderate difficulty, deliberate effort
is required to provide coverage to the area 3

Long travel time to growing area, large
open expanse of harvest area 4

Growing area is a marsh, short sight
distance, canals system, extensive shoals 5

(d) Using the values determined in B.(4)(a), (b), and (c), calculate the total score for the area as follows:

RISK FACTORS	SCORE (1-5)	WEIGHT	RATING	EXPLAIN RATING (optional)	ADJUSTMENT OF RATING (if needed)
SHELLFISH PRODUCTIVITY (a)		0.40			
EASE OF HARVEST (b)		0.40			
DIFFICULTY OF PATROL (c)		0.20			
			SUBTOTAL		

The rating for each risk factor is calculated by multiplying the risk factor score by the weight for that factor. The subtotal is calculated by adding all three of the risk factor ratings.

(e) The following criteria should be used to adjust the rating, if warranted:

(i) If a community-policing program is in place, the subtotal may be reduced by up to 0.25 points. If such a program leads to frequent citations, the subtotal may be reduced by up to 0.5 points. Community policing may include but is not limited to telephone hot lines, out-reach programs, financial incentives, local law enforcement activities not covered by B.(5), or private security arrangements.

(ii) If specialized equipment is available to the patrol agency, the subtotal may be reduced by up to 0.40 points. The actual reduction should be dependent upon the type of equipment that is available and its frequency of use. For example, frequent use of an aircraft can warrant a 0.4 point reduction, and frequent use of night vision or periodic use of aircraft can warrant a 0.2 point reduction.

(iii) If a growing area is conditionally managed or is poorly marked, the subtotal may be increased by up to 0.2 point.

Adding or subtracting the appropriate adjustment(s) calculates the total score.

(f) The following risk categories shall be applied to the total score:

TOTAL SCORE	RISK CATEGORY
less than 3	Low
3 or less than 4	Medium
4 or greater	High

(5) The Authority may delegate patrol activity to any State or local enforcement authority. If patrol activities are delegated, the Authority shall:
(a) Develop an memorandum of agreement with the delegated agency to assure that patrol requirements are met; and
(b) Require the delegated agency to maintain and file records of its patrol activities consistent with those required in B.(7).

(6) Officers responsible for the patrol of shellfish growing areas shall obtain the following training:
(a) Basic law enforcement training, before assuming their patrol duties;
(b) Training on shellfish control regulations within the jurisdiction of the patrol agency, before assuming independent patrol duties;
(c) In-service training on the shellfish control regulations within the jurisdiction of the patrol agency, when the regulations change.

(7) The Authority shall prepare and revise, as necessary, a patrol policy document which records the Authority's patrol organization and its activities to deter illegal shellstock harvesting. This documentation shall include:
(a) Citation of the law providing the legal basis for enforcement authority;
(b) Citation of the laws and regulations, including penalties, which are directly related to effective control of illegal harvest activities;
(c) The organizational structure of the unit responsible for patrol activities, including;
(i) Patrol unit(s) name, address, and phone number;
(ii) The roster and chain of command;
(iii) Area assignments that support the frequencies of patrol delineated in B.(2); and
(iv) A listing of specific vessels, vehicles, and equipment that support the frequencies of patrol delineated in B.(2);
(d) Summaries of training in shellfish patrol techniques;
(e) The methods used to inform officers of growing area classifications and status, and of any special activities licensed in the area;
(f) A listing of growing areas where patrol is required;
(g) An identification of any patrol problems;

(h) The type and frequency of reporting by patrol personnel;
(i) Copy of agreements with other agencies responsible for shellfish control activities; and
(j) Citations/summons for the past year. If available, this information may include:
(i) The number of convictions or dismissals;
(ii) Fines in dollar amount;
(iii) Equipment or property confiscations and forfeitures;
(iv) License suspensions or revocations; and
(v) Jail sentences; and
(vi) Written warnings.

(8) Upon request by FDA, the Authority shall provide any available documentation that is used to support the determination that the patrol program was effective in providing the required frequency of patrol. Ordinarily, this does not include providing reports not normally maintained by the Authority.

(9) To comply with the Standardized Evaluation Criteria, the authority shall:
(a) Have a patrol policy document (Critical item);
(b) Update patrol documents every year (Key item);
(c) Meet NSSP patrol training requirements (Key item);
(d) Patrol all areas that require patrol (Critical item);
(e) Meet NSSP requirements for frequency of patrol (Key item);
(f) Have formalized Memorandum of Agreement with other agency per Chapter VIII@.0sB(5) (Key item);
(g) Have a risk management plan per chapter VII@.01B(3)(b)(c)(d) (Critical item); and
(h) Have a complete risk management plan per Chapter VIII@.01B(3)(b)(c)(d) (Other item).

C. Licensing of Harvesting.

(1) The Authority shall assure that a license is required to commercially harvest shellstock, including shellstock harvested from aquaculture.

(2) Each license shall:
(a) Not be valid for more than one year;
(b) Require the harvester to sell only to dealers listed on the Interstate Certified Shellfish Shippers List; and
(c) Allow the harvester, at his discretion, to place shellstock in containers for transport of shellstock from a growing area to land or to a dealer.

(3) A license to harvest shall not allow a harvester to engage in shellstock packing as defined in this Ordinance unless the harvester is a shellstock shipper or packs for a dealer.

(4) In the case of riparian or leased land, unless the riparian owner or lessee employs a licensed harvester, the Authority shall require a riparian owner or lessee to be licensed as a harvester prior to harvesting his shellstock. A licensed riparian owner or lessee may employ unlicensed harvesters to work his property or lease.

(5) When a person has a special license to harvest shellstock for depuration, the Authority may not require individuals working under the supervision of the licensed harvester to have their own license.

(6) The Authority shall inform each licensed harvester as to:
   (a) The classification and current status assigned to each growing area; and
   (b) The methods used to notify harvesters of changes in growing area status or classification.

(7) When the Authority authorizes shellstock relaying under Chapter V. or shellstock depuration under Chapter XV., the Authority shall issue special licenses to harvesters for the taking of shellfish from areas classified as restricted, conditionally restricted, or in the closed status of the approved or conditionally approved classification. The licenses shall specify the limitations and conditions for harvesting shellstock including requirements for the harvester to keep records which:
   (a) For depuration:
      (i) Specify the date and amount of shellstock harvested from each area; and
      (ii) Record the name of the depuration facility to which the shellstock was consigned or sold; and
   (b) For relaying, meet the requirements of Chapter V.03D.

(8) The Authority shall maintain a record of all licenses and special licenses issued.

D. Penalties.
(1) The Authority shall develop a written guideline or enforcement policy which is used to recommend penalties to the courts.
(2) Authority shall insert appropriate references to its penalties.

E. Identification of Certain Growing Areas.
(1) The Authority shall chart, describe, and mark the boundaries of growing areas classified as restricted, conditionally restricted, or prohibited, or in a closed status. The boundary descriptions shall:
   (a) Be marked by fixed objects or landmarks; or
   (b) Be described in a manner which allows easy recognition; and
   (c) Allow successful prosecution of any illegal commercial harvesting activity.
(2) The Authority:
   (a) Shall notify harvesters of the boundaries established under §E.(1) by dissemination of information with licenses, publication, or direct notification including registered mail; and
   (b) May use warning signs.

F. Prohibited Classification. The Authority shall exercise effective supervision over each depletion or seed gathering operation and maintain complete written documentation.

Requirements for Harvesters.

.01 General.

A. Each harvester shall have a valid license, and a special license if necessary, in his possession while engaged in shellstock harvesting activities.

B. Persons who are working in a boat crew under the supervision of a licensed harvester need not have a valid harvester's license.

C. In the case of riparian or leased land, unless the riparian owner or lessee employs a licensed harvester, the riparian owner or lessee shall be licensed as a harvester prior to harvesting his shellstock. A licensed riparian owner or lessee may employ unlicensed harvesters to work his property or lease.

02. Shellstock Harvesting and Handling.

A. Harvesters. Any harvester who engages in shellfish packing as defined in this Ordinance shall:
   (1) Be a dealer; or
   (2) Pack shellstock for a dealer.

B. Vessels.
   (1) The operator shall assure that all vessels used to harvest and transport shellstock are properly constructed, operated, and maintained to prevent contamination, deterioration, and decomposition of the shellstock.
      (a) Decks and storage bins shall be constructed and located to prevent bilge water or polluted overboard water from coming into contact with the shellstock.
      (b) Bilge pump discharges shall be located so that the discharge shall not contaminate shellstock.
      (c) Containers used for storing shellstock shall be clean and fabricated from safe materials.
      (d) Boat decks and storage bins used in the harvest or transport of shellstock for direct marketing shall be:
         (i) Kept clean with potable water or water from a growing area in the approved classification or in the open status of the conditionally approved classification; and
         (ii) Provided with effective drainage.
      (e) Vessels and all other equipment coming in contact with shellstock during handling or transport for relaying or depuration shall be thoroughly cleaned before the vessels or equipment are used to transport or handle shellfish for direct marketing.
      (f) When necessary, effective coverings shall be provided on harvest boats to protect shellstock from exposure to:

(i) Hot sun;
(ii) Birds; and
(iii) Other adverse conditions.

(2) Cats, dogs, and other animals shall not be allowed on vessels.

C. Disposal of Human Sewage from Vessels.

(1) Human sewage shall not be discharged overboard from a vessel used in the harvesting of shellstock, or from vessels which buy shellstock while the vessels are in growing areas.

(2) The Authority shall educate all licensed harvesters and shellstock dealers concerning the public health significance of discharging human sewage overboard.

(3) An approved marine sanitation device (MSD), portable toilet or other sewage disposal receptacle shall be provided on the vessel to contain human sewage.

(4) Portable toilets shall:

(a) Be used only for the purpose intended;
(b) Be secured while on board and located to prevent contamination of shellstock by spillage or leakage;
(c) Be emptied only into a sewage disposal system;
(d) Be cleaned before being returned to the boat; and
(e) Not be cleaned in equipment used for washing or processing food.

(5) Use of other receptacles for sewage disposal may be approved by the Authority if the receptacles are:

(a) Constructed of impervious, cleanable materials and have tight fitting lids; and
(b) Meet the requirements in §C.(4).

D. Shellstock Washing.

(1) Shellstock shall be washed reasonably free of bottom sediments as soon after harvesting as practicable.

(2) The harvester shall be primarily responsible for washing shellstock.

(3) If shellstock washing is not feasible at the time of harvest, the dealer shall assume this responsibility.

(4) Water used for shellstock washing shall be obtained from:

(a) A potable water source; or
(b) A growing area in the:
(i) Approved classification; or
(ii) In the open status of the conditionally approved classification.

(5) If the harvester or dealer elects to use tanks or a recirculating water system to wash shellstock, the shellstock washing activity shall be constructed, operated, and maintained in accordance with Chapter XI.02.A.(3) and Chapter XIII.02.A.(3).

E. Shellstock Identification.

(1) Each harvester shall affix a tag to each container of shellstock which shall be in place while the shellstock is being transported to a dealer.

(2) If the shellstock was harvested at more than one location, each container shall be tagged at its growing area.

(3) When the harvester is also the dealer, the harvester has the option to tag the shellfish with a harvester's tag or a dealer's tag meeting the requirements outlined in §X.05.

(4) The harvester's tags shall:

(a) Be durable, waterproof and sanctioned by the Authority prior to use; and

(b) Be at least 2 5/8 inches x 5 ¼ inches (6.7 x 13.3 cm) in size.

(5) The harvester's tag shall contain the following indelible, legible information in the order specified below:

(a) The harvesters' identification number as assigned by the Authority;

(b) The date of harvest;

(c) The most precise identification of the harvest location or aquaculture site as is practicable, including the initials of the state of harvest, and the Authority's designation of the growing area by indexing, administrative or geographic designation. If growing areas have not been indexed by the Authority, then an appropriate geographical or administrative designation must be used (e.g. Long Bay, Decadent County, lease number, bed, or lot number).

(d) The type a0nd quantity of shellstock; and

(e) The following statement in bold capitalized type on each tag **"THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER ISEMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90DAYS."**

(6) If the shellstock is removed from the original container, the tag on the new container shall meet the requirements in §.02E.

(7) Bulk tagging of a lot of shellstock during transport from harvest area to the Dealer facilities.

(a) When shellstock are harvested from one harvest area on a single day, multiple containers may be utilized on a wrapped pallet, in a tote, in a net brailer, or other container and the unit tagged with a single tag in accordance with the requirements of §.02E.

(b) In addition to the information required in §.02E the unit tag shall also include:

(i) A statement that "All shellstock containers in this lot have the same harvest data and area of harvest"; and

(ii) Number of individual containers in the unit.

(8) Bulk Sale of Shellstock. If shellstock are sold in bulk, the harvester or dealer shall provide a transaction record prior to shipment. This transaction record shall contain all the information required in §.02E. with the addition of the name of the consignee.

.03 Shellstock Temperature Control.

Note: The Authority shall select one of the following options for implementation in its state.

OPTION I (Mandatory for confirmed *Vibrio vulnificus* problem) *If the waters of a state have been confirmed as an original source of product associated with two (2) or more Vibrio vulnificus illnesses, the Authority shall adopt the following harvest time to temperature controls in the time-temperature matrix below only for shellfish intended to be consumed raw.*

A. For the purposes of this section, temperature control is defined as the management of the environmental temperature of shellstock by means of ice, mechanical refrigeration or other approved means which is capable of lowering the temperature of the shellstock and will maintain it at 50 degrees Fahrenheit (10 degrees Centigrade) or less.

Time-Temperature Matrix for *Vibrio vulnificus:*

ACTION LEVEL	WATER TEMPERATURE	MAXIMUM HOURS FROM HARVEST TO TEMPERATURE CONTROL
LEVEL 1	<65° F	36 hours
LEVEL 2	65° F - 74 °F (18 °C - 23 °C)	14 hours
LEVEL 3	>74 °F - 84 °F (>23 °C - 28 °C)	12 hours
LEVEL 4	> 84 °F (>28 °C)	10 hours

B. The Authority shall establish the water temperature to be applied in the matrix above for each growing area by averaging the previous 5 years maximum monthly water temperatures.

C. The time to refrigeration in the above matrix shall be based upon the first shellstock harvested.

D. During Action Levels 2, 3, and 4, the product shall be shaded.

E. The Authority may approve other measures proposed by the industry to provide controls equivalent to the time-temperature requirements in the above matrix.

F. The Authority shall ensure the dealer has adequate methods in place to demonstrate compliance with the time/temperature matrix.

OPTION 2

If a growing area in the state has been confirmed as an original source of product associated with two (2) or more Vibrio parahaemolyticus illness within the past three years, the Authority shall adopt the following harvest time to temperature controls in the time-temperature matrix below or use Option 1. This Vibrio parahaemolyticus control measure applies only to shellfish from the affected growing area(s) which are intended to be consumed raw.

For the purposes of this control measure, identify and define growing areas in the state affected by Vibrio parahaemolyticus based on hydrographic and geographic parameters and other considerations relevant to control of a naturally occurring pathogen.

A. For the purposes of this section, temperature control is defined as the management of the environmental temperature of shellstock by means of ice, mechanical refrigeration or other approved means which is capable of lowering temperature of the shellstock to, and will maintain it at 50 ^{o} Fahrenheit (10^{o} Centigrade) or less.

B. Ocean Quahogs (*Arctica islandia*) and surf clams (*Spisula solidissima*) are exempted from this temperature control plan when these products are intended for thermal processing.

C. Temperature determinations for application in the time-temperature matrix below shall be based on average monthly maximum air temperatures for defined regions within the state. The average monthly maximum air temperature for each region shall be established by determining the mean daily high temperature for the month in each of the previous five years as reported by the National Weather Service and then averaging the five resulting temperatures. Ocean Quahogs (*Arctica islandia*) are exempted from this temperature control plan.

D. The Authority shall ensure the dealer has adequate methods in place to demonstrate compliance with the time/temperature matrix.

Time-Temperature Matrix for *Vibrio parahaemolyticus*

ACTION LEVEL	AVERAGE MONTHLY MAXIMUM AIR TEMPERATURE	MAXIMUM HOURS FROM HARVEST TO TEMPERATURE CONTROL
LEVEL 1	<66 ^{o}F (18 ^{o}C)	36 hours
LEVEL 2	66 ^{o}F - 80 ^{o}F (19 ^{o}C - 27 ^{o}C)	12 hours
LEVEL 3	≥81 ^{o}F (≥27 ^{o}C)	10 hours

OPTION 3

For those states that do not have to follow Option 1 or Option 2, the following time/temperature matrix will apply.

A. For the purposes of this section, temperature control is defined as the management of the environmental temperature of shellstock by means of ice, mechanical refrigeration or other approved means which is capable of lowering temperature of the shellstock to, and will maintain it at, 50 ^{o} Fahrenheit (10 ^{o} Centigrade) or less.

B. Ocean Quahogs (*Arctica islandia*) and surf clams (*Spisula solidissima*) are exempted from this temperature control plan when these products are intended for thermal processing.

C. Temperature determinations for application in the time-temperature matrix below shall be based on average monthly maximum air temperatures for defined regions within the state. The average monthly maximum air temperature for each region shall be established by determining the mean daily high temperature for the month in each of the previous five years as reported by the National Weather Service, and then averaging the five resulting temperatures. Ocean Quahogs (*Arctica islandia*) are exempted from this temperature control plan.

D. The Authority shall ensure the dealer has adequate methods in place to demonstrate compliance with the time/temperature matrix.

ACTION LEVEL	AVERAGE MONTHLY MAXIMUM AIR TEMPERATURE	MAXIMUM HOURS FROM HARVEST TO TEMPERATURE CONTROL
LEVEL 1	<66 ^{o}F (18 ^{o}C)	36 hours
LEVEL 2	66 ^{o}F - 80 ^{o}F (19 ^{o}C - 27 ^{o}C)	24 hours
LEVEL 3	$\geq$ 81 ^{o}F ($\geq$ 27 ^{o}C)	20 hours

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IX. TRANSPORTATION

Requirements for the Authority

@.01 General.

A. The Authority shall apply these requirements to all shellfish shipped in interstate commerce.

B. The Authority shall assure that:
(1) Shellfish are transported and maintained in accordance with the requirements of this Chapter; and
(2) Shellfish shipments originate from a dealer.

C. The Authority shall use the temperatures included in the sections below entitled @.02 Shipment Acceptability, @.03 Shipment Rejection, and @.04 Bacteriological Examination of Shellfish Shipments as the initial basis for taking regulatory action against any shellfish shipment in interstate commerce.

D. If an interstate shipment of shellfish is monitored, the monitoring shall take place within 24 hours of the shellfish entering the State.

@.02 Shipment Acceptability. Shellfish shipments shall be considered acceptable when:

A. Shipments are properly identified with tags and shipping documents;

B. Shellstock is alive and cooled to an internal shellstock body temperature of 50^{o} Fahrenheit (10 ^{o} Centigrade) or less;

C. Shucked shellfish is cooled to a temperature of 45^{o} Fahrenheit (7.2 ^{o} Centigrade) or less; and

D. The time-temperature indicating device shows that the ambient air temperature has exceeded 45 ^{o} Fahrenheit (7.2 ^{o} Centigrade) but the shellstock internal body temperature is 50 ^{o} Fahrenheit (l0 ^{o} Centigrade) or less; and

E. All other conditions of shipment in this Chapter are met.

@.03 Shipment Rejection.

Additional Guidance
Page 330

A. Shellfish shall be rejected when:
(1) Shellfish are not properly identified with tags or shipping documents;
(2) The internal shellstock body temperature exceeds 60 ^{o} Fahrenheit (15.6 Centigrade) unless the harvest initiation time can be documented and

indicates that the time from harvest has not exceeded the requirements in Chapter VIII §@.03;

(3) Shucked shellfish exceeds 50° Fahrenheit (10° Centigrade); or

(4) The Authority determines that the product is unwholesome or unsafe for human consumption.

B. The Authority shall notify the shipping dealer, the receiving dealer, and the Authority in the State where the shipment originated of the shipment's rejection.

@.04 Bacteriological Examination of Shellfish Shipments.

If the State chooses to sample, the following protocol shall be used.

A. Bacteriological samples of any shellfish taken for the purpose of rejection of shipments from out-of-state dealers shall be collected within twenty-four hours of the shellfish entering a State.

B. Bacteriological examination shall be made of the shellfish shipment if:

(1) The internal body temperature of the shellstock exceeds 50° Fahrenheit (10 ° Centigrade) and is less than or equal to 60 ° Fahrenheit (15.6 ° Centigrade) unless the harvest initiation time can be documented and indicates that the time from harvest has not exceeded the requirements in Chapter VIII §@.03;

(2) The shucked shellfish temperature exceeds 45°Fahrenheit (7.2 ° Centigrade) and is less than or equal to 50 ° Fahrenheit (10 ° Centigrade);

(3) The shipping time exceeds four hours and there is no temperature recording device or the recording device is inoperative; or

(4) The Authority determines it is necessary.

Requirements for the Harvester/Dealer

01. Trucks or Other Vehicles Used to Transport Shellstock to the Original Dealer.

A. The harvester, or dealer who transports shellstock from the harvester to the original dealer, shall assure that all trucks used to transport shellstock are properly constructed, operated, and maintained to prevent contamination, deterioration, and decomposition.

B. Storage bins on trucks or other vehicles used in the transport of shellstock for direct marketing shall be:

(1) Kept clean with potable water or water from an approved area or conditionally approved area in the open status; and

(2) Provided with effective drainage.

C. Shellstock shall be transported in adequately refrigerated trucks when the shellstock have been previously refrigerated or when ambient air temperature and time of travel are such that unacceptable bacterial growth or deterioration may occur.

D. Prechilling trucks or other vehicles shall be required when ambient air temperatures are such that unacceptable bacterial growth or deterioration may occur.

E. When mechanical refrigeration units are used, the units shall be:
(1) Equipped with automatic controls; and
(2) Capable of maintaining the ambient air temperature in the storage area at temperatures of 45^{o} Fahrenheit (7.2 ^{o} Centigrade) or less.

F. Any ice used to cool shellstock during transport shall meet the requirements of Chapter XI.02A.(2).

G. Cats, dogs, and other animals shall not be allowed in any part of the truck or other vehicle where shellstock is stored.

02. Receiving Shellfish

A. The dealer shall reject or discard any shellfish shipments which:
(1) Do not originate from a licensed harvester or dealer; and/or
(2) Are unwholesome, inadequately protected, or whose source cannot be identified.

B. Transportation agents or common carriers used by a dealer are not required to be certified.

C. The dealer shall:
(1) Inspect incoming shellfish shipments to assure that the shipments are received under the conditions required in this Chapter;
(2) Ensure that shellstock are not permitted to remain without ice, mechanical refrigeration, or other approved means of lowering the internal body temperature of the shellstock to, or maintaining it at, 50^{o} Fahrenheit (10^{o} Centigrade) or less for more than 2 hours at points of transfer such as loading docks;
(3) Ensure that shucked shellfish are not permitted to remain without ice, mechanical refrigeration, or other approved means of maintaining shellfish temperature at 45° Fahrenheit (7.2° Centigrade) or less; and
(4) Ensure that frozen shellfish remain frozen.

.03 Transportation Containers.

A. All containers used to transport shellstock shall be:
   (1) Constructed to allow for easy cleaning; and
   (2) Operated and maintained to prevent product contamination.

B. All containers shall be cleaned with:
   (1) Potable water; and
   (2) Detergents, sanitizers, and other supplies acceptable for food contact surfaces.

.04 Cargo Protection From Cross Contamination.

A. General. All containers used for storing shellfish shall be clean and fabricated from safe materials.

B. Shellfish Cargo Only.
   (1) The entire cargo shall consist of shellfish products only.
   (2) Except for bulk shipments, shellstock shipments shall be shipped on pallets.
   (3) If the conveyance does not have a channeled floor, pallets shall be used for all shellfish.

C. Mixed Cargoes. Shellfish shall be shipped as part of a mixed cargo of seafood or other food product only when:
   (1) Shellfish products are protected from contamination by the other cargo;
   (2) All cargo is placed on pallets; and
   (3) No other cargo is placed on or above the shellfish unless all cargo is packed in sealed, crush resistant, waterproof containers.

D. Ice. Any ice used to cool shellfish shall meet the requirements of Chapter XI.02A.(2).

.05 Shipping Times.

A. Shipping Time is No More Than Four Hours.
   (1) When the shipping time is four hours or less, the dealer shall ship all shellfish:
      (a) Well iced; or
      (b) Using other acceptable means of refrigeration.
   (2) When mechanical refrigeration units are used, the units shall be equipped with automatic controls and shall be capable of maintaining the ambient air in the storage area at temperatures of 45^{o} Fahrenheit (7.2^{o} Centigrade) or less.
   (3) The dealer shall not be required to provide thermal recorders during shipment.

(4) Lack of ice or other acceptable types of refrigeration shall be considered an unsatisfactory shipping condition.

B. Shipping Time is Greater Than Four Hours.

(1) When the shipping time is greater than four hours, the dealer shall ship all shellfish in:

(a) Mechanically refrigerated conveyances which are equipped with automatic controls and capable of maintaining the ambient air in the storage area at temperatures of 45° Fahrenheit (7.2 ° Centigrade) or less; or

(b) Containers with an internal ambient air temperature maintained at or below temperatures of 45 ° Fahrenheit (7.2 ° Centigrade) or less.

(2) Unless the dealer has an approved HACCP plan with an alternate means of monitoring time-temperature, the initial dealer shall assure that a suitable time-temperature recording device accompanies each shipment of shellfish.

(3) The initial dealer shall note the date and time on the temperature-indicating device, if appropriate.

(4) Each receiving dealer shall write the date and time on the temperature-indicating device, if appropriate, when the shipment is received and the doors of the conveyance or the containers are opened.

(5) The final receiving dealer shall keep the time-temperature recording chart or other record of time and temperature in his files and shall make it available to the Authority upon request.

(6) An inoperative temperature-indicating device shall be considered as no recording device.

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X. GENERAL REQUIREMENTS FOR DEALERS

.01 General HACCP Requirements.

A. Hazard Analysis. Every dealer shall conduct a hazard analysis to determine the food safety hazards that are reasonably likely to occur for each kind of shellfish product processed by that dealer and to identify the preventive measures that the dealer can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during , and after harvest. A food safety hazard that is reasonably likely to occur is one for which a prudent dealer would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of shellfish product being processed in the absence of those controls. In the hazard analysis, the dealer shall consider the critical control points listed in Chapters XI, XII, XIII, XIV and XV.

B. HACCP Plan. Every dealer shall have and implement a written HACCP plan. A HACCP plan shall be specific to:
   (1) Each location where shellfish products are processed by that dealer; and
   (2) Each kind of shellfish product processed by the dealer. The plan may group kinds of shellfish products together, or group kinds of production methods together, if the food safety hazard, critical control points, critical limits, and procedures required to be identified and performed in §.01C. are identical for all shellfish products so grouped or for all production methods so grouped.

C. Contents of the HACCP Plan. The HACCP plan shall, at a minimum:
   (1) List the food safety hazards that are reasonably likely to occur, as identified in accordance with §.01A. and that thus must be controlled for each shellfish product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:
      (a) Natural toxins;
      (b) Microbiological contamination;
      (c) Chemical contamination;
      (d) Pesticides;
      (e) Drug residues;
      (f) Unapproved use of direct or indirect food or color additives; and
      (g) Physical hazards;
   (2) List the critical control points for each of the identified food safety hazards, including as appropriate:
      (a) Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occurs before, during, and after harvest. At a minimum, the critical control points shall include those identified

in Chapter XI.01, Chapter XII.01, Chapter XIII.01, Chapter XIV.01 and Chapter XV.01, as applicable. As an alternative, the dealer may establish other critical control points which the dealer can demonstrate to the Authority provide equivalent public health protection. If the dealer can demonstrate to the Authority through a hazard analysis that the food safety hazard is not reasonably likely to occur, the critical control point is not required with the exception of receiving which shall always be considered as a critical control point.

(b) Critical control points designed to control food safety hazards that could be introduced in the processing plant environment. As an alternative, the dealer may establish other critical control points which the dealer can demonstrate to the Authority provide equivalent public health protection. If the dealer can demonstrate to the Authority through a hazard analysis that the food safety hazard is not reasonably likely to occur, the critical control point is not required. At a minimum, the critical control points shall include those identified in Chapter XI.01A., Chapter XII.01A., Chapter XIII.01A., Chapter XIV.01A and Chapter XV.01A., as applicable.

(3) List the critical limits that must be met at each of the critical control points. At a minimum, the critical limits shall include those listed in Chapter XI.01, Chapter XII.01, Chapter XIII.01, Chapter XIV.01 and Chapter XV.01, as applicable. As an alternative the dealer may establish other critical limits which the dealer has demonstrated provide equivalent public health protection with the exception of receiving which shall always be considered as a critical control point. In any case, the critical limits identified in Chapter XI.01, Chapter XII.01, Chapter XIII.01, Chapter XIV.01, and Chapter XV.01 shall be met as components of good manufacturing practices.

(4) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits.

(5) Include any corrective action plans that have been developed in accordance with §.01F.(2), to be followed in response to deviations from critical limits at critical control points.

(6) Provide for a record keeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(7) List the verification procedures, and frequency thereof, that the dealer will use in accordance with §.01G.(1).

D. Signing and Dating the HACCP Plan.

(1) The HACCP plan shall be signed and dated, either by the most responsible individual on site at the processing facility or by a higher-level official of

the dealer. This signature shall signify that the HACCP plan has been accepted for implementation by the dealer.

(2) The HACCP plan shall be signed and dated:
  (a) Upon initial acceptance;
  (b) Upon any modification; and
  (c) Upon verification of the plan in accordance with §.01G.(1)(a).

E. Sanitation. Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with §.02 they need not be included in the HACCP plan, and vice versa.

F. Corrective Actions.
(1) Whenever a deviation from a critical limit occurs, a dealer shall take corrective action either by:
  (a) Following a corrective action plan that is appropriate for the particular deviation, or
  (b) Following the procedures in §.01F.(3).
(2) Dealers may develop written corrective action plans, which become part of their HACCP plans in accordance with §.01C.(5), by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:
  (a) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and
  (b) The cause of the deviation is corrected.
(3) When a deviation from a critical limit occurs and the dealer does not have a corrective action plan that is appropriate for that deviation, the dealer shall:
  (a) Segregate and hold the affected product, at least until the requirements of §.01F.(3)(b) and (c) are met;
  (b) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review. Adequate training may or may not include training in accordance with §.01I.;
  (c) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;
  (d) Take corrective action, when necessary, to correct the cause of the deviation;
  (e) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with §.01I., to determine whether the HACCP plan needs to be modified to

reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.

(4) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with §.01G. and the record keeping requirements of §.01H.

G. Verification.

(1) Every processor shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented. Verification shall include, at a minimum:

(a) A reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. These changes may include: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with §.01I. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of §.01C.

(b) Ongoing verification activities including:

(i) A review of any consumer complaints that have been received by the dealer to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;

(ii) The calibration of process-monitoring instruments; and

(iii) At the option of the dealer, the performing of periodic end product or in-process testing.

(c) A review, including signing and dating, by an individual who has been trained in accordance with § .01I., of the records that document:

(i) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within one (1) week of the day that the records are made;

(ii) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with §.01F. This review shall occur within one (1) week of the day that the records are made; and

(iii) The calibrating of any process monitoring instruments used at critical control points and the performing of any periodic

end product or in process testing that is part of the dealer's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made.

(2) Dealers shall immediately follow the procedures in §.01F. whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

(3) The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with §.01G(1)(b)(ii) and (iii) shall be documented in records that are subject to the record keeping requirements of §.01H.

H. Records.

(1) All records required by §.01 and §.02 shall include:

(a) The name and location of the dealer;

(b) The date and time of the activity that the record reflects;

(c) The signature or initials of the person performing the operation; and

(d) Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed.

(2) All records required by §.01 and §.02 shall be retained at the processing facility for at least one (1) year after the date they were prepared in the case of refrigerated products and for at least two (2) years after the date they were prepared in the case of frozen products.

(3) Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility for at least two (2) years after their applicability to the product being produced at the facility.

(4) If the processing facility is closed for a prolonged period between seasonal operations, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the seasonal operations but shall be immediately returned for official review upon request.

(5) All records required by §.01 and §.02 and HACCP plans required by §.01B. and §.01C. shall be available for official review and copying at reasonable times.

(6) Tags on containers of shellstock are not subject to the requirements of this section unless they are used to fulfill the requirements of Chapter X.05.

(7) The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and electronic signatures.

I. Training.

(1) At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to shellfish processing at least equivalent to that received under standardized curriculum recognized as adequate by the SSGA or who is otherwise qualified through job experience to perform these functions:

(a) Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan that is appropriate for a specific processor, in order to meet the requirements of §.01C.;

(b) Reassessing and modifying the HACCP plan in accordance within the corrective action procedures specified in §.01F.(3)(e), and the HACCP plan in accordance with the verification activities specified in § .01G.(1)(a); and

(c) Performing the record review required by §.01G.(1)(c).

(2) Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum as determined by the Authority.

(3) The trained individual need not be an employee of the dealer.

Additional Guidance
Page 339

.02 General Sanitation Requirements.

A. Sanitation Monitoring. Each dealer shall monitor conditions and practices that are both appropriate to the plant and the food being processed with sufficient frequency to ensure, at a minimum, conformance with the requirements specified in Chapter XI.2, Chapter XII.02, Chapter XIII.02, Chapter XIV.02 and Chapter XV.02. The requirements specified in these Sections relate to the following sanitation items:

(1) Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice, hereinafter referred to as: Safety of water for processing and ice production;

(2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product, hereinafter referred to as: Condition and cleanliness of food contact surfaces;

(3) Prevention of cross contamination from unsanitary objects to food, food packaging materials, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product, hereinafter referred to as: Prevention of cross contamination;

(4) Maintenance of hand washing, hand sanitizing, and toilet facilities, hereinafter referred to as: Maintenance of hand washing, hand sanitizing and toilet facilities;

(5) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds,

sanitizing agents, condensate, and other chemical, physical, and biological contaminants, hereinafter referred to as: Protection from adulterants;

(6) Proper labeling, storage, and use of toxic compounds, hereinafter referred to as: Proper labeling, storage, and use of toxic compounds;

(7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces, hereinafter referred to as: Control of employees with adverse health conditions; and

(8) Exclusion of pests from the food plant hereinafter referred to as: Exclusion of pests.

While monitoring of those specified conditions and practices (listed in 1-8) that are not appropriate to the plant and the food being processed is not required, compliance with such conditions and practices remains mandatory.

B. Sanitation Monitoring Records. Each dealer shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by §.02A. These records are subject to the requirements of §.01H.

C. Relationship to HACCP Plan. Sanitation controls may be included in the HACCP plan, required by §.01B. However, to the extent that they are monitored in accordance with §.02A. they need not be included in the HACCP plan, and vice versa.

Additional Guidance
Page 405

.03 Other Model Ordinance Requirements.

A. Each dealer shall comply with the requirements specified in Chapter XI.03, Chapter XII.03, Chapter XIII.03, Chapter XIV.03 and Chapter XV.03 that are appropriate to the plant and the food being processed. However, monitoring and record keeping for these conditions and practices is not required, unless specifically stated.

B. Recalls.

(1) Dealers shall adopt written procedures for conducing recalls of adulterated misbranded shellfish products. These written procedures for conducting recalls shall be based on, and complementary to, the FDA Enforcement Policy on Recalls, CFR Title 21, Chapter 1, Subchapter A, Part 7-Enforcement Policy, (2002 NSSP Guide for the Control of Molluscan Shellfish, Federal Regulations, page 394).

(2) Dealers hall follow their written recall procedures to include timely notification of the SSCA of a situation requiring recall, timely notification of consignee who received the affected product, and effective removal or correction of the affected product.

.04 Certification Requirements.

A. General.
(1) No person shall act as a dealer prior to obtaining certification.
(2) Any person who wants to be a dealer shall:
(a) Make application to the Authority for certification;
(b) Have and implement a HACCP plan, and have a program of sanitation monitoring and record keeping in compliance with 21 CFR 123 as it appears in the *Federal Register* of December 18, 1995, except for the requirement for harvester identification on a dealer's tag.
(3) Each dealer shall have a business address at which inspections of facilities, activities, or equipment can be conducted.

B. Types of Certification.
(1) Shucker-packer. Any person who shucks shellfish shall be certified as a shucker-packer.
(2) Repacker.
(a) Any person who repacks shucked shellfish shall be certified as a shucker-packer or repacker;
(b) Any person who repacks shellstock shall be certified as a shellstock shipper, shucker-packer, or repacker;
(c) A repacker shall not shuck shellfish.
(3) Shellstock Shipper. Any person who ships and receives shellstock in interstate commerce shall be certified as a shellstock shipper, repacker, or shucker-packer.
(4) Reshipper. Any person who purchases shellstock or shucked shellfish from dealers and sells the product without repacking or relabeling to other dealers, wholesalers or retailers shall be certified as a reshipper.

.05 Shellstock Identification.

[Note: All Federally allocated shellfish (surf and quahog) caught in Federally regulated waters must follow the National Marine Fisheries Service tagging protocol. These Federal sequential tags will supersede the tagging requirements in § .05*.]*

A. General.
(1) The dealer shall keep the harvester's tag affixed to each container of shellstock until the container is:
(a) Shipped; or
(b) Emptied to wash, grade or pack the shellstock.
(2) When the dealer is also the harvester and he elects not to use a harvest tag, the dealer shall affix his dealer tag to each container of shellstock prior to shipment.

B. Tags.

(1) The dealers' tags shall:

(a) Be durable, waterproof and sanctioned by the Authority prior to use; and

(b) Be at least 2 5/8 inches by 5 1/4 inches (6.7 x 13.3 cm) in size.

(2) The dealer's tag shall contain the following indelible, legible information in the order specified below:

(a) The dealer's name and address;

(b) The dealer's certification number as assigned by the Authority

(c) The original shellstock shipper's certification number. If depurated the original shellstock shipper's certification number is not required;

(d) The date of harvest; or if depurated, the date of depuration processing;

(e) If depurated, the depuration cycle number or lot number;

(f) The most precise identification of the harvest location as is practicable including the initials of the state of harvest, and the Authority's designation of the growing area by indexing, administrative or geographic designation. If the Authority has not indexed growing areas, then an appropriate geographical or administrative designation must be used (e.g. Long Bay, Decadent County, lease number, bed, or lot number).

(g) When the shellstock has been transported across state lines and placed in wet storage in a dealer's operation, the statement:
"THIS PRODUCT IS A PRODUCT OF (NAME OF STATE) AND WAS WET STORED AT (FACILITY CERTIFICATION NUMBER) FROM (DATE) TO (DATE)";

(h) The type and quantity of shellstock; and

(i) The following statement in bold capitalized type on each tag:
"THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS."

(j) All shellstock intended for raw consumption shall include a consumer advisory. The following statement, from Section 3-602.11 of the 1999 Food Code, or an equivalent statement, shall be included on all shellstock:0
"RETAILERS, INFORM YOUR CUSTOMERS"
"Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."

(3) When both the dealer and harvester tags appear on the container, the dealer's tag is not required to duplicate the information on the harvester's tag.

(4) If the shellstock is removed from the original container, the tag on the new container shall meet the requirements in §.05B.

C. Bulk Tagging Lots of Shellstock for Sales Between Dealers.

(1) When a single lot of shellstock is sold, multiple containers may be used on a wrapped pallet, in a tote, in a net bailer, or other container and the unit tagged with a single tag in accordance with §.05 B. (1-4).

(a) This bulk tagging provision shall not apply to sales to reshippers;

(b) The shipment must be accompanied by a transaction record stating the name of the consignee who must be a certified dealer;

(c) In addition to the information required in Section .05 b. (1-4) the unit tag shall also include:

(i) A statement that "All shellstock containers in this lot have the same harvest date and area of harvest"; and

(ii) Number of individual containers in the unit.

D. Tagging of a Lot of Shellstock During Intermediate Processing.

(1) When the shellstock is removed from the original container, the dealer shall:

(a) Keep the harvester tag for 90 days;

(b) Keep track of the growing area and date of harvest for shellstock; and

(c) Maintain the lot identity of all shellstock during any intermediate stage of processing.

(2) A dealer receiving bulk tagged lots of shellstock must have an intermediate processing plan approved by the Authority to ensure that each lot of shellstock is kept separate and identified in a way which prevents commingling or misidentification.

(3) In order for a dealer to tag a lot container (e.g. a pallet) of shellstock in lieu of meeting the requirement in §.05B. for a harvester or dealer tag on each individual container, the dealer shall have an intermediate processing plan approved by the Authority, which establishes the procedures, the dealer shall use to tag the lot during the washing, packing or staging of shellfish.

(4) Unless the dealer is included in the Authority's commingling plan under Chapter I@.01F., the dealer's intermediate processing plan for tagging a lot of shellstock during the intermediate stage of processing shall ensure that each lot of shellstock is separated and identified in a way which prevents commingling or misidentification. The identification shall be provided by:

(a) A harvester's or dealer's tag which meets the requirements of §.05B.; or

(b) A tag for each lot of shellstock that contains the following information:

(i) A statement that "All shellstock containers in this lot have the same harvest date and area of harvest";

(ii) Harvest date;

(iii) Growing area;

(iv) Original dealer certification number; and

(v) Number of individual containers in each lot of shellstock container (e.g. a pallet) after washing, packing or staging has been completed.

(5) When a dealer has an approved intermediate processing plan, the dealer shall tag each lot of shellstock in accordance with the intermediate processing plan while the lot of shellstock is being processed in the plant.

E. Transaction Record. If shellstock are sold in bulk, the dealer shall provide a transaction record prior to shipment. This transaction record shall contain all the information required in §.07B. with the addition of the name of the consignee.

.06 Shucked Shellfish Labeling.

A. Shellfish Labeling.

(1) If a firm stores shucked shellfish under refrigerated conditions using in-plant reusable containers, the dealer shall maintain lot integrity.

(2) If the shucker-packer uses returnable containers to transport shucked shellfish between dealers for the purpose of further processing or packing, the returnable containers are exempt from the labeling requirements in this section of the regulation. When returnable containers are used, the shipment shall be accompanied by a transaction record containing:

(a) The original shucker-packer's name and certification number;

(b) The shucking date; and

(c) The quantity of shellfish per container and the total number of containers.

(3) If the dealer uses master shipping cartons, the master cartons are exempt from these labeling requirements when the individual containers within the carton are properly labeled.

(4) At a minimum the dealer shall label each individual package containing fresh or frozen shucked shellfish meat in a legible and indelible form in accordance with CFR 21, Part 101; Part 161, Subpart B (161.30, and 161.136) and the Federal Fair Packaging and Labeling Act.

(5) The dealer shall assure that:

(a) The shucker-packer's or repacker's certification number is on the label of each package of fresh or frozen shellfish;

(b) Packages containing less than 64 fluid ounces have:

(i) A "SELL BY DATE" which is a reasonable subsequent shelf-life or the words "BEST IF USED BY" followed by a date when the product would be expected to reach the end of its shelf-life; and

(ii) The date as a month and day of the month.

(c) Packages containing 64 fluid ounces or more have on the lid and sidewall or bottom the "DATE SHUCKED" indicated as the number of the day of the year or the month and day of the month.

(6) The dealer shall assure that if the product is frozen, then the year is added to the dates in §(4).

(7) If the dealer thaws and repacks frozen shellfish, the dealer shall label the shellfish container as previously frozen.

(8) The dealer shall provide all label information in a legible and indelible form.

B. Shucked Shellfish. If the dealer elects to repack shellfish, the dealer shall pack and label all shellfish in accordance with §.06 except that the original date of shucking shall be used in establishing the SELL BY DATE.

.07 Shipping Documents and Records.

A. Shipping Documents.

(1) Each shellfish shipment shall be accompanied by a shipping document.

(2) The shipping document shall contain:

(a) The name, address, and certification number of the shipping dealer;

(b) The name and address of the major consignee; and

(c) The kind and quantity of the shellfish product.

(3) The receiving dealer shall:

(a) Maintain in his files a copy of the completed shipping document; and

(b) Make the shipping document available to the Authority upon request.

(4) If the shipment is subdivided to different dealers, each receiving dealer shall maintain records sufficient to trace his portion back to the original shipment.

B. Transaction and Shipping Records.

(1) Each dealer shall have a business address at which transaction records are maintained.

(2) Each dealer shall maintain accurate and legible transaction records that are sufficient to:

(a) Document that the shellfish are from a source authorized under this Ordinance;

(b) Permit a container of shellfish to be traced back to the specific incoming lot of shucked shellfish from which it was taken;

(c) Permit a lot (or commingled lots as per Chapter I.@.01.F.) of shucked shellfish or a lot of shellstock to be traced back to the growing area(s), date(s) of harvest, and if possible, the harvester or group of harvesters.

(3) Purchase and sales shall be recorded:

(a) In a permanently bound ledger book; or

(b) Using other recording methods acceptable to and authorized by the Authority.

(4) The transaction records shall be retained:

(a) In the case of fresh shellfish, for a minimum of one year; and

(b) In the case of frozen shellfish, for at least two years or the shelf life of the product, whichever is longer.

(5) If computer records are maintained, the Authority shall approve the format and its use.

.08 Wet Storage in Artificial Bodies of Water.

A. General.

(1) If the dealer chooses to practice wet storage in artificial bodies of water, the dealer shall meet the requirements of Chapter VII.01 and .02.

(2) For the purpose of permitting, each wet storage site or operation shall be evaluated annually. The evaluation shall include the operation's plan and operating procedures for an onshore activity as submitted by the dealer.

(3) Prior to commencing construction, all plans for construction or remodeling of onshore wet storage facilities or operations shall be reviewed and authorized by the Authority.

(4) The wet storage facility or operation evaluation shall include a review of:

(a) The purpose of the wet storage activity, such as holding, conditioning or increasing the salt content of shellstock;

(b) Any species specific physiological factors that may affect design criteria; and

(c) The plan giving the design of the onshore storage facility, source and quantity of water to be used for wet storage, and details of any water treatment system.

B. Operation Specifications.

(1) General. Each onshore wet storage operation shall meet the following design, construction, and operating requirements.

(a) Effective barriers shall be provided to prevent entry of birds, animals, and vermin into the area.

(b) Storage tanks and related plumbing shall be fabricated of safe material and shall be easily cleanable. This requirement shall include:

(i) Tanks constructed so as to be easily accessible for cleaning and inspection, self-draining and fabricated from nontoxic, corrosion resistant materials; and

(ii) Plumbing designed and installed so that it can be cleaned and sanitized on a regular schedule, as specified in the operating procedures.

(c) Storage tank design, dimensions, and construction are such that adequate clearance between shellstock and the tank bottom shall be maintained.

(d) Shellstock containers, if used, shall be designed and constructed so that the containers allow the free flow of water to all shellstock within a container.

(2) Buildings. When a building is used for the wet storage operation:

(a) Floors, walls, and ceilings shall be constructed in compliance with the applicable provisions of Chapter XI; and

(b) Lighting, plumbing, water and sewage disposal systems shall be installed in compliance with applicable provisions of Chapter XI.

(3) Outdoor Tank Operation. When the wet storage operation is outdoors or in a structure other than a building, tank covers shall be used. Tank covers shall:

(a) Prevent entry of birds, animals or vermin; and

(b) Remain closed while the system is in operation except for periods of tank loading and unloading, or cleaning.

C. Water Supply.

(1) General.

(a) Except for wells, the quality of the surface source water prior to treatment shall meet, at a minimum, the bacteriological standards for the restricted classification.

(b) Any well used as source water for wet storage shall meet the requirements of Chapter XI.02.

(c) Except when the source of the water is a growing area in the approved classification, a water supply sampling schedule shall be included in the dealer's operating procedures and water shall be tested according to the schedule.

(d) Results of water samples and other tests to determine the suitability of the water supply shall be maintained for at least 2 years.

(e) Disinfection or other water treatment such as the addition of salt cannot leave residues unless they are Generally Recognized as Safe (GRAS) or unless they do not interfere with the shellstock's survival, quality or activity during wet storage.

(f) Disinfected water entering the wet storage tanks shall have no detectable levels of the coliform group as measured by a recognized multi-tube MPN test per 100 ml. for potable water.

(g) When the laboratory analysis of a single sample of disinfected water entering the wet storage tanks shows any positive result for the coliform group, daily sampling shall be immediately instituted until the problem is identified and eliminated.

(h) When the problem that is causing disinfected water to show positive result for the coliform group is eliminated, the effectiveness of the correction shall be shown on the first operating day following correction through the immediate collection, within a 24 hour period, of a set of three samples of disinfected water and one sample of the source water prior to disinfection.

(i) For water that is disinfected by ultra-violet treatment, turbidity shall not exceed 20 nephelometric turbidity units (NTUs) measured in accordance with *Standard Methods for the Examination of Water and Wastewater*, APHA.

(j) The disinfection unit(s) for the water supply shall be cleaned and serviced as frequently as necessary to assure effective water treatment.

(2) Continuous Flow-through System.

(a) If the system is of continuous flow-through design, water from a growing area classified as:

(i) Approved may be used, without disinfection, in wet storage tanks provided that the near shore water source used for supplying the system meets the approved classification bacteriological criteria at all times that shellstock are being held in wet storage; or

(ii) Other than approved may be used if the source water is continuously subjected to disinfection and it is sampled daily following disinfection.

(b) When a source classified as other than approved is used, a study shall be required to demonstrate that the disinfection system will consistently produce water that tests negative for the coliform group under normal operating conditions. The study shall:

(i) Include five sets of three samples from each disinfection unit collected for five consecutive days at the outlet from the disinfection unit or at the inlet to at least one of the wet storage tanks served by the disinfection system;

(ii) Include one sample daily for five consecutive days from the source water prior to disinfection;

(iii) Use NSSP recognized methods to analyze the samples to d determine coliform levels;

(iv) Require all samples of disinfected water to be negative for the coliform group; and

(v) Be repeated if any sample of disinfected water during the study is positive for the coliform group.

(c) Once sanctioned for use, the water system shall be sampled daily to demonstrate that the disinfected water is negative for the coliform group.

(3) Recirculating Water System.

(a) A study shall be required to demonstrate that the disinfection system for the recirculating system will consistently produce water that tests negative for the coliform group under normal operating conditions. The study shall meet the requirements in §C.(2)(b) above.

(b) Once sanctioned for use, the recirculating water system shall be sampled weekly to demonstrate that the disinfected water is negative for the coliform group.

(c) When make-up water of more than 10 percent of the water volume in the recirculating system is added from a growing area source classified as other than approved, a set of three samples of disinfected water and one sample of the source water prior to

disinfection shall be collected within a 24 hour period to reaffirm the ability of the system to produce water free from the coliform group.

(d) When ultra-violet treatment is used as the water disinfectant, each time new ultraviolet bulbs are installed, a set of three samples of disinfected water and one sample of the source water prior to disinfection shall be collected within a 24 hour period to reaffirm the ability of the system to produce water free from the coliform group.

D. Shellstock Handling.

(1) Shellstock shall be thoroughly washed with water from a source authorized by the Authority and culled prior to wet storage in tanks. Due to the adverse effects of culling on mussel physiology, culling of mussels may be done after wet storage, subject to permission from the Authority.

(2) Unless the dealer is in the Authority's commingling plan under Chapter I@.01F., different lots of shellstock shall not be commingled during wet storage in tanks. If more than one lot of shellstock is being held in wet storage at the same time, the identity of each lot of shellstock shall be maintained.

(3) Bivalve mollusks shall not be mixed with other species in the same tank. Where multiple tank systems use a common water supply system for bivalve mollusks and other species, wet storage water shall be effectively disinfected prior to entering tanks containing the bivalve mollusks.

XI. SHUCKING AND PACKING

Requirements for the Authority.

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this section in regulation.]

@.01 Heat Shock.

A. The Authority shall approve the scheduled process for heat shock. The schedule may be developed by the Authority or qualified persons with adequate facilities for conducting the appropriate studies;

B. The Authority shall assure that the critical factors, which may affect the heat shock process, have been adequately studied and provided for in establishing the process. The critical factors shall include:
(1) Type and size of shellfish;
(2) Time and temperature of exposure;
(3) Type of process;
(4) Size of tank, tunnel or retort;
(5) Water to shellfish ratios in tanks; and
(6) Temperature and pressure monitoring devices;

C. The Authority shall assure that heat shock process does not:
(1) Change the physical and organoleptic properties of the species;
(2) Kill the shellfish prior to shucking; and
(3) Increase microbial deterioration of the shucked shellfish.

D. The Authority shall retain records covering all aspects of the establishment of the heat shock process.

Requirements for Dealers.

01. Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall shuck and pack only shellstock which is:
(1) Obtained from a licensed harvester who has:
(a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; and **[C]**
(b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; or **[C]**
(2) Obtained from a dealer who has identified the shellstock with a tag on each container or transaction record with each bulk shipment. **[C]**

B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that:
(1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X.08; and **[C]**
(2) Once placed under temperature control and until sale to the processor or final consumer, shellstock shall be;
(a) Iced; or **[C]**
(b) Placed and stored in a storage area or conveyance maintained at 45 ^{o}Fahrenheit (7.2 ^{o}Centigrade) or less; and **[C]**
(c) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in §B(1) or §B(2) for more than 2 hours at points of transfer such as loading docks. **[C]**

C. Processing Critical Control Point - Critical Limits. The dealer shall ensure that:
(1) For shellstock which has not been refrigerated prior to shucking, shucked meats are chilled to an internal temperature of 45^{o} F (7.2 ^{o} Centigrade) or less within three hours of shucking. **[C]**
(2) For shellstock refrigerated prior to shucking, shucked meats are chilled to an internal temperature of 45^{o}F (7.2 ^{o} Centigrade) or less within four hours of removal from refrigeration. **[C]**
(3) If heat shock is used, once heat shocked shellstock is shucked, the shucked shellfish meats shall be cooled to 45 ^{o} Fahrenheit (7.2 ^{o} Centigrade) or less within two hours after the heat shock process. **[C]**

D. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store shucked and packed shellfish in covered containers at an ambient temperature of 45 ^{o} Fahrenheit (7.2 ^{o} Centigrade) or less or covered with ice. **[C]**

.02 Sanitation.

A. Safety of Water for Processing and Ice Production.
(1) Water Supply.
(a) The dealer shall provide a potable water supply in accordance with applicable federal, state and local regulations. **[C]**
(b) If the water supply is from a private source, the dealer shall make arrangements to have the water supply sampled by persons recognized by the Authority and tested at laboratories sanctioned or certified by the Authority: **[K]**
(i) Prior to use of the water supply; **[C]**
(ii) Every six months while the water supply is in use; and **[K]**
(iii) After the water supply has been repaired and disinfected. **[$S^{C/K}$]**
(c) The dealer shall assure that any steam used in food processing or that comes in contact with food contact surfaces is free from any

additives, or deleterious substances consistent with federal and state laws and regulations. **[K]**

(2) Ice Production. Any ice used in the processing, storage, or transport of shellstock or shucked shellfish shall:

(a) Be made on-site from potable water in a commercial ice machine; or **[C]**

(b) Come from a facility sanctioned by the Authority or the appropriate regulatory agency. **[C]**

(3) Shellstock Washing.

(a) Water from either a potable water supply or a growing area in the approved classification shall be used to wash shellstock. **[C]**

(b) If the dealer uses any system to wash shellstock which recirculates water, the dealer shall:

(i) Obtain approval for the construction or remodeling of the system from the Authority. **[K]**

(ii) Provide a water treatment and disinfection system to treat an adequate quantity of water to a quality acceptable for shellstock washing which, after disinfection, meets the coliform standards for drinking water, and does not leave any unacceptable residues in the shellstock; and **[C]**

(iii) Test bacteriological water quality daily; **[$S^{C/K}$]**

(c) The dealer may use ultra-violet (UV) disinfection in the recirculating wash water system, provided that the turbidity of the water to be disinfected shall not exceed 20 nephelometric turbidity units (NTUs) measured using the method in the APHA *Standard Methods for the Examination of Water and Wastewater*. **[K]**

(4) Plumbing and Related Facilities.

(a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:

(i) Prevent contamination of water supplies; **[C]**

(ii) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. **[C]** The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage. **[K]**

(b) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials and tank construction shall be such that it:

(i) Is easily accessible for cleaning and inspection; **[K]**

(ii) Is self-draining; and **[K]**

(iii) Meets the requirements for food contact surfaces. **[K]**

B. Condition and Cleanliness of Food Contact Surfaces.

(1) Equipment and utensil construction for food contact surfaces.

(a) Except for equipment in continuous use and placed in service prior to January 1, 1989, the dealer shall use only equipment that

conforms to *Shellfish Industry Equipment Construction Guides* (August l993), U.S. Department of Health and Human Services. **[K]**

(b) The dealer shall use only equipment and utensils, including approved plastic ware and finished product containers, which are:
  (i) Constructed in a manner and with materials that can be cleaned, sanitized, maintained or replaced in a manner to prevent contamination of shellfish products;**[K]**
  (ii) Free from any exposed screws, bolts, or rivet heads on food contact surfaces; and **[K]**
  (iii) Fabricated from food grade materials. **[K]**

(c) The dealer shall assure that all joints on food contact surfaces:
  (i) Have smooth easily cleanable surfaces; and **[K]**
  (ii) Are welded. **[K]**

(d) Shucking blocks shall be provided which are:
  (i) Easily cleanable; **[K]**
  (ii) Fabricated from safe material; **[K]**
  (iii) Solid, one piece construction; and **[K]**
  (iv) Easily removed from the shucking bench, unless the block is an integral part of the bench. **[K]**

(e) The dealer shall provide a temperature measuring device accurate to +/- 2^{o} Fahrenheit for use in monitoring product temperatures. **[K]**

(f) All equipment used in heat shock processing shall meet the requirements of Chapter XI.02.B.(1) (a), (b), and (c). **[K]**

(g) All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in Chapter XI.02.B.(1) (a), (b), and (c). **[K]**

(2) Cleaning and sanitizing of food contact surfaces.

(a) Food contact surfaces of equipment, utensils and containers shall be cleaned and sanitized to prevent contamination of shellfish and other food contact surfaces. The dealer shall:
  (i) Provide adequate cleaning supplies and equipment, including three compartment sinks, brushes, detergents, and sanitizers, hot water and pressure hoses shall be available within the plant; **[K]**
  (ii) Sanitize equipment and utensils prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated; **[K]**
  (iii) Provide a test kit or other device that accurately measures the parts per million concentration of the chemical sanitizing agent in use; **[K]** and
  (iv) Wash and rinse equipment and utensils at the end of each day. **[K]**

(b) All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination. **[O]**

(c) Shellfish shall be protected from contamination by washing and rinsing shucking containers and sanitizing before each filling. **[K]**

(d) Containers which may have become contaminated during storage shall be washed, rinsed, and sanitized prior to use or shall be discarded. **[K]**

(e) Shucked shellfish shall be packed in clean covered containers and stored in a manner which assures their protection from contamination. **[K]**

(f) If used, the finger cots or gloves shall be:

(i) Made of impermeable materials except where the use of such material is inappropriate or incompatible with the work being done; **[O]**

(ii) Sanitized at least twice daily; **[K]**

(iii) Cleaned more often, if necessary **[K]**;

(iv) Properly stored until used; and **[K]**

(v) Maintained in a clean, intact, and sanitary condition. **[K]**

C. Prevention of Cross Contamination.

(1) Protection of shellfish.

(a) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer. **[$S^{C/K}$]**

(b) Shucked shellfish shall be protected from contamination. **[$S^{C/K}$]**

(c) Shellstock shall not be placed in containers with standing water for the purposes of washing shellstock or loosening sediment. **[K]**

(d) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination. **[$S^{K/0}$]**

(2) Employee practices.

(a) Where the same employee works in both the shucking and packing activities, the employee shall wash his hands thoroughly after entering. **[K]**

(b) The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate hand washing facility:

(i) Before starting work; **[K]**

(ii) After each absence from the work station; **[K]**

(iii) After each work interruption; and **[K]**

(iv) Any time when their hands may have become soiled or contaminated. **[K]**

D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.

(1) Hand washing facilities with warm water at a minimum temperature of 110 ° Fahrenheit (43 ° Centigrade), dispensed from a hot and cold mixing or combination faucet, shall be provided. **[$S^{K/O}$]**
(2) Sewage **[C]** and liquid disposable wastes **[K]** shall be properly removed from the facility.
(3) An adequate number of conveniently located, toilets shall be provided. **[K]**
(4) The dealer shall provide each toilet facility with an adequate supply of toilet paper **[K]** in a suitable holder **[$S^{K/O}$]**.

E. Protection from Adulterants.
(1) Shellfish shall be protected from contamination while being transferred from one point to another during handling and processing. **[K]**
(2) Any lighting fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in areas where shellfish are exposed shall be of the safety type or protected to prevent food contamination in case of breakage. **[O]**
(3) Food contact surfaces shall be protected from contamination by adulterants by using cleaning compounds and sanitizing agents only in accordance with applicable federal and state laws and regulations. **[K]**
(4) Protection of ice used in shellfish processing.
(a) Any ice, which is not made on site in the shellfish processing facility, shall be inspected upon receipt and rejected if the ice is not delivered in a way so as to be protected from contamination. **[$S^{C/K}$]**
(b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice. **[$S^{C/K}$]**
(5) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed. **[$S^{K/C}$]**

F. Proper Labeling, Storage and Use of Toxic Compounds.
(1) Storage of toxic compounds.
(a) The dealer shall assure that only toxic substances necessary for plant activities are present in the facility. **[K]**
(b) Each of the following categories of toxic substances shall be stored separately:
(i) Insecticides and rodenticides; **[K]**
(ii) Detergents, sanitizers, and related cleaning agents; and **[K]**
(iii) Caustic acids, polishes, and other chemicals. **[K]**
(c) The dealer shall not store toxic substances above shellfish or food contact surfaces. **[K]**
(2) Use and labeling of toxic compounds.
(a) When pesticides are used, the dealer shall apply pesticides in accordance with applicable federal and state regulations to control

insects and rodents in such a manner to prevent the contamination of any shellfish or packaging materials with residues. **[K]**

(b) Cleaning compounds and sanitizing agents shall be labeled and used only in accordance with applicable federal and state laws and regulations. **[K]**

(c) Toxic substances shall be labeled and used in accordance with the manufacturer's label directions. **[K]**

G. Control of Employees with Adverse Health Conditions.

(1) The dealer shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces. The diseases which are transmissible from food workers through food are those determined by the US Centers for Disease Control and Prevention, in compliance with the Americans with Disabilities Act, and published in the *Federal Register.* **[K]**

(2) If an employee with an infected wound keeps it covered with a proper bandage, an impermeable barrier, and a single-use glove for a hand lesion, the dealer may allow the employee to work in the shellfish processing facility without additional restrictions. **[K]**

H. Exclusion of Pests. The dealer shall operate his facility to assure that pests are excluded from the facility and processing activities. **[K]**

.03 Other Model Ordinance Requirements.

A. Plants and Grounds.

(1) General.

(a) The physical facilities shall be maintained in good repair. **[O]**

(b) Animals or unauthorized persons shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. **[K]**

(c) Air pump intakes shall be located in a protected place. Air filters shall be installed on all blower air pump intakes. Oil bath type filters are not allowed. **[O]**

(2) Flooding:

(a) Facilities in which shellfish are stored, shucked, packed, repacked or reshipped shall be located so that these facilities are not subject to flooding during ordinary high tides. **[C]**

(b) If facilities are flooded:

(i) Shellfish processing, shucking or repacking activities shall be discontinued until the flood waters have receded from the building; and the building is cleaned and sanitized. **[C]**

(ii) Any shellfish coming in contact with the floodwaters while in storage shall be destroyed; or discarded in non-food use. **[C]**

(3) The dealer shall operate his facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from his facility and activities. **[$S^{C/K}$]**

(4) Separation of operations.

(a) Facilities for shucking and packing activities shall be separated by use of

(i) Separate rooms; **[K]**

(ii) Partitions; or **[K]**

(iii) Sufficient spacing. **[K]**

(b) Manufacturing activities, which could result in the contamination of the shellfish, shall be separated by adequate barriers. **[K]**

(5) The dealer shall provide toilet room doors which are tight fitting, self-closing, and do not open directly into a processing area. [K]

(6) Plant Interior.

(a) Sanitary conditions shall be maintained throughout the facility. **[O]**

(b) All dry area floors shall be hard, smooth, easily cleanable; and **[O]**

(c) All wet area floors used in areas to store shellstock, process food, and clean equipment and utensils shall be constructed of easily cleanable, impervious, and corrosion resistant materials which:

(i) Are graded to provide adequate drainage; **[O]**

(ii) Have even surfaces, and are free from cracks that creates sanitary problems and interferes with drainage; **[O]**

(iii) Have sealed junctions between floors and walls to render them impervious to water; and **[O]**

(d) Walls and Ceilings. Interior surfaces of rooms where shellfish are stored, handled, processed, or packaged shall be constructed of easily cleanable, corrosion resistant, impervious materials **[O]**.

(7) Grounds. Grounds around the facility shall be maintained to be free from conditions which may result in shellfish contamination. These conditions may include:

(a) Rodent attraction and harborage; and **[O]**

(b) Inadequate drainage. **[O]**

B. Plumbing and Related Facilities.

(1) Hand washing facilities shall be provided which are:

(a) Convenient to work areas; **[O]**

(b) Separate from the three compartment sinks used for cleaning equipment and utensils; and **[K]**

(c) Directly plumbed to an approved sewage disposal system. **[$S^{O/K}$]**

(2) The dealer shall provide at least one hand sink in the packing room. **[O]**

(3) The dealer shall provide at each hand washing facility:

(a) A supply of hand cleansing soap or detergent; **[K]**

(b) A conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; **[O]**
(c) An easily cleanable waste receptacle; and **[O]**
(d) Hand washing signs in a language understood by the employees; **[O]**

(4) All plumbing and plumbing fixtures shall be designed, installed, modified, repaired, and maintained to provide a water system that is adequate in quantity and under pressure, and includes:
(a) Cold and warm water at all sinks; and **[K]**
(b) Hand washing facilities adequate in number and size for the number of employees, and located where supervisors can observe employee use; **[K]**

(5) Adequate floor drainage, including backflow preventers such as air gaps, shall be provided where floors are:
(a) Used in shellstock storage; **[K]**
(b) Used for food holding units **[K]** (e.g. refrigeration units);
(c) Cleaned by hosing, flooding, or similar methods **[K]**; and
(d) Subject to the discharge of water or other liquid waste including three compartment sinks on the floor during normal activities. **[K]**

(6) A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations; **[$S^{C/K}$]**

(7) Installation of drainage or waste pipes over food processing or food storage areas, or over areas in which containers and utensils are washed or stored shall not be permitted. **[K]**

C. Utilities.
(1) The dealer shall ensure that ventilation, heating, or cooling systems do not create conditions that may cause the shellfish products to become contaminated. **[$S^{C/K}$]**
(2) The dealer shall provide lighting throughout the facility that is sufficient to promote good manufacturing practices. **[$S^{C/K}$]**

D. Insect and Vermin Control.
(1) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in his facility including:
(a) Tight fitting, self-closing doors; **[K]**
(b) Screening of not less than 15 mesh per inch; **[K]** and
(c) Controlled air current. **[K]**

E. Disposal of Other Wastes.
(1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations. **[O]**

(2) Shell and other non-edible materials shall be promptly and effectively removed from the shucking bench or table. **[O]**

(3) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin. **[O]**

F. Equipment Construction for Non-food Contact Surfaces.

(1) The dealer shall use only equipment, including approved plastic ware, which is constructed in a manner and with materials that can be cleaned, sanitized, maintained, or replaced. **[O]**

(2) The dealer shall use easily cleanable, corrosion-resistant, impervious materials, free from cracks to construct:

(a) Shucking benches and contiguous walls; and **[O]**

(b) Stands or stalls and stools for shucker. **[O]**

(c) Any non-food contact surfaces in shellfish storage or handling areas. **[O]**

(3) Shucking benches shall drain completely and rapidly, and shall drain away from any shellfish on the benches. **[O]**

G. Cleaning Non-food Contact Surfaces.

(1) Cleaning activities for equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellfish and food contact surfaces. **[K]**

(2) All conveyances and equipment, which come into contact with stored shellstock, shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination. **[O]**

H. Shellfish Storage and Handling. The dealer shall:

(1) Assure that shellstock is:

(a) Reasonably free of sediment **[O]**; and

(b) Culled; **[K]**

(2) Completely empty shucking buckets at the packing room so that no overage is returned to the shucker; **[K]**

(3) Inspect incoming shipments and shall reject dead or inadequately protected shellstock; **[K]**

(4) Not allow the use of dip buckets for hand or knife rinsing; **[K]**

(5) Not have on the premises any usable containers or container covers bearing a certification number different from the one issued for those premises unless documentation exists to verify the legitimate source of the containers and the containers contain shellfish from that source; **[K]**

(6) Wash, blow, and rinse all shellfish meats in accordance with 21 CFR 161§130. **[K]**

(7) Thoroughly drain, clean as necessary, and pack shucked shellfish meats promptly after delivery to the packing room; **[K]**

(8) Conduct packing activities so as to conform to applicable food additive regulations; **[K]**

(9) Store packaged shellfish, if they are to be frozen, at an ambient temperature of 0 ^{o} Fahrenheit (-17.8 ^{o} Centigrade) or less; and frozen solid within twelve hours following the initiation of freezing. **[$S^{K/0}$]**

(10) Not commingle shellstock during shucking unless the dealer is included in the Authority's commingling plan.**[K]**

I. Heat Shock. A dealer may elect to use heat shock to prepare shellstock for shucking.

(1) The dealer shall:

(a) Post the schedule for the heat shock process in a conspicuous location; and **[K]**

(b) Make sure all responsible persons are familiar with the requirements. **[K]**

(c) Cool all hot dipped shellstock immediately after the heat shock process **[K]**. This cooling shall be accomplished by:

(i) Dipping in a ice bath; or **[K]**

(ii) Use of flowing potable water. **[K]**

(2) If a heat shock tank is used, and the water is maintained at or above 140 degrees the dealer shall completely drain and flush the tank at the end of each day's operation so that all the mud and debris that have accumulated in the dip tank are eliminated. If the temperatures are maintained below 140 degrees, the dealer shall completely drain and flush the tank at three hour intervals. **[K]**

J. Personnel. Any employee handling shucked shellfish shall be required to:

(1) Wear effective hair restraints; **[O]**

(2) Remove any hand jewelry that cannot be sanitized or secured; **[O]**

(3) Wear finger cots or gloves if jewelry cannot be removed; **[O]**

(4) Wear clean outer garments, which are rinsed or changed as necessary to be kept clean. **[O]**

(5) In any area where shellfish are shucked or packed and in any area that is used for the cleaning or storage of utensils, the dealer shall not allow employees to:

(a) Store clothing or other personal belongings; **[O]**

(b) Eat or drink; **[K]**

(c) Spit; and **[K]**

(d) Use tobacco in any form. **[K]**

K. Supervision.

(1) A reliable, competent individual shall be designated to supervise general plant management and activities; **[K]**

(2) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellfish or food contact surfaces. **[K]**

(3) All supervisors shall be:

(a) Trained in proper food handling techniques and food protection principles; and **[K]**

(b) Knowledgeable of personal hygiene and sanitary practices. **[K]**

(4) The dealer shall require:

(a) Supervisors to monitor employee hygiene practices, including hand washing, eating, and smoking at work stations, and storing personal items or clothing. **[K]**

(b) Supervisors to assure that proper sanitary practices are implemented, including:

(i) Plant and equipment clean-up; **[K]**

(ii) Rapid product handling; and **[K]**

(iii) Shellfish protection from contamination. **[K]**

(c) Employees

(i) To be trained in proper food handling and personal hygiene practices, and **[K]**

(ii) To report any symptoms of illness to their supervisor. **[K]**

XII. REPACKING OF SHUCKED SHELLFISH

.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall repack only shellfish which:
(1) Originated from a dealer; and **[C]**
(2) Are identified with a label as outlined in Chapter X.06. **[C]**

B. Processing Critical Control Point - Critical Limits. The dealer shall ensure that repacked shucked shellfish do not exceed an internal temperature of 45° Fahrenheit (7.2° Centigrade) for more than 2 hours. **[C]**

C. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store repacked shellfish in covered containers at an ambient temperature of 45° Fahrenheit (7.2° Centigrade) or less or covered in ice. **[C]**

.02 Sanitation.

A. Safety of Water for Processing and Ice Production.
(1) Water Supply.
(a) The dealer shall provide a potable water supply in accordance with applicable federal, state and local regulations. **[C]**
(b) If the water supply is from a private source, the dealer shall make arrangements to have the water supply sampled by persons recognized by the Authority and tested at laboratories sanctioned or certified by the Authority: **[K]**
(i) Prior to use of the water supply; **[C]**
(ii) Every six months while the water supply is in use; and **[K]**
(iii) After any water supply has been repaired and disinfected. **[S C/K]**
(c) The dealer shall assure that any steam used in food processing or that comes in contact with food contact surfaces if free from any additives or deleterious substances consistent with federal and state laws and regulations. **[K]**
(2) Ice Production. Any ice used in the processing, storage, or transport of shellstock or shucked shellfish shall:
(a) Be made on-site from potable water in a commercial ice machine; or **[C]**
(b) Come from a facility sanctioned by the Authority or the appropriate regulatory agency. **[C]**
(3) Plumbing and Related Facilities.
(a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:
(i) Prevent contamination of water supplies; **[C]**

(ii) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. **[C] The** dealer shall install and maintain in good working order devices to protect against backflow and back siphonage. **[K]**

B. Condition and Cleanliness of Food Contact Surfaces.

(1) Equipment and utensil construction for food contact surfaces.

(a) Except for equipment in continuous use and placed in service prior to January 1, 1989, the dealer shall use only equipment that conforms to *Shellfish Industry Equipment Construction Guides* (August l993), U.S. Department of Health and Human Services. **[K]**

(b) The dealer shall use only equipment and utensils, including approved plastic ware which is:

(i) Constructed in a manner and with materials that can be cleaned, sanitized, maintained or replaced in a manner to prevent contamination of shellfish products; and **[K]**

(ii) Free from any exposed screws, bolts, or rivet heads on food contact surfaces; and **[K]**

(iii) Fabricated from food grade materials. **[K]**

(c) The dealer shall assure that all joints on food contact surfaces:

(i) Have smooth easily cleanable surfaces; and **[K]**

(ii) Are welded. **[K]**

(d) All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in Chapter XI.02.B.(1)(a), (b), and (c). **[K]**

(e) The dealer shall provide a temperature measuring device accurate to +/- 2^{o} Fahrenheit for use in monitoring product temperatures. **[K]**

(2) Cleaning and sanitizing of food contact surfaces.

(a) Food contact surfaces of equipment, utensils and containers shall be cleaned and sanitized to prevent contamination of shellfish and other food contact surfaces. The dealer shall:

(i) Provide adequate cleaning supplies and equipment, including three compartment sinks, brushes, detergents, and sanitizers, hot water and pressure hoses shall be available within the plant; **[K]**

(ii) Sanitize equipment and utensils prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated; **[K]**

(iii) Provide a test kit or other device that accurately measures the parts per million concentration of the chemical sanitizing agent in use; and **[K]**

(iv) Wash and rinse equipment and utensils at the end of each day. **[K]**

(3) Containers which may have become contaminated during storage shall be washed, rinsed, and sanitized prior to use or shall be discarded. **[K]**

(4) Shucked shellfish shall be repacked in clean containers:
   (a) Fabricated from food grade materials; and **[K]**
   (b) Stored in a manner which assures their protection from contamination. **[K]**

(5) If used, the finger cots or gloves shall be:
   (i) Made of impermeable materials except where the use of such material is inappropriate or incompatible with the work being done; **[O]**
   (ii) Sanitized at least twice daily; **[K]**
   (iii) Cleaned more often, if necessary; **[K]**
   (iv) Properly stored until used; **[K]** and
   (v) Maintained in a clean, intact, and sanitary condition.**[K]**

C. Prevention of Cross Contamination.

(1) Protection of shellfish.
   (a) Shucked shellfish shall be protected from contamination. **[$S^{C/K}$]**
   (b) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination. **[$S^{K/0}$]**

(2) Employee practices.
   (a) The dealer shall assure that all employees working in direct contact with shellfish processing activities or food contact surfaces maintain a high level of personal hygiene and cleanliness. **[K]**
   (b) The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate hand washing facility:
      (i) Before starting work; **[K]**
      (ii) After each absence from the work station; **[K]**
      (iii) After each work interruption; and **[K]**
      (iv) Any time when their hands may have become soiled or contaminated. **[K]**

D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.

(1) Hand washing facilities with warm water at a minimum temperature of 110 Fahrenheit (43 Centigrade), dispensed from a hot and cold mixing or combination faucet, shall be provided. **[$S^{K/O}$]**

(2) Sewage **[C]** and liquid disposable wastes **[K]** shall be properly removed from the facility.

(3) An adequate number of conveniently located, toilets shall be provided. **[K]**

(4) The dealer shall provide each toilet facility with an adequate supply of toilet paper**[K]** in a suitable holder. **[$S^{K/O}$]**

E. Protection from Adulterants.

(1) Shellfish shall be protected from contamination while being transferred from one point to another during handling and processing. **[K]**

(2) Any lighting fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in areas where shellfish are exposed shall be of the safety type or protected to prevent food contamination in case of breakage. **[O]**

(3) Food contact surfaces shall be protected from contamination by adulterants by using cleaning compounds and sanitizing agents only in accordance with applicable federal and state laws and regulations. **[K]**

(4) Protection of ice used in shellfish processing.

(a) Any ice, which is not made on site in the shellfish processing facility, shall be inspected upon receipt and rejected if the ice is not delivered in a way so as to be protected from contamination. **[$S^{C/K}$]**

(b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice. **[$S^{C/K}$]**

(5) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed. **[$S^{C/K}$]**

F. Proper Labeling, Storage and Use of Toxic Compounds.

(1) Storage of toxic compounds.

(a) The dealer shall assure that only toxic substances necessary for plant activities are present in the facility. **[K]**

(b) Each of the following categories of toxic substances shall be stored separately:

(i) Insecticides and rodenticides; **[K]**

(ii) Detergents, sanitizers, and related cleaning agents; and **[K]**

(iii) Caustic acids, polishes, and other chemicals. **[K]**

(c) The dealer shall not store toxic substances above shellfish or food contact surfaces. **[K]**

(2) Use and labeling of toxic compounds.

(a) When pesticides are used, the dealer shall apply pesticides in accordance with applicable federal and state regulations to control insects and rodents in such a manner to prevent the contamination of any shellfish or repackaging materials with residues. **[K]**

(b) Cleaning compounds and sanitizing agents shall be labeled and used only in accordance with applicable federal and state laws and regulations. **[K]**

(c) Toxic substances shall be labeled and used in accordance with the manufacturers label directions. **[K]**

G. Control of Employees with Adverse Health Conditions.

(1) The dealer shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces. The diseases, which are transmissible from food workers through food, are those determined by the US Centers for Disease Control

and Prevention, in compliance with the Americans with Disabilities Act, and published in the *Federal Register*. **[K]**

(2) If an employee with an infected wound keeps it covered with a proper bandage, an impermeable barrier, and a single-use glove for a hand lesion, the dealer may allow the employee to work in the shellfish processing facility without additional restrictions. **[K]**

H. Exclusion of Pests. The dealer shall operate his facility to assure that pests which may be a source of shellfish contamination are excluded from his facility and his activities. **[K]**

.03 Other Model Ordinance Requirements.

A. Plants and Grounds.

(1) General.

(a) The physical facilities shall be maintained in good repair. **[O]**

(b) Animals or unauthorized persons shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. **[K]**

(c) Air pump intakes shall be located in a protected place. Air filters shall be installed on all blower air pump intakes. Oil bath type filters are not allowed. **[O]**

(2) Flooding:

(a) Facilities in which shellfish are stored, shucked, packed, repacked or reshipped shall be located so that these facilities are not subject to flooding during ordinary high tides. **[C]**

(b) If facilities are flooded:

(i) Shellfish processing, shucking or repacking activities shall be discontinued until the flood waters have receded from the building; and the building is cleaned and sanitized. **[C]**

(ii) Any shellfish coming in contact with the floodwaters while in storage shall be destroyed; or discarded in non-food use. **[C]**

(3) The dealer shall operate his facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from his facility and activities. **[$S^{C/K}$]**

(4) The dealer shall provide toilet room doors which are tight fitting, self-closing, and do not open directly into a processing area. **[K]**

(5) Plant Interior.

(a) Sanitary conditions shall be maintained throughout the facility. **[O]**

(b) All dry area floors shall be hard, smooth, easily cleanable; and **[O]**

(c) All wet area floors used in areas to process food and clean equipment and utensils shall be constructed of easily cleanable, impervious, and corrosion resistant materials which:

(i) Are graded to provide adequate drainage; **[O]**

(ii) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage; **[O]**

(iii) Have sealed junctions between floors and walls to render them impervious to water; and **[O]**

(d) Walls and Ceilings. Interior surfaces of rooms where shellfish are stored, handled, processed, or shall be constructed of easily cleanable, corrosion resistant, impervious and packaged materials. **[O]**

(6) Grounds. Grounds around the facility shall be maintained to be free from conditions which may result in shellfish contamination. These conditions may include:

(a) Rodent attraction and harborage; and **[O]**

(b) Inadequate drainage. **[O]**

B. Plumbing and Related Facilities.

(1) Hand washing facilities shall be provided which are:

(a) Convenient to work areas; **[O]**

(b) Separate from the three compartment sinks used for cleaning equipment and utensils; and **[K]**

(c) Directly plumbed to an approved sewage disposal system. **[$S^{O/K}$]**

(2) The dealer shall provide at least one hand sink in the packing room. **[O]**

(3) The dealer shall provide at each hand washing facility:

(a) A supply of hand cleansing soap or detergent; **[K]**

(b) A conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; **[O]**

(c) An easily cleanable waste receptacle; and **[O]**

(d) Hand washing signs in a language understood by the employees. **[O]**

(4) All plumbing and plumbing fixtures shall be designed, installed, modified, repaired, and maintained to provide a water system that is adequate in quantity and under pressure, and includes:

(a) Cold and warm water at all sinks; and **[K]**

(b) Hand washing facilities adequate in number and size for the number of employees, and located where supervisors can observe employee use; **[K]**

(5) Adequate floor drainage, including backflow preventers such as air gaps, shall be provided where floors are:

(a) Used for food holding units (e.g. refrigeration units); **[K]**

(b) Cleaned by hosing, flooding, or similar methods; and **[K]**

(c) Subject to the discharge of water or other liquid waste including three compartment sinks on the floor during normal activities. **[K]**

(6) A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations; **[$S^{C/K}$]**

(7) Installation of drainage or waste pipes over food processing or food storage areas, or over areas in which containers and utensils are washed or stored shall not be permitted. **[K]**

C. Utilities.

(1) The dealer shall ensure that ventilation, heating, or cooling systems do not create conditions that may cause the shellfish products to become contaminated. [$S^{C/K}$]

(2) The dealer shall provide lighting throughout the facility that is sufficient to promote good manufacturing practices. **[$S^{C/K}$]**

D. Insect and Vermin Control.

(1) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in his facility including:

(a) Tight fitting, self-closing doors; **[K]**

(b) Screening of not less than 15 mesh per inch; and **[K]**

(c) Controlled air currents. **[K]**

E. Disposal of Other Wastes.

(1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations. **[O]**

(2) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin. **[O]**

F. Equipment Construction for Non-food Contact Surfaces.

(1) The dealer shall use only equipment, including approved plastic ware, which is constructed in a manner and with materials that can be cleaned, sanitized, maintained, or replaced; and **[O]**

(2) The dealer shall use easily cleanable, corrosion-resistant, impervious materials, free from cracks to construct any non-food contact surfaces in shellfish storage or handling areas. **[O]**

G. Cleaning Non-food Contact Surfaces.

(1) Cleaning activities for equipment and utensils shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellfish and food contact surfaces. **[K]**

(2) All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination. **[O]**

H. Shellfish Storage and Handling.

(1) The dealer shall:

(a) Not commingle shellfish from different lots; **[K]**

(b) Repack shucked shellfish meats only into containers labeled with the authorized certification number; **[K]**

(c) Not have on the premises any usable containers or container covers bearing a certification number different from the one issued for those premises unless documentation exists to verify the legitimate source of the containers and the containers contain shellfish from that source. **[K]**

(d) Wash, blow, and rinse all shellfish meats in accordance with 21 CFR 161§130. **[K]**

(e) Thoroughly drain, clean as necessary, and repack **[K]** shucked shellfish meats promptly;

(f) Conduct repacking activities so as to conform to applicable food additive regulations; **[K]**

(g) Store packaged shellfish, if they are to be frozen, at an ambient temperature of 0 ^{o} Fahrenheit (-17.8 ^{o} Centigrade) or less and frozen solid within twelve hours following the initiation of freezing. **[$S^{K/O}$]**

I. Heat Shock. N/A

J. Personnel. Any employee handling shucked shellfish shall be required to:

(1) Wear effective hair restraints; **[O]**

(2) Remove any hand jewelry that cannot be sanitized or secured; **[O]**

(3) Wear finger cots or gloves if jewelry cannot be removed. **[O]**

(4) Wear clean outer garments, which are rinsed or changed as necessary to be kept clean. **[O]**

(5) In any area where shellfish are shucked or packed and in any area that is used for the cleaning or storage of utensils, the dealer shall not allow employees to:

(a) Store clothing or other personal belongings; **[K]**

(b) Eat or drink; **[K]**

(c) pit; and **[K]**

(d) use tobacco in any form. **[K]**

K. Supervision.

(1) A reliable, competent individual shall be designated to supervise general plant management and activities; **[K]**

(2) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellfish or food contact surfaces. **[K]**

(3) All supervisors shall be:

(a) Trained in proper food handling techniques and food protection principles; and **[K]**

(b) Knowledgeable of personal hygiene and sanitary practices. **[K]**

(4) The dealer shall require:

(a) Supervisors to monitor employee hygiene practices, including hand washing, eating, and smoking at work stations, and storing personal items or clothing. **[K]**

(b) Supervisors to assure that proper sanitary practices are implemented, including:
  (i) Plant and equipment clean-up; **[K]**
  (ii) Rapid product handling; and **[K]**
  (iii) Shellfish protection from contamination. **[K]**

(c) Employees
  (i) to be trained in proper food handling and personal hygiene practices, and **[K]**
  (ii) to report any symptoms of illness to their supervisor. **[K]**

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XIII. SHELLSTOCK SHIPPING

Exceptions. Shellstock Shippers are not required to pack shellstock in a building that complies with Sections .02 and .03 of this chapter when the Authority has determined that a shellstock shipper's practices and conditions do not warrant requiring shellstock to be packed in a building.

01. Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall ship or repack only shellstock that is:
   (1) Obtained from a licensed harvester who has:
      (a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as identified by the tag; and **[C]**
      (b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; or **[C]**
   (2) Obtained from a dealer who has identified the shellstock with a tag on each container. **[C]**

B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that:
   (1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X.08; and **[C]**
   (2) Once placed under temperature control and until sale to the processor or final consumer, shellstock shall be:
      (a) Iced; or **[C]**
      (b) Placed in a storage area or conveyance maintained at 45 ^{o} Fahrenheit (7.2 ^{o} Centigrade) or less; and **[C]**
      (c) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in §B (1) or §B (2) for more than 2 hours at points of transfer such as loading docks. **[C]**

02. Sanitation.

A. Safety of Water for Processing and Ice Production.
   (1) Water Supply.
      (a) The dealer shall provide a potable water supply in accordance with applicable federal, state and local regulations. **[C]**
      (b) If the water supply is from a private source, the dealer shall make arrangements to have the water supply sampled by persons recognized by the Authority and tested at laboratories sanctioned or certified by the Authority: **[K]**
         (i) Prior to use of the water supply; **[C]**
         (ii) Every six months while the water supply is in use; and **[K]**

(iii) After any water supply has been repaired and disinfected. **[$S^{C/K}$]**

(c) The dealer shall assure that any steam used in food processing or that comes in contact with food contact surfaces if free from any additives or deleterious substances consistent with federal and state laws and regulations. **[K]**

(2) Ice Production. Any ice used in the processing, storage, or transport of shellstock shall:

(a) Be made on-site from potable water in a commercial ice machine; or **[C]**

(b) Come from a facility sanctioned by the Authority or the appropriate regulatory agency. **[C]**

(3) Shellstock Washing.

(a) Water from either a potable water supply or a growing area in the approved classification shall be used to wash shellstock. **[C]**

(b) If the dealer uses any system to wash shellstock which recirculates water, the dealer shall:

(i) Obtain approval for the construction or remodeling of the system from the Authority. **[K]**

(ii) Provide a water treatment and disinfection system to treat an adequate quantity of water to a quality acceptable for shellstock washing which, after disinfection, meets the coliform standards for drinking water, and does not leave any unacceptable residues in the shellstock; and **[C]**

(iii) Test bacteriological water quality daily **[$S^{C/K}$]**

(c) The dealer may use ultra-violet (UV) disinfection in the recirculating wash water system, provided that the turbidity of the water to be disinfected shall not exceed 20 nephelometric turbidity units (NTUs) measured using the method in the APHA *Standard Methods for the Examination of Water and Wastewater*. **[K]**

(4) Plumbing and Related Facilities.

(a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:

(i) Prevent contamination of water supplies; **[C]**

(ii) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. **[C]** The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage. **[K]**

(b) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials and tank construction shall be such that it is easily accessible for cleaning and inspection; **[K]**

(i) Is self-draining; and **[K]**

(ii) Meets the requirements for food contact surfaces. **[K]**

B. Condition and Cleanliness of Food Contact Surfaces.

(1) Equipment and utensil construction for food contact surfaces.

(a) Except for equipment in continuous use and placed in service prior to January 1, 1989, the dealer shall use only equipment that conforms to *Shellfish Industry Equipment Construction Guides* (August l993), U.S. Department of Health and Human Services. **[K]**

(b) The dealer shall use only equipment and utensils, including approved plastic ware, which is:

(i) Constructed in a manner and with materials that can be cleaned, sanitized, maintained or replaced in a manner to prevent contamination of shellstock; and **[K]**

(ii) Free from exposed screws, bolts or rivet heads on food contact surfaces and **[K]**

(iii) Fabricated from food grade materials. **[K]**

(c) The dealer shall assure that all joints on food contact surfaces:

(i) Have smooth easily cleanable surfaces; and **[K]**

(ii) Are welded. **[K]**

(d) All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in Chapter XI.02B.(1) (a), (b), and (c). **[K]**

(2) Cleaning and Sanitizing of Food Contact Surfaces.

(a) Food contact surfaces of equipment, utensils and containers shall be cleaned and sanitized to prevent contamination of shellstock and other food contact surfaces. The dealer shall:

(i) Provide adequate cleaning supplies and equipment, including three compartment sinks, brushes, detergents, and sanitizers, hot water and pressure hoses shall be available within the plant; **[K]**

(ii) Sanitize equipment and utensils prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated; **[K]**

(iii) Provide a test kit or other device that accurately measures the parts per million concentration of the chemical sanitizing agent in use; and **[K]**

(iv) Wash and rinse equipment and utensils at the end of each day. **[K]**

(b) Containers which may have become contaminated during storage shall be washed, rinsed and sanitized prior to use or shall be discarded. **[K]**

(3) If used, the finger cots or gloves shall be:

(a) Made of impermeable materials except where the use of such material is inappropriate or incompatible with the work being done; **[O].** Sanitized at least twice daily;

(b) Cleaned more often, if necessary; **[K]**

(c) Properly stored until used; and **[K]**

(d) Maintained in a clean, intact, and sanitary conditions. **[K]**

C. Prevention of Cross Contamination.

(1) Protection of Shellfish.

(a) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer. **[$S^{C/K}$]**

(b) Shucked shellfish shall be protected from contamination. **[$S^{C/K}$]**

(c) Shellstock shall not be placed in containers with standing water for the purposes of washing shellstock or loosening sediment. **[K]**

(d) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination. **[$S^{C/K}$]**

(2) Employee practices.

(a) The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate handwashing facility:

(i) Before starting work; **[K]**

(ii) After each absence from the work station; **[K]**

(iii) After each work interruption; and **[K]**

(iv) Any time when their hands may have become soiled or contaminated. **[K]**

D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.

(1) Hand washing facilities with warm water at a minimum temperature of 110 ^{F}ahrenheit (43 ^{o} Centigrade), dispensed from a hot and cold mixing or combination faucet, shall be provided. **[$S^{K/O}$]**

(2) Sewage **[K]** and liquid disposable wastes **[K]** shall be properly removed from the facility.

(3) An adequate number of conveniently located, toilets shall be provided. **[K]**

(4) The dealer shall provide each toilet facility with an adequate supply of toilet paper **[K]** in a suitable holder. **[$S^{K/O}$]**

E. Protection from Adulterants.

(1) Shellstock shall be protected from contamination while being transferred from one point to another during handling and processing; **[K]**

(2) Any lighting fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in areas where shellstock are exposed shall be of the safety type or protected to prevent food contamination in case of breakage. **[O]**

(3) Food contact surfaces shall be protected from contamination by adulterants by using cleaning compounds and sanitizing agents only in accordance with applicable federal and state laws and regulations. **[K]**

(4) Shellstock shall be packed in clean containers. **[K]**

(5) Protection of ice used in shellstock processing.

(a) Any ice, which is not made on site in the shellstock processing facility, shall be inspected upon receipt and rejected if the ice is not delivered in a way so as to be protected from contamination. **[$S^{C/K}$]**

(b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice. **[$S^{C/K}$]**

(6) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed. **[$S^{C/K}$]**

F. Proper Labeling, Storage and Use of Toxic Compounds.

(1) Storage of toxic compounds.

(a) The dealer shall assure that only toxic substances necessary for plant activities are present in the facility. **[K]**

(b) Each of the following categories of toxic substances shall be stored separately:

(i) Insecticides and rodenticides; **[K]**

(ii) Detergents, sanitizers, and related cleaning agents; and **[K]**

(iii) Caustic acids, polishes, and other chemicals. **[K]**

(c) The dealer shall not store toxic substances above shellfish or food contact surfaces. **[K]**

(2) Use and labeling of toxic compounds.

(a) When pesticides are used, the dealer shall apply pesticides in accordance with applicable federal and state regulations to control insects and rodents in such a manner to prevent the contamination of any shellstock or packaging materials with residues. **[K]**

(b) Cleaning compounds and sanitizing agents shall be labeled and used only in accordance with applicable federal and state laws and regulations. **[K]**

(c) Toxic substances shall be labeled and used in accordance with the manufacturer's label directions. **[K]**

G. Control of Employees with Adverse Health Conditions.

(1) The dealer shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellstock or with food contact surfaces. The diseases which are transmissible from food workers through food are those determined by the US Centers for Disease Control and Prevention, in compliance with the Americans with Disabilities Act, and published in the *Federal Register.* **[K]**

(2) If an employee with an infected wound keeps it covered with a proper bandage, an impermeable barrier, and a single-use glove for a hand lesion, the dealer may allow the employee to work in the shellfish processing facility without additional restrictions. **[K]**

H. Exclusion of Pests. The dealer shall operate his facility to assure that pests, which may be a source of shellstock contamination, are excluded from his facility and his activities. **[K]**

.03 Other Model Ordinance Requirements.

A. Plants and Grounds.

(1) General.

(a) The physical facilities shall be maintained in good repair. **[O]**

(b) Animals or unauthorized persons shall not be allowed in those portions of the facilities where shellstock are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. **[K]**

(2) Flooding:

(a) Facilities in which shellstock are stored, packed, repacked or reshipped shall be located so that these facilities are not subject to flooding during ordinary high tides. **[C]**

(b) If facilities are flooded:

(i) Shellstock processing, repacking or shipping activities shall be discontinued until the floodwaters have receded from the building; and the building is cleaned and sanitized. **[C]**

(ii) Any shellstock coming in contact with the floodwaters while in storage shall be destroyed; or discarded in non-food use. **[C]**

(3) The dealer shall operate his facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from his facility and activities. [$S^{C/K}$]

(4) The dealer shall provide toilet room doors which are tight fitting, self-closing, and do not open directly into a processing area. [K]

(5) Plant Interior.

(a) Sanitary conditions shall be maintained throughout the facility. **[O]**

(b) All dry area floors shall be hard, smooth, easily cleanable and in good repair; and **[O]**

(c) All wet area floors used in areas to store shellstock, process food, and clean equipment and utensils shall be constructed of easily cleanable, impervious, and corrosion resistant materials which:

(i) Are graded to provide adequate drainage; **[O]**

(ii) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage; **[O]**

(iii) Have sealed junctions between floors and walls to render them impervious to water; and **[O]**

(d) Walls and Ceilings. Interior surfaces of rooms where shellstock are stored, handled, processed, or shall be constructed of easily cleanable, corrosion resistant, impervious packaged materials. **[O]**

(6) Grounds. Grounds around the facility shall be maintained to be free from conditions which may result in shellstock contamination. These conditions may include:

(a) Rodent attraction and harborage; and **[O]**

(b) Inadequate drainage. **[O]**

B. Plumbing and Related Facilities.

(1) Hand washing facilities shall be provided which are:

(a) Convenient to work areas; **[O]**

(b) Separate from the three compartment sinks used for cleaning equipment and utensils; and **[K]**

(c) Directly plumbed to an approved sewage disposal system.**[$S^{O/K}$]**

(2) All plumbing and plumbing fixtures shall be designed, installed, modified, repaired, and maintained to provide a water system that is adequate in quantity and under pressure, and includes:

(a) Cold and warm water at all sinks; and **[K]**

(b) Hand washing facilities adequate in number and size for the number of employees, and located where supervisors can observe employee use; **[K]**

(3) Hand washing facilities: The dealer shall provide at each hand washing facility:

(a) A supply of hand cleansing soap or detergent; **[K]**

(b) A conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; **[O]**

(c) An easily cleanable waste receptacle; and **[O]**

(d) Hand washing signs in a language understood by the employees; **[O]**

(4) Adequate floor drainage, including backflow preventers such as air gaps, shall be provided where floors are:

(a) Used in shellstock storage; **[K]**

(b) Used for food holding units **[K]** (e.g. refrigeration units);

(c) Cleaned by hosing, flooding, or similar methods; and **[K]**

(d) Subject to the discharge of water or other liquid waste including three compartment sinks on the floor during normal activities; **[K]**

(5) A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations; **[K]**

(6) Installation of drainage or waste pipes over food processing or food storage areas, or over areas in which containers and utensils are washed or stored shall not be permitted. **[K]**

C. Utilities.

(1) The dealer shall ensure that ventilation, heating, or cooling systems do not create conditions that may cause the shellfish products to become contaminated. **[$S^{C/K}$]**

(2) The dealer shall provide lighting throughout the facility that is sufficient to promote good manufacturing practices. **[$S^{C/K}$]**

D. Insect and Vermin Control.

(1) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in his facility including:

(a) Tight fitting, self-closing doors; **[K]**
(b) Screening of not less than 15 mesh per inch; and **[K]**
(c) Controlled air currents. **[K]**

E. Disposal of Other Waste
(1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations. **[O]**
(2) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin. **[O]**

F. Equipment Construction for Non-food Contact Surfaces.
(1) The dealer shall use only equipment, including approved plastic ware, which is constructed in a manner and with materials that can be cleaned, sanitized, maintained, or replaced; and **[O]**
(2) The dealer shall use easily cleanable, corrosion-resistant, impervious materials, free from cracks to construct any non-food contact surfaces in shellstock storage or handling areas. **[O]**

G. Cleaning of Non-food Contact Surfaces.
(1) Cleaning and sanitizing activities for equipment and utensils shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellstock and food contact surfaces. **[K]**
(2) All conveyances and equipment, which come into contact with stored shellstock, shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination. **[O]**

H. Shellstock Storage and Handling.
(1) The dealer shall:
(a) Assure that shellstock is:
(i) Alive; **[K]**
(ii) Reasonably free of sediment; and **[O]**
(iii) Culled. **[K]**
(b) Not commingle shellstock during repacking unless the dealer is included in the Authority's commingling plan. **[K]**
(2) The dealer shall inspect incoming shipments and shall reject dead or inadequately protected shellstock. **[K]**
(3) A dealer whose activity consists of trucks or docking facilities only shall:
(a) Have a permanent business address at which records are maintained and inspections can be performed; and **[K]**
(b) Not repack shellstock. **[K]**
(4) A dealer who stores or repacks shellstock shall have:
(a) His own facility for proper storage or repacking of shellstock; or **[K]**
(b) Arrangements with a facility approved by the Authority for the storage or repacking of shellstock. **[K]**

I. Heat Shock – N/A

J. Personnel. In any area where shellstock are stored and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:
(1) Store clothing or other personal belongs; **[O]**
(2) Eat or drink; **[K]**
(3) Spit; and **[K]**
(4) Use tobacco in any form. **[K]**

K. Supervision.
(1) A reliable, competent individual shall be designated to supervise general plant management and activities; **[K]**
(2) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellstock or food contact surfaces. **[K]**
(3) All supervisors shall be:
(a) Trained in proper food handling techniques and food protection principles; and **[K]**
(b) Knowledgeable of personal hygiene and sanitary practices. **[K]**
(4) The dealer shall require:
(a) Supervisors to monitor employee hygiene practices, including hand washing, eating, and smoking at workstations, and storing personal items or clothing. **[K]**
(b) Supervisors to assure that proper sanitary practices are implemented, including:
(i) Plant and equipment clean-up; **[K]**
(ii) Rapid product handling; and **[K]**
(iii) Shellfish protection from contamination. **[K]**
(c) Employees:
(i) to be trained in proper food handling and personal hygiene practices, and **[K]**
(ii) to report any symptoms of illness to their supervisor. **[K]**

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XIV. RESHIPPING

Exceptions. Reshippers are not required to comply with the building requirements in Sections .02 and .03 of this chapter when the Authority has determined that a reshipper's practices and conditions do not warrant requiring a building.

.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall reship only shellfish which:
   (1) Originated from a dealer; **[C]**
   (2) Are identified with a tag as outlined in Chapter X.05 or a label as outlined in Chapter X.06. **[C]**

B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that once placed under temperature control and until sale to the processor or final consumer, shellstock shall be:
   (1) Iced; or **[C]**
   (2) Placed in a storage area or conveyance maintained at 45 ^{o} Fahrenheit (7.2 ^{o} Centigrade) or less; and **[C]**
   (3) Not permitted to remain without ice, mechanical refrigeration, or other approved means of refrigeration for more than 2 hours at points of transfer such as loading docks. **[C]**

C. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store shucked shellfish at an ambient temperature of 45 ^{o} Fahrenheit (7.2 ^{o} Centigrade) or less. **[C]**

02. Sanitation.

A. Safety of Water for Processing and Ice Production.
   (1) Water Supply.
      (a) The dealer shall provide a potable water supply in accordance with applicable federal, state and local regulations. **[C]**
      (b) If the water supply is from a private source, the dealer shall make arrangements to have the water supply sampled by persons recognized by the Authority and tested at laboratories sanctioned or certified by the Authority: **[K]**
         (i) Prior to use of the water supply; **[C]**
         (ii) Every six months while the water supply is in use; and **[K]**
         (iii) After any water supply has been repaired and disinfected. **[$S^{C/K}$]**
   (2) Ice Production. Any ice used in the storage or transport of shellstock or shucked shellfish shall:

(a) Be made on-site from potable water in a commercial ice machine; or **[C]**

(b) Come from a facility sanctioned by the Authority or the appropriate regulatory agency. **[C]**

(3) Plumbing and Related Facilities.

(a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:

(i) Prevent contamination of water supplies. **[C]**

(ii) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source **[C]**. The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage. **[K]**

B. Condition and Cleanliness of Food Contact Surfaces. Equipment and utensil construction for food contact surfaces. All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in Chapter XI.02B.(1) (a), (b), and (c). **[K]**

C. Prevention of Cross Contamination.

(1) Protection of shellfish.

(a) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer. **[$S^{C/K}$]**

(b) Shucked shellfish shall be protected from contamination. **[$S^{C/K}$]**

(c) Equipment shall be stored in a manner to prevent splash, dust, and contamination. **[$S^{K/O}$]**

(2) Employee practices. The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate hand washing facility:

(a) Before starting work; **[K]**

(b) After each absence from the work station; **[K]**

(c) After each work interruption; and **[K]**

(d) Any time when their hands may have become soiled or contaminated. **[K]**

D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.

(1) Hand washing facilities with warm water at a minimum temperature of 110 ° Fahrenheit (43 ° Centigrade), dispensed from a hot and cold mixing or combination faucet, shall be provided. **[$S^{K/O}$]**

(2) Sewage **[C]** and liquid disposable wastes **[K]** shall be properly removed from the facility.

(3) An adequate number of conveniently located, toilets shall be provided. **[K]**

(4) The dealer shall provide each toilet facility with an adequate supply of toilet paper **[K]** in a suitable holder. **[$S^{K/O}$]**

E. Protection from Adulterants.

(1) Shellfish shall be protected from contamination while being transferred from one point to another during handling and processing. **[K]**

(2) Any lighting fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in areas where shellfish are exposed shall be of the safety type or protected to prevent food contamination in case of breakage. **[O]**

(3) Food contact surfaces shall be protected from contamination by adulterants by using cleaning compounds and sanitizing agents only in accordance with applicable federal and state laws and regulations. **[K]**

(4) Protection of ice used in shellfish reshipping.

(a) Any ice, which is not made on site in the shellfish processing facility, shall be inspected upon receipt and rejected if the ice is not delivered in a way so as to be protected from contamination. **[$S^{C/K}$]**

(b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice. **[$S^{K/C}$]**

(5) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed. **[$S^{C/K}$]**

F. Proper Labeling, Storage and Use of Toxic Compounds.

(1) Storage of toxic compounds.

(a) The dealer shall assure that only toxic substances necessary for plant activities are present in the facility. **[K]**

(b) Each of the following categories of toxic substances shall be stored separately:

(i) Insecticides and rodenticides; **[K]**

(ii) Detergents, sanitizers, and related cleaning agents; and **[K]**

(iii) Caustic acids, polishes, and other chemicals. **[K]**

(c) The dealer shall not store toxic substances above shellfish. **[K]**

(2) Use and labeling of toxic compounds.

(a) When pesticides are used, the dealer shall apply pesticides in accordance with applicable federal and state regulations to control insects and rodents in such a manner to prevent the contamination of any shellfish or packaging materials with residues. **[K]**

(b) Cleaning compounds and sanitizing agents shall be labeled and used only in accordance with applicable federal and state laws and regulations. **[K]**

(c) Toxic substances shall be labeled and used in accordance with the manufacturer's label directions. **[K]**

G. Control of Employees with Adverse Health Conditions.

(1) The dealer shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces. The diseases which are transmissible from food workers

through food are those determined by the US Centers for Disease Control and Prevention, in compliance with the Americans with Disabilities Act, and published in the *Federal Register*. **[K]**

(2) If an employee with an infected wound keeps it covered with a proper bandage, an impermeable barrier, and a single-use glove for a hand lesion, the dealer may allow the employee to work in the shellfish processing facility without additional restrictions. **[K]**

H. Exclusion of Pests. The dealer shall operate his facility to assure that pests which may be a source of shellfish contamination are excluded from his facility and his activities. **[K]**

.03 Other Model Ordinance Requirements.

A. Plants and Grounds.
(1) General.
(a) The physical facilities shall be maintained in good repair. **[O]**
(b) Animals or unauthorized persons shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. **[K]**
(2) Flooding:
(a) Facilities in which shellfish are stored, shucked, packed, repacked or reshipped shall be located so that these facilities are not subject to flooding during ordinary high tides. **[C]**
(b) If facilities are flooded:
(i) Shellfish processing, shucking, repacking, or reshipping activities shall be discontinued until the flood waters have receded from the building; and the building is cleaned and sanitized **[C]**
(ii) Any shellfish coming in contact with the floodwaters while in storage shall be destroyed; or discarded in non-food use. **[C]**
(3) The dealer shall operate his facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from his facility and activities. [C/K]
(4) The dealer shall provide toilet room doors which are tight fitting, self-closing, and do not open directly into a processing area. [K]
(5) Plant Interior.
(a) Sanitary conditions shall be maintained throughout the facility. **[O]**
(b) All dry area floors shall be hard, smooth, easily cleanable; and **[O]**
(c) All wet area floors used in areas to store shellstock, process food, and clean equipment and utensils shall be constructed of easily cleanable, impervious, and corrosion resistant materials which:
(i) Are graded to provide adequate drainage; **[O]**

(ii) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage; **[O]**

(iii) Have sealed junctions between floors and walls to render them impervious to water; and **[O]**

(d) Walls and Ceilings. Interior surfaces of rooms where shellfish are stored, handled, processed, or packaged shall be constructed of easily cleanable, corrosion resistant, impervious materials. [**O]**

(6) Grounds. Grounds around the facility shall be maintained to be free from conditions which may result in shellfish contamination. These conditions may include:

(a) Rodent attraction and harborage; and **[O]**

(b) Inadequate drainage. **[O]**

B. Plumbing and Related Facilities.

(1) Hand washing facilities shall be provided which are:

(a) Convenient to work areas; **[O]**

(b) Separate from the three compartment sinks used for cleaning equipment and utensils; and **[K]**

(c) Directly plumbed to an approved sewage disposal system. **[$S^{O/K}$]**

(2) All plumbing and plumbing fixtures shall be designed, installed, modified, repaired, and maintained to provide a water system that is adequate in quantity and under pressure, and includes:

(a) Cold and warm water at all sinks; and **[K]**

(b) Hand washing facilities adequate in number and size for the number of employees, and located where supervisors can observe employee use; **[K]**

(3) The dealer shall provide at each hand washing facility:

(a) A supply of hand cleansing soap or detergent; **[K]**

(b) A conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; **[O]**

(c) An easily cleanable waste receptacle; and **[O]**

(d) Hand washing signs in a language understood by the employees; **[O]**

(4) Adequate floor drainage, including backflow preventers such as air gaps, shall be provided where floors are:

(a) Used in shellstock storage; **[K]**

(b) Used for food holding units (e.g. refrigeration units); **[K]**

(c) Cleaned by hosing, flooding, or similar methods; and **[K]**

(d) Subject to the discharge of water or other liquid waste including three compartment sinks on the floor during normal activities. **[K]**

(5) A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations; **[$S^{C/K}$]**

(6) Installation of drainage or waste pipes over food processing or food storage areas, or over areas in which containers and utensils are washed or stored shall not be permitted. **[K]**

C. Utilities.

(1) The dealer shall ensure that ventilation, heating, or cooling systems do not create conditions that may cause the shellfish products to become contaminated.**[S$^{C/K}$]**

(2) The dealer shall provide lighting throughout the facility that is sufficient to promote good manufacturing practices. **[S$^{C/K}$]**

D. Insect and Vermin Control.

(1) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in his facility including:

(a) Tight fitting, self-closing doors; **[K]**

(b) Screening of not less than 15 mesh per inch; and **[K]**

(c) Controlled air currents; **[K]**

E. Disposal of Other Wastes.

(1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations. **[O]**

(2) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin; and **[O]**

F. Equipment Construction for Non-food Contact Surfaces.

(1) The dealer shall use only equipment, including approved plastic ware, which is constructed in a manner and with materials that can be cleaned, sanitized, maintained, or replaced. **[O]**

(2) The dealer shall use easily cleanable, corrosion-resistant, impervious materials, free from cracks to construct any non-food contact surfaces in shellfish storage or handling areas. **[O]**

G. Cleaning Non-food Contact Surfaces.

(1) Cleaning activities for equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellfish and food contact surfaces. **[K]**

(2) All conveyances and equipment that come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination. **[O]**

H. Shellfish Storage and Handling

(1) The dealer shall:

(a) Buy shellfish only from sources certified by the Authority or listed in the ICSSL; and **[K]**

(b) Add his name and certification number to the package. **[K]**

(2) The dealer shall not:

(a) Comingle, sort, or repack shellstock or shucked shellfish; or **[K]**

(b) Remove or alter any existing tag or label. **[K]**

(3) A dealer whose activity consists of trucks only shall:

(a) Have his own facility for the storage of shellfish; or **[K]**

(b) Have arrangements with a facility approved by the Authority for the storage of shellfish; and **[K]**

(c) Have a permanent business address at which records are maintained and inspections can be performed. **[K]**

I. Heat Shock – N/A

J. Personnel. In any area where shellfish are stored and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:

(1) Store clothing or other personal belongs; **[O]**

(2) Eat or drink; **[K]**

(3) Spit; and **[K]**

(4) Use tobacco in any form. **[K]**

K. Supervision.

(1) A reliable, competent individual shall be designated to supervise general plant management and activities; **[K]**

(2) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellfish or food contact surfaces. **[K]**

(3) All supervisors shall be:

(a) Trained in proper food handling techniques and food protection principles; and **[K]**

(b) Knowledgeable of personal hygiene and sanitary practices. **[K]**

(4) The dealer shall require:

(a) Supervisors to monitor employee hygiene practices, including hand washing, eating, and smoking at work stations, and storing personal items or clothing. **[K]**

(b) Supervisors to assure that proper sanitary practices are implemented, including:

(i) Plant and equipment clean-up; **[K]**

(ii) Rapid product handling; and **[K]**

(iii) Shellfish protection from contamination. [**K]**

(c) Employees

(i) to be trained in proper food handling and personal hygiene practices **[K]**

(ii) to report any symptoms of illness to their supervisor. **[K]**

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XV. DEPURATION.

Note: In those States where depuration is not practiced, this Chapter may be deleted from the Ordinance, as well as references to depuration throughout the Ordinance.

Requirements for the Authority

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this Chapter in regulation.]

A. Prior to authorizing depuration, the Authority shall develop and maintain an effective program to:
   (1) Control shellstock harvesting by special license in accordance with Chapter VIII.@.01 C;
   (2) Control shellstock transportation between the harvest area and the depuration facility to prevent shellstock from being illegally diverted to direct marketing;
   (3) Approve the design and construction of the depuration facility or activity including subsequent changes;

B. If shellstock is transported interstate to be depurated, the Authorities in both States shall execute a memorandum of agreement to provide adequate control measures to prevent diversion prior to depuration.

C. The Authority shall review and approve the Depuration Plant Operating Manual prior to granting depuration certification.

D. The Authority shall review the depuration plant performance index and other records as part of the monthly inspections to verify that the process and CCP are effective and the process verification analysis is being performed properly.

E. The Authority shall maintain adequate records for each depuration facility. The following records for each facility shall be kept for the period of five years:
   (1) Inspection reports and reviews of the plant performance in accordance to §D. (above);
   (2) Current Depuration Plant Operation Manuals for each dealer (§.02).

F. The Authority shall assure that each dealer has procedures to assure that no shellstock which has not been depurated is removed from the depuration facility without the direct supervision of the Authority.

Requirements for the Dealer

.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall receive and depurate only shellstock which is:
   (1) Obtained from a licensed harvester who has:
      (a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; **[C]** and
      (b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; **[C]** and
   (2) Originates from a dealer who has identified the shellstock with a tag on each container or transaction record with each bulk shipment; **[C]** and
   (3) Obtained from a special licensed harvester who has:
      (a) Harvested or supervised the harvest of shellstock from a Restricted or Conditionally Restricted area in the open status; **[C]** and
      (b) Identified the shellstock by transaction records which include the harvest area, the special-licensed harvester's name, harvester license number(s), the harvest date, and the amount of shellstock shipped in each lot. **[C]**

B. Processing Critical Control Points - Critical Limits. The dealer shall assure that:
   (1) All depuration lots are treated for a minimum of 44 hours; **[C]** and
   (2) The water treatment system is operating to design specifications; **[C]** and
   (3) All critical limits established during verification of the specific depuration process are being met. **[C]**

C. Finished Shellstock Storage Critical Control Point - Critical Limits. The dealer shall assure that:
   (1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X.08; **[C]** and
   (2) Once placed under temperature control while in the possession of the dealer, shellstock shall be:
      (a) Iced; **[C]** or
      (b) Placed in a storage area or conveyance maintained at 45° Fahrenheit (7.2° Centigrade) or less; **[C]** and
      (c) Not permitted to remain outside temperature control for more than 2 hours at points of transfer such as loading docks. **[C]**

.02 Sanitation

A. Safety of Water for Processing and Ice Production
   (1) Water Supply.
      (a) Dealers shall provide a potable water supply in accordance with applicable federal, state and local regulations. **[C]**

(b) If the water supply is from a private source, the dealer shall make arrangements to have the water supply sampled by persons recognized by the Authority and tested at laboratories sanctioned or certified by the Authority: **[K]**
  (i) Prior to use of the water supply; **[C]**
  (ii) Every six months while the water supply is in use; **[K]** and
  (iii) After any water supply has been repaired and disinfected.**[S$^{C/K}$]**

(2) Ice production. Any ice used in the processing or storage of shucked shellfish shall:
  (a) Be made on-site from potable water in a commercial ice machine; **[C]** or
  (b) Come from a facility approved by the Authority or the appropriate regulatory agency. **[C]**

(3) Shellstock washing
  (a) Water from either a potable water supply, a growing area in the approved classification, a saltwater well approved by the authority, or the restricted area at the time and place of harvest, shall be used to wash shellstock. **[C]**
  (b) If the dealer uses any system to wash shellstock which recirculates water, the dealer shall:
    (i) Obtain approval for the construction or remodeling of the system from the Authority; **[K]**
    (ii) Provide a water treatment and disinfection system to treat an adequate quantity of water to a quality acceptable for shellstock washing, which, after disinfection, meets the coliform standards for drinking water; and does not leave any unacceptable residues in the shellstock; **[C]**
    (iii) Test wash water daily for bacteriological water quality; **[S$^{C/K}$]**
    (iv) Clean, service, and test disinfection units at the frequency necessary to ensure effective disinfection. **[K]**
  (c) The dealer may use ultra-violet (UV) disinfection in his recirculating wash water system, provided that the turbidity of the water to be disinfected~~:~~
    (i) shall not exceed 20 nephelometric turbidity units (NTUs); **[K]** and
    (ii) Is measured using the method in the APHA *Standard Methods for the Examination of Water and Wastewater*. **[K]**
  (d) Food contact plumbing which is designed and installed to permit effective cleaning and sanitization shall be used. **[C]**

(4) Depuration Process Water. The dealer shall:
  (a) Continuously treat process water with a disinfection system approved by the Authority that does not leave any unacceptable residue in the shellstock; **[C]** and

(b) Verify that the disinfection system produces process seawater with no detectable coliform organisms as measured using an NSSP approved method in the tank influent according to the following sampling protocols.

(i) If the source water is an approved growing area, approved well, or other approved source, then the tank influent produced by each disinfection unit is evaluated once per process batch; **[C]**

(ii) If the source water is a restricted growing area, then:

(*a*) A study meeting the requirements of Chapter X.08C.(2)(b) is required; **[C]**

(*b*) The tank influent produced by each disinfection unit is evaluated daily; **[C]** and

(*c*) Source water prior to final disinfection must meet the water quality criteria for restricted for depuration in accordance with Chapter IV.02G-H. **[C]**

(iii) If the source water is a recirculating water system, then:

(*a*) A study meeting the requirements of Chapter X.08C.(2)(b) **[C]** is required; and

(*b*) The tank influent produced by each disinfection unit is verified daily. **[C]**

(*c*) A prohibited growing area may not be used for source water. **[C]**

(5) Plumbing and Related Facilities.

(a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:

(i) Prevent contamination of water supplies; **[C]** and

(ii) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. **[C]** The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage. **[K]**

(b) Shellstock storage tanks and related plumbing shall be fabricated from safe materials, and tank construction shall be such that it :

(i) is easily accessible for cleaning and inspection; **[K]**

(ii) is self-draining; **[K]** and

(iii) meets the requirements for food contact surfaces; **[K]** and

(c) Depuration Plant Design and Construction. The dealer shall ensure that:

(i) Depuration tanks, processing containers, and piping are fabricated from non-toxic corrosion-resistant materials and are easily cleanable; **[K]**

(ii) Depuration tank design, hydraulics, and typical container configuration are such that process water is evenly

circulated throughout all the shellfish containers within a given tank; **[K]**

(iii) Shellfish containers allow process water to flow freely and uniformity to all shellfish within each container. **[K]**

(6) Depuration unit

(a) Depuration unit including depuration tanks, all reservoir tanks, and related piping shall be fabricated from safe materials, and depuration unit construction is such that it:

(i) Is easily accessible for cleaning and inspection; **[K]**

(ii) Is self-draining; **[K]** and

(iii) Meets the requirements for food contact surfaces. **[K]**

B. Condition and Cleanliness of Food Contact Surfaces.

(1) Equipment and utensil construction for food contact surfaces.

(a) Except for equipment in continuous use and placed in service prior to January 1, 1989, the dealer shall use only equipment which conforms to Shellfish Industry Equipment Construction Guides (August 1993), U.S. Department of Health and Human Services. **[K]**

(b) The dealer shall use only equipment and utensils, including approved plastic ware which is:

(i) Constructed in a manner and with materials that can be cleaned, sanitized, maintained or replaced in a manner to prevent contamination of shellfish products; **[K]**

(ii) Free from any exposed screws, bolts, or rivet heads on food contact surfaces **[K]** and

(iii) Fabricated from food grade materials. **[K]**

(c) The dealer shall assure that all joints on food contact surfaces:

(i) have smooth easily cleanable surfaces; **[K]** and

(ii) are welded. **[K]**

(d) All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in §.02 B (1) (a), (b), and (c). **[K]**

(2) Cleaning and sanitizing of food contact surfaces.

(a) Food contact surfaces of the depuration units, equipment and containers shall be cleaned and sanitized to prevent contamination of shellstock and food contact surfaces. The dealer shall:

(i) Provide applicable adequate cleaning supplies and equipment, brushes, detergents, and sanitizers, hot water and pressure hoses. **[K]**

(ii) Wash, rinse and sanitize equipment prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated; **[K]**

(b) All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and a frequency as necessary to prevent shellstock contamination. **[O]**

(c) Containers which may have become contaminated during storage shall be properly washed, rinsed and sanitized prior to use or are discarded. **[K]**

(d) Shellstock depuration tanks shall be cleaned and sanitized on a regular schedule as part of a plant sanitation standard operating procedure. **[K]**

C. Prevention of Cross Contamination.

(1) Protection of shellfish.

(a) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer. **[$S^{C/K}$]**

(b) Shellstock shall not be placed in containers with standing water for the purposes of washing shellstock or loosening sediment; **[K]**

(2) Employee practices.

(a) The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate hand washing facility:

(i) Before starting work; **[K]**

(ii) After each absence from the work station; **[K]**

(iii) After each work interruption; **[K]** and

(iv) Any time when their hands may have become soiled or contaminated. **[K]**

D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities

(1) Hand washing facilities with warm water at a minimum temperature of 110° Fahrenheit (43° Centigrade), dispensed from a hot and cold mixing or combination faucet, shall be provided; **[$S^{K/O}$]**

(2) Sewage **[C]** and liquid disposable wastes **[K]** shall be properly removed from the facility.

(3) An adequate number of conveniently located toilets shall be provided.**[K]**

(4) The dealer shall provide each toilet facility with an adequate supply of toilet paper **[K]** in a suitable holder. **[$S^{K/O}$]**

E. Protection from Adulterants.

(1) Shellstock shall be protected from contamination while being transferred from one point to another during handling and processing; **[K]**

(2) Any lighting fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in areas where shellstock are exposed shall be of the safety type or protected to prevent food contamination in case of breakage. **[O]**

(3) Conveyances or devices used to transport shellstock shall be constructed, maintained and operated to prevent contamination of the shellstock. If overhead monorails or conveyors are used, the dealer shall take

precautions to assure that hydraulic fluids or lubricants do not leak or drip onto the shellstock or conveyance surfaces. **[K]**

(4) Adequate ventilation shall be provided to minimize condensation in areas where shellfish are stored, processed or packed. **[$S^{K/C}$]**

(5) Shellstock packing activities shall be conducted to provide adequate protection from contamination and adulteration. **[K]**

(6) Protection of ice used in shellstock shipping.

(a) Any ice which is not made on-site in the depuration facility shall be inspected upon receipt and rejected if the ice is not delivered in a way so as to be protected from contamination. **[$S^{C/K}$]**

(b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice. **[$S^{C/K}$]**

F. Proper Labeling, Storage and Use of Toxic Compounds.

(1) Storage of toxic compounds.

(a) The dealer shall assure that only toxic substances necessary for plant activities are present in the facility. **[K]**

(b) Each of the following categories of toxic substances shall be stored separately:

(i) Insecticides and rodenticides; **[K]**

(ii) Detergents, sanitizers, and related cleaning agents; **[K]** and

(iii) Caustic acids, polishes, and other chemicals. **[K]**

(c) The dealer shall not store toxic substances above shellfish or food contact surfaces. **[K]**

(2) Use and labeling of toxic compounds.

(a) When pesticides are used, the dealer shall apply pesticides in accordance with applicable federal and state regulations to control insects and rodents in such a manner to prevent the contamination of any shellfish or packaging materials with residues. **[K]**

(b) Cleaning compounds and sanitizing agents shall be used only in accordance with applicable federal and state laws and regulations. **[K]**

(c) Detergents, sanitizers, and other cleaning supplies shall be used only in strict accordance with the manufacturer's label instructions. **[K]**

(d) Toxic substances shall be used only in strict accordance with the manufacturer's label instructions. **[K]**

G. Control of Employees with Adverse Health Conditions.

(1) The dealer shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces. The diseases which are transmissible from food workers through food are those determined by the US Centers for Disease Control

and Prevention, in compliance with the Americans with Disabilities Act, and published in the *Federal Register.* **[K]**

(2) If an employee with an infected wound keeps it covered with a proper bandage, an impermeable barrier, and a single-use glove for a hand lesion, the dealer may allow the employee to work in the shellfish processing facility without additional restrictions. **[K]**

H. Exclusion of Pests. The dealer shall operate his facility to assure that pests are excluded from his facility and his activities. **[K]**

.03 Other Model Ordinance Requirements

A. Plants and Grounds.
(1) General
(a) The physical facilities shall be maintained in good repair. **[O]**
(b) Animals or unauthorized persons shall not be allowed in those portions of the facilities where shellstock are stored, handled, processed, or packaged and food handling equipment and packaging materials are cleaned or stored. **[K]**

(2) Flooding. Facilities in which shellstock are stored, packed, or repacked shall be located so that these facilities are not subject to flooding during ordinary high tides. If facilities are flooded: **[C]**
(a) Shellstock processing or repacking activities shall be discontinued until the floodwaters have receded from the building; and the building is cleaned and sanitized. **[C]**
(b) Any shellstock coming in contact with the floodwaters while in storage shall be destroyed; or discarded in non-food use. **[C]**

(3) The dealer shall operate his facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from his facility and activities. **[$S^{C/K}$]**

(4) Separation of operations. Manufacturing activities which could result in the contamination of the shellstock shall be separated by adequate barriers. **[K]**

(5) Plant Interior.
(a) Sanitary conditions shall be maintained throughout the facility. **[O]**
(b) Interior surfaces are kept in good repair. **[O]**
(c) All dry area floors are hard, smooth, easily cleanable and in good repair; **[O]** and
(d) All wet area floors used in areas to store shellstock, food processing, and cleaning equipment are constructed of easily cleanable, impervious, and corrosion resistant materials which:
(i) Are graded to provide adequate drainage; **[O]**
(ii) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage; **[O]** and
(iii) Have sealed junctions between floors and walls to render them impervious to water. **[O]**

(6) Walls and Ceilings. Interior surfaces of rooms where shellstock are stored, handled, processed, or packaged and food handling equipment and packaging materials shall be constructed of easily cleanable, corrosion resistant, impervious and light colored materials. **[O]**

(7) Grounds. Grounds around the facility shall be maintained to be free from conditions which may result in shellfish contamination. These conditions may include:
   (a) Rodent attraction and harborage; [O]
   (b) Inadequate drainage. [O]

B. Plumbing and Related Facilities.

(1) Hand washing facilities shall be provided which are:
   (a) Convenient to work areas; **[O]**
   (b) Separate from the three compartment sinks used for cleaning equipment and utensils**[K]**; and
   (c) Directly plumbed to an approved sewage disposal system. **[$S^{O/K}$]**

(2) The dealer shall provide at each hand washing facility:
   (a) A supply of hand cleansing soap or detergent; **[K]**
   (b) A conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; **[O]**
   (c) An easily cleanable waste receptacle; **[O]** and
   (d) Hand washing signs in a language understood by the employees; **[O]**

(3) All plumbing and plumbing fixtures shall be designed, installed, modified, repaired, and maintained to provide a water system that is adequate in quantity and under pressure, and includes:
   (a) Cold and warm water at all sinks; **[K]** and
   (b) Hand washing facilities adequate in number and size for the number of employees, and are located where supervisors can observe employee use. **[K]**

(4) Adequate floor drainage, including backflow preventers such as air gaps, shall be provided where floors are:
   (a) Used in shellstock storage; **[K]**
   (b) Used for food holding units (e.g. refrigeration units); **[K]**
   (c) Cleaned by hosing, flooding, or similar methods; **[K]** and
   (d) Subject to the discharge of water or other liquid waste, including, if applicable, three compartment sinks, on the floor during normal activities; **[K]**

(5) A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations; **[$S^{C/K}$]**

(6) Installation of drainage or waste pipes over processing or storage areas, or over areas in which containers and utensils are washed or stored shall not be permitted. **[K]**

C. Utilities.
Ventilation, heating, or cooling systems shall not create conditions that may cause the shellstock to become contaminated. **[$S^{C/K}$]**

D. Insect and Vermin Control.
The dealer shall employ necessary internal and external insect and vermin control measures to assure that insects and vermin are not present in the facility, including:
(1) Tight fitting, self-closing doors; **[K]**
(2) Screening of not less that 15 mesh per inch; **[K]** or
(3) Controlled air currents. **[K]**

E. Disposal of Wastes.
(1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations. [O]
(2) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage , or breeding places for insects and vermin. [O]

F. Equipment Construction for Non-food Contact Surfaces.
(1) The dealer shall use only equipment which is constructed in a manner and with materials that can be cleaned, sanitized, maintained or replaced in a manner to prevent contamination of shellstock. **[O]**
(2) The dealer shall use easily cleanable, corrosion resistant, impervious materials, free from cracks, to construct any non-food contact surfaces in shellfish storage or handling areas. **[O]**

G. Cleaning and Sanitizing of Non-food Contact Surfaces.
(1) Cleaning activities for the depuration unit and equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellstock and food contact surfaces. **[K]**
(2) All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination. **[O]**

H. Shellstock Storage and Handling.
(1) The dealer shall assure that shellstock is:
(a) Reasonably free of sediment; **[O]** and
(b) Culled. **[K]**
(2) Shellstock shall be stored in a protected location which assures complete and rapid drainage of water away from the shellstock by:
(a) Placing shellstock at an adequate height off the floor; **[K]**or
(b) Grading the floor. **[O]**
(3) Any mechanical refrigeration equipment used for shellstock storage shall be adequate in size and are equipped with:

(a) An automatic temperature regulating control; **[K]** and
(b) Installed thermometers to accurately measure temperature within the storage compartments. **[K]**

(4) Inspect incoming shipments and shall reject dead or inadequately protected shellstock. **[K]**
(5) Ensure that separate dry storage facilities are provided for depurated and undepurated shellfish. **[K]**
(6) Cull and wash the shellstock prior to loading into the depuration tanks. This process may occur before the shellstock is received at the facility by;
(a) Licensed harvester(s) at the harvest site; **[K]** or
(b) Certified dealer(s) at their certified facility. **[K]**
(7) Assure that culled shellfish are destroyed or disposed of in such a manner as to prevent their use for human food. **[K]**
(8) Transport, store, and handle shellstock so that:
(a) Shellstock potential for normal physiological activity during depuration is not compromised; **[K]** and
(b) Shellstock quality is not degraded. **[K]**
(9) Assure that different harvest lots of shellfish are not commingled during washing, culling, processing, or packing. If more than one harvest lot of shellfish are being processed at the same time, the identity of each harvest lot is maintained throughout the stages of depuration. **[K]**
(10) Wash and cull shellstock after depuration and pack the shellstock in clean shipping containers fabricated from safe materials. **[K]**
(11) Depurated packaged shellstock shall be protected from contamination at all times and be held at an ambient temperature not to exceed 45° Fahrenheit (7.2° Centigrade). **[K]**

I. Heat Shock. N/A

J. Personnel. Any employee handling shucked shellfish shall be required to:
(1) Wear effective hair restraints; **[O]**
(2) Remove any hand jewelry that cannot be sanitized or secured; **[O]**
(3) Wear finger cots or gloves if jewelry cannot be removed; **[O]**
(4) Wear clean outer garments, which are rinsed or changed as necessary to be kept clean. **[O]**
(5) In any area where shellfish are shucked or packed and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:
(a) Store clothing or other personal belongings; **[O]**
(b) Eat or drink; **[K]**
(c) Spit; **[K]** and
(d) Use tobacco in any form. **[K]**

K. Supervision.

(1) A reliable, competent individual shall be designated to supervise general plant management and activities; **[K]**

(2) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellstock or food contact surfaces. **[K]**

(3) All supervisors shall be:

(a) Trained in proper food handling techniques and food protection principles; **[K]** and

(b) Knowledgeable of personal hygiene and sanitary practices. **[K]**

(4) The dealer shall require:

(a) Supervisors to assure that proper sanitary practices are implemented, including:

(i) Plant equipment clean up; **[K]**

(ii) Rapid product handling; **[K]** and

(iii) Shellstock protection from contamination. **[K]**

(b) Employees

(i) to be trained in proper food handling and personal hygiene practices, **[K]** and

(ii) to report any symptoms of illness to their supervisor. **[K]**

L. Plant Operating Manual.

The dealer shall prepare a written Depuration Plant Operations Manual (DPOM) according to Minimum Requirements of a Depuration Plant Operations Manual (below); and update the DPOM as necessary. A copy of the DPOM shall be kept in a location readily accessible to the trained personnel responsible for the depuration activity. The minimum requirements for a Depuration Plant Operating Manual shall address:

(1) Introduction including;

(a) Status of document (to create, revise, or update DPOM);

(b) Ownership and principal(s) involved with operation of facility;

(c) Address and phone number of owners and principles; and

(d) Summary of proposed use of the depuration facility including statement of objectives of the operation of the plant, species to be processed, proposed periods of facility operation, proposed sources of shellfish, including potential harvest areas, and maximum capacity of plant.

(2) Description of the Facility including;

(a) Site plan drawings;

(b) Facility layout including detailed schematic of the entire depuration system;

(c) Schematic drawing of process;

(d) Product flow diagram showing product movement through facility (may be combined with §B. (3);

(e) Statement that construction materials and fabrication will meet the requirements of §.04, §.08, and §.09; and

(f) Schematic of seawater delivery and distribution system.

(3) Design Specifications of Depuration Unit including;
   (a) Depuration tank diagram including tank dimensions and construction details, influent and effluent locations, operating water level, and typical container configuration;
   (b) Process water system describing type of system (flow-through or recirculating), pretreatment and filtration systems, disinfection system, and hydraulic schematic;
   (c) Shellfish containers construction and material meets §.04 and §.08 of this Chapter; and
   (d) List of equipment including washing, culling, and packing equipment, material handling equipment, and cleaning and sanitation equipment.

(4) Laboratory to be utilized for microbial analyses (in house, government agency, private commercial);

(5) Depuration process monitoring including:
   (a) Sampling protocols including frequency of sampling, number of samples, sampling locations, and methodology for process water analyzing , incoming shellstock, depurated shellstock, and growing waters;
   (b) Monitoring equipment maintenance and calibration procedures and copy of activity log forms that will be used for data entry;
   (c) Process water monitoring protocol for physical and chemical parameters; and
   (d) Data analysis and evaluation.

(6) Standard Operating Procedure for:
   (a) Receiving and holding;
   (b) Washing, culling, and placement of undepurated product in process tanks;
   (c) Depuration unit operation;
   (d) Monitoring of depuration unit operation;
   (e) Removal of depurated product from process tanks;
   (f) Storage parameters and procedures;
   (g) Labeling/tagging procedures;
   (h) Plant cleaning and sanitation; and
   (i) Data analysis.
   (j) Recall procedures.

(7) Record Keeping. List categories of information that will be recorded. Include copies of proposed forms to be used in each category. A single form may be used for several categories if properly designed.
   (a) Shipping and receiving records;
   (b) Plant Operation Log, including provisions for recording the values for chemical and physical parameters;
   (c) Maintenance and Sanitation Log(s);
   (d) Laboratory records;

M. Process Verification.

The Dealer shall continually:

(1) Perform process verification on a continuous basis according to the following protocol:

(a) Following completion of a minimum of 44 hours of depuration, collect and assay at least one end-product sample from each lot of shellstock to be depurated in the depuration unit.

(b) Determine daily, or as results become available, the depuration performance indices defined as the geometric mean and 90th percentile of fecal coliform (FC) from assay data of the most recent ten (10) consecutive harvest lots for each species depurated and for each restricted harvest area used.

(c) Compare daily, or as a results become available, the depuration performance indices with the following Critical Limits for the Indices of Depuration Plant Performance.

Limits for Verification of Depuration Plant Performance
Fecal coliforms per 100 grams

Species	Geometric Mean	90th Percentile
Soft Clams *(Mya arenaria)*	50	130
Hard Clams *(Mercenaria mercenaria*)	20	70
Oysters	20	70
Manilla Clams	20	70
Mussels	20	70

(d) If the depuration performance indices for a specific species from a specific growing area are less than or equal to the above Critical Limits for the Indices of Depuration Plant Performance, then the process is considered verified for that species from that growing area.

(e) For the purpose of making calculations, fecal coliform counts that signify the upper or lower limit of sensitivity of the test (MPN or ETCP) shall be increased or decreased by one significant figure. Thus, <9.0 becomes 8.9, <17 becomes 16 and >248 becomes 250. Individual plates which are too numerous to count (TNTC) are

considered to have >100 colonies per plate. A sample containing "TNTC" plates is collectively rendered as having a count of 10,000.

(2) Conditional Protocol Verification. If the depuration performance indices for a specific growing area fail to meet the Critical Limits for the Indices of Depuration Plant Performance, or if a new restricted growing area is used as a source of shellfish for depuration, or if a new depuration process has generated less than 10 process batches of data, the process is considered to be unverified and the dealer shall adhere to the following conditional protocols:

(a) The depuration processor shall collect and assay at least one zero hour and three end-product samples from each harvest lot;

(b) Environmental parameters including process water temperature, salinity, dissolved oxygen, and turbidity and/or other operational conditions may inhibit the physiological process and must be identified. The conditions(s), once identified and quantified, become critical control points (CCP) for specific species in the specific plant and the hazard analysis and HACCP plan shall be revised accordingly

(c) Shellstock which are processed during this conditional protocol must meet the following release criteria before they may be released to market:

(i) Geometric mean (from three samples) of soft clams not to exceed 110 and no single sample to exceed 170; or

(iii) Geometric mean (from three samples) of other clam species, mussels, or oysters not to exceed 45 and no single sample to exceed 100.

(d) If the harvest lot fails to meet the release criteria, the depuration processor may choose to subject the product to additional depuration processing whereupon the shellfish can be resampled for release criteria or the disposition of the shellfish shall be as follows:

(i) The Authority, in consultation with the depuration processor, may order the destruction of the shellfish; or

(ii) The Authority, in consultation with the depuration processor, may allow non-food use of the shellfish; or

(iii) The Authority, in consultation with the depuration processor, may allow the shellfish to be relayed in accordance with Chapter V.

(e) When in Conditional Protocol Verification due to a failure of an established harvest area to meet the above Indices for Depuration Plant Performance, determine daily, or as results become available, the depuration performance indices defined as the geometric mean and 90^{th} percentile of fecal coliform (FC) from assay data of the most recent ten (10) consecutive end product samples for each species depurated and for each harvest area used

(i) Compare these depuration performance indices with the above Critical Limits for the Indices of Depuration Plant Performance for this species.

(ii) If these depuration performance indices are less than or equal to the above Critical Limits for the Indices of Depuration Plant Performance for this species, the process is then considered to be verified for this species from this particular harvest area; and the process reverts to the Process Verification protocol in .03L(1).

(iii.) If either the geometric mean or the 90th percentile values exceed the above Critical Limits for the Indices of Depuration Plant Performance for this species, the process shall remain in Conditional Protocol Verification for this species from this particular harvest area until the above Indices of Depuration Plant Performance are attained.

(f) When in Conditional Protocol Verification due to the use of a new harvest area as the source of shellfish or if a new depuration process has generated less than 10 process batches of data, determine daily, or as results become available, the depuration performance indices defined as the geometric mean and 90th percentile of fecal coliform (FC) from assay data of the most recent ten (10) consecutive harvest lots for each species depurated and for each harvest area used.

(i) Compare these depuration performance indices with the above Critical Limits for the Indices of Depuration Plant Performance for this species.

(ii) If these depuration performance indices are less than or equal to the above Critical Limits for the Indices of Depuration Plant Performance for this species, the process is then considered to be verified for this species from this particular harvest area; and the process reverts to the Process Verification protocol in XV.03L.(1).

(iv) If less than 10 process batches of data have been collected or either the geometric mean or the 90th percentile values exceed the above Critical Limits for the Indices of Depuration Plant Performance for this species, from this particular harvest area, the process shall remain in Conditional Protocol Verification for this species from this particular harvest area until 10 batches of data have been collected and the above Indices of Depuration Plant Performance are attained.

(3) When depuration units with multiple tanks are used, it is necessary to determine whether the individual tanks are similar.
   (a) Tanks are considered similar if the difference between physical tank dimensions and process water flow rate is less than 10%.
   (b) If they are not similar, then the process verification protocols contained in Section .03 (1) - (2) must be employed for each tank.

(4) The dealer shall ensure that all microbiological assays of end-point samples of shellstock:
   (a) Are analyzed by a laboratory which has been evaluated and approved pursuant to the requirements in Chapter III, using an NSSP-approved method;
   (b) Sample size consists of a pool of at least 12 shellfish selected at random from each designated container (more than 12 individuals may be required in the case of smaller shellfish); and
   (c) Samples are collected at locations within the depuration unit that are considered to be most compromised as regards shellfish activity, based on the sampling plan contained in the Depuration Plant Operations Manual.

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XVI. POST-HARVEST PROCESSING

Post-Harvest Processing.

(A) If a dealer elects to use a process to reduce the level(s) of one target pathogen or some target pathogens, or all pathogens of public health concern in shellfish, the dealer shall:

(1) Have a HACCP plan approved by the Authority for the process that ensures that the target pathogen(s) are at safe levels for the at risk population in product that has been subjected to the process.

(a) For processes that target *Vibrio vulnificus*, the level of *Vibrio vulnificus* in product that has been subjected to the process shall be non-detectable (<3 MPN/gram), to be determined by use of the *Vibrio vulnificus* FDA approved EIA procedure of Tamplin, et al, as described in Chapter 9 of the FDA *Bacteriological Analytical Manual*, 7th Edition, 1992.

(b) For processes that target *Vibrio parahaemolyticus*, the level of *Vibrio parahaemolyticus* in product that has been subjected to the process shall be non-detectable (<1 CFU/0.1 gram).

(c) For processes that target other pathogens, the level of those pathogens in product that has been subjected to the process shall be below the appropriate FDA action level, or, in the absence of such a level, below the appropriate level as determined by the ISSC.

(d) The ability of the process to reliably achieve the appropriate reduction in the target pathogen(s) shall be validated by a study approved by the Authority, with the concurrence of FDA.

(e) The HACCP plan shall include:

(i) Process controls to ensure that the end point criteria are met for every lot; and,

(ii) A sampling program to periodically verify that the end point criteria are met.

(2) Package and label all shellfish in accordance with all requirements of this Ordinance. This includes labeling all shellfish which have been subjected to the process but which are not frozen in accordance with applicable shellfish tagging and labeling requirements in Chapter X.05 and X.06.

(3) Keep records in accordance with Chapter X.07.

(B) A dealer who meets the requirements of this section may label product that has been subjected to the reduction process as:

(1) "Processed for added safety", if the process reduces the levels of all pathogens of public health concern to safe levels for the at risk population;

(2) "Processed to reduce [name of target pathogen(s)] to non-detectable levels," if the process reduces one or more, but not all, pathogens of public health concern to safe levels for the at risk population, and if that level is non-detectable; or

(3) "Processed to reduce [name of target pathogen(s)] to non-detectable levels for added safety," if the process reduces one or more, but not all, pathogens of public health concern to safe levels for the at risk population, and if that level is non-detectable; or

(4) A term that describes the type of process applied (e.g. "pasteurized," "individually quick frozen," "pressure treated") may be substituted for the word "processed" in the options contained in (B)(1)-(3).

(C) For the purposes of refrigeration, if the product is dead, the product shall be treated as shucked product. If the product is live, the product shall be treated as shellstock.

III. PUBLIC HEALTH

REASONS AND EXPLANATIONS

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MODEL ORDINANCE
PUBLIC HEALTH REASONS AND EXPLANATIONS

National Shellfish Sanitation Program

Introduction

Oysters, clams, and mussels are unique foods that have been enjoyed by consumers for many years. The popularity of shellfish as a food can be traced through several centuries of American history. The value of these renewable natural resources to the early settlers was reflected in colonial legislation designed to encourage their wise use.

Public health controls of shellfish became a national concern in the U.S. in the late 19th and early 20th century when public health authorities noted a large number of illnesses associated with consuming raw oysters, clams, and mussels. During the winter of 1924, there occurred a widespread typhoid fever outbreak, which resulted in a request that the Surgeon General of the United States Public Health Service develop necessary control measures to ensure a safe shellfish supply to the consuming public. In accordance with this request, the Surgeon General called a conference, which was held in Washington, D.C., on February 19, 1925.

The members of the conference recommended eight resolutions for the sanitary control of the oyster industry, which formed the basis for development of the National Shellfish Sanitation Program. The conference also established a committee to develop further necessary guidelines to recommend practices for the sanitary control of the shellfish industry.

The basic concepts in formulating a program of national public health controls were reiterated by the Surgeon General in his letter of August 12, 1925, to State health officers and all others concerned. This letter set forth the following understandings:

1. "The Public Health Service considers that the responsibility for the sanitary control of the shellfish industry rests chiefly upon the individual States; and that the requisite coordination and uniformity of control may best be achieved by mutual agreement among the States, with the assistance and cooperation of the Public Health Service..."

2. "In accordance with this principle, it is considered that each producing State is directly responsible for the effective regulation of all production and handling of shellfish within its confines, not merely for the protection of its own citizens, but equally for safeguarding such of its product as goes to other States..."

3. "In order that each state may have full information concerning the measures carried out in other States, the Public Health Service will undertake systematic surveys of the machinery and efficiency of sanitary control as actually established in each producing State, and will

report thereon for the information of the authorities of other States. It is believed that, in addition to furnishing valuable information, these reports will have an important influence in stimulating the development of better sanitary control and in promoting substantial uniformity on a higher plane."

"The officers of the Public Health Service assigned to this survey work will assist the State agencies in determining their sanitary problems, in formulating plans for adequate sanitary control, and in making actual sanitary surveys as far as practicable."

4. "In addition to the above, the Public Health Service will continue to extend the services which it is already rendering, especially in conducting scientific investigations of fundamental importance to control, and in serving as a clearinghouse for the interchange of information and the discussion of policies between State authorities."

To implement this program, the members of the 1925 conference agreed that the producing states would issue "Certificates," i.e., a permit to operate, to shellfish shippers that met agreed upon sanitary standards. The Public Health Service would serve as a clearinghouse for information on the effectiveness of the State control programs.

The procedures used by the Public Health Service in fulfillment of its obligations under the Public Health Service Act resulted from an understanding that implementation and enforcement of the necessary public health controls could best be accomplished under State laws with federal technical support and industry participation. The National Shellfish Sanitation Program is dependent entirely upon the States adopting the recommended requirements and the cooperative and voluntary efforts of State regulatory agencies and the shellfish industry.

The NSSP went beyond the original objective set forth in the 1925 Conference of insuring that shellfish shipped interstate would not be the cause of communicable disease. In the 1940's paralytic shellfish poison became a matter of public health concern and steps were taken to protect the public against this hazard. In 1957 it was recognized that shellfish might concentrate certain radionuclides and that a radiation surveillance activity might become a necessary addition to the established procedures. In the 1960's and 1970's it became apparent that shellfish have the ability to concentrate poisonous and deleterious substances such as metals, pesticides, hydrocarbons, etc. to potentially unsafe levels. To ensure the safety of shellfish, the State must supervise the growing, harvesting, relaying and transportation of shellfish. It is also important that shellfish be protected against contamination.

If State supervision is to be effective, the activity must be supported by legal authority. This authority may be either a specific law or a regulation. The success with which the State is able to regulate the several components of the shellfish industry provides a measure of the adequacy of the statutory authority. The unique nature of shellfish as a food consumed whole and raw also makes it necessary for the State shellfish control agency to have authority to take immediate emergency action without recourse to lengthy administrative procedures, to halt harvesting and processing of shellfish. This authority should include placing restrictions on harvesting on the basis of a potential as well as an actual public health hazard. As examples, a State may find it

necessary to close a shellfish growing area following a breakdown of a wastewater treatment plant or the unexpected finding of marine toxin(s), or when a growing area is implicated in confirmed illnesses.

Periodic revisions of State shellfish laws or regulations may be necessary to cope with new public health hazards and to reflect new knowledge. Examples of changes or developments which have called for revision of State laws include: (1) the increased use of pleasure boats with the resulting probability of contamination of shellfish growing areas with fresh untreated fecal material, (2) the conditionally approved area concept resulting from the construction of wastewater treatment facilities, (3) the effect of non-point source pollution, and (4) the ability of shellfish to concentrate certain radionuclides and hazardous chemicals. Experience has demonstrated that all actual and potential shellfish growing waters of the State must be classified by their sanitary suitability for shellfish harvesting. Harvesting should be permitted only from those areas that have been found by sanitary survey to meet the criteria of this Manual. Harvesting should accordingly be specifically prohibited from areas which do not meet the criteria, or which have not been surveyed, or which have outdated survey information.

The National Shellfish Sanitation Program (NSSP) is the federal/state cooperative program recognized by the U.S. Food and Drug Administration (FDA) and the Interstate Shellfish Sanitation Conference (ISSC) for the sanitary control of shellfish produced and sold for human consumption. The purpose of the NSSP is to promote and improve the sanitation of shellfish (oysters, clams, mussels and scallops in any form, except when the final product form is the adductor muscle only) moving in interstate commerce through federal/state cooperation and uniformity of State shellfish programs. Participants in the NSSP include agencies from shellfish producing States, FDA, and the shellfish industry. Under international agreements with FDA, foreign governments also participate in the NSSP. Other components of the NSSP include program guidelines, State growing area classification and dealer certification programs, and FDA evaluation of State program elements.

In 1984, the FDA entered into a Memorandum of Understanding (MOU) with the Interstate Shellfish Sanitation Conference recognizing the ISSC as the primary voluntary national organization of State shellfish regulatory officials that provides guidance and counsel on matters for the sanitary control of shellfish. The purpose of the ISSC is to provide a formal structure for State regulatory authorities to participate in establishing updated regulatory guidelines and procedures for uniform state application of the Program. The ISSC has adopted formal procedures for state representative to review shellfish sanction issues and develop regulatory guidelines. Following FDA concurrence, these guidelines are published in revision of the NSSP Model Ordinance. Following FDA concurrence, these guidelines are published in revision for the NSSP Model Ordinance.

The NSSP Guide for the Control of Molluscan Shellfish consists of a Model Ordinance, supporting guidance documents, recommended forms, and other related materials associated with the Program. The Model Ordinance includes guidelines to ensure that the shellfish produced in States in compliance with the guidelines are safe and sanitary. The Model Ordinance provides

readily adoptable standards and administrative practices necessary for the sanitary control of molluscan shellfish.

Chapter I. Shellfish Sanitation Program

Requirements for the Authority
@01. Administration

A. Scope. Because shellfish can be contaminated either in the growing area before harvest or during activities involved in harvesting, processing, distribution, or shipping, State laws or regulations must provide an adequate legal basis for sanitary control of all of these phases of handling shellfish. This legal authority must enable one or more departments or agencies of the state to regulate and supervise the classification of growing areas, harvest, relaying and transport of shellstock at its source; the shipment, tagging and storage of shellstock; the operation of depuration plants; and the shucking, packing, labeling and repacking of shellfish. The State must be able to apply the NSSP requirements to every actual and potential growing area, and to all shellfish harvesters to insure that shellfish available to certified dealers have been produced and harvested under acceptable sanitary conditions. The state must also have the authority to certify and suspend or revoke the certification of interstate shellfish shippers; to conduct laboratory examinations of shellfish; to prevent the sale of unsafe shellfish or shellfish from uncertified dealers by such legal means as detention, monetary fines, seizure, embargo and destruction; and to suspend harvesting and certificates of interstate shippers in public health emergencies.

B. Records. States must maintain data and files that will provide evidence and demonstrate the effective administrative management of the shellfish sanitary control program as part of their participation in the NSSP. States must keep records in a central file to facilitate the FDA review of their shellfish sanitation programs and must assist the FDA in making such reviews. The purpose of this FDA review is to evaluate the adequacy of each state program in meeting the requirements of the NSSP Model Ordinance. The maintenance of proper records, organized files and adoption of accepted public administrative procedures provides the State control agencies with the means to conduct an effective program. The State program should have clearly written administrative procedures to affect the controls specified in the NSSP Model Ordinance.

C. Shared Responsibilities. When two or more State agencies are involved in the sanitary control of the shellfish industry, a clear statement of each agency's responsibilities should be developed in the form of a memorandum of understanding. This administrative practice eliminates misunderstandings concerning agency responsibility and ensures that all aspects of shared program responsibility are addressed.

D. Administrative Procedures. If state supervision is to be effective, the activity must be supported by legal authority applied through law, regulation or appropriate administrative procedures. Periodic revisions of state shellfish laws, regulations or administrative procedures may be necessary to cope with new public health hazards and to reflect new knowledge. The success with which the State is able to regulate the several components of the shellfish industry provides a measure of the adequacy of the statutory authority.

E. Epidemiologically Implicated Outbreaks of Shellfish-Related Illness. The intrinsic risk associated with consumption of raw or partially cooked shellfish products compels the shellfish

control authority to act quickly and effectively when shellfish are implicated in a food-borne outbreak. Development of administrative procedures in advance of outbreaks supports quick effective action and **PUBLIC HEALTH REASONS AND EXPLANATIONS** avoids costly mistakes and inadvertent destruction of evidence through delay.

F. Commingling. Commingling means the act of combining different lots of shellstock or shellfish from different days in the same growing area, or combining different lots of shellstock from different growing areas. Health departments and other appropriate state and federal agencies must be able to determine the source of shellfish contamination when an outbreak of disease attributable to shellfish occurs so they can prevent any further illnesses from this source. Separating shellfish from different sources is necessary to maintain lot identity during harvest, transport, storage, shucking, and repacking operations. This lot separation assists in tracing shellfish back to its source when questions of public health safety arise. Maintaining lot identity will prevent implication of sources that are not associated with the outbreak and can prevent unnecessary regulatory action and liability. When commingling is allowed under any state management plan, the objective is to minimize the commingling of different dates of harvest and different growing areas. For additional information concerning commingling, see the NSSP Model Ordinance Guidance Document: *Shellstock Tagging* (ISSC/FDA, 2002).

@.02 Dealer Certification

A. - D. General, Initial Certification, Renewal of Certification, and Revocation or Suspension of Certification. A principal objective of the NSSP has been to provide a mechanism for health officials and consumers to receive information as to whether lots of shellfish shipped in interstate commerce meet acceptable and agreed upon sanitation and quality criteria. This NSSP objective is achieved through establishment of criteria and procedures to allow a producing or processing state to "certify" to receiving states that the product from a specific dealer has been grown, harvested, transported, processed, or shipped in compliance with the NSSP Model Ordinance guidelines. Dealer certification is dependent on a dealer maintaining acceptable operational and sanitary conditions and is determined through uniform inspections by standardized inspectors. For more information concerning standardized inspections, see the NSSP Model Ordinance Guidance Document: *Shellfish Plant Inspection Standardization Procedures* (ISSC/FDA, 2002).

State officials who certify dealers must fully comply with the administrative requirements for certification for the process to remain viable. For the certification process to be effective, dealers must fully comply with the applicable Model Ordinance sanitation guidelines pertaining to the type of operation involved. For a full discussion of the certification process, see the NSSP Model Ordinance Guidance Document: *Dealer Certification and the Interstate Certified Shellfish Shippers List (ICSSL)* (ISSC/FDA, 2002).

E. Interstate Certified Shellfish Shippers List (ICSSL). Placement of a dealer on the ICSSL serves as nationwide notification to receiving states and the shellfish industry of dealer certification. Food control officials throughout the United States use the ICSSL to determine that shellfish offered for sale at the wholesale or retail level have been produced under the sanitary

guidelines of the NSSP Model Ordinance. These officials generally rely upon the certification process instead of holding up shipments or sales of shellfish lots pending examination. The ICSSL is also used by the seafood and other food industries to find sources of safe shellfish. For a full discussion of the ICSSL purpose and use, see the NSSP Model Ordinance Guidance Documents: *Dealer Certification and the Interstate Certified Shellfish Shippers List (ICSSL)* (ISSC/FDA, 2002).

F. Inspections. Through inspections by both the shellfish control agency and the dealer, as part of the dealer's HACCP plan, unsanitary conditions may be detected and corrected. Unannounced shellfish control agency inspections serve to verify that NSSP Model Ordinance guidelines are being met by the dealer. For additional information concerning inspections, see the NSSP Model Ordinance Guidance Documents: *Shellfish Plant Inspection Standardization Procedures* (ISSC/FDA, 2002).

G. Performance Based Inspection Program (PIP). Performance based inspections for dealers with a significant history of satisfactory compliance result in improved regulatory efficiency. Regulatory inspections can be concentrated on more high-risk shellfish operations or operations with poor performance histories. Dealers recognized as having a record of excellent performance may be rewarded with the privilege of a reduced number of inspections.

H. Enforcement. The unique nature of shellfish as a food consumed whole and raw in the form as it comes from the growing area requires the state shellfish control authority to have sufficient growing area patrol capacity to enforce the public health based restrictions on harvesting and to obtain meaningful penalties for violation of those harvesting restrictions. Information concerning enforcement activities at the growing area level can be found in the NSSP Model Ordinance, Chapter V, @04 and Chapter VIII, @01, B., *Patrol of Growing Areas* (ISSC/FDA, 2002) and in Guidance Documents: *Growing Area Patrol and Enforcement* and *Shellstock Relay* (ISSC/FDA, 2002). Dealer certification is intended to provide an unbroken chain of sanitation control to a lot of shellfish from the moment of harvest to its sale at the wholesale or retail level. Dealers having major non-conformities with the NSSP Model Ordinance should not be certified. Certified dealers found to have major non-conformities should have their licenses or permits suspended or certifications revoked. Information concerning enforcement activities at the dealer certification level can be found in the NSSP Model Ordinance Guidance Documents: *Dealer Certification and the Interstate Certified Shellfish Shippers List (ICSSL)* (ISSC/FDA, 2002).

Chapter II. Risk Assessment and Risk Management

Requirements for the Authority
@.01 Outbreaks of Shellfish-Related Illness.

Shellfish are filter feeders and therefore have the ability to concentrate microorganisms, including human pathogens and toxigenic micro-algae, from the water column if these organisms are present in the growing area. Concentrations in the shellfish may be as much as 100 times that found in the water column. If the microorganisms concentrated are harmful to humans, and if, in the case of human pathogens, the shellfish are consumed raw or partially cooked, human disease can result.

When illness has occurred, immediate closure of the implicated growing area and/or recall of implicated product will significantly reduce the chance of additional illnesses. Additional information concerning investigation of an outbreak of shellfish related illness believed to be associated with a naturally occurring pathogen can be found in the NSSP Model Ordinance Guidance Documents: *Guidance for a Time-Temperature Evaluation of a Shellfish Implicated Outbreak* (ISSC/FDA, 2002). Additional information concerning the disease causing potential of shellfish can be found in the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters, Guidance for Developing Marine Biotoxin Contingency Plans*, and *Shellstock Relay* (ISSC/FDA, 2002).

Documentation of the information supporting growing area classification, proper tagging and record keeping, expeditious follow-up on reported illnesses, effective recall of implicated product and public warning announcements are all requisite to protecting public health. Shellfish growing areas implicated through epidemiological association between illness and shellfish consumption must be closed immediately to prevent additional implicated product from reaching the consumer. Broad closures of Growing Areas, in addition to reducing the chance of additional illnesses, will: improve identification of specific sites where harvesting is taking place; reduce the size of areas available to harvest; reduce the practice of mixing together shellstock from different growing areas; and reduce illegal harvesting because legitimate harvesters will self-police their ranks to prevent false tagging. In addition, shellfish product from the implicated growing areas should be detained and an effective recall of product initiated.

When the source of the illness is found to be the distribution and processing system, shellfish product should be also detained and an effective recall of product initiated, and the problem immediately corrected.

@.02 Presence of Human Pathogens in Shellfish Meats.

Human pathogens have been found in shellfish in the absence of human illness. These pathogens can be present at levels below that of an infectious dose, and may originate either as naturally occurring organisms in the growing area or from contamination of the growing area or of the shellfish during its handling, storage, transport or processing. Continued finding of the presence

of human pathogens in shellfish from a specific growing area with no evidence of illness in the consumers may or may not constitute a human health risk, In these circumstances, the shellfish control authority needs to act quickly to initiate a thorough investigation to determine if the pathogen source is either the growing area or the system used for distributing and processing the product. If the source can be determined, the authority needs to take immediate steps to correct the problem through appropriate actions such as eliminating the source, reclassifying the growing area or changing a distribution or processing procedure.

When the source of the organism cannot be identified or if the organism is naturally occurring, the authority should conduct a risk assessment using all available information to determine if the human consumer is at risk. When the risk is determined to be negligible, no further action is required. A determination that some risk exists may prompt further action to protect the consumer such as allowing the shellfish to be harvested with an advisory to immunologically compromised individuals, allowing shellfish to be used only for cooked product, or closing the growing area.

@.03 Presence of Toxic Substances in Shellfish Meats

Because shellfish are filter feeders, they can readily accumulate toxigenic micro-algae and other substances from the water column. These substances include heavy metals, chlorinated hydrocarbons and other poisonous or deleterious substances. The presence of these substances does not necessarily constitute a health risk, as toxicity is dependent on both concentration (dose) and length of exposure.

To protect the consumer, the shellfish control authority needs to evaluate the levels of toxic substances that may be present in the shellfish against known tolerance levels in human foods or other appropriate information, and determine what action, if any, should be taken. Additional information concerning this topic can be found in the NSSP Model Ordinance Guidance Documents: *Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood* (ISSC/FDA, 2002); and *Guidance for Developing Marine Biotoxin Contingency Plans* (ISSC/FDA, 2002).

Chapter III. Laboratory

Requirements for the Authority
@.01 Quality Assurance.

Laboratory results from the bacteriological and chemical testing of shellfish growing waters and meats are widely used in the National Shellfish Sanitation Program to determine the safety of shellfish for human consumption. Experience with the bacteriological and toxicological examination of shellfish and shellstock growing waters has indicated that minor differences in laboratory procedures or techniques might cause wide variations in the results. Improper handling of the sample may also cause variations in results during collection or transportation to the laboratory. The APHA *Recommended Procedures for the Examination of Seawater and Shellfish*, which are revised periodically, offer reliable information for minimizing these variations. Assuring uniformity nationwide in the application of a laboratory quality assurance program is necessary to substantiate the validity of analytical results. Integral to laboratory quality assurance is a strong program for the evaluation of laboratory performance.

@.02 Methods.

American Public Health Association (APHA) *Recommended Procedures for the Examination of Seawater and Shellfish* shall be followed for the collection, transportation, and examination of samples of shellfish and shellfish waters (17). The official reference of the NSSP for the examination of shellfish for *Vibrio cholerae, V. vulnificus, and V. parahaemolyticus* is the FDA *Bacteriological Analytical Manual* (BAM) (18). State laboratories should conduct the test for these organisms when routine tests of marine foods implicated in foodborne outbreaks fail to demonstrate other enteric pathogens or bacterial toxins (8).

Use of standardized laboratory methods and procedures produces results acceptable to all regulatory agencies and allows comparative evaluation of data across laboratories. The APHA reference and FDA's BAM contain procedures for the virological examination of seawater and shellfish. However, the use of these procedures should be limited to special studies such as the development of new approaches for assessing, controlling, or improving shellfish sanitary quality, investigation of shellfish-borne disease outbreaks and other research studies. Routine virus monitoring of shellfish or their waters is not recommended due to the technical complexity, time required, high cost, and limitations of the detection and recovery method. For methods used in the NSSP, see the NSSP Model Ordinance Guidance Documents: *Approved NSSP Laboratory Tests* (ISSC/FDA, 2002).

Chapter IV. Shellstock Growing Areas

Requirements for the Authority
@.01 Sanitary Survey

A. General. One of the goals of the NSSP is to control the safety of shellfish for human consumption by preventing its harvest from contaminated growing areas. The positive relationship between sewage pollution of shellfish growing areas and disease has been demonstrated many times (24, 25). Shellfish-borne infectious diseases are generally transmitted via a fecal-oral route. The pathway can become quite circuitous. The cycle usually begins with fecal contamination of the growing waters. Feces deposited on land surfaces can release pathogens into surface waters via runoff. Most freshwater streams eventually empty into an estuary where fecal bacteria and viruses may accumulate in sediment and subsequently can be re-suspended (26).

Shellfish pump large quantities of water through their bodies during the normal feeding process. During this process the shellfish also concentrate microorganisms, which may include pathogenic microorganisms. Epidemiological investigations of shellfish-caused disease outbreaks have found difficulty in establishing a direct numerical correlation between the bacteriological quality of water and the degree of hazard to health. Investigations made from 1914 to 1925 by the states and the Public Health Service, a period when disease outbreaks attributable to shellfish were more prevalent, indicated that typhoid fever or other enteric diseases would not ordinarily be attributed to shellfish harvested from water in which not more than 50 percent of the 1 cc portions of water examined were positive for coliforms (an MPN of approximately 70 per 100 ml), provided the areas were not subject to direct contamination with small amounts of fresh sewage which would not be revealed by bacteriological examination.

Following the oyster-borne typhoid outbreaks during the winter of 1924-25 in the United States (27), the National Shellfish Sanitation Program was initiated by the States, the Public Health Service, and the shellfish industry. Water quality criteria were then stated as: (1) the area is sufficiently removed from major sources of pollution so that the shellfish would not be subjected to fecal contamination in quantities which might be dangerous to the public health, (2) the area is free from pollution by even small quantities of fresh sewage, and (3) bacteriological examination does not ordinarily show the presence of the coli-aerogenes group of bacteria in 1 cc dilution of the growing area water. Once the standards were adopted in the United States in 1925, reliance on this three-part standard for evaluating the safety of shellfish harvesting areas has generally proven effective in preventing major outbreaks of disease transmitted by the fecal-oral route. Similar water quality criteria have been used in other countries with favorable results.

Nevertheless, some indicators and pathogens are capable of persisting in terrestrial soil, fresh and marine waters, and aquatic sediment for many days while others are even capable of growth external to a host (24, 28, 29). A small number of shellfish-borne illnesses have also been associated with bacteria of the genus *Vibrio* (30, 31, 32, 33, 34). The vibrios are free-living

aquatic microorganisms, generally inhabiting marine and estuarine waters (33, 35, 36, 37). Among the marine vibrios classified as pathogenic are strains of non-01 *Vibrio cholerae*, *V. parahaemolyticus*, and *V. vulnificus* (37, 38, 39). All three species have been recovered from coastal waters in the United States and other parts of the world (33, 36, 39, 40, 41, 42, 43, 44, 45). These and other vibrios have been detected in some environmental samples recovered from areas free of overt sewage contamination and coliform (30, 33, 35).

In general, shellfish-borne vibrio infections have tended to occur in coastal areas in the summer and fall when the water was warmer and vibrio counts were higher (30, 32, 33). *V. parahaemolyticus* and non-01 *V. cholerae* are commonly reported as causing diarrhea illness associated with the consumption of seafood including shellfish (30, 31, 32, 33, 46, 47). In contrast, *V. vulnificus* has been related to two distinct syndromes: wound infections, often with tissue necrosis and bacteremia, and primary septicemia characterized by fulminant illness in individuals with severe chronic illnesses such as liver disease, hemochromatosis, thalassemia major, alcoholism or malignancy (30, 48). Increasing evidence shows that individuals with such chronic diseases are susceptible to septicemia and death from raw seafoods, especially raw oysters (30, 31, 32, 34, 37, 39, 43, 45, 48, 49, 50). Shellfish-borne vibrio infections can be prevented by cooking seafood thoroughly, keeping them from cross contamination after cooking, and eating them promptly or storing them at hot (60°C or higher) or cold (4°C or lower) temperatures. If oysters and other seafoods are to be eaten raw, consumers are probably at lower risk to vibrio infection during months when seawater is cold than when it is warm (51, 52).

In addition to pathogenic microorganisms, poisonous or deleterious substances may enter shellfish growing areas via industrial or domestic waste discharges, seepage from waste disposal sites, agricultural land or geochemical reactions (53, 54, 55). The potential public health hazard posed by these substances must also be considered in assessing the safety of shellfish growing areas.

The primary responsibility of the shellfish control authority is to ensure the public health safety of the shellfish growing areas through compliance with the NSSP Model Ordinance. The Authority must perform a sanitary survey that collects and evaluates information concerning actual and potential pollution sources that may adversely affect the water quality in each growing area. Based on the sanitary survey information, the authority determines what use can be made of the shellstock from the growing area and assigns the growing area to one of five classifications. The survey information must be updated periodically to ensure that it remains current and must be readily accessible to both the Authority and the harvester. Experience has shown that the minimum sanitary survey components required in this chapter are necessary for a reliable sanitary survey. A more detailed explanation is provided in the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters* (ISSC/FDA, 2002).

B. Sanitary Survey Required. The findings of the sanitary survey represent a comprehensive analysis of data from several sources used to determine the proper classification of a growing area. Therefore, the Authority is required to complete the survey before determining the

classification of a growing area and the appropriate use of shellstock from the area. If no harvesting is to be permitted in a growing area, the sanitary survey is unnecessary.

C. Sanitary Survey Performance. Since the sanitary survey must be kept current to routinely verify the classification of the growing area, specified frequencies for updating the various survey components are necessary. Lack of written documentation precludes accurate assessment on a routine basis, and requires that, to protect the public health, the growing area be placed in the prohibited classification or closed status of its classification. A more detailed explanation is provided in the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters* (ISSC/FDA, 2002).

D. Shoreline Survey Requirements. The shoreline survey (also known as the pollution source survey) is the sanitary survey component in which the actual and potential pollution sources that may adversely affect the growing area are identified. These sources may introduce infectious disease agents or poisonous and deleterious substances to the growing waters where they may be taken up and concentrated by shellfish. Detailed and accurate information concerning the pollution sources is necessary for a proper growing area classification. A more detailed explanation is provided in the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters* (ISSC/FDA, 2002).

The key to the accurate classification of shellfish growing areas is the sanitary survey. The principal components of a sanitary survey include: (1) an evaluation of the pollution sources that may affect the areas, (2) an evaluation of the meteorological factors, (3) a review of hydrographic factors that may affect distribution of pollutants throughout the area, and (4) an assessment of water quality.

A pollution source survey should be conducted of the shoreline area and watershed to locate direct discharges (e.g., municipal and industrial waste discharges, package treatment units, and malfunctioning septic tanks) and non-point sources of pollution (e.g., storm water runoff and agricultural and wildlife area runoff). Municipal and industrial wastewater treatment facilities should be evaluated in terms of design capacity versus actual loading, type and concentration of pollutants discharged, and the type and effectiveness of pollution control devices.
Following these evaluations, hydrographic and meteorological characteristics that may affect the distribution of pollutants to the area should be determined. Examples of these are tidal amplitude and type, water circulation patterns, depth, salinity, stratification characteristics, rainfall patterns and intensity, and prevailing winds.

Information from pollution source evaluations and hydrographic studies should be considered in developing an evaluation of the water quality in a growing area. The purpose of this evaluation is to develop specific information to assist in defining classification boundaries. In many instances, bacteriological and related salinity data can be used to develop information on hydrographic characteristics of the area.

In designing a water quality evaluation, the following should be considered. Most water samples should be collected from the surface, since pollution discharged into freshwater streams or

brackish estuarine waters usually tends to remain near the surface or above the denser seawater. Sample collection should be timed to be representative of the major pollution impacts, since shellfish respond rapidly to an increase in the number of bacteria in their surrounding waters. A sanitary survey report is needed to integrate data from several sources into a comprehensive analysis to determine the proper classification for the area. This report should include a compilation of relevant data, a data analysis utilizing recognized statistical techniques, conclusions as to the appropriate classification of the area, and recommendations for necessary follow-up actions. The report may also consider relevant resource management, social, economic, or political factors that may influence the establishment of boundaries and open and closed periods for conditionally approved and restricted areas.

Maintaining the sanitary survey consists primarily of routinely evaluating major pollution sources, collecting water quality data from key stations under adverse conditions, and analyzing the data to assure that the sanitary survey continues to be representative of current sanitary conditions in the growing area. The growing area must be subjected promptly to a more intense and comprehensive sanitary survey reevaluation when routine monitoring reveals a substantial change in the sanitary conditions. A reevaluation report is then needed and a determination must be made as to the proper classification of the area.

Experience with the shellfish certification program indicates a tendency to omit or de-emphasize some components of the sanitary survey unless a central state file of all shellfish sanitary survey reports, maintenance data and analysis, and reevaluation reports is maintained. This is particularly true where responsibility for shellfish sanitation is divided between two or more state agencies. Maintenance of a central state file for all shellfish sanitary survey information will also simplify the appraisal of state programs by the FDA and will prevent loss of historical data which may be useful in evaluating the sanitary quality of an area.

@.02 Bacteriological Standards

A. General. The NSSP recognizes the use of two different indicator organisms for evaluating shellfish growing water quality. The water quality standards for the two indicators are numerically different from one another but are believed to afford the same level of public health protection (Hunt and Springer, 1974). The Authority may use either indicator and its companion water quality standard in any growing area.

B. Water Sample Stations. The location of water sample collection stations can markedly affect the water quality detected. The NSSP requires that stations be of sufficient number and located to capture the effect of pollution sources so that the water quality affecting the shellfish can be adequately evaluated.

C. Exceptions. Application of the water quality standards under the NSSP is based on the collection of a specified minimum number of samples at a specified frequency over a 3-year period. When a new growing area is under evaluation for classification, 3 years of historic data may not exist. This section sets the minimum number of samples that must be collected as part of the required sanitary survey to determine the appropriate growing area classification for these new growing areas. The requirements are more stringent for growing areas that have pollution

sources that affect water quality. No water quality samples are required to place a growing area in the prohibited classification.

D. - F. Standards for the Approved Classification of Growing Areas in the Remote Status, Affected by Point Sources, or Affected by Nonpoint Sources. Based on the information gathered in the sanitary survey, the shellfish authority determines the appropriate classification of the shellfish growing area. The shellfish authority makes a decision to place a growing area in either the approved, conditionally approved, restricted, or conditionally restricted growing area classification. The growing area classification determines how the shellstock may be used following harvest. Water samples collected as part of the sanitary survey or as a required update of the sanitary survey are used to determine if the water quality meets the water quality standards for the growing area classification. The NSSP recognizes two water quality-monitoring strategies: adverse pollution condition and systematic random sampling. Presence of point sources of pollution requires the use of the adverse pollution condition sampling strategy to collect data for the application of the water quality standard. In growing areas not affected by point sources, the Authority may elect to use either system. The presence or absence of point sources of pollution and the water sample monitoring strategy used dictate the frequency of samples that must be collected. If the water quality meets approved classification water quality standards, the growing area is placed in the approved classification. If the water quality does not meet the water quality standards for the approved classification or meets the water quality standards only under certain conditions, the Authority places the area in another more suitable classification. For a fuller explanation of the classification of growing waters and the water quality monitoring strategies, see the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters, Systematic Random Sampling Monitoring Strategy*, and *Management Plans for Growing Areas in the Conditional Classification* (ISSC/FDA, 2002).

A field sampling and data analysis design that employs a systematic random sampling plan, assumes that a statistically representative cross section of all meteorological, hydrographic, and/or other pollution events will be included in the data set. Therefore, all shellfish growing area data collected shall be used during classification. This sampling and data analysis design may be applied to approved and restricted shellfish growing areas that are affected by only randomly occurring pollution events. Additionally, this sampling strategy may be used to classify shellfish growing areas where water quality is influenced by seasonal water uses or where harvesting is controlled by seasonal resource management restrictions.

Systematic random sampling cannot be applied to areas impacted by point source pollution. This field sampling and data analysis design presumes that if intermittent, unfavorable changes in water quality occur, they will be revealed in the bacteriological sampling results. These unfavorable sampling results will then contribute to the variation of the data set. Data sets displaying greater levels of variation will consequently exhibit an elevated estimated 90th percentile. The Authority's option to use a systematic random sampling strategy is therefore, contingent upon the acceptance of the estimated 90th percentile, as the statistic to measure the variance of a data set. This statistic shall, along with the geometric mean or median, be used when evaluating each sampling station for compliance with NSSP growing area criteria.

An example of an acceptable systematic sampling plan is one that documents a preestablished sampling schedule in the growing area central file. Monthly or bimonthly sampling regimes are acceptable as long as there is no avoidance of unfavorable conditions and a reasonable attempt is made to collect samples on the preestablished days. Field sampling crews will *not* be required to take unnecessary risks to sample on any particular day. The sampling plan will address unsafe sampling (boating) conditions by designating an alternate sampling day or by allocating extra sampling days in the schedule that may be used when needed.

If the growing area is intended for year-round harvesting, the sampling regime should stipulate the collection of samples throughout the year. If the growing area is intended to be approved for direct harvest for only part of the year, the random sampling plan would need only to address that period when the area is available for harvest. The only exception to this obligation to a random sampling regime is that the Authority will direct sampling to a particular tidal condition, if that condition unfavorably impacts the quality of the growing area.

The estimated 90th percentile was suggested in ISSC issue 8109 and its addendum, to address the public health concerns associated with variation in shellfish growing water-monitoring data. The estimated 90th percentile will weigh every MPN value in the data set. This statistic will aid the evaluation of the growing water data by accurately describing the results of the field sampling. When environmental events (such as rainfall) produce unfavorable effects on water quality, a randomly collected set of growing water data may, while still meeting the "10 percent above 43" criterion, display a greater level of variance than that associated with NSSP criteria. The "percentage factor" was not intended to allow for variation in the data caused by changes in environmental conditions at the time of sampling. The "percentage factor" was intended for use with a normally distributed data set, and reflects the inherent variation of the MPN analytical method.

If growing water data collected following unfavorable pollution events are combined with data collected under normal conditions, variation is increased. The estimated 90th percentile will reflect this variation. Therefore, the estimated 90th percentile will facilitate the use of a systematic random sampling strategy, while protecting against the potential public health problems that may result when shellfish are consumed from growing waters that are adversely affected by intermittent pollution events. For more information on systematic random sampling, see the NSSP Model Ordinance Guidance Documents: *Systematic Random Sampling Monitoring Strategy* (ISSC/FDA, 2002).

G. - H. Standard for the Restricted Classification of Growing Areas Affected by Point Sources or Nonpoint Sources and Used as a Shellstock Source for Depuration. Classification as a restricted growing area used as a shellstock source for depuration is an option available to the Authority as an alternative to placing a growing area in the prohibited classification. Shellstock harvested from these waters are subjected to depuration, which is a process of reducing the levels of pathogenic organisms that may be present in the shellstock by using a controlled aquatic environment as a treatment process. Following successful depuration, the shellfish are safe to eat.

Water samples are collected to determine if the water quality meets the water quality standards for this growing area classification. The NSSP recognizes two water quality-monitoring strategies: adverse pollution condition and systematic random sampling. Presence of point sources of pollution requires the use of the adverse pollution condition monitoring system to collect data for the application of the water quality standard. In growing areas not affected by point sources, the Authority may elect to use either system. The presence or absence of point sources of pollution and the monitoring system used dictate the frequency of samples that must be collected for application of the water quality standards. If the water quality meets the water quality standard for this classification, the growing area is placed in the restricted classification. If the water quality does not meet this water quality standard, or meets the water quality standard only under certain conditions, the Authority places the area in either the prohibited or the conditionally restricted classifications. For a fuller explanation of the classification of growing waters and the water quality monitoring strategies, see the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters, Systematic Random Sampling Monitoring Strategy*, and *Management Plans for Growing Areas in the Conditional Classifications* (ISSC/FDA, 2002).

@.03 Growing Area Classification

A. General. The probable presence or absence of pathogenic microorganisms in shellfish waters is important in deciding how shellfish obtained from an area may be used. All actual and potential growing waters should thus be classified according to the information developed in the sanitary survey. Classification should not be revised upward without careful consideration of trends and currently available data. Included in the sanitary survey file should be a written report with analysis supporting the classification.

The classification in which a growing area is placed dictates how the shellstock from that area may be used i.e. sold directly to the consumer to eat or required to be subjected to natural or artificial cleansing prior to sale to the consumer. Therefore, the Authority must make every effort to use the sanitary survey information to determine the correct classification in which to place the growing area to minimize public health risk to the consumer. Any change from a more restrictive growing area classification to a less restrictive classification requires a written sanitary survey report that carefully and thoughtfully evaluates the changes in the information and data supporting the current classification to justify the less restrictive classification.

The status of a growing area is different from its classification. A growing area is generally in the open status for harvest subject to the limitations of its classification. When the conditions for the open status are not satisfied, the growing area may be placed in the closed status of its classification. For example, in a public health emergency such as deterioration of growing area water quality following a hurricane, a growing area in the approved classification would be placed in the closed status until the water quality is determined to meet the water quality standards for its classification. After a closure, a reevaluation must be made prior to reopening. The growing area would be returned to its open status when the water quality returns to normal provided it continues to meet all other criteria for the approved classification.

Some growing areas are so remote that there is no possibility of contamination. If an area qualifies for remote status, less restrictive monitoring requirements are imposed.

B. Approved Classification. A review of epidemiological investigations of disease and marine biotoxin outbreaks attributable to the consumption of shellfish reveals that three general situations prevail insofar as contamination of approved growing areas are concerned.

Firstly, improperly conducted or outdated sanitary surveys or misapplication of approved area criteria have unwittingly allowed sewage contamination of approved areas. Such areas have been shown to be the source of shellfish involved in shellfish associated disease outbreaks. The misapplication of approved area criteria includes the improper interpretation of the upper 10 percentile criteria to permit an area that is contaminated 10 percent of the time to be classified as approved.

A report of a 1910 outbreak of typhoid fever involving 41 persons notes that raw sewage from a city with a population of 30,000 was discharged only a few hundred feet away from clam beds and floats (56, 57). In 1947, a case of typhoid fever was attributed to clams harvested 200 yards from the outlet of a municipal sewage treatment plant (58). In the latter case, the coliform MPN of the harbor water exceeded 12,000 per 100 ml and the area had been posted as closed to shellfish harvesting. In 1961, clams were responsible for at least 15 cases of infectious hepatitis. Subsequent water quality samples from the area found total coliform levels ranged between 900 to 2,400 MPN per 100 ml. The highest fecal coliform level observed was 2,100 MPN per 100 ml (59).

In 1978, at least 2,000 persons were victims of oyster-associated food poisoning. The causative agent was determined to be the Norwalk virus. The oysters were contaminated by sewage and runoff during periods of heavy rainfall (60, 61). In 1977, there were over 700 cases of viral gastroenteritis associated with the consumption of sewage-contaminated cockles (62). Between November 1, 1980 and April 30, 1981, 450 cases of infectious hepatitis A were reported from the consumption of cockles (63).

Secondly, shellfish associated illnesses have been caused by chance contamination of growing areas. These growing areas were contaminated by fresh fecal material, which was not diffused throughout the entire area and was not readily detectable by ordinary bacteriological sampling procedures (27, 64, 65, 66). This possibility of chance contamination was recognized by Dr. Gurion in his report on a 1902 typhoid outbreak in which he noted "There is a zone of pollution established by the mere fact of the existence of a populated city upon the banks of a stream or tidal estuary which makes the laying down of oysters and clams in these waters a pernicious custom if persisted in, because it renders these articles of food dangerous at times, and always suspicious (67)."

In 1956, an outbreak of infectious hepatitis (691 cases) attributed to oysters, which were contaminated in a wet storage area, is another example of chance contamination (65). Similarly in 1939, 87 cases of typhoid were attributed to fecal contamination of a storage area by a typhoid carrier (64).

Finally, shellfish illnesses have been traced back to areas where an intermittent pollution source contaminated the shellfish. These areas should have been managed and classified as conditionally approved, or classified as restricted.
Shellfish from waters meeting approved area criteria are unlikely to be involved in the spread of disease that can be attributed to fecal contamination of the shellfish. This is because, in part, a total coliform MPN of 70/100 ml is equivalent to the fecal material contributed from one person diluted in about 2.27 x 10^8 liters (8 million cubic feet) of coliform-free water. In addition, such a small amount of sewage reaching the growing area is likely to have been so treated, diluted, or aged that it will be of negligible public health significance. This also means an element of time and distance to permit mixing of sewage or fecal material with large volumes of diluting water. An increasing amount of saltwater will increase the rate at which many terrestrial microorganisms die out. Many reports have been published on the natural die-off of microorganisms in the marine environment (68, 69, 70, 71, 72, 73, 74, 75,76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86).

In general, microbial inactivation in seawater occurs by two different processes -physical dilution by diffusion and a process of biological inactivation (79). The inactivation process appears to be associated with the following factors: specific bacteriophages, sunlight and solar radiation, temperature, absorption and sedimentation, predation, antibiosis, action of inorganic salts, nutrient deficiencies, and action of heavy metals and other substances.

Studies have shown that enteric bacteria in seawater may survive from a few hours to five days and longer (82). Field and laboratory studies have demonstrated that enteric viruses can survive in marine water and shellfish from a few days to over 130 days (87). The survival of viruses in seawater becomes greatly prolonged once they become associated with sediments. Virus concentrations may be many-fold greater in sediments than in overlying water. In general, viruses survive longer at lower temperatures, at low salinity, and in waters contaminated by sewage. Evidence from many field studies indicates that a constant relationship does not exist between either pathogen (bacterial or viral) or coliform content of shellfish and overlying water (70, 72, 80, 81, 82, 83, 87).

The effectiveness of sewage treatment processes must be considered in evaluating the sanitary quality of a growing area since the bacterial and viral content of the effluent will be determined by the degree of treatment which is obtained (3, 88, 89, 90). The results of bacteriological sampling must also be correlated with sewage treatment plant operation and evaluated in terms of the minimum treatment which can be expected with the possibility of malfunctioning, overloading, or poor operations.

The ability of shellfish to concentrate chemical pollutants from water and sediment may lead to accumulation of these poisonous and deleterious substances to levels that may constitute a public health hazard (55, 91, 92, 93, 94, 95, 96, 97, 98, 99). The degree to which these added substances are concentrated depends upon such variables as the species of shellfish, water temperature and salinity, the level of contaminants in the waters, and the physiological conditions of the shellfish (100, 101, 102). Concentration factors in oysters may range from near unity for Strontium 90 to

as high as 10^4 for DDT (93, 96, 101, 103). Anatomical distribution in shellfish and biological half-life of the substances are also highly variable (92, 93, 94, 101).

Although there have been at least nine closures of shellfish growing areas in the United States due to findings of added poisonous or deleterious substances (55, 104, 105), there have been no documented illnesses attributed to consumption of shellfish from these areas. The level of surveillance for these substances in a shellfish control program may vary widely. Review of existing background data derived from national and international monitoring programs (53, 106, 107, 108) and assessment of potential sources of the substances should enable program managers to determine if a potential problem exists that may indicate a need for further field study. Sampling for specific chemical contaminants in shellfish is recommended only when the pollution source survey reveals a potential problem, or if there is concern due to lack of information.

Limiting maximum permissible concentrations of radioisotopes and unidentified mixtures in water and food has been established (109, 110). Current standards should be consulted in evaluating public health significance in market shellfish. The NSSP Model Ordinance Guidance Documents: *Action Levels, Tolerances, and Guidance Levels for Poisonous or Deleterious Substances in Seafood*, (ISSC/FDA, 2002) contains current FDA action levels and tolerances for poisonous and deleterious substances in seafood. Existing data are insufficient to establish levels for other substances at this time. Information on procedures for developing action levels and guidelines may be found in the September 30, 1977 *Federal Register* (111). In the absence of specific levels, decisions must be made on a case-by-case basis utilizing the best available knowledge.

The approved classification for a growing area requires that the sanitary survey has determined that there are no unacceptable concentrations of fecal material, pathogenic microorganisms, or poisonous and deleterious substances. There are no NSSP limitations on the harvest of shellstock from growing areas placed in this classification.

C. Conditional Classification. The basic concept of the NSSP is to control the safety of shellfish by preventing their harvest from contaminated growing areas. In reviewing growing area classifications and sanitary surveys conducted by national and international control officials, it appears that a common misinterpretation is the classification of an area as *approved* when in fact the area should have been classified as *conditionally approved*. Critical investigations usually reveal that the area is subject to intermittent pollution events. Careful consideration of an intermittent pollution event, development and application of a management plan, and cooperation and compliance by all parties may also allow upgrading of an area to a *conditionally approved* or *conditionally restricted* classification instead of requiring the area to be *restricted* or *prohibited* at all times.

Intermittent pollution to shellfish growing waters has been a significant cause of shellfish-borne infectious disease outbreaks worldwide. In 1978, at least 20,000 persons were involved in an outbreak of oyster-associated gastroenteritis attributed to Norwalk virus (112). The investigation of the outbreak indicated that a combination of meteorological and hydrographic events had

caused inadequately treated and diluted sewage from a nearby municipal facility to reach the area. In an incident in 1982, at least 471 persons developed gastroenteritis after consumption of sewage contaminated oysters when a combination of raw sewage bypasses, high rainfall, strong winds, and abnormally low tides caused contamination of an area that was classified as approved (113). In both of these instances, application of the conditionally approved area concept probably could have prevented the outbreaks.

A common situation where this classification might be appropriate is when water quality is, to some degree, dependent upon the operation of a wastewater treatment plant. For example, the boundaries of an approved shellfish area might be improperly determined during a period when a wastewater treatment plant is operating at a satisfactory level. If there is some interruption in treatment, it follows that there will be some degradation of water quality in the growing area which may require a relocation of the boundaries. The degree of relocation would depend upon such items as the distance between the pollution source and the growing area, hydrography, the amount of water, and the amount of pollution.

The concept is also applicable to other situations in which there may be a rapid or seasonal change in water quality. Examples of such situations include:

The water quality in a growing area adjacent to a resort community may vary according to seasons of the year. During the summer months, when the community experiences a significant population increase, water quality may be adversely affected. However, during the winter when there are few people in the community, water quality might improve sufficiently to allow approval of the area. In some states, this is known as a seasonal closure.

The water quality in a protected harbor in a sparsely settled area, which provides anchorage for a fishing fleet, several months a year might vary. When the fishing fleet is in, the harbor water might be of poor sanitary quality. However, during the remainder of the year the quality of the harbor water might be satisfactory. The area would be closed for shellfish harvesting when the fishing fleet is using the harbor.

The water quality in an area may fluctuate with the discharge of a major river, or rainfall in the area may cause runoff of pollutants into the growing area. This type of pollution is often referred to as non-point pollution. During periods of low runoff, such an area might be of satisfactory quality and thus be approved for shellfish harvesting.

The first step in determining whether an area should be classified as conditionally approved or conditionally restricted is to determine whether sufficient state resources are available to manage, survey, monitor, control harvesting, affect closures, and reopen the area as required. It should be noted that sources of pollution must be routinely monitored; coordination between state, local and industry officials must be timely; performance standards must be monitored; and closures must be immediate and effective. States electing to classify areas as conditionally approved have found the public resource investment to be substantial.

The second step in determining whether an area should be placed in the conditionally approved or conditionally restricted classification is to evaluate the potential sources of pollution in terms of their effect on water quality in the area. Some potential sources of pollution include: bypasses and overflows within a sewage collection and treatment system, intermittent discharges from boats, seasonally used areas, animals, land runoff, and freshwater flows.

The third step in establishing a conditionally approved or conditionally restricted area is to evaluate each source of pollution in terms of the water quality standards to be maintained, and to formulate performance standards for each pollution source having a significant effect on the sanitary quality of the area. The following are examples of different types of performance standards that might be developed:

Performance standards or closure criteria may be based upon the bacteriological quality of effluent from sewage treatment plants. This might be stated in terms of chlorine residual if the bacteriological quality of the effluent can be positively related to chlorine residual. The following is an example of a performance standard for an effluent discharge (114): "The median coliform MPN, in any one month, shall not exceed 500 per 100 ml, based on not less than 16 composite samples per month, and not more than 10 percent of the samples shall have an MPN in excess of 10,000 per 100 ml. Determinations of the chlorine residual of the effluent should be made hourly and recorded in the permanent plant records."

A performance standard may be based upon total quality of sewage, which can be discharged from any given unit, or from a combination of units, without causing the basic water quality standards to be exceeded.

A performance standard may be based upon the amount of vessel traffic in the area and the concomitant amount of sewage, which can be expected.
Performance standards may be based upon the amount of rainfall in the immediate area. An example could be: "The area will be closed when there has been 5 cm (2 inches) or more rainfall registered at a rain gauge at (specified area within a 24-hour period)."

Performance standards may be based upon the height of a river stage. An example could be: "When the river at (a specified area) reaches 3.66 meters (12 feet) or above, the area will be closed."

The design of a waste treatment plant and the plant effluent specifications may be critical to the designation of an area classified as conditionally approved or conditionally restricted. Design criteria which may be useful in determining the quality of sewage which can be discharged into an area without exceeding the desired water quality standards include: population equivalent (coliform) of sewage, predicted survival of coliform in seawater, effectiveness of chlorination and the total quality of clean dilution water in an area. Results of many studies on the survival of bacteria in seawater have been published (115).

The mechanical equipment at critical sewage treatment or pumping units should be such that interruptions will be minimized. Wherever possible, operations should be automatically recorded

on charts. Requirements that might be imposed depend upon the importance of the unit's relationship to water quality. Important design features of a sanitary waste collection system that should be considered include:

Storm water should be excluded from the sanitary system. There should be stand-by equipment to insure that treatment or pumping will not be interrupted. It should be taken into account that interruptions may occur because of damage to a single unit or a power failure.

The pumps and critical units should be fitted with meters or gauges so the regulatory agency can monitor performance standards.

Installation of recording scales to indicate rate of chlorine use is helpful. Chlorine flow meters are available that integrate hydraulic flow with chlorine demand.

Liquid level recording gauges fitted with alarms and located in overflow channels of sewage treatment plants and wet wells of lift stations are useful. They can be set to indicate when overflow takes place. It is good operating procedure to date recording charts. Gauges should be calibrated and maintained so that indicated discharge rates are accurate.

Automatic devices to warn of failure or malfunctioning at self-operated pumping stations or treatment plants can be an important control.

Another factor to consider in developing a conditionally approved or conditionally restricted area is that a prohibited area must be interposed between the conditionally approved or restricted area and the source of pollution. The size of such area should be based on the total time it would take for the operating agency to detect a failure, notify the state shellfish control agency, and for the latter agency to issue a notice to stop shellfish harvesting. It is recommended that the area be of such size that the flow time through the safety area is at least twice that required for the notification process to become effective. Due consideration should be given to the possibility that closure actions might be necessary on holidays or at night.

The length of time a conditionally approved or conditionally restricted area should be closed following a temporary closure will depend upon several factors including the species of shellfish, water temperature, shellfish activity and cleansing rates, presence of silt or other chemicals that might interfere with the physiological activity of the shellfish, and the degree of pollution of the area.

The conditional classifications are designed to address growing areas that are subject to intermittent microbiological pollution. These optional classifications offer the Authority an alternative to placing the area in the restricted or prohibited classification year round when during certain times of the year or under certain conditions, the shellstock from the growing area may be safely harvested. Public health protection and the control of shellfish safety in the use of the conditional classifications are afforded through the use of a management plan. The management plan for each growing area placed in a conditional classification is based on the information gathered during the sanitary survey. The plan establishes a strict set of criteria that

must be met for the growing area to remain in the open status. Failure to meet the criteria automatically places the growing area in the closed status, with immediate notice to the public, the affected industry, and the plan's participants. Two of the most important components of the management plan are: the acceptance of and the agreement to the conditions of the management plan by the one or more Authorities involved, other local, state and federal agencies which may be involved, the affected shellfish industry, and the persons responsible for the operation of any treatment plants or other discharges that may be involved; and the annual reevaluation of compliance with the plan to assure public health protection. Use of the conditional classification requires more intense monitoring and more frequent reevaluation because of the intermittent nature of the pollution event.

When the Authority has sufficient resources to manage a conditional classification, the use of the conditional classification could allow the safe use of growing areas that might otherwise not be available to the shellfish industry. For a complete discussion of the conditional classification, see the NSSP Model Ordinance Guidance Documents: *Management Plans for Growing Areas in the Conditional Classifications* (ISSC/FDA, 2002). For additional information concerning the classification of growing waters and the sanitary survey, see the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters* (ISSC/FDA, 2002).

D. Restricted Classification. The restricted area classification is an option available to state shellfish control agencies to use instead of a prohibited classification. The establishment of a restricted area might be considered in instances where an area does not meet approved area criteria but is not grossly polluted. Another common situation where this classification might be appropriate is for areas affected by non-point pollution from either urban or rural sources that cause the water quality to fluctuate unpredictably or of sufficient frequency that a conditionally approved area is not feasible. In such instances, the state may, at its option, classify these areas as restricted and may limit the use of the shellfish to relaying, container relaying, or depuration operations.

Relaying is a process of reducing the levels of microorganisms that may be present in the shellstock by moving the shellstock to growing areas in the approved classification and using the shellstock's ability to cleanse itself naturally as a treatment process. Depuration is a process of reducing the levels of pathogenic organisms that may be present in the shellstock by using a controlled aquatic environment (i.e. a land based facility) as a treatment process.

The sanitary and bacteriological criteria to be applied by the state for classifying restricted areas are to be developed by the state shellfish control agency. The criteria may vary according to the use to be made of the shellfish and according to the effectiveness of the relay and/or depuration process to which the shellfish will be subjected. The effectiveness of the process is determined by a study as provided for in the Model Ordinance, Chapter V, Shellstock Relaying and Chapter XV, Depuration. The purpose of this study is to establish the bacteriological quality requirements for the shellfish processing. Effectiveness of the process is likely to vary from one cleansing area to another, from one species of shellfish to another, and from one depuration plant to another.

The classification criteria may be based upon the quality of the shellfish or the water in the restricted area in addition to other sanitary parameters.

Before classifying an area as restricted, the state shellfish control agency should make a determination of whether sufficient state resources are available to monitor pollution sources; to provide coordination between state, local and industry officials; to issue special harvesting permits; and to supervise harvesting and transportation of shellfish to depuration facilities or relay sites. Some states that have classified areas as restricted have found the resource investment to be substantial. For a complete discussion of relay, see the NSSP Model Ordinance Guidance Documents: *Shellstock Relay* (ISSC/FDA, 2002). For a complete discussion of depuration, see the NSSP Model Ordinance Public Health Reasons and Explanations Chapter XV Depuration (ISSC/FDA, 2002).

E. Prohibited Classification. The positive relationship between disease and consuming contaminated shellfish has been clearly established. Prevention of consumption of contaminated shellfish is the primary objective of the NSSP. The prohibited area classification is the most restrictive growing area classification, used for areas subject to gross pollution. The use of this classification is also required, as a precautionary measure, for any growing area where the shellfish authority has not performed a sanitary survey, and for a growing area immediately adjacent to a sewage treatment plant outfall, irrespective of the level of effluent treatment provided. The harvesting of shellstock is not allowed for any human food use. For additional information concerning the classification of growing waters and the sanitary survey, see the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters* (ISSC/FDA, 2002)

@.04 Marine Biotoxin Control

Marine biotoxins may be ingested by molluscan shellfish feeding on toxic dinoflagellates. Dinoflagellates in their vegetative stage flourish seasonally when water conditions are favorable. Toxic blooms of dinoflagellates can occur unexpectedly or may follow predictable patterns. Paralytic shellfish poisoning (PSP), neurotoxic shellfish poisoning (NSP) and domoic acid poisoning, also known as amnesic shellfish poisoning (ASP) are the three types of poisonings most commonly associated with oysters, clams, mussels and scallops in the United States.

Cases of paralytic shellfish poisoning, including several fatalities resulting from poisonous shellfish, have been reported from both the Atlantic and Pacific coasts. The minimum quantity of poison, which will cause intoxication in the susceptible person, is not known. Epidemiological investigations of paralytic shellfish poisoning in Canada have indicated 200 to 600 micrograms of poison will produce symptoms in susceptible persons. A death has been attributed to the ingestion of a probable 480 micrograms of poison. Investigations indicate that lesser amounts of the poison have no deleterious effects on humans. Growing areas should be closed at a level to provide an adequate margin of safety, since in many instances, toxicity levels will change rapidly (116, 117).

A review of the literature and research dealing with the source of the poison, the occurrences and distribution of poisonous shellfish physiology and toxicology, characteristics of the poison, and prevention and control of poisoning has been prepared (21).

In Gulf coast areas, toxicity in shellfish has been associated (118, 119) with red tide outbreaks caused by massive blooms of the toxic dinoflagellate, *Karemia breve* (formerly *Ptychodiscus brevis*) (120). Toxic symptoms in mice suggest a type of neurotoxic shellfish poisoning rather than symptoms of paralytic shellfish poisoning. The most common public health problem associated with *Karemia breve* blooms is respiratory irritation; however, neurotoxic shellfish poisonings associated with *Karemia breve* blooms have been reported in Florida (121). Uncooked clams from a batch eaten by a patient with neurotoxic symptoms were found to contain 118 mouse units per 100 grams of shellfish meat.

Toxic dinoflagellates are indigenous to most coastal and estuarine waters on the Atlantic, Gulf, and Pacific coasts of America, as well as in many other parts of the world. Blooms of these organisms can occur unexpectedly and rapidly. This phenomenon occurred in New England in 1972 when shellfish suddenly became toxic in a previously unaffected portion of the coastline and resulted in many illnesses (122). During 1991 and 1992, there was a spread of domoic acid producing organisms throughout the world including the detection of high numbers of *Pseudonitzschia pseudodellcatissima* in Australia and *Pseudonitzschia pseudoseratia* in California. Domoic acid was also recovered from shellfish in Washington and Oregon. All shellfish producing states or MOU countries must have a contingency plan that defines administrative procedures, laboratory support, sample collection procedures, and patrol procedures to be implemented on an emergency basis in the event of the occurrence of shellfish toxins (9). A model state contingency plan for control of marine biotoxins is provided in the NSSP Model Ordinance Guidance Documents, A.2., *Guidance for Developing Marine Biotoxin Contingency Plans* (ISSC/FDA, 2002).

All states or MOU countries must monitor toxin levels to establish a baseline historical reference. Thereafter, states or MOU countries where shellfish toxins are likely to occur must monitor toxin levels on a routine basis to meet the approved area requirements for direct market harvesting. Experience with monitoring for shellfish toxins suggests that an effective program should include the following:

Sampling stations should be located at sites where past experience has shown toxin is most likely to appear first.

Samples should be collected of shellfish species which are most likely to reveal the early presence of toxin and which are most likely to show the highest toxin levels. For example, mussels have been found to be useful for early PSP detection.

The frequency and period for collection of samples should be based upon historical patterns. This assumes several years of baseline data in order to establish stations and sampling plans.

An information network should be established between the health and marine resource communities and the state shellfish control agency. Any toxin-like illnesses related to shellfish and environmental phenomena such as dinoflagellate blooms, fish kills, or bird kills, which might indicate the early stages of an increase in toxin levels (9) should be rapidly communicated over the network.

Sampling stations and frequency of sampling should be increased when monitoring data or other information suggests that toxin levels are increasing.

Sample collection, sample transportation, and sample analysis procedures should be developed so that in an emergency sample results will be known within 12 hours.

When monitoring data or other information indicates that toxin levels have increased to the quarantine levels, growing area closures must be immediately implemented. The determination of which growing areas should be closed should include consideration of the rapidity with which toxin levels can increase to excessive levels and the inherent delays in the state sample collection procedures. It may be appropriate to close growing areas adjacent to known toxic areas until increased sampling can establish which areas are toxin free and that toxin levels have stabilized.

Shellfish growing areas closed because marine biotoxins have exceeded quarantine levels may be reopened for growing after a sufficient number of samples and other environmental indices, if used, have established that the level of toxin will remain below quarantine levels for an extended period. For example, experience has shown that appropriate reopening criteria include a minimum of three samples collected over a period of at least 14 days. These samples should show the absence of PSP or levels below 80 micrograms per 100 grams.

A. Contingency Plan. The suitability of some areas for harvesting shellstock is periodically influenced by the presence of toxigenic micro-algae. Recent increases in toxigenic micro-algae distribution dictate that a more comprehensive series of public health controls be adopted. The need exists to make contingency plans to address the contamination of a growing area by toxigenic micro-algae or a disease outbreak caused by marine biotoxin. This contingency plan must describe administrative procedures, laboratory support, sample collection procedures, and patrol procedures to be implemented on an emergency basis in the event of the occurrence of marine biotoxin in shellstock. The primary goal of this planning should be to ensure that maximum public health protection is provided in growing areas subject to marine biotoxin contamination. For a fuller discussion of marine biotoxin disease and its management in shellfish growing areas, see the NSSP Model Ordinance Guidance Documents: G*uidance for Developing Marine Biotoxin Contingency Plan* (ISSC/FDA, 2002).

B. Marine Biotoxin Monitoring. The primary purpose of a marine biotoxin-monitoring program is to prevent illness or death among the shellfish consuming public. The monitoring program should use the "indicator station" and "critical species" concepts to develop an early warning system to prevent harvest of biotoxin contaminated shellstock. For a full discussion, see the NSSP Model Ordinance Guidance Documents: G*uidance for Developing Marine Biotoxin Contingency Plan* (ISSC/FDA, 2002).

C. Closed Status of Growing Areas. In the event of a toxigenic micro-algae bloom, shellstock-growing areas shall be placed in the closed status for harvesting to prevent human consumption of biotoxin-contaminated shellfish. The biotoxin level governing the need to place the growing area in the closed status will vary depending on the species of toxigenic micro-algae and the species of bivalve shellfish. Since the ability to concentrate biotoxins varies among species, it is possible for one species in a growing area to have safe levels of biotoxin while another species in the same growing area will have dangerous biotoxin concentrations. In this situation, the Authority may permit the harvesting of one species with no adverse public health consequences while prohibiting the harvest of another species. In these situations, the Authority must closely monitor the growing area and develop a sufficient database for use in making this determination.

The Authority must develop criteria, which must be met before a growing area can be returned to the open status for harvesting. These criteria should integrate public health, conservation, and economic considerations. The criteria should also employ a sufficient number of samples and other environmental indices, if used, to establish that the level of toxin will remain, for an extended period of time, at levels safe for human consumption. For additional discussion concerning biotoxin contamination of shellstock, see the NSSP Model Ordinance Guidance Documents: G*uidance for Developing Marine Biotoxin Contingency Plan* (ISSC/FDA, 2002).

D. Heat Processing. Heat treatment can reduce the toxicity of some biotoxins. When heat treatment is used, the Authority must require that the processor provide adequate demonstration of the destruction of the biotoxin and adequate controls to assure that the end product is safe for human consumption.

E. Records. Good record keeping is essential to the successful management of a marine biotoxin contingency plan. Appropriate records of monitoring data, evaluation reports, and closure and reopening notices should be compiled and maintained by the Authority. This information is important in defining the severity of the problem, as well as for a retrospective evaluation of the adequacy of the entire control program.

@.05 Marinas

A. Marina Proper. Under the NSSP, any growing area within the confines of the marina proper is presumed to be contaminated for some period of time. Therefore, no growing area within the marina proper can be placed in the approved classification.

B. Adjacent Waters. The microbiological and chemical contamination associated with marina facilities may result in the contamination of adjacent shellfish growing waters. The NSSP has developed a set of evaluation criteria to be used in determining if the growing waters adjacent to a marina are affected by microbiological contaminants associated with sewage. Since there are significant regional differences in all factors that affect pollution loading from marinas, sufficient flexibility must be allowed to account for these differences. The Authority has the option of applying the specified occupancy and discharge rates necessary to conduct a dilution analysis. The Authority may also opt to conduct studies to document different rates for specific areas.

Best professional judgment of qualified individuals and best available technology must be applied to determine adequate restrictions on harvesting in and around marinas.

Chapter V. Shellstock Relaying

Requirements for the Authority

@.01 General. Relaying is the practice of harvesting bivalve shellstock from polluted growing or growing areas and placing them in unpolluted bodies of water for a sufficient time for the shellstock to reduce contaminating microorganisms or chemicals to safe levels. Through the natural cleansing process in relaying, shellstock resource that would otherwise not be available for human consumption is made safe and becomes accessible to the shellfish industry and the consumer. As early as 1911, public health officials were investigating the use of natural cleansing through relaying to reduce pathogenic organism levels in oysters (Clem, 1994). For a complete discussion of relaying activities, see the NSSP Model Ordinance Guidance Documents: *Shellstock Relay* (ISSC/FDA, 2002).

@.02 Contaminant Reduction. Research has shown that shellfish have the ability to purge themselves of certain microbial and chemical contaminants when placed in clean saline water. The rate of purging depends on the specific contaminants, species of shellfish, and environmental factors such as temperature and salinity. The shape of the containers used to hold the shellstock may also affect the purging rate. Because of the differences in purging rates among shellfish species and contaminants, a specific study must be performed in each growing area used for relaying to determine the purging rates, and the relay activity must be carried out in strict conformance with criteria established from the study. For a fuller discussion of the factors effecting contaminant reduction during relay, see the NSSP Model Ordinance Guidance Documents: *Shellstock Relay* (ISSC/FDA, 2002).

@.03 Licenses to Relay Shellstock. Licensing of each person who harvests shellstock is an important control measure to help protect against contaminated shellstock reaching the consumer and to help maintain accurate source identity records. Special permits must be issued to licensed harvesters for taking shellstock from contaminated growing areas and transporting them to other growing areas for the purpose of natural cleansing. Use of special permits with special harvesting conditions facilitates the shellfish authority's prevention of contaminated product being diverted for sale to the consumer prior to treatment rendering the shellstock safe for consumption. For more information concerning relay, see the NSSP Model Ordinance Guidance Documents: *Shellstock Relay* (ISSC/FDA, 2002).

@.04 Management of Relaying Activities. Because shellstock relaying involves the harvesting and transport of contaminated shellstock and its treatment to render it safe for human consumption, great care must be taken to assure that contaminated product does not inadvertently reach the consumer. This requires direct supervision of the operation and good enforcement by the shellfish authority. Techniques such as special licenses, testing of shellstock before and after relay activities, special tagging of shellstock during relay, special marking of the growing areas used for natural cleansing, record keeping, and additional patrol activities are used to ensure that effective contaminant purging is completed before the shellstock is marketed to the consumer. For additional information concerning the management of shellstock relaying, see the NSSP Model Ordinance Guidance Documents: *Shellstock Relay* (ISSC/FDA, 2002).

Requirements for Harvesters

.01 Harvester License Required. Licensing of each person who harvests shellstock is an important control measure to help protect against contaminated shellstock reaching the consumer and to help maintain accurate source identity records. Harvesters must work with the shellfish authority to foster the use and enforcement of special permits to prevent bypassing of the natural cleansing treatment process. Compliance with permit requirements is extremely important. Prevention of sale of contaminated shellstock to the consumer is the primary objective of the NSSP. Use of special permits with special harvesting conditions facilitates the shellfish authority's prevention of contaminated product being diverted for sale to the consumer prior to treatment rendering the shellstock safe for consumption. For more information concerning relay, see the NSSP Model Ordinance Guidance Documents: *Shellstock Relay* (ISSC/FDA, 2002).

Chapter VI. Shellfish Aquaculture

Oysters, clams, mussels and scallops are filter feeders and therefore have the ability to concentrate microorganisms, including human pathogens and toxigenic micro-algae, and poisonous or deleterious substances from the water column if these organisms or substances are present in the growing area. Concentrations in the shellfish may be as much as 100 times that found in the water column. If the microorganisms concentrated are harmful to humans, and if, in the case of human pathogens, the shellfish are consumed raw or partially cooked, human disease can result. Poisonous or deleterious substances can induce illness or death immediately or through long-term exposure, may contribute to the development of cancer in humans. Additional information concerning the disease causing potential of shellfish can be found in the NSSP Model Ordinance Guidance Documents: G*uidance for Developing Marine Biotoxin Contingency Plan, Sanitary Survey and the Classification of Growing Waters*, and *Shellstock Relay* (ISSC/FDA, 2002).

The culturing of molluscan shellfish in natural and artificial growing areas is known as aquaculture. This may include the cultivation of molluscan shellfish with non-molluscan species in a common aquaculture system known as polyculture. Oysters, clams, mussels and scallops raised in aquaculture operations are subject to the same potential for contamination as they are growing in the wild. In land-based operations, there may be some additional risk of accumulation in the shellstock of animal drugs used to stimulate growth and control mollusk diseases, or fish diseases in the case of polyculture. Since some components of aquaculture such as relaying, wet storage, depuration, growing water classification and tagging, are similar to other activities covered in the NSSP Model Ordinance, they are regulated under those Model Ordinance chapters. The shellfish authority must have an adequate legal basis and sufficient resources to regulate public health concerns pertinent to bivalve shellstock aquaculture.

Polyculture and land-based monoculture operations must be under adequate control to assure the shellstock product harvested will be acceptable for human consumption. The shellstock authority must establish detailed procedures for issuing permits for shellfish aquaculture, approving culturing sites and boundaries, controlling of harvesting, sampling of shellstock, monitoring environmental parameters, keeping records, imposing quarantine measures, controlling the use of animal drugs to stimulate growth or treat diseases, and developing other control measures as may be necessary. The shellfish authority should work with FDA in its review of the plans for a land based aquaculture operation.

Of particular concern in land-based systems is the use of a closed or recirculating water system. Potential exists for shellstock contamination through the failure of the water treatment system to sufficiently disinfect the water to control levels of human pathogens that might be introduced through the water supply or other means. There is also potential for the increased concentration of poisonous and deleterious substances such as animal drugs or antifouling agents in the water supply and subsequently the shellstock over time.

Prior to its harvest for sale in interstate commerce, the aquaculturist must demonstrate that the water in the land-based system met the NSSP Model Ordinance criteria for direct sale of

shellstock to the consumer. If the water supply does not meet those criteria, the aquaculturist must subject the shellstock to relaying or depuration prior to sale. Relay is a process of reducing the levels of microorganisms that may be present in the shellstock by moving the shellstock to growing areas in the approved classification and using the shellstock's ability to cleanse itself naturally over time as a treatment process. Depuration is a process of reducing the levels of pathogenic organisms that may be present in the shellstock by using a controlled aquatic environment (i.e. a land based facility) as a treatment process.

The cultivation of shellfish with other species in a common aquaculture system is known as polyculture. There are some additional public health concerns related to polyculture. Greater potential may exist for contamination of oysters, clams, mussels and scallops with human pathogens and animal drugs in polyculture. However, the extent of that potential is not known. The extensive use of tanks, sea enclosures, floating rafts, ponds, etc. in polyculture makes the oysters, clams, mussels or scallops highly vulnerable to pollution from various sources, including their association with the other species present in the polyculture operation. The usage of anti-fouling agents, (tributyltin, copper, etc.) hormones, and antibiotics in finfish aquaculture has evoked concern about its environmental effects and potential threat to human health through bioaccumulation in shellfish. Therefore, a conservative approach to polyculture is provided in the NSSP Model Ordinance requirements.

Chapter VII. Wet Storage in Approved and Conditionally Approved Growing Areas

The purpose of wet storage is to improve palatability of shellfish by desanding or increasing their salt content, or to provide temporary storage for depurated shellfish or shellfish from approved or conditionally approved harvest areas. Wet storage facilities are not designed and operated to increase the safety of shellfish. Therefore, all controls pertaining to shellfish for direct consumption must be applied.

Effective control measures must be established and implemented by the Authority to ensure that wet stored shellfish are protected from becoming contaminated. These control measures include review of the plans for proposed wet storage areas or flats; review of the design and operating procedures for onshore facilities; periodic inspections of wet storage facilities; and, evaluation of the water quality for compliance with the requirements of the *Model Ordinance*.

The types, location, and uses of wet storage operations are highly variable and may range from temporary storage near shore in approved areas to onshore tanks using recirculating–natural or synthetic seawater for the purpose of desanding, temporary storage, or salt uptake. Consequently, it is not possible to provide detailed guidelines in the *Model Ordinance* and it is necessary for each separate operation to be developed and evaluated on its own merit with respect to overall Program guidelines.

Removing shellfish from growing beds for storage in areas close to shore may subject such shellfish to constant or intermittent pollution. Shellfish in wet storage tanks are similarly subjected to pollution if the tank water is obtained from a polluted source. An example of health consequences due to such contamination is the outbreak (691cases) of infectious hepatitis in Sweden in 1956 attributed to oysters contaminated in a wet storage area (30).

Shellfish on floats near shore may be more directly exposed to potential contamination from boats and surface runoff than are shellfish in their natural growing areas. Therefore, particular emphasis should be placed on a sanitary survey of the vicinity to ensure that chance contamination does not occur (31).

Careful consideration must be given to designing and operating onshore wet storage tanks to ensure that shellfish are not contaminated during holding or do not die from physiological stresses such as low dissolved oxygen and unsuitable temperatures or salinity (32, 33). Excessive mud on the shells and dead shellfish may increase bacterial loads in the tanks and lead to increased microbial levels in the shellfish during wet storage. Hence, washing and culling the shellfish prior to wet storage is essential.

Chapter VIII. Control of Shellfish Harvesting

Requirements for the Authority. Other portions of this section of the Guide have described the public health reasons for limiting shellfish harvesting to areas free of contamination and shellfish toxins. Methods have been described for the evaluation and classification of such areas. However, classification is not effective unless the State can prevent illegal harvesting of shellfish from closed areas. For a full discussion of control activities, see the NSSP Model Ordinance Guidance Documents: *Growing Area Patrol and Enforcement* (ISSC/FDA, 2002).

For the most part, control of illegal harvesting depends upon the police activities as described in this chapter, @01.B. Adequate delineation of closed areas is fundamental to effective patrol. The type of area identification will be determined by the structure of the local shellfish industry and the legal requirements for each State to permit successful prosecution. Posting a warning sign is one method of informing shellfish harvesters that an area is closed to the taking of shellfish for public health reasons.

Other methods for identification of closures include telephone, maps issued at checkpoints, or with harvesting licenses, direct mail, and news media. It is recommended that the advice of the State's legal counsel be obtained to insure that the marking of closed areas and notifications to shellfish harvesters are such that persons harvesting from closed areas can be successfully prosecuted.

The primary objective of the NSSP is to ensure that shellfish are only harvested from areas free of excessive concentrations of pathogenic microorganisms and poisonous or deleterious substances. Growing areas may be classified as to their public-health suitability for shellfish harvesting on the basis of information obtained by sanitary surveys in accordance with Chapter IV., @01. However, if local shellfish harvesters are not convinced of the need for restrictions, shellfish may be harvested surreptitiously from closed areas. *Thus, the patrol element of the NSSP is important to ensure compliance with the public-health safeguards resulting from the sanitary survey.* The fact that the law prohibits the removal of shellfish from certain areas will deter the majority of the population from attempting to harvest such shellfish, provided they are aware of the law and of the areas which are closed. Where traditional gathering practices have prevailed, local public opinion may not support the need for such closures. In such cases, favorable opinion may be developed through an educational program or a locally demonstrated need resulting from an outbreak of shellfish-associated illness or intoxication.

The type of patrol needed for any particular situation cannot be specified and is determined by the nature of areas to be patrolled, means of access, methods of harvesting, and species. Patrol equipment should be such that the officers can apprehend persons illegally harvesting shellfish in a closed area. Equipment that has proven effective for apprehension of illegal harvesters includes: small, high-speed, readily transportable boats capable of operating in open waters; automobiles; aircraft; communications for coordinating patrol activities; radar surveillance systems; and night scopes.

Organization of the patrol activity must take into consideration the need for night, weekend, holiday, undercover and surprise patrols. Various patrol methods may be used depending on the nature of the area to be patrolled and the type of industry.

Complete removal of shellfish from polluted areas provides a safeguard against contaminated shellfish reaching the market. In some cases, depletion may be the method selected to eliminate an irresistible temptation for harvesters. Depletion may be more economical and effective than patrol of closed areas and will serve to protect public health.

Educational programs should be developed for both industry and the public describing the public health necessity for eliminating shellfish harvesting from closed areas. Programs developed specifically for participation of key industry people may be especially helpful in eliciting cooperative efforts of the entire industry. Such programs should focus on incentives to eliminate harvesting and marketing of shellfish from closed areas.

The adequacy of state laws as a basis for prosecution is an important component of this activity. Shellfish patrol will be ineffective and or compromised if State laws are so written or interpreted that violators can not successfully be prosecuted and if penalties are so small that they are economically unimportant. It is important that periodic assessments are made by the State control or patrol agency of the degree of success of court actions taken in response to illegal harvesting. Information of this nature is necessary for both the analysis of the effectiveness of the program and for education purposes. Prosecution will be difficult where local public opinion does not support the need for the restriction or the courts are not fully aware of the public health hazards associated with the crime.

Requirements for Harvesters. Precautions exercised in gathering shellfish from approved growing areas may be nullified if shellfish are contaminated with bilge water or polluted overboard water, or in the case of trucks, with contaminated water on the floor or hazardous materials on or adjacent to the shellstock. Also, several investigations have been conducted by States and the FDA regarding shipments of shellfish where product deterioration resulted when shellstock was held or shipped under adverse conditions such as direct sunlight and warm temperatures (159, 160, 161, 162). These studies reaffirm the critical role that adequate shellstock protection and refrigeration plays when ambient temperatures are high. Product deterioration and bacterial growth occurs when shellstock is left exposed for several hours on harvest boats. If this shellstock is transported in trucks without adequate prechilling and in-transit refrigeration, product deterioration continues.

The majority of studies on microbiological quality of shellfish point up the need to refrigerate shellstock quickly after harvesting and maintain the product below 10°C (50°F) throughout processing, distribution and storage. It should be noted that a study by Cook and Ruple reported in 1989, showed that 10°C (50°F) storage of summer harvested Eastern oyster shellstock from the U.S. Gulf Coast, prevented the multiplication of fecal coliforms and vibrios, including *Vibrio vulnificus* (24). Universally, food control officials consider shellfish as a potentially hazardous food that is capable of supporting rapid and progressive growth of infectious or toxigenic microorganisms. Other foods in this category are milk, milk products, eggs, meat, poultry and

fish. Generally, FDA recommends that potentially hazardous food be held at 7.2°C (45°F) or below, and if large volumes are involved in processing, methods be employed to rapidly cool the product to an internal temperature of 7.2°C (45°F) within four hours (20).

Several studies have established that some pathogenic *Vibrio* species and other autochthonous bacteria may be present in marine sediments throughout the year (26, 27, 28). One study of *Vibrio* species and *Aeromonas hydrophila* in sediments of Apalachicola Bay, Florida, routinely detected *V. parahaemolyticus*, *V. alginolyticus*, and *A. hydrophila* and during some portions of the year at relatively high levels (up to 46,000 organisms per gram). Additionally, *V. vulnificus*, *V. cholerae*, *V. fluvialis* were detected at levels up to 2,400 organisms per gram of sediment (27)
.
Furthermore, there is evidence that some pathogenic organisms will survive in shellfish for a considerable length of time after harvesting and that some bacterial pathogens may multiply in the absence of adequate refrigeration (164, 173, 182). I
Vibrio species can also survive on inadequately cleaned equipment in a processing plant (29). Washing sediments from shellstock at the time of harvest helps to protect the shellfish and the processing equipment from becoming contaminated. Washing shellstock also helps to prevent quantities of mud and other bacteria from being mixed with the shucked shellfish, thereby contributing to high bacterial counts in the finished product (17, 30). Muddy shellstock also makes it difficult to maintain shucking rooms in a clean, sanitary condition.

Water used for shellstock washing should be of good sanitary quality, to avoid possible contamination of the shellstock. There are instances when shellstock washing by the harvester might introduce a sanitary hazard because of the possible tendency of the harvester to wash the shellstock with polluted water from a harbor area, rather than with clean water from a growing area. Therefore, the Authority may waive the requirement for shellstock washing by the harvester when there are climatic, technical, or sanitary reasons for such action. In such event, the processor becomes responsible for washing shellstock.

It is necessary to protect the shellfish from pollution by disease-causing organisms that may be present in body wastes discharged from boats. This item is intended to protect the shellfish from chance pollution during harvesting. The likelihood of body wastes being discharged from boats will be considered in evaluating the sanitary quality of the harvesting area. If discharges are not adequately controlled, the area cannot meet the classification requirements for an approved harvesting area.

Licensing of each person who harvests shellfish for sale to a certified dealer is an important control measure to help protect against illegally harvested shellfish and to help maintain accurate source identity records. Harvesters must provide information necessary to create a record of the origin, quantity, and date of harvest that can be used to trace lots of questionable shellstock back to the source(s). Investigation of disease outbreaks can be severely hindered if the source of the shellfish cannot be readily identified. This can result in shellfish from the unacceptable source continuing to be used and continuing to cause illness. Health authorities may be forced to close safe areas, to ban safe shipments or to seize safe lots as a public health precaution if the source of contaminated shellfish cannot be accurately and rapidly determined.

Chapter IX. Transportation

Requirements for the Authority. Studies conducted during the period from pre-1925 to 1989 showed that the bacteriological examination of shellfish is an important *tool* in detecting: product mishandling; temperature abuse; and gross errors in growing area classification (1, 3, 4, 5, 6, 11, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170). The studies also demonstrated that shellfish will generally reflect the bacteriological quality of the water in which they have grown. However, this relationship is not consistent. Variation reflects differences in species and product forms and seasonal conditions at the time of harvest (1, 166). Some studies concluded that there is no single uniform bacteriological standard which could be applied to all species of shellfish (166).

Efforts to develop satisfactory bacteriological criteria for interstate shipments of shellfish (especially oysters) as received at the wholesale market level were begun in 1950 (169). During the period from 1950 to 1964, there were many studies conducted to determine the bacteriological changes associated with shellfish harvesting, shucking - packing and marketing. Throughout this period various coliform and plate count standards were developed under the NSSP. However, it wasn't until 1965, that the fecal coliform and standard plate count criteria were applied to all species of shucked oysters at the "wholesale market level" (wholesale market level not defined) (166). In 1968, the NSSP Workshop adopted these criteria, presumably for all species and product forms of oysters, clams and mussels (7).

Certified dealers are responsible to assure that shellfish purchased for direct sales, further shipments, or processing are safe and wholesome. The safety of shellfish is predicated on the cleanliness of the growing area waters from which they are obtained, and the sanitary practices applied during harvesting and shipping.

The positive relationship between sewage-polluted shellfish and enteric disease has been demonstrated many times (39, 64, 112, 113, 123). Because physiologically active shellfish pump and filter large quantities of water as part of their feeding process, rapid intake and concentration of bacteria, viruses, marine toxins, and other poisonous and deleterious substances may occur (93, 107, 119, 121, 127, 129, 164, 180, 181). Therefore, the shellfish may contain higher levels of chemical contaminants or pathogens than are found in the water in which they grow.

The shellfish-water bacteria ratio depends upon the shellfish species, water temperature, presence of certain chemicals, and varying physiological capabilities of the individual animals (107, 127,129). If the water in which the shellfish are grown is polluted, it may be assumed that the shellfish will also contain pathogenic bacteria or viruses capable of causing disease in man.

In addition, shellfish contaminated by added trace metals can result in illness to man if consumed in sufficient quantities (99, 183). Health hazards also may result from the presence of naturally occurring biotoxins produced by certain marine dinoflagellates (122, 144, 149, 184). The occurrence of these poisons is related to the concentration of toxic dinoflagellates in the growing area. The contamination of shellfish by these dinoflagellates usually occurs in well-defined areas

and, in some instances, only during certain seasons (122, 149) not widespread over all shellfish producing areas.

Cooking does not necessarily ensure safety of contaminated shellfish since, in ordinary cooking processes; shellfish may not be heated sufficiently to ensure a kill of pathogenic organisms, although a considerable reduction will take place (165, 177, 185). Also, normal cooking processes cannot be relied upon to destroy paralytic shellfish poison (149).

Certified dealers have three principal responsibilities to assure that the consumer receives a safe product. The first is to purchase only safe and wholesome raw products. The second is to maintain the product in a sanitary manner. The final responsibility is to ship the product under sanitary conditions. The tagging and shipping records requirements, the sanitary shipping practices requirements, and the raw product inspection requirements are necessary to fulfill these responsibilities.

Chapter X. General Requirements for Dealers

.01 General HACCP Requirements.

HACCP is a preventive system of hazard control. It consists first of an identification of the likely hazards that could be presented by a specific product, followed by the identification of the critical control points in a specific production process where a failure to control would likely result in a hazard being created or allowed to persist. These critical control points (CCP) are then systematically monitored, and records are kept of that monitoring. Corrective actions are also documented when problems occur.

The application of HACCP controls by the molluscan shellfish industry, coupled with inspections by Shellfish Control Authorities based on the HACCP system, are a more effective and efficient system for ensuring the safety of molluscan shellfish products than the traditional Good Manufacturing Practices-based system. Adoption of HACCP controls by the molluscan shellfish industry will provide a basis for enhanced consumer confidence in the safety of molluscan shellfish.

The first step in the HACCP process, called Hazard Analysis, should include an assessment of both the likelihood that a food safety hazard will occur and its severity if it does occur. To be addressed by the HACCP system, the hazards must be such that their prevention, elimination, or reduction to acceptable levels is essential to the production of safe food. Even factors beyond the control of the processor, such as how the food will be distributed and how it will be consumed, must be considered because these factors could influence how it should be processed. A hazard is a biological, chemical, or physical property that may cause a food to be unsafe.

All dealers must conduct a hazard analysis or have one conducted on their behalf. The hazard analysis need not be performed according to a standardized regime, nor must it be documented in writing for review by the State Shellfish Control Authority.

The hazard analysis must identify the hazard of pathogen contamination at the receiving CCP as a significant hazard for all raw, molluscan shellfish products. For this reason, all dealers must have and implement a written HACCP plan. Other hazards may also be identified (e.g., natural toxins, pesticides and environmental contaminants) at receiving and at other CCPs. In general, the CCPs identified in chapters XI.01, XII.01, XIII.01, and XIV.01 must be listed in HACCP plans for molluscan shellfish products. However, a dealer has the option to demonstrate, through the performance of a hazard analysis, that a particular hazard does not exist for a particular product or processing method, or that it can be controlled at another CCP in a manner that provides an equivalent level of public health protection. This option is not provided for the hazard of pathogen contamination at the receiving step.

In addition to listing the food safety hazards that are reasonably likely to occur in the food and the critical control points necessary to control these hazards, the HACCP plan must establish the critical limits for the preventive measures at each CCP. Critical limits can be thought of as boundaries of safety for each CCP. They may be derived from sources such as regulatory

standards and guidelines, literature surveys, experimental studies, and experts. In general, the critical limits listed in chapters XI.01, XII.01, XIII.01, and XIV.01 must be listed in HACCP plans for molluscan shellfish products. However, a dealer has the option to demonstrate that another critical limit provides an equivalent level of public health protection. This option is not provided for the hazard of pathogen contamination at the receiving step.

Monitoring procedures must also be included in the plan. Monitoring is a planned sequence of observations or measurements to assess whether a critical control point is under control and to produce an accurate record for future use in verification. Monitoring: 1) tracks the system's operation so that a trend toward a loss of control can be recognized, and a process adjustment can be made before a deviation occurs; and 2) indicates when loss of control and a deviation has actually occurred, and corrective action must be taken. Monitoring intervals must be frequent enough to permit the dealer to determine whether the hazard is under control.

While the HACCP system is intended to prevent deviations from a planned process from occurring, perfection is rarely, if ever achievable. When a deviation from a critical limit occurs, corrective action must be sufficient to: 1) ensure that no product enters commerce that is injurious to health or is otherwise adulterated as a result of the deviation; and 2) correct the cause of the deviation. These goals can be achieved by either predetermining what corrective actions will be taken when a critical limit failure occurs and then following those procedures, or following the minimum generic-type procedures described in X.01F(3).

The HACCP plan must also list the records that are necessary to document the result of monitoring at CCPs. These records must contain the actual values and observations obtained during monitoring. This requirement ensures that preventive monitoring is occurring in a systematic way.

.02 General Sanitation Requirements. General Sanitation Requirements apply to Chapters XI, XII, XIII, and XIV as appropriate to the activity being conducted and as required in the Model Ordinance: (1) Safety of Water for Processing and Ice Production; (2) Condition and Cleanliness of Food Contact Surfaces; (3) Prevention of Cross Contamination; (4) Maintenance of Hand Washing, Hand Sanitizing, and Toilet Facilities; (5) Protection from Adulterants; (6) Proper Labeling, Storage, and Use of Toxin Compounds; (7) Control of Employees with Adverse Health Conditions; (8) Exclusion of Pests.

.03 Other Model Ordinance Requirements. Other Model Ordinance Requirements apply to Chapters XI, XII, XIII, and XIV as appropriate to the activity being conducted: (1) Plants and Grounds; (2) Plumbing and Related Facilities; (3) Utilities; (4) Insect and Vermin Control; (5) Disposal of Other Wastes; (6) Equipment Construction for Non-Food Contact Surfaces; (7) Cleaning and Sanitizing of Non-Food Contact Surfaces; (8) Shellfish Storage and Handling; (9) Heat Shock; (10) Post-Harvest Processing; (11) Toxic Materials; (12) Personnel; (13) Supervision.

.04 Certification Requirements. A principal objective of the NSSP has been to provide a mechanism for health officials and consumers to receive information as to whether lots of shellfish shipped in interstate commerce meet acceptable and agreed upon sanitation and quality criteria. Although these requirements pertain only to interstate shipments, it is recommended that the same requirements be imposed on intrastate operations. To accomplish this, the NSSP includes criteria and procedures to assure that producing and processing states receive only product that has been grown, harvested, transported, processed, and/or shipped in compliance with NSSP guidelines. Certification is dependent on a dealer maintaining acceptable operational and sanitary conditions. The state must have adequate legal authority to regulate the sanitary requirements for harvesting, transporting, shucking-packing, and repacking of shellfish to be shipped interstate. This authority may be either a specific law or a regulation. The success with which the state is able to regulate all components of the shellfish industry provides a measure of the adequacy of the statutory authority.

The unique nature of shellfish as a food eaten whole and raw also makes it necessary that the Authority have authority to take immediate emergency action to halt sale and distribution of shellfish without recourse to lengthy administrative procedures. As an example, a state may find it necessary to detain lots of shellfish following reports of illness traced to a certain source of shellfish before confirmatory laboratory analysis can be conducted to document the causative agent. In taking such action, the responsible regulatory agency should be cognizant of the need to use rapid analytical methods for determining status of these highly perishable products. Periodic revisions of state shellfish laws or regulations may be necessary to cope with new public health hazards and to reflect new knowledge. Examples of changes or developments that have called for revision of state laws include the construction of depuration plants, changes in conservation laws, or the exploitation of a new resource.

State officials who certify dealers must fully comply with the requirements for certification for the process to remain viable. Certification is intended to provide an unbroken chain of sanitation control to a lot of shellfish from the moment of harvest to its sale at the wholesale or retail level. For the certification process to be effective, certified dealers must fully comply with the applicable sanitation requirements pertaining to the type of operation involved.

The minimum plant sanitation and management guidelines for interstate shellfish shippers are described in Model Ordinance Chapters XI., XII., XIII., XIV., and XV. Only those shellfish firms that meet the guidelines are eligible for certification as Interstate Shellfish Shippers and may be listed in FDA's monthly publication of the ICSSL. Plants having major non-conformities should not be certified and certified plants found to have major non-conformities should have their license or permits suspended or certification canceled. This "List" is mailed to over 6,000 persons to inform them of approved sources of shellfish. Food control officials throughout the United States use the "List" to determine that shellfish offered for sale or used in food service establishments have been produced under the sanitary guidelines of the NSSP. These officials are asked to rely upon the certification process by not holding up shipments or sales of shellfish lots pending examination.

Inspections of certified shellfish dealers should be conducted at such frequency as is necessary to assure compliance with NSSP requirements. The recommended frequency of inspection for shucker packers, repackers, and depuration plants when operating is at least monthly and for shellstock shippers and reshippers at least quarterly. To conduct effective inspections, it is necessary that inspectors have adequate equipment and supplies to measure compliance with applicable requirements. Since the type of equipment and supplies required for an inspection will vary with the type of establishment, it is recommended that a checklist of equipment be developed for each dealer classification.

.05-.07 Shellstock Identification, Shucked Shellfish Labeling, Shipping Documents and Records.

The NSSP requires that the product be identified with certain information showing that the shellfish were harvested by licensed diggers and shipped and processed by certified dealers. This information assists in tracing the product back through the distribution system to the growing area in the event the shellfish are associated with a disease outbreak. The requirement for placing the certificate number and date marking on the sidewall or bottom of durable containers holding 1873 ml (64 fluid ounces) or more is to discourage re-use of these containers for illegal purposes.

In case of an outbreak of disease attributable to shellfish, it is necessary that health departments and other appropriate state and federal agencies be able to determine the source of contamination, and thereby to prevent any further outbreaks from this source. This can be done most effectively by following the course of a shipment, through all the various dealers who have handled it, back to the point of origin by means of records kept by the shellfish dealers. Maintaining adequate records is considered by some industry members to be a burden. This has resulted in various unacceptable practices being encountered by health officials, including no written records of purchase, undated shippers tags maintained in an unordered manner, new shipping tags being placed on a lot without records to correlate the original identity of the lot with the new identity, and shellfish on the premises with no tags. Although these dealers often have "records" in the most general sense, these records are not in the form that meets the intent of the NSSP certification requirement to provide traceability on a lot-by-lot basis. As a result, follow-up investigations of disease outbreaks have been stymied, identification of the cause of the outbreak has been delayed, and outbreaks have continued. The NSSP Guide Section V, Suggested Forms, contains an example of a typical ledger that may be used to provide the required information.

An example where the failure to maintain adequate records was identified as one of the principal contributing factors to a series of continuing disease outbreaks was in 1981 and 1982. The outbreaks continued for several months and affected thousands of people. An investigation by the states involved and FDA revealed that some states were unable to enforce the record keeping and tagging requirements of the NSSP. FDA found in one state that approximately one-third or the certified dealers inspected failed to maintain adequate records. State officials realized that an improved labeling or manifest system was needed to track shellfish in the marketplace back to the distributor and to the digger. However, they also recognized that no single source identity

and record keeping system would be applicable to all situations in each state. Therefore, specific requirements should be developed by each state to achieve the NSSP requirements.

Additionally, the Federal Food, Drug and Cosmetic Act requires that food labels provide an accurate statement which includes the name and address of either the manufacturer, packer, or distributor; the net amount of food in the package; the common or usual name of the food; and the ingredients, unless the product conforms to standard of identity requirements. Foods shipped in interstate commerce having labels that do not meet these requirements are deemed misbranded and in violation of Section 405 of the Food, Drug and Cosmetic Act.

.08 Wet Storage in Artificial Bodies of Water.

The purposes of wet storage are the temporary storage of approved shellfish, desanding and improving palatability. Wet storage facilities are not designed and operated to increase safety of the shellfish. Therefore, all controls pertaining to shellfish for direct consumption should be applied.

The types, locations, and purposes of wet storage operation are highly variable and may range from temporary storage near shore in approved areas to onshore tanks using recirculating, synthetic seawater for the purpose of desanding and salt uptake. Consequently, it is not possible to provide detailed guidelines in the Model Ordinance and it is necessary for each separate operation to be developed and evaluated on its own merit with respect to overall program guidelines.

Removing shellfish from growing beds to storage areas close to shore and habitations may subject such shellfish to constant or intermittent pollution. Shellfish in wet storage tanks are similarly subjected to pollution if the tank water is obtained from a polluted source. An example of such contamination is the 1956 outbreak of infectious hepatitis in Sweden (691 cases) attributed to oysters contaminated in a wet storage area (65).

Shellfish on floats nearshore may be more directly exposed to potential contamination from boats and surface runoff than are shellfish in their natural growing areas. Therefore, particular emphasis should be placed on a sanitary survey of the vicinity to assure that chance contamination does not occur (176).

Careful consideration must be given to designing and operating onshore wet storage tanks to assure that shellfish are not contaminated during holding or do not die from physiological stresses such as low dissolved oxygen and unsuitable temperatures or salinity (132, 177). Excessive mud on the shells and dead shellfish may increase bacterial loads in the tanks and lead to increased microbial levels in the shellfish during storage. Hence, washing and culling the shellfish prior to storage is essential.

Proper hydraulic design of the tank is important to assure an adequate quantity and quality of water with minimum turbulence at suitable temperatures to achieve the intended purpose of the storage operation. Inadequate flow or "dead spots" can lead to oxygen deficiency and shellfish

mortality if the shellfish are physiologically active. Minimum turbulence will permit feces and pseudo feces generated by active shellfish to settle out without being resuspended and ingested. Tanks fabricated with safe material, which are easily cleanable, will prevent possible adulteration with chemicals migrating from the tank into the water and will facilitate cleaning and sanitizing.

Commingling of bivalve mollusks with other species in tanks may subject the bivalve mollusks to contamination from pathogenic organisms from the non-molluscan animals. Fish, crabs, lobsters, and other marine species may be harvested from polluted areas and may have ingested pathogens or accumulated them on their body surfaces. Therefore, holding such animals in the same tank with bivalve mollusks presents a risk of cross contamination. This risk can be avoided by using separate tanks for non-bivalve molluscan species. Where the same water is used for all tanks, effective disinfection must be provided prior to entering the tank holding the bivalve species.

Chapters XI, XII, XIII, and XIV. – SHELLFISH PROCESSING AND HANDLING

Requirements for Dealers.

.01 Critical Control Points. [NOTE: these Critical Control Points apply to Chapters XI, XII, XIII, and XIV as appropriate to the activity being conducted and as required in the Model Ordinance.]

A. Receiving Critical Control Point. Certified dealers are responsible to assure that shellfish purchased for direct sales, further shipments, or processing are safe and wholesome. The safety of shellfish is predicated on the cleanliness of the growing area waters from which they are obtained and the sanitary practices applied during harvesting and shipping. The positive relationship between sewage-polluted shellfish and enteric disease has been demonstrated many times. If the water in which shellfish are grown is polluted, it may be assumed that the shellfish will also contain pathogenic bacteria or viruses capable of causing disease in man. Harvesters and shippers must provide information necessary to create a record of the origin, quantity, and date of harvest, which can be used to trace lots of questionable shellfish back to the sources(s).

B. Shellstock Storage Critical Control Point. There is evidence that some pathogenic organisms will survive in shellfish for a considerable length of time after harvesting and that some bacterial pathogens may multiply in the absence of adequate refrigeration.

C. Processing Critical Control Point. The bacteria count of the final pack is related to the elapsed time after shucking when the shellfish are held at temperatures favorable to the rapid growth of bacteria. Factors which influence the length of time required to lower the temperature of shucked shellfish to 7.2°C (45□F) include the temperature of blower or other process water, the speed of the individual shucker or shucking machinery, the frequency with which the shucking containers are delivered to the packing room, ambient air temperature in the plant, and the temperature of the shellstock being shucked. To maintain optimum bacteriological quality, it is preferable that the elapsed time between shucking and cooling to a temperature of 7.2°C (45°F) does not exceed four hours. More rapid processing is very desirable.

D. Shucked Meat Storage Critical Control Point. Shucked shellfish are an excellent medium for the growth of bacteria. Thus, it is very important that the packaged shellfish be cooled and refrigerated promptly so that bacteria growth is minimized. Studies have shown that bacterial growth is significantly reduced at storage temperatures of less than 7.2°C (45°F) and that storage in wet ice is the most effective method for refrigeration of shucked meats.

.02 Sanitation Requirements. [NOTE: these General Sanitation Requirements apply to chapters XI, XII, XIII, and XIV as appropriate to the activity being conducted and as required in the Model Ordinance.]

A. Safety of Water for Processing and Ice Production. Water should be safe and sanitary to avoid contamination of food-contact surfaces and the product. Ice may become contaminated by

non-potable water or may become contaminated during freezing or in subsequent storage or handling. When non-hermetically sealed containers of shellfish are stored in unsanitary ice, a partial vacuum may form within the containers and draw water from the melting ice into the container and contaminate packed shellfish. Special attention should be given to ice used for direct contact chilling of shellfish meats to assure that the ice is of acceptable quality. Water used for shellstock washing should be of good quality, to avoid possible contamination of the shellstock. The organisms causing typhoid fever, hepatitis, and other gastrointestinal diseases may be present in the body discharges of cases or carriers, and thus be present in the drainpipes in the plants. Correctly installed plumbing protects the water supplies against cross connections and back siphonage.

B. Condition and Cleanliness of Food Contact Surfaces. Colanders, shucking pails, skimmers, blowers, and other equipment or utensils which come into contact with the shucked shellfish and which have cracked, rough, or inaccessible surfaces or are easily cracked or chipped, or which are made of improper material, are apt to harbor accumulations of organic material in which bacteria or other microorganisms may grow. These microorganisms may later cause illness among those who eat the shellfish, or spoilage in the shucked shellfish. Slime and foreign material, which accumulate in blower pipes below the liquid level, afford an excellent breeding place for bacteria. This material may be dislodged and forced into the batch of shellfish in the blower, thus increasing the bacterial content of the shellfish. Cleaned and sanitized equipment and utensils reduce the chance of contaminating shellfish during shucking and processing. Shellfish furnish an excellent growth medium for spoilage microorganisms, and small numbers of these microorganisms on improperly sanitized equipment may multiply to very high levels in the finished pack. Use of sanitizers is not effective unless the equipment is first thoroughly cleaned and rinsed.

C. Prevention of Cross Contamination. The nature of shellfish operations is such that the shellfish require protection from undesirable microorganisms, chemicals, filth, or other extraneous materials. This protection is achieved by properly selecting the plant location so that it is not contaminated by floodwaters. It is normal during shucking operations for shucker's clothing to become very soiled. If shuckers enter the packing room, shucked stock, cans, and other equipment may become contaminated. A delivery window has proven to be an effective means of keeping shuckers out of the packing room. If shellstock are stored where polluted ground or surface water or floor drainage can accumulate, the shellstock may become contaminated.

D. Maintenance of Hand Washing, Hand Sanitizing, and Toilet Facilities. Hand washing by employees is an important public health measure. Providing convenient, properly constructed and plumbed facilities, supplied with soap and towels encourages employees to wash hands frequently and correctly. Washing of hands with soap and drying with single service towels or a hand-drying device improves the sanitizing of the hands. Disease-causing microorganisms may be present in body discharges of employees that are cases or carriers of communicable disease organisms. When sewage disposal facilities are of a satisfactory type, there is less possibility that the shellfish being processed may become contaminated with fecal material carried by flies, rodents, or by other means.

E. Protection from Adulterants. Shielded light fixtures help protect the food, equipment, and employees from glass fragments should the fixture break. Ventilation, plumbing, and air intakes for blowers can all introduce adulterants into the area where shellfish are stored or processed. Care must be exercised to prevent the entrance or leakage of adulterants. Shellfish can also be contaminated by hydraulic fluid or other lubricants, dirt or other filth, or contaminated ice. Care must be used to prevent adulterants in these items from contacting shellfish.

F. Proper Labeling, Storage, and Use of Toxic Compounds. In order to reduce the potential for contamination, stored poisonous or toxic materials should be limited to those necessary to maintain the establishment. Proper labeling, use, storage, and handling are essential to prevent accidental contamination of shellfish and to assure the safety of workers and the consumer.

G. Control of Employees with Adverse Health Conditions. It is considered good public health practice for any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, to be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel should be instructed to report such health conditions to their supervisors.

H. Exclusion of Pests. Controlling flies, cockroaches, and other insects may prevent shellfish and food-contact surfaces from being contaminated with disease organisms. Controls should be directed at preventing the entrance of insects, rodents, and other vermin into the building, and at depriving them of food, water, and shelter.

.03 Other Model Ordinance Requirements.

A. Plants and Grounds. The plant and building facilities should be kept clean so as to minimize the chance of contamination of shellfish during processing. Rooms or lockers should be provided for clothing, aprons, and gloves to eliminate the tendency to store such articles on the shucking benches or in packing rooms, where they interfere with plant clean up and operations. Properly graded floors, of durable, impervious material, maintained in good condition, permit rapid disposing of liquid and solid wastes, and facilitate easy cleaning of the plant. Smooth, washable walls and ceilings are more easily kept clean and are, therefore, more

likely to be kept clean. A light colored paint or finish aids in the distribution of light and in the detection of unclean surfaces. Clean walls and ceilings are conducive to sanitary handling of shellfish. Maintaining the plant grounds and using physical barriers provides protection from filth, chemicals, microorganisms, or other extraneous materials. Miscellaneous equipment and articles may interfere with plant operations and make clean up more difficult.

B. Plumbing and Related Facilities. Adequate toilet and Hand washing facilities, including running water, soap, and sanitary drying facilities also are essential to personal cleanliness of the workers.

C. Utilities. Adequate lighting encourages and facilitates keeping rooms, equipment, and the product clean by making dirt and unsanitary conditions conspicuous. Comfortable working conditions increase the efficiency of the workers, and may promote sanitary practices. Adequate ventilation reduces condensation and aids in retarding the growth of mold. Excessive temperatures also promote growth of spoilage microorganisms in shellfish and on food-contact surfaces.

D. Insect and Vermin Control. Controlling flies, cockroaches, and other insects may prevent shellfish and food-contact surfaces from becoming contaminated with disease organisms. Controls should be directed at preventing the entrance of insects, rodents, and other vermin into the building, and at depriving them of food, water, and shelter. Fly control measures, such as insecticide spraying, may also be necessary on the shell pile.

E. Disposal of Other Wastes. Shellstock shipping and shucking facilities can protect against infestation by vermin if building entrances are protected, the grounds do not provide harborage, and there is no food available in the buildings or on the grounds. Removing shell and organic processing wastes from the plant and properly disposing of these wastes can play a key role in controlling vermin. Methods found to be suitable for removing these materials without contaminating the shucked product include conveyors, baskets, barrels, wheelbarrows, and shell drop-holes. When shells are to be temporarily piled or stored on the premises, special controls may be needed. Organic wastes, including culled shellfish, clam siphons, and surf and ocean quahog viscera, need to be discarded into separate containers from the shells in the plant during shucking. These wastes can then be disposed of separately from the shell at, for example, a landfill. Proper disposal and prompt removal of shell and non-edible wastes from the plant also makes it possible to keep the premises clean, and decreases the likelihood that any product or food-contact surfaces will become contaminated.

F. Equipment Construction for Non-Food Contact Surfaces. Unless shucking benches, stands, blocks, and stalls are made of smooth material and are easily cleaned, they will become very dirty and may contaminate the shellfish.

G. Cleaning of Non-Food Contact Surfaces. Determining an adequate cleaning procedure for facilities and equipment will depend upon which method of sanitizing is selected and what equipment and utensils are identified to be washed in a sink or washed "in place." Detergents and brushes, including special brushes that may be needed for cleaning equipment, such as blower lines, should be available. Cleaning and sanitizing of equipment and utensils should be initiated immediately after processing operations are finished. Postponing clean-up operations results in more difficult cleaning, creates conditions conducive to growth of bacteria and mold, which may not be completely removed, and may result in product contamination.

H. Shellfish Storage and Handling. The sanitary requirements for individual shellfish dealers are variable since they may engage in several different phases of processing and distribution. Some shellstock shippers may have only a truck that is used to ship shellstock from a harvester to a processor or the market. Other shippers must have a building where shellstock is stored, repacked, or labeled. Consequently, the applicable sanitary controls must be based on an evaluation of the individual characteristics of the operation. Single-service and single-use containers, which have not been stored and handled in a sanitary manner, may become contaminated and thus may contaminate the packaged shellfish. Unacceptable practices that can interfere with the prompt handling, packing, and refrigerating of shellfish include holding shucked meats at the shucking station for prolonged periods, return of overage to the shucker, and bench grading of shucked meat. Another frequently encountered unacceptable practice is soaking of shucked meats for prolonged periods in water for the purpose of increasing yield through uptake of fresh water by the shellfish.

I. Heat Shock. The primary objective of heat shock is to facilitate shucking of shellfish. Due consideration in developing the scheduled process must be given to a large number of factors which affect the heat shock process. Heat penetration into the shellfish will vary with species and size. Even regional variations in shell thickness and shape may affect the length of time required to reach the desired internal temperature. The temperature and time of exposure must be such that the adductor muscle is sufficiently relaxed to open easily but must allow the shellfish to remain alive. The scheduled process may be developed from studies conducted by the state, by a knowledgeable processor in cooperation with state shellfish control authorities, by shellfish experts such as university biologists, or by any other person with adequate knowledge of the technical control procedures. The person responsible for developing the scheduled process should retain all records of process operations so the FDA may review them and state shellfish control authority if questions arise regarding the adequacy of the scheduled process or its use.

J. Post-Harvest Processing. *Vibrio vulnificus* has been identified as an organism of concern to at-risk consumers of shellfish. Post-harvest treatments which can demonstrate that the process achieves end point criteria of non-detectable (<3 MPN/gram) for *Vibrio vulnificus* can provide a product that has a reduced level of risk for these at-risk consumers. Applying those processes enables the dealer to label treated products "Processed to reduce *Vibrio vulnificus* to non-detectable levels."

K. Toxic Materials. Proper labeling, use, storage, and handling are essential to prevent accidental contamination of shellfish and to ensure the safety of workers and the consumer.

L. Personnel. Disease producing agents may be carried on the hands of shuckers and packers unless proper Hand washing is practiced. Finger cots, gloves, and shields, unless effectively sanitized periodically, will accumulate bacteria that may contaminate the shucked shellfish. Employees handling shucked shellfish need to sanitize their hands as an added public health control practice.

M. Supervision. Hand washing by employees is an important public health measure. Unless someone is made specifically responsible for this practice, it is apt to be forgotten or overlooked. Similarly, one person must be responsible for plant clean up. In general, it is considered to be good practice to clearly assign supervisory personnel the responsibility for assuring compliance by all personnel with all requirements.

Chapter XV. Depuration

Requirements for the Authority

@.01 Administration

Depuration is intended to reduce the number of pathogenic organisms that may be present in shellfish harvested from moderately polluted (restricted) waters to such levels that the shellfish will be acceptable for human consumption without further processing. The process is not intended for shellfish from heavily polluted (prohibited) waters nor to reduce the levels of poisonous or deleterious substances that the shellfish may have accumulated from their environment. The acceptability of the depuration process is contingent upon the Authority exercising very stringent supervision over all phases of the process.

The depuration process shall be under the effective supervision of the Authority. The Authority shall have a management plan which details procedures for regulating the harvesting from restricted areas; controlling the transport of shellfish between the harvest area and to the depuration plant; approving plant design and operation, including subsequent changes; certifying and inspecting plants in accordance with the requirements of the *Model Ordinance*; and, prohibiting interstate shipments in the event that nonconformities are found which compromise the validity of the process. A Memorandum of Understanding (MOU) shall be developed between appropriate Authorities when more than one Authority is involved in the management plan.

Extensive administrative procedures are essential if the Authority is to adequately control a very complex operation such as depuration. There are numerous critical control points where significant deviation can result in the distribution of contaminated shellfish. Control over the harvesting areas is needed to ensure that the shellfish are not so contaminated that cleansing will be inadequate. Adequate control measures must be taken to prevent diversion of undepurated shellfish into the marketplace. Shellstock delivered to the depuration plant must be properly identified with information necessary to trace each harvest lot back to the harvest area, date of harvest, and harvester or group of harvesters.

Shellfish destined for depuration plants shall be protected as necessary during harvesting and transporting to prevent further contamination and undue physiological stress that could reduce the effectiveness of the depuration process. Thermal and physical shock can adversely affect the pumping action of shellfish and reduce the rate of elimination of microorganisms. Additional contamination of the shellfish during harvest could raise bacterial levels to such a point that adequate depuration will not occur. Thermal abuse may also cause bacterial levels to reach the point that depuration may not be effective in 48 hours. The types of protection that may be provided to prevent thermal abuse include; but, are not limited to: furnishing shade in warm weather; providing refrigeration in transit; ensuring rapid transit to the depuration plant; preventing freezing in cold weather; preventing breakage of shells; and, optimizing holding or storage time before depuration.

Depurated shellfish require an increased level of control compared to shellfish from approved areas because of the increased potential for contamination. These controls must include packaging and labeling that will serve to help identify the deputation cycle of each harvest lot and to deter illegal commingling of undepurated shellfish with depurated shellfish. Such controls include prohibition against commingling of harvest lots during packing, tags that identify the shellfish as being depurated, and a prohibition against repackaging after the shellfish leave the depuration plant. It is recommended that tamper-evident seals be used on the packages as a further deterrent. Design, construction and operation of the plant must adhere to guidelines established in the *Model Ordinance*. Finally, the inspection program must be adequate to detect critical deviations and to effect immediate correction or prevent the sale of suspect shellfish.

Requirements for the Deputation Processor

.01 Critical Control Points

A. Receiving Critical Control Point

Shellfish intended for deputation must be harvested only from growing areas meeting the water quality requirements for approved, conditionally approved, restricted, or conditionally restricted areas in the open status.

It has been amply demonstrated that shellfish harvested from prohibited areas should not be used for depuration. Depuration studies have been conducted on the relationship of initial levels of indicator bacteria and viruses to the levels of these indicators after varying lengths of time. These studies have indicated that consistent reductions of both bacteria and viruses to low levels can be achieved with moderately polluted shellfish, but satisfactory results cannot be obtained with heavily contaminated shellfish.

It is also essential that shellfish harvested from restricted or conditionally restricted areas be controlled so these shellfish are not illegally diverted and sold. This usually necessitates special procedures for monitoring harvest operations and tagging the shellfish. Methods that may be employed include the use of specially designed, labeled, or colored containers; or the use of colored or distinctly shaped tags. If shellfish are transported in bulk, other methods to distinguish the shellfish as originating from restricted or conditionally restricted areas may need to be employed. Recommended measures include continuous surveillance of the boat or truck, transporting in trucks sealed with a serially numbered, tamper-evident seal, or a count by the Authority of the quantity shipped and quantity received at the depuration plant.

B. Processing Critical Control Points

Depuration is a complex biological process. Individual species respond in different ways to various combinations of operational criteria including water turbidity, salinity and temperature, depth of shellfish in the baskets, and tank design. Consequently, it is necessary to establish process effectiveness on a continuous basis. Continuous process verification is accomplished by comparing the means and variability of end-product data from consecutive harvest lots for each species of shellfish harvested with species-specific critical limits for these parameters established empirically through extensive field work (82). The depuration process is considered to be verified or operating effectively for the harvest lot and species harvested if the end-product data meets these established species-specific critical limits. New harvest areas, harvest areas having little end-product data, and harvest areas which have failed process verification are all subject to addition, more rigorous requirements under the conditional protocol. This process is designed to prevent potentially adulterated shellfish from unproven or ineffective depuration from reaching the marketplace.

C. Finished Shellstock Storage Critical Control Point

Depurated shellfish must be stored in a manner that maintains quality and prevents the shellfish from becoming contaminated. Two options are available to meet this requirement. The first is to bring and maintain the product under appropriate temperature control (45ºF) by icing or refrigeration. In this way any low levels of bacteria that remain in the shellfish after depuration will be prevented from growing and reaching the point at which they may become harmful. The second option is to wet store depurated shellfish in waters of appropriate sanitary quality which meet the requirements of Chapters VII or X in the *Model Ordinance*.

.02 Sanitation

A. Safety of Water for Processing and Ice Production. The source of the process water and the water treatment system must be such that an adequate volume and quality of process water can be provided to accomplish effective depuration. Currently all plants in the United States use ultraviolet light (UV) for disinfection of process water. Numerous studies have shown UV treatment to be highly effective for inactivating bacteria and viruses provided the units are properly operated and maintained. In choosing a UV treatment system, consideration should be given as to whether the process water will be recirculating or flow through and whether the type of plant and flow rate are compatible with the UV treatment system.

As with any disinfection system, microbial inactivation is strongly dependent on the dose-time relationship which, for UV treatment is primarily a function of water depth and turbidity. Contact time is a function of the flow rate of the water and cross-sectional area or volume of the unit. In order for the UV lights to remain effective, the tubes must be kept clean to prevent

build-up of materials which reduce radiation intensity. The amount of radiation must be monitored and the UV tubes replaced when they are no longer effective.

Ozone has been used for many years in Europe for treating depuration process water. Care must be taken in using ozone or other chemicals which may react with organic and inorganic components in the water to form compounds which adversely affect physiological activity (69, 74). Disinfection with ozone and other chemicals could constitute a food additive situation requiring FDA approval before use.

Ice should be produced using potable water to avoid contamination. Care should also be exercised to avoid contamination of the ice during freezing or in subsequent storage and handling.

Shellfish washing should make use of water of good sanitary quality to avoid possible contamination or added contamination of the shellfish. Whatever the source, shellfish wash water must be of the sanitary quality of potable or drinking water .

B. Condition and Cleanliness of Food Contact Surfaces. The need to effectively clean and sanitize processing tanks, containers and pipes carrying process water is well established. The inadequate cleaning and sanitizing of process equipment can result in microorganisms being resuspended in the process water and increasing the bacterial loading to such a level that adequate depuration will not occur.

Processing tanks and containers used to hold shellfish that have cracked, rough or inaccessible surfaces, or made of improper material, are apt to harbor accumulations of organic material in which bacteria, including pathogens, may reside and grow. Such organisms can be regularly introduced into the system and these potentially may contaminate the shellfish. Surfaces, therefore, must be smooth and easily cleanable if bacteria are to be flushed out in the cleaning and sanitizing process. Uncleanable surfaces can result in inconsistent depuration effectiveness, and, possibly, the reintroduction of pathogens into the shellfish.

C. Prevention of Cross Contamination. Shellfish must be stored in a manner that will protect them from contamination while in dry storage and at transfer points. Employees should be encouraged to practice good personal hygiene, as they may be a source of cross-contamination.

D. Maintenance of Hand Washing, Hand Sanitizing, and Toilet Facilities. Adequate toilet, hand washing and sanitizing facilities must be provided. Hand washing by employees is an important public health measure. Providing convenient, properly constructed and plumbed facilities, supplied with soap and towels encourages employees to wash their hands frequently and correctly. Washing of hands with soap and drying with single service towels or a hand-drying device improves the sanitizing of the hands.

E. Protection from Adulterants. Shielded light fixtures help protect the shellfish from contamination with glass fragments should the fixture break. Ventilation, plumbing, and air intakes can all introduce adulterants into the area where shellfish are stored or processed. Shellfish can also be contaminated by hydraulic fluid or other lubricants, dirt or other filth, or contaminated ice. Care must be used to prevent adulterants from any source from contacting the shellfish or shellfish contact surfaces.

F. Proper Labeling, Storage, and Use of Toxic Compounds. In order to reduce the potential for contamination, stored poisonous or toxic materials should be limited to those necessary to maintain the plant. Proper labeling, use, storage, and handling are essential to prevent accidental contamination of shellfish and to assure the safety of workers and the consumer. Only those chemical agents necessary for plant operations shall be present in the plant and shall be used only in accordance with labeling.

G. Control of Employees with Adverse Health Conditions. It is considered good public health practice for any person who, by medical examination or supervisory observation, is shown to have, or appears to have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of shellfish, shellfish contact surfaces, or shellfish packaging materials becoming contaminated, to be excluded from any operations which could be expected to result in such contamination until the condition is corrected. Personnel should be instructed to report such health conditions to their supervisors.

H. Exclusion of Pests. Controlling flies, cockroaches, and other insects may prevent shellfish and shellfish contact surfaces from being contaminated with disease causing organisms. Controls should be directed at preventing the entrance of insects, rodents, and other vermin into the plant and at depriving them of food, water, and shelter.

. 03 Other Model Ordinance Requirements.

A. Plants and Grounds. Physical facilities of the plant including the processing system shall be kept in good repair, and are cleaned and sanitized as necessary. No miscellaneous equipment is stored in processing or holding areas. The plant and building facilities should be kept clean so as to minimize the chance of contamination of shellfish during processing. Rooms or lockers should be provided for clothing, aprons and gloves to eliminate the tendency to store such articles where they may interfere with plant cleanup and operations. Properly graded floors, of durable, impervious material, maintained in good condition, permit rapid disposing of liquid and solid wastes, and facilitate easy cleaning of the plant. Smooth, washable walls and ceilings are more easily kept clean and, therefore, are more likely to be kept clean. A light colored paint or finish aids in the distribution of light and in the detection of unclean surfaces. Clean walls and ceilings are conducive to sanitary handling of shellfish. Maintaining the plant grounds and using physical barriers provides protection from filth, chemicals, microorganisms, or other extraneous

materials. Miscellaneous equipment and articles may interfere with plant operations and make cleanup more difficult.

The grounds about a depuration plant must be free from conditions that may result in contamination of shellfish at any time during processing and storage. The plant building or structure shall be suitable in size, construction, and design to prevent contamination of shellfish by animals and other pests; to keep untreated and treated shellfish separate; and to facilitate adequate cleaning, sanitizing, operation, and maintenance of the depuration facilities. Processing tanks, containers, piping and conveyances must be enclosed within a protective structure.

It is essential that depuration plants be designed and constructed so shellfish will be adequately protected and consistently depurated. Research on the depuration process and experience gained in commercial facilities has led to some generally accepted standards that are critical for effective depuration. Other design and construction criteria are less clearly defined, and only general guidance is available. Additionally, the plant must be designed and constructed so adequate cleaning and sanitizing can be accomplished (36), and to facilitate proper operation.

B. Plumbing and Related Facilities. Adequate toilet and hand washing facilities, including running water, soap, and sanitary drying facilities are essential to personal cleanliness of the workers. Adequate floor drainage and backflow preventers are installed where appropriate. Drainage or waste pipes are not installed over shellfish processing or storage areas; nor, are they installed in areas in which shellfish containers and utensils are stored. Such precautions will minimize the potential for cross contamination.

C. Utilities. Adequate lighting encourages and facilitates keeping rooms, equipment, and the product clean by making dirt and unsanitary conditions conspicuous. Comfortable working conditions increase the efficiency of the workers, and may promote sanitary practices. Adequate ventilation reduces condensation and aids in retarding the growth of mold. Adequate ambient temperature control prevents excessive temperatures that promote growth of spoilage microorganisms and potential pathogens in shellfish and on shellfish contact surfaces.

D. Insect and Vermin Control. Controlling flies, cockroaches, and other insects may prevent shellfish and shellfish contact surfaces from becoming contaminated with disease causing organisms. Controls should be directed at preventing the entrance of insects, rodents, and other vermin into the plant and at depriving them of food, water, and shelter.

E. Disposal of Wastes. Depuration facilities can protect against infestation by vermin if building entrances are protected, the grounds do not provide harborage, and there is no food available in the plant or on the grounds. Removing shell culled shellfish and organic processing wastes from the plant and properly disposing of these wastes can play a key role in controlling vermin. Proper disposal and prompt removal of shell and non-edible wastes from the plant make

it possible to keep the premises clean and decreases the likelihood that any shellfish or shellfish contact surfaces will become contaminated.

F. Equipment Construction for Non-Food Contact Surfaces. Unless storage and handling equipment are made of smooth material and are easily cleaned, they will become very dirty and may contaminate the shellfish.

G. Cleaning of Non-Food Contact Surfaces. Cleaning of the depuration tanks and equipment must be performed in a manner and at a frequency that will preclude the potential for contamination of the shellfish or shellfish contact surfaces.

H. Shellfish Storage and Handling. Washing of shellfish prior to depuration rids shells of sand, mud, and detritus that may interfere with depuration and may make tank cleaning difficult. The type of harvest method may negate the need for additional washing however. At other times, thorough washing at the plant may be necessary to adequately remove mud. Depurated shellfish shall be washed and culled after depuration and packaged in clean containers fabricated from safe materials. Different harvest lots of shellfish must not be commingled during packing. After depuration, washing removes feces and pseudo-feces that may cling to shells and may recontaminate the shellfish meats during processing or consumption. Non-depurated shellfish must be stored in a manner that maintains their physiological ability to cleanse themselves and prevents post harvest contamination. Otherwise, depuration may not be effective. Depurated shellfish must be stored in a manner that will maintain their quality and prevent recontamination.

I. Personnel. Personnel are not allowed to store clothing or other belongings, eat, drink or smoke in areas where shellfish are processed or stored. Such activities could lead to cross contamination of the shellfish or shellfish contact surfaces.

J. Supervision. Management shall clearly designate a knowledgeable and competent individual to be present at the plant and be accountable that appropriate operating procedures and proper personal hygiene practices are followed. The supervisor will also maintain complete and accurate records that will permit each batch of depurated shellfish to be traced back to its source, and will account for all product sample results and measurements of critical parameters for each cycle. One person must be responsible for plant cleanup. In general, it is considered to be good practice to clearly assign supervisory personnel the responsibility for ensuring compliance by all personnel with all requirements.

K. Plant Operating Manual. The plant must prepare a written Depuration Plant Operations Manual (DPOM). A copy of this Manual must be kept in a location that is accessible to plant personnel responsible for the depuration activity. The DPOM will be kept current and contain all the information and records relevant to the operation of the depuration plant, and will be formatted to include the following:

(1) Introduction.
The introduction must contain information relative to the current status of the DPOM (create, revise, update, etc.), ownership of the plant, proposed schedule of operation, potential harvest areas and plant capacity.

(2) Description of the Facility.
The DPOM must contain site plan drawings for the plant, the facility layout including a detailed schematic of the entire depuration system, a schematic drawing of the process, shellfish flow diagram showing the movement of the shellfish throughout the plant, and a schematic of the process water delivery and distribution system. Essentially, the documentation provided should show that the plant has the capability to achieve effective depuration of the shellfish, provide adequate storage before and after depuration, and prevent commingling of both depurated and undepurated shellfish and treated shellfish from different harvest lots.

(3) Design Specifications of the Depuration Unit.
During design and construction of depuration systems, careful consideration must be given to hydraulic flow through the tank. Non-uniform flow may result in dead spots and oxygen depletion that lead to inadequate depuration at some locations in the tank. Choice of' design criteria may be based on existing studies or new studies which verify effectiveness of any new designs. Furfari reports accepted design criteria for tank loading rates, water flow, and container arrangement. Tank water volume is recommended to be at least 6,400 liters per cubic meter of shellfish (8 cubic feet of water per U.S. bushel) for hard clams and eastern oysters and 4,000 liters per cubic meter of shellfish (5 cubic feet per bushel) for soft clams. A minimum flow rate of 107 liters per minute per cubic meter of shellfish (1 gallon per bushel) is recommended to maintain adequate oxygen levels. A clearance space of at least 7.6 cm (3 inches) is recommended for separating containers of shellfish in the tanks and between the shellfish containers and the bottom and sides of the tanks.
Critical factors, such as water chemistry, tank dimensions, rate of flow, tank loading, and clearance between. Shellfish containers and tank walls must be controlled if the shellfish are to pump effectively and eliminate pathogenic organisms that may be present. The source of water and the water treatment system must be such that an adequate volume and quality of water can be provided to accomplish effective depuration. Currently, all plants in the United States use ultraviolet light for disinfection of process water. Numerous studies have shown UV treatment to be highly effective for inactivating bacteria and viruses provided the units are properly operated and maintained. In choosing a UV treatment system, consideration should be given to whether any pretreatment that may be needed to reduce turbidity is provided, whether the process water will be recirculating or flow through, and whether the type of plant and the flow rates are compatible with the UV treatment system. As with any disinfection system, microbial inactivation is strongly dependent on the dose-time relationship which for UV treatment.

is primarily a function of water depth and turbidity. Contact time is a function of flow rate of the water and the cross-sectional area or volume of the unit. In order for the UV lights to remain effective, they must be kept clean to prevent build-up of materials which reduce radiation intensity. The amount of radiation must be monitored and the UV tubes replaced when they are no longer effective.

(4) Laboratory to be Utilized for Microbial Analyses.
Sample analyses shall be conducted by a laboratory approved by the Authority pursuant to the requirements of Chapter III in the *Model Ordinance*. Use of an approved laboratory ensures the quality and reliability of the analytical results.

(5) Depuration Process Monitoring.
If shellfish are released for sale before they are adequately depurated, adulterated shellfish may reach the market. It is essential; therefore, to implement an adequate sampling program designed to determine if critical environmental conditions are being met and if the shellfish being released to the market meet accepted criteria. Extensive field-testing has resulted in a set of species-specific critical limits being established which indicate the effectiveness of depuration process. These limits are referred to as the Critical Limits for the Indices of Depuration Plant Performance.

(6) Standard Operating Procedures.
Since effective depuration is dependent upon the control of a wide range of interrelated variables, it is essential that a set of standard operating procedures (SOPs) be developed which specify the exact procedures to be used for every aspect of the depuration process from receipt of the shellfish to data analysis, labeling and tagging. Use of SOPs help to ensure that appropriate actions are taken at each stage in the depuration process. By so doing, the probability that effective depuration and safe handling will be achieved is considerably increased and the incidence of processing mistakes is minimized.

(7) Record Keeping.
It is essential that detailed identification information be maintained on all harvest lots and shipping containers of depurated shellfish. In the events that an outbreak of illness occurs, or a question arises concerning the product, responsible state and federal authorities must be able to trace the implicated shellfish back to a specific depuration cycle, and to the harvest area. Additionally, maintaining complete and accurate records of all transactions serves to promote business integrity wherein all harvesters, processors, and dealers are fully accountable for their product. Records of product samples and critical parameters within the plant are necessary to determine if the plant is operating in accordance with the DPOM. Plant records should be kept for at least two (2) years in order that adequate investigations can be conducted in the event of a suspected illness and in order that the Authority can make process reviews.

L. Process Verification

Depuration is a complex biological process. Individual species respond in different ways to various combinations of operational criteria including water turbidity, salinity and temperature, depth of shellfish in the baskets, and tank design (***Richards***). Consequently, it is necessary to establish process effectiveness on a continuous basis. Continuous process verification is accomplished by comparing the means and variability of end-product data for consecutive harvest lots for each species of shellfish with species-specific critical limits for these parameters established empirically through extensive fieldwork and referred to as the Critical Limits for the Indices of Depuration Plant Performance. The depuration process is considered to be verified or operating effectively for the harvest lot and species harvested if the end-product data meets the established species-specific critical limits for the Indices of Depuration Plant Performance.

New harvest areas, harvest areas having little end-product data, and harvest areas which have failed process verification are all subjected to additional, more rigorous requirements under what is known as the conditional protocol. This process is designed to prevent potentially adulterated shellfish from unproven or ineffective depuration from reaching the market.

References:

[1] Richards, G.P. 1988. Microbial Purification of Shellfish: A Review Depuration and Relaying. Journal of Food Protection **51**, 218-251.

[2] Furfari, S.A. 1982. Current Shellfish Purification Practices. Shellfish Sanitation Branch, Food and Drug Administration, Washington, D.C.

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IV. GUIDANCE DOCUMENTS

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CHAPTER I GENERAL

.01 EVALUATION STANDARDS

Background: 1995 Evaluation Standards Committee

As the result of an issue submitted at the 1994 ISSC annual meeting, the 1995 ISSC Evaluation Standards Committee was created. The Committee was charged with reviewing the standards of the Evaluation Research Society and making a recommendation to the ISSC as to whether these standards should be included in the NSSP and the form the inclusion should take. The Committee reviewed these standards as well as the American Evaluation Association's (AEA) *Guiding Principles for Evaluators*. The Committee recommended that the ISSC adopt the five principles of the AEA. The Committee consensus was that these principles should apply to all participants of the ISSC and should be included in the FDA state program evaluation manual currently in development. The Committee also submitted a resolution to the ISSC voting delegates recommending that the principles be adopted by the ISSC and that FDA incorporate these principles into its state program evaluation manual. The ISSC adopted the both the Committee's recommendation and resolution at its 1995 Annual meeting for use in the NSSP.

Evaluation Standards

In 1995, at its Annual Meeting, the ISSC adopted the following principles of the American Evaluation Association and requested that the Food and Drug Administration conduct its evaluations consistent with these principles.

- *Systematic Inquiry:* Evaluators conduct systematic, databased inquiries about whatever is being evaluated.
- *Competence*: Evaluators provide competent performance to stakeholders.
- *Integrity/Honesty:* Evaluators ensure the honesty and integrity of the entire evaluation process.
- *Respect for People:* Evaluators respect the security, dignity and self-worth of the respondents, program participants, clients, and other stakeholders with whom they interact.
- *Responsibilities for General and Public Welfare:* Evaluators articulate and take into account the diversity of interest and values that may be related to the general and public welfare.

02. PROCEDURES FOR INITIATING A NEW STATE PROGRAM UNDER THE NATIONAL SHELLFISH SANITATION PROGRAM

The requirements of the NSSP are contained in its Model Ordinance. Implementation of the Model Ordinance is a shared responsibility of federal, state, tribal and local governments and the shellfish industry. The Model Ordinance establishes the minimum requirements necessary to effectively manage and enforce an interstate program, and is written for ease of legal adoption at all levels of government. It is intended to be adopted by state and tribal regulators to address the interstate movement of shellfish. The Model Ordinance provides a uniform legal instrument for enforcement, better nationwide public health protection, and facilitates the shipment of high quality shellfish in interstate commerce.

The ISSC provides the formal structure wherein state regulatory authorities, with FDA concurrence, can change the Model Ordinance and establish other guidelines and procedures for the sanitary control of the shellfish industry. For additional Information concerning the origin of the Model Ordinance and the ISSC, see the historical overview by Clem (1994) and the NSSP Guide for the Control of Molluscan Shellfish (ISSC/FDA, 2002).

To ensure uniformity in the administration and implementation of the requirements of the NSSP Model Ordinance at the state and tribal regulatory agency level, the FDA reviews their programs on an annual basis. New state or tribal regulatory programs under the NSSP are required to have their proposed program reviewed prior to its initiation to assure that any shellstock produced under the state or tribal program for movement in interstate commerce meets the requirements of the Model Ordinance.

New State or Tribal Program

The Authority must apply to the FDA for evaluation and be found in conformity with the NSSP before initiating a state or tribal shellfish sanitation program or a new program element within an existing state or tribal program. The FDA will act on any application submitted by the Authority within 30 days. If the FDA has not acted within 30 days, the Authority may proceed with the new shellfish sanitation program.

When two or more State or tribal agencies will be involved in the sanitary control of the shellfish industry, a clear statement of each agency's responsibilities should be developed in the form of a memorandum of understanding. This administrative practice eliminates misunderstandings concerning agency responsibility and ensures that all aspects of shared program responsibility are addressed.

States and tribes are responsible for maintaining shellfish programs that conform to the requirements contained in the Model Ordinance. These requirements should be mandatory within each State program.

References

Clem, David. 1994. Historical Overview. In: *Environmental Indicators and Shellfish Safety*. Eds. C.R. Hackney and M.D. Pierson. Chapman and Hall, New York. pp. 1-29

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CHAPTER II. GROWING AREAS

01. TOTAL COLIFORM STANDARDS

@.02 Bacteriological Standards

Note: The National Shellfish Sanitation Program (NSSP) allows growing areas to be classified using either a total or fecal coliform standard. The NSSP further allows the application of either standard to different water bodies within the state. Once properly classified applying either standard for classification, the NSSP allows the use of the adverse pollution condition or the systematic random sampling strategy for routine classification monitoring as appropriate to the situation in the growing area. For maximum flexibility, a state may wish to adopt the use of both standards and both monitoring strategies as appropriate with each standard. At the Interstate Shellfish Sanitation Conference's annual meeting in 1992, Task Force II recommended that this portion of the *Model Ordinance* be codified according to the standard used and the monitoring strategy employed. The *Model Ordinance* has subsequently been recodified in this manner. This codification represents the delineation of the standards based on total coliforms. The division of the standards based on fecal coliforms is outlined in the main body of the *Model Ordinance* (Chapter IV).

A. General. Either the total coliform or fecal coliform standard shall be applied to a growing area.

B. Sampling Stations. The Authority shall ensure that the number and location of sampling stations is adequate to effectively evaluate all pollution inputs into the growing area.

C. Exceptions.

(1) Except for growing areas classified as prohibited, in any growing area where there are pollution sources which impact the water quality, a minimum of 30 samples, collected under various environmental conditions, shall be required to classify a growing area not previously classified under Chapter IV @ .03.

(2) Except for growing areas classified as prohibited, a minimum of 15 samples shall be required to classify any growing area not previously classified under Chapter IV @ .03 when there are no pollution sources impacting the water quality.

(3) The Authority is not required to apply the total coliform standard if a detailed study verified by laboratory findings demonstrates that the coliforms recovered from the growing area are not of direct fecal origin and do not indicate a public health hazard.

D. Standard for the Approved Growing Area Classification in the Remote Status.

(1) Water Quality. The bacteriological quality of every station in the growing area shall meet the total coliform standard below.

(2) Total Coliform Standard for the Remote Status. The total coliform geometric mean MPN of the water sample results for each sampling station shall not exceed 70 MPN per 100 ml; and not more than 10% of the samples shall exceed an MPN of:

(a) 230 MPN per 100 ml for a 5-tube, decimal dilution test;

(b) 330 MPN per 100 ml for a 3-tube, decimal dilution test; or

(c) 140 MPN per 100 ml for the 12-tube, single dilution test.

(3) Required Sample Collection.

(a) A minimum of 2 samples per sampling station shall be collected annually.

(b) A minimum of the most recent 15 samples collected per sampling station shall be used to calculate the geometric mean and 10% criteria of the data to determine compliance with the standard established for the approved classification of remote growing areas.

E. Standard for the Approved Classification of Growing Areas Affected by Point Source Pollution.

(1) Water Quality. The bacteriological quality of every station in the growing area shall meet the total coliform standard in E §. (2).

(2) Total Coliform Standard for Adverse Pollution Condition Monitoring. The total coliform geometric mean MPN of the water quality sample results for each sampling station shall not exceed 70 per 100 ml, and, not more than 10 % of the samples shall exceed an MPN of:

(a) 230 MPN per 100 ml for a 5-tube, decimal dilution test;

(b) 330 MPN per 100 ml for a 3-tube, decimal dilution test; or

(c) 140 MPN per 100 ml for the 12-tube, single dilution test.

(3) Required Sample Collection.

(a) A minimum of 5 samples shall be collected annually under adverse pollution conditions from each sample station in the growing area.

(b) A minimum of the most recent 15 samples collected under adverse pollution conditions from each sample station shall be used to calculate the geometric mean and 10% criteria of the data to determine compliance with this standard.

(c) Sampling station locations shall be adjacent to actual or potential sources of pollution.

F. Standard for the Approved Classification of Growing Areas Affected by Nonpoint Source Pollution.

(1) Exception. If the tidal stage increases the total coliform concentration, the Authority shall use sample results collected during that tidal stage to classify the area.

(2) Pollution Sources. Harvest waters shall be:

(a) Impacted only by randomly occurring, intermittent environmental events; and,

(b) Not impacted by discharges from sewage treatment facilities or combined sewer overflows.

(3) Water Quality. The bacteriological quality of every station in the growing area shall meet the total coliform standard in §F (4) or §F (6) as appropriate to the monitoring strategy being used.

(4) Total Coliform Standard for Systematic Random Sample Monitoring. The total coliform geometric mean of the water sample results for each sampling station shall not exceed 70 MPN per 100 ml and the estimated 90^{th} percentile shall not exceed an MPN of:

(a) 230 MPN per 100 ml for a 5-tube, decimal dilution test;

(b) 330 MPN per 100 ml for a 3-tube, decimal dilution test; or

(c) 140 MPN per 100 ml for a 12-tube, single dilution test.

(5) Estimated 90th Percentile. The estimated 90th percentile shall be calculated by:

(a) Determining the geometric mean and logarithmic (base 10) standard deviation for the sample result from each sampling station; then

(b) Multiplying the log standard deviation in (a) by 1.28; and

(c) Adding the product from (b) to the log mean of sample results, and;

(d) Taking the antilog of the results in (c) to get the estimated 90th percentile.

(e) MPN values that signify the upper or lower range of sensitivity of the MPN test used in the 90th percentile calculation shall be increased or decreased by one significant digit.

(6) Total Coliform Standard for Adverse Pollution Condition Monitoring. The total coliform geometric mean MPN of the water sample results for each sample station shall not exceed 70 MPN per 100 ml and not more than 10% of the samples shall exceed an MPN of:

(a) 230 MPN per 100 ml for a 5-tube, decimal dilution test; or

(b) 330 MPN per 100 ml for a 3-tube, decimal dilution test; or

(c) 140 MPN per 100 ml for a 12-tube, single dilution test.

(7) Required Sample Collection.

(a) Adverse Pollution Condition Monitoring. The Authority shall collect samples at the same frequency as described in §E. (3) for application of the standard under §E. (2).

(b) Systematic Random Sample Monitoring. The requirement for systematic random sample monitoring shall be met when:

(i) Sample station locations are adequate to produce the data to effectively evaluate all nonpoint sources of pollution;

(ii) Sample collection is scheduled sufficiently far in advance to support random collection with respect to environmental conditions. Compliance requires that prior to implementation, the schedule for random sampling shall be documented in the master file for the growing area and adhered to. If conditions at the time of scheduled sample collection are hazardous to the safety of the individuals assigned to collect samples, sample collection shall be rescheduled in accordance with provisions in the sampling schedule;

(iii) A minimum of 6 random samples shall be collected annually from each sampling station in the growing area; and

(iv) A minimum of the 30 most recent randomly collected samples from each sampling station shall be used to calculate the geometric mean and 90th percentile to determine compliance with this standard.

(c) Transition from Adverse Pollution Condition Monitoring to Systematic Random Sample Monitoring. If the Authority:

(i) Does not have 30 recent randomly collected sample results from each station, then the previous 15 samples collected under adverse pollution conditions may be used with the most recent random samples to meet the minimum 30 sample requirements for a transition period not to exceed 3 years; and

(ii) Uses the transition period described in (i), as additional random samples are collected, the random samples shall chronologically replace the samples collected under adverse pollution conditions (e.g. sample 31 replaces sample 1).

G. Standard for the Restricted Classification of Growing Areas Affected by Point Source Pollution and Used as a Shellfish Source for Shellfish Depuration.

(1) Water Quality. The bacteriological quality of every sample station in the growing area shall meet the total coliform standard in §G. (2).

(2) Total Coliform Standard for Adverse Pollution Condition Monitoring. The total coliform geometric mean MPN of the water sample results for each station shall not exceed 700 per 100 ml and not more than 10% of the samples shall exceed an MPN of:

(a) 2,300 MPN per 100 ml for a 5-tube, decimal dilution test; or
(b) 3,300 MPN per 100 ml for a 3-tube, decimal dilution test; or
(c) 1,386 MPN per 100 ml for a 12-tube, single dilution test.

(3) Required Sample Collection. Samples shall be collected in accordance with §E. (3).

H. Standard for the Restricted Classification of Growing Areas Affected by Nonpoint Source Pollution and Used as a Shellfish Source for Shellfish Depuration.

(1) Exception. If the tidal stage increases the total coliform concentration, the Authority shall use samples collected under that tidal stage to classify the area.

(2) Pollution Sources. Growing areas shall meet the requirements in §F. (2).

(3) Water Quality. The bacteriological quality of every sample station in the growing area shall meet the total coliform standard in §H. (4) or §H. (6) as appropriate to the monitoring strategy being used.

(4) Total Coliform Standard for Systematic Random Sample Monitoring. The total coliform geometric mean MPN of the water sample results for each sample shall not exceed 700 per 100 ml and the estimated 90^{th} percentile shall not exceed:

(a) 2.300 MPN per 100 ml for a 5-tube, decimal dilution test; or
(b) 3,300 MPN per 100 ml for a 3-tube, decimal dilution test; or,
(c) 1,386 MPN per 100 ml for a 12-tube, single dilution test.

(5) Estimated 90^{th} percentile. The estimated 90^{th} percentile shall be calculated by the same method described in §F. (5).

(6) Total Coliform Standard for Adverse Pollution Condition Monitoring. The total coliform geometric mean MPN of the water sample results for each station shall not exceed 700 MPN per 100 ml and not more than 10% of the samples shall exceed an MPN of:

(a) 2,300 MPN per 100 ml for a 5-tube, decimal dilution test; or
(b) 3,300 MPN per 100 ml for a 3-tube, decimal dilution test; or
(c) 1,386 MPN per 100 ml for a 12-tube, single dilution test.

(7) Required Sample Collection.

(a) Adverse Pollution Condition Monitoring. The Authority shall collect samples at the same frequency as described in §E. (3). for application of the standard under §H. (6).

(b) Systematic Random Sample Monitoring. The Authority shall collect samples in the same manner and at the same frequency as specified in §F. (6)(b) for application of the standard under §H. (4).

02. GUIDANCE FOR DEVELOPING MARINE BIOTOXIN CONTINGENCY PLANS

NSSP guidance documents provide the public health principles supporting major components of the NSSP and its Model Ordinance, and summaries of the requirements for that component. NSSP *Model Ordinance* requirements apply only to interstate commerce although most states apply the requirements intrastate. For the most up to date and detailed listing of requirements, the reader should consult the most recent edition of the Model Ordinance.

Introduction

Shellfish are filter feeders and, therefore, they have the ability to concentrate toxigenic dinoflagellates from the water column when present in shellfish growing waters. The toxins produced by these dinoflagellates can cause illness and death in humans. Toxins are accumulated in the viscera and/or other tissues of shellfish and are transferred to humans when the shellfish are eaten (Gordan et al, 1973). These toxins are not normally destroyed by cooking or processing and cannot be detected by taste. Most of these toxins are detected through animal testing. However, some involve the use of instrument based or biochemical analyses for detection. Since the dinoflagellates are naturally occurring, their presence in the water column or traces of their toxin in shellfish meat does not necessarily constitute a health risk, as toxicity is dependent on concentration (dose) in the shellfish. To protect the consumer, the Authority must evaluate the concentration of toxin present in the shellfish or the dinoflagellate concentration in the water column against the levels established in the NSSP Model Ordinance to determine what action, if any, should be taken.

There are three types of shellfish poisonings which are specifically addressed in the NSSP Model Ordinance: paralytic shellfish poisoning (PSP), neurotoxic shellfish poisoning (NSP) and amnesic shellfish poisoning (ASP), also known as domoic acid poisoning. All three are dangerous toxins, and PSP and ASP or domoic acid can cause death at sufficiently high concentrations. In addition, ASP can cause lasting neurological damage. PSP is caused by dinoflagellates of the genus *Alexandrium* (formerly *Gonyaulax*). NSP is caused by brevetoxins produced by the dinoflagellates of the genus *Karemia* (formerly *Gymnodinium*). Both of these dinoflagellates can produce “red tides”, i.e. discolorations of seawater caused by blooms of the algae. Toxic blooms of these dinoflagellates can occur unexpectedly or follow predictable patterns. The unpredictably in occurrence of toxic blooms was demonstrated in New England in 1972 when shellfish suddenly became toxic in a previously unaffected portion of the coastline and resulted in many illnesses (Schwalm.1973). Historically, *Alexandrium* blooms have occurred between April and October along the Pacific coasts from Alaska to California and in the Northeast from the Canadian Provinces to Long Island Sound (U.S. Public Health Service, 1958); but these patterns may be changing. The blooms generally last only a few weeks and most shellfish (with the exception of clams which retain the toxin for longer periods) clear themselves rapidly of the toxin once the bloom dissipates. NSP, which is less common, has occurred from the Carolinas and extends throughout the Gulf Coast states. It shows no indication of regular recurrence and shellfish generally take longer to eliminate the toxin (Liston, 1994).

The minimum concentration of PSP toxin that will cause intoxication in susceptible persons is not known. Epidemiological investigations of PSP in Canada, however, have indicated 200 to 600 micrograms of PSP toxin will produce symptoms in susceptible persons. A death has been attributed to the ingestion of a probable 480 micrograms of PSP toxin. Investigations indicate that lesser amounts of the toxin have no deleterious effects on humans. Shellfish growing areas should be closed at a PSP toxin level, which provides an adequate margin of safety, since in many instances PSP toxicity levels can change rapidly. The NSSP Model Ordinance requires that growing areas be placed in the closed status when the PSP toxin concentration is equal to or exceeds the action level of 80 micrograms per 100 grams of edible portion of raw shellfish (FDA, 1977; FDA, 1985).

In shellfish growing areas where low levels of PSP routinely occur, harvesting for thermal processing purposes may be an alternative to consider. Thermal processing as defined by applicable FDA regulations (21 CFR 113) will reduce but not entirely destroy the PSP content of the shellfish. If thermal processing is practiced, the Authority must develop and implement procedures to control the harvesting and transportation of the affected shellfish to the processing plant.

In Gulf coast areas, toxicity in shellfish has been associated with red tide outbreaks caused by massive blooms of the toxic dinoflagellate, Karemia brevis. The most common public health problem associated with *Karemia* blooms is respiratory irritation; however, neurotoxic shellfish poisonings associated with *Karemia* brevis blooms have been reported in Florida (Center for Disease Control, 1973 [a] and [b]). Uncooked clams from a batch eaten by a patient with neurotoxic symptoms were found to contain 118 mouse units per 100 grams of shellfish meat. The NSSP Model Ordinance mandates that growing areas be placed in the closed status when any NSP toxin is found in shellfish meat, or when the cell counts for members of the genus Karemia in the water column exceed 5,000 cells per liter of water.

ASP is caused by domoic acid, which is produced by diatoms of the genus *Pseudonitzachia*. Blooms of *Pseudonitzachia* are of relatively short duration. However, during the 1991-1992 incident in Washington, high toxin levels persisted for several months (Liston, 1994). The NSSP Model Ordinance requires that growing areas be placed in the closed status when the domoic acid concentration is equal to or exceeds 20 parts per million in the edible portion of raw shellfish.

The suitability of some growing areas for shellfish harvesting is periodically influenced by the presence of PSP, NSP, domoic acid, or other marine biotoxins. The occurrence of these toxins is often unpredictable, and the potential for them to occur exists along most coastlines of the United States and other countries having shellfish sanitation Memoranda of Understanding (MOU) agreements with the United States. As a result, states or countries with MOUs with the U.S. need to make contingency plans to address shellfish-borne intoxications.

Controlling Marine Biotoxins in Shellfish

The contingency plan must describe administrative procedures, laboratory support, sample collection procedures, and patrol procedures to be implemented on an emergency basis in the event of the occurrence of shellfish toxicity (Wilt, 1974). The primary goal of this planning should be to ensure that maximum public health protection is provided. To achieve this goal the following objectives should be met:

- An early warning system should be developed and implemented.

- Procedures should be established to define the severity of occurrences.

- The state or MOU country should be able to respond effectively to minimize illness.

- Adequate intelligence and surveillance information should be gathered and evaluated by the Authority.

- Procedures should be instituted to return the biotoxin contaminated areas to the open status of their growing area classification.

Under the certification provisions of the NSSP, FDA and receiver states should have the assurance that shellfish producing states or MOU countries are taking and can take adequate measures to prevent harvesting, shipping, and consumption of toxic shellfish. To provide this assurance, the NSSP requires the Authority to develop and adopt a marine biotoxin contingency plan for all marine and estuarine shellfish growing areas. The Authority's plan should specify how each of the objectives listed above will be accomplished. This document provides recommended guidelines to be used in preparing a plan to meet these objectives.

Recommended Contingency Plan Guidelines

- *Provide an early warning system:*

    1. Communication procedures should be established with other appropriate agencies to rapidly report to the Authority any abnormal environmental phenomenon that might be associated with shellfish growing areas such as bird or fish kills, water discoloration or abnormal behavior of shellfish or marine scavengers.
    2. The Authorities should establish procedures for health agencies to report any toxin-like illnesses.
    3. An early warning phytoplankton and/or shellfish-monitoring program should be implemented. These monitoring programs should use the "key station" (for both phytoplankton and shellfish monitoring) and "critical species" concepts (for shellfish monitoring).

- Sampling stations should be located at sites where past experience has shown toxin is most likely to appear first.

• When monitoring shellfish, samples should be collected of species which are most likely to reveal the early presence of toxin and which are most likely to show the highest toxin levels. For example, mussels have been found to be useful for early PSP detection.
• The frequencies and periods for collection of samples should be established recognizing the randomness of PSP blooms. This assumes several years of baseline data in order to establish stations and sampling plans.
• Frequency of sampling should be adequate to monitor for fluctuations in coastal phytoplankton populations.

4. Channels of communication concerning shellfish toxicity should be established with other states, countries (in the case of MOU countries), FDA, and other responsible officials. A marine biotoxin control official should be designated by the Authority to receive and distribute all marine biotoxin related information. Consultation with adjacent jurisdictions, marine biologists and other environmental officials might also be useful (Felsing, 1966; Quayle, 1969; Prakash et al., 1971)

• *Define the severity of the problem:*

1. A procedure should be established to promptly expand the sampling program for marine biotoxins in the event of increased toxicity/cell counts at any indicator monitoring stations identified within the plan. Sampling stations and frequencies of sampling should be increased when monitoring data or other information suggests that toxin levels are increasing. The procedure should include plans for obtaining the additional resources necessary to implement the expanded sampling and laboratory analysis program.

2. Information should be available concerning the location of commercial shellfish resource areas in the state.

3. Criteria should be developed to define the circumstances under which growing areas will be placed in the closed status because of marine biotoxin contamination. The criteria should integrate public health, conservation, and economic considerations. Principal items of concern include consideration of the rapidity with which toxin levels can increase to excessive levels, the inherent delays in sample collection, the number of samples required to initiate action, the size of the area to be closed (including a safety zone), and the type of harvesting restrictions to be invoked (all species or specific species). It may be appropriate to close harvesting areas adjacent to known toxic areas until increased sampling can establish which areas are toxin free and that toxin levels have stabilized.

Procedures should be established to promptly identify which shellfish products or lots might be potentially contaminated, and to determine the distribution of these products or lots.

- *Respond effectively to minimize illness:*

  1. A summary should be provided citing the laws and regulations in the state (or MOU country) that promptly and effectively allow the Authority to restrict harvesting, withdraw interstate shipping permits, and to embargo/recall any potentially toxic shellfish already on the market in the event of a marine biotoxin episode. The plan should clearly define the timeframe involved in taking appropriate legal action.

  2. The administrative procedures necessary to place growing areas in the closed status, to withdraw interstate certification of dealers, and to embargo and recall shellfish should be delineated. The timeframe necessary to accomplish these actions should also be specified.

  3. A plan should be developed which will define what type of patrol program is necessary to properly control harvesting in toxin contaminated growing areas. The program should be tested to ensure prompt implementation in the event it is needed.

  4. Procedures should be developed to promptly disseminate information on the occurrences of toxic phytoplankton blooms to the industry and local health agencies.

  5. Procedures should be established to coordinate control activities taken by state and federal agencies or departments and district, regional, or local health authorities.

- *Gather follow-up data:*

  1. Appropriate records of illnesses should be compiled and maintained by the Authority. These records should include data on the incidence of illness and appropriate case history data. This information may be important in defining the severity of the problem, as well as for a retrospective evaluation of the adequacy of the entire control program.

  2. Records of shellfish sample results from toxin testing should include analysis of trends, detoxification curves, phytoplankton and water sample analyses, and pertinent environmental observations.

- *Return growing areas to the open status of their NSSP classification:*

  1. Once a growing area is placed in the closed status because of marine biotoxin contamination, a procedure should be instituted to gather data necessary to decide when the area can be returned to the open status of its classification. A system of representative samples to establish detoxification curves should be part of this procedure.

  2. The Authority should develop a set of criteria that must be met before a growing area can be returned to the open status. These criteria should integrate public health,

conservation, and economic considerations, and employ a sufficient number of samples and other environmental indices, if used, to establish that the level of toxin or cell counts are below the closure level. For example, experience has shown that appropriate reopening criteria for PSP include a minimum of three samples collected over a period of at least 14 days. These samples should show the absence of PSP or levels below 80 micrograms per 100 grams of shellfish tissue.

3. A program of consumer education should be continued as long as any area remains in the closed status because of marine biotoxin contamination.

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03. SANITARY SURVEY AND THE CLASSIFICATION OF GROWING WATERS

NSSP guidance documents provide the public health principles supporting major components of the NSSP and its Model Ordinance, and summaries of the requirements for that component. NSSP Model Ordinance requirements apply only to interstate commerce although most states apply the requirements intrastate. For the most up to date and detailed listing of requirements, the reader should consult the most recent edition of the Model Ordinance.

Oysters, clams, mussels and scallops are filter feeders that pump large quantities of water through their bodies when actively feeding. During this process, molluscan shellfish can concentrate microorganisms, toxigenic micro-algae and poisonous or deleterious substances from the water column when they are present in the growing waters (Kennedy *et al.*, 1996). Concentrations in the shellfish may be as much as 100 times that found in the water column. If human pathogens are concentrated to an infective dose, and if the shellfish are consumed raw or partially cooked, human disease can result. If toxigenic micro-algae are present and producing toxin, human illness or death can occur, and cooking is not reliable as an effective barrier against intoxication.

The goal of the NSSP is to control the safety of shellfish for human consumption by preventing harvest from contaminated growing waters. In implementing this concept, the NSSP uses five classifications for growing areas: approved, conditionally approved, restricted, conditionally restricted, and prohibited. The placement of a growing area in any one classification is based upon the growing area's conformance with the requirements established for that classification. Conformance with a classification's requirements is established through the sanitary survey.

The positive relationship between sewage pollution of shellfish growing areas and disease has been demonstrated many times (Rippey [a] and [b], 1994). Shellfish-borne infectious diseases are generally transmitted through a fecal-oral route (i.e., the shellfish become contaminated by sewage and are eaten by humans). The pathway can be quite circuitous. The cycle usually begins with fecal contamination of the growing waters. Feces deposited on land surfaces can release pathogens into surface waters via storm water runoff or collected wastes can be discharged directly into a waterway. The runoff or discharge may go directly into the growing area or indirectly as is the case with wastes transported by freshwater streams to estuarine or marine waters. Information concerning the relationship between sewage pollution of bivalve shellfish growing areas and human disease is available in several good summaries (Hackney and Potter 1994 [a] and [b]; Jaykus *et al*, 1994; Stelma and McCabe, 1990).

Epidemiological investigations of shellfish-caused disease outbreaks have found difficulty in establishing a direct cause and effect between a numerical correlation and pollution source strength, bacteriological quality of water, and the degree of hazard to health. Tidal fluctuations and pollution source variations contribute to a high degree of variability in water quality. Investigations made from 1914 to 1925 by the states and the Public Health Service, a period when disease outbreaks attributable to shellfish were more prevalent, indicated that typhoid fever or other enteric diseases would not ordinarily be attributed to shellfish harvested from water in which not more than 50 percent of the 1 cc (cubic centimeter) portions of water examined were

positive for the coliform group (an MPN of approximately 70 per 100 ml), provided the areas were not subject to direct contamination with small amounts of fresh sewage which could not be detected by bacteriological examination.

Following the oyster-borne typhoid outbreaks during the winter of 1924-25 in the United States (Lumsden, 1925), the National Shellfish Certification Program, now the National Shellfish Sanitation Program (NSSP), was initiated by the states, the Public Health Service, and the shellfish industry (Frost, 1925). The 1925 criteria for safe growing areas were stated as: (1) the area is sufficiently removed from major sources of pollution so that the shellfish would not be subjected to fecal contamination in quantities which might be dangerous to the public health, (2) the area is free from pollution by even small quantities of fresh sewage, and (3) bacteriological examination does not ordinarily show the presence of the coli-aerogenes group of bacteria in 1 cc dilutions of the growing area water. The collective application of these criteria was known as the sanitary survey, which was used to determine if an area was safe for shellfish harvesting for human consumption. These criteria were adopted in the United States in 1925. Reliance on these criteria and others to measure excess variability in water quality were combined together with sanitary reconnaissance (shoreline survey), hydrographic and meteorological considerations, and patrol of closed harvest areas has generally proven effective in preventing major outbreaks of disease transmitted by the fecal-oral route. For a complete discussion of the history of the NSSP, see the historical overview by David Clem (1994) and the NSSP Guidance Document, *History of the Interstate Shellfish Sanitation Program* (ISSC/FDA, 2002).

The ability of shellfish to concentrate chemical pollutants from water and sediment can lead to accumulation of these poisonous and deleterious substances to levels that constitute a public health hazard (Kurland *et al.*, 1960; Texas Dept. Of Health, 1977). These poisonous or deleterious substances may enter shellfish growing areas through industrial or domestic waste discharges, seepage from waste disposal sites, agricultural land, geochemical reactions, or naturally occurring toxigenic micro-algae (O'Connor and Beliaeff, 1995; Liston, 1994). The degree to which these substances are concentrated depends upon such variables as the species of shellfish, water temperature and salinity, the level of contaminants in the waters, and the physiological conditions of the shellfish (Capuzzo, 1996; Roderick and Schneider, 1994; Rosijadi, 1996). The potential public health hazard posed by these substances must also be considered in assessing the safety of shellfish growing areas.

For a full discussion of the public health risk associated with micro-toxigenic algae, see the NSSP Guidance Document, *Guidelines for Developing a Marine Biotoxin Contingency Plan* (ISSC/FDA, 2002).

Components of the Sanitary Survey

A review of epidemiological investigations of disease outbreaks attributable to the consumption of bivalve shellfish reveals that three general situations occur in the contamination of growing areas placed improperly in the approved classification. First, improperly conducted or outdated sanitary surveys or misapplication of water quality data have unwittingly allowed harvesting from sewage contaminated growing areas. Second, fresh fecal material present and not diluted,

diffused, or not detected by ordinary bacteriological sampling procedures caused shellstock contamination (Lumsden, 1925). Dr. Gurion recognized the possibility of chance contamination as early as 1902 in his report on a typhoid outbreak:

"There is a zone of pollution established by the mere fact of the existence of a populated city upon the banks of a stream or tidal estuary which makes the laying down of oysters and clams in these waters a pernicious custom if persisted in, because it renders these articles of food dangerous at times, and always suspicious (Gurion, 1917)."

Third, shellfish illnesses have been traced back to areas where an intermittent pollution source contaminated the shellfish. Some of these areas could have been placed in the conditionally approved classification and managed to avoid harvest of polluted shellstock, provided the occurrences of the sources of pollution could be predicted and the boundaries of their effects determined. For a full discussion of the use of the conditional classifications, see the NSSP Guidance Document, *Management Plans for Growing Areas in the Conditional Classifications* (ISSC/FDA, 2002).

The first critical control point in preventing food-borne illness from shellfish consumption is identifying growing areas of acceptable sanitary quality. The completion of a sanitary survey is of paramount importance in making the distinction between acceptable and unacceptable growing areas, and is the key to accurate growing area classification as approved, conditionally approved, restricted, conditionally restricted, or prohibited. Under the NSSP Model Ordinance, a sanitary survey is required for each growing area prior to its approval by the state as a source of shellfish for human consumption or as a source for shellfish to be used in a depuration or relay operation. A sanitary survey is an in-depth evaluation of all environmental factors that have a bearing on the water quality in a shellfish growing area. The environmental factors include both actual and potential pollution sources, whether natural or man-made, and meteorological and hydrographic characteristics of the growing area. The principal components of a sanitary survey are: (1) identification and evaluation of the pollution sources that may affect the areas, (2) an evaluation of the meteorological factors, (3) an evaluation of hydrographic factors that may affect distribution of pollutants throughout the area, and (4) an assessment of water quality. For a complete discussion of the sanitary survey, see *Sanitary Surveys of Growing Waters* (Garreis, 1994).

(1) An evaluation of the pollution sources that may affect the growing areas. A pollution source survey (also known as a shoreline survey) must be conducted of the growing area shoreline and watershed to locate direct discharges (e.g., municipal and private sewage and industrial waste discharges, sewage package treatment units, malfunctioning septic tanks and animal manure treatment lagoons) and non-point sources of pollution (e.g., storm water runoff, and runoff from agricultural and wildlife areas). Municipal and industrial wastewater treatment facilities should be evaluated in terms of actual loading versus design capacity, type and concentration of pollutants discharged, effectiveness of their treatment processes and pollution control devices. For additional information concerning sewage treatment plant discharges and their control, see the NSSP Guidance Document, *Management Plans for Growing Areas in the Conditional*

Classifications (ISSC/FDA, 2002) and the U.S. Environmental Protection Agency documents concerning increasing reliability of sewage treatment plants (USEPA [a] and [b], 1974).

The following survey procedures should be followed in the shoreline survey.

● *Survey Assignment*

Each shoreline survey area must be determined and assigned by the Authority. Each survey area must be identified by a unique designation. All survey data must be identified by this unique designation that allows for tracking of all forms used in the survey. All shoreline survey data must be documented and filed promptly.

● *Examination of Individual Properties for Pollution Sources*

• The boundaries of the shoreline survey area must be determined by an in-field investigation of the area topography and the proximity of individual properties to the growing area. Those properties with the potential to impact growing water quality must be included within the boundaries of the shoreline survey area. Once the boundaries of the shoreline survey area have been determined, all businesses and residences must be examined and all potential discharges of wastes (raw sewage, kitchen wastes, laundry wastes, agricultural wastes, etc.) must be evaluated.
• The location of each property with a pollution source adversely impacting the growing area must be provided.
• If the property has a pollution source adversely impacting a growing area, one of the two notations listed below must be made concerning its impact on water quality.
a) Direct Impact: A pollution source having direct impact is defined as any waste discharge which has immediate impact on the growing area. An attempt should be made to quantify the volume of the discharge.
b) Indirect Impact: A pollution source having an indirect impact is defined as any waste discharge which reaches the growing area in a roundabout way. An attempt should be made to quantify the volume of the discharge.
• All sanitary, industrial, or agricultural pollution sources must be located on a map of the survey area.
• All animal farms must be evaluated. Evaluation must include the number and type of animals.
• All marinas must be evaluated in accordance with the requirements of the Model Ordinance.
• Notations must be made of any flocks of waterfowl and an estimation of their number given. Populations of wild animals such as deer and muskrat should be noted and where possible an estimation of their number given.
• Drainage ditches must be evaluated.
• Any other potential source of pollution, which in the surveyor's opinion might influence water quality, must be noted.
• At the end of each shoreline survey, the surveyor must write a summation. The surveyor must also provide a comprehensive map of the survey area identifying the location of each pollution source found.

The level of surveillance for poisonous and deleterious substances in a shellfish control program may vary widely. The intensity of the surveillance is frequently driven by a history of marine biotoxin contamination, sanitary survey findings, or findings from investigations by other state or federal agencies or academia. Review of existing background data derived from national and international monitoring programs can also be useful (O'Connor, 1996; Beliaeff *et al*, 1997). An assessment of possible sources in the sanitary survey should enable shellfish control program managers to determine if a potential problem exists and whether a need for further field study exists. Sampling for specific chemical contaminants in shellfish is recommended only when the pollution source survey reveals a potential problem, or if there is concern because of a lack of information.

When poisonous or deleterious substances are found in shellstock, the Authority must evaluate the levels that may be present against known tolerance levels in human foods or other appropriate information, and determine what action, if any, should be taken. Additional information concerning this topic can be found in the NSSP Guidance Documents: *FDA Action Levels, Tolerances and Other Values for Poisonous or Deleterious Substances in Seafood* (ISSC/FDA, 2002); *Shellstock Relay* (ISSC/FDA, 2002); and *Guidance for Developing Marine Biotoxin Contingency Plans* (ISSC/FDA, 2002). In the absence of specific tolerance or action levels, decisions must be made on a case-by-case basis using the best available knowledge.

(2) An evaluation of meteorological factors. Climate and weather can affect the distribution of pollutants or can be the cause of pollutant delivery to a growing area. Prevailing winds can determine the distribution of pollutants in a growing area. Rainfall patterns and intensity can affect water quality through pollutant delivery in runoff or cause flooding which can affect the volume and duration of pollutant delivery. An example of the effects of meteorology occurred in 1982. In the late fall, the arrival of cold fronts caused strong winds, abnormally low tides and high rainfall which resulted in raw sewage bypasses from overloaded sewage treatment plants. This combination of meteorological events resulted in raw sewage reaching a growing area causing shellfish- borne illness in 471 persons (Casper, 1982).

(3) An evaluation of hydrographic factors that may affect distribution of pollutants throughout the area. Examples of hydrographic factors are tidal amplitude and type, water circulation patterns, and the amount of fresh water. These factors, along with water depths and stratification caused by density (salinity and temperature) differences, and wastewater and other waste flow rates are used to determine dilution, and time of transport. Tracer dye studies provide site-specific dilution, dispersion and time of travel information, and can be used in calibration of site-specific hydrodynamic models.

(4) An assessment of water quality. In general, microbial reduction in seawater occurs by two different processes - physical dilution by advection and diffusion, and a process of biological inactivation. Dilution factors are physical and predictable with a direct relationship between pollution loads and dilution water available. The inactivation process is more variable and appears to be associated with the following factors: sunlight and solar radiation, absorption and sedimentation, temperature, predation, antibiosis, action of inorganic salts, nutrient deficiencies, the action of heavy metals and other substances, and effects of specific bacteriophage. Kator

(1994) has provided a good summary of current knowledge concerning inactivation of bacteriological and chemical indicators caused by the effects of environmental factors.

Field and laboratory studies have demonstrated that enteric viruses can survive in marine water and shellfish from a few days to several months (Jaykus, 1994). In general, viruses survive longer at lower temperatures, at low salinity and when bound to sediments.

Evidence from many field studies indicates that a constant relationship does not exist between the bacterial pathogen, viral pathogen or coliform group levels in shellstock and the presence of these organisms in the overlying water column (Kator, 1994; Jaykus *et al*, 1994). Experience in the NSSP, however, has shown that shellstock from waters meeting the water quality standards for the approved classification are unlikely to be involved in shellfish-associated disease outbreaks attributed to fecal contamination of the growing area. In part, this is because the coliform group (total coliform) water quality standard of 70 MPN per 100 milliliters of growing water is equivalent to the fecal material contributed from one person diluted in about 2.27×10^8 liters (8 million cubic feet) of water free from the coliform group. Such a small amount of sewage reaching the growing area is likely to have been so treated, diluted, or aged that it will be of negligible public health significance.

The NSSP in its Model Ordinance allows for the Authority to classify a growing area using either a total coliform group or fecal coliform MPN standard as part if its sanitary survey. The two standards are believed to afford the same level of public health protection (Hunt and Springer, 1974). The NSSP Model Ordinance further allows the application of either standard to different water bodies within the state. The NSSP Model Ordinance also recognizes two distinct water quality monitoring strategies to collect the total coliform group or fecal coliform monitoring data for application of the standards: Adverse pollution conditions are to be established for initial classification, but if no point source pollution source impact is found the systematic random sampling monitoring strategy can be used for monitoring. The Authority may adopt the use of both the total coliform group and fecal coliform standards and both monitoring strategies, if applicable, for each standard.

The difference between the adverse pollution condition monitoring strategy and the systematic random sampling monitoring strategy is determined by 3 factors:
(1) The presence or absence of point source impact in the growing area;
(2) The timing of water sample collection; and
(3) The way in which the MPN data are calculated for comparison to the standard.

An adverse pollution condition (APC) is a state or situation, caused by meteorological, hydrological or seasonal events or point source discharges, that has historically resulted in elevated total coliform group or fecal coliform levels in a particular growing area. In using this monitoring strategy, sample collection must be timed to be representative of the major pollution impacts, since shellfish respond rapidly to an increase in the number of microorganisms in their surrounding waters. The APC monitoring strategy must be used in initial growing area classification to assess the impact by sewage treatment facilities, combined sewer overflows, or other point source discharges and to evaluate the impact of nonpoint pollution. The results of

bacteriological sampling must be correlated with sewage treatment plant operation and evaluated in terms of treatment and nonpoint pollution contributions at the time of sampling. These results, combined with considerations for malfunctions, overloads, poor operation, and nonpoint triggering conditions are used in the initial classification.

The systematic random sampling monitoring strategy can be used in approved or restricted growing areas except those that are affected by point source pollution. This strategy assumes that monitoring conducted on a pre-established schedule at an adequate frequency will capture weather or rainfall conditions that trigger nonpoint pollution contribution. For a full discussion of this strategy, see the NSSP Guidance Document, *Systematic Random Sampling Monitoring Strategy* (ISSC/FDA, 2002).

Total coliform group or fecal coliform data collected under either the APC or the systematic random sampling monitoring strategy are reported as a MPN i.e. a statistical estimate of the number of bacteria per unit volume of water and is determined from the number of positive results in a series of fermentation tubes used in a particular laboratory test. A complete discussion of the MPN test can be found in *Standard Methods for the Examination of Water and Wastewater* (APHA, 1985). In the APC monitoring strategy, the application of the two-part water quality standards for both total coliform group and fecal coliform involves use of a median or geometric mean and a "percentage factor". The "percentage factor" corrects for the inherent variation of the MPN analytical method when used with a normally distributed data set. In the systematic random sampling strategy, the application of the two part water quality standards for both the total coliform group and fecal coliform involves use of a median or geometric mean and an estimated 90th percentile as the statistic to measure the variance of the data set. The use of the strategy requires that the times of samples be scheduled in advance, so monitoring runs are made with no consideration for meteorological conditions. For a more in-depth explanation, see the NSSP Guidance Document, *Systematic Random Sampling Monitoring Strategy* (ISSC/FDA, 2002).

A written sanitary survey report is needed to integrate the data from the pollution source survey, the hydrographic and meteorological investigations, and the water sampling into a comprehensive information analysis. The purpose of this analysis is to determine the appropriate classification for the growing area and the geographic boundaries of the classification. This report must include a compilation of relevant data, a water sample data analysis using appropriate data sorting to determine adverse pollution conditions and recognized statistical techniques, conclusions as to the appropriate growing area classification, and recommendations for necessary follow-up actions. The report may also consider relevant resource management, social, economic, or political factors that may influence the establishment of the classification boundaries, when and the time periods for the open and closed status when conditionally approved and conditionally restricted classifications are proposed. Pollution conditions that cause closure, and conditions and time periods for seasonal openings must be included in the management plan.

Keeping the sanitary survey current consists primarily of routinely evaluating major pollution sources, collecting water quality data from sampling stations under the selected NSSP water quality monitoring strategy, and analyzing the data to assure that the classification continues to represent current sanitary conditions in the growing area. The sanitary survey must be repeated fully every 12 years. In the interim, the sanitary quality of each growing area must be reviewed as often as is necessary to ensure that the classification is appropriate. Certain sanitary survey components are required by the Model Ordinance to be updated annually and triennially (every third year). The growing area must be subjected promptly to a more intense and comprehensive sanitary survey reevaluation when monitoring or other information reveals a substantial change in the sanitary conditions. A reevaluation report is required and must include a determination as to whether a change in growing area classification is necessary.

The Authority is required to collect and maintain survey data and information for each growing area in a centrally located file. Experience with the sanitary survey program for determining the appropriate classification for each growing area indicates a tendency to omit or de-emphasize some components of the sanitary survey unless a central state file of all sanitary survey reports, update information, and reevaluation reports is maintained. This is particularly true when responsibility for shellfish sanitation is divided between two or more state agencies. Maintenance of a central state file also simplifies the appraisal of state programs by the FDA and prevents loss of useful historical data.

Minimum Requirements of the Sanitary Survey Report

The following outline contains the minimum requirements for the written growing area sanitary survey report required in the NSSP Model Ordinance.

A. Executive Summary

B. Description of Growing Area
   (1) Location map or chart showing growing area
   (2) Description of area and its boundaries
   (3) History of growing area classification
      • Date of last sanitary survey
      • Previous classification(s) map(s)

C. Pollution Source Survey
   (1) Summary of Sources and Location
      • Information gathered under the shoreline survey procedures outlined above.
      • Map or chart showing the location of major sources of actual or potential pollution in the survey area.
      • Table of sources of pollution cross-referenced to the survey area map.

   (2) Identification and evaluation of pollution sources
      • Domestic wastes (discussion and maps)

- Storm water
- Agricultural waste (farms, feedlots, & slaughterhouse operations)
- Wildlife areas
- Industrial wastes

D. Hydrographic and Meteorological Characteristics

(1) Tides (type and amplitude), and currents (velocity and direction)

(2) Rainfall

- Amount
- When (e.g. time of year)
- Frequency of significant rainfalls
- Winds (Seasonality and effects on pollution dispersion)

(4) River discharges (volume and seasonality)

(5) Discussion concerning effects of pollution distribution and hydrographic factors (dilution, dispersion, and time of travel) on water quality throughout ~~in~~ the growing area

- Salinity, depth, and stratification characteristics
- Computer model verification if used for classification.

E. Water Quality Studies

(1) Map of sampling stations

(2) Sampling plan and justification

- Adverse condition sampling
- Random sampling

(3) Sample Data Analysis and Presentation: Tables containing the basic NSSP statistics (number of samples, median or geometric mean, and the respective variability factors)

- Station by station monitoring data array collected under the adverse condition or systematic random sampling monitoring strategy
- Daily sampling results and number of samples collected for survey
- Overall compliance with NSSP criteria
- Sorting of data by environmental pollution condition
- Classification assigned to each station

F. Interpretation of Data in Determining Classification to Be Assigned to Growing Area: A discussion of how actual or potential pollution sources, wind, tide, rainfall, etc. affect or may affect water quality, that will address the following:

(1) Effects of meteorological and hydrographic conditions on bacterial loading

(2) Variability in the bacteriological data and causes

G. Conclusions

(1) Map or chart showing classification assigned to growing area(s) (closure lines, boundary lines separating various classifications)

(2) Legal description of growing area boundaries

(3) Management plan for growing area if in the conditionally approved or conditionally restricted classification

(4) Recommendations for sanitary survey improvement

- Changes in monitoring schedules, addition of sampling stations or station relocation, etc.
- Comments

Growing Area Classifications

As a result of the information gathered during the sanitary survey, the Authority should be able to distinguish those growing areas suitable for harvest of shellstock for direct human consumption, those growing areas where the shellfish will require treatment to make them safe for human consumption, and those growing areas unsuitable to harvest for human consumption. The probable presence or absence of pathogenic microorganisms, marine biotoxin or other poisonous or deleterious substances in growing area waters is important to the Authority in deciding how the shellfish obtained from the growing area should be used. The Authority's decision, based on the sanitary survey information, will place all actual and potential growing areas in one of the five possible NSSP growing area classifications.

The five growing area classifications are approved, conditionally approved, restricted, conditionally restricted and prohibited. Except for an emergency situation such as conditions following a hurricane when a growing area in the approved classification may be placed temporarily in the closed status, a growing area in the approved classification is always in the open status. The remaining four growing area classifications all place some type of restriction on shellstock harvesting. For more information concerning the enforcement of these restrictions, see the NSSP Guidance Document, *Growing Area Patrol and Enforcement of Growing Area Restrictions* (ISSC/FDA, 2002).

Growing areas are placed in the approved classification when the sanitary survey information and marine biotoxin surveillance data indicate that fecal material, pathogenic microorganisms, poisonous, or deleterious substances are not present in the growing area in unacceptable concentrations. Shellstock harvested from these growing areas may be sold directly to the public for consumption raw or cooked.

Use of the conditionally approved and conditionally restricted classifications by the Authority is optional. The conditional classifications are designed to address growing areas that are subject to intermittent microbiological pollution. These classifications offer the Authority an alternative to placing the area in the restricted or prohibited classification year round when, during certain times of the year or under certain conditions, the shellstock from the growing area may be safely harvested. The concept also applies to situations where conditions are acceptable for harvest when wastewater treatment plant operation is satisfactory, but not when a malfunction occurs. A management plan is required that describes the controls to provide public health protection in the use of the conditional classifications. For a full explanation of the conditional classifications and their use, see the NSSP Guidance Document, *Management Plans for Growing Areas in the Conditional Classifications* (ISSC/FDA, 2002).

A growing area may be placed in the restricted classification instead of the prohibited classification when the sanitary survey indicates a limited degree of pollution. This option may be used when the sanitary survey for the growing area indicates that the levels of fecal material or poisonous or deleterious substances in the growing area are such that additional treatment through depuration or relay can render the shellstock safe for human consumption. A common situation in the use of the restricted classification occurs when a growing area is affected by non-point source pollution from either urban or rural sources. In this situation, the water quality fluctuates unpredictably or with sufficient frequency that the use of the conditionally approved classification is precluded. The Authority should use the restricted classification only when sufficient depuration or relay studies have been conducted to establish raw product quality requirements at the harvest level; and when the Authority has sufficient administrative and technical resources to properly administer this classification. These resources include monitoring of pollution sources; providing coordination between state, local and industry officials; issuing special harvesting permits; and supervising the harvesting and transport of shellstock to relay sites or depuration facilities. For a complete discussion of the supervision requirements at the harvest level, see the NSSP Guidance Document, *Shellstock Relay* (ISSC/FDA, 2002).

Use of the restricted classification requires the Authority to develop the controls necessary to assure that the shellfish are relayed or depurated prior to consumption. Bacteriological water quality standards are applied on a growing area specific basis. The criteria may vary according to the use to be made of the shellstock and the effectiveness of the relay or depuration process used to cleanse the shellstock. Process effectiveness is determined through a study, which establishes the fecal coliform density in the shellstock at the time of harvest, and the density that can be achieved at the completion of the process. Effectiveness of the process is likely to vary between growing areas used for natural cleansing treatment in relay operations and between depuration facilities used for controlled cleansing treatment. The species of shellstock may also affect the effectiveness of the relay or depuration process. For a complete discussion of relay and depuration, see the NSSP Guidance Documents, *Shellstock Relay* (ISSC/FDA, 2002) and *Shellstock Depuration* (ISSC/FDA, 2002).

A growing area is placed in the prohibited classification when the sanitary survey or marine biotoxin surveillance program indicates that fecal material, pathogenic microorganisms, poisonous or deleterious substances, marine biotoxin, or radionuclides may reach the harvest area in excessive concentrations. The NSSP Model Ordinance also requires that a growing area for which there is no sanitary survey be placed in the prohibited classification as a precautionary measure. Taking shellstock from a prohibited area for any human food purpose is not allowed.

Depletion of prohibited areas can be an effective deterrent to illegal harvesting as it provides a safeguard against contaminated shellfish reaching the market and eliminates a temptation for harvesters. Depletion may be more economical and effective than patrol of prohibited areas in protecting public health. In a depletion operation, all market sized shellstock and as many of the smaller sized shellstock as can be gathered by reasonable methods are removed from the growing area. To be effective, depletion operations should be conducted at sufficient intervals to keep growing areas free of commercial quantities of market-sized shellstock. When commercial

harvesters conduct depletion operations, the Authority or the Patrol Authority must provide effective supervision.

The NSSP Model Ordinance also requires that an area in the prohibited classification (closed safety zone) must be established between any sewage treatment plants or other waste discharge of public health significance and any growing area placed in the approved, conditionally approved, restricted, or conditionally restricted classification. The size of the prohibited area should be based on the effectiveness and level of sewage treatment; the location of the shellstock resource that would be affected; the classification of adjacent waters, the total time it would take for the person responsible for the operation of the sewage treatment facility to detect a failure and notify the Authority; the time it would take the Authority to issue a notice to stop shellstock harvesting, and the degree of effluent dilution. Due consideration should be given to the possibility that emergency actions might be necessary on holidays or at night.

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04. ACTION LEVELS, TOLERANCES AND GUIDANCE LEVELS FOR POISONOUS OR DELETERIOUS SUBSTANCES IN SEAFOOD

Because shellfish are filter feeders, they can readily accumulate substances from the water column. The types of poisonous or deleterious substances that have been recovered from shellfish include heavy metals, pesticides, petroleum products, polychlorinated biphenyls, and naturally occurring marine biotoxins. The source of these contaminants may be industrial, agricultural, mining, spillage, sewage, dredging operations, sludge dumps, and naturally occurring toxigenic marine organisms.

The FDA has established action levels, tolerances and guidance levels for poisonous or deleterious substances to control the levels of contaminants in human food including seafood (FDA Federal Register, 1977; FDA, 1985). Action levels are established and revised according to criteria specified in the ***Code of Federal Regulations*** (21 CFR 109 and 509), and are revoked when a regulation establishing a tolerance for the same substance and use becomes effective. Action levels and tolerance represent limits at or above which FDA will take legal action to remove adulterated products, including shellfish, from the market. Action levels and tolerances, are established based on the unavoidability of the poisonous or deleterious substance and do not represent permissible levels of contamination where it is avoidable. Guidance levels are used to assess the public health impact of the specified contaminant.

Table 1 lists action levels, tolerances and guidance levels established by the FDA for poisonous or deleterious substances in seafood including shellfish. Notices are published in the ***Federal Register*** as new action levels are established or as existing action levels are revised or revoked. Should any of these notices affect Table 1, FDA will issue an interpretation advising NSSP participants of this revision or addition.

Table 1 - Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood

Deleterious Substance	Level	Food Commodity[b]	Reference
Aldrin/Dieldrin[d]	0.3 ppm	All Fish	CPGsec575.100[c]
Chlordane	0.3 ppm	All Fish	CPG sec 575.100[c]
Chlordecone[e]	0.3 ppm 0.4 ppm	All Fish Crabmeat	CPG sec 575.100[c]
DDT, DDE, TDE[f]	5.0 ppm	All Fish	CPG sec 575.100[c]
Diquat[h]	0.1 ppm	All Fish	40 CFR 180.226
Glyphosate[h]	0 .25 ppm 3.0 ppm	Fin Fish Shellfish	40 CFR 180.364
Toxic Elements			
Arsenic	76 ppm 86 ppm	Crustacea Molluscan Shellfish	FDAGuidance Document
Cadmium	3 ppm 4 ppm	Crustacea Molluscan Shellfish	FDA Guidance Document
Chromium	12 ppm 13 ppm	Crustacea Molluscan Shellfish	FDA Guidance Document
Lead	1.5 ppm 1.7 ppm	Crustacea Molluscan Shellfish	FDA Guidance Document
Nickel	70 ppm 80 ppm	Crustacea Molluscan Shellfish	FDA Guidance Document
Methyl Mercury	1.0 ppm	All Fish	CPG sec 540.600
Heptachlor/Heptachlor Epoxide[g]	0.3 ppm	All Fish	CPG sec 575.100
Mirex	0.1 ppm	All Fish	CPG sec 575.100

Polychlorinated Biphenyls (PCBs)[h]	2.0 ppm	All Fish	21 CFR 109.30
2,4-D[h]	1.0 ppm	All Fish	40 CFR 180.142

Natural Toxins

Paralytic Shellfish Poison (PSP)	80µg/100g	All Fish	CPG sec 540.250
Neurotoxic Shellfish Poison (NSP)[a]	Non-Detectable	Clams, mussels Oysters, fresh frozen or canned	NSSP MO
Amnesic Shellfish Poison (ASP)	20 ppm	All Fish (except in the viscera of Dungeness crab where 30 ppm is permitted	Compliance Program 7303.842

Note: the term "fish" refers to fresh or saltwater fin fish, crustaceans, other forms of aquatic animal life other than birds or mammals and all mollusks as defined in *21 CFR 123.3(d).*

Footnotes for Table 1

a) The value for neurotoxic shellfish poison (NSP) is not an FDA action level or tolerance. The NSSP considers the presence of any detectable NSP toxin to be hazardous to human health.
b)
c) Unless otherwise specified, the action levels, tolerances and other values listed apply to both the raw and processed food commodity. Procedures for sample collection and analyses are specified in Sections 420 and 450 of the ***FDA Investigations Operation Manual***; ***FDA Pesticide Analytical Manual (PAM)*** Volume I or II; ***AOAC Official Methods of Analysis***; ***APHA Recommended Procedures for the Examination of Sea Water and Shellfish***, Fourth Edition, 1970; or, peer reviewed literature for domoic acid (ASP) methodologies.
c) References designated as CPG represent the FDA Compliance Policy Guides and all associated numbers as they appear in appropriate sections of FDA's Compliance Policy Guides Manual.

d) The action level for aldrin and dieldrin are for residues of the pesticides individually or in combination. However, in adding amounts of aldrin and dieldrin do not count aldrin or dieldrin found at the level below 0.1 ppm for fish.

e) Previously listed as Kepone, the tradename for chlordecone.

f) The action level for DDT, TDE, and DDE are for residues of the pesticides individually or in combination. However, in adding amounts of DDT, TDE, and DDE do not count any of the three found below 0.2 ppm for fish.

g) The action level for heptachlor and heptachlor epoxide are for the pesticides individually or in combination. However, do not count heptachlor or heptachlor epoxide found below 0.1 ppm.

h) The levels published in 21 CFR and 40 CFR represent tolerances rather than guidance levels or action levels.

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05. MANAGEMENT PLANS FOR GROWING AREAS IN THE CONDITIONAL CLASSIFICATION

NSSP guidance documents provide the public health principles supporting major components of the NSSP and its Model Ordinance, and summaries of the requirements for that component. NSSP Model Ordinance requirements apply only to interstate commerce although most states apply the requirements intrastate. For the most up to date and detailed listing of requirements, the reader should consult the most recent edition of the Model Ordinance.

The goal of the NSSP is to control the safety of shellfish for human consumption by preventing its harvest from contaminated growing areas. In implementing this goal, the NSSP uses five classifications for growing areas: approved, conditionally approved, restricted, conditionally restricted, and prohibited. The placement of a growing area in any one classification is based upon the growing area's conformance with the requirements established for that classification. For a full explanation of this concept, see the public health explanation in NSSP Guidance Document, Sanitary *Survey and the Classification of Growing Waters* (ISSC/FDA, 2002).

The conditional classifications are designed to address growing areas that are subject to intermittent microbiological pollution. These classifications offer the Authority an alternative to placing the area in the restricted or prohibited classification year round when during certain times of the year or under certain conditions, the shellstock from the growing area may be safely harvested. Public health protection from unsafe shellfish in the use of the conditional classifications is afforded through the use of a management plan. Using a thorough investigation conducted as part of the sanitary survey, the Authority determines that the growing area will be in the open status of its conditional classification for a reasonable period of time; that the factors which determine this period of time are known, predictable and are not so complex that the factors cannot be reasonably managed; and that the bacteriological water quality can be correlated with the factors affecting the distribution of pollutants in the growing area. The management plan for each growing area placed in a conditional classification is based on the information gathered during the investigation. The plan establishes a strict set of criteria, which must be met for the growing area to remain in the open status. Failure to meet the criteria automatically places the growing area in the closed status, with immediate notice to the public, the affected industry, and the plan's participants. Two of the most important components of the management plan are the acceptance of and the agreement to the conditions of the management plan by the one or more Authorities involved, other local, state and federal agencies which may be involved, the affected shellfish industry, and the persons responsible for the operation of any treatment plants or other discharges that may be involved; and the annual reevaluation of the compliance with the plan to assure public health protection.

The criteria for the approved classification of the NSSP require that the growing area be not subject to human or animal fecal matter at levels that present an actual or potential public health risk, and not be contaminated with pathogenic organisms, poisonous or deleterious substances or marine biotoxin. From the review of growing area classifications and sanitary surveys conducted by national and international Authorities, it appears that a common misuse of the approved classification is the placement of a growing area in the approved classification when the use of

the conditionally approved classification would have been more appropriate. Critical investigation usually reveals that the growing area is improperly classified because it is subject to intermittent pollution events, which is a contravention of the criteria for the approved classification.

Intermittent pollution events have been identified as a significant cause of shellfish-borne infectious disease outbreaks worldwide. As an example, in the fall of 1982, at least 471 persons developed gastroenteritis after consumption of sewage contaminated oysters from a growing area that had been placed in the approved classification (Casper, 1982). An investigation into the outbreak demonstrated that the growing area could probably be safely open to harvesting in the summer when the prevailing winds are southerly and tides are high. In the late fall, the arrival of cold fronts can cause high rainfall, strong winds and abnormally low tides and raw sewage bypasses from overloaded sewage treatment plants. Under these conditions, sewage reached the growing area causing the outbreak. As a result of the investigation, the Authority learned that it should have placed the growing area in the conditionally approved classification and developed a management plan to automatically close the area in the late fall through spring when climatic conditions were likely to render the growing area unsafe. Under the management plan, the area would be reopened to harvesting in the summer when favorable conditions prevailed and would be intensively monitored to ensure that the summer conditions were met. In this instance, application of the conditionally approved area concept probably could have prevented the outbreak.

Use of the Conditional Classification

Use of the conditional classifications is a voluntary option for the Authority. There are two types of conditional areas: conditionally approved and conditionally restricted. Any growing area in the conditionally approved classification must meet the criteria for the approved classification when it is in the open status of this classification. When the growing area is in the closed status of this classification, it may be used for relaying or depuration if it meets the requirements for the restricted classification and if this use is specified in its management plan, or it may be closed to any use. Any growing area in the conditionally restricted classification must meet the criteria for the restricted classification when it is in the open status of this classification and no harvesting is permitted when it is in its closed status.

Growing areas that are subject to intermittent microbiological pollution from predictable pollution events may be placed in the conditionally approved or conditionally restricted classification under the NSSP. Examples of predictable pollution events include the failure of wastewater treatment facilities to maintain a performance standard needed to maintain an established effluent quality; changes in seasonal populations affecting growing area water quality; and nonpoint source pollution events such as caused by as certain rainfall intensities. Conditional classifications may also be used to manage growing areas affected by toxigenic micro-algae that produce marine biotoxins.

An example of a common situation where use of the conditionally approved classification might be appropriate is when water quality is dependent upon the operation and performance of a sewage treatment plant. In this example, the growing area would meet the criteria for the approved classification when the sewage treatment plant is performing satisfactorily. If there is some interruption in sewage treatment, the likely result will be degradation of water quality in the growing area. This degradation would require the establishment of a prohibited area large enough to dilute and assimilate the effluent discharged during the interruption in treatment. If an interruption can be predicted and is at a manageable frequency necessitating repeated closings (e.g. one or two times a year), the Authority may consider a conditionally approved classification for a portion of the growing area classified as prohibited. Interruptions could include a disinfection failure or certain climatic conditions which are known to affect the wastewater treatment facility's performance). Although many Authorities are burdened by administrative procedures, the use of a management plan for the conditional classification allows the Authority to act quickly to implement closures, and avoid unnecessary delays in returning the conditionally approved portion of the growing area to the open status. The added administrative burden might be offset by the shellfish resource gained by upgrading a prohibited portion of a growing area to the conditionally approved classification.

The concept of the conditionally approved classification is also applicable to other situations in which there may be a rapid or seasonal change in water quality. Examples include:

- The water quality in a growing area adjacent to a resort community may vary according to seasons of the year. During the summer months, when the community experiences a significant population increase, water quality may be adversely affected. However, during the winter when there are few people in the community, water quality might improve sufficiently to allow the growing area to be placed in the open status. In some states, this is known as a seasonal closure.
- The water quality in a protected harbor in a sparsely settled area, which provides anchorage for a fishing fleet several months a year, might vary. When the fishing fleet is in the harbor, the water might be of poor sanitary quality. The area would be closed for shellstock harvesting when the fishing fleet is using the harbor. During the remainder of the year, however, the quality of the harbor water might meet the criteria for the approved classification and be opened to shellstock harvesting.
- The water quality in an area may fluctuate with the discharge of a major river, or rainfall in the area may cause runoff of pollutants from adjacent land surfaces (non-point pollution) into the growing area. During periods of low runoff or river discharge, the area might meet the criteria for the approved classification.

The use of the conditional classification option offers the Authority the ability to increase the availability of water for shellfishing that would otherwise be closed. The management plan dictates the circumstances and procedures for immediate response to situations requiring closure. The administrative procedures included in the management plan allows the Authority to reopen the area to harvesting as soon as the pollution condition is over and the water quality and shellstock have returned to acceptable quality.

Suitability of the Conditional Classification

The first step is to determine, through a thorough investigation conducted as part of the sanitary survey, if the growing area is suitable for conditional management by evaluating the potential sources of pollution in terms of their effect on water quality. Information must be gathered to support the supposition that the growing area will be in the open status of its conditional classification for a reasonable period of time; that the pollution events which determine this period of time are known, predictable and are not so complex that the factors of these events cannot be reasonably managed; and that the bacteriological water quality can be correlated with the factors affecting the distribution of pollutants in the growing area. The investigation may also consider relevant resource management, social, economic, or political factors that may influence the open and closed periods, and the establishment of boundaries, for the conditional classification of a growing area. The management plan for each growing area placed in a conditional classification is based on the information gathered during the investigation. Some potential sources of pollution which could be managed under a conditional classification management plan include: bypasses and overflows within a sewage collection and treatment system, intermittent discharges from boats, seasonally related pollution occurrences, animals, land runoff, and freshwater flows.

The second step in determining the suitability of conditional classifications is to determine whether the Authority has sufficient resources available to survey, manage, monitor, control harvesting, close and reopen the area as required. Use of these classifications imposes additional manpower and resource burdens on the Authority. For example sources of pollution must be routinely monitored; coordination between state, local and industry officials must be timely; performance standards must be monitored; and closures must be immediate and effective. Any Authority that has elected to use the conditionally approved or conditionally restricted classifications has found the resource investment to be substantial and this investment must be balanced against the benefit of the additional shellfish resource available.

The third step is to evaluate each source of pollution in terms of the pollution load and to determine if performance standards can be formulated for each pollution source having a significant effect on the sanitary quality of the growing area. The conditional classification management plan must establish a strict set of criteria, which must be met for the growing area to remain in the open status. The following are examples of different types of performance standards that could be used:

• Performance standards might stipulate the bacteriological quality of effluent from sewage treatment plants. The microbiological quality can be monitored in terms of disinfection residual or dosage for ultraviolet light disinfection. An example of a performance standard for an effluent discharge is: "The median fecal coliform MPN, in any one month, shall not exceed 200 per 100 ml, based on not less than 16 samples per month, and not more than 10 percent of the samples shall have an MPN in excess of 1,000 per 100 ml. This fecal coliform limit shall be presumed to be met if the chlorine residual in the effluent is at least 1.0 ppm and the chlorine residual in the effluent is continuously recorded on a chart by chlorine residual analyzer or is measured hourly and recorded in the daily monitoring records as required for the plant's NPDES permit."

• For disinfection by ultraviolet (UV) light, the disinfection is based on dosage. An example of a performance standard is, "A minimum UV dose of 37 mW-Sec/cm^2 is to be maintained. The calculation of intensity of the UV light is to include factors for effluent quality, including turbidity, suspended solids, and transmittance. The effluent factors contributing to the dose, including turbidity, suspended solids, transmittance, and flow will be continuously measured and recorded. An alarm will be activated if any of the factors are above design limits."
• Performance standards might be based upon the amount of vessel traffic in the area and the concomitant amount of sewage that can be expected.
• Performance standards might be based upon the amount of rainfall in the immediate area. An example is: "The growing area will be closed to harvesting for (number of days) when there has been 2 inches or more rainfall registered at a rain gauge at (specified location) within a 24-hour period."
• Performance standards might be based upon the height of a river stage. An example could be: "When the river at (a specified area) reaches 3.66 meters (12 feet) or higher, the growing area will be closed."

The design of a waste treatment plant and the plant effluent specifications are critical to the use of the conditional classifications. Design criteria which may be useful in determining the quality of sewage which can be discharged into an area without exceeding the desired water quality standards include: population equivalent (fecal coliform) of sewage, predicted survival of fecal coliform in seawater, effectiveness of disinfection and the amount of clean dilution water in an area.

The mechanical equipment at critical sewage treatment or plant components should be such that interruptions will be minimized. Requirements, which might be imposed, depend upon the importance of the unit's relationship to maintenance of water quality in the growing area. Important design features, which should be considered in the design of the sewage collection system, include:

• Exclusion of storm water runoff from sewer collection systems and use of devices such as flow equalization tanks to control effects of storm water infiltration on treatment plant performance;
• Provision of stand by power at critical sewage pumping stations through the use of on-site emergency generators, or other alternate power sources;
• Use of gauges, charts and other recording devices to monitor flows and performance standards; and
• Use of alarms, telemetering or other devices to report immediately failure of any critical components at the wastewater treatment plant and in the collection system at sewage pumping stations.

A detailed discussion of ways to increase the reliability of sewage treatment plants can be found in *Protection of Shellfish Waters* (USEPA, 1974) and *Design Criteria for Mechanical, Electric and Fluid System Component Reliability* (USEPA, 1974).

The fourth step is to determine the water quality, which will occur in the growing area when the performance standards are not met, and what portion of the growing area will be affected. Once

these determinations are made, the Authority can select the appropriate management strategy for the portion of the growing area that will be placed in the closed status when performance standards are not met, and can select the boundaries for the closed status. The boundaries of that portion of the growing area to be placed in the closed status would depend upon such items as the distance and travel time from the pollution source to the area, the concentration of pollutants in the discharge during the breakdown condition, amount of effluent and hydrographic factors including dilution available in the receiving water.

The use of the conditional classification where a sewage treatment plant is the pollution source being managed requires a fifth step. An area in the prohibited classification (closed safety zone) must be established between the sewage treatment plant and the growing area placed in the conditionally approved or conditionally restricted classification. The size of the prohibited area should be based on the level of sewage treatment; the total time it would take for the person responsible for the operation of the sewage treatment facility to detect a failure and notify the Authority; and the time it would take the Authority to issue a notice to stop shellstock harvesting. The size of the area in the prohibited classification should allow for a effluent travel time through the prohibited area that is at least twice that required for the notification process to become effective. Due consideration should be given to the possibility that emergency actions might be necessary on holidays or at night. A minimum effluent dilution is to be determined at the prohibited boundary and can be the controlling factor in situations where there is efficient detection and notification of breakdowns.

The length of time that a growing area should be in the closed status of its conditional classification will depend upon several factors. These factors include the degree of pollution in the growing area and flushing capacity of the estuary, the species of shellfish, water temperature, shellstock activity and cleansing rates, and presence of silt or other chemicals that might interfere with the physiological activity of the shellstock. Additional information on the natural cleansing of shellstock is provided in the NSSP Guidance Document, *Shellstock Relay* (ISSC/FDA, 2002).

Minimum Requirements for a Conditional Area Management Plan

The management plan for a growing area in the conditionally approved or conditionally restricted classification must meet certain minimum requirements to ensure that the safety of the shellfish for human consumption is maintained. The use and success of the conditional classification depends upon a thorough and accurate management plan. Therefore, it is important that all aspects of the management plan be fully considered and implemented. The minimum requirements to be addressed are:

A. An understanding of and agreement to the conditions of the management plan by the one or more Authorities involved, other local, state and federal agencies which may be involved, the affected shellfish industry, and the persons responsible for the operation of any treatment plants or other discharges that may be involved;

B. A written management plan for the growing area being placed in the conditional classification, which includes a general description of the growing area with a map showing the area's boundaries, and which addresses all items in C through H;.

C. A sanitary survey that shows the growing area will be in the open status of its conditional classification for reasonable periods of time. The survey must provide a description of the factors determining the growing area's suitability for being classified conditionally approved or conditionally restricted, and the supporting information and data.

D. A description of the predictable pollution event or events that are being managed and the performance standards established for each pollution source contributing to the pollution event including:

(1) For a wastewater treatment facility, the performance standard should be based on:

- Peak effluent flow
- Bacteriological quality of the effluent
- Physical and chemical quality of the effluent
- Bypasses from the treatment plant or its collection system
- Design, construction, and maintenance to minimize mechanical failure or overloading (i.e. The reliability of the treatment system and collection system components)
- Provisions for verifying and monitoring efficiency of the wastewater treatment plant and the feedback system for addressing inadequate treatment.
- Identification of conditions that lead to wastewater treatment plant failure and closure of the conditionally approved area.

(2) For meteorological or hydrological events, the performance standard should be based on:

- Identification of the specific meteorological and/or hydrologic event that will cause the growing area to be placed in the closed status;
- Discussion and data analyses concluding that effects on water quality from these specific meteorological and/or hydrologic events are predictable, and that the data are sufficient to establish meaningful performance standards or criteria for the establishment and implementation of a management plan for the growing area placed in the conditional classification; and
- The predicted number of times, based on historical findings, that the pollution event will occur within one year.

(3) For seasonal events, such as marina operation, seasonal rainfall, and waterfowl migration, the performance standard should be based on:

- Identification of the seasonal event that will cause the growing area to be placed in the closed status, including its estimated duration; and
- Discussion and data concluding that the seasonal event is predictable, and that the data are sufficient to establish meaningful performance standards or criteria for the establishment and implementation of a management plan for a growing area placed in the conditional classification;

E. A description of the plan for monitoring water quality including numbers and frequency;

F. A description of how the closed status for the conditional classification will be implemented, which must include:

(1) A clear statement that when the performance standards are not met, the growing area will immediately be placed in the closed status;

(2) A requirement to notify the Authority or Authorities that the management plan performance standards have not been met, including:.

• The name of the agency or other party responsible for notifying the Authority;

• The anticipated response time between the performance standards not being met and notification of the Authority; and

• The procedures for prompt notification including contingencies such as night, weekend and absences of key personnel;

(3) A description of the implementation and enforcement, including:

• The response time between the notification to the Authority of the failure to meet performance standards and activation of the legal closure of the growing area by the Authority;

• The procedures and methods to be used to notify the shellfish industry; and

• The procedures and methods to be used to notify the patrol agency (enforcement agency) including:

- The name of the responsible patrol agency;
- The anticipated response time between the Authority's legal closure of the growing area and notification of closure to the patrol agency; and
- A description of the patrol agencies anticipated activities to enforce the closed status.

G. A description of the criteria that must be met prior to reopening a growing area in the closed status, including the need to determine that:

(1) The performance standards established in the management plan are again fully met;

(2) The flushing time for pollution dissipation is adequate;

(3) A time interval has elapsed which is sufficient to permit reduction of human pathogens as measured by the coliform indicator group in the shellstock;

(4) Where necessary, the bacteriological quality of the water must be verified; and

(5) Shellstock feeding activity is sufficient to achieve reduction of pathogens to levels present prior to the pollution event.

H. A commitment to a reevaluation of the management plan at least annually using, at a minimum, the reevaluation requirements in the NSSP Model Ordinance.

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06. SHELLSTOCK RELAY

NSSP guidance documents provide the public health principles supporting major components of the NSSP and its Model Ordinance, and summaries of the requirements for that component. NSSP Model Ordinance requirements apply only to interstate commerce although most states apply the requirements intrastate. For the most up to date and detailed listing of requirements, the reader should consult the most recent edition of the Model Ordinance.

Relaying is the practice of harvesting shellstock from polluted growing areas and placing them in unpolluted bodies of water for a sufficient time for the shellstock to reduce contaminating microorganisms and chemical contaminants to safe levels. When adequate controls are used during the relay process, shellstock resources that would otherwise not be available for human consumption are made safe through natural cleansing, and become accessible to the shellfish industry and the consumer.

Research has shown that shellstock has the ability to purge itself of certain microbial and chemical contaminants when placed in clean saline water. The rate of purging depends on the specific contaminants, species of shellstock, and several environmental factors. As early as 1911, public health officials were investigating the use of natural cleansing through relaying to reduce pathogenic organism levels in oysters (Clem, 1994).

Factors Affecting Natural Cleansing

Shellstock, which is heavily contaminated with microorganisms, may require additional time for natural cleansing. (Metcalf and Stiles, 1968; Canzonier, 1971; Metcalfe, 1979) The length of time required for the cleansing process is influenced by many factors including level of pollution in the shellstock when it is removed from the polluted waters. Roderick and Schneider (1994) have prepared an excellent summary of the current knowledge concerning depuration and relaying of shellstock. Their work identifies four critical factors that affect the physiological activity, pumping rate and behavioral responses of shellstock: water temperature, salinity, dissolved oxygen, and turbidity and suspended solids. Shumway (1996) reports that temperature is the most important factor affecting the eastern oyster. Both temperature and salinity have an important effect on eastern oyster pumping rates, which is important for natural cleansing, with temperature being the most important parameter.

Investigations by marine biologists have confirmed that the physiological activities of shellstock are reduced when the water temperature falls below a certain value. This finding is important because viruses, other pathogens and chemical contaminants cannot be eliminated from shellstock if the shellstock is not actively pumping water. Loosenoff (1958) showed that pumping rates in the eastern oyster rose steadily as water temperature climbed from 8^0C to 28^0C. Pumping was reported as severely reduced or non-existent below 2^0C. Generally investigators agree that the pumping rates in the eastern oyster are reduced at less than 10^0C (50^0F) (Shumay, 1996).

Cabelli (1971) reported that few coliform organisms were recovered from the northern quahog (*Mercenaria mercenaria*) when the temperature was below 10^0 C (50^0F), even though they were collected from heavily polluted waters. Cabelli (1970) also reported the lower limit of the water temperature of the water acceptable for cleansing of soft clams is about 10^0C (50^0F). Burkhardt et al (1992) found that hibernating shellfish become very active after the threshold temperature is reached, and that bacterial and viral indicators accumulate and eliminate differently.

Jaykus *et al* (1994) have prepared a good summary of the current knowledge concerning the viruses associated with shellstock and their elimination through relaying and depuration. In their discussion of the relationship between viruses in shellstock and the coliform indicators used as bacteriological standards, the investigators report "no meaningful relationships have been found between virus presence in clams and oysters and a variety of bacteriological and physicochemical parameters for water and shellfish."

There is considerable information available, particularly for the eastern oyster *(Crassostrea virginica),* concerning the bioaccumulation and elimination of metals and lipophilic organic contaminants from shellstock (Roesijadi, 1996; Capuzzo, 1996). Pringle (1968) showed that different species of shellstock accumulate varying levels of heavy metals depending upon the pollution level. The chemicals become incorporated into the tissues of the various organs. The rate of release of metals depends on initial levels and species of shellstock. Some metals in some species of shellstock took up to 84 days to deplete. Morrison (1979) reported that the slower depletion of metals as compared to microbiological contaminants indicates that the 14-day cleansing period traditionally used in relaying is not appropriate for removal of metals and their isotopes.

Similarly, most chemicals are not significantly reduced by depuration. It has been found that in soft shell clams, reduction of benzo-a-pyrene to its biological half-life (50% removal) took up to 11 days, depending on temperature and initial level (Jackim, 1977). Removal of over 90% of the polynuclear aromatic (PNA) hydrocarbons took more than over 5 ½ weeks in the same series of experiments. In depuration studies of the pesticide kepone in oysters relayed from the James River to non-kepone contaminated waters of the York and Rappahannock Rivers in Virginia, Bender (1977) found dramatic effects of temperature on the depuration rates. In the summer, the biological half-life of kepone was about one week, while during the winter about 40 days were required for residue levels to decline by the same amount.

Use of containers to hold shellstock during the natural cleansing process may have some effect on rate of contaminant elimination. Quayle (1976) demonstrated rapid purging rates of *E. coli* from Pacific oysters held in wire mesh baskets. Within 48 hours, the level of bacteria in the oysters was the same as the level in oysters harvested from local areas in the approved classification. Becker (1977) reported depth of oysters in baskets was a critical factor. Full baskets did not show effective cleansing in 96 hours, while single layers were effectively cleansed in 48-96 hours.

When use of containers is proposed to hold shellstock during the natural cleansing process, special studies should be made to evaluate the design of the container, and its effect on the rate of natural cleansing. Such studies should be conducted for each container relay operation, each harvesting area, and each relay site.

Relaying Operations

The NSSP recognizes two methods of handling the shellstock during the natural cleansing process: (1) replanting the shellstock directly on the bottom in clean waters; and (2) placing the shellstock in containers (container relaying) which are then floated, suspended from racks, or placed on the bottom in clean waters.

Shellstock may be harvested and transferred for natural biological cleansing from growing areas in the restricted classification, in the closed status of the conditionally approved classification, or in the open status of the conditionally restricted classification. All growing areas used for natural cleansing must be in the approved classification or in the open status of the conditionally approved classification. For more information concerning the classification of growing waters, see the NSSP Guidance Document: *Sanitary Survey and the Classification of Growing Waters* (ISSC/FDA, 2002).

Prior to the initiation of the relaying operation, a decision is required as to whether the purpose of the operation is natural shellstock cleansing to remove microbial or poisonous and deleterious substances or both. Requirements, particularly the time allotted for natural cleansing, may differ depending on the type of contaminant. If the intent of the relay operation is to reduce shellstock microbial contaminants, the shellstock must not also be contaminated with poisonous or deleterious substances that would not be effectively reduced to acceptable levels during the cleansing period. For more information concerning acceptable levels of poisonous and deleterious substances in shellstock, see the NSSP Guidance Document: *FDA Action Levels, Tolerances and Other Values for Poisonous or Deleterious Substances in Seafood* (ISSC/FDA, 2002).

Licensing of each person who harvests shellstock is an important control measure to help protect against contaminated shellstock reaching the consumer and to help maintain accurate source identity records. This is particularly important when harvesters are transporting contaminated shellstock as part of a relay operation. Special permits must be issued to licensed harvesters for taking shellstock from contaminated growing areas and transporting them to other growing areas for the purpose of natural cleansing. The permits must be good for no more than one year, must be issued only for a specific relay operation, and must specify any limitations and conditions for harvesting.

The water quality in the harvest area to which the shellstock are relayed and the bacteriological and/or chemical quality of the relayed lots of shellstock to be subjected to natural cleansing must be verified throughout the relay process. In addition, the identity of the relayed shellstock should

be maintained throughout harvesting, transport, processing, packaging, and distribution in the event the shellfish needs to be traced back to its source.

The generally accepted minimum time period for elimination of microbial contaminants from shellstock is 14 days when environmental conditions are suitable for natural cleansing. Longer periods may be required if environmental conditions are not optimum. Shorter time periods may be permitted at some locations or during some periods of the year if there is an adequate study to support the reduced time frame and there is intensive monitoring during the process. Container relaying is particularly amenable to shorter time periods for microbial elimination.

The Authority or the shellfish industry may conduct relay operations. The relay operation must be effectively supervised by the Authority to assure that all the shellstock are actually relayed to harvest areas in the approved classification or in the open status of the conditionally approved classification and sufficiently cleansed. Relay control procedures should preclude any opportunity for shellstock to be inadvertently diverted to sale for human consumption before the natural cleansing process is completed. Controls must be applied to all phases of the operation including initial harvesting, transportation, replanting, the cleansing period, and final harvesting for marketing.

Control procedures must, at a minimum:

(1) Require that the source and species of shellstock being relayed be identified;

(2) Require information concerning:

(a) The quality (bacteriological or chemical) of the water and the shellstock prior to harvest for relay;

(b) The quality of the water and the shellstock indigenous to the area to be used for natural cleansing; and

(c) The quality of the shellstock when the required period of natural cleansing has ended;

(3) Specify the time period of the year when relaying may be conducted;

(4) Use special markings to designate portions of harvest areas where relayed shellstock may be placed for natural cleansing;

(5) Require special harvesting permits for relay operations;

(6) Specify the method of shellstock transportation to the site of natural cleansing, the shellstock deposition method and the method by which different lots of shellstock will be separated during cleansing;

(7) Specify the records to be maintained and filed with the Authority; and

(8) Meet the requirements of the NSSP Model Ordinance.

Control procedures may include monitoring environmental parameters, establishing interagency agreements, imposing quarantine measures, increasing patrols, and developing unique control measures as may be necessary.

A record of water temperature, salinity, and other critical variables must be maintained when it is known that the limiting values of environmental factors may be approached and when minimum relay times are being used.

When container relaying is used, a system of container identification is necessary to locate and avoid re-harvesting of shellfish from containers that have not been left in place long enough for sufficient cleansing.

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07. SYSTEMATIC RANDOM SAMPLING MONITORING STRATEGY

NSSP guidance documents provide the public health principles supporting major components of the NSSP and its Model Ordinance, and summaries of the requirements for that component. NSSP Model Ordinance requirements apply only to Interstate commerce although most states apply the requirements intrastate. For the most up to date and detailed listing of requirements, the reader should consult the most recent edition of the *Model Ordinance.*

The first critical control point in preventing food-borne illness from shellfish consumption is identifying shellfish growing areas of acceptable sanitary quality. The completion of a sanitary survey is of paramount importance in making the distinction between acceptable and unacceptable growing areas, and is the key to accurate growing area classification as approved, conditionally approved, restricted, conditionally restricted, or prohibited. A sanitary survey is required under the National Shellfish Sanitation Program's (NSSP) *Model Ordinance* for each growing area prior to its approval by the state as a source of shellfish for human consumption or as a source for shellfish to be used in a depuration or relay operation. The principal components of a sanitary survey are: (1) identification and evaluation of the pollution sources that may affect the areas, (2) an evaluation of the meteorological factors, (3) an evaluation of hydrographic factors that may affect distribution of pollutants throughout the area, and (4) an assessment of water quality. For an in depth discussion of the sanitary survey, see the NSSP Guidance Document, *Sanitary Survey and the Classification of Growing Waters* (ISSC/FDA, 2002).

The NSSP in its *Model Ordinance* allows the Authority to classify a growing area using either a total or fecal coliform standard as part if its sanitary survey. The two standards are believed to afford the same level of public health protection. The NSSP *Model Ordinance* also recognizes two distinct water quality monitoring strategies to obtain total coliform or fecal coliform monitoring data: the adverse pollution condition strategy to be used for initial classification and for monitoring; and, the systematic random sampling strategy that can be used only for monitoring if no input from point source pollution is present.

Total coliform or fecal coliform monitoring data collected under either the adverse pollution condition or the systematic random sampling strategy and the data collected for initial classification are reported as MPN values. An MPN or most probable number is a statistically derived estimate of the number of bacteria per unit volume of water sampled. The value of the MPN is determined from the combination of positive and negative results obtained from a series of fermentation tubes used in a particular laboratory test. A complete discussion of the MPN test can be found in *Standard Methods for the Examination of Water and Wastewater* (APHA, 1985).

NSSP water quality standards for growing area classification have two components. The first component establishes a median MPN value. The second component intended for use with data collected under uniform conditions represents the variability inherent in the testing procedure and a small allowance for some additional variability peculiar to the changing conditions in the water being sampled. The original NSSP "variability factor" for the total coliform group, an MPN of 230 per 100 milliliters of sample was developed to include 90% of the samples collected

under uniform conditions in which the only sources of variability operational are due to the test procedure and the allowance for some additional variability arising from changing conditions in the water being sampled. Therefore, if only these two sources of variability are active in the sample data, then no more than 10% of the samples derived under these conditions will exceed an MPN value of 230 per 100 milliliters of sample when the 5-tube, decimal dilution MPN procedure is used. This is referred to in the NSSP as the 10% criteria where no more than 10% of the samples should exceed the variability factor established for the standard and the testing procedure being used.

This same type of reasoning has been applied to both the total and fecal coliform groups and appropriate 10% criteria developed for the MPN test employed (330 and 140 MPN per 100 milliliters for the total coliform group tested by the 3-tube, decimal dilution and the 12-tube, single dilution MPN procedures, respectively, and 43, 49 and 28 MPN per 100 milliliters for the fecal coliform group tested by the 5 and 3 -tube, decimal dilution and 12-tube, single dilution MPN procedures, respectively. Because these variability factors were derived for use with data sets collected under uniform conditions, they do not address wide swings in water quality that result from changing environmental conditions driven by random pollution events such as runoff carried pollutants following rainfall. Therefore, the 10% criteria is not considered sufficient to protect public health when shellfish are taken from growing area waters adversely affected by known meteorological or hydrological events, that occur intermittently, and are shown to degrade water quality.

While many growing area waters may meet the NSSP median value and 10% criteria, some shellfish growing area sampling stations still display a considerable level of variation in the MPN sample results. Sampling data of this type may indicate that the shellfish growing areas are intermittently polluted during adverse pollution conditions and pose a risk to the shellfish consuming public. The NSSP has never intended to place a growing area that is polluted 10% of the time in the approved classification. The dilemma facing the Authority, therefore, is how to distinguish between the inherent variation of the MPN test and the variability resulting from intermittent environmental conditions that degrade water quality. When environmental events (such as rainfall) produce unfavorable effects on water quality, the data may contain data points that vary widely from the median value of the established classification. Such a data set would probably contain upper outliers that represent periods when the shellfish may be exposed to significantly greater quantities of pollution. In this situation, the determination of NSSP conformity to the established classification standard for a set of growing water samples from a particular station may become an arbitrary function of the mechanics of sampling (timing and/or frequency) rather than an actual characteristic of the growing area. Use of a statistical method, the estimated ninetieth percentile, will detect these random pollution events that may cause a data set to be skewed because of a few high MPN values.

When shellfish water sampling data collected following intermittent pollution events are combined with data collected under normal conditions, variability is increased. The estimated ninetieth percentile will reflect this increased variability. Therefore, use of the estimated ninetieth percentile will protect against the potential public health problems that may result when

shellfish are consumed from growing waters that are adversely affected by intermittent pollution events and improperly classified.

The method for calculating the ninetieth percentile for use in evaluating growing water bacteriological data was suggested by the Georgia Department of Natural Resources, as an addendum to Interstate Shellfish Sanitation Conference (ISSC) in issue 8109. The ISSC adopted the systematic random sampling monitoring strategy and the method recommended for calculating the ninetieth percentile at its 1989 ISSC Annual Meeting

Water Quality Assessment

In the adverse pollution condition monitoring strategy, the water quality standards for both total and fecal coliforms use the 10% criteria, the variability portion of the standard to adjust for the inherent variability of the MPN testing procedure in data with uniform bacterial densities. In the systematic random sampling strategy, the application of the water quality standard employs the variability portion of the standard to detect the impact of intermittent environmental events on water quality above and beyond those attributed by the MPN testing procedure alone.

A field sampling and data analysis design that employs a systematic random sampling plan for routine monitoring assumes that a statistically representative cross section of all meteorological, hydrographic, or other pollution events will be included in the data set. Therefore, all shellfish growing area data collected under the systematic random sampling plan are used to determine compliance with the appropriate total coliform or fecal coliform water quality standard. This sample collection and data analysis design may be applied only to growing areas that are affected by randomly occurring pollution events triggered by rainfall and runoff and that meet the standard for the approved or restricted classification. This sampling strategy may also be used to monitor growing areas where water quality is influenced by seasonal water uses or where harvesting is controlled by seasonal resource management restrictions. In this situation, monitoring must be done during the season when the growing waters are open. Systematic random sampling is not intended to nor should it be applied to areas impacted by point source pollution.

The systematic random sampling monitoring strategy and data analysis design presumes that if intermittent, unfavorable changes in water quality occur, they will be revealed in the bacteriological sampling results. These unfavorable sampling results will contribute to the variability of the data set. Data sets displaying high levels of variability will consequently exhibit an elevated estimated ninetieth percentile. The Authority's option to use the systematic random sampling strategy is, therefore, contingent upon acceptance of the estimated ninetieth percentile as the statistic used to measure the variability of the data set. Also required is that timing of monitoring runs be preplanned far in advance so that effects of random nonpoint pollution events will be captured if they occur. This statistic, along with the geometric mean of the data set, can be used when evaluating each sampling station for compliance with the NSSP water quality standards.

An example of an acceptable systematic sampling plan is one that documents a pre-established sampling schedule in the growing area central file. Monthly or bimonthly sampling regimes are

acceptable and the schedule is maintained so there is no avoidance of unfavorable conditions. A reasonable attempt must be made to collect samples on the pre-established days regardless of navigational conditions. Field sampling crews, however, are not required to take unnecessary risks to sample on any particular day. The sampling plan must address unsafe sample collection (boating) conditions by designating an alternate sampling day or by allocating extra sampling days in the schedule that may be used when needed.

If the growing area is to be used year-round for harvesting, the random sampling plan should stipulate the collection of samples throughout the year. If the growing area is intended to be approved for direct harvest for only part of the year, the random sampling plan would need only to address that period when the area is available for harvest. The only exception to this obligation in a random sampling regime is that the Authority will require sampling during a particular tidal condition, if that condition unfavorably impacts the water quality of the growing area.

Estimating the Ninetieth Percentile

Use of the systematic random sampling strategy involves calculating the estimated ninetieth percentile of the data. This statistic measures variability in the data and should not be exceeded by random pollution events if the growing area is properly classified. When the Authority elects to employ the systematic random sampling strategy, the following guideline must be used to calculate the estimated ninetieth percentile.

The estimated ninetieth percentile must be obtained using the following equation:

$$\text{Est. 90th percentile value} = \text{Antilog}\left[(S_{log})1.28^{A} \tilde{+}_{log}\right]$$

Where

S_{log} = base 10 logarithmic standard deviation.

x_{log} = base 10 log mean

[A] The value 1.28 is obtained from the standard normal distribution

Other:

• For the purpose of mathematical calculations, MPN values that signify the upper or lower range of sensitivity for that test shall be increased or decreased one significant number. (MPN counts are reported in the form of two significant numbers.) For example, an MPN value of ‘less than 2’ shall be decreased by one to 1.9 to indicate the lower level of sensitivity of the five tube, decimal dilution MPN test. In a similar manner, 2.9 shall be used to indicate the MPN value of ‘less than 3’ for the three tube, decimal dilution MPN test. Therefore

it would follow that a MPN value of 1700 shall be used to indicate the MPN value 'greater than 1600' for the five tube MPN test.

• Logarithms may be rounded to three decimal places.

• Antilogs of log MPN calculations may be rounded to the ***next lower integer*** (zero decimal places) [example - antilog (0.556) = 3]

• The standard deviation of the log MPN data shall be calculated in the following manner:

$$S_{log} = \sqrt{\frac{\sum (x - \bar{x})^2}{n - 1}}$$

Application of the Guideline:

Example 1

(1) Convert MPN values to base 10 logarithms.

Obs	MPN	Log_{10}	Obs	MPN	Log_{10}
1	2.9	0.462	16	3.6	0.556
2	2.9	0.462	17	3.6	0.556
3	2.9	0.462	18	3.6	0.556
4	2.9	0.462	19	9.1	0.959
5	2.9	0.462	20	9.1	0.959
6	2.9	0.462	21	9.1	0.959
7	2.9	0.462	22	9.1	0.959
8	2.9	0.462	23	9.1	0.959
9	3.6	0.556	24	9.1	0.959
10	3.6	0.556	25	23	1.362
11	3.6	0.556	26	23	1.362
12	3.6	0.556	27	23	1.362
13	3.6	0.556	28	43	1.633
14	3.6	0.556	29	43	1.633
15	3.6	0.556	30	460	2.663

(2) Calculate Geometric Mean and Standard Deviation.

Median	-	3.6
Percentage greater than 43	-	3.3 %
Geometric Mean (Antilog $\underline{0}_{log}$)	-	(Antilog 0.834) or 6
Log Standard Deviation (S_{log})	-	0.506

(3) Calculate Estimated 90th Percentile using above equation.

Est. 90^{th} = Antilog $[(S_{log})1.28 + \underline{0}_{log}]$

= Antilog $[\underline{(0.506)}1.28 + \underline{0.834}]$

Est. 90^{th} = Antilog [1.482] or 30

(4) Interpret.

The geometric mean of the data set is less than 14 and the estimated 90th percentile is less than 49 (three tube, decimal dilution test). This station meets the NSSP fecal coliform water quality standard for the approved classification.

Example 2

(1) Convert MPN values to base 10 logarithms.

Obs	MPN	Log_{10}	Obs	MPN	Log_{10}
1	1.9	0.279	16	2.0	0.301
2	1.9	0.279	17	4.5	0.653
3	1.9	0.279	18	4.5	0.653
4	1.9	0.279	19	7.8	0.892
5	1.9	0.279	20	7.8	0.892
6	1.9	0.279	21	7.8	0.892
7	1.9	0.279	22	11	1.041
8	1.9	0.279	23	11	1.041
9	2.0	0.301	24	23	1.362
10	2.0	0.301	25	23	1.362
11	2.0	0.301	26	23	1.362
12	2.0	0.301	27	23	1.362

13	2.0	0.301	28	33	1.519
14	2.0	0.301	29	540	2.732
15	2.0	0.301	30	1700	3.230

(2) Calculate Geometric Mean and Standard Deviation.

Median - 2.0

Percentage greater than 43 - 6.6 %

Geometric Mean (Antilog $\underline{0}_{log}$) - (Antilog 0.788) or 6

Log Standard Deviation (S_{log}) - 0.737

(3) Calculate Estimated 90th Percentile using above equation -

Est. 90^{th} = Antilog $[(S_{log})1.28 + \underline{0}_{log}]$

= Antilog [(.737)1.28 + .788]

Est. 90^{th} = Antilog [1.731] or 53

(4) Interpret.

While this station's geometric mean is less than 14, the standard deviation that resulted from the high values in this data set, would lead one to conclude that water quality may have been adversely affected by storm water runoff or another intermittent pollution event. The estimated 90th percentile was 53 (greater than 43 - for the five tube, decimal dilution MPN test). Therefore this station ***would not meet*** the NSSP fecal coliform water quality standard for the approved classification.

References

U.S. Food and Drug Administration (FDA). 1965. National Shellfish Sanitation Program Manual of Operations, Part I. FDA, Washington, D.C., p. 11, footnote 6.

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American Public Health Association. 1985. *Standard Methods for the Examination of Water and Wastewater*, 16th Ed. American Public Health Association, American Water Works Association, Water Pollution Control Federation, Washington D.C.

08. GROWING AREA PATROL AND ENFORCEMENT

NSSP guidance documents provide the public health principles supporting major components of the NSSP and its Model Ordinance, and summaries of the requirements for that component. NSSP Model Ordinance requirements apply only to Interstate commerce although many states apply the requirements intrastate. For the most up to date and detailed listing of requirements, the reader should consult the most recent edition of the Model Ordinance.

The primary objective of the NSSP is to ensure that shellstock is only harvested from areas free of excessive concentrations of pathogenic microorganisms and poisonous or deleterious substances. Under the NSSP, growing areas, based on their public-health suitability for shellstock harvesting, are placed in one of five shellstock harvesting classifications. Information obtained from sanitary surveys sets the basis to determine the appropriate growing area classification. All classifications, except for the approved classification, place some type of restriction on harvesting. For more information concerning growing area classification, see the NSSP Guidance Document, *Sanitary Survey and the Classification of Growing Waters* (ISSC/FDA, 2002).

If harvesters are not convinced of the need for the restrictions, shellstock may be harvested surreptitiously from areas in the closed status or the in prohibited classification. Therefore, the patrol element of the NSSP is vital to ensure compliance with the public-health safeguards resulting from the classification of growing waters. The fact that the law prohibits the removal of shellstock from contaminated areas will deter the majority of the population from attempting to harvest the shellstock.

Patrol Activity

Control procedures are necessary in a comprehensive shellfish sanitation program to assure that shellstock are harvested only from growing areas in the approved classification or the open status of the conditionally approved classification. Under special permits and close supervision of the Patrol Authority, shellstock may also be harvested from growing areas in the restricted or conditionally restricted classification for cleansing treatment through relay or depuration prior to sale to the consumer.

The Patrol Authority is responsible to provide sufficient personnel and equipment that will act as a deterrent to illegal shellstock harvesting from growing areas in the closed status or in the prohibited classification. In addition, the Patrol Authority must have sufficient legal authority to apprehend and to effectively prosecute persons apprehended harvesting shellstock illegally. Penalties for such violations must be sufficient to discourage illegal harvesting.

Specific patrol requirements applicable to technical and administrative situations vary from state to state. Consequently, the NSSP requires each Patrol Authority to develop a patrol policy document and to keep it current. This policy document must fully describe the Patrol Authority's organization and its activities to deter illegal harvesting. In addition, it must include information concerning the Patrol Authority's legal basis and the laws and regulations to be

enforced, personnel, equipment, training in shellfish patrol techniques, patrol activities and record keeping. The NSSP requires the policy document to be updated and reviewed annually.

The type of patrol needed for any particular situation cannot be specified and is determined by the nature of areas to be patrolled, means of access, methods of harvesting, and species. Patrol equipment allows the officers to apprehend persons illegally harvesting shellstock. Equipment that has proven effective for apprehension of illegal harvesters includes: small, high-speed, readily transportable boats; automobiles; aircraft; communications for coordinating patrol activities; radar surveillance systems; and night scopes. Organization of the patrol activity must take into consideration the need for night, weekend, holiday, and undercover patrols. Various patrol methods may be used depending on the nature of the area to be patrolled and the type of industry.

Adequate delineation of growing areas in the closed status or prohibited classification is fundamental to effective patrol enforcement. The type of growing area identification used will be determined by the structure of the local shellfish industry and the legal requirements that permit successful prosecution in each state or local jurisdiction. Posting a warning sign is one method of informing shellstock harvesters that an area is off-limits to the taking of shellstock for public health reasons. Other identification methods for off-limit growing areas include information access through toll free or other telephone systems, maps issued at checkpoints or with harvesting licenses, direct mail, and news media. The Patrol Authority or other appropriate Authority should seek the advice of the state's legal counsel to ensure that the marking of growing areas in the closed status or prohibited classification and notifications to shellstock harvesters are sufficient to provide for the successful prosecution of persons harvesting from these areas.

Application of legal penalties sufficient to defer the taking of shellstock from growing areas in the closed status or the prohibited classification is a necessary component for effective enforcement in a shellfish sanitation program. The adequacy of state or local laws as a basis for prosecution is an important to this activity. The Patrol Authority will be ineffective or compromised if state or local laws are written or interpreted so that violators can not successfully be prosecuted and if penalties are so small that they are economically unimportant. Periodic assessments, by the Patrol Authority or another appropriate Authority, of the degree of success of court actions taken in response to illegal harvesting is necessary for both the analysis of the effectiveness of the program. Prosecution will be difficult if the courts are not fully aware of the public-health hazards associated with the crime. Written policies or guidelines that are used to recommend penalties on specific cases to the courts must be developed by the Patrol Authority or another appropriate Authority. Courts should be encouraged to apply effective penalties, and records should be kept to determine the effectiveness of the penalty system.

Licensing shellstock harvesters is an important control measure to help protect against illegally harvested shellstock. The appropriate Authority shall license each person who harvests shellstock. In the case of leased land, either the lessee or the person who harvests from the lease must be licensed. The appropriate Authority must maintain a record of all licenses granted.

Special permits must be issued to licensed harvesters for taking shellstock from contaminated growing areas for use in relay or depuration operations.

Depletion of prohibited areas can be an effective deterrent to illegal harvesting, and may be more economical and effective in protecting public health than patrol of prohibited areas. Complete removal of shellstock from prohibited areas provides a safeguard against contaminated shellstock reaching the market and eliminates a temptation for harvesters. In a depletion operation, all market sized shellstock and as many of the smaller sized shellstock as can be gathered by reasonable methods are removed from the growing area. To be effective, depletion operations should be conducted at sufficient intervals to keep growing areas free of commercial quantities of market-sized shellstock. When commercial harvesters conduct depletion operations, the Authority or the Patrol Authority must provide effective supervision.

All relay operations must be under the effective supervision of the Patrol Authority or other appropriate Authority. Supervision must ensure that shellstock harvested for relay cannot be illegally diverted to the market and only shellstock that have completed the required period of treatment are marketed. The supervising official must be authorized and equipped to enforce the relay operation procedures and to supervise the harvest, transport, and re-deposition of the shellstock. The Patrol Authority must also provide ~~for~~ effective supervision of the relay areauntil completion of the relaying operation. For additional information concerning relay operations, see the NSSP Guidance Document, *Shellstock Relay* (ISSC/FDA, 2002).

All shellstock harvested for depuration must also be under the effective supervision of the Patrol Authority or other appropriate Authority so that the shellstock cannot be illegally diverted to the market before depuration. The supervising official must be authorized and equipped to enforce the depuration operation procedures and to supervise the harvest and transport of shellstock to the depuration operation. For additional information concerning depuration, see the NSSP Guidance Document: *Shellstock Depuration* (ISSC/FDA, 2002).

Recommendations for FDA Evaluation of State Program Patrol Element

The NSSP requires the FDA to evaluate the patrol of growing areas and its enforcement component on an annual basis. Technical assistance may be provided to FDA by a representative of a patrol agency(ies) through use of these procedures that have been agreed to by the FDA and the ISSC. Both FDA and the ISSC have agreed that these procedures do not apply to special investigations by either party.

The following procedures should be used in conducting patrol evaluations:

A. The person in charge of the patrol agency must be advised of the intent to conduct patrol evaluations, approximate patrol dates desired, recommended patrol areas or districts, and other pertinent information.
B. If requested by the state shellfish patrol agency, FDA will meet with the person in charge or his designee prior to participating in patrols to gain a better understanding of patrol program activities.

C. Agency patrol documents and past FDA reports of areas to be evaluated should be reviewed.
D. The FDA Standardized Patrol Evaluation Format must be used in conducting patrol evaluations.
E. FDA evaluators must allow adequate time in the field with primary patrol officers to fully evaluate an area.

Following individual patrol evaluations, the FDA evaluator must:

A. Prepare draft reports for the individual patrol areas evaluated and an overall draft patrol evaluation report and promptly send them for review to the technical advisor who participated in the evaluation.
B. Send copies of draft reports to the person in charge of the patrol agency for comment prior to finalizing evaluation reports.
C. Meet with the person in charge of the Patrol Authority, if requested by the Patrol Authority to further qualify the accuracy of the final report.

When an FDA evaluator, in the field and unaccompanied by a patrol officer, observes an alleged violation, the FDA evaluator must immediately report the alleged violation to the Patrol Authority.

FDA Standardized Patrol Evaluation

When an FDA evaluator conducts an evaluation of a patrol area, the following information must be collected:

1. Background information such as:
   - Patrol evaluation date and time
   - Accompanying officer(s)
   - Patrol area name and/or number
   - Weather, tide, and other pertinent information
   - Type of harvest (recreational or commercial)
2. Agency and patrol area organization including identification of:
   - Laws, regulations and policies which apply to shellfish control activities
   - Number and positions of personnel within the region and within the patrol area
   - Supervision for that patrol area and region
3. Patrol area information including:
   - An officer's or officers' knowledge of the area and experience within the agency and related agencies
   - Variations in patrol area coverage (days, nights, weekends, and holidays)
   - Transplants, relay, or aquaculture operations in the patrol area (if appropriate)
   - Coverage of adjacent areas, and back-up to primary officer(s) for this patrol area
   - Equipment used for patrolling the area including the primary vehicle, boats and motors, radios, visual assisting tools and other equipment.
4. Coverage of markets and retail stores as appropriate.
5. Other responsibilities of officer or officers while on patrol.

6. Records of enforcement activities for the area during the last year.
7. Problems unique to the patrol area.

To comply with Standardized Evaluation Criteria, the authority shall:

1.	Have a patrol policy document	CRITICAL item
2.	Update patrol policy document every year.	KEY item
3.	Meet the NSSP patrol training requirements.	KEY item
4.	Patrol all areas that require patrol	CRITICAL item
5.	Meet NSSP requirements for frequency of patrol	KEY item
6.	Have formalized MOA with other agency per Chapter VIII@.01.B(5).	KEY item
7.	Have a risk management plan per Chapter VIII@.01.B(3)(b)(c)(d).	CRITICAL item
8.	Have a complete risk management plan per Chapter VIII@.01.B(3)(b)(c)(d).	Other item

The authority shall ensure the following COMPLIANCE CRITERIA procedures are implemented when an FDA evaluation identifies deficiencies with NSSO MO criteria.

a) During the closeout meeting for patrol evaluation, the Shellfish Specialists shall identify any patrol deficiency to the state patrol agency;

b) Within 15 days of the closeout meeting, the Shellfish Specialist should provide a written Program Element Evaluation Report (PEER), including supporting documentation, to the State patrol agency;

c) Within 30 days of receiving the PEER, the State patrol agency should provide a written response that indicates:
   - The item(s) was corrected;
   - A correction plan has been developed with a completion date; or,
   - The reasons why the State disagrees with FDA's finding(s).

d) Within 15 days of receipt FDA should review the State response, and respond to the State;

e) Any CRITICAL item deficiency should be corrected within 30 days of acceptance by FDA of the correction plan;

f) Any KEY item deficiency should be corrected within one year of acceptance by FDA of the correction plan.

g) An OTHER item deficiency should be corrected within 60 days of acceptance by FDA of the correction plan.

FDA shellfish specialists shall be responsible for monitoring the progress of state action plans.

References

Interstate Shellfish Sanitation Conference (ISSC). 2002. Shellstock Depuration (document in development). *In* ISSC (ed), NSSP Guide for the Control of Molluscan Shellfish. Interstate Shellfish Sanitation Conference, Columbia, S.C.

Interstate Shellfish Sanitation Conference (ISSC). 2002. Sanitary Surveys and the Classification of Growing Waters. *In* ISSC (ed), NSSP Guide for the Control of Molluscan Shellfish. Interstate Shellfish Sanitation Conference, Columbia, S.C.

Interstate Shellfish Sanitation Conference (ISSC). 2002. Shellstock Relay. *In* ISSC (ed), NSSP Guide for the Control of Molluscan Shellfish. Interstate Shellfish Sanitation Conference, Columbia, S.C.

09. Control of Shellfish Harvesting

Requirements for the Authority. Other portions of this section of the Guide have described the public health reasons for limiting shellfish harvesting to areas free of contamination and shellfish toxins. For a full discussion of control activities, see the NSSP guidance document, *Growing Area Patrol and Enforcement of Growing Area Restrictions* (ISSC/FDA, 2001).

For the most part, control of illegal harvesting depends upon the patrol activities as described in this chapter, @01.B. Adequate delineation of closed areas is fundamental to effective patrol. The type of area identification will be determined by the structure of the local shellfish industry and the legal requirements for each State to permit successful prosecution. Posting a warning sign is one method of informing shellfish harvesters that an area is closed to the taking of shellfish for public health reasons.

Other methods for identification of closures include telephone, maps issued at checkpoints, or with harvesting licenses, direct mail, and news media. It is recommended that the advice of the State's legal counsel be obtained to insure that the marking of closed areas and notifications to shellfish harvesters are such that persons harvesting from closed areas can be successfully prosecuted.
However, if local shellfish harvesters are not convinced of the need for restrictions, shellfish may be harvested surreptitiously from closed areas. *Thus, the patrol element of the NSSP is important to ensure compliance with the public-health safeguards resulting from the sanitary survey.* The fact that the law prohibits the removal of shellfish from certain areas will deter the majority of the population from attempting to harvest such shellfish, provided they are aware of the law and of the areas which are closed.

The type of patrol needed for any particular situation cannot be specified and is determined by the nature of areas to be patrolled, means of access, methods of harvesting, and species. Patrol equipment should be such that the officers can apprehend persons illegally harvesting shellfish in a closed area. Equipment that has proven effective for apprehension of illegal harvesters includes: small, high-speed, readily transportable boats capable of operating in open waters; automobiles; aircraft; communications for coordinating patrol activities; radar surveillance systems; and night scopes.

Organization of the patrol activity must take into consideration the need for night, weekend, holiday, undercover and surprise patrols. Various patrol methods may be used depending on the nature of the area to be patrolled and the type of industry.

Complete removal of shellfish from polluted areas provides a safeguard against contaminated shellfish reaching the market. In some cases, depletion may be the method selected to eliminate an irresistible temptation for harvesters. Depletion may be more economical and effective than patrol of closed areas and will serve to protect public health.

Educational programs should be developed for both industry and the public describing the public health necessity for eliminating shellfish harvesting from closed areas. Programs developed specifically for participation of key industry people may be especially helpful in eliciting

cooperative efforts of the entire industry. Such programs should focus on incentives to eliminate harvesting and marketing of shellfish from closed areas.

The adequacy of state laws as a basis for prosecution is an important component of this activity. Shellfish patrol will be ineffective and or compromised if State laws are so written or interpreted that violators can not successfully be prosecuted and if penalties are so small that they are economically unimportant. It is important that periodic assessments are made by the State control or patrol agency of the degree of success of court actions taken in response to illegal harvesting. Information of this nature is necessary for both the analysis of the effectiveness of the program and for education purposes. Prosecution will be difficult where courts are not fully aware of the public-health hazards associated with the crime.

APPROVED NATIONAL SHELLFISH SANITATION PROGRAM LABORATORY TESTS:

MICROBIOLOGICAL AND BIOTOXIN ANALYTICAL METHODS

1. Microbiological Methods

Application/ Sample Type	Total Coliform[1]			Fecal Coliform[2]					Standard Plate Count[3]
				A1M		APHA			
	APHA Decimal Dilution MPN	12 tube single dilution MPN	Other	Decimal dilution MPN	12 tube single dilution MPN	Decimal dilution MPN	12 tube single dilution MPN	ETCP	
Growing Area Survey & Classification									
Seawater	X	X		X	X	X	X		
Controlled Relaying									
Seawater	X	X		X	X	X	X		
Shellfish						X			
Wet Storage									
Seawater			X						
Shellfish						X			
Controlled Purification									
UV Effluent			X						
Shellfish						X	X	X	
Market Shellfish									
Shellstock						X			X
Shucked						X			X

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References

(1) Total Coliform Methods

♦ American Public Health Association. 1970. *Recommended Procedures for the Examination of Sea Water and Shellfish*, 4th Edition, APHA, New York, N.Y. [Decimal Dilution MPN test]

♦ American Public Health Association, American Water Works Association, and Water Environmental Federation. 1992. Section 9221. Examination of a 100 ml aliquot by the Multiple Tube Fermentation Method (MTF). *Standards Methods for the Examination of Water and Wastewater*, 18th Edition, APHA/AWWA/WEF. Washington, D.C. [Decimal Dilution MPN test]

♦ Redman, J.H. 1974. A simpler multiple fermentation tube test for monitoring the bacteriological quality of shellfish harvest waters; the examination of twelve 1.0 ml sample portions, p.123-124. *In* Wilt, D.S. (ed.), *Proceedings 8th National Shellfish Sanitation Workshop*,. U.S. Food and Drug Administration, Washington, D.C. [12-tube, Single Dilution MPN test]

♦ Springer, J.A. 1974. Statistical considerations in using the twelve-tube MPN test for routine monitoring of shellfish waters, p.125-126. *In* Wilt, D.S. (ed.), *Proceedings 8th National Shellfish Sanitation Workshop*. U.S. Food and Drug Administration, Washington, D.C. [12-tube, Single Dilution MPN test]

(2) Fecal Coliform Methods

♦ A-1M, 1990 AOAC International – *Official Methods of Analysis*, 15th Edition. Association of Official Analytical Chemists. Washington, D.C. [A-1 Modified MPN test]

♦ American Public Health Association. 1970. *Recommended Procedures for the Examination of Sea Water and Shellfish*, 4th Edition, APHA, New York, N.Y.

♦ U.S. Food and Drug Administration. 2001. (Reissued 2-14-01). NSSP Interpretation, 99-III@.02-100, Options for the use of the 12-tube, single dilution MPN test. [12-tube, Single Dilution MPN test for seawater]

♦ U.S. Food and Drug Administration. 2001 (Issued 2-14-01). NSSP Interpretation 99-XV-03L-101, Method for determining fecal coliform levels in end product depurated shellfish. [12-tube, single dilution MPN test for the controlled purification of shellfish]

♦ Cabelli, V.J. and W.P. Heffernan. 1970. Accumulation of *Escherichia coli* by the northern quahog. Appl. Microbiol. 19:239-244. [ETCP for the controlled purification of hard- and soft-shelled clams]

(3) Standard Plate Count Method

♦ American Public Health Association. 1970. *Recommended Procedures for the Examination of Sea Water and Shellfish*, 4th Edition, APHA, New York, N.Y.

2. Marine Biotoxin Methods

Application/Sample Type	Paralytic Shellfish Poison (PSP)	Neurotoxic Shellfish Poison (NSP)
Growing Area Survey & Classification		
Shellfish	**x**	**x**
Controlled Relaying		
Shellfish	**x**	**x**

References:

1. Paralytic Shellfish Poison (PSP) and Neurotoxic Shellfish Poison (NSP) Methods
   - ♦ American Public Health Association. 1970. *Recommended Procedures for the Examination of Sea Water and Shellfish*, 4th Edition, APHA, New York, N.Y.

3. Type III and Type IV Microbiological Test Methods

Application/ Sample Type	Total Coliform	Fecal Coliform	Other
Growing Area Survey & Classification			
Seawater			
Controlled Relaying			
Seawater			
Shellfish			
Wet Storage			
Seawater			
Shellfish			
Controlled Purification			
UV Effluent	**Type III**[1]		
Shellfish			
Market Shellfish			
Shellstock			
Shucked			

Footnotes:

1. Single step direct mEndo-LES Membrane Filter Technique used in the Newburyport Depuration Plant, Massachusetts.

4. Type III and Type IV Marine Biotoxin Test Methods

Application/Sample Type	NSP	DSP	ASP	Other
Growing Area Survey & Classification				
Shellfish			**Type III**[1]	
Controlled Relaying				
Shellfish			**Type III**[1]	

Footnotes:

1. Peer recognized HPLC Methods with or without clean up.

11. EVALUATION OF LABORATORIES BY STATE SHELLFISH LABORATORY EVALUATION OFFICERS INCLUDING LABORATORY EVALUATION CHECKLISTS

NSSP Guidance Documents provide the public health principles supporting major components of the NSSP and its Model Ordinance, and summaries of the requirements for that component. NSSP Model Ordinance requirements apply only to interstate commerce although most states apply the requirements intrastate. For the most up to date and detailed listing of requirements, the reader should consult the most recent edition of the Model Ordinance.

Laboratory results from the bacteriological and marine toxin testing of shellfish growing waters and meats are widely used in the National Shellfish Sanitation Program (NSSP) to aid in determining the safety of shellfish for human consumption. Experience with the bacteriological and marine biotoxin analyses of shellfish and shellfish waters have indicated that minor differences in laboratory procedures or techniques might cause wide variations in the results. Improper handling of the sample may also cause variations in results during collection or transportation to the laboratory. To ensure uniformity nationwide in the application of standards for shellfish and shellfish growing waters, a laboratory quality assurance program is necessary to substantiate the validity of analytical results. A laboratory quality assurance program is the systematic application of the practices essential to remove or minimize errors that may occur in any laboratory operation caused by personnel, apparatus, equipment, media, reagents, sampling procedures, and analytical methodology (APHA, 1985). Integral to laboratory quality assurance is a strong program for the external assessment or evaluation of laboratory performance.

Requirements for evaluating laboratories that analyze samples under the NSSP have increased significantly since the 1970's. The number of laboratories participating in the shellfish program has also increased. Several states now have multiple laboratories that provide these analyses. Some states have officially designated city, county or private laboratories to conduct analyses supporting their shellfish sanitation programs. Some states are also authorizing the use of private laboratories to monitor depuration operations. More states are maintaining a marine biotoxin analytical capability in their laboratories; and more foreign laboratories are involved in the NSSP. Historically, FDA has evaluated all these laboratories. Reduction in FDA staffing has made it difficult to evaluate the many state, county, municipal, and foreign shellfish laboratories operating in support of the NSSP. If states with multiple laboratory support would exercise their option to accept responsibility for evaluating their laboratories by employing a State Shellfish Laboratory Evaluation Officer (State Shellfish LEO), FDA would be able to better meet its NSSP responsibilities.

Selection of State Shellfish LEOs should be based on the following criteria:

(1) The individual must be administratively attached to a State central shellfish sanitation laboratory that has been found by the FDA to be in full conformance with NSSP requirements. To avoid the appearance of impropriety and maintain objectivity in the evaluation process, individuals certified as State Shellfish LEOs will not be allowed to evaluate their own laboratories. FDA will maintain the responsibility for evaluating these laboratories.

(2)The individual must be an experienced analyst and should have laboratory supervision experience. To maintain the integrity of the evaluation process, this individual should not, however, have overall supervisory responsibility for the laboratory or laboratories to be evaluated If deemed necessary by an FDA Laboratory Evaluation Officer, the individual must conduct several laboratory evaluations jointly with the FDA Laboratory Evaluation Officer.

(3) During the joint on-site laboratory evaluations with an FDA Laboratory Evaluation Officer, the individual must demonstrate competence in evaluating the laboratory's capability to support the NSSP. The evaluation will be performed and documented using the most current version of the applicable FDA Shellfish Laboratory Evaluation Checklist.

(4) The individual must submit a written narrative report of the joint on-site evaluation to the FDA co-evaluator for review and comment. The report should consist of the completed FDA Shellfish Laboratory Evaluation Checklist and a narrative discussion that accurately and concisely describes the overall operation of the laboratory. All nonconformities noted should be described in this evaluation write-up; and, where relevant an explanation provided relating the potential impact of the deficiency on the analytical results. Recommendations for corrective action or, if applicable, suggestions to enhance laboratory operations must also be included in this write-up.

The FDA will issue a letter certifying each individual who successfully completes the certification process and will clear the evaluation report(s) for distribution to the laboratories evaluated with copies to the appropriate Shellfish Specialist. Certification is normally effective for a period of three (3) years. Once certified, the individual is then expected to assume the following responsibilities:

- Conduct on-site laboratory evaluations at least every three (3) years. However, more frequent evaluations are strongly encouraged and may be required with marginally performing laboratories, or when major changes in workloads or priorities have occurred or when there has been a substantial turnover of personnel, or, at the specific request of State Shellfish Control Authorities;

- Provide appropriate post-evaluation follow-up for each laboratory evaluated;

- Prepare timely narrative evaluation reports for all laboratories evaluated incorporating the requirements specified in 4 above;

- Distribute completed evaluation reports to the appropriate FDA Laboratory Evaluation Officer and Regional Shellfish Specialist;

- Inform the appropriate FDA Laboratory Evaluation Officer when a laboratory has been found to be nonconforming;

- Develop/coordinate/implement/conduct yearly proficiency testing for all laboratories in the state supporting the NSSP; and,

- Prepare at least annually (in December) a summary list of qualified analysts for each laboratory supporting the NSSP in the state and transmit it to the appropriate FDA Laboratory Evaluation Officer.

Recertification of State Shellfish LEOs will normally occur triennially and will be based on satisfactorily meeting the following criteria:

(1)The individual must continue to be administratively attached to a central state shellfish laboratory which is in full conformance with NSSP requirements;

(2) The individual is not the supervisor of any of the laboratories to be evaluated;

(3) The individual must demonstrate continued competence in evaluating the capability of laboratories to support the NSSP. If considered necessary, the individual will be required to perform one to several joint evaluations with the FDA Laboratory Evaluation Officer;

(4) The individual must submit a written narrative report of the joint evaluation(s) to the FDA co-evaluator for review and comment. The report should consist of the completed FDA Shellfish Laboratory Evaluation Checklist and the narrative portion should be prepared as described above;

(5) The individual must have all state laboratory evaluations, split-sample (proficiency) test examinations, and reports current;

(6) The individual should receive training, as necessary, in laboratory evaluations and analytical procedures to remain proficient.

State Shellfish LEOs who successfully complete this process will be issued a letter of recertification by FDA and be cleared to distribute the evaluation reports to the laboratories evaluated with a copy to the appropriate Regional Shellfish Specialist. Normally recertification is effective for a period of three (3) years. Individuals who fail to meet the requirements for recertification will lose their certification until it is demonstrated that all requirements including adequate training are met.

References

American Public Health Association. 1985. *Standard Methods for the Examination of Water and Wastewater.* 16th Ed. American Public Health Association, American Water Works Association, Water Pollution Control Federation. Washington, D.C.

Food and Drug Administration. 1994. *Standard Procedures for State Shellfish Laboratory Evaluation Officers*. U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Field Programs, Division of Cooperative Programs, Shellfish Safety Branch, Washington, D.C.

Laboratory Evaluation Checklist – Microbiology

PUBLIC HEALTH SERVICE **U.S. FOOD AND DRUG ADMINISTRATION** **SHELLFISH PROGRAM IMPLEMENTATION BRANCH** **SHELLFISH SAFETY TEAM** **5100 PAINT BRANCH PARKWAY** **COLLEGE PARK, MD 20740-3835** **TEL. 301-436-2151/2147 FAX 301-436-2672**		
SHELLFISH LABORATORY EVALUATION CHECKLIST		
LABORATORY:		
ADDRESS:		
TELEPHONE: **FAX:** **EMAIL:**		
DATE OF EVALUATION:	**DATE OF REPORT:**	**LAST EVALUATION:**
LABORATORY REPRESENTED BY:	**TITLE:**	
LABORATORY EVALUATION OFFICER:	**SHELLFISH SPECIALIST:** **REGION:**	
OTHER OFFICIALS PRESENT:	**TITLE:**	

Items which do not conform are noted by:

C- Critical K – Key O – Other NA – Not Applicable Conformity is noted by a "√"

NSSP Form Lab-100 rev. 2001-11-27

Laboratory Evaluation Checklist – Microbiology - 2

Check the applicable analytical methods:	
	Multiple Tube Fermentation Technique for Seawater (APHA)[PART II]
	Multiple Tube Fermentation Technique for Seawater USING ma-1 [PART II]
	Multiple Tube Fermentation Technique for Shellfish Meats (APHA)[PART III]
	Standard Plate Count for Shellfish Meats [Part III]
	Elevated Temperature Coliform Plate Method for Shellfish Meats [PART III]

PART 1 – QUALITY ASSURANCE			
CODE	**REF**		**ITEM**
K	8, 11		**Quality Assurance Plan**
			1. Written Plan (Check √ those items which apply.)
			a. Organization of the laboratory
			b. Staff training requirements
			c. Standard operating procedures
			d. Internal quality control measures for equipment calibration, maintenance, repair and for performance checks.
			e. Laboratory safety
			f. Internal performance assessment
			g. External performance assessment
C	8		2. QA Plan Implemented
K	11		3. Participates in a proficiency testing program annually.
			Specify Program(s)_____

CODE	**REF.**		**Work Area**
O	8, 11		1. Adequate for workload and storage.
K	11		2. Clean, well lighted.
K	11		3. Adequate temperature control.
O	11		4. All work surfaces are nonporous, easily cleaned and disinfected.
K	11		5. Microbiological quality and density of air is < 15 colonies/plate in a 15 minute exposure determined monthly and results recorded.
O	11		6. Pipette aid used, mouth pipetting not permitted.

NSSP Form Lab-100 rev. 2001- 11- 27

Laboratory Evaluation Checklist – Microbiology - 3

CODE	REF.		Equipment
O	9		1. To determine the pH of prepared media, the pH meter has a standard accuracy of 0.1 units.
O	14		2. pH electrodes, consisting of pH half cell and reference half cell or equivalent combination electrode (free from Ag/AgCl or contains an ion exchange barrier preventing passage of Ag ions into the medium which may effect the accuracy of the pH reading).
K	11		3. The effect of temperature on the pH is compensated for by an ATC probe or by manual adjustment.
K	8		4. pH meter is calibrated daily or with each use and records are maintained.
K	11		5. A minimum of two standard buffer solutions is used to calibrate the pH meter. The first must be near the electrode isopotential point (pH 7). The second near the expected sample pH (i.e. pH 4 or pH 10). (Standard buffer solutions are used once daily and discarded.
O	8, 15		6. Electrode effectiveness is determined daily or with each use.
		■	Method of determination_____.
K	9		7. Balance provides a sensitivity of at least 0.1 g at a load of 150 g.
K	11,13		8. Balance checked monthly using NIST Class S or ASTM Class 1 or 2 weights or equivalent and records are maintained.
K	11		9. Refrigerator temperature(s) monitored at least once daily and recorded.
K	1		10. Refrigerator temperature maintained at 0^o to 4^o C.
C	9		**11. The temperature of the incubator is maintained at 35+ 0.5^{o}C.**
C	11		**12. Thermometers used in the air incubator(s) are graduated at no greater than 0.5^{o}C increments.**
K	9		13. Working thermometer located on top and bottom shelves of use in the air incubator(s).
C	11		**14. Temperature of the waterbath is maintained at 44.5 + 0.2^{o}C under any loading capacity.**
C	9		**15. The thermometers used in the waterbath are graduated in 0.1^{o}C increments.**
O	13		16. The waterbath has adequate capacity for workload.
K	9		17. The level of water in the waterbath covers the level of liquid in the incubating tubes.
K	8, 11		18. Air incubator/waterbath temperatures are taken twice daily and recorded.
K	13		19. Working thermometers are tagged with identification, date of calibration, calibrated temperature and correction factor.
K	4		20. All working thermometers are appropriately immersed.
K	11		21. A standards thermometer has been calibrated by NIST or one of equivalent accuracy at the points 0^o, 35^o and 44.5^{o}C (45.5^{o}C for ETCP). Calibration records maintained.
K	9		22. Standards thermometer is checked annually for accuracy by ice point determination. Results recorded and maintained.
		■	Date of most recent determination_____.
K	13		23. Incubator and waterbath working thermometers are checked annually against the standards thermometer at the temperatures at which they are used. Records maintained.

NSSP Form LAB-100 rev. 2001-11-27

Laboratory Evaluation Checklist – Microbiology - 4

CODE	REF		Labware and Glassware Washing
O	9		1. Utensils and containers are clean borosilicate glass, stainless steel or other noncorroding materials
K	9		2. Culture tubes are of a suitable size to accommodate the volume for nutritive ingredients and samples
K	9		3. Sample containers are made of glass or some other inert material (i.e. polypropylene).
O	9		4. Dilution bottles and tubes are made of borosilicate glass or plastic and closed with rubber stoppers, caps or screw caps with nontoxic liners.
K	9		5. Graduations are indelibly marked on dilution bottles and tubes or an acceptable alternative method is used to ensure appropriate volumes.
K	9		6. Pipettes used to inoculate the sample deliver accurate aliquots, have unbroken tips and are appropriately graduated. Pipettes larger than 10 ml are not used to deliver 1ml; nor, are pipits larger than 1ml used to deliver 0.1ml.
K	9		7. Reusable sample containers are capable of being properly washed and sterilized.
K	9		8. In washing reusable pipits, a succession of at least three fresh water rinses plus a final rinse of distilled/deionized water is used to thoroughly rinse off all the detergent.
C	9 [redacted]		**9. In washing reusable sample containers, glassware and plasticware, the effectiveness of the rinsing procedure is established annually or when detergent (brand or lot) is changed by the Inhibitory Residue Test as described in the current edition of Standard Methods for the Examination of Water and Wastewater. Records are kept.** **Date of most recent testing**_____ **Average difference between Groups A and B**_____ **Average difference between Groups B and D**_____ **Detergent Brand**_____**Lot #**_____
K	**11**		10.Once during each day of washing several pieces of glassware (pipettes, sample bottles, etc.) from one batch are tested for residual acid or alkali w/aqueous 0.04% bromthymol blue. Records are maintained.

CODE	REF.		Sterilization and Decontamination
O	9		1. Autoclave(s) are of sufficient size to accommodate the workload.
O	8		2. Routine autoclave maintenance performed (e.g. pressure relief valves, exhaust trap, chamber drain) and records maintained.
O	8		3. Autoclave(s) and/or steam generators serviced annually or as needed by qualified technician and records maintained.
C	11		**4. Autoclave(s) provides a sterilizing temperature of 121°C (tolerance 121 ± 2°C) as determined weekly using a calibrated working maximum registering thermometer or equivalent (thermocouples, platinum resistance thermometers).**
K	11		5. An autoclave standards thermometer has been calibrated by the National Institute of Standards and Technology (NIST) or its equivalent at 121°C.

NSSP Form LAB-100 rev. 2001-11-27

Laboratory Evaluation Checklist – Microbiology - 5

K	16		6. The autoclave standards thermometer is checked every five years for accuracy at either 121°C or at the steam point. Date of most recent determination_____
K	1		7. Working autoclave thermometers are checked against the autoclave standards thermometer at 121°C yearly. Date of last check _____ Method _____
K	11		8. Spore suspensions are used monthly to evaluate the effectiveness of the autoclave sterilization process. Results recorded.
O	11		9. Heat sensitive tape is used with each autoclave batch.
K	11, 13		10. Autoclave sterilization records including length of sterilization, total heat exposure time and chamber temperature are maintained. Type of record: Autoclave log, computer printout or chart recorder tracings *(circle appropriate type or types)*
K	11		11. For dry heat sterilized material, the hot-air sterilizing oven provides heating and sterilizing temperature in the range of 160 to 180°C.
K	9		12. A thermometer capable of determining temperatures accurately in the range of 160 to 180°C is used to monitor the operation of the hot-air sterilizing oven when in use.
K	13		13. Records of temperatures and exposure times are maintained for the operation of the hot-air sterilizing oven during use.
K	11		14. Spore strips are used quarterly to evaluate the effectiveness of the sterilization process in the hot-air oven. Records are maintained.
K	11		15. Resuable sample containers are sterilized for 60 minutes at 170°C in a hot-air oven or autoclaved for 15 minutes at 121°C.
O	1		16. The sterility of reusable/disposable sample containers is determined for each batch/lot.
K	9		17. Reusable pipettes are stored and sterilized in aluminum or stainless steel canisters or equivalent alternative.
K	9		18. Reusable pipettes (in canisters) are sterilized in a hot-air oven at 170°C for 2 hours.
O	2		19. The sterility of reusable/disposable pipettes is determined with each batch/lot. Results are recorded and maintained.
K	18		20. Hardwood applicators transfer sticks are properly sterilized.
O	13		21. Spent broth cultures and agar plates are decontaminated by autoclaving for at least 30 minutes before conventional disposal.

CODE	REF.	Media Preparation	
K	3, 5		1. Media is commercially dehydrated except in the case of medium A-1 which is prepared from the individual components and modified MacConkey agar which may be prepared from its components.
O	11		2. Dehydrated media and media components properly stored in cool, clean, dry place.
O	11		3. Dehydrated media are labeled with date of receipt and date opened.
C	12		**4. Caked or expired media are discarded**.
C	11		**5. Make-up water is distilled or deionized *(circle one)* and exceeds 0.5 megohm resistance or is less than 2μ Siemens/cm conductivity at 25°C to be tested and recorded monthly for resistance or conductivity *(circle the appropriate)*.**

NSSP Form LAB-100 rev. 2001-11-27

Laboratory Evaluation Checklist – Microbiology – 6

C	11		**6. Make-up water is analyzed for residual chlorine monthly and is at a non-detectable level (≤0.1 ppm). Records are maintained.** **Specify method of determination .**
K	11		7. Make-up water is free from trace (<0.05mg/L) dissolved metals, specifically Cd, Cr. Cu, Ni, Pb, and Zn as determined annually with total heavy metal content < or equal to 1.0mg/L and records are maintained.
K	11		8. Make-up water contains <1000 CFU/ml as determined monthly using the heterotrophic plate count method and records are maintained.
K	11		9. Media are sterilized according to the manufacturer's instructions.
K	9		10. Volume and concentration of media in the tube are suitable for the amount of sample inoculated.
C	11		**11. Total time of exposure of sugar broths to autoclave temperatures does not exceed 45 minutes.**
C	1		**12. Media sterility and positive and negative controls are run with each lot of commercially prepared media or are run with each batch of media prepared from its components as a check of media productivity. Results recorded and records maintained.**
O	9		13. Sterile phosphate buffered dilution water or 0.5% peptone water is used as the sample diluent. ***(circle appropriate choice)*.**
K	11		14. pH is determined after sterilization to ensure that it is consistent with manufacturer's requirements and records are maintained.

CODE	REF.		Storage of Prepared Culture Media
O	9		1. Prepared culture media are stored in a cool, clean, dry space where excessive evaporation and the danger of contamination are minimized.
K	5,11		2. Brilliant green bile 2% broth and A-1 media are stored in the dark.
K	13		3. Stored media are labeled with expiration date or sterilization date.
O	9		4. Storage of prepared culture media at room temperature does not exceed 7 days.
O	2		5. Storage under refrigeration of prepared media with loose fitting closures shall not exceed 1 month.
O	11		6. Storage under refrigeration of prepared media with screw-cap closures does not exceed 3 months.
K	17		7. All prepared media stored under refrigeration are held at room temperature overnight prior to use. Culture tubes containing any type of precipitate or Durham tubes containing air bubbles are discarded.

NSSP Form Lab-100 rev. 2001- 11 – 27

Laboratory Evaluation Checklist – Microbiology - 7

PART II – SEAWATER SAMPLES			
CODE	**REF.**	**ITEM**	
		Collection and Transportation of Samples	
C	11		**1. Containers are of suitable size to contain at least 100 ml and to allow headspace for shaking. Seawater samples are collected in clean, sterile, water tight, properly labeled sample containers.**
K	1		2. Sample identified with collectors name, harvest area, time and date of collection.
C	9		**3. After collection, seawater samples shall be kept at a temperature between 0 and 10°C until examined.**
K	1		4. A temperature blank is used to determine the temperature of samples upon receipt at the laboratory. Results are recorded and maintained.
C	9		**5. Examination of the sample is initiated as soon as possible after collection. However, seawater samples are not tested if they are held beyond 30 hours of refrigeration**.

CODE	**REF.**	**Bacteriological Examination of Seawater by the APHA MPN**	
C	9		**1. Lactose broth or lauryl tryptose broth is used as the presumptive medium.** ***(circle appropriate one)***
C	9		**2. Sample and dilutions of sample are mixed vigorously (25 times in a 12" arc in 7 seconds) before inoculation.**
C	9		**3. In a multiple dilution series not less than 3 tubes per dilution are used (5 tubes are recommended**).
C	6		4. **In a single dilution series not less than 12 tubes are used (for depuration at least 5 tubes are used).**
K	6		5. In a single dilution series, the volumes examined are adequate to meet the needs of routine monitoring. Sample volume inoculated _____ Range of MPN_____ Strength of media used_____
K	9		6. Inoculated media are placed in an air incubator at 35± 0.5°C for up to 48 ± 3 hours.
K	2		7. Positive and negative control cultures accompany samples throughout the procedure. Records are maintained. Positive Control _____ Negative Control _____
K	9		8. Inoculated media are read after 24 ± 2 hours and 48 ± 3 hours of incubation and transferred at both intervals if positive for gas.

NSSP Form LAB-100 rev. 2001-11-27

Laboratory Evaluation Checklist – Microbiology 8

CODE	REF.		Confirmed Test for Seawater by APHA MPN
C	9		**1. Brilliant green bile 2% broth (BGB) is used as the confirmatory medium for total coliforms.**
C	9		**2. EC medium is used as the confirmatory medium for fecal coliforms.**
K	9, 11		3. Transfers made to BGB/EC by either sterile loop or sterile hardwood applicator stick from positive presumptives incubated for 24 and 48 hours ***(Circle the method of transfer)***.
K	2		4. When the inoculation of both EC and BGB broths is performed using the same loop or transfer stick, the order of inoculation is EC first, followed by BGB.
C	9		**5. BGB tubes are incubated at 35 $\pm$ 0.5°C.**
K	9		6. BGB tubes are read after 48 $\pm$ 3 hours of incubation.
C	9		**7. EC tubes are incubated in a circulating waterbath at 44.5 $\pm$ 0.2°C for 24 $\pm$ 2 hours.**
C	9		**8. The presence of any amount of gas or effervescence in the culture tube constitutes a positive test.**

CODE	REF.		Computation of Results
K	9		1. Results of multiple dilution tests are read from tables in *Recommended Procedures*, 4th Edition.
K	7		2. Results from single dilution series are calculated from Hoskins' equation or interpolated from Figure 1 Public Health Report 1621 entitled "Most Probable Numbers for Evaluation of Coli aerogenes Tests by Fermentation Tube Method".
K	7, 9		3. Results are reported as MPN/100 ml of sample.

NSSP Form LAB 100 rev. 2001-11-27

Laboratory Evaluation Checklist – Microbiology - 9

CODE	REF.		Bacteriological Examination of Seawater by the MA-1 Method
C	5		**1. Medium A-1 sterilized for 10 minutes at 121°C.**
C	9		**2. Sample and dilutions of sample are mixed vigorously (25 times in a 12" arc in 7 seconds) before inoculation.**
C	9		**3. In a multiple dilution series not less than 3 tubes per dilution are used (5 tubes are recommended).**
C	6		**4. In a single dilution series at least 12 tubes are used.**
K	6		5. In a single dilution series, the volumes examined are adequate to meet the needs of routine monitoring. Sample volume inoculated _____ Range of MPN_____ Strength of media used_____
K	2		6. Positive and negative control cultures accompany samples throughout the procedure. Records are maintained. Positive Control _____ Negative Control _____
C	2,5		**7. Inoculated media are placed in an air incubator fat 35 ± 0.5°C for 3 ± 0.5 hours of resuscitation.**
C	5		**8. After 3 ± 0.5 hours resuscitation at 35°C, inoculated media are incubated at 44.5 ± 0.2 °C in a circulating waterbath for the remainder of the 24 ± 2 hours.**
C	5		**9. The presence of any amount of gas or effervescence in the culture tube constitutes a positive test.**

CODE	REF.		Computation of Results
K	9		1. Results of multiple dilution tests are read from tables in *Recommended Procedures*, 4th Edition.
K	7		2. Results from single dilution series are calculated from Hoskins' equation or interpolated from Figure 1 Public Health Report 1621 entitled "Most Probable Numbers for Evaluation of Coli aerogenes Tests by Fermentation Tube Method".
K	7, 9		3. Results are reported as MPN/100 ml of sample.

NSSP Form LAB-100 rev. 2001-11-27

Laboratory Evaluation Checklist – Microbiology - 10

PART III – SHELLFISH SAMPLES			
CODE	**REF.**	**ITEM**	
		Collection and Transportation of Samples	
C	9		**1. A representative sample of shellstock is collected.**
K	9		2. Shellstock is collected in clean, waterproof, puncture resistant containers.
K	9		3. Shellstock labeled with collector's name, type of shellstock, the source, the harvest area, time, date and place (if market sample) of collection.
C	9		**4. Shellstock samples are maintained in dry storage between 0 and 10°C until examined.**
C	1		**5. Examination of the sample is initiated as soon as possible after collection. However, shellfish samples are not examined if the time interval between collection and examination exceeds 24 hours.**

CODE	REF	Preparation of Shellstock for Examination	
K	2,11		1. Shucking knives, scrub brushes and blender jars are (autoclave) sterilized for 15 minutes prior to use.
O	2		2. Blades of shucking knives are not corroded.
O	9		3. Prior to scrubbing and rinsing debris off shellstock, the hands of the analyst are thoroughly washed with soap and water.
O	2		4. The faucet used to provide the potable water for rinsing the shellstock does not contain an aerator.
K	9		5. Shellstock are scrubbed with a stiff, sterile brush and rinsed under water of drinking water quality.
O	9		6. Shellstock are allowed to drain in a clean container or on clean towels prior to opening.
K	9		7. Prior to opening, the hands (or gloved hands) of the analyst are thoroughly washed with soap and water and rinsed in 70% alcohol.
K	9		8. Shellstock are not shucked directly through the hinge.
C	9		**9. Contents of shellstock (liquor and meat) are shucked into a sterile, tared blender jar or other sterile container.**
K	9		10. At least 200 grams of shellfish meat is used for analysis.
K	2, 19		11. The sample is weighed to the nearest 0.1gram and an equal amount by weight of (tempered for ETCP) diluent is added.
O	9		12. Sterile phosphate buffered dilution water or 0.5% peptone water is used as the sample diluent (***circle the appropriate choice***)
K	3		13. Sterile phosphate buffered saline is used as a sample diluent for the ETCP procedure.
C	9		**14. Samples are blended at high speed for 60 to 120 seconds.**
K	9		15. For other shellstock, APHA *Recommended Procedures* are followed for the examination of freshly shucked and frozen shellfish meats.

NSSP Form LAB-100 rev. 2001-11-27

Laboratory Evaluation Checklist – Microbiology - 11

CODE	REF.		MPN Analysis for Fecal Coliform Organisms, Presumptive Test, APHA
C	9		**1. Appropriate strength lactose or lauryl tryptose broth is used as presumptive media in the analysis. *(circle appropriate choice)***
K	9		2. Immediately (within 2 minutes) after blending, the ground sample is diluted and inoculated into tubes of presumptive media.
C	9		**3. No fewer than 5 tubes per dilution are used in a multiple dilution MPN series.**
C	9		**4. Allowing for the initial 1:1 dilution of the sample, appropriate portions are inoculated (i.e., 2 ml of original 1:1 dilution for the 1 g portion) and diluted for subsequent inoculation (i.e., 22 ml of l:1 diluted sample to 88 ml of diluent or the equivalent for 0.1 g portion.**
K	6		5. In a single dilution series, the volumes examined are adequate to meet the needs of routine monitoring. Sample volume inoculated _____ Range of MPN_____ Strength of media used_____
C	2		**6. Positive and negative control cultures accompany samples throughout the procedure. Records are maintained.** **Positive Control _____ Negative Control _____**
K	9		7. Inoculated media are incubated at 35 ± 0.5°C.
K	10		8. Presumptive tubes are read at 24 ± 2 hours of incubation and transferred if positive.
CODE	**REF.**		**Confirmed Test for Fecal Coliforms – APHA**
C	9		**1. EC medium is used as the confirmatory medium.**
K	9, 11		2. Transfers are made to EC medium by either sterile loop or hardwood sterile applicator sticks from positive presumptives incubated for 24 hours ***(circle the method of transfer).***
C	9		**3. EC tubes are incubated in a circulating waterbath at 44.5 ± 0.2°C for 24 ± 2 hours.**
K	9		4. EC tubes are read for gas production after 24 ± 2 hours of incubation.
C	9		**5. The presence of any amount of gas or effervescence in the Durham tube constitutes a positive test.**
CODE	**REF.**		**Computation of Results for MPN Analyses**
K	9		1. Results of multiple dilution tests are read from tables in *Recommended Procedures,* 4th Edition and multiplied by the appropriate dilution factor.
K	7		2. Results from single dilution series are calculated from Hoskins' equation or interpolated from Figure 1 Public Health Report 1621 entitled "Most Probable Numbers for Evaluation of Coli aerogenes Tests by Fermentation Tube Method".
K	9		3. Results are reported as MPN/100 grams of sample.

NSSP FORM LAB-100 rev. 2001-11-27

Laboratory Evaluation Checklist – Microbiology - 12

CODE	REF.		Standard Plate Count Method
O	20		1. A standard plate count analysis is performed in conjunction with the analysis for fecal coliform organisms.
K	9		2. In the standard plant count procedure at least four plates, duplicates of two dilutions are used to provide 30 to 300 colonies per plate.
K	2		3. Fifteen to 20 ml of tempered sterile plate count agar is used.
K	9		4. Agar tempering bath maintains the agar at 44 to 46°C.
O	9		5. Temperature control of the plate count agar is used in the tempering bath.
K	9		6. Not more than 1 ml nor less than 0.l ml of sample or sample dilution is plated.
C	9		**7. Samples or sample dilutions to be plated are mixed vigorously (25 times in a 12" arc in 7 seconds) before plating.**
K	11		8. Control plates are used to check the sterility of the air, agar and the diluent.
K	9, 21		9. Solidified plates are incubated at 35 ± 0.5°C for 48 ± 3 hours inverted and stacked no more than four high.
K	9		10. Quebec Colony Counter or its equivalent is used to provide the necessary magnification and visibility for counting plates.
K	1		11. A hand tally or its equivalent is used for accuracy in counting.

CODE	REF.		Computation of Results
K	9		1. Colony counts determined in accordance with Part III, A, Sections 4.31 through 4.33 Recommended *Procedures*, 4th Edition.
O	19		2. Colony counts reported as APC/g of sample.

NSSP Form LAB-100 rev. 2001-11-27

Laboratory Evaluation Checklist – Microbiology - 13

CODE	REF.		Bacteriological Examination of Shellfish Using the ETCP
K	9		1. Sample homogenate is cultured within 2 minutes of blending.
K	3		2. Double strength Modified MacConkey Agar is used.
C	3		**3. Hydrated double strength Modified MacConkey Agar is heated to boiling, removed from the heat, and boiled again. This agar is never autoclaved.**
K	2, 3		4. Twice boiled, double strength Modified MacConkey Agar and sterile phosphate buffered saline are maintained in a tempering bath at 45 to 50°C until used. Prepared Modified MacConkey Agar is used on the day it is made.
C	2, 3		**5. The equivalent of 6 grams of the homogenate is placed into a sterile container and the contents brought up to 60 ml with tempered, sterile phosphate buffered saline.**
K	3		6. Sixty (60) ml of tempered, twice boiled double strength Modified MacConkey Agar is added.
K	2, 3, 22		7. The container is gently swirled or rotated to mix the contents, which are then, distributed uniformly over 6 to 8 petri plates.
C	1		**8. Media and diluent sterility are determined with each use. Results are recorded and records maintained.**
C	1		**9. To determine media productivity, positive and negative control cultures are pour plated in an appropriate concentration to accompany samples throughout the procedure.**
		■	**Positive control_____ Negative control _____**
C	3, 13		**10. Plates are incubated inverted within 3 hours of plating in air at 45.5 ± 0.5°C for 18 to 30 hours. Plates are stacked not more than four high.**
C	3		**11. Incubator temperature is maintained at 45.5 ± 0.5°C.**

CODE	REF.		Expression of Results
K	11		1. Quebec Colony counter or its equivalent is used to provide the necessary magnification and visibility.
O	1		2. A hand tally or its equivalent is used to aid in counting.
C	3, 6		**3. All brick red colonies greater than 0.5mm in diameter are totaled over all the plates and multiplied by a factor of 16.7 to report results as CFU/100 grams of sample.**

NSSP Form LAB-100 rev. 2001-11-27

Laboratory Evaluation Checklist – Microbiology - 14

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NSSP Form LAB-100 rev. 2001-11-27

Laboratory Evaluation Checklist – Microbiology - 16

SHELLFISH LABORATORY EVALUATION CHECKLIST

SUMMARY OF NONCONFORMITIES

Page	Item	Observation	Documentation Required

NSSP Form LAB-100 rev. 2001-11-27 **Page ____ of ____**

Laboratory Evaluation Checklist – Microbiology – 17

LABORATORY STATUS	
LABORATORY	**DATE**
LABORATORY REPRESENTATIVE:	
MICROBIOLOGICAL COMPONENT: (Part I-III)	

A. Results

Total # of Critical (C) Nonconformities in Parts I-III _____
Total # of Key (K) Nonconformities in Parts I-III _____
Total # of Critical, Key and Other (O)
Nonconformities in Parts I-III _____

B. Criteria for Determining Laboratory Status of the Microbiological Component:

1. **Does Not Conform Status**: The Microbiological component of this laboratory is not in conformity with NSSP requirements if:
   A. The total # of Critical nonconformities is **≥ 4 or**
   B. The total # of Key nonconformities is **≥ 13 or**
   C. The total # of Critical, Key and Other is **≥ 18**

2. **Provisionally Conforms Status**: The microbiological component of this laboratory is determined to be provisionally conforming to NSSP requirements if the number of critical nonconformities is **≥ 1 but ≤ 3**

C. Laboratory Status (*circle appropriate*)
Does Not Conform **Provisionally Conforms** **Conforms**

Acknowledgment by Laboratory Director/Supervisor:

All corrective Action will be implemented and verifying substantiating documentation received by the Laboratory Evaluation Officer on or before _____

Laboratory Signature:_____ Date:_____

LEO Signature:_____ Date:_____

NSSP Form LAB-100 rev. 2001-11-27

Laboratory Evaluation Checklist – PSP - 1

PUBLIC HEALTH SERVICE **U.S. FOOD AND DRUG ADMINISTRATION** **SHELLFISH PROGRAM IMPLEMENTATION BRANCH** **SHELLFISH SAFETY TEAM** **5100 PAINT BRANCH PARKWAY** **COLLEGE PARK, MD 20740-3835** **TEL. 301-436-2151/2147 FAX 301-436-2672**		
SHELLFISH LABORATORY EVALUATION CHECKLIST		
LABORATORY:		
ADDRESS:		
TELEPHONE: **FAX:** **EMAIL:**		
DATE OF EVALUATION:	**DATE OF REPORT:**	**LAST EVALUATION:**
LABORATORY REPRESENTED BY:	**TITLE:**	
LABORATORY EVALUATION OFFICER:	**SHELLFISH SPECIALIST:** **REGION:**	
OTHER OFFICIALS PRESENT:	**TITLE:**	
Items which do not conform are noted by: C- Critical K – Key O – Other NA – Not Applicable Conformity is noted by a "√"		

NSSP Form Lab-100 rev. 2001-02-14

Laboratory Evaluation Checklist – PSP - 2

PART I – QUALITY ASSURANCE		
Code		**Item Description**
		Quality Assurance (QA) Plan
K		1. Written Plan adequately covers all the following: (check √ those that apply) a.____ Organization of the laboratory. b.____ Staff training requirements. c.____ Standard operating procedures. d.____ Internal quality control measures for equipment, calibration, maintenance, repair and performance. e.____ Laboratory safety. f.____ Quality assessment. g.____ Proper animal care.
C		**2. QA plan implemented.**
		1.2 Work Area
O		1. Adequate for workload and storage.
O		2. Clean and well lighted.
O		3. Adequate temperature control.
O		4. All work surfaces are nonporous and easily cleaned.
C		**5. A separate, quiet area with adequate temperature control for mice acclimation and injection is maintained.**
		1.3 Laboratory Equipment
O		1. The pH meter has a standard accuracy of 0.1 unit.
K		2. pH paper in the appropriate range (i.e. 1-4) is used with minimum accuracy of 0.5 pH units.
K		3. pH electrodes consist of pH half cell and reference half cell or equivalent combination electrode (free from Ag/AgCl or contains an ion exchange barrier to prevent passage of Ag ions into the medium that may result in inaccurate pH readings).
K		4. pH meter is calibrated daily or with each use. Records maintained.
K		5. Effect of temperature has been compensated for by an ATC probe or by manual adjustment.
K		6. A minimum of two standard buffer solutions (2 & 7) is used to calibrate the pH meter. Standard buffer solutions are used once and discarded.
K		7. Electrode efficiency is determined daily or with each use following either slope or millivolt procedure.
K		8. The balance provides a sensitivity of at least 0.1g at a load of 150 grams.
K		9. The balance calibration is checked monthly using NIST Class S or ASTM Class 1or 2 weights or equivalent. Records maintained.

NSSP Form LAB 100 rev. 2001-02-14

Laboratory Evaluation Checklist – PSP - 3

Code		Item Description
K		10. Refrigerator temperature is maintained between 0 and 4˚C.
O		13. Freezer temperature is monitored at least once daily. Record maintained.
O		14. All glassware is clean.
O		15. Once during each day of washing, several pieces of glassware from each batch washed are tested for residual detergent with aqueous 0.04% bromthymol blue solution. Records are maintained.
		1.4 Reagent and Reference Solution Preparation and Storage
C		**1. Opened PSP reference stand solution (100 µg/ml) is not stored.**
K		2. PSP working standard solution (1 µg/ml) and all dilutions are prepared with dilute HCl, pH 3 water, using 'Class A' volumetric glassware (flasks and pipettes) or prepared gravimetrically.
K		3. Refrigerated storage of PSP working standard solution (1 µg/ml) does not exceed 6 months and is checked gravimetrically for evaporation loss.
K		4. PSP working dilutions are discarded after use.
K		5. Make up water is distilled or deionized (*circle one*) and exceeds 0.5 megohm resistance or is less than 2 µSiemens/cm conductivity at 25ºC to be tested and recorded monthly for resistance or conductivity *(circle the appropriate)*.
O		6. Make up water is analyzed for residual chlorine monthly and is at a nondetectable level ($\leq$ 0.1 ppm). Records maintained.
K		7. Make up water is free from trace (< 0.5 mg/l) dissolved metals specifically Cd, Cr, Cu, Ni, Pb, and Zn as determined annually with total heavy metal content $\leq$1.0 mg/l. Records maintained.
O		8. Makeup water contains < 1000 CFU/ml as determined monthly using the heterotrophic plate count method. Records maintained
		1.5 Collection and Transportation of Samples
O		1. Shellstock are collected in clean, waterproof, puncture resistant containers.
K		2. Samples are appropriately labeled with the collector's name, harvest area and time and date of collection.
K		3. Immediately after collection, shellstock samples are placed in dry storage for transport (e.g. cooler) which is maintained between 0 and 10ºC. Upon receipt at the lab, samples are placed under refrigeration

NSSP Form LAB-100 rev. 2001-02-1

Laboratory Evaluation Checklist – PSP - 4

Code		Item Description
K		4. The time from collection to completion of the bioassay should not exceed 24 hours. However, if there are significant transportation delays, then shellstock samples are processed immediately as follows (*circle the appropriate choice*): a. Washed, shucked, drained, frozen until extracted; b. Washed, shucked, drained, homogenized and frozen; c. Washed, shucked, drained, extracted, the supernatant decanted and refrigerated (**best choice**); or d. The laboratory has an appropriate contingency plan in place to handle samples which can't be analyzed within 24 hours due to transportation issues.
K		5. Frozen shucked product or homogenates are allowed to thaw completely and all liquid is included as part of the sample before being processed further.
PART II – EXAMINATION OF SHELLFISH FOR PSP TOXIN		
		2.1 Preparation of Sample
C		1. At least 12 animals are used per sample or the laboratory has an appropriate contingency plan for dealing with non-typical species of shellfish.
O		2. The outside of the shell is thoroughly cleaned with fresh water.
O		3. Shellstock are opened by cutting adductor muscles.
O		4. The inside of the shell is rinsed with fresh water to remove sand or other foreign material.
O		5. Shellfish meats are removed from the shell by separating adductor muscles and tissue connecting at the hinge.
K		6. Damage to the body of the mollusk is minimized in the process of opening.
O		7. Shucked shellfish are drained on a #10 mesh sieve (or equivalent) without layering for 5 minutes.
K		**8. Pieces of shell and drainage are discarded.**
C		**9. Drained meats or thawed homogenates are blended at high speed until homogenous** (60 – 120 seconds)**.**
		2.2 Extraction
K		1. 100 grams of homogenized sample is weighed into a beaker.
K		2. An equal amount of 0.1 N/0.18 N HCl is added to the homogenate and thoroughly mixed (*circle the appropriate normality*).
C		**3. pH is checked and, if necessary adjusted to between pH 2.0 and 4.0.**
C		**4. Adjustment of pH is made by the dropwise addition of either the acid (5 N HCl) or base (0.1N NaOH) while constantly stirring the mixture.**
C		**5. The homogenate/acid mixture is promptly brought to a boil, 100 ∀ 1ºC, then gently boiled for 5 minutes**.
O		6. The homogenate/acid mixture is boiled under adequate ventilation (i.e. fume hood).
O		7. The extract is cooled to room temperature.
C		**8. The pH of the extract is determined and adjusted, if necessary to between pH 2 and 4, preferably to pH 3 with the stirred dropwise addition of 5 N HCl to lower the pH or 0.1N NaOH to raise the pH.**

NSSP Form LAB-100 rev. 2001-02-14

Laboratory Evaluation Checklist – PSP - 5

Code		Item Description
K		9. The extract volume (or mass) is adjusted to 200 mls (or grams) with dilute HCl, pH 3 water.
K		10. The extract is returned to the beaker, stirred to homogeneity and allowed to settle to remove particulates; or, if necessary, an aliquot of the stirred supernatant is centrifuged at 3,000 RPM for 5 minutes before injection.
K		11. If mice cannot be injected immediately then the supernatant should be removed from the centrifuge tubes and refrigerated for up to 24 hours.
K		12. Refrigerated extracts are allowed to reach ambient temperature before being bioassayed.
		2.3 Bioassay
O		1. A 26-gaugue hypodermic needle is used for injection.
K		2. Healthy mice in the weight range of 17 –23 grams (19 – 21 grams preferable) from a stock colony are used for routine assays. Mice are not reused for bioassay. Stock strain used _____ Source of mice_____
C		**3. Mice are allowed to acclimate for at least 24 hours prior to injection. In some cases up to 48 hours may be required.**
C		**4. A conversion factor (CF) has been determined as _____. Month and year when current CF determined_____.**
C		**5. CF value is checked weekly if assays are done on several days during the week, or, once each day that assays are performed if they are performed less than once per week.** **Date of most recent CF check _____** **CF verified/CF not verified** *(Circle appropriate choice)*
C		**6. If the CF is not verified, 5 additional mice are injected with the dilution used in the CF check to complete a group of 10 mice. Ten additional mice are also injected with this dilution to produce a second group of 10 mice. The CF is calculated for each group of 10 mice and averaged to give the CF to be used in sample toxicity calculations for the day's or week's work only. All subsequent work must make use of the original laboratory CF value unless this value continues to fail to be verified by routine CF checks.**
C		**7. If the CF fails to be verified, the cause is investigated and the situation corrected. If the cause cannot be determined with reasonable certainty and fails > 3 times per year, the bioassay is restandardized.**
O		8. Mice are weighed to the nearest 0.5 gram.
C		**9. Mice are injected intrapertioneally with 1 ml of the acid extract.**
K		10. For the CF check, at least 5 mice are used.
C		**11. At least 3 mice are used per sample in routine assays.**
C		**12. Elapsed time is accurately determined and recorded.**

NSSP Form LAB-100 rev. 2001-02-14

Laboratory Evaluation Checklist – PSP - 6

Code		Item Description
K		13. If death occurs, the time of death to the nearest second is noted by the last gasping breath.
C		**15. If median death time(2 out of 3 mice injected die) is < 5 minutes, a dilution is made with dilute HCl, pH 3 water, to obtain a median death time in the range of 5 to 7 minutes.**
		2.4 Calculation of Toxicity
C		**1. The death time of each mouse is converted to mouse units (MU) using Sommer's Table (Table 6 *Recommended Procedures*, 4th edition). The death time of mice surviving beyond 60 minutes is considered to be < 0.875 MU.**
K		2. A weight correction in MU is made for each mouse injected using Table 7 in *Recommended Procedures*, 4th edition.
C		**3. The death time of each mouse in MU is multiplied by a weight correction in MU to give the corrected mouse unit (CMU) for each mouse.**
C		**4. The median value of the array of corrected mouse units (CMU) is determined to give the median corrected mouse unit (MCMU).**
C		**5. The concentration of toxin is determined by the formula, MCMU x CF X Dilution Factor X 200.**
C		**6. Any value greater than 80 µg/l00 grams of meat is actionable.**

NSSP Form LAB-100 rev. 2001-02-14

Laboratory Evaluation Checklist – PSP - 7

REFERENCES

1. Adams, W.N. and S.A. Furfari. 1984. Evaluation of laboratory performance of the AOAC method for PSP toxin in shellfish. *J. Assoc. Off. Anal. Chem.* Vol 67, 6:1147-1148.
2. American Public Health Association. 1970. *Recommended Procedures for the Examination of Sea Water and Shellfish*, 4th Edition. APHA, Washington, D.C.
3. American Public Health Association. 1992. *Standard Method for the Examination of Dairy Products*, 16th Edition. APHA, Washington, D.C.
4. Association of Official Analytical Chemists International. 1990. *Methods of Analysis*, 15th Edition. AOAC, Arlington, VA.
5. APHA/WEF/AWWA. 1992. *Standard Methods for the Examination of Water and Wastewater*, 18th Edition. APHA, Washington, D.C.
6. Title 21, Code of Federal Regulations, Part 58, *Good Laboratory Practice for Nonclinical Laboratory Study*. U.S. Government Printing, Washington, D.C.
7. National Research Council. 1996. *Guide for the Care and Use of Laboratory Animals*. National Academy Press, Washington, D.C.
8. Personal communication with USFDA Washington Seafood Laboratory Branch, Office of Seafood, CFSAN, 1998-1999.

NSSP Form LAB-100 rev. 2001-02-14

Laboratory Evaluation Checklist – PSP - 8

LABORATORY:			**DATE OF EVALUATION:**
SHELLFISH LABORATORY EVALUATION CHECKLIST **SUMMARY OF NONCONFORMITIES**			
Page	**Item**	**Observation**	**Documentation Required**

NSSP Form LAB-100 rev. 2001-02-14 **Page ____ of ____**

Laboratory Evaluation Checklist – PSP - 9

LABORATORY STATUS	
LABORATORY	**DATE**
LABORATORY REPRESENTATIVE:	
PARALYTIC SHELLFISH POISON COMPONENT: PARTS I and II	

A. Results

Total # of Critical (C) Nonconformities _____
Total # of Key (K) Nonconformities _____
Total # of Critical, Key and Other (O) nonconformities _____

B. Criteria for Determining Laboratory Status of the PSP Component

1. **Does Not Conform Status** The PSP component of this laboratory is not in conformity with NSSP requirements if:
   A. The total # of Critical nonconformities is **≥ 3 or**
   B. The total # of Key nonconformities is **≥ 6 or**
   C. The total # of Critical, Key and Other is **≥ 10**

2. **Provisionally Conforms Status**: The PSP component of this laboratory is determined to be provisionally conforming to NSSP requirements if the number of critical nonconformities is ≥ 1 but < 3

C. Laboratory Status (*circle appropriate*)
Does Not Conform - Provisionally Conforms - Conforms

Acknowledgment by Laboratory Director/Supervisor:

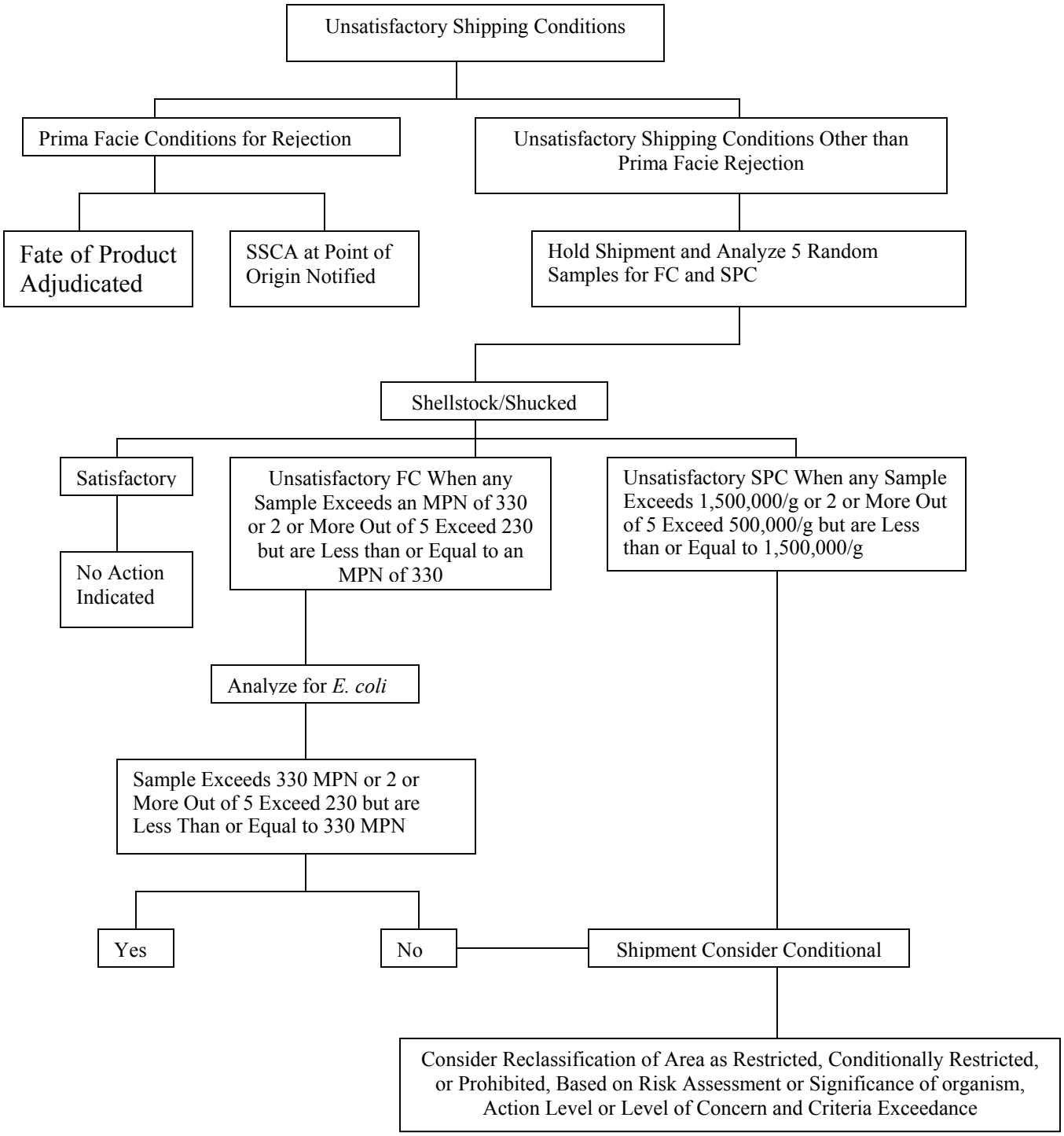
All corrective Action will be implemented and verifying substantiating documentation received by the Laboratory Evaluation Officer on or before _____

Laboratory Signature:_____ Date:_____

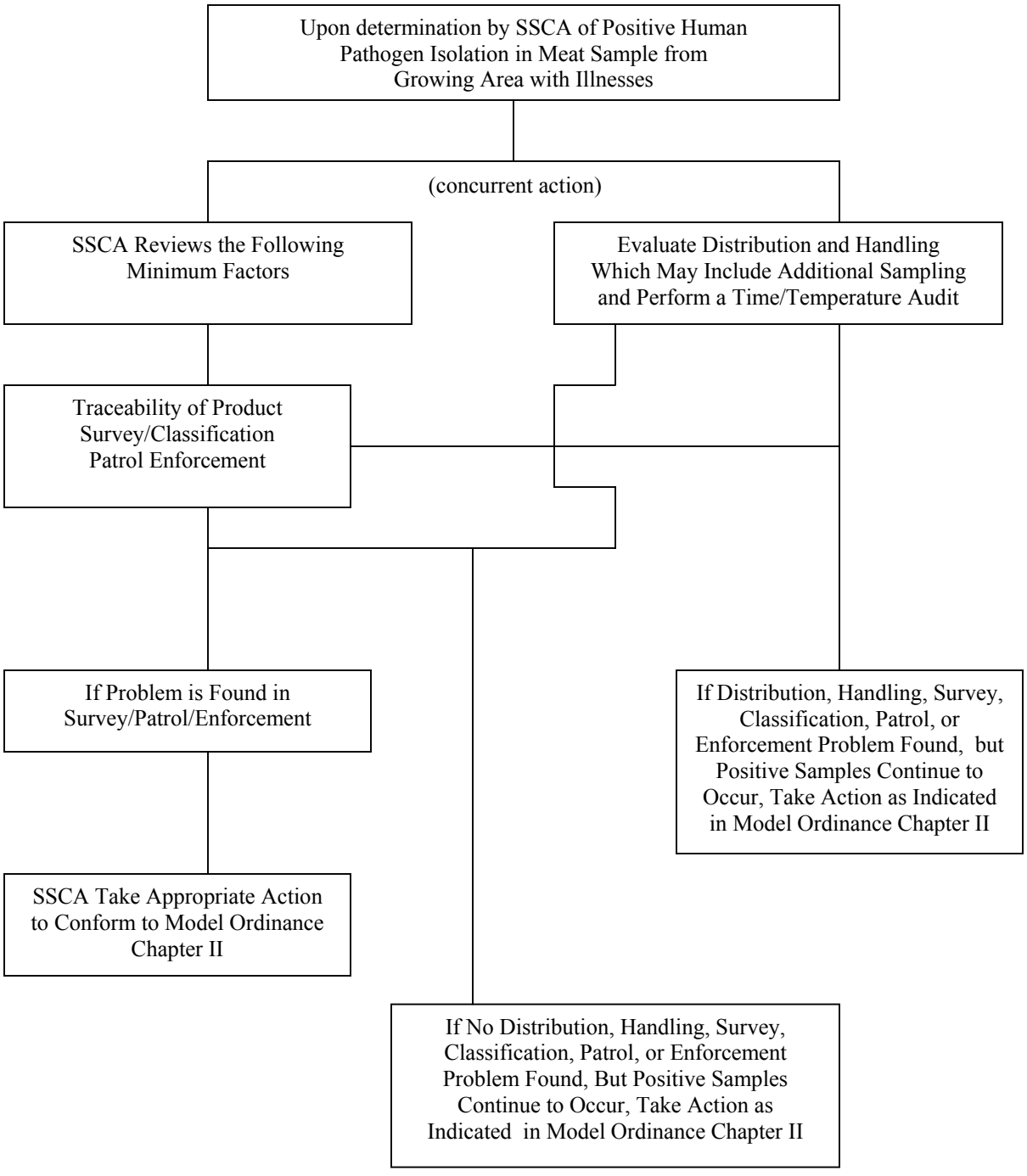
LEO Signature:_____ Date:_____

NSSP Form LAB-100 rev. 2001-02-14

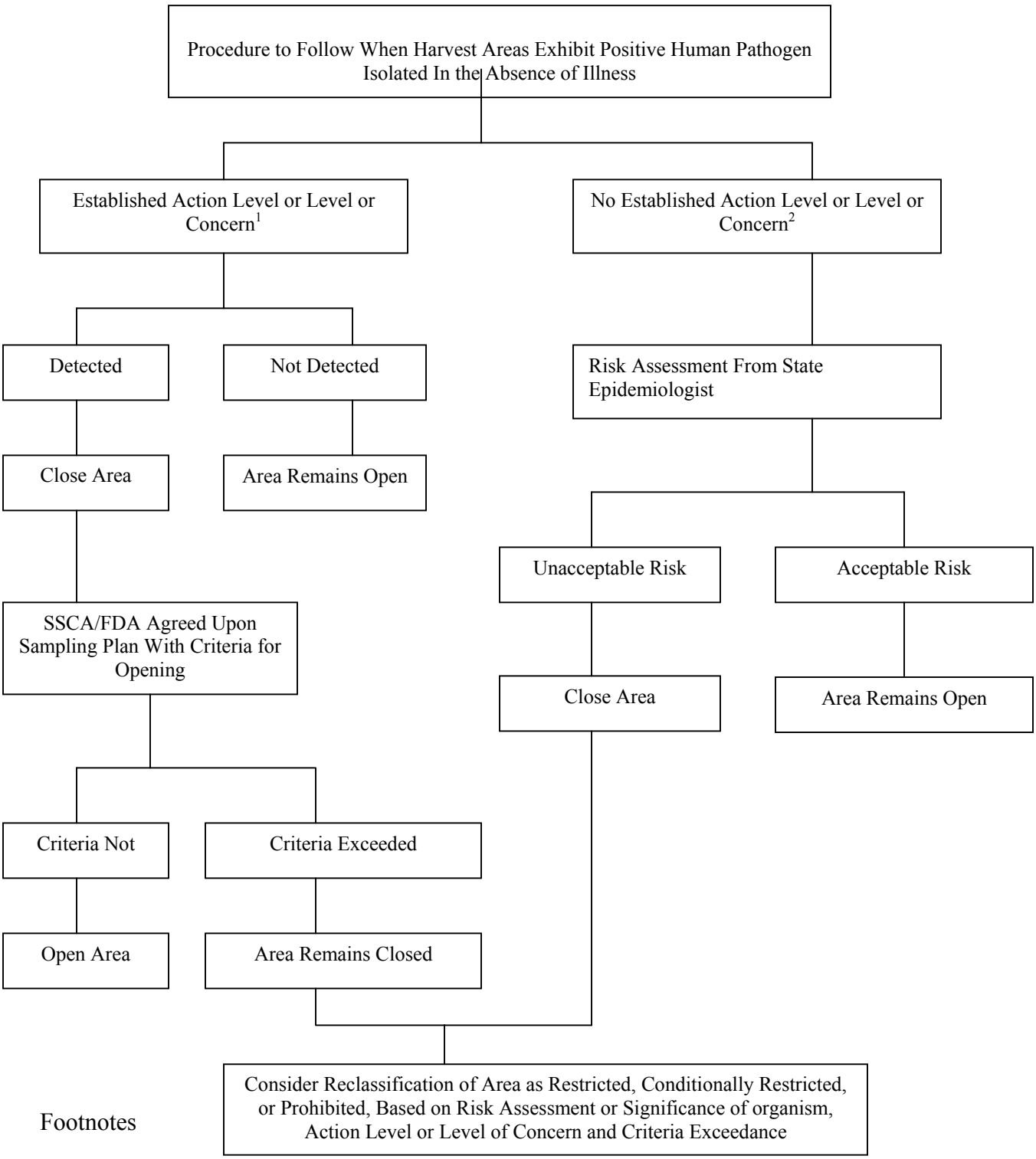
12. BACTERIOLOGICAL EXAMINATION OF SHELLFISH SHIPMENTS DECISION TREE



13. PROTOCOL FOR REVIEWING CLASSIFICATION OF AREAS IMPLICATED BY PATHOGENS IN SHELLFISH MEAT SAMPLES



PROTOCOL FOR REVIEWING CLASSIFICATION OF AREAS IMPLICATED BY PATHOGENS IN SHELLFISH MEAT SAMPLES



Footnotes

[1] FDA has established action levels or levels of concern for certain microbial pathogens in molluscan shellfish. The Agency will consider enforcement action against the shipment of molluscan shellfish if the following levels of pathogens are detected:

< ***Salmonella*** - positive for the presence of the organism;

< Enterotoxigenic ***Escherichia coli*** (ETEC) - 1,000 per gram, heat-labile toxin (LT) or heat-stable enterotoxin (ST) positive (may be determined by MPN method);

< ***Vibrio cholerae*** - presence of toxin-producing 01 or non-01 organisms;

< ***Vibrio parahaemolyticus*** - levels equal to or greater than a MPN count of 10,000 per gram and Kanagawa positive or negative; and

< ***Staphylococcus aureus*** - positive for staphylococcal enterotoxin or when the viable MPN count is 10,000 per gram.

[2]Other pathogens under review include: ***Listeria monocytogenes***, non-toxin producing non-01 ***Vibrio cholerae***, and ***Vibrio vulnificus***. In the absence of an established action level or level of concern for these pathogens, enforcement action is considered on a case-by-case basis taking into account all the factors associated with the specific situation.

Calculating the 90th Percentile for End-Product Depurated Shellfish

Process verification in depuration is performed continuously to ensure that the microbial contaminant load is being effectively reduced. Two indices of performance, the geometric mean and the 90th percentile have been developed to describe the effectiveness of the depuration process. Critical limits for these parameters have been established empirically by shellfish species. For soft clams (*Mya arenaria*), a geometric mean of 50 and a 90th percentile of 130 have been set. For hard clams, oysters, manilla clams and mussels, a geometric mean of 20 and a 90th percentile of 70 have been adopted.

Geometric means and 90th percentiles are determined daily or as end-product results become available from the analysis of the most recent ten (10) consecutive harvest lots per species, per restricted harvest area used. If the critical limits for either the geometric mean and/or the 90th percentile are exceeded, the process is considered to be unverified; and, additional sampling requirements must be instituted to ensure effective process control.

End-product depurated shellfish samples are analyzed using two different methods of recovery, a pour plate procedure and a single dilution MPN test. Calculation of the 90th percentile for these samples is complicated by the fact that fecal coliforms recovered by the MPN and ETCP methods follow different statistical distributions. To accommodate these differences and maintain a high likelihood for detecting an unacceptable amount of process variability without having to change or alter the formula used requires the use of nonparametric or "distribution free statistics." Using "distribution free statistics," the 90th percentile for end-product depurated shellfish samples is calculated by arraying the fecal coliform count data in ascending order and applying the formula $(n + 1)P/100$.

As an example of the use of this formula, the *Model Ordinance* requires that the 90th percentile of the fecal coliform analytical data be calculated from the most recent ten (10) consecutive harvest lots for each shellfish species depurated from each restricted harvest area. Fecal coliform count data, whether from the ETCP or MPN procedure for these ten (10) lots must be arrayed from the smallest to the largest value using the arithmetic (not logarithmically transformed) count data. Applying the formula, n would equal 10 for the ten (10) most recent consecutive harvest lots required by the *Model Ordinance*. P, the percentile of interest would be 90. Multiplying the formula out gives the position of the 90th percentile in the arrayed data. Performing these calculations, $10 + 1 = 11$, $11 \times 90 = 990/100 = 9.9$. Thus, the 90th percentile for end-product depurated shellfish data is the value of the 9.9th sample in the ten (10) sample array.

Using the ten (10) samples as required by the *Model Ordinance*, the 90th percentile for end-product depurated shellfish samples would always be the value of the 9.9th sample in the ascending array of the arithmetic count data. To calculate this value from the arrayed data, interpolation between samples 9 and 10 is necessary. This is best illustrated using several samples.

Example 1

For soft clams, the ten (10) most recent consecutive harvest lots from a particular restricted harvest area produced the following end-product fecal coliform count data which has been arrayed in ascending order for ease in calculation.

Sample #	FC Count (MPN/100 grams)
1	8.9 (<9.0)
2	9.0
3	9.0
4	9.0
5	9.0
6	18
7	18
8	18
9	29
10	248

a. By convention and for the purpose of these calculations, fecal coliform counts that signify the upper or lower limit of sensitivity of the test (MPN or ETCP) shall be increased or decreased by one significant figure. For example <9.0 becomes 8.9, <17 becomes 16 and >248 becomes 250. Individual plates which are too numerous to count (TNTC) are considered to have >100 colonies per plate. A sample containing "TNTC" plates is collectively rendered as having a count of 10,000.

b. The 90th percentile for a ten (10) sample array is the 9.9th sample in the array. The value for the 9.9th sample in the array is interpolated by subtracting the value for sample #9 from the value for sample #10 in the array. This value is subsequently multiplied by 0.9 and then added to the value of sample #9 to give the value for the 9.9th sample in the array or the 90th percentile.

c. In this example, sample #9 which is 29 is subtracted from sample #10 which is 248 to give 219. 219 is subsequently multiplied by 0.9 to give 197.1. 197.1 is then added to the value of sample #9, which is 29 to give 226.1. Rounding this off to 226, the value of the 90th percentile becomes 226.

Example 2

Soft clams from another restricted harvest area produced the following end-product depurated fecal coliform counts which have been arrayed in ascending order for ease in calculation.

Sample #	FC Count (MPN/100 grams)
1	16 (<17)
2	16 (<17)
3	16 (<17)
4	17
5	17
6	33
7	50
8	50
9	67
10	84

In this example as above, the 90th percentile equals the value of the 9.9th sample in this ten (10) sample array. The value for the 9.9th sample in the array is interpolated by subtracting the value of sample # 9 which is 67 from the value of sample #10 which is 84 to give 17. 17 is then multiplied by 0.9 to give 15.3 which is added to the value of sample #9 which is 67 to give 82.3. Rounding this value off to 82, the value for the 90th percentile becomes 82.

Example 3

In this case, oysters from a restricted harvest area produced the following end-product depurated fecal coliform counts which have been arrayed in ascending order for ease in calculation.

Sample #	FC Count (MPN/100 grams)
1	**8.9 (<9.0)**
2	**8.9 (<9.0)**
3	**8.9 (<9.0)**
4	**8.9 (<9.0)**
5	**9.0**
6	**9.0**
7	**9.0**
8	**18**
9	**88**
10	**88**

In this example as in the other two, the 90th percentile equals the value of the 9.9th sample in the ten (10) sample array. Unlike the other two examples, however, the values for samples # 9 and #10 are identical making interpolation unnecessary in finding the value for the 9.9th sample in this array. This value is by convention identical to the value for samples #9 and #10. In this case, the value is 88.

Conditional Protocol

In examples 1 and 3 above, the values of the 90th percentiles calculated exceeded the critical limits set for the individual shellfish species depurated. Such high levels of variability when detected in the performance of the depuration process subsequently trigger the conditional protocol. Implementation of the conditional protocol requires the institution of a number of additional control measures designed to ensure adequate depuration. One such control measure involves the analysis of at least one (1) zero hour shellfish sample from each harvest lot. Like end-product depurated shellfish samples, the Elevated Temperature Coliform Plate Method may also be used for these analyses. However, the 12-tube, single dilution MPN test must not be used because of its limited

effective count range (from 9 to 248). Instead, the 5-tube, 3-decimal dilution MPN test must be used to accommodate the expanded range in fecal coliform counts which may be encountered.

CHAPTER III. HARVESTING, HANDLING, PROCESSING, DISTRIBUTION

01. Shellfish Industry Equipment Construction Guide

Introduction

Since 1925 the Public Health Service, the States and the shellfish industry have cooperated in a program designed to maintain a high level of sanitation in the growing, harvesting, and processing of oysters, clams and mussels to be marketed as a fresh or frozen product. The basic sanitary standards used in this program are fully described in PHS Publication No. 33, Manual of Recommended Practice for Sanitary Control of the Shellfish Industry, Parts I and II. General construction standards for equipment used by the shellfish industry are an integral part of these basic standards.

The need for more specific construction guides for equipment used by the shellfish industry was reviewed at the 1958 Shellfish Sanitation Workshop[1] and the Public Health Service (PHS) was requested to initiate development of such guides. As result of this request, the PHS developed drafts of equipment construction guides. Agencies and organizations which received these initial drafts and thus contributed to the development of the completed construction guides included: Oyster Institute of North America, Bureau of Commercial Fisheries, Food and Drug Administration, Canadian Department of National Health and Welfare, and two equipment manufacturing companies. The completed construction guides were reviewed and adopted by the 1961 National Shellfish Sanitation Workshop. Subsequently, the 1993 annual meeting of the Interstate Shellfish Sanitation Conference asked FDA to review and update the definitions to be consistent with other documents such as Model Code, Pasteurized Milk Ordinance, National Sanitation Foundation, and Code of Federal Regulations. FDA agreed to provide an update to the committee.

It is the purpose of this guide to describe construction and fabrication procedures which will ensure that blower tanks, skimmers, returnable shipping containers, shellfish shucking buckets and pans and will meet the equipment construction standard of the Cooperative program and the functional needs of the industry. However, the development of new methods of equipment construction or fabrication with acceptable materials, construction and fabrication is also encouraged. Therefore, shellfish equipment specifications developed which differ in design, material, fabrication, or otherwise do not to conform with the following standards, but which in the fabricator's opinion are equivalent to or better may be submitted for consideration.

Scope

This guide covers the sanitary construction aspects of (1) shellfish blower tanks, including the sanitary piping for air, water, and drain lines; (2) the stand-supported skimmer, including the supporting stand; (3) returnable shipping containers; (4) shellfish shucking buckets; (5) shellfish shucking pans; (6) tables; (7) conveyors; (8) mechanical shucking devices.

This guideline will aid FDA, state regulatory officials and other interested individuals in making evaluations of the materials, construction and fabrication of equipment used to collect, convey, store, transport, process and package molluscan shellfish products.

This guideline will also provide manufacturers with knowledge of what documentation reviewers might expect them to provide in order to verify the acceptability of materials, construction and fabrication.

Definitions

(1) ***Air break*** - A piping arrangement in which a drain from a fixture, appliance, or device discharge indirectly into another fixture, receptacle, or interceptor at a point below the flood level rim.

(2) ***Air Gap*** - The unobstructed vertical distance (twice the diameter of largest inlet pipe) through the free atmosphere between the water inlet supplying a tank, plumbing fixture or other device and the effective overflow level of the receptacle.

(3) ***Air Under Pressure*** - The pressure of which has been increased by mechanical means to exceed atmospheric pressure, and which is used for agitation of shucked shellfish.

(4) ***Alternate Materials*** - Is whenever specific materials are mentioned, it is understood that the use of materials proven to be equally satisfactory from the standpoint of sanitation and protection of food is acceptable.

(5) ***Blower*** - A tank-like device for immersion washing of shucked shellfish. Air may be introduced at the bottom of the tank to produce agitation.

(6) ***Coatings*** - The results of a process where a different material is deposited to create a new surface. There is appreciable build-up of new material, typically more than 1µm.

(7) ***Corrosion Resistant Materials*** - Those materials that maintain their original surface characteristics under normal exposure to the foods being contacted, normal use of cleaning compounds and bactericidal, and other conditions of use.

(8) ***Cleaned-in-place*** - Refers specifically to the cleaning and sanitizing of food processing equipment and piping in its assembled condition by recirculation of the necessary rinse, detergent and sanitizing solutions under appropriate conditions of time, temperature, detergency and physical action.

(9) ***Dead End*** - Area or space wherein a product, ingredient, cleaning, or sanitizing agent, or other extraneous matter may be trapped, retained or not completely displaced during operational or cleaning procedures.

(10) ***Drain gate and chute*** - The opening located either in the blower or skimmer through which the washed shellfish are eliminated.

(11) ***Drain valve*** - The valve through which the wash water is released to the floor or waste line.

(12) ***Easily Cleanable*** - A surface which is readily accessible and is made of such materials, has a finish and is so fabricated that residue may be effectively removed by normal cleaning methods.

(13) ***Equipment*** - Blower, skimmer, tables, shucking benches, can seamer, sinks, refrigerators, and similar items other than utensils, used in the operation of a shellfish processing facility.

(14) ***Filter Media*** - Filters for the air intake of a blower shall consist of fiberglass with down stream backing dense enough to prevent fiberglass break off from passing through, cotton flannel, wool flannel, non-woven fabric or other suitable materials which under conditions of use, are non-toxic and nonshedding and which do not release toxic volatile or other contaminants to the air, or volatile which may impart any flavor or odor to the product. Disposable filter media are not intended to be cleaned or re-used.

(15) ***Flood Level Rim*** - The edge of the receptacle from which water overflows.

(16) ***Food contact surface*** - Surface of equipment or a utensil which food normally comes into contact; or a surface of equipment or a utensil from which food or liquid may drain, drips, or splash into a food; or onto a surface normally in contact with food. Food contact surfaces include, but are not limited to, equipment and utensils such as; shucking knives and handles, shucking hammers and handles, shucking blocks, ice scoops and shovels, ice bins, skimmers, blower tanks, shucking pails, shellstock grinders.

(17) ***Metals*** - Metals which are nontoxic, nonabsorbent and corrosion resistant under conditions of intended use.

(18) ***Nonfood Contact Surfaces*** - All exposed surfaces other than food or splash contact surfaces.

(19) ***Nontoxic Materials*** - Materials which are free of substances which may render shellfish injurious to health or which may adversely affect the flavor, odor, composition or bacteriological quality of the product and which meet the requirements of the Federal Food Drug and Cosmetic Act as amended.

(20) ***Plastic*** - A material that contains as an essential ingredient an organic substance of high molecular weight, is solid in its finished state, and at some stage in its manufacture or in its processing into finished articles, can be shaped by flow.

(21) ***Rim*** - An unobstructed open edge of a fixture.

(22) ***Readily accessible*** - Exposed or capable of being exposed for cleaning and inspection without the use of tools.

(23) ***Readily Demountable or Removable*** - Capable of being taken away from a unit with the bare ands or the use of simple tools such as screwdriver, pliers or an open end wrench.

(24) ***Returnable Shipping Container*** - Multiple use container for holding or shipping of

shucked shellfish.

(25) ***Safe Materials*** - Articles manufactured from or composed of materials that may not reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of any food.

(26) ***Sealed*** - Free of cracks or other openings that permit the entry or passage of moisture.

(27) ***Molluscan Shellfish*** - All edible species of oysters, clams, mussels and whole scallops or roe-on scallops (scallops are excluded when the final product is the shucked adductor muscle only). Shellfish products which may contain any material other than the meats and /or shell liquor of oysters, clams, mussels or scallops will be regarded as a "processed food" and will not be included in the Cooperative Program.

(28) ***Shellfish Shucking Bucket*** - Containers for temporarily holding shucked shellfish during the shucking process.

(29) ***Shellfish Shucking Pan*** - Containers for temporarily holding shucked shellfish during the shucking process.

(30) ***Shucked Shellfish*** - Shellfish, or parts thereof, which have been removed from their shells.

(31) ***Single Service Articles*** - Any metal or plastic containers, lids and closures, wrapping materials such as burlap or hessian bags and similar materials intended for one-time use, one person use and then discarded.

(32) ***Skimmers*** - A perforated tray in which shucked shellfish are sprayed washed and/or drained.

(33) ***Skimmers Paddle*** - The utensils used as the gate on the skimmer exit chute and/or one used to scrape the product through the exit chute.

(34) ***Smooth*** - A surface free of pits and inclusions having a clean ability or better than the following:
- (a) food contact a No. 4 (150 grit) or better finish as obtained with silicon carbide, properly applied on stainless steel surface;
- (b) Non-food contact surfaces free of visible scale.

(35) ***Splash Contact Surfaces*** - Any surfaces other than food contact surfaces which are subject to routine splash (wet or dry), spillage and contamination during normal use.

(36) ***Toxic*** - Having an adverse physiological effect on man.

(37) ***Utensils*** - Any implement used in the preparation, transportation, and storage of

molluscan bivalves such as shucking knives, skimmer paddles, strainers, shucking buckets, shucking pans, etc.

(38) ***Weld*** - Permanent seams or joints. When welded seams are used, the weld area and the deposited material shall be as corrosion-resistant as the parent material.

Materials

I. Metals

A. Stainless Steel

Stainless steel is a family of iron based alloys that must contain at least 10.5% Chromium (**Cr**). The presence of chromium creates an invisible surface film that resists oxidation and makes the material “passive” or corrosion resistant (i.e. “stainless”). This family can be simply and logically grouped into five (5) branches. Each of these branches has specific properties and a basic grade or “type.” In addition, further alloy modifications can be made to "tailor" the chemical composition to meet the needs of different corrosion conditions, temperature ranges, strength requirements, or to improve welding, machine, work hardening and form.

Stainless is designated by three different systems: Metallurgical structure - Austenitic; Grade - 304 (most used see photos 1 and 2 for Polish No. 3 and No 4) and Unified Numbering System UNS.

Stainless steel product contact surfaces of the American Iron and Steel Institute (AISI) 303, 304, 316 Series[3] or corresponding Alloy Cast Institute (ACI) types.[4] Cast grades of stainless steel corresponding to types 303, 304, and 316 are designated CF-16F, CF-8, and CF-8M, respectively. The chemical compositions of these cast grades are covered by ASTM specifications A351/A351M, A743/A743M and A744/A744M.[5] Metal which under conditions of intended use is at least as corrosion resistant as stainless steel of the foregoing types, and is nontoxic and nonabsorbent, can also be used, except that:

Equipment may also be made of stainless steel of the AISI 400 Series that is made as corrosion resistant as AISI 300 Series by surface treatment or coating(s) or made of nontoxic, nonabsorbent metal that is as corrosion resistant, under the conditions of intended use, as stainless steel of the AISI 300 Series.

B. Optional Metal Alloys

Metal alloy of the following types may be used but only in applications requiring disassembly and manual cleaning. (See **Table 1**; values are in percentages)

Equipment made of optional metal alloy may have product contact surfaces modified by surface treating or coating.

Photo 1 – *Stainless Steel Type 304, No.3 Polish satisfactory for many industrial and commercial products requiring a good polished surface. Typical applications include vent hoods.*

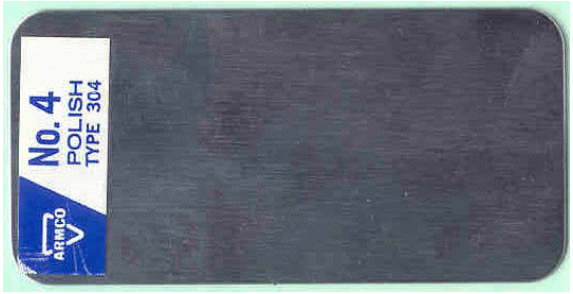


Photo 2 - *Stainless Steel Type 304, No.4 Polish is exceptionally uniform normally used without further finishing. This is the established standard for dairy and food processing equipment because it is easy to keep clean and sanitary.*

C. Electroless Nickel Alloy Coating

An electroless nickel alloy coating having the following composition is acceptable:

Nickel — 90% minimum
Phosphorous — 6% minimum and 10% maximum as supersaturated solution of nickel phosphide in nickel
Trace amounts of carbon, oxygen, hydrogen and nitrogen
No other elements

Equipment to be manually or mechanically cleaned may be covered by an engineering coating of electroless nickel alloy conforming to the applicable provisions of military specification MIL-C-26074 E, as amended. [6]

Equipment may also be made of other nontoxic structurally suitable metal(s) that have their product contact surfaces modified by surface coating(s).

D. Solder

Solder, when used, should be silver bearing solder and should be corrosion resistant, free of cadmium, lead and antimony, nonabsorbent, and should not impart any toxic substance to the product when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment (or sterilization).

TABLE 1 -- OPTIONAL METAL ALLOYS

	UNS NO8367	**UNS S21800**	**UNS S20161**	**UNS N26055**	**UNS N26455**	**UNS S17400**	**UNS S15500**	**UNS S32900**	**UNS R20500**	**UNS R50400**
	ASTM A743 Grade CN-3MN	ASTM A743 Grade CF-10 SMnN		ASTM A494 Grade CY5SnBiM	ASTM A494 Grade CW-2M	ASTM A747 Grade CB7Cu-1	ASTM A747 Grade CB7Cu-2		ASTM A560 Grade 50Cr-50Ni	ASTM B67 Grade C-2
C	0.03	0.1	0.015	0.05	0.02	0.07	0.07	0.2	0.1	0.1
Mn	2.00	7.00 -9.00	4.00 - 6.00	1.5	1.00	0.70	0.70	1.00	0.30	
Si	1.00	3.50 -4.50	3.00 - 4.00	0.5	0.80	1.00	1.00	0.75	1.00	
P	0.040	0.040	0.040	0.03	0.03	0.035	0.035	0.040	0.02	
S	0.010	0.030	0.040	0.03	0.03	0.03	0.03	0.030	0.02	
Cr	20.0-22.0	16.00 - 18.00	15.0 - 18.0	11.0 - 14.0	15.0 - 17.5	5.50-17.7	14.0-15.5	23.0-28.0	48.0 - 52.0	
Ni	23.5-25.5	8.00-9.00	4.00-6.00	Balance	Balance	3.60-4.60	4.50-5.50	2.5-5.0	Balance	
Mo	6.0-7.0			2.0-3.5	15.0-17.5			1.0-2.0		
Cb						0.15-0.35	0.15-0.35			
Cu	0.75					2.5-3.2	2.5-3.2			
N	0.18- 0.26	0.08- 0.18	0.08-0.020			0.05	0.05		0.30	
Fe	Balance	Balance	Balance	2.00	2.00	Balance	Balance	Balance	1.00	0.30
Sn				3.0-5.0						
Bi				3.0-5.0						
W					1.0					
Tl									0.50	Balance
Al									0.25	
Other										H=0.015 N=0.03 O=0.25

NOTE: Metal alloys or metals other than the above may be as corrosion resistant as 300 Series Stainless steel. This may be shown when metal alloys or metals are tested in accordance with ASTM G31 Laboratory Immersion Corrosion Testing of Metals and have a corrosion rate of less than 20 mil per year. The test parameters such as the type of chemical(s), their concentration(s) and temperature(s) should be representative of cleaning and sanitizing conditions used in dairy equipment. **Alloys containing lead, leachable copper or other toxic metals should not be used.**

E. Aluminum

Aluminum is satisfactory for certain dry products applications. Aluminum may be used for

liquid or high moisture content product contact surfaces only when a specific functional requirement exists and the parts are not subjected to strong caustic cleaning solutions or to the corrosive action of dissimilar metals.

The aluminum type chosen for the application shall be demonstrated to be appropriate and acceptable for the intended use. (Provisions have been made in existing 3-A (dry product) Standards for Aluminum Association designations 5052, 6061, 6063, A-360, A-380, A-319, A-315G, and C-413, Danish Standards DS#3002 and #4261, and ASTM standards B179, and S12c for certain specified uses.)

F. Nonmetals

Non-metallic materials may be used for food contact and non-food contact equipment and service items. When utilized these materials shall be in compliance with appropriate sections of the 21 Code of Federal Regulations, Parts 170-199 (21 CFR 170-199).

These materials shall be relatively inert, resistant to scratching, scoring, and distortion by the temperature, chemicals, and methods to which they are normally subjected in operation, or by cleaning and bactericidal treatment. They shall be non-toxic, fat resistant, relatively non-absorbent, relatively insoluble and shall not release component chemicals or impart a flavor to the product.

1. Rubber and **rubber-like materials** may be used where functionally appropriate.

Rubber and rubber-like materials when used for the above specified application(s) should conform with the applicable provisions of the "3-A Sanitary Standards for Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment", Number 18- (or equivalent).

2. Plastic materials may be used where functionally appropriate.

Plastic materials when used for the above specified application(s) should conform with the applicable provisions of the "3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment," number 20 - (or equivalent).

When used in sight and/or light openings and as direct reading gauge tubes, plastic should be of a clear, heat resistance type.

3. Durability of rubber and plastic

Rubber and rubber-like materials and plastic materials having product contact surfaces should be of such composition as to retain their surface and conformational characteristics when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment (or sterilization).

4. Bonded Rubber

The final bond and residual adhesive, if used, on bonded rubber and rubber-like materials and bonded plastic materials should be nontoxic[7].

G. Materials for Non-product Contact Surfaces

Materials for non-product contact surfaces should be of corrosion-resistant material or material that is rendered corrosion resistant. If coated, the coating used should adhere. All non-product contact surfaces should be relatively nonabsorbent, durable, and cleanable. Parts removable for cleaning having both product contact and non-product contact surfaces should not be painted.

II. Fabrication

A. Surface Texture

All product contact surfaces should have a finish at least as smooth as No. 4 ground finish on stainless steel sheets and be free of imperfections such as pits, folds and crevices in the final fabricated form. Surface finish equivalent to 150 grit or better as obtained with silicon carbide, properly applied on stainless steel sheets, constitutes a No.4 ground finish. A maximum Ra of 32 micro-inch (0.80), when measured according to the recommendations in ANSI/ASME B46.1[8] - Surface Texture, is considered to be equivalent to a No. 4 finish.

B. Permanent Joints

1. Welding

Where welding is involved, the carbon content of the stainless steel should not exceed 0.08%.

All permanent joints in metallic product contact surfaces should be continuously welded. Welded areas on product contact surfaces should be at least as smooth as No. 4 ground finish on stainless steel sheets, and be free of imperfections such as pits, folds, and crevices when in the final fabricated form except that:

2. Soldering

In such cases where welding is impractical, soldering, may be employed where necessary for essential functional reasons. Silver bearing solder may be used for producing fillets for minimum radii or other appropriate functional purposes.

3. Press fits or shrink-fits

Press-fits or shrink-fits may be used to produce crevice free permanent joints in metallic product contact surfaces when neither welding nor soldering is practical. Joints of these types may only be used to assemble parts having circular cross sections, free of shoulders or relieved areas. For example: they may be used to assemble round pins or round bushings into round holes. In both of these fits the outside diameter of the part being inserted is greater than the inside diameter of the hole.

In the case of the press-fit the parts are forced together by applying pressure. The pressure required is dependent upon the diameter of the parts, the amount of interference and the distance the inner member is forced in.

In shrink-fits, the diameter of the inner member is reduced by chilling it to a low

temperature. Dry ice is commonly used to shrink the inner member. Heat may also be applied to the outer member of the press-fit. Less assembly force is required for this type of fit.

The design of these fits depends on a variety of factors. The designer should follow recommended practices to assure that a crevice-free joint is produced. A recognized authoritative reference is Machinery's handbook published by Industrial Press Inc., 200 Madison Avenue, New York, NY 10157.

4. Surface finish

Press-fitting, shrink-fitting or soldering should produce contact surfaces which are at least as smooth as No. 4 ground finish on stainless steel sheets and which are free of imperfections such as pits, folds and crevices.

C. Bonded Materials

Bonded rubber and rubber-like materials and bonded plastic materials having product contact surfaces should be bonded in a manner that the bond is continuous and mechanically sound so that when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment (or sterilization if applicable) the rubber and rubber-like material or the plastic material does not separate from the base material to which it is bonded.

D. Coatings

Coatings, if used, should be free from surface delamination, pitting, flaking, spalling (chipping), blistering and distortion when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment (or sterilization).

E. Cleaning and Inspection

Equipment that is to be mechanically cleaned should be designed so that the product contact surfaces and all non-removable appurtenances thereto can be mechanically cleaned and are easily accessible and readily removable for inspection. Removable parts shall be readily demountable employing simple hand tools, which are available to operating or cleaning personnel; except that equipment that is to be CIP cleaned should have representative product contact surfaces easily accessible for inspection.

Product contact surfaces, not designed to be mechanically cleaned, should be accessible for cleaning and inspection when in an assembled position or when removed.

Appurtenances having product contact surfaces should be readily removable using simple hand tools or they should be cleanable when assembled or installed and should be easily accessible for inspection.

F. Draining

All product contact surfaces, when properly installed, should be self-draining except for normal clingage. However, if the product contact surfaces are not self-draining, they should have sufficient pitch to suitable drain points so they can be drained.

G. Fittings, Valves, Instruments and Similar Appurtenances

Sanitary fittings and connections which conform with the appropriate 3-A Sanitary Standards are acceptable. All other fittings must be reviewed using the criteria in this document.

The thermometer connections and/or openings, if provided or required, should be located so that the thermometer is not influenced by a heating or cooling jacket.

If the fittings for temperature sensing devices do not pierce the tank lining, either the temperature sensing element receptacles should be securely attached to the exterior of the lining or means to attach the temperature sensing element(s) securely to the exterior of the lining should be provided.

H. Sanitary Tubing

All metal tubing should conform with the applicable provisions for welded sanitary product pipelines found in the 3-A Accepted Practices for Permanently Installed Product and Solution Pipelines and Cleaning Systems Used in Milk and Milk Product Processing Plants, Number 605- or equivalent and with the 3-A Sanitary Standards for Polished Metal Tubing for Dairy Products, Number 33- or equivalent.

I. Gaskets

Gaskets having a product contact surface should be removable or bonded.

Grooves in gaskets should be no deeper than their width unless the gasket is readily removable and reversible for cleaning, (i.e., storage tank door gaskets).

Gasket retaining grooves in product contact surfaces for removable gaskets should not exceed 1/4" (6.35 mm) in depth or be less than 1/4" (6.35 mm) wide except those for standard O-rings smaller than 1/4" (6.35 mm) and those allowed in the 3-A Standard for Sanitary Fittings, Number 63.

J. Radii

All internal angles 135° or less on product contact surfaces should have a minimum radii of 1/4" (6.35 mm) except that:

1. Minimum radii for fillets of welds where head(s) and the side wall(s) of tanks join should not be less than 3/4" (19.05 mm).

2. Smaller radii may be used when they are required for essential functional reasons. In no case should such radii be less than 1/32" (0.794 mm).

3. The radii in gasket retaining grooves or grooves in gaskets should be not less than 1/16" (1.59 mm) except for those standard, 1/4" (6.35 mm) and smaller O-rings, and those provided for in the "3-A Standards for Sanitary Fittings", Number 63.

4. The radii in grooves for standard 1/4 in. (6.35 mm) and smaller O-rings should be at least:

0.016 in. (0.406 mm) for 1/16 in. (1.59 mm) O-rings
0.031 in. (0.787 mm) for 3/32 in. (2.38 mm) O-rings
0.031 in. (0.787 mm) for 1/8 in. (3.18 mm) O-rings
0.062 in. (1.575 mm) for 3/16 in. (4.76 mm) O-rings
0.094 in. (2.388 mm) for 1/4 in. (6.35mm) O-rings

K. Threads

There should be no threads on product contact surfaces accept where necessary for non-permanent joints in piping and for making various attachments to equipment.

In such case(s) the threads should conform with the "Acceptable Sanitary Thread@. The thread angle should be not less than 60º and with not more than eight threads to the inch (25.4 mm), nor less than 5/8" (15.88 mm) major basic diameter. The length of the nut should not exceed three-quarters of the basic thread diameter. The nut should be of the open type. Equipment with exposed threads as described above should be manually cleaned. Equipment with enclosed threads, (such as "acorn" nuts used to attach impeller blades to pump shafts), should be designed for mechanical cleaning.

L. Perforated Product Contact Surfaces

Perforations in product contact surfaces may be round, square, or rectangular. If round the holes should be a minimum of 1/32" (0.794 mm) in diameter. If square, or rectangular, the least dimension should be no less than 0.020" (0.51 mm) with corner radii of no less than 0.0050" (0.13 mm). All perforations should be free of burrs.

M. Shafts and Bearings

Shafts entering equipment should have a seal of the packless type and sanitary design, and should be readily accessible for cleaning and inspection.

Where a shaft passes through a product contact surface, in a milk room or processing area, the portion of the opening surrounding the shaft should be protected to prevent the entrance of contaminants.

Bearings having a product contact surface should be of a non-lubricated type.

Lubricated bearings, including the permanent sealed type, should be located outside the product contact surface with at least 1" (25.4 mm) clearance open for inspection between the bearing and any product contact surface unless specifically provided for in a 3-A standards.

GENERAL EQUIPMENT AND SERVICE ITEMS

I. Blower Tank

A. Material

1. All product-contact surfaces shall be of A.I.S.I.[2] Type No. 304 stainless steel or equally corrosion resistant metal that is non-toxic and non-absorbent except that:

(a) Plastic materials may be used for the blower tank drain gate and drain valve. These materials shall be relatively inert, resistant to scratching, scoring, and distortion by the temperature, chemicals, and methods to which they are normally subjected in operation, or by cleaning and bactericidal treatment. They shall be non-toxic, fat resistant, relatively nonabsorbent, relatively insoluble, and shall not release component chemicals or impart a flavor to the product[3].

(b) Rubber and rubber-like materials may be used for blower tanks paddles or gate, drain gate, and drain valve. These materials shall be relatively inert, resistant to scratching, scoring, and distortion by the temperature, chemicals, and methods to which they are normally subjected in operation, or by cleaning and bactericidal treatment. They shall be non-toxic, fat resistant, relatively non-absorbent, relatively insoluble and shall not release component chemicals, nor impart a flavor to the product.[3]

2. All non-product contact surfaces shall be of inherently corrosion-resistant material, shall be rendered corrosion-resistant, or shall be painted. Surfaces to be painted shall be effectively prepared for painting; and the paint used shall adhere, be relatively non-absorbent, and shall provide a smooth, cleanable and durable surface. Parts having both product-contact and non-product-contact shall not be painted.

B. Fabrication

1. All product-contact surfaces shall be at least smooth as No. 4 ground finish on stainless steel sheets.

2. All seams in product-contact surfaces shall be welded with the welds ground smooth and polished to not less than a No. 4 finish. All outside seams shall be smooth and waterproof. All weld areas and deposited weld material shall be substantially as corrosion-resistant. ***(Figure 1)***

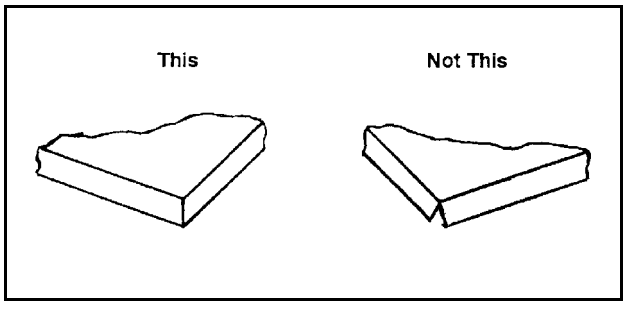


Figure 1 – Product contact surface seams

3. All appurtenances, including drain gates and chutes having product-contact surfaces, shall be easily removable for cleaning, or shall be readily cleanable in place.

4. All product-contact surfaces shall be easily accessible, visible, and readily cleanable, either

when in an assembled position or when removed.

5. All internal angles of 135° or less on product contact surfaces shall have minimum radii of 1/4" (6.35 mm), except that minimum radii for fillets or welds in product-contact surfaces may be smaller for essential functional reasons. In no case shall radii n 1/8" (3.18 mm). ***(Figure 2)***

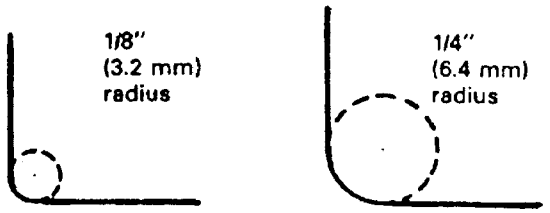


Figure 2 – Internal angles of 135º or less on product contact areas

6. All sanitary pipe fittings shall conform to "3-A Sanitary Standards for Fittings Used on Milk and Milk Products Equipment," and supplements thereto.[4] (***Figure 3***)

7. Nonproduct-contact surfaces shall have a smooth finish, be free of pockets and crevices, and readily cleanable.

8. Legs shall be of sufficient length to provide at least 12" (30.5 cm) clearance between the lowest fixed point of the tank and the floor, shall be smooth with rounded ends, and shall not hollow tube stock, they shall be effectively sealed. If legs are of hollow tube stock, they shall be effectively sealed. (***See Figures 4 and 5)***

9. All threads on product-contact surfaces shall comply with specifications for threads contained in the 3-A Sanitary Standards for Fittings.[4]

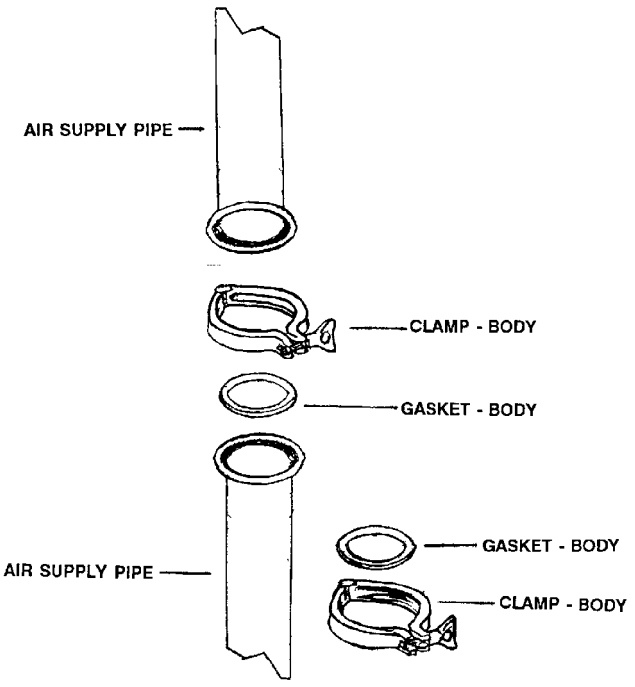


Figure 3 – Sanitary Pipe Fitting

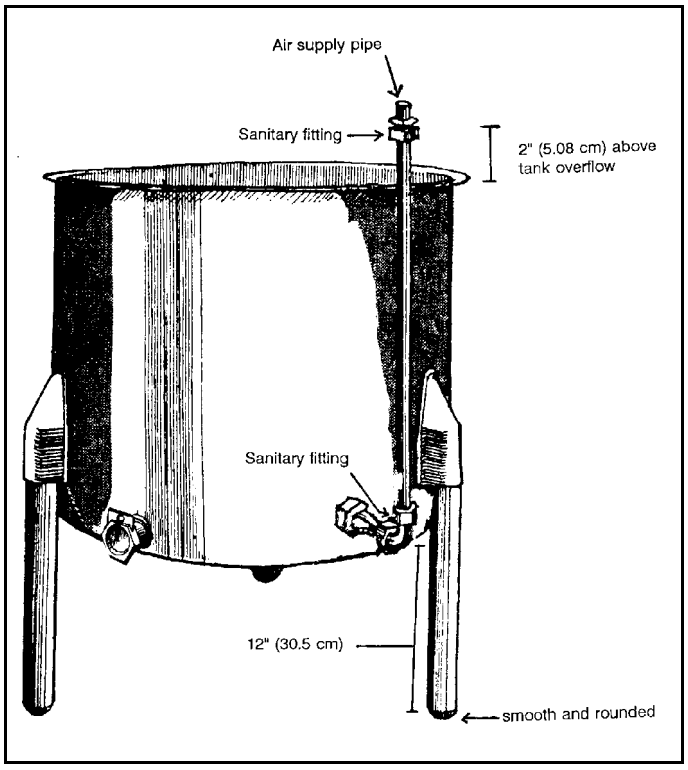


Figure 4 – Blower Tank

Figure 5 – Close up for a smooth and rounded leg

10. External and internal sections of the air pipe shall be easily cleanable to a point at least two inches above the tank overflow level. ***(Figure 4)***

11. The false bottom shall be so constructed as to be as rigid and, in any event, of at least 16 U.S. Standard gage stainless steel, or equivalent material. ***(Figure 6)***

12. Perforations or slots in the false bottom shall not be less than 3/16 inch (4.76 mm) in the minimum diameter and the end radius of the perforations shall be not less than 3/32 inch (2.38 mm). After perforation, the flat surface of the sheet from which the perforating punch or drill emerges on the down stroke shall be polished to the equivalent of not less than a No. 4 ground finish. **(*Figure 6*)**

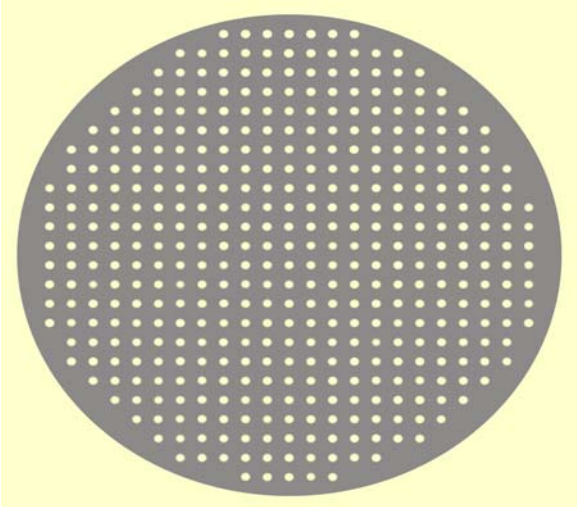


Figure 6 – Blower false bottom plate

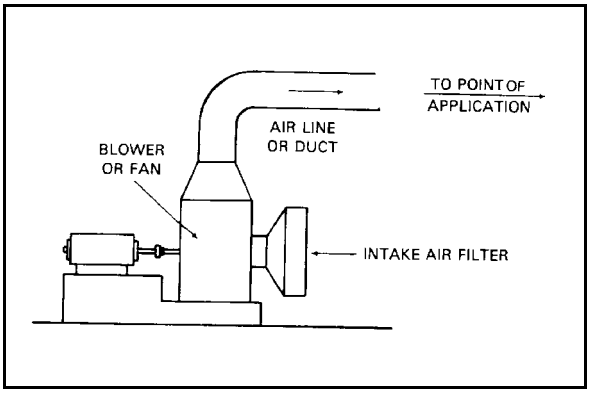


Figure 7 – Air pump

13. The compressing equipment shall be of such design so as to preclude contamination of the air with lubricant vapors and fumes. The air supply shall be taken from a clean space or from relatively outer air, and shall pass through a filter upstream from the compressing equipment. This filter shall be so located and constructed that it is easily accessible for examination, and the filter media are easily removable for cleaning or replacing. The filter shall be protected from weather, drainage, water, product spillage and physical damage ***(Figure 7).***

14. Air distribution piping, fittings, and gaskets between the downstream terminal filter and any product or product contact surface shall sanitary 3-A design.

15. Air lines shall be easily cleanable construction to a point 2" (5.08 cm) above the tank overflow.
(Figure 4)

16. Filter should be located as close as possible to point of use.

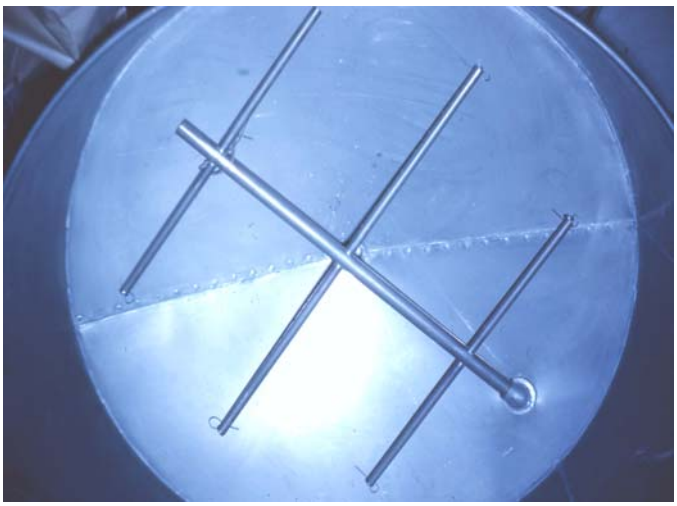


Figure 8 – Air manifold installed inside the blower tank

17. Air distribution piping or manifold located inside the blower tank shall be designed so as to preclude contamination of the product. This manifold shall be designed to be easily removed from the tank and removable end caps to facilitate sanitary cleaning. **(*Figures 8 and 9*)**

18. Perforations or slots in the manifold or air distribution pipe shall not be less than 1/8" (3.18 mm) in the minimum diameter. After perforation, the pipe from which the perforation punch or drill emerges on the down stroke shall be polished to the equivalent of not less than a No. 4 ground finish. ***(Figure 9)***

19. Wire mesh shall not be used as a filter.

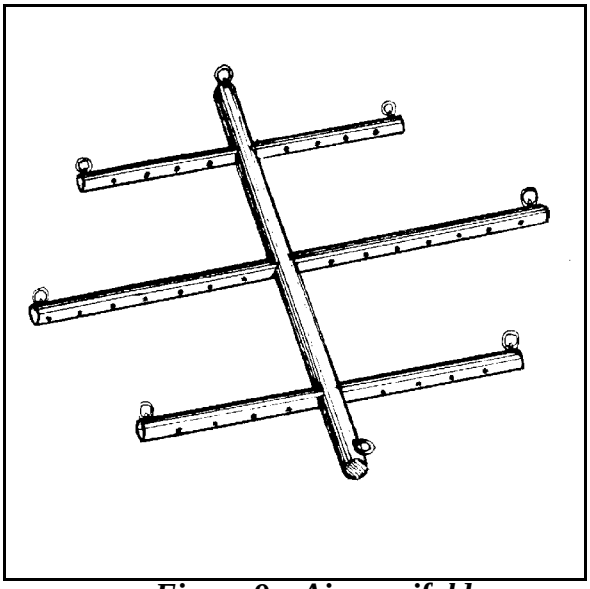


Figure 9 – Air manifold located inside tank

20. The blower tank shall be constructed so that it will not buckle or sag and so that it will be self-draining. Product-contact surfaces shall be constructed of not less than 16 U.S. standard gage stainless steel or equivalent material.

21. Maximum dimension of the tank from point of overflow to drain valve flange shall not exceed 40" (101.6 cm).

22. Drain valves and flange shall comply with the 3-A Sanitary Standards for Fitting used on Milk and Milk Products Equipment. The flange shall be welded to the body of the blower tank.

23. There shall be no exposed screw, bolt, or rivet heads in product-contact surfaces.

II. SKIMMERS

A. Material

1. All product-contact surfaces shall be of A.I.S.I. type No. 304 stainless steel, or equally corrosion-resistant metal that is non-toxic and nonabsorbent, except that:

(a) Suitable plastic materials or rubber and rubber-like materials may be used for the skimmer paddle or gate. These materials shall be relatively inert, resistant to scratching, scoring, and distortion by temperature, chemicals, and methods to which they are normally subjected in operation, or by cleaning and bactericidal treatment. They shall be non-toxic, fat resistant, relatively nonabsorbent, relatively insoluble, and shall not release component chemicals nor impart a flavor to the product.[3]

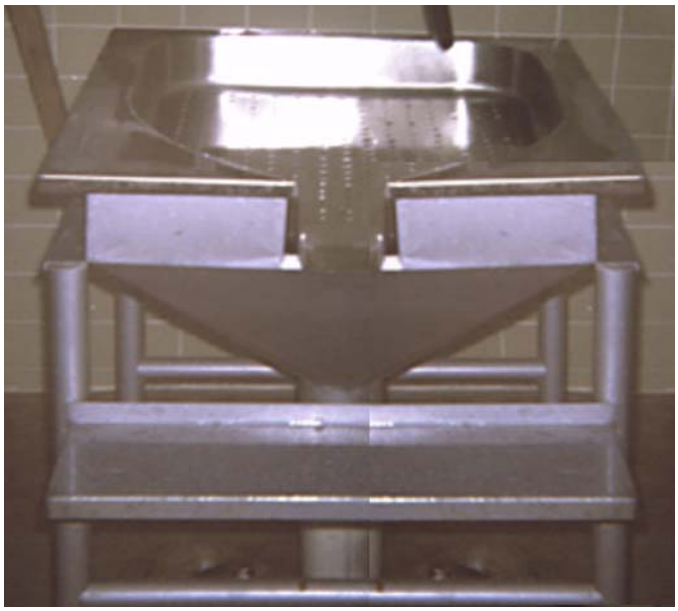


Figure 10 – Photo front view of a skimmer

2. All non product-contact surfaces shall be inherently corrosion-resistant, and except for funnel drain, shall be painted. Surfaces to be painted shall be effectively prepared for painting and the paint used shall adhere, be relatively nonabsorbent, and shall provide a smooth, cleanable, and durable surface. Parts having both product and non product-contact surfaces shall not be painted.

B. Fabrication

1. All product-contact surfaces shall be at least as smooth as a No. 4 ground finish on stainless steel sheets.

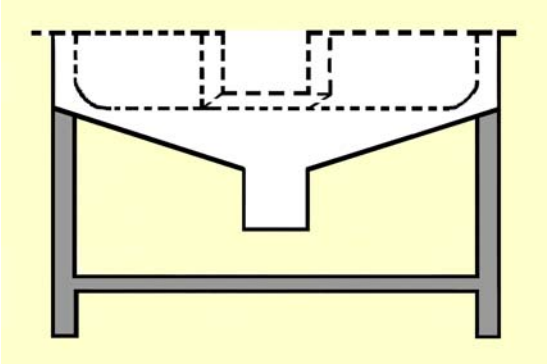


Figure 11 – Front view of skimmer frame; broken lines are the removable part of the skimmer food contact area

2. All seams in product-contact surfaces shall be welded with the welds ground smooth and polished to not less than a No. 4 ground finish. All outside seams shall be smooth and waterproof. All weld

areas and deposited weld metal shall be substantially as corrosion resistant as the parent metal.

3. All appurtenances having product-contact surfaces shall be easily removable for cleaning, or shall be readily cleanable in place.

4. All product-contact surfaces shall be easily accessible, visible, and readily cleanable, either when in an assembled position or when removed. The skimmer shall be demountable from the supporting stand for cleaning. (***Figure 11)***

5. All internal angles of 135° or less on product-contact surfaces shall have minimum radii of 1/4" (6.35 mm) except that minimum radii for fillets of welds in product-contact surfaces may be smaller for essential functional reasons. (***Figure 2***)

6. The skimmer shall be constructed so that it will not buckle or sag while in use, so that both the perforated area and drainage funnel are self-draining, and so as to provide plane surfaces free of depressions, indentations, or bulges which prevent draining when the pitch is not greater than 1" (25.4 mm) in 50" (127 cm). (Corners and rims of a perforated skimmer should be adequately reinforced to prevent damage from handling during cleaning and bactericidal treatment.)

7. The product-contact surfaces shall be constructed of not less than 16 U.S. standard gage stainless steel or equivalent material. The perforations or slots in the strainer shall be at least 1/4" (6.35 mm) in diameter or width, respectfully (***Figure 12 and Dimension A, Figure 13)*** and not more than 1 1/4" (31.75 mm) apart (***Dimension B, Figure 13***)[5]. The strainer area shall have no perforations within 1/2" (12.7 mm) of the edge (***Dimension C, Figure 13***).[4] After perforations, the flat surface of the sheet from which the perforating punch or drill emerges on the down stroke shall be polished to the equivalent of not less than a No. 4 ground finish. No bracing for the skimmer or the skimmer support stand shall block any perforations unless the brace is made of corrosion-resistant material and fabricated in a manner suitable for a product-contact surface, and unless it can be readily removed for cleaning. A minimum of 3 1/2" (8.89 cm) shall be provided between the strainer and the top of the skimmer (***Dimension E, Figure 13***).

8. A minimum vertical clearance of 2" (5.08 cm) shall be provided between the perforated skimmer area and the drainage funnel. (***Dimension D, Figure 13***).

9. The funnel drain shall have a discharge opening of a size sufficient to discharge the drainage without pooling above, and be not less than equivalent to a diameter of 4" (10.16 cm). The funnel drain shall terminate in a free discharge, a distance of at least 6" (15.24 cm) above the floor or the drain connection if located at a higher elevation than the floor. (***Figure 13***)

10. There shall be no threads on product contact surfaces except as provided for in the 3-A Sanitary Standards for Fittings.

11. Legs shall be smooth with rounded ends, and have no exposed threads. If legs are of hollow tube stock, they shall be effectively sealed. (***Figure 5***)

12. Frames, frame legs, and supporting edge for the skimmer shall have:

(a) Structural parts not in contact with the product, and parts constructed with a smooth finish so as to be readily cleanable.

(b) Self-draining exterior surfaces.

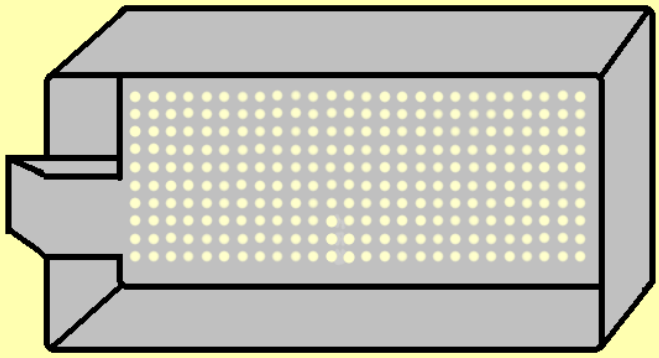


Figure 12 – Skimmer perforations or slots in the strainer shall be at least ¼" in diameter

(c) A minimum of 6" (15.24 cm) of space between the lowest part of the frame and the floor to provide ready access for cleaning legs and feet and those parts not readily removable.

13. The frame shall provide continuous support for the outside edge of the skimmer strainer. ***(Figure 14)***

14. The receiving-container shelf under the skimmer chute, where provided as an integral part of the skimmer support frame, shall be constructed of nonabsorbent, corrosion-resistant material and located so that the receiving-container rim will be at least two feet above the floor. (***Figure 14***)

15. All seams in the funnel drain area shall be smooth and waterproof, and substantially as corrosion resistant as the parent metal.

16. There shall be no exposed bolts, screws, or rivets in the product-contact surfaces.

17. Caster, rollers can be mounted on the skimmer. These shall be of such material, design and construction as to permit its being easily moved by one person. Casters shall be so installed as to be easily cleanable.

18. Reinforcing and framing members are to be placed in such a manner as to be easy to clean. All framing and reinforcing members shall be so placed as to eliminate harborage for vermin. The ends of all hollow sections of reinforcing and framing members shall be closed.

(a) Horizontal angle reinforcing and gussets shall not be placed where food or debris may accumulate thereon.

(b) Where angles are used horizontally, they shall have one leg turned down wherever the nature of the equipment permits or shall be formed integral with the sides.

(c) All vertical sections shall be either completely closed or open to the floor.

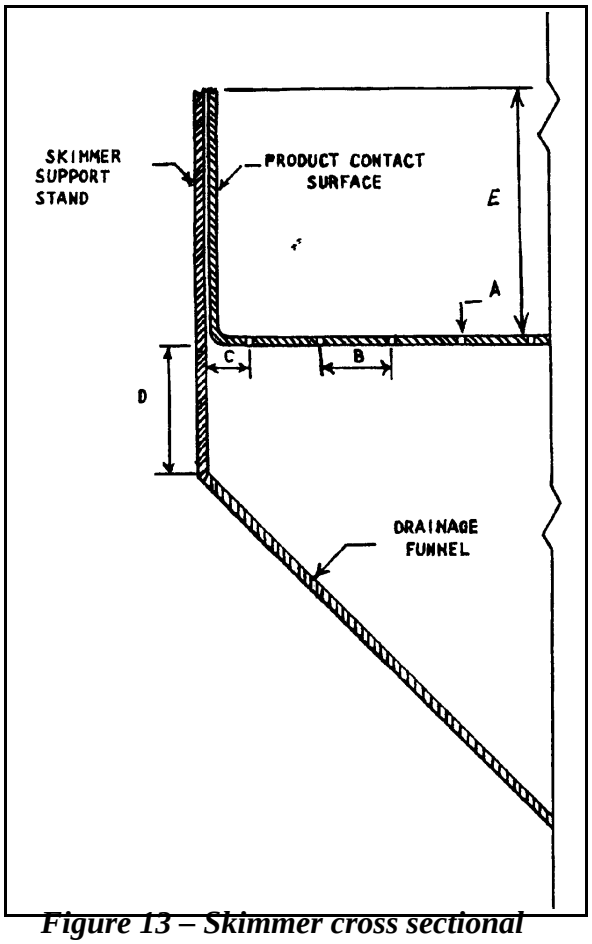


Figure 13 – Skimmer cross sectional side view

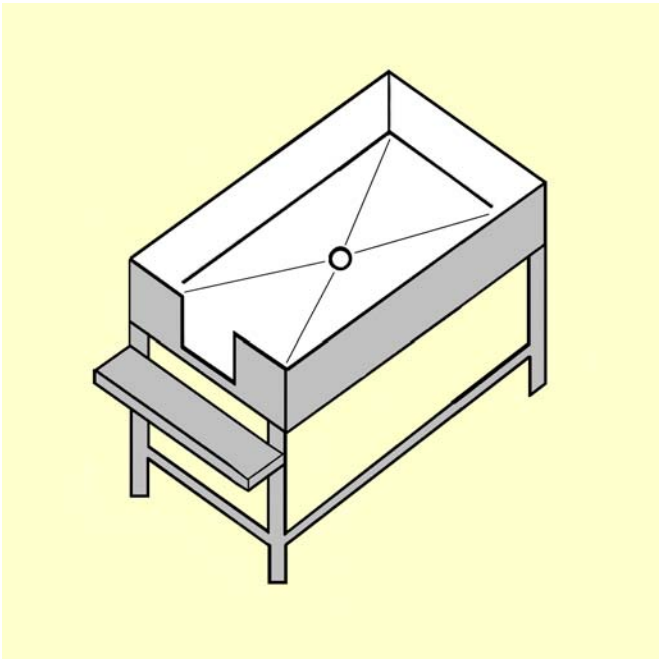


Figure 14 – Skimmer frame table

III. RETURNABLE SHIPPING CONTAINERS

A. Material

1. All metallic product-contact surfaces shall be of A.I.S.I. type No. 304 stainless steel or Aluminum Association type No. 5052-0 alloy, or equally corrosion-resistant metal that is nontoxic.

2. Plastic materials may be used as a food-contact surface or non food-contact surface. When used, these materials shall be relatively inert, resistant to scratching, scoring, and distortion by the temperature, chemicals, and methods to which they are normally subjected in operation, or by cleaning and bactericidal treatment. They shall be non-toxic, fat resistant, relatively nonabsorbent, relatively insoluble, and shall not release component chemicals or impart flavor to the product.[3]

3. If constructed of stainless steel, the containers shall not be constructed of less than 20 gauge material. If constructed of aluminum alloy the material shall not have a thickness less than 0.064" (1.63 mm).

4. All non product-contact surfaces shall be of corrosion-resistant material, and shall provide a smooth, cleanable, and durable surface.

B. Fabrication

1. All product-contact surfaces shall be at least as smooth as a number 4-ground finish on stainless steel, or equivalent surface finish on aluminum.

2. All internal angles of 135° or less on product contact surfaces shall have minimum radii of 1/4" (6.35 mm).

3. There shall be no seams, crevices, or other openings within the food-contact surfaces.

4. The container rim shall be rolled so as to permit easy and complete cleaning. The bead shall either be an open type with an external radii of not less than 3/16" (4.76 mm) or a sealed closed type.

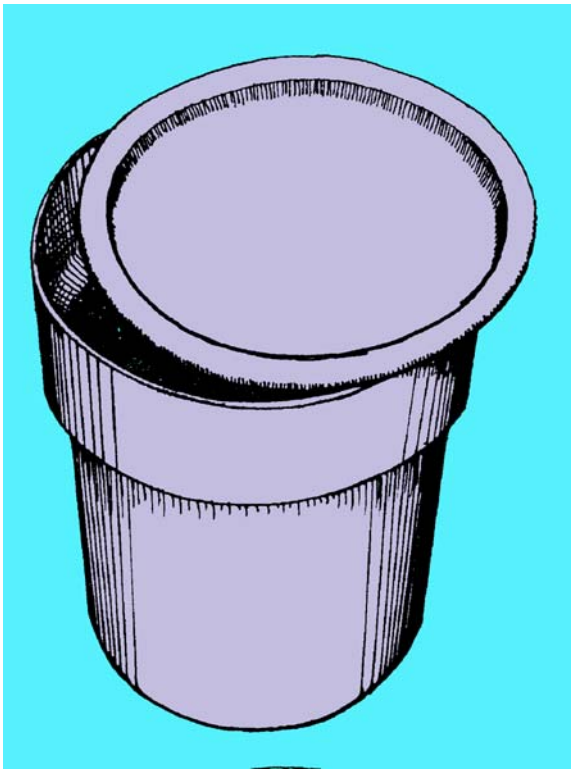


Figure 15 – Returnable container with lid

5. The container lid shall be so constructed as to afford easy and complete cleaning, shall be reasonably tight fitting, and a lip shall extend at least one inch down the outside of the container. Provisions shall be made for sealing the container so that any tampering will be evident. (***See Figure 15***)

6. Handles shall be provided on 5-gallon or larger containers. The handles shall be considered as a non product-contact surface.

IV. SHUCKING BUCKETS AND PANS

A. Material

1. All metallic product-contact surfaces shall be of A.I.S.I. type No. 304 stainless steel or Aluminum Association type No. 5052-0 aluminum alloy, or equally corrosion-resistant metal that is nontoxic.

2. Plastic materials may be used as a food-contact surface or non food-contact surface. When used, these materials shall be relatively inert, resistant to scratching, scoring, and distortion by the temperature, chemicals, and methods to which they are normally subjected in operation, or by cleaning and bactericidal treatment. They shall be non-toxic, fat resistant, relatively nonabsorbent, relatively insoluble, and shall not release component chemicals or impart flavor to the product.[3]

3. If constructed of stainless steel, the buckets shall not be constructed of less than 22 gauge material and the pans shall not be constructed with less than 24 gauge material or if constructed of aluminum alloy, the material shall not have a thickness less than 0.064"(1.63 mm).

4. All non product-contact surfaces shall be of corrosion-resistant material and shall provide a smooth, cleanable, and durable surface.

B. Fabrication

1. All product-contact surfaces shall be as smooth as a number 4 ground finish on stainless steel or equivalent surface finish on aluminum.

2. All internal angles of 135° or less on product-contact surfaces shall have minimum radii of 1/4" (6.35 mm)

3. The shellfish shucking bucket shall not exceed a nine-pint capacity, except for the soft clam (*Mya arenaria*) shucking pan which shall not exceed a four pint capacity. ***(Figures 16 and 17)***

4. There shall be no seams, crevices or other openings within the food-contact surfaces, except that two holes 180° apart shall be permitted in the side of each bucket near the top to accommodate a removable ball-type handle. ***(See Figure 18)***

Figure 16 – Mya arenaria shucking pan, four pint capacity

Figure 17 – Oyster shucking bucket, nine pint capacity

5. The container rim shall be so constructed as to afford maximum strength and protection against damage, and shall be so rolled as to permit easy and complete cleaning. The bead shall be open type with an external radii of not less than 3/16" (4.76 mm) or a sealed closed type.

6. The bail, if provided, shall be considered as contact surface and subject to material specifications as outlined in paragraph A of this standard. The bail shall be not less than 3/16" in diameter (4.76 mm); it shall be so constructed that it will be held into place by spring
tension. The bail shall be so constructed that it can be easily removed from the shucking ucket for cleaning purposes.

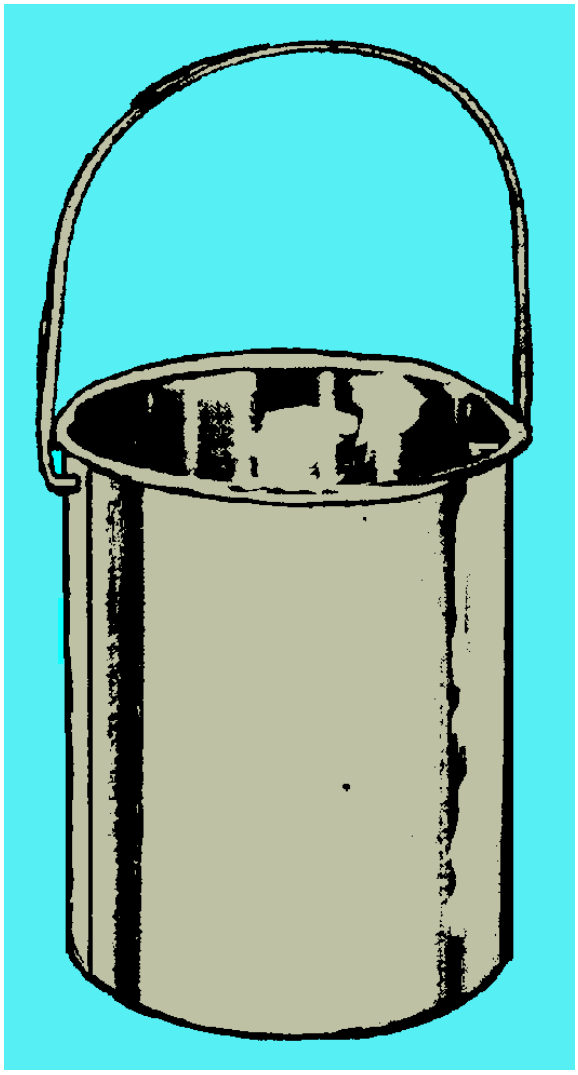


Figure 18 – Shucking bucket handle 180º apart side by side

V. TABLES

A. Materials

1. All metallic product contact surfaces shall be of A.I.S.I. type No. 304 stainless steel or equally corrosion resistant metal that is nontoxic and non-absorbent.

2. Only such materials shall be used in the construction of a table as will withstand wear, penetration of vermin, the corrosive action of food, cleaning compounds and such other elements as may be found in the environment. Such materials shall not impart an odor, color, taste or toxic material to the food.

3. Whenever alternate materials are used, the use of such materials proven to be equally satisfactory from the standpoint of sanitation and protection of food is acceptable.

4. All non-product contact surfaces shall be inherently corrosion resistant, and shall provide a smooth, cleanable and durable surface. Parts having both product and non-product contact surfaces shall not be painted.

B. Fabrication

1. All product contact surfaces shall be at least as smooth as a No. 4 ground finish on stainless steel sheets.

2. All seams in product contact surfaces shall be welded with the welds ground smooth and polished to not less than a No. 4 ground finish. All outside seams shall be smooth and waterproof. All weld areas and deposited weld metal shall be substantially as corrosion resistant as the parent metal.

3. All product contact surface shall be easily accessible, visible and readily cleanable, either when in an assembled position or when removed.

4. All internal angles of 135° or less on product contact surfaces shall have minimum radii of 1/4" (6.35 mm) except that minimum radii for fillets of welds in product contact surface may be smaller for essential functional reasons.

5. The table shall be constructed so that it will not buckle or sag while in use, so as to provide plane surface free of depressions, indentations, or bulges which prevents draining when the pitch is not greater than 1" (2.54 cm).

6. The product contact surfaces shall be constructed of not less than 16 U.S. standard gauge stainless steel or equivalent material.

7. The splash contact surfaces shall be of smooth, easily cleanable and corrosion resistant

materials, or they shall be rendered corrosion resistant with a material which is non-cracking, non-chipping and non-spalling. Paint shall not be used.

8. Non-food contact surfaces shall be smooth and of corrosion resistant material or shall be rendered corrosion resistant or painted. Lead base paint shall not be used.

9. When welded seams are used, the weld area and the deposited weld material shall be as corrosion resistant as the parent material. The welded area surface requiring routine cleaning in surface in contact with food shall be smooth.

10. All exposed external angles or corners are to be sealed and smooth.

11. All joints and seams in the food zone shall be sealed and shall be smooth as he surfaces being joined. Wherever feasible and practical, equipment or parts in the food zone shall be stamped, extruded, formed or cast in one piece.

12. Exposed threads, screws, bolts and rivet heads, nuts shall be eliminated from the food contact surfaces.

13. Food contact surfaces which during the course of fabrication are so worked as to reduce their corrosion resistant characteristics, shall receive such additional treatment as is necessary to render, or to return them to a corrosion resistant state.

14. All exposed edges and nosings on horizontal surfaces shall be integral with tops, regardless of profiles, and where exposed to fingers and cleaning and cleaning they shall be made smooth.

(a) Nosings shall be open 3/4" (19.05 mm) or completely closed against the body of the unit on a all sides to prevent the harborage of insects.

(b) The space between the top and the flange shall be not less than 3/4" (19.05 mm).

(c) The space between the sheared edge and the frame angle shall not be less than 3/4" (19.05 mm) to provide access for cleaning. ***(Figure 19***)

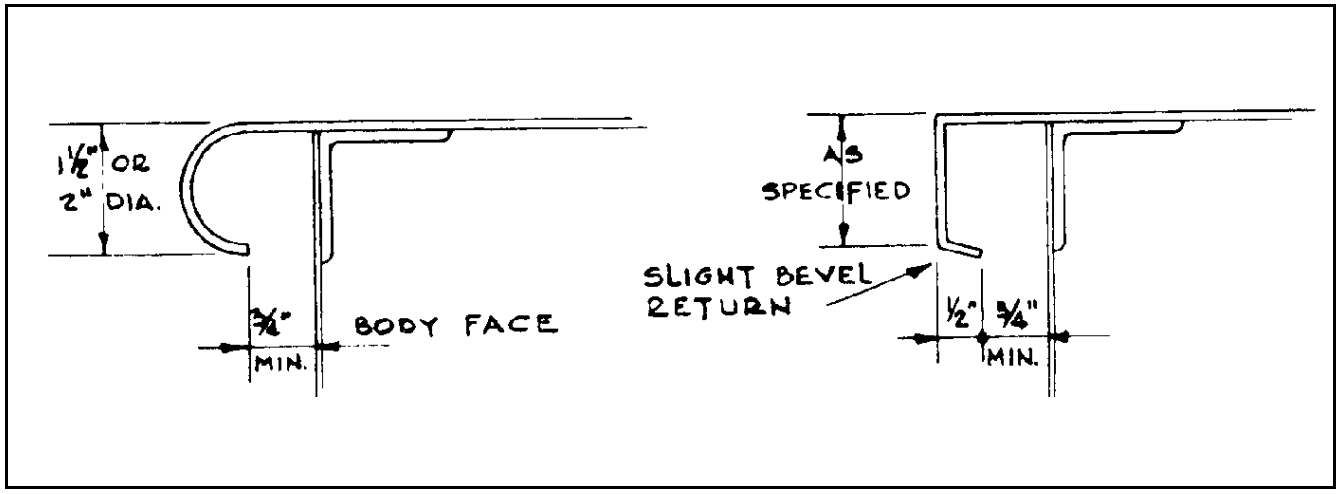


Figure 19 – Exposed edges and nosings on horizontal surfaces

15. Legs and feet shall be non-absorbent and of sufficient rigidity to provide support with a minimum cross bracing and so fastened to the body of the equipment. (***Figure 20***)

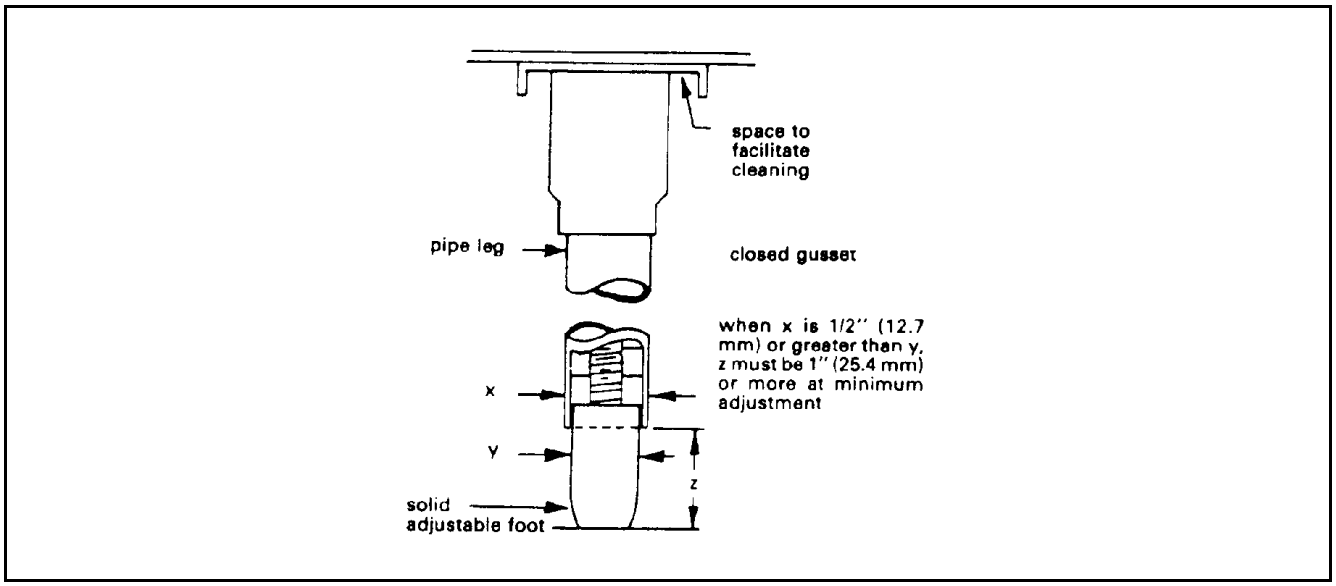


Figure 20 – Legs and gussets

(a) When the outside dimension of the leg is greater that the outside dimension of the foot by ½" (12.7 mm) or more in the same plane, the foot shall, at minimum adjustment extended 1" (2.54 cm) below the leg.

(b) All opening to hollow sections between feet and legs shall be drip proof construction with no opening greater than 1/32" (0.794 mm) All other opening to hollow sections shall be

sealed.

(c) Gussets, when used, shall be assembled to the equipment in such a manner as to insure easy cleanability and to eliminate insect harborage. The assembly shall have no recessed areas or spaces. (***Figure 21***)

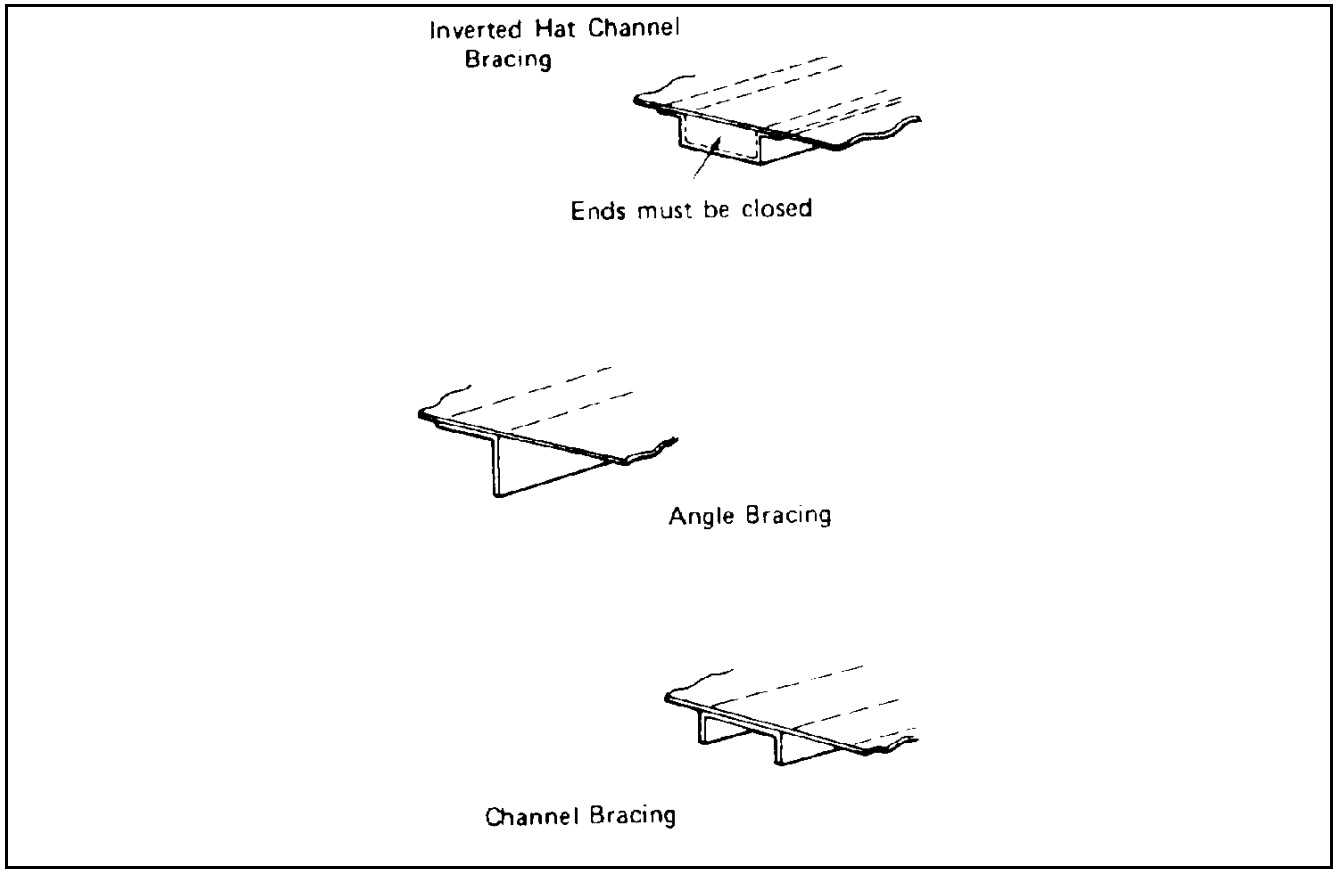


Figure 21 – Reinforcing and framing

16. Reinforcing and framing members not totally enclosed are to be placed in such a manner as to be easy to clean. (***Figure 21***)

(a) All framing and reinforcing members shall be so placed as to eliminate harborage for vermin.

(b) The ends of all hollow sections of reinforcing and framing members shall be sealed.

(c) Horizontal angle reinforcing and gussets shall not be placed where food or garbage may accumulate thereon.

(d) Where angles are used horizontally, they shall have one leg turned down wherever the nature of the equipment permits, or shall be integral with the sides.

(e) All vertical sections shall be either completely closed or open to the floor.

VI. CONVEYORS

A. Materials

1. Only those corrosion resistant materials capable of maintaining original surface characteristics under the prolonged influence of the use environment, including the expected food contact and normal use of cleaning compounds and sanitizing solutions.

2. Belt materials shall be nontoxic, oil proof and of such construction that raw edges and sides will be sealed. The belt shall be relatively nonabsorbent. Belt lacings or fastenings shall meet the applicable clean ability requirements for food, splash and nonfood zones.

3. Whenever alternate materials are used, the use of such materials proven to be equally satisfactory from the standpoint of sanitation and protection of food is acceptable.

B. Fabrication

1. Conveyor belt, belt support pan, rollers, driving mechanism and pulleys shall be readily accessible for cleaning.

2. The base of conveyor units shall have readily removable access panels to permit cleaning.

3. Readily removable catch pans of proper design and adequate capacity shall be provided wherever spillage, splash and similar debris may accumulate. Food waste collection and disposal stations shall be designed, constructed and equipped to facilitate the collection and/or disposal of shell waste in an acceptable manner and to be easily cleaned.

4. Drains, when provided in connection with conveyors shall be equipped with readily removable strainer baskets or similar device.

5. Motors shall be so located as to be protected against splash, spillage and the like, or to be otherwise protected.

6. In the non-food zone, exposed threads and projecting screws and studs should be used only when it has been demonstrated that other fastening methods are impractical and they shall be eliminated from the splash contact surfaces.

(a) Exposed rivet, screw, or bolt in the splash zone shall be of low profile type such as brazier, or modified brazier rivets or pan and oval screw and bolt heads. (***Figure 22***)

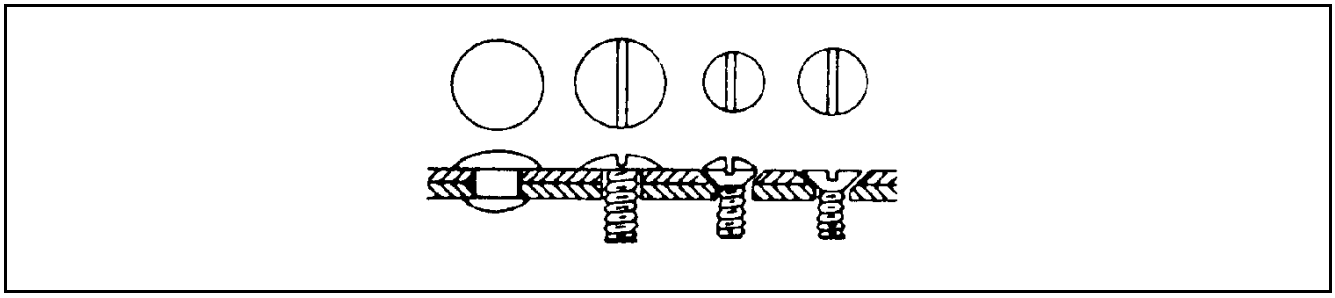


Figure 22 – Low profile fasteners for nonfood contact surfaces

VII. OYSTER SHUCKING GRINDERS

A. Materials

1. Only those corrosion resistant materials capable of maintaining original surface characteristics under the prolonged influence of the use environment, including the expected food contact and normal use of cleaning compounds and sanitizing solutions. The machine is designed to operate in a wet spray environment.

2. Food contact surfaces shall be effectively washed to remove or completely loosen soils by manual or mechanical means such as the application of detergents; hot water; brushes; or high pressure sprays.

3. Parts of a shellstock grinder which are considered food contact surfaces include; the blade, the area behind the blade including the motor shaft from the blade to the motor housing, and the inside surface of the housing or cover surrounding the blade. These food contact parts shall be manufactured from high impact materials that are easily cleanable and non-corrosive. The grinder must be constructed to be easily disassembled and assembled to facilitate inspection, maintenance, cleaning, and sanitizing. ***(Figure 23)***

B. Fabrication

1. The motor shaft should be of corrosion resistant material.

2. Juncture point where the motor shaft enters the blade chamber must be sealed to reduce dirt and detritus deposition around the shaft.

3. The blade must be made from a single piece of high impact non-corrosive material. Blade teeth must be an integral part of the blade, or if grinding surfaces are used instead of teeth, they must be welded to the face of the blade with all welds ground smooth.

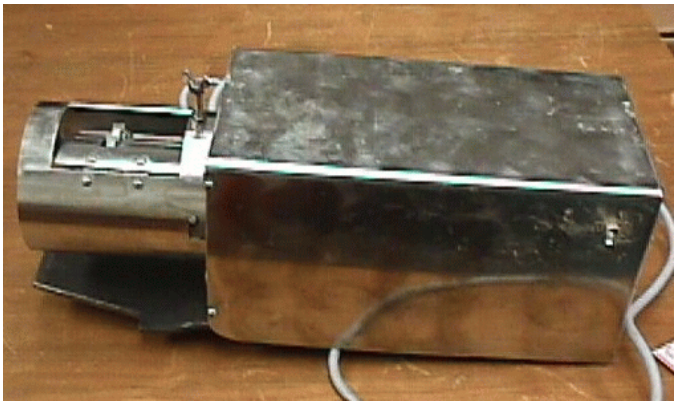


Figure 23
Mechanical stainless steel oyster grinder

4. The housing around the blade assembly must be constructed of material that is corrosion resistant.

5. Bolts or screws must be constructed of corrosion resistant material to prevent rust and corrosion.

(6) The inside surface of the blade housing must be smooth, and if welded ground smooth for easy cleaning.

(7) The blade housing must be designed with an easily removable cover that will open up the entire blade assembly area to facilitate inspection, cleaning, sanitizing, and maintenance.

Notes:

1. Proceedings, 1958 Shellfish Sanitation Workshop, U.S. Public Health Service, Washington DC.

2. American Iron and Steel Institute. Copy of the AISI Steel Products Manual, Stainless & Heat Resisting Steels can be obtained from the Iron and Steel Society, 410 Commonwealth Drive, Warrendale, PA 15086, Telephone 412-776-9460.

3. Plastic, rubber, and rubber-like materials used for equipment may be subject to the Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act. The acceptability of such materials under Food Additive Amendment shall be obtained from equipment manufactures.

4. Sanitary standards describing the construction of valves, fittings, and pumps may be obtained from International Association of Milk and Environmental Sanitarians, Inc., 200 W Merle Hay Centre, Suite 404, Cedar Rapids, IA, 52402, Telephone 319-395-9151, FAX 319-393-1102.

5. Skimmer size: The Food and Drug Administration definition and standard of identity for raw oysters states in part: "The oysters are drained on a strainer or skimmer which has an area of at least 300 square inches per gallon of oysters drained, and has perforations of at least 1/4 of an inch in diameter and not more than 1 1/4 inches apart, or perforations of equivalent areas and distribution. (Definitions and Standards under the Federal Food, Drug, and Cosmetic Act, Title 21, Part 36, Federal Register, August 27, 1946)."

References:

3-A Sanitary Standard Committee, 3-A Sanitary Standards for Sanitary Fitting for Milk and Milk Products Number 63-00 (08-17 Amended), 6245 Executive Boulevard, Rockville, MD 29852.

3-A Sanitary Standard Committee, 3-A Sanitary Accepted Practices for Supplying Air Under Pressure in Contact with Milk, Milk Products and Food Contact Surfaces Serial #60403, 6245 Executive Boulevard, Rockville, MD 29852.

3-A Sanitary Standard Committee, 3-A Sanitary Standards for Mechanical Conveyors For Dry Milk and Milk Products #41-00, 6245 Executive Boulevard, Rockville, MD 29852.

3-A Sanitary Standard Committee, 3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, No. 20-17, 6245 Executive Boulevard, Rockville, MD 29852.

3-A Sanitary Standard Committee, 3-A Sanitary Standards for Uninsulated Tanks for Milk and Milk Products, No. 32-01, 6245 Executive Boulevard, Rockville, MD 29852.

Building Officials & Code Administrators, The BOCA National Plumbing Code, 1987: Model plumbing regulations for the protection of public health, safety and welfare, 4051 W. Flossmoor Rd. Country Club Hills, IL 60477, 1988.

C.D.B. Company, Equipment for the Shellfish Industry, 335 Hill-N-Date Drive, York, PA 17403.

Lunsford, L.R., Shellfish Industry: Equipment Construction Guides, U.S. Department of Health, Education and Welfare, Public Health Service, Division of Environmental Engineering and Food Protection, Washington 25, D.C., Public Health Service Publication No. 943, Adopted by the 1961 National Shellfish Sanitation Workshop (April 1962).

National Sanitation Foundation, Food Service Equipment Standards, 3475 Plymouth Road, Ann Arbor, Michigan, 48106, September 1978.

Office of the Federal Register, 21 Code of Federal Regulations, Parts 170-199, U.S. Government Printing Office, Washington, DC, 1992.

Stainless Steel Information Center, Specialty Steel Industry of North America, STAINLESS STEEL:An introduction to a versatile, aesthetically pleasing and "full life cycle" material, 3050 K Street, N.W. Washington, DC 20007. Website http://www.ssina.com

U.S. Food and Drug Administration, Milk and Milk Product Equipment: A Guide for Evaluating Sanitary Construction, Developed by the Milk Safety Branch, Division of Cooperative Programs, 200 "C" Street, SW, Washington, DC 20204.

U.S. Food and Drug Administration, Grade "A" Pasteurized Milk Ordinance, Developed by the Milk

Safety Branch, Division of Cooperative Programs, 200 "C" Street, SW, Washington, DC 20204, 1991 Revision.

U.S. Food and Drug Administration, Standards for the Fabrication of Single Service Containers and Closures for Milk and Milk Products, Developed by the Milk Safety Branch, Division of Cooperative Programs, 200 "C" Street, SW, Washington, DC 20204, 1991 Revision.

U.S. Food and Drug Administration, Food Service Sanitation Manual: A Model Food Service Sanitation Ordinance, H.E.W. Publication No. (FDA) 78-2081, Developed by the Division of Retail Food Protection, Division of Cooperative Programs, 200 "C" Street, SW, Washington, DC 20204, 1978.

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02. SHELLFISH PLANT INSPECTION STANDARDIZATION PROCEDURES

INTRODUCTION TO PLANT STANDARDIZATION

PURPOSE: In 1988, the Interstate Shellfish Sanitation Conference (ISSC) adopted**,** as a primary goal**,** an initiative to standardize FDA Regional Shellfish Specialists and State Standardization Officers. The Conference affirmed that standardization of shellfish regulators will result in uniform plant inspections and strengthen consumer confidence in shellfish products. In 1991, the Conference adopted issue 91-222 requiring the certification of the shellfish plant inspections before listing in the Interstate Certified Shellfish Shipper's List (ICSSL), effective January 1, 1994. As a result of that issue, FDA developed procedures to standardize Regional Shellfish Specialists and State Standardization Officers. The requirements and criteria described in this Standardization procedures document apply only to standardization of the Regional Shellfish Specialists and State Standardization Officers.

OBJECTIVE: The standardization process provides regulatory personnel the opportunity to standardized their knowledge and skills related to the National Shellfish Sanitation Program (NSSP) Model Ordinance (MO) with the knowledge and skills of FDA's National Plant Standard(s) and/or Regional Shellfish Specialists. The process and criteria for demonstrating uniformity in the required performance areas are described in Chapter 4.

Through the application of this procedure, the *CANDIDATE* should demonstrate uniformity with "the standard" or “State Standardization Officer” through his/her knowledge and expertise in the application and interpretation of the MO requirements for HACCP principles, sanitation, and the use of the NSSP STANDARDIZATION SHELLFISH PROCESSING PLANT INSPECTION FORM. The application of this procedure is not intended to provide basic shellfish plant sanitation training to individual candidates.

DEFINITIONS: The following definitions apply in the interpretation and application of this procedure.

(1) CANDIDATE means an individual applying for initial Standardization who has completed the prerequisite requirements or/and an applicant who is applying for re-standardization.

(2) MODEL ORDINANCE (MO) also known as “GUIDE FOR THE CONTROL OF MOLLUSCAN SHELLFISH” provides readily adoptable standards and

administrative practices necessary for the sanitary control of molluscan shellfish.

(3) NATIONAL STANDARDIZATION OFFICER known as ("FDA's National Plant STANDARD") means an FDA individual(s) at the national level responsible for interpreting NSSP MO requirements for shellfish plant operations. The Standard represents the FDA position on all Standardization issues. The standard is also responsible for standardizing FDA Regional Shellfish Specialists.

(4) NOMINEE means the applicant designated for standardization based on the procedures contained in this document.

(5) STANDARDIZATION means the process whereby a *CANDIDATE* demonstrates the knowledge and skills necessary to be considered uniform with the *STANDARD* as defined in the National Shellfish Sanitation Program's (NSSP), Plant Standardization Procedures.

(6) STANDARDIZED INSPECTOR means a state/federal shellfish plant inspector who has been authorized to certify shellfish shippers as demonstrated by successfully passing a standardized test.

(7) STATE STANDARDIZATION OFFICER means a state shellfish program employee who has met the qualification requirements in the National Shellfish Sanitation Program Plant Standardization Procedures and successfully completed field standardization inspections with a Standardized FDA Regional Shellfish Specialist.

STANDARDIZATION PARTICIPANTS

FDA

The FDA National Plant Standard(s) will be responsible for standardizing all Regional Shellfish Specialists. Standardized FDA Regional Shellfish Specialists will Standardize the State's "Standardization Officer" *CANDIDATE(S)*. The FDA National Standard will conduct standardization inspections to evaluate and assure the proficiency of the FDA Regional Shellfish Specialists. The Standardization inspection process will consist of three (3) practice inspections and five (5) standardization inspections.

STATE

Each participating state will sponsor an adequate number of individuals for positions as State Standardization Officers and inspectors to guarantee that each certified shellfish dealer is routinely inspected for compliance with the MO plant processing requirements**.** The State should select no more than two (2) individuals as Shellfish Standardization Officers**.** The FDA Regional Shellfish Specialists will conduct standardization inspections to evaluate and assure the proficiency of the State Standardization Officer(s). The Standardization inspection process will consist of three (3) practice inspections and five (5) standardization inspections.

State Standardization Inspectors are standardized by State Standardization Officers**.** Each State shall provide the necessary resources to support the training of state shellfish inspectors by the State Standardization Officer(s) to ensure that each shellfish firm receives uniform routine inspections. The State Standardization Officer also has the option of sanctioning the participation of local, city, and/or county shellfish plant inspectors. It is recommended that the State Standardization standardize State Standardization Inspector candidates utilizing the same standardization procedures identified for State Standardization Officers.

QUALIFICATIONS FOR STANDARDIZATION

This chapter defines those requirements that the *CANDIDATE* must complete prior to standardization. In order for a *CANDIDATE* to engage in the process of initial field standardization, they will qualify by completing the prerequisite and experience requirements specified in this chapter. Those requirements only apply to first time applicants applying for standardization.

QUALIFICATIONS FOR STATE PERSONNEL:

When nominating a *CANDIDATE*, the supervisor making the nomination should provide the required *CANDIDATE* background information on the STANDARDIZATION NOMINATION FORM (Attachment 1). This information will be maintained in a file at the appropriate FDA Office.

NOMINATION - To be eligible for standardization, the *CANDIDATE* should be a senior inspector with experience and responsibility in the shellfish program.

JOB EXPERIENCE - The *CANDIDATE* should be responsible for conducting molluscan shellfish plant inspections and providing training in shellfish inspection procedures. It is a requirement that the *CANDIDATE* has at least one (1) year of full time experience performing shellfish plant inspections within the past three (3) years.

CLASSROOM TRAINING - Prior to field standardization, the *CANDIDATE* must successfully complete the following courses:

- 3 or 2 day Seafood Alliance HACCP (Basic Seafood HACCP)
- 2 day Seafood Regulators Training
- ***FD 1040*** Basic Shellfish Plant Sanitation; and
- ***FD 2041*** Shellfish State Standardization Officer Training (**not recommended for State Standardized inspectors unless specifically offered**)

EDUCATION - It is a recommended that the *CANDIDATE* have at least 20 hours of training in the application of Food Science and related studies in Microbiology and/or Epidemiology, HACCP principles/Plan Review, and State regulations.

QUALIFICATIONS FOR FDA PERSONNEL

When nominating a *CANDIDATE*, the supervisor making the nomination should provide the required *CANDIDATE* background information on the STANDARDIZATION NOMINATION FORM (Attachment 1). This information will be maintained in a file at the Division of Cooperative Program Office.

NOMINATION - To be eligible for standardization, the *CANDIDATE* must be a FDA Regional Shellfish Specialist.

JOB EXPERIENCE - Experience will be in accordance with FDA's defined position description including job responsibilities.

CLASSROOM TRAINING - Prior to field standardization, the *CANDIDATE* must successfully complete the following courses:

- 3 or 2 day Seafood Alliance HACCP (Basic Seafood HACCP)
- 2 day Seafood Regulators
- ***FD # 1040*** Basic Shellfish Plant Sanitation and
- ***FD # 2041*** Shellfish State Standardization Officer

EDUCATION – Education will be in accordance with FDA's defined position description.

All Standardization ***CANDIDATES*** shall meet the following performance criteria:

(a) **HACCP:** The *CANDIDATE* shall demonstrate the ability to verify that HACCP Plan exists and is being adequately implemented by the dealer.

(b) **SANITATION ITEMS:** The *CANDIDATE* shall demonstrate the ability to recognize, through records review, the "8" National Shellfish Sanitation Program (NSSP), Model Ordinance (MO), “02 Sanitation Items" are being adequately monitored and that those records are accurate and complete.

(c) **ADDITIONAL MO REQUIREMENTS**. The *CANDIDATE* shall demonstrate knowledge of the NSSP Model Ordinance, “03 Other Model Ordinance Requirements", and “Good Manufacturing Practice” (GMP) by correctly identifying deficiencies relating to those items during the field evaluation process.

(d) **INSPECTION EQUIPMENT**: The *CANDIDATE* shall be equipped and familiar with the equipment necessary to conduct a Shellfish plant inspection. The *CANDIDATE shall* be evaluated on the proper use of inspection equipment during the standardization process.

The following is a ***MINIMUM*** list of required forms and equipment for use during shellfish plant inspections:

- Current Edition of the NSSP Standardized Shellfish Processing Plant Inspection Form)
- Administrative materials (Model Ordinance, Field Guide, etc.)
- Head cover: baseball cap, hair net, lab coat or equivalent protection, etc**.**
- Calibrated stem or digital thermometer with not >2°F increments.
- Chemical test kit or strips for Chorine, Quaternary, or Iodine sanitizers.
- Flashlight; and
- A 70 % solution of Isopropyl alcohol or equivalent "wipes".
- A camera (Optional)

Communication: The *CANDIDATE* shall demonstrate the ability to effectively communicate with plant management about deficiencies noted during the evaluation. Many different types of communication skills and approaches are necessary and valuable during the inspection process. The CANDIDATE shall be required to take the lead in communicating with industry personnel during all inspections and the STANDARD shall evaluate the CANDIDATE'S communication skills.

INTRODUCTION*:* The CANDIDATE shall be required to make all introductions. A complete introduction consists of:

(a) Introducing all persons participating in the inspection;
(b) Describing the purpose and flow of the inspection;
(c) Identifying and explaining to the PERSON IN CHARGE that it will be necessary to ask questions about the operation during the inspection; and
(d) Explaining that this is not intended as a regulatory inspection and that there will be no written report left at the end of the inspection; however, significant findings will be brought to the attention of the PERSON IN CHARGE.

In addition to verbal and written communication, the CANDIDATE shall also use the inspection process to communicate and demonstrate FOOD SAFETY concepts by example. Activities such as proper hand washing, sanitizing thermometer before probing shellfish, and wearing the proper inspection apparel should be used to reinforce spoken and written communications.

INTERVIEW WITH THE PERSON IN CHARGE: The CANDIDATE shall conduct a discussion with the PERSON IN CHARGE to determine:

(a) If a HACCP PLAN exists, and if so, whether the PERSON IN CHARGE understands the principles of the HACCP PLAN and is ensuring that the employees are effectively using the plan:

EXIT CONFERENCE: The CANDIDATE, at the exit of conference shall clearly convey and discuss in detail with the PERSON IN CHARGE the inspection findings including:

(a) The compliance status of the firm describing each significant violative condition and, where appropriate, acceptable compliance alternatives,
(b) The response and plans of the PERSON IN CHARGE for correcting violations, and
(c) Corrective actions observed during the inspection. Such proactive food safety measures shall be commended.

Explain the public health significance of the deficiencies and demonstrate the ability to discuss and resolve in a courteous and professional manner, issues that the PERSON IN CHARGE might not agree with or clearly understand.

Table 1: Summary of evaluation methods for initial STANDARDIZATION.

PERFORMANCE AREA	FIELD STANDARDIZATION
HACCP (Items 1 - 7)	Evaluation of existing HACCP Plan
Sanitation (Items 8 - 16)	Evaluation/inspection
Additional MO Requirements (Items 17 - 30)	Evaluation/inspection
Inspection Equipment	Observation
Communication	Observation

PRE-STANDARDIZATION FIELD PROCEDURE

Pre-standardization - This phase consists of three (3) joint "practice" field inspections by the *CANDIDATE* and the *STANDARD*. During these "practice" inspections there will be open discussion between the *CANDIDATE* and the *STANDARD* on all matters relating to the standardization process including: the NSSP Model Ordinance interpretations, inspection form debiting requirements (where is "it" marked on the form); questions and discussions relating to the firm's HACCP plan; related Sanitation and Monitoring records and Corrective Action. The current edition of the NSSP Standardized Shellfish Processing Plant Inspection Form will be used during all aspects of the standardization procedure.

During pre-standardization inspections, the *STANDARD* and *CANDIDATE* shall conduct the inspection together and discuss each noted deficiency. They shall agree on the number of times and locations where a specific deficiency was observed in the plant.

Following pre-standardization, the *STANDARD* may decide that the *CANDIDATE* is unprepared to proceed to the formal field standardization process. If the *STANDARD* determines the *CANDIDATE* needs additional field training, after discussion with the *CANDIDATE*, they may decide to complete additional "practice" inspections. If the *STANDARD* determines that more "practice" inspections will not help in the candidate's understanding of the process and/ or procedure then the candidate and candidate's supervisor will be informed.

FIELD STANDARDIZATION PROCEDURE

The Field Standardization Process consists of the *STANDARD* and the *CANDIDATE* jointly conducting five (5) shellfish plant evaluations. Always select five (5) Shucker/packer (SP) plants if they are available. If a state has less than five (5) Shucker/packer's (SP), then the remaining plants will be selected according to the following priority:

1) Repackers (RP)
2) Shellstock Shippers (SS)
3) Reshippers (RS)

During all joint field inspections, the *CANDIDATE* will be the lead person. He or she will be responsible for the following: Introduction (determining who is the "most responsible" person), requesting the firm's HACCP Plan and its related documents, and sanitation monitoring records. The minimum number of records required for review will be at least three months. The ***CANDIDATE shall*** also conduct the "exit" interview and discuss all significant deficiencies with management.

STANDARDIZATION SCORING

Comparison of Findings: Following each inspection, the STANDARD shall compare his/her findings with the CANDIDATE. At the conclusion of the field standardization, the *STANDARD* shall tabulate and compare the CANDIDATE's inspection findings to determine if the CANDIDATE has successfully completed the requirements for Standardization. The STANDARD shall discuss any differences, results and other observations with the CANDIDATE.

The *STANDARD* will evaluate each inspection report to determine the number of disagreements ***(using Standardization Requirements below)*** between the *STANDARD* and the *CANDIDATE.* Disagreements shall be recorded on the Comparative Results form provided as Attachment 2.

CANDIDATE SCORING: The STANDARD shall grade each inspection report by circling each incorrectly marked item. The STANDARD shall determine the number of disagreements on items and record that number in the form provided in ATTACHMENT 3. For inspectional equipment and communication scoring is not used but impacts the outcome of the CANDIDATE's performance.

The *CANDIDATE* shall meet the following level of agreement to achieve Standardization after completing five (5) formal field evaluations.

(a) HACCP: (item 1-7)
The *CANDIDATE* **SHALL NOT DISAGREE** with the *STANDARD* more than an average of three (3) times in five (5) evaluations.**

(b) Sanitation Items: (item 8- 16)
The *CANDIDATE* **SHALL NOT DISAGREE** with the *STANDARD* more than an average of three (3) times in five (5) evaluations. **

(c) Other Model Ordinance Requirements: (item 17 –30)
The *CANDIDATE* **SHALL NOT DISAGREE** with the *STANDARD* more than an average of four (4) times in five (5) evaluations. **

(d) Inspection Equipment: The *CANDIDATE* **SHALL** have all essential equipment, listed in Chapter 4 "Performance Criteria for Field Standardization" available for use during each inspection. This section shall rate as **SATISFACTORY or NEEDS IMPROVEMENT.**

(e) Communications: The *Candidate* **SHALL** communicate per the requirements in Chapter 4 "Performance Criteria for Field Standardization". This section shall rate as **SATISFACTORY or NEEDS IMPROVEMENT.**

****NOTE: With the exception of CANDIDATES deficiencies that were not observed by the STANDARD**

CRITERIA FOR SUCCESS STANDARDIZATION:

To achieve standardization, the CANDIDATE shall meet requirements for the Performance criteria (a-c) described in Chapter 4. The CANDIDATE may receive "Needs Improvement" classification in the section inspectional equipment and communications and still be standardized.

When either inspection equipment or communication performance area are classified as needing improvement, the CANDIDATE and the CANDIDATE'S supervisor shall be notified that the "Needs Improvement" area(s) must be satisfactorily addressed before restandardization is granted. Prior to restandardization, the CANDIDATE'S supervisor must notify the STANDARD that the area(s) or concern has been addressed.

STANDARDIZATION RESULTS

REPORTING

The *STANDARD* and *CANDIDATE SHALL* describe on the narrative section on the NSSP SHELLFISH PROCESSING PLANT FORM each specific deficiency and location within the firm where the deficiency was observed. The CANDIDATE shall not fail to recognize any critical items. After each inspection has been completed, the STANDARD shall compare the number and description of the deficiencies found in the plant for each item on the narrative section of the NSSP Standardized Shellfish Processing Plant Inspection Form. The STANDARD shall determine if both observed the same specific deficiencies throughout the plant.

The *STANDARD* will use the Comparative Results Form (Attachment 2) to determine the level of agreement between the *STANDARD* and *CANDIDATE*. At the conclusion of the formal Field Standardization exercise, the *STANDARD* will complete a Composite Results Report (Attachment 3).

After successfully completing the Field Standardization Exercise, the *CANDIDATE* will be granted the TITLE of *STANDARDIZATION OFFICER OR STANDARDIZATION INSPECTOR.* A certificate recognizing that accomplishment will be forwarded to the *CANDIDATE*, along with formal notification to the *CANDIDATE'S* supervisor, within thirty (30) days.

STANDARDIZATION (MAINTENANCE)

STANDARDIZATION EXPIRATION:

The *CANDIDATE'S* STANDARDIZATION is valid for a period of 5 years. Expiration dates will appear on the CERTIFICATE issued by the *STANDARD.*

STANDARDIZATION MAINTENANCE:

The maintenance process consists of joint inspections conducted during evaluation activities. Maintenance will also be provided in the form of updated FD 2041 Shellfish State Standardization Officer courses, ORA University web based course, updated field standardization guides, and other guidance/technical assistance activities on an as needed basis.

TERMINATION, SUSPENSION, OR REVOCATION OS STANDARDIZATION

TERMINATION OF FIELD STANDARDIZATION:

(a) The *STANDARD* has the option to terminate the field exercise at any time during the procedure if the *CANDIDATE*, in the opinion of the *STANDARD*, is not achieving the required level of agreement for STANDARDIZATION.

(b). The STANDARD shall notify the CANDIDATE and the CANDIDATE'S supervisor in writing of the reasons for failure.

(c) The *STANDARD* will document the reason(s) for termination of the field. This information shall be forwarded to the CANDIDATE'S supervisor and a copy shall be placed in the FDA file. All evidence and conclusions reached by the FDA shall be documented in writing by the STANDARD and shall be kept for 3 years in accordance with the Freedom of Information Act.

SUSPENSION/REVOCATION OF STANDARDIZATION CERTIFICATION

SUSPENSION OR REVOCATION **:**

(a) Fails to utilize and/or properly complete the current NSSP Standardized Shellfish Processing Plant Inspection Form.

(b) Fails to properly code (critically code) deficiencies (critical, key, and other) on the NSSP STANDARDIZATION SHELLFISH PROCESSING PLANT INSPECTION FORM.

(c) Fails to fulfill the required maintenance activities described in *CHAPTER 9.*

(d) Before suspension or revocation, the *STANDARD* will consult with appropriate personnel in the FDA and/or the *State's* agency to reach a decision on whether:

i. The standardization shall be suspended temporarily with notice regarding conditions required for reinstatement; or

ii. The standardization shall be revoked.

(e) When a STANDARDIZATION certificate is revoked or suspended, the *STANDARD SHALL* notify the supervisor in writing, of his/her decision.

(f) The *STANDARD* will document the reason(s) for suspension or revocation of the standardization certification. This information shall be forwarded to the CANDIDATE'S supervisor and a copy shall be placed in the FDA file. All evidence and conclusions reached by the FDA shall be documented in writing by the writing by the STANDARD and shall be kept for 3 years in accordance with the Freedom of Information Act.

RE-STANDARDIZATION AFTER SUSPENSION OR REVOCATION**.**

THE *CANDIDATE* may apply for re-standardization, within thirty (30) days, after suspension or revocation. He or she must contact and work with the appropriate FDA or

*State Standardization Officer to correct all prior deficiencies before the re-standardization process begins.

NOTE: State Standardization Officers can only standardize their inspectors. Only FDA National Standards or standardized FDA Regional Specialists can standardize state standardization officers.

APPEALS

FILING AN APPEAL.

Candidate after being notified of a failure to successfully achieve Standardization or re-standardization may appeal the decision. Should the *CANDIDATE* elect to appeal, this action must be initiated within thirty days (30) of the date of the written notification of the failure, suspension or revocation. The appeal's request shall be addressed to the FDA Standard Officer at FDA, Division of Cooperative Programs, 5100 Paint Branch Parkway, College Park, MD 20740.

APPEAL BOARD MEMBERS**.**

The FDA National Plant Standard and representatives from the ISSC and FDA Regional Shellfish Specialist will comprise the STANDARDIZATION Appeals Board. The ISSC will select states representatives to participate in the appeals process

HEARINGS.

If the Appeal Board finds the appeal unjustified**,** the decision of the FDA *STANDARD* will stand.

If the Appeal Board determines that the State Standardization Officer's appeal is justified, the *State Standardization Officer* and the FDA *STANDARD* will be notified in writing that a hearing will be scheduled.

HEARING PROCEDURE.

(A) At the hearing, the following procedure will be followed:

(1) The *State Standardization Officer* will present his/her argument for reversing the FDA *STANDARD'S* decision;

(2) The Appeal Board will have the opportunity to question the action or conduct of the State Standardization Officer and the FDA *STANDARD*; and

(3) The Appeal Board will render a decision.

ATTACHMENT 1

STANDARDIZATION NOMINATION FORM

TO:

FROM:

SUBJECT: REQUEST FOR STANDARDIZATION

DATE:

<table>
<tr><td colspan="2">Name:
Title:</td></tr>
<tr><td colspan="2">Agency Name:</td></tr>
<tr><td colspan="2">Address:</td></tr>
<tr><td colspan="2">City/State/Zip:</td></tr>
<tr><td colspan="2">Telephone:</td></tr>
<tr><td colspan="2">Fax:</td></tr>
<tr><td colspan="2">Education: (list degree or include a transcript)</td></tr>
<tr><td></td><td>Length of Service:</td></tr>
<tr><td></td><td>Describe shellfish experience:</td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td rowspan="2">CHECK (√) BELOW COURSES ATTENDED:
Basic Shellfish Plant Sanitation ( )
Basic Seafood HACCP Alliance Course ( )
Regulator’s HACCP Course ( )
List Other Courses</td><td rowspan="2">How many routine shellfish plant evaluations per year?

1 - 5 ( ) 6 - 10 ( ) >20 ( )</td></tr>
<tr><td></td></tr>
</table>

ATTACHMENT 2
COMPOSITE PERFORMANCE REPORT

FIRM NAME:	Candidate(O)	Standard(X)	Disagreements
#1 HACCP Plan			
#2 Plan Elements (a) Hazards			
#2 Plan Elements (b) Records			
#2 Plan Elements (c) Critical Limits			
#2 Plan Elements (d) Signed and Dated			
#2 Plan Elements (e) Critical Control Points			
#2 Plan Elements (f) Monitoring			
#2 Plan Elements (g) Verification Procedures			
#2 Plan Elements (h) Corrective Action if identified			
#3 HACCP Training			
#4 Plan Implementation (a) Receiving			
#4 Plan Implementation (b) Shellstock Storage			
#4 Plan Implementation (c) Processing			
#4 Plan Implementation (d) Shucked Meat Storage			
#4 Plan Implementation (e) Other Critical Limits			
#5 Approved Source Control Failure			
#6 Time/Temperature Control Failure			
#7 Other Critical Control Failure			
TOTAL NUMBER OF DISAGREEMENTS			
SANITATION ITEMS			
#8 Safety of water for processing and ice production			
#9 Condition and cleanliness of food contact surfaces			
#10 Prevention of cross-contamination			
#11 Maintenance of hand-washing, hand sanitizing, toilet facilities			
#12 Protection from adulterants			
#13 Proper labeling, storage, and use of toxic compounds			
#14 Control of employees with adverse health conditions			
#15 Exclusion of pests			
#16 Sanitation Monitoring and Records			
TOTAL NUMBER OF DISAGREEMENTS			
ADDITIONAL MODEL ORDINANCE REQUIREMENTS			
#17 Plants and Grounds			
#18 Plumbing and related facilities			
#19 Utilities			
#20 Insects and vermin control			
#21 Disposal of other waste			
#22 Equipment construction (non-food contact surfaces)			
#23 Cleaning non-food contact surfaces			
#24 Shellfish storage and handling			
#25 Heat shock			
#26 Personnel			
#27 Supervision			
#28 Transportation (To include only the person shipping)			
#29 Labeling and Tagging (Other than receiving)			
#30 Shipping Documents and Records			
TOTAL NUMBER FO DISAGREEMENTS			

FIELD REQUIREMENT FOR THE SUCCESSFUL COMPLETION OF STANDARDIZATION

In order for the candidate to successfully complete standardization he/she must meet the following field standardization criteria after five (5) evaluations:

- HACCP inspection form items 1 - 7.
  Disagreements with the ***standard cannot exceed an average of three (3).***

- Sanitation inspection form items 8 - 16.
  Disagreements with the standard ***cannot exceed an average of three (3).***

- Additional Model Ordinance inspection form items 17 - 30.
  Disagreements with the standard ***cannot exceed an average of four (4).***

ATTACHMENT 3

SHELLFISH PLANT STANDARDIZATION

"Candidate vs Standard: Composite performance chart"

NUMBER OF DISAGREEMENTS

FIRM NAME	HACCP	**SANITATION ITEMS**	**ADDITIONAL MO REQUIREMENTS**
TOTAL			
*Average Score			
Acceptable Avg. Score	3	3	4
INSPECTIONAL EQUIPMENT	**SATISFACTORY**	**NEEDS IMPROVEMENT**	
COMMUNICATION	**SATISFACTORY**	**NEEDS IMPROVEMENT**	

*THE CANDIDATE'S AVERAGE COMPOSITE SCORE THROUGH FIVE (5) FORMAL STANDARDIZATION INSPECTIONS MEETS (OR DOESN'T MEET) THE ACCEPTABLE AVERAGE SCORE REQUIRED TO ACHIEVE STANDARDIZATION.

STANDARDIZATION LOCATION:
DATE(S):
CANDIDATE:
STANDARD:

NSSP STANDARDIZED SHELLFISH PROCESSING PLANT INSPECTION FORM

Agency Name:							Date	
Type of Inspection	o Certification o Pre-operational o Routine o Follow-up o Standardization							
Dealer Name:							Certification Number	
Dealer Address:								
	Hazard Analysis Critical Control Point (HACCP)							
1.	HACCP Plan Yes o No o Required for Certification							
2.	Plan Elements **Identified and Adequate**	✔/✘ NA	Code		✔/✘ NA	Code	Overall Code	
	(a) Hazards		O	(e) Critical Control Points		K		
	(b) Records		O	(f) Monitoring		K		
	(c) Critical Limits		K	(g)Verification Procedures		O		
	(d) Name, Address, Signed and Dated		O	(h) Corrective Action if identified		K		
3.	HACCP Training	o Yes o No		Code	O			

4.	Plan Implementation	Corrective Actions (C)		Verification Procedures (K)		Monitoring Procedures (K)		Records Accurate/ Maintained (K) Records Format Signed/Dated Firm's Name (O)		Overall Code
		✔/✘	Code	✔/✘	Code	✔/✘	Code	✔/✘	Code	
(a)	**Receiving**									
(b)	**Shellstock Storage**									
(c)	**Processing**									
(d)	**Shucked Meat Storage**									
(e)	**Other Critical Limits**									

5.	**Approved Source Control Failure**			C
6.	**Time/Temperature Control Failure**			C
7.	**Other Critical Control Failure**			C
	Sanitation Items	**Citation**	✔/✘	Code
8.	Safety of water for processing and ice production	.02A		
9.	Condition and cleanliness of food contact surfaces	.02B		
10.	Prevention of cross-contamination	.02C		
11.	Maintenance of hand-washing, hand sanitizing, and toilet facilities	.02D		
12.	Protection from adulterants	.02E		
13.	Proper labeling, storage, and use of toxic compounds	.02F		
14.	Control of employees with adverse health conditions	.02G		
15.	Exclusion of pests	.02H		
16.	Sanitation Monitoring and Records			K
	Additional Model Ordinance Requirements	CITATION	✔/✘	***CODE***
17.	Plants and Grounds	.03A		
18.	Plumbing and related facilities	.03B		
19.	Utilities	.03C		
20.	Insects and vermin control	.03D		
21.	Disposal of other waste	.03E		
22.	Equipment construction (non-food contact surfaces)	.03F		
23.	Cleaning non-food contact surfaces	.03G		
24.	Shellfish storage and handling	.03H		
25.	Heat shock	.03I		
26.	Personnel	.03J		
27.	Supervision	.03K		
28.	Transportation (To include only the person shipping)	IX.05		K
29.	Labeling and Tagging (Other than receiving)	X.05, .06		S (K/O)
30.	Shipping Documents and Records	X.07		K

Dealer's Signature	Inspector's Signature

DEALER CERTIFICATION AND THE INTERSTATE CERTIFIED SHELLFISH SHIPPERS LIST (ICSSL)

A principal objective of the ICSSL is to provide a mechanism for state health officials and consumers to receive information as to whether lots of shellfish shipped in interstate commerce meet acceptable sanitation criteria. This is achieved through criteria and procedures to allow a producing or receiving state to "certify" that the product from a specific dealer has been grown, harvested, transported, processed, or shipped in compliance with the National Shellfish Sanitation Program (NSSP) Model Ordinance (MO). Dealer certification depends on maintaining acceptable operational and sanitary conditions. This determination is based on nationally uniform inspections by standardized inspectors.

State health officials who certify dealers must fully comply with the administrative requirements for certification for the process to remain viable. For the certification process to be effective, dealers must fully comply with the applicable NSSP MO sanitation requirements pertaining to the type of operation involved.

The NSSP MO requires that dealers obtain certification from the Authority prior to shipping shellfish in interstate commerce. Only those shellfish dealers who meet the NSSP MO requirements are eligible to be listed in FDA's monthly publication of the ICSSL. A unique certification number that is used to mark his product identifies each dealer.

Persons desiring to receive copies of the ICSSL should contact FDA, Division of Cooperative Programs, Shellfish Safety Team, HFS-628, 5100 Paint Branch Parkway, College Park, Maryland 20740.

Use of the Interstate Shellfish Dealer's Certificate (FDA Form 3038)

The Interstate Shellfish Dealer's certificate, FDA Form 3038, is used by the Authority to place a dealer on the ICSSL, to report changes to a certificate, and to remove a dealer from the ICSSL. The certificate allows FDA to collect the necessary information to list certified dealers in the ICSSL. Dealers should be informed by the state officer of the probable date their names will appear on the ICSSL. Dealers should be advised against making interstate shipments prior to that date. If shipments need to be made before the appearance of the shipper's name on the ICSSL, the Authority in the dealer's state must notify the appropriate agency in each of the receiving states and the FDA regional and headquarters offices.

When the Authority cancels a dealer certification, the appropriate FDA Region or District Office must be notified and a completed Form FDA 3038 must be mailed to FDA. When a certificate is renewed, the certificate must be sent to FDA and received by FDA's Division of Cooperative Programs (HFS-625) prior to the date of ICSSL printing (usually the 10th of the month) for the month that the original certificate expires. A certificate will be withdrawn automatically from the ICSSL on the date of expiration unless FDA has received the new certificate.

Instructions For Completing the Interstate Shellfish Dealer's Certificate (FDA Form 3038)

The original copy, or Part 1, of the Shellfish Dealer's Certificate is mailed to FDA, Division of Cooperative Programs, Shellfish Safety Team, HFS-628, 5100 Paint Branch Parkway, College Park, Maryland 20740; Part 2 is mailed to FDA Regional Shellfish Specialist; and, Part 3 is retained by the state shellfish control Authority. The original certificate with the appropriate signatures shall be mailed not later than the first of the month for publication in the ICSSL.

To input information check the applicable box.

Section I — Completed by State Shellfish Certification Agency

1. **Shellfish Dealer/Shipper:** Name, Address (including Street, Number, City or Town) ZIP, Telephone

2. **Certification:**
   a) **Certificate Number** – Unique number assigned to each certified shellfish dealer.
   b) **Date Certified** – Date the dealer was certified as meeting the NSSP criteria.
   c) **State** – Two letter State code.
   d) **Expiration Date** – Date the certificate expires.
   e) **Category Symbol** – Two letter code designating dealer process (*i.e. DP, SP, RP, SS, RS*).

3. **Date of On-Site Inspection:** Date the plant was inspected for certification.

4. **Standardized State Shellfish Plant Inspector:** Print the name of the inspector who conducted the on-site inspection.

5. **Expiration Date of Inspector's Certificate of Standardization:** Print the expiration date that appears on the Inspector's certificate.

6. **Cancellation Date:** Date the firm has been either decertified or recommended for de-listing.

7. **Reason for Cancellation:** Check applicable box; Other denotes voluntary or seasonal suspension of activities.

8. a) **State Shellfish Certification Officer:** Printed name of official to authenticate information.
   b) **Signature:** Official's signature. In the case that a state has only <u>one</u> Standardized State Shellfish Plant Inspector, sign this block.
   c) **Date Certificate sent to FDA:** Self-explanatory.

Section II – Completed by Division of Cooperative Programs – FDA

9. **Date Certificate Received:** Date the signed original Form FDA 3038 is received by FDA.

10. **Date Certificate Published:** Date when the certified dealer's name is scheduled for publication on the ICSSL.

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SHELLSTOCK TAGGING

Shellstock tagging has a very direct role in public health protection. In the event of a shellfish related illness, tags are a tool, which, used in concert with records, should provide for trace ability of live shellstock from the final consumer back through every middle man, (retailer, wholesaler, carrier, and dealer) who handled the product, to a specific growing area, harvest date, and ultimately, if possible, the individual person who harvested the shellstock.

When an outbreak of disease attributable to shellfish occurs, health departments and other appropriate state and federal agencies must be able to determine the source of shellfish contamination to prevent any further outbreaks from this source. This can be done most effectively by using the records kept by the shellfish harvesters and dealers to trace a shellfish shipment, through all the various dealers who have handled it, back to its point of origin. Shellstock tags are the first important records concerning the origin of shellfish.

Harvesters must provide information necessary to create a record of the origin, quantity, and date of harvest, which can be used to trace a lot of questionable shellstock back to its source or sources. Investigation of disease outbreaks can be severely hindered if the source of the shellfish cannot be readily identified. Inability to identify the source can result in shellstock from the unacceptable source continuing to be used and continuing to cause illness. Health authorities may be forced to close a safe growing area, to ban a safe shellstock shipment or to seize a safe lot of shellstock as a public health precaution if the source of contaminated shellfish cannot be accurately and rapidly determined.

Maintaining adequate records is considered by some industry members to be a burden. This has resulted in various unacceptable practices being encountered by health officials, including no written records of purchase, undated shellstock shippers tags maintained in an unordered manner, new shipping tags being placed on a lot of shellstock without records to correlate the original identity of the lot with the new identity, and shellfish on the premises with no tags. Although these dealers often have "records" in the most general sense, these records are not in the form that meets the intent of the NSSP certification requirement to provide trace ability on a lot-by-lot basis. As a result, follow-up investigations of disease outbreaks have been stymied, identification of the cause of the outbreak has been delayed, and outbreaks have continued. For more information concerning dealer certification, see the NSSP Guide Guidance Document: *Dealer Certification and the Interstate Certified Shellfish Shippers List* (ISSC/FDA, 2002).

An example where the failure to maintain adequate records was identified as one of the principal contributing factors to a series of continuing shellfish associated disease outbreaks occurred in 1981 and 1982. The outbreaks continued for several months and affected thousands of people. An investigation by the states involved and FDA revealed that some states were unable to enforce the record keeping and tagging requirements of the NSSP. FDA found in one state that approximately one-third or the certified dealers inspected failed to maintain adequate records. State officials realized that an improved tagging, labeling or manifest system was needed to track shellfish in the marketplace back to the distributor and to the harvester.

When a lot of shellstock is sold in bulk (e.g. by the truckload without being placed in containers), the harvester or dealer must provide a transaction record prior to shipment. If the transaction record is generated by the harvester, the record must contain information identical to that required on the harvester's tags and must also include the name of the consignee. If the transaction record is generated by the dealer, the record must contain information identical to that required on dealer's tags and must include the name of the consignee.

The NSSP recognizes two types of shellstock tags: harvester tags and dealer tags. Many of the requirements are the same for both tag types. There are some additional requirements for dealer tags when the product has been wet stored or depurated. Transaction records which provide the same information as the harvester's or dealer's tag may be used in lieu of tags for lot of shellstock sale and lot of shellstock shipment.

Shellstock harvest location needs to be consistently defined on all tags. The tags should provide the most precise identification of the harvest location or aquaculture site as is practicable; this identification must include at least the state (initials) in which the shellstock were harvested in the designated growing area within the state as assigned by the Authority of the producer state. If harvest areas have not been indexed by the Authority, then an appropriate geographical or administrative designation must be used (e.g. Long Bay, Decadent County, lease number, bed or lot number).

Each harvester or aquaculturist and each dealer must affix an approved, durable, waterproof tag, containing all the information required by the NSSP Model Ordinance, to each container of shellstock. Minimal required tag size is 2 5/8 by 5 1/4 inches (6.7 by 13.3 cm). Example tags are provided in Attachment 1. The harvesters, tags must be in placed while the shellstock is being transported to the dealer unless the harvest has occurred at more than one harvest location or aquaculture site; then each container must be tagged at the harvest location or aquaculture site. In certain situations, the truck may be considered the container for transport of bulk loads of shellstock from the growing area to the dealer. For dealers, tagging must be done prior to shipment. When the dealer is also the harvester, the dealer's tag may also be used as the harvester's tag.

HARVESTER TAG REQUIREMENTS

Information on the harvester's tags must be legible, indelible and arranged in the following specific order:

- A place may be provided where the dealer's name, address and certification number as assigned by the Authority may be added;
- The harvester's identification number as assigned by the Authority;
- The date of harvesting;

- The most precise identification of the harvest location or aquaculture site as is practicable; this identification must include at least the state (initials) in which the shellfish were harvested and the designated growing area with that state as assigned by the Authority of the producer state. If growing areas have not been indexed by the Authority, then an appropriate geographical or administrative designation must be used (e.g. Long Bay, Decadent County, lease number, bed or lot number);

- Type and quantity of shellfish;

- The following statement, in bold capitalized type on each bag: "THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS." and

- All shellstock intended for raw consumption shall include a consumer advisory and followed the Time-Temperature Matrix Control. The following statement, from section 3-602.11 of the 1999 Food Code, or an equivalent statement shall be included on all shellstock: “RETAILERS, INFORM YOUR CUSTOMERS” “Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of food borne illness, especially if you have certain medical conditions”

DEALER TAG REQUIREMENTS

Dealer tagging is required upon harvest or receipt from a harvester, processing and packaging of shellstock by the dealer, or sale and shipment of shellstock by the dealer to other dealers for subsequent sale, processing or additional packaging. The information on the dealer’s tags must be legible, indelible and arranged in the following specific order:

- The dealer's name, address, and certification number as assigned by the Authority;

- The original shellstock shipper's certification number;

- The date of harvesting;

- The most precise identification of the harvest location or aquaculture site as is practicable; this identification must include at least the state (initials) in which the shellfish were harvested and the designated growing area with that state as assigned by the Authority of the producer state. If growing areas have not been indexed by the Authority, then an appropriate geographical or administrative designation must be used (e.g. Long Bay, Decadent County, lease number, bed or lot number);

- Type and quantity of shellstock;

- The following statement, in bold capitalized type, that "THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS." And

- All shellstock intended for raw consumption shall include a consumer advisory and followed the Time-Temperature Matrix Control. The following statement, from section 3-602.11 of the 1999 Food Code, or an equivalent statement shall be included on all shellstock: "RETAILERS, INFORM YOUR CUSTOMERS" "Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of food borne illness, especially if you have certain medical conditions."

When both the dealer and harvester tags appear on the container, the dealer tag is not required to list the date of harvesting, and the harvest location or the aquaculture site. A harvester's tag must be in place while the shellstock is being transported to a dealer. The dealer must keep the harvester's tag in place until the container of shellstock is shipped or until it is broken open for washing, grading and packing. Once the container is broken open, the dealer must:

- keep the harvester tag for 90 days;
- keep track of the growing area and date of harvest of all shellstock; and
- maintain the lot identity of all shellstock in an intermediate stage.

Except for shellstock that originated from a depuration-processor, shellstock transported across state lines and placed in wet storage must include the following information on its shipping tag after removal from wet storage:

- All information required on a dealer's tag as specified above; and

- The statement that "THIS PRODUCT IS A PRODUCT OF (NAME OF STATE) AND WAS WET STORED AT (FACILITY CERTIFICATION NUMBER) FROM (DATE) TO (DATE)"

Lot of shellstock tagging in the washing, packing and staging of shellstock is permissible only when the lot container (i.e., the pallet) is tagged as required in a protocol approved by the Authority. The protocol shall provide for lots of shellstock to be separated and identified to prevent commingling or misidentification. The tag on each lot of shellstock shall contain the following minimum information:

ALL SHELLFISH CONTAINERS IN THIS LOT HAVE THE SAME DATE AND AREA OF HARVEST.
Harvest Date_____
Harvest Area _____
Original Dealer/Shipper # _____
# of units in this lot container _____

The dealer's tag must be put on all containers of shellstock before they are shipped to another dealer or retailer. Prior to shipment, all containers of shellstock must remain easily identified and continue to be separated to prevent commingling or misidentification. The protocol approved by the Authority shall provide for lots of shellstock to be separated and identified so as to prevent commingling or misidentification. The allowable means of identification are:

- A harvester's tag containing the information required above on harvester's tags;
- A dealer's tag containing the information required above on dealers tags; and
- A lot of shellstock tag designed in the manner required above for lot tags.

TAG REQUIREMENTS FOR RELAYING

In relay operations, the method of shellstock identification (tagging, bulk load records, etc.) is left to the discretion of the Authority. When the relay process is conducted using containers, a need exists to develop a container identification system to locate and avoid removal of containers before the natural cleansing process is complete. Once the relay operation is complete, the shellstock is subject to the tagging requirements for harvesters and dealers.

DEPURATION TAG REQUIREMENTS

Shellstock that has been subjected to depuration requires an increased level of control because of the increased potential for contamination. These controls must include packaging and tagging that will serve to help identify the depuration cycle of each harvest lot and to deter illegal commingling of shellstock which has not been depurated with depurated shellstock. The Authority may require the harvester to use special tags or to provide additional information on the tags. At a minimum, the harvester's tags (or transaction records used for bulk shipments) must identify the growing area, provide the harvester's special license number, and specify the harvest date and the quantity of shellstock.

The dealer's (i.e. the depuration processor) tags must, at a minimum, include the following information in a legible and indelible form:

- The dealer's name and address;
- The dealer's certification number as assigned by the Authority;
- The date of depuration processing;
- The depuration cycle number or lot number;
- The most precise identification of the harvest location as is practicable including the initials of the state of harvest, and the Authority's designation of the growing area by

indexing, administrative or geographic designation. If growing areas have not been indexed by the Authority, then an appropriate geographical or administrative designation must be used (e.g. Long Bay, Decadent County, lease number, bed or lot number);

- The type and quantity of shellstock;

- The statement, in bold capitalized type, that "**THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS.**" And

- All shellstock intended for raw consumption shall include a consumer advisory and followed the Time-Temperature Matrix Control. The following statement, from section 3-602.11 of the 1999 Food Code, or an equivalent statement shall be included on all shellstock: “RETAILERS, INFORM YOUR CUSTOMERS” “Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of food borne illness, especially if you have certain medical conditions.”

References

Interstate Shellfish Sanitation Conference. 2002. Dealer Certification and the Interstate Certified Shippers List. In: NSSP Guide for the Control of Molluscan Shellfish. Interstate Shellfish Sanitation Conference, 209 Dawson Road, Suite 2, Columbia, South Carolina, 29223.

Interstate Shellfish Sanitation Conference. 2002. Shellstock Depuration (document in development). In: NSSP Guide for the Control of Molluscan Shellfish. Interstate Shellfish Sanitation Conference, 209 Dawson Road, Suite 2, Columbia, South Carolina, 29223.

Interstate Shellfish Sanitation Conference. 2002. Shellstock Relay. In: NSSP Guide for the Control of Molluscan Shellfish. Interstate Shellfish Sanitation Conference, 209 Dawson Road, Suite 2, Columbia, South Carolina, 29223.

Interstate Shellfish Sanitation Conference.2002. Sanitary Survey and the Classification of Growing Waters. In: NSSP Guide for the Control of Molluscan Shellfish. Interstate Shellfish Sanitation Conference, 209 Dawson Road, Suite 2, Columbia, South Carolina, 29223.

Attachment 1

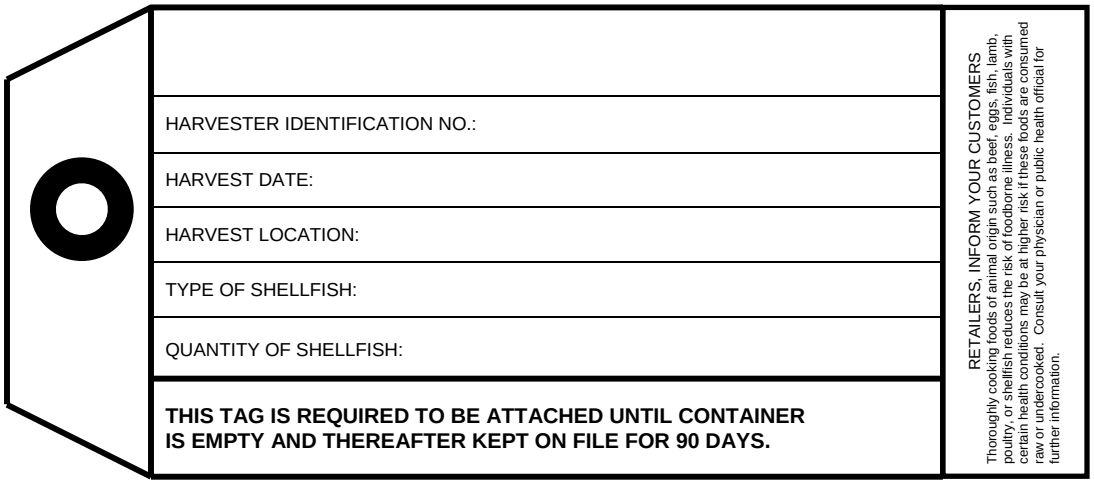
In the event of a shellfish related illness, tags are a tool, which, used in concert with records, should provide for trace ability of live shellstock from the final consumer back through every middle man, (retailer, wholesaler, carrier, and dealer) who handled the product, to a specific growing area, harvest date, and ultimately, if possible, the individual person who harvested the shellstock.

The following options are recommended for inclusion on tags to improve the effectiveness of the NSSP tagging program.
• Include the statement "**Perishable; keep refrigerated**" on the tag in bold print.
• Include the "Date Shipped" on the tag.
• Maintain flexibility in the tagging program to take advantage of evolving materials and technology (e.g. UPC coding)

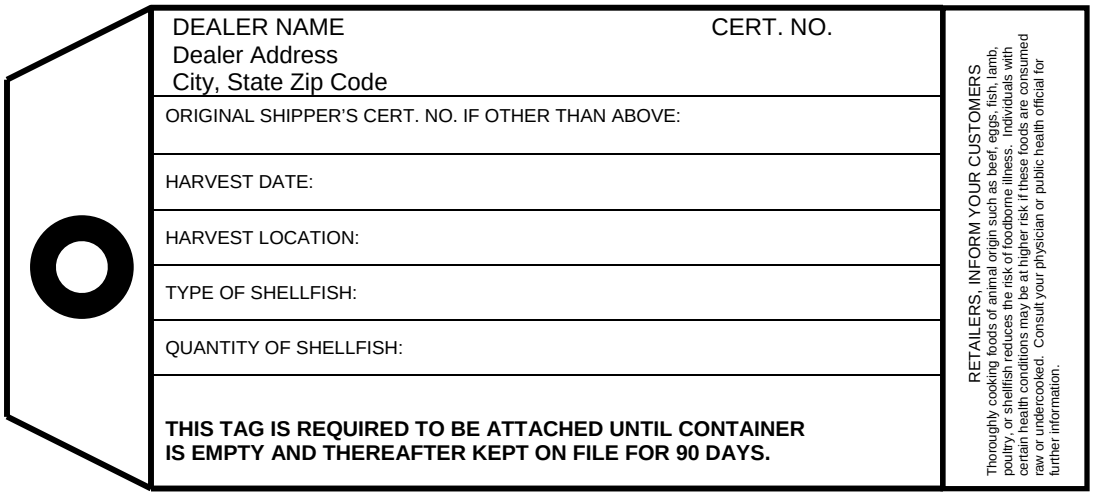
Tag Construction: Durable, waterproof and a minimum size of 2 5/8 inches by 5 1 / 4 inches (6.7 cm by 13.3 cm)

Examples of Shellstock Tags

This tag is an example of a harvester's tag with the minimum NSSP required information in the required order.

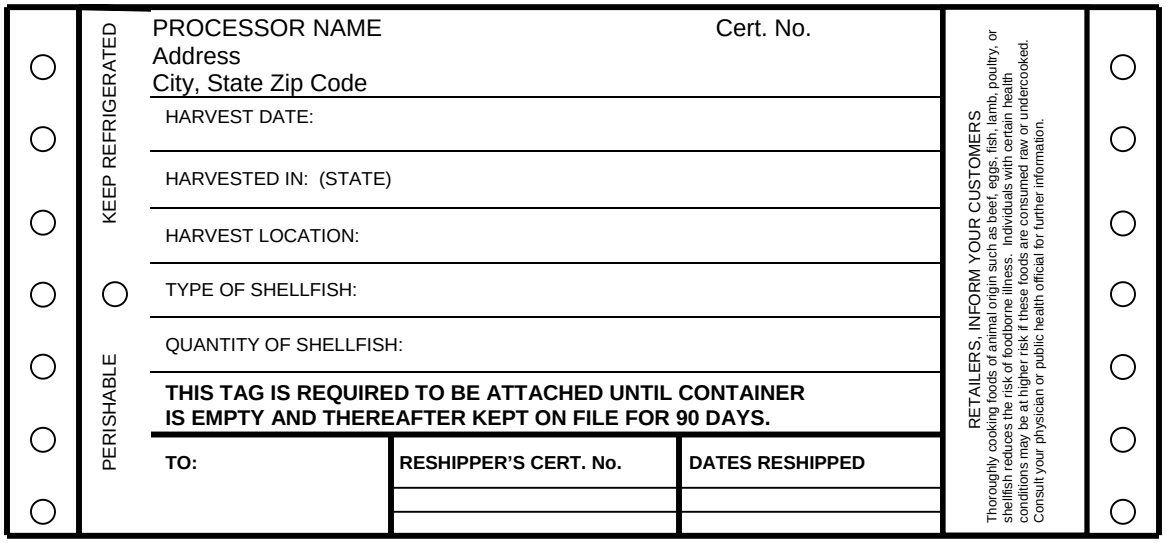


This tag is an example of a dealer's tag with the minimum NSSP required information in the required order.

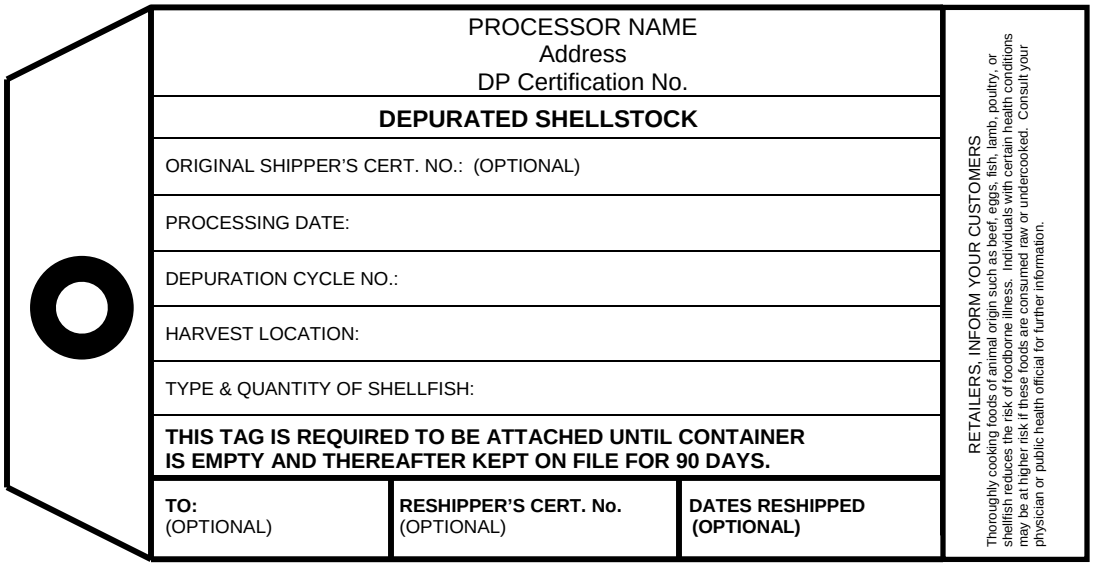


While both of the previous examples contain the minimum required information in the required order, many firms also customize the tags with additional information. Such information might include space for the consignee's address, date shipped, reshipper certification number, date reshipped, and a "Perishable- Keep Refrigerated" statement. Some firms also opt to preprint the types of shellfish with a check-off space. When customizing the tag, the order of the minimum required information cannot be changed.

This tag is an example of a dealer tag which meets the NSSP requirements and has been modified to include additional information. It also has the pin feed feature to allow printing on the dot matrix printer.



This tag is an example of a tag for depurated shellstock with the minimum NSSP required information in the required order.



PROCESSOR NAME
Address
DP Certification No.

DEPURATED SHELLSTOCK

ORIGINAL SHIPPER'S CERT. NO.: (OPTIONAL)

PROCESSING DATE:

DEPURATION CYCLE NO.:

HARVEST LOCATION:

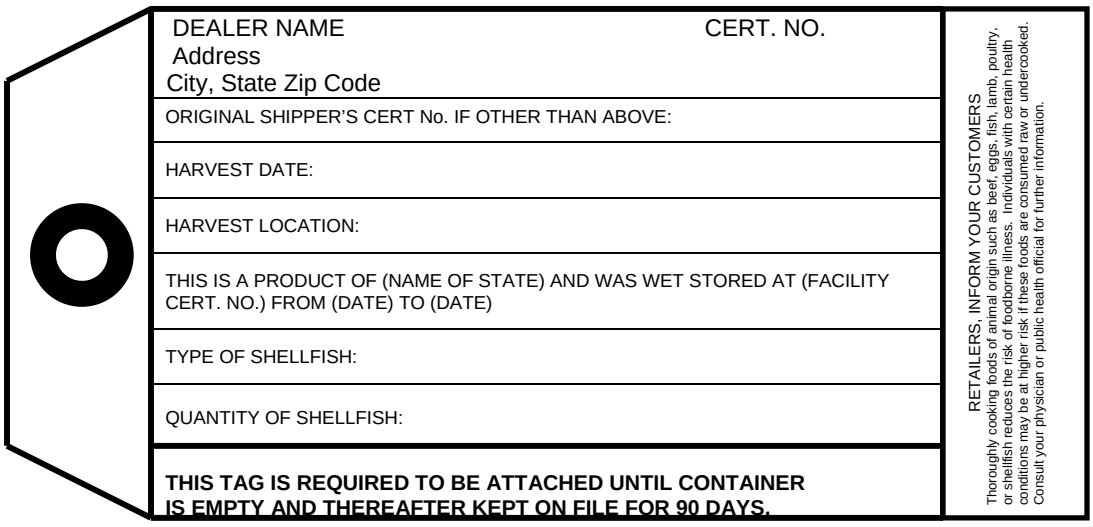
TYPE & QUANTITY OF SHELLFISH:

THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS.

TO: (OPTIONAL)	**RESHIPPER'S CERT. No.** (OPTIONAL)	**DATES RESHIPPED (OPTIONAL)**

RETAILERS, INFORM YOUR CUSTOMERS
Thoroughly cooking foods of animal origin such as beef, eggs, fish, lamb, poultry, or shellfish reduces the risk of foodborne illness. Individuals with certain health conditions may be at higher risk if these foods are consumed raw or undercooked. Consult your physician or public health official for further information.

When shellstock is transported interstate and placed in wet storage, special tagging requirements must be met. See the NSSP Model Ordinance for details. This tag is an example of a dealer tag modified for labeling product transported across State lines and subsequently wet stored.



DEALER NAME CERT. NO.
Address
City, State Zip Code

ORIGINAL SHIPPER'S CERT No. IF OTHER THAN ABOVE:

HARVEST DATE:

HARVEST LOCATION:

THIS IS A PRODUCT OF (NAME OF STATE) AND WAS WET STORED AT (FACILITY CERT. NO.) FROM (DATE) TO (DATE)

TYPE OF SHELLFISH:

QUANTITY OF SHELLFISH:

THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS.

RETAILERS, INFORM YOUR CUSTOMERS
Thoroughly cooking foods of animal origin such as beef, eggs, fish, lamb, poultry, or shellfish reduces the risk of foodborne illness. Individuals with certain health conditions may be at higher risk if these foods are consumed raw or undercooked. Consult your physician or public health official for further information.

Tags are available through various sources. In some states, the Authority sells the tags which are sequentially numbered for accountability. There are also grower's associations which bulk purchase tags for their members at considerable savings. Individual dealers can also have tags printed at local print shops.

Tyvek is one example of a durable waterproof material commonly used for shellstock tags.

Some states require additional information on tags which exceeds the NSSP requirements. A dealer should verify the receiving state's requirements prior to shipment to that state.

GUIDANCE FOR A TIME-TEMPERATURE EVALUATION OF A SHELLFISH IMPLICATED OUTBREAK

Because shellfish are filter feeders, they can concentrate microorganisms, marine biotoxin and poisonous or deleterious substances from the water column when these substances are present in the growing area. In addition, shellfish, like any other food product, can become unfit for human consumption through the introduction of contaminants during handling, storage, transport, distribution and processing. Furthermore, improper handling and storage can contribute to the increase of naturally occurring pathogens to hazardous levels in shellfish meats. The intrinsic risk from illness induced by microorganisms associated with consumption of raw or partially cooked shellfish products compels the shellfish control authority to act quickly and effectively when shellfish are implicated in a food-borne outbreak. When illness has occurred, the Authority needs to immediately begin an investigation before critical evidence is inadvertently lost or destroyed.

Currently, the NSSP Model Ordinance does not call for any action if illness is limited to only one person. This is appropriate for molluscan shellfish borne illness caused by microorganisms associated with pollution events. However, when naturally occurring marine bacteria such as *Vibrio vulnificus* or *Vibrio parahaemolyticus* are suspected to cause the illness an evaluation of the possibility of time-temperature abuse of the product is critical to understanding how the illness may have been prevented. A time-temperature audit provides information regarding the time-temperature experience of the product implicated as well as the health conditions of any ill persons which may have contributed to their susceptibility to the disease. Although the gathering of this data has been a public health focus for several years, there has been no effort to standardize how or what data are gathered during an illness investigation. When naturally occurring marine bacteria are believed to be the source of the shellfish implicated illness or outbreak, the time-temperature history of the product and the health of the persons may be more relevant than the traditional investigatory focus on tracing the origin of the product back to the shellfish growing area.

For additional information concerning the *Vibrio* organisms, see Watkins and McCarthy (1994) and the NSSP Guidance Document: *Vibrio* (ISSC/FDA, 2002).

Time-Temperature Evaluation of a Shellfish Implicated Outbreak

The Authority should promptly conduct an audit of the time-temperature history of the implicated product in a shellfish disease outbreak to the extent practicable. The Authority should use all records from any measuring devices in conveyances or coolers used to transport the product, or any records of conditions associated with the implicated product as it moved from harvest to consumption. Where necessary, the Authority in the state of shellfish product origin should be contacted to provide assistance in gathering information. The audit must include the retail market or restaurant where the victim bought the shellfish product, the facility of the person who sold the product that the retail market or restaurant, the facilities of all dealers and

common carriers who handled the product following its harvest, and the practices and facilities of the person who harvested the shellfish. The audit should include, but should not be limited to, the following points.

In the retail market or restaurant implicated in the shellfish illness outbreak, the Authority should, at a minimum,

Record the ambient temperature in the establishment; observe the time-temperature control in the establishment, i.e. how the product was handled:

Examine the establishment's records for the temperature of the storage device or facility used for the implicated product while at the establishment, or observe and record the temperature of the storage device or facility during the investigation; observe and record the temperature and age of the remaining product at the establishment. The age of the product must be cross checked with transaction records;

Observe the controls to prevent cross contamination of the implicated product; and provide for the immediate sampling and testing for the suspect organism(s) of any remaining product from the retail or food service location implicated in the outbreak.

The Authority should determine if the dealer or person who sold the product to the retail market or the restaurant is on the ICSSL. If the person is not on the ICSSL, the Authority should gather any pertinent information regarding the status of time-temperature controls practiced by this person such as:

- Inspection reports for the person's facility;
- Observed temperature of the person's conveyance used to transport shellfish product; and
- Presence or absence of adequate refrigeration capability in the person's conveyance.

If the dealer is on the ICSSL, the Authority should conduct an inspection of the dealer's facility and records for purposes of gathering data from time-temperature control procedures and practices at that facility including:

- The presence or absence of adequate refrigeration capability of the dealer's conveyance;
- The presence or absence of temperature records for the delivery conveyance;
- The observed temperature and time-temperature control practices on the dealer's loading dock;

The transaction records demonstrating the product's age from the date of harvest of the implicated product; and

- The dealer's observed product rotation practice (i.e., the existence of product of widely differing ages).

For additional information concerning the ICSSL, see the NSSP Guide for the Control of Molluscan Shellfish: *Dealer Certification and the Interstate Certified Shellfish Shippers List* (ISSC, 1997).
The Authority should gather data similar to that above from all dealers or common carriers (certified or uncertified) between the point of first receipt from the harvester and the retail market or restaurant.

The Authority should inspect the original dealer's facility (i.e. the point of first receipt from the harvester). If the original dealer's facility is in another state, the Authority should request the appropriate Authority in that state to perform an audit and to share the results of the audit. This audit should, at a minimum,:

- Determine if there are adequate provisions for product refrigeration;
- Observe temperature and/or records of temperature for the dealer's refrigeration facility;
- Observe general time-temperature control procedures and practices; and
- Observe the temperature and age of shellfish product on-site under receipt from harvesters or under storage.

To the extent practicable, the Authority should gather information concerning the time-temperature control capability of the harvester of record for the implicated product. If the product was harvested in another state, the Authority should request the appropriate Authority in that state to perform an audit and to share the results of the audit. This audit should, at a minimum, determine:

- If adequate shading was provided for harvested shellfish product;
- The existence of mechanical refrigeration for storage of harvested product; and
- If records of prior enforcement actions against the harvester exist.

In cases where *Vibrio* species are the suspected organisms causing the illness or outbreak, the Authority should investigate the health status of the victim(s) to determine:

- If there were underlying health problems which may have contributed to the occurrence of the illness(es);
- If the victim(s) was aware of his underlying condition;
- If the victim(s) was aware of his high-risk status;
- If the victim(s) had been advised not to consume raw shellfish; and
- If the establishment had posted point-of-sale information for high-risk consumers.

References

NSSP Guide for the Control of Molluscan Shellfish. 2002. *Dealer Certification and the Interstate Certified Shippers List*. Interstate Shellfish Sanitation Conference, 209 Dawson Road, Suite 2, Columbia, South Carolina, 29223.

NSSP Guide for the Control of Molluscan Shellfish. 2002. *Vibrio*. Interstate Shellfish Sanitation Conference, 209 Dawson Road, Suite 2, Columbia, South Carolina, 29223.

Watkins, W. and S. McCarthy. 1994. *Proceedings of the 1994 Vibrio vulnificus Workshop*. U.S. Department of Health and Human Services, Public Health Service, Office of Seafood (HFS-400), Shellfish Sanitation Branch, 200 C Street, SW, Washington, D.C. 175 pages.

CHAPTER IV. NATURALLY OCCURRING PATHOGENS

01. *Vibrio* Risk Management for Oysters

Background

Current information concerning *Vibrio vulnificus*, which is responsible for several shellfish associated illnesses and deaths each year can be found in Watkins and McCarthy (1994).

A small number of shellfish-borne illnesses have also been associated with bacteria of the genus *Vibrio* (Bonner, 1983; Blake *et al.*,1979; Morris, 1985; Joseph *et al.*,1982; Roderick, 1982). The *Vibrios* are free-living aquatic microorganisms, generally inhabiting marine and estuarine waters (Joseph *et al*, 1982: Spira, 1984; Colwell 1984; Bachman, 1983). Among the marine *Vibrios* classified as pathogenic are strains of non-01 *Vibrio cholerae, V. parahaemolyticus,* and *V. vulnificus* (Bachman, 1983; Desmarchelier, 1984; Blake, 1980). All three species have been recovered from coastal waters in the United States and other parts of the world (Joseph, 1982; Colwell, 1984; Blake, 1980; DePoala, 1981; Madden, 1982; Davey, 1982; Oliver, 1983; Tamplin, 1982; NIH, 1984). These and other *Vibrios* have been detected in some environmental samples recovered from areas free of overt sewage contamination and coliform (Bonner, 1983; Joseph, 1982; Spira, 1984).

In general, shellfish-borne vibrio infections have tended to occur in coastal areas in the summer and fall when the water was warmer and vibrio counts were higher (Bonner, 1983; Morris, 1985; Joseph, 1982). *V. parahaemolyticus* and non-01 *V. cholerae* are commonly reported as causing diarrhea illness associated with the consumption of seafood including shellfish (Bonner, 1983; Blake, 1979; Morris, 1985; Joseph, 1982; Baross and Liston, 1970; Morris, 1981). In contrast, *V. vulnificus* has been related to two distinct syndromes: wound infections, often with tissue necrosis and bacteremia, and primary septicemia characterized by fulminant illness in individuals with severe chronic illnesses such as liver disease, hemochromatosis, thalassemia major, alcoholism or malignancy (Bonner *et al.*, 1983; Tacket, 1984). Increasing evidence shows that individuals with such chronic diseases are susceptible to septicemia and death from raw seafood, especially raw oysters (Bonner *et al.*, 1983; Blake, 1979; Morris, 1985; Rodrick, 1982; Bachman, 1983; Blake, 1980; Oliver, 1983; NIH, 1984; Tacket, 1984; Oliver 1982; FDA, 1985). Shellfish-borne vibrio infections can be prevented by cooking seafood thoroughly, keeping them from cross contamination after cooking, and eating them promptly or storing them at hot (60^{o}C or higher) or cold (4^{o}C or lower) temperatures. If oysters and other seafood are to be eaten raw, consumers are probably at lower risk to vibrio infection during months when seawater is cold than when it is warm (Blake, 1983 and 1984).

02. *Vibrio vulnificus* Management Plan

The voting delegates at the 1999 Annual Meeting in New Orleans created the Vibrio Management Committee (VMC). Subsequently, *Vibrio vulnificus* and *Vibrio parahaemolyticus* subcommittees have been charged to develop appropriate illness control measures for these two pathogens. The VMC provides guidance and oversight to the subcommittees. Subcommittee recommendations are reviewed by the VMC before submittal to Task Forces. At the 2001 annual meeting, Task Forces reviewed the VMC's recommendation of reducing the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia with the intention to submit the recommendation to the voting delegates. The goal is to reduce the rate of illness reported in California, Florida, Louisiana and Texas due to the consumption of commercially harvested raw or undercooked oysters by 40 percent, for years 2005 and 2006 (average) and by 60 percent for years 2007 and 2008 (average) from the average illness rate for the years 1995 - 1999 of 0.306/million. The list of states may be adjusted if after a thorough review, epidemiological and statistical data demonstrates that it would be appropriate. The rate of illness shall be calculated as the number of illnesses adjusted for population. This adjustment will be performed in consultation with statisticians and epidemiologists from California, Florida, Louisiana and Texas and Federal agencies. The baseline data and all future data for measuring illness reduction shall be the reported illnesses in the California, Florida, Louisiana and Texas for the period 1995 to 1999, inclusive, as compiled by the Southeast Regional Office of the U.S. Food and Drug Administration. The data used for measuring goal attainment shall begin with 2002 data. For the purpose of maintaining an accurate count of the number of illnesses report by each state (California, Florida, Louisiana and Texas), the following will apply:

(a) Illness cases counted are those reported by California, Florida, Louisiana and Texas;
(b) Each illness case is recorded under the state that reports it;
(c) Each case is not counted more than once; and
(d) In the event more than one report per case is filed, the case is recorded under the state of diagnosis.

The formula for calculating the rate of illness is as follows:

$$\frac{\text{number of cases}}{\text{population}}$$

The V.v. subcommittee members will include, at a minimum, balanced representation from industry and state shellfish control authorities from *Vibrio vulnificus* Illness Source States California, Florida, Louisiana and Texas, FDA, NOAA, EPA, CDC, state epidemiologists; as well as industry and shellfish control representatives from other regions. *Vibrio vulnificus* Illness Source States are those states reporting two (2) or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state. Etiologically confirmed

means those cases in which laboratory evidence of a specific agent is obtained and specified criteria are met

Recognizing the increasing importance and roles for the Committee, leadership will be expanded and structured in a similar manner as stated in the ISSC By-Laws for Task Forces (reference: ISSC By-Law, Article I Task Forces). The VMC Chair shall alternately be selected from a state shellfish control authority and from industry. The Board Chairman, with approval of the Board, shall appoint a VMC Chair and Vice-Chair. If the VMC Chair represents a state shellfish control authority, the Vice-Chair shall be an industry representative. At the end of the VMC Chair's term of office, the Vice Chair will become Chairman and a new Vice Chair will be appointed who represents the same segment of the Conference as the outgoing VMC Chair. A VMC Chair and Vice Chair should be appointed before October 1, 2001 in order to be consistent with plans for annual VMC meetings and with the effective date of *Vibrio vulnificus* Risk Management Plans. Likewise, the term of office shall be for (2) years.

The VMC will meet at least annually to develop and approve annual VMC work plans for *Vibrio vulnificus* illness reduction and review progress. A series of work plans, each covering a one-year period shall be adopted. The first work plan and progress review period will cover a seventeen-month period from August 1, 2001 to December 31, 2003 followed subsequently by annual work plans. Work plans will include goals, tasks, performance measures and assessment methods to track and achieve progress towards the illness reduction goals. The work plans will be developed by the VMC and approved by the VMC membership. The chair of the VMC will deliver a written annual progress report, including a summary of the previous year's progress made in the education program, to the ISSC March executive board meeting. The report shall be made available to the general membership. The annual work plan structure, outlined below, provides adaptive management and assures consistent progress towards the illness reduction goals. If annual assessment of progress towards achieving the illness rate reduction goals show inadequate progress the VMC shall incorporate actions into current and subsequent work plans to assure success in achieving those goals. In addition, if annual review shows inadequate progress the VMC will develop issues for deliberation at the 2005 biennial meeting to consider actions such as:

- increased educational efforts,
- limited harvest restriction,
- reduction in time from harvest to refrigeration,
- phased-in post-harvest treatment requirements, or
- other equivalent controls.

Work plans developed by the VMC shall include the following elements and shall define the administrative procedures and resources necessary for accomplishment (i.e. establishment and maintenance):

(a) An ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* infection. The Education Program’s objectives will be 1) to increase the target audience’s awareness that

eating raw, untreated oysters can be life-threatening to them, and; 2) to change the at-risk group's oyster-eating behavior, i.e., to reduce or stop eating raw, untreated oysters. The ISSC Vibrio Management Committee and the *Vibrio vulnificus* Education Subcommittee will evaluate Year 2001 survey results and compare them with the Year 2003 or 2004 survey results determine the effectiveness in meeting the two objectives of the *Vv* education effort: (1) Show 40% increase in awareness of risk from Vv; and (2) Show 15% increase in at-risk consumers no longer eating raw oysters while minimizing impacts to non-at-risk consumer raw oyster consumption.

(i) The Consumer Education Program will focus educational efforts in California, Florida, Louisiana and Texas. The Education Program will make educational materials available to additional states upon request.

(ii) Educational approaches will emphasize partnerships with health and advocacy organizations, and include dissemination of printed materials, posting materials on the Internet, broadcast of television spots, press releases, and other measures deemed effective such as the USDA Physician Notification Program.

(iii) Survey assessments at the state level shall be used as a means of assessing the baseline knowledge and effectiveness of educational interventions.

(b) Administration of a survey to determine the current *Vibrio vulnificus* disease reporting and education in each state.

(c) Creation of a working group to work cooperatively with local, state, and federal agencies and programs to assist in the collection of environmental and epidemiological data to further expand on the current information available. A coordinator may be utilized to facilitate the activities of this working group to develop standardized collection of environmental and epidemiological information from harvest to consumer.

(d) Industry-implemented post-harvest controls to reduce *Vibrio vulnificus* levels in oyster shellstock which may include: time-temperature, post harvest treatment (i.e. hydrostatic pressure, cool pasteurization, IQF, and irradiation--pending approval), rapid chilling and other emerging technologies.

(e) Pursuit of ISSC options such as industry education and communication; FDA label incentives; PHT specific growing area classifications; targeted time/temperature assessment by FDA during annual shellfish program evaluations; assistance, as necessary, for the further study and possible implementation of dockside icing to investigate its effects on shelf life and

variations in the effectiveness of the method as a result of seasonal and regional differences and incentives to add refrigeration capacity to harvest vessels. The goal will be to provide incentives necessary to post-harvest treat 25 percent of all oysters intended for the raw, half-shell market during the months of May through September harvested from a Source State by the end of the third year (December 31, 2004). The assessment will include the capacity of all operational plants and the capacity of plants under construction. Should the 25 percent goal not be accomplished, the VMC will investigate and report their findings as to why the goal was not reached.

(f) Development by the VMC of a list of issues relating to public health, various technologies~~,~~ including Post-harvest treatments; marketability; shelf -life and similar matters that lend themselves to investigation. The VMC will work with FDA, NOAA, CDC, EPA, the shellfish industry and other entities as appropriate to obtain or facilitate the investigation of the issues listed and take the results into account as it develops plans or recommended Issues for the ISSC.

(g) Provision for a VMC compilation and review of the data on rates of illness, which will be made available to the ISSC at the ISSC Biennial meeting following the year in which the data was gathered. In the event that the data is not available at the time of the meeting, the VMC shall meet and review the data when it becomes available and issue a compilation report, which will be made available to the entire ISSC membership. In the event there is no Biennial meeting scheduled for a certain year, the VMC shall meet and review the data when it becomes available and issue a compilation report which will be made available to the entire membership.

(h) Provision for a VMC evaluation of the effectiveness of reduction efforts, which will be conducted at the end of the fifth year (December 31, 2006). The evaluation will determine whether the 40 percent, 5-year goal to reduce the rate of illness or education/consumer intervention or post harvest controls performance measures set forth in prior work plans have been achieved. Should the VMC evaluation indicate the 40 percent, 5 year goal has not been accomplished, the committee will identify additional harvest controls in the 2007 - 2008 work plan to assure achievement of the 60 percent reduction in the rate of illness goal by the close of the seventh year. In addition, the VMC will evaluate the requirements in Section 04.C. with the possibility of changing the controls to achieve remaining illness reduction goals.

Should a disagreement arise between FDA and the Authority on the equivalency of a control as described in .04(C), the V.v. Subcommittee will be requested to provide guidance.

03. *Vibrio parahaemolyticus* Interim Control Plan

A. Contingency Plan.

(1) If the waters of a state have been confirmed as an original source of oysters associated with two or more confirmed *V. parahaemolyticus* illnesses annually in the most recent three years (excluding years when growing areas were closed at least half of the period from June through September), or with an outbreak in the last three years, the Authority should develop and adopt a *V. parahaemolyticus* contingency plan.

(2) The plan should define the administrative procedures and resources necessary to accomplish the following:

(a) Identify and define growing areas in the state affected by *V. parahaemolyticus* based on hydrographic and geological parameters and other considerations relevant to control of a naturally occurring pathogen;

(b) Conduct an oyster meat sampling and assay program in those areas which have been associated with a *V. parahaemolyticus* illness;

(c) Close affected oyster growing areas;

(d) Prevent harvesting of affected oysters;

(e) Provide for oyster recall if an oyster growing area is closed as a result of illness;

(f) Notify the shellfish industry and the local health jurisdictions in the state of the potential for illnesses due to *V. parahaemolyticus* prior to historical times of onset or at a minimum of once a year;

(g) Issue a health advisory to the public about the potential problem and advise the industry to educate wholesalers, retailers, and consumers about the potential problem, with recommendations that oysters not be consumed raw during periods historically affected by *V. parahaemolyticus*.

(3) The plan may include agreements or memoranda of understanding between the Authority and individual oyster harvesters and processors to allow harvesting of oysters from growing areas which have been placed in the closed status, as specified in C. for:

(a) Post-harvest treatment by a process which has been demonstrated to reduce *V. parahaemolyticus* levels in oysters to non-detectable; or,

(b) Shucking and labeling “for cooking only”; or,

(c) Under specific circumstances, as approved by the Authority, where the oyster shellstock will be sold to a retailer or food establishment, food processor, or to a shucker-packer and labeled in accordance with (3)(b); or,

(d) Under specific circumstances, as approved by the Authority, where the oyster shellstock will be cooked and controls exist to ensure cooking.

B. *Vibrio parahaemolyticus* Monitoring

(1) In all areas where two or more confirmed *V. parahaemolyticus* illnesses have occurred annually in the most recent three years (excluding years when growing areas were closed at least half of the period from June through September), representative samples of oysters should be collected at least monthly during harvest periods historically associated with illnesses and otherwise as determined by the Authority. All samples will be analyzed using the direct plating procedures and gene probe methods or enrichment PCR procedures for total (*tlh*+ colonies) and pathogenic (*tdh*+ colonies) *V. parahaemolyticus.* *

(2) In all areas where a confirmed *V .parahaemolyticus* outbreak has occurred within the last three years, representative samples of oysters should be collected when environmental conditions are favorable for V. parahaemolyticus growth and/or periods historically associated with illness as determined by the Authority Samples should be collected and analyzed weekly during the year of and the first year after an outbreak, and at least monthly during the second and third years after an outbreak. All samples will be analyzed using the direct plating procedures and gene probe methods or enrichment PCR procedures for total (*tlh*+ colonies) and pathogenic (*tdh*+ colonies) *V. parahaemolyticus.*

(3) In order to determine the number of samples that would be appropriate for *V. parahaemolyticus* monitoring, the following factors should be considered:
   (a) The size of the growing area;
   (b) The amount of oyster shellstock typically harvested from the area;
   (c) The sensitivity of the methodology.

(4) In the event that emerging technologies and research identify pathogenic strains other than or in addition to *tdh*+ strains, the Authority may adopt and FDA may approve other or additional monitoring and control methods for preventing *V. parahaemolyticus* illnesses.

C. Closed Status of Growing Area Based On Monitoring Results.

(1) The growing area as defined in accordance with A.(2)(a) should be placed in the closed status for oyster harvest, except as allowed under A.(3), if a total of 5 or more pathogenic (*tdh*+) *V. parahaemolyticus* colony-forming units (CFU) per 0.1 gram, confirmed by at least one pathogenic (*tdh*+) *V. parahaemolyticus* CFU per 0.1 gram by replicate analysis, are found for any oyster sample from the harvest area. If any sample shows total (*tlh*+) *V. parahaemolyticus* counts above 5,000 CFU per gram, then additional samples (twice the number collected as determined by the Authority) should immediately be collected and analyzed for pathogenic *V. parahaemolyticus*. Should any of these additional samples show 5 or more pathogenic *V. parahaemolyticus* CFU per 0.1 gram, confirmed by at least one pathogenic *V. parahaemolyticus* by replicate analysis, the area will be placed in the closed status for oyster harvest, except as allowed under A.(3).

(2) The closed status should remain in effect until two consecutive representative samples of oyster meats, collected a minimum of four days apart, show fewer than 5 pathogenic (*tdh*+) *V. parahaemolyticus* CFU in 0.1 gram, or show no pathogenic *V. parahaemolyticus* by replicate analysis. If any sample shows total *V. parahaemolyticus* counts above 5,000 CFU per gram, then additional samples (twice the number collected as determined by the Authority) should immediately be collected and analyzed for pathogenic (*tdh*+) and total (*tlh*+) *V. parahaemolyticus*. Should those samples show fewer than 5 pathogenic (*tdh*+) *V. parahaemolyticus* CFU in 0.1 gram, or show no pathogenic *V. parahaemolyticus* by replicate analysis, the growing area should be opened.

(3) The analysis leading to a decision to return a growing area to the open status should be adequately documented.

D. Illness Outbreak.

(1) When a growing area is implicated in a *V. parahaemolyticus* illness outbreak, the Authority shall follow the procedures prescribed in Chapter II Section@.01A through E. If a growing area is closed due to an illness outbreak, the closed status should remain in effect until two consecutive representative samples of oyster meats, collected a minimum of four days apart, show no pathogenic (*tdh*+) *V. parahaemolyticus* CFU in replicate 0.1 gram portions of oyster meat and less than 5,000 total (*tlh*+) *V. parahaemolyticus* CFU per gram.

(2) If additional confirmed *V. parahaemolyticus* illnesses occur within 2 weeks of re-opening, they should be considered a continuation of the illness outbreak. The growing area should immediately be placed in the closed status, and re-opening may only occur when environmental conditions shift to those unfavorable to the growth of *V. parahaemolyticus*, or the Authority, in conjunction with the state epidemiologist, develops and implements a sampling plan.

E. Records.

The Authority should maintain a copy of all of the following records:

(1) All information, including monitoring data, relating to the levels of *V. parahaemolyticus* in the oyster growing areas;

(2) Copies of notices placing growing areas in the closed status;

(3) Evaluation reports; and,

(4) Copies of notices returning growing areas to the open status.

* Direct plating procedure by Cook, D.W. et al, 1999. Procedure for enumeration of *Vibrio parahaemolyticus* in shellfish meats. A collaborative study by shellfish producing states, FDA, and the ISSC; gene probe methods for total (*tlh*+ colonies) *V. parahaemolyticus* (McCarthy, S.A. et al, 1999. TRS. Appl. Microbiol.28:66-70) and

virulent (tdh+ colonies) *V. parahaemolyticus* (McCarthy, S.A. et al, 1999. Abstracts of the 99th General Meeting of the American Society for Microbiology, p.512).
[References for the direct plating, digoxygenin DNA probe method and the enrichment PCR procedure adapted to the VpICP can be provided.]

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V. SUGGESTED FORMS

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Shellfish Harvest Record

Company Name: _____

Certificate No.: _____

Harvest Area	Harvest Date	Species	Quantity

Page _____

SHELLFISH HARVEST / PURCHASE RECORD

Cert. No.	Quantity	Species	Harvest Area	Harvest Date	Purchase Date	Harvester Cert. #

Page_____

SHELLFISH SALES RECORD

Date Sold	Sold To	Quantity	Species	Harvest Date	Harvest Area	Harvester Cert. #

Page _____

EXPORT HEALTH CERTIFICATE

STATE OF _____

ADDRESS _____

STATEMENT OF LICENSURE AND CERTIFICATION

Exported By: **Certificate # _____** **Consigned To:**

License (*Check one*): Shellstock Shipper ☐ Shucker-Packer ☐

Shipped Via:	Port of Embarkation:	Port of Debarkation:		
Identifying Marks:	Total # of Containers:	Total Marked Weight:		
Product:	Class, Type, Style:	Count:	Lot Weight:	Labels/Brand:

The above-named exporter hereby certifies through its authorized agent that this product was harvested from the following harvest area or areas:

Agent's Signature: _____ Date: _____

The _____ State Department of Health routinely inspects shellfish operations and shellfish harvest areas to determine their compliance with state shellfish sanitation laws and the requirements of the National Shellfish Sanitation Program. The above named exporter is currently licensed and certified by the Department as indicated above. The above named harvest area is currently certified by the Department of Health as approved for harvest.

By:_____ Date:_____

(Appropriate state official/title)

VI. NSSP POLICY SETTING DOCUMENTS

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service
Food and Drug Administration
Washington DC 20204

POLICY STATEMENT
CONSUMPTION OF RAW MOLLUSCAN SHELLFISH

Molluscan shellfish are animal-derived protein foods that are widely consumed and play an important role in the diets of some consumers. Most animal-derived protein foods are cooked prior to consumption. Cooking can reduce a number of potentially pathogenic organisms and the risk of illness. However, molluscan shellfish are often consumer raw or partially cooked. Therefore, some cases of illness are inevitable from consuming them in this way.

The majority of illnesses that occur from the consumption of raw molluscan shellfish are the result of pollution. They are not life threatening to the general population and commonly range from mild intestinal disorders of short duration to acute gastroenteritis. More serious illnesses can occur, but are rare.

Certain medically compromised individuals are at increased risk from common marine vibrio bacteria that are unrelated to pollution. Therefore, it may not be possible to address this risk through environmental controls. Although the reported number of illnesses and fatalities from these bacteria in the United States each year is small in comparison with other food borne illnesses, the best advice for medically compromised individuals is not to eat raw molluscan shellfish. At most risk are those affected by: AIDS; chronic alcohol abuse; liver, stomach or blood disorders; cancer; diabetes; and kidney disease. Those uncertain of their health should seek the advice of their physician.

To reduce the risk of illnesses associated with raw shellfish consumption, the Food and Drug Administration (FDA) administers the National Shellfish Sanitation Program (NSSP). The NSSP is a tripartite cooperative program of Federal and State public health officials and the shellfish industry working together to improve shellfish safety. FDA is committed to the NSSP partnership as providing the best means of making molluscan shellfish as safe as possible. States annually spend millions of dollars to monitor waters to assure that they are safe before harvesting is permitted. FDA routinely audits the States' classification of shellfish harvesting areas to verify that none pose a threat to public health. FDA has also increased its cooperative efforts with State and Federal law enforcement officers to prevent illegal harvesting from closed waters, a practice that probably leads to most shellfish illnesses. Adhering to NSSP controls will help to keep risks to a minimum.

January 12, 1993

ISSC POLICY STATEMENT
CONSUMPTION OF RAW MOLLUSCAN SHELLFISH

Introduction

The Interstate Shellfish Sanitation Conference (ISSC) was organized in 1982 to address the safety and sanitation of molluscan shellfish (oysters, mussels, clams, and whole and roe-on scallops. The ISSC has a formal Memorandum of Understand with the U.S. Food and Drug Administration (FDA) to promote shellfish sanitation through the National Shellfish Sanitation Program (NSSP), a tripartite cooperative program of Federal and State public health officials and the shellfish industry working together to improve shellfish safety. The ISSC recognizes the success of this Program, which is founded on the premise that through appropriate controls, molluscan shellfish can be consumed raw by most people with reasonable risk. The ISSC remains committed to that premise.

Policy Statement

Molluscan shellfish are animal-derived protein foods that are widely consumed and play an important role in the diets of some consumers. Most animal-derived protein foods are cooked prior to consumption. Cooking can reduce a number of potentially pathogenic organisms and the risk of illness. Consumption of raw shellfish, as with consumption of other types of raw animal-derived protein foods, increases the risk of illness. The majority of illnesses related to the consumption of raw molluscan shellfish are a result of pollution. These illnesses are not life threatening to the general population and commonly range from mild intestinal disorders of short duration to acute gastroenteritis. More serious illnesses can occur, but are rare.

To reduce the potential risk associated with consumption of raw molluscan shellfish, the FDA in cooperation with the States administers the National Shellfish Sanitation Program. States monitor shellfish growing waters to determine that they are safe before harvesting is permitted. The FDA routinely audits the States' classification of shellfish harvesting areas to verify that none pose a threat to public health. The FDA has also increased its cooperative efforts with State and Federal law enforcements officers to prevent illegal harvesting from closed waters and ensures that all shellfish in interstate commerce are properly labeled or has a tag identifying the harvest area and shipper. The tagging and labeling requirement of the NSSP is designed to ensure that only shellfish from approved growing waters reach interstate commerce. Adherence to NSSP controls minimizes risks. Recognizing the NSSP partnership provides the best possible means of ensuring that molluscan shellfish are safe, the FDA, the States, and the ISSC are committed to continued support of the Program.

Certain medically compromised individuals are at increased risk from common marine bacteria that are unrelated to pollution. Therefore, it may not be possible to address this risk through environmental controls. Although the reported number of illnesses and fatalities from these bacteria in the United States each year is small in comparison with other food borne illnesses, total abstinence from raw molluscan shellfish is the best advice for medically compromised individuals. Those at greatest risk include, but are not restricted to those affected by: AIDS; chronic alcohol abuse; liver, stomach or blood disorders; cancer, diabetes and kidney disease. Those uncertain of their health status should seek the advice of their physician.

INTERSTATE SHELLFISH SANITATION CONFERENCE
RESOLUTION 97 - 01

SUBJECT: Post-Harvest Treatment Processing

TEXT OF RESOLUTION:

WHEREAS, the effect of naturally occurring *Vibrio vulnificus* in raw shellstock oysters has been a problem that has caused considerable concern for the Interstate Shellfish Sanitation Conference (ISSC), the FDA, State public health regulators, the molluscan shellfish industry and the general public; and

WHEREAS, the ISSC had previously adopted a position (stated in a resolution by the 1991 conference) that "in absence of definitive information regarding *Vibrio vulnificus*, the only realistic approach is education of the high risk groups"; and

WHEREAS, the ISSC also had recommended that "states and industry take immediate steps to institute harvesting, processing and handling procedures which will eliminate illnesses attributable to *Vibrio vulnificus*"; and

WHEREAS, the State public health regulators and shellfish control agencies are awaiting guidance from the ISSC and FDA regarding Post-Harvest Treatment (PHT) processes; therefore

BE IT RESOLVED, that the ISSC encourages the development and SSCA approval of PHT processes which are able to consistently and reliably reduce *Vibrio vulnificus* to non-detectable levels in raw molluscan shellfish.

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VII. SHELLFISH FEDERAL REGULATIONS

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PART 7 - ENFORCEMENT POLICY

Authority: Secs. 201-903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-393); secs. 301, 351, 354-360F, 361 of the Public Health Service Act (42 U.S.C. 241, 262, 263b-263n, 264).
Source: 42 FR 15567, Mar. 22, 1977, unless otherwise noted.

Subpart A - General Provisions

§ 7.1 Scope.

This part governs the practices and procedures applicable to regulatory enforcement actions initiated by the Food and Drug Administration pursuant to the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.) and other laws that it administers. This part also provides guidelines for manufacturers and distributors to follow with respect to their voluntary removal or correction of marketed violative products. This part is promulgated to clarify and explain the regulatory practices and procedures of the Food and Drug Administration, enhance public understanding, improve consumer protection, and assure uniform and consistent application of practices and procedures throughout the agency.

[43 FR 26218, June 16, 1978]

§ 7.3 Definitions.

(a) *Agency* means the Food and Drug Administration.

(b) *Citation* or *cite* means a document and any attachments thereto that provide notice to a person against whom criminal prosecution is contemplated of the opportunity to present views to the agency regarding an alleged violation.

(c) *Respondent* means a person named in a notice who presents views concerning an alleged violation either in person, by designated representative, or in writing.

(d) *Responsible individual* includes those in positions of power or authority to detect, prevent, or correct violations of the Federal Food, Drug, and Cosmetic Act.

(e) [Reserved]

(f) *Product* means an article subject to the jurisdiction of the Food and Drug Administration, including any food, drug, and device intended for human or animal use, any

cosmetic and biologic intended for human use, and any item subject to a quarantine regulation under part 1240 of this chapter. Product does not include an electronic product that emits radiation and is subject to parts 1003 and 1004 of this chapter.

(g) *Recall* means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or a stock recovery.

(h) *Correction* means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.

(i) *Recalling firm* means the firm that initiates a recall or, in the case of a Food and Drug Administration-requested recall, the firm that has primary responsibility for the manufacture and marketing of the product to be recalled.

(j) *Market withdrawal* means a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the Food and Drug Administration or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.

(k) *Stock recovery* means a firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm, i.e., the product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use.

(l) *Recall strategy* means a planned specific course of action to be taken in conducting a specific recall, which addresses the depth of recall, need for public warnings, and extent of effectiveness checks for the recall.

(m) *Recall classification* means the numerical designation, i.e., I, II, or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.

(1) Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

(2) Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

(3) Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

(n) *Consignee* means anyone who received, purchased, or used the product being recalled.

[42 FR 15567, Mar. 22, 1977, as amended at 43 FR 26218, June 16, 1978; 44 FR 12167, Mar. 6, 1979]

§ 7.12 Guaranty.

In case of the giving of a guaranty or undertaking referred to in section 303(c)(2) or (3) of the act, each person signing such guaranty or undertaking shall be considered to have given it.

§ 7.13 Suggested forms of guaranty.

(a) A guaranty or undertaking referred to in section 303(c)(2) of the act may be:

(1) Limited to a specific shipment or other delivery of an article, in which case it may be a part of or attached to the invoice or bill of sale covering such shipment or delivery, or

(2) General and continuing, in which case, in its application to any shipment or other delivery of an article, it shall be considered to have been given at the date such article was shipped or delivered by the person who gives the guaranty or undertaking.

(b) The following are suggested forms of guaranty or undertaking under section 303(c)(2) of the act:

(1) Limited form for use on invoice or bill of sale.

(Name of person giving the guaranty or undertaking) hereby guarantees that no article listed herein is adulterated or misbranded within

the meaning of the Federal Food, Drug, and Cosmetic Act, or is an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

(Signature and post-office address of person giving the guaranty or undertaking.)

(2) General and continuing form.

The article comprising each shipment or other delivery hereafter made by (name of person giving the guaranty or undertaking) to, or in the order of (name and post-office address of person to whom the guaranty or undertaking is given) is hereby guaranteed, as of the date of such shipment or delivery, to be, on such date, not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, and not an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

(Signature and post-office address of person giving the guaranty of undertaking.)

(c) The application of a guaranty or undertaking referred to in section 303(c)(2) of the act to any shipment or other delivery of an article shall expire when such article, after shipment or delivery by the person who gave such guaranty or undertaking, becomes adulterated or misbranded within the meaning of the act, or becomes an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

(d) A guaranty or undertaking referred to in section 303(c)(3) of the act shall state that the shipment or other delivery of the color additive covered thereby was manufactured by a signer thereof. It may be a part of or attached to the invoice or bill of sale covering such color. If such shipment or delivery is from a foreign manufacturer, such guaranty or undertaking shall be signed by such manufacturer and by an agent of such manufacturer who resides in the United States.

(e) The following are suggested forms of guaranty or undertaking under section 303(c)(3) of the act:

(1) For domestic manufacturers:

(Name of manufacturer) hereby guarantees that all color additives listed herein were manufactured by him, and (where color additive regulations require certification) are from batches certified in accordance with the applicable regulations promulgated under the Federal Food, Drug, and Cosmetic Act.

(Signature and post-office address of manufacturer.)

(2) For foreign manufacturers:

(Name of manufacturer and agent) hereby severally guarantee that all color additives listed herein were manufactured by (name of manufacturer), and (where color additive regulations require certification) are from batches certified in accordance with the applicable regulations promulgated under the Federal Food, Drug, and Cosmetic Act.

(Signature and post-office address of manufacturer.)

(Signature and post-office address of agent.)

(f) For the purpose of a guaranty or undertaking under section 303(c)(3) of the act the manufacturer of a shipment or other delivery of a color additive is the person who packaged such color.

(g) A guaranty or undertaking, if signed by two or more persons, shall state that such persons severally guarantee the article to which it applies.

(h) No representation or suggestion that an article is guaranteed under the act shall be made in labeling.

Subpart B - [Reserved]

Subpart C - Recalls (Including Product Corrections) - Guidelines on Policy, Procedures, and Industry Responsibilities

Source: 43 FR 26218, June 16, 1978, unless otherwise noted.

§ 7.40 Recall policy.

(a) Recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration. Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well being from products that present a risk of injury or gross deception or are otherwise defective. This section and §§ 7.41 through 7.59 recognize the voluntary nature of recall by providing guidelines so that responsible firms may effectively discharge their recall responsibilities. These sections also recognize that recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the Food and Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall.

(b) Recall may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of the Food and Drug Administration. A request by the Food and Drug Administration that a firm recall a product is reserved for urgent situations and is to be directed to the firm that has primary responsibility for the manufacture and marketing of the product that is to be recalled.

(c) Recall is generally more appropriate and affords better protection for consumers than seizure, when many lots of product have been widely distributed. Seizure, multiple seizure, or other court action is indicated when a firm refuses to undertake a recall requested by the Food and Drug Administration, or where the agency has reason to believe that a recall would not be effective, determines that a recall is ineffective, or discovers that a violation is continuing.

§ 7.41 Health hazard evaluation and recall classification.

(a) An evaluation of the health hazard presented by a product being recalled or considered for recall will be conducted by an ad hoc committee of Food and Drug Administration scientists and will take into account, but need not be limited to, the following factors:

(1) Whether any disease or injuries have already occurred from the use of the product.

(2) Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.

(3) Assessment of hazard to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.

(4) Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.

(5) Assessment of the likelihood of occurrence of the hazard.

(6) Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

(b) On the basis of this determination, the Food and Drug Administration will assign the recall a classification, i.e., Class I, Class II, or Class III, to indicate the relative degree of health hazard of the product being recalled or considered for recall.

§ 7.42 Recall strategy.

(a) *General*. (1) A recall strategy that takes into account the following factors will be developed by the agency for a Food and Drug Administration-requested recall and by the recalling firm for a firm-initiated recall to suit the individual circumstances of the particular recall:

(i) Results of health hazard evaluation.

(ii) Ease in identifying the product.

(iii) Degree to which the product's deficiency is obvious to the consumer or user.

(iv) Degree to which the product remains unused in the market place.

(v) Continued availability of essential products.

(2) The Food and Drug Administration will review the adequacy of a proposed recall strategy developed by a recalling firm and recommend changes as appropriate. A recalling firm should conduct the recall in accordance with an approved recall strategy but need not delay initiation of a recall pending review of its recall strategy.

(b) *Elements of a recall strategy.* A recall strategy will address the following elements regarding the conduct of the recall:

(1) *Depth of recall*. Depending on the product's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend, as follows:

(i) Consumer or user level, which may vary with product, including any intermediate wholesale or retail level; or

(ii) Retail level, including any intermediate wholesale level; or

(iii) Wholesale level.

(2) *Public warning*. The purpose of a public warning is to alert the public that a product being recalled presents a serious hazard to health. It is reserved for urgent situations where other means for preventing use of the recalled product appear inadequate. The Food and Drug Administration in consultation with the recalling firm will ordinarily issue such publicity. The recalling firm that decides to issue its own public warning is requested to submit its proposed public warning and plan for distribution of the warning for review and comment by the Food and Drug Administration. The recall strategy will specify whether a public warning is needed and whether it will issue as:

(i) General public warning through the general news media, either national or local as appropriate, or

(ii) Public warning through specialized news media, e.g., professional or trade press, or to specific segments of the population such as physicians, hospitals, etc.

(3) *Effectiveness checks*. The purpose of effectiveness checks is to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action. The method for contacting consignees may be accomplished by personal visits, telephone calls, letters, or a combination thereof. A guide entitled ``Methods for Conducting Recall Effectiveness Checks" that describes the use of these different methods is available upon request from the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. The recalling firm will ordinarily be responsible for conducting effectiveness checks, but the Food and Drug Administration will assist in this task where necessary and appropriate. The recall strategy will specify the method(s) to be used for and the level of effectiveness checks that will be conducted, as follows:

(i) Level A—100 percent of the total number of consignees to be contacted;

(ii) Level B—Some percentage of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis, but is greater that 10 percent and less than 100 percent of the total number of consignees;

(iii) Level C—10 percent of the total number of consignees to be contacted;

(iv) Level D—2 percent of the total number of consignees to be contacted; or

(v) Level E—No effectiveness checks.

[43 FR 26218, June 16, 1978, as amended at 46 FR 8455, Jan. 27, 1981]

§ 7.45 Food and Drug Administration requested recall.

(a) The Commissioner of Food and Drugs or his designee under § 5.20 of this chapter may request a firm to initiate a recall when the following determinations have been made:

(1) That a product that has been distributed presents a risk of illness or injury or gross consumer deception.

(2) That the firm has not initiated a recall of the product.

(3) That an agency action is necessary to protect the public health and welfare.

(b) The Commissioner or his designee will notify the firm of this determination and of the need to begin immediately a recall of the product. Such notification will be by letter or telegram to a responsible official of the firm, but may be preceded by oral communication or by a visit from an authorized representative of the local Food and Drug Administration district office, with formal, written confirmation from the Commissioner or his designee afterward. The notification will specify the violation, the health hazard classification of the violative product, the recall strategy, and other appropriate instructions for conducting the recall.

(c) Upon receipt of a request to recall, the firm may be asked to provide the Food and Drug Administration any or all of the information listed in § 7.46(a). The firm, upon agreeing to the recall request, may also provide other information relevant to the agency's determination of the need for the recall or how the recall should be conducted.

§ 7.46 Firm-initiated recall.

(a) A firm may decide of its own volition and under any circumstances to remove or correct a distributed product. A firm that does so because it believes the product to be violative is requested to notify immediately the appropriate Food and Drug Administration district office listed in § 5.115 of this chapter. Such removal or correction will be considered a recall only if the Food and Drug Administration regards the product as involving a violation that is subject to legal action, e.g., seizure. In such cases, the firm will be asked to provide the Food and Drug Administration the following information:

(1) Identity of the product involved.

(2) Reason for the removal or correction and the date and circumstances under which the product deficiency or possible deficiency was discovered.

(3) Evaluation of the risk associated with the deficiency or possible deficiency.

(4) Total amount of such products produced and/or the time span of the production.

(5) Total amount of such products estimated to be in distribution channels.

(6) Distribution information, including the number of direct accounts and, where necessary, the identity of the direct accounts.

(7) A copy of the firm's recall communication if any has issued, or a proposed communication if none has issued.

(8) Proposed strategy for conducting the recall.

(9) Name and telephone number of the firm official who should be contacted concerning the recall.

(b) The Food and Drug Administration will review the information submitted, advise the firm of the assigned recall classification, recommend any appropriate changes in the firm's strategy for the recall, and advise the firm that its recall will be placed in the weekly FDA Enforcement Report. Pending this review, the firm need not delay initiation of its product removal or correction.

(c) A firm may decide to recall a product when informed by the Food and Drug Administration that the agency has determined that the product in question violates the law, but the agency has not specifically requested a recall. The firm's action also is considered a firm-initiated recall and is subject to paragraphs (a) and (b) of this section.

(d) A firm that initiates a removal or correction of its product which the firm believes is a market withdrawal should consult with the appropriate Food and Drug Administration district office when the reason for the removal or correction is not obvious or clearly understood but where it is apparent, e.g., because of complaints or adverse reactions regarding the product, that the product is deficient in some respect. In such cases, the Food and Drug Administration will assist the firm in determining the exact nature of the problem.

§ 7.49 Recall communications.

(a) *General*. A recalling firm is responsible for promptly notifying each of its affected direct accounts about the recall. The

format, content, and extent of a recall communication should be commensurate with the hazard of the product being recalled and the strategy developed for that recall. In general terms, the purpose of a recall communication is to convey:

(1) That the product in question is subject to a recall.

(2) That further distribution or use of any remaining product should cease immediately.

(3) Where appropriate, that the direct account should in turn notify its customers who received the product about the recall.

(4) Instructions regarding what to do with the product.

(b) *Implementation*. A recall communication can be accomplished by telegrams, mailgrams, or first class letters conspicuously marked, preferably in bold red type, on the letter and the envelope: ``drug [or food, biologic, etc.] recall [or correction]". The letter and the envelope should be also marked: ``urgent" for class I and class II recalls and, when appropriate, for class III recalls. Telephone calls or other personal contacts should ordinarily be confirmed by one of the above methods and/or documented in an appropriate manner.

(c) *Contents*. (1) A recall communication should be written in accordance with the following guidelines:

(i) Be brief and to the point;

(ii) Identify clearly the product, size, lot number(s), code(s) or serial number(s) and any other pertinent descriptive information to enable accurate and immediate identification of the product;

(iii) Explain concisely the reason for the recall and the hazard involved, if any;

(iv) Provide specific instructions on what should be done with respect to the recalled products; and

(v) Provide a ready means for the recipient of the communication to report to the recalling firm whether it has any of the product, e.g., by sending a postage-paid, self-addressed postcard or by allowing the recipient to place a collect call to the recalling firm.

(2) The recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message. Where necessary, follow-up communications should be sent to those who fail to respond to the initial recall communication.

(d) *Responsibility of recipient*. Consignees that receive a recall communication should immediately carry out the instructions set forth by the recalling firm and, where necessary, extend the recall to its consignees in accordance with paragraphs (b) and (c) of this section.

§ 7.50 Public notification of recall.

The Food and Drug Administration will promptly make available to the public in the weekly FDA Enforcement Report a descriptive listing of each new recall according to its classification, whether it was Food and Drug Administration-requested or firm-initiated, and the specific action being taken by the recalling firm. The Food and Drug Administration will intentionally delay public notification of recalls of certain drugs and devices where the agency determines that public notification may cause unnecessary and harmful anxiety in patients and that initial consultation between patients and their physicians is essential. The report will not include a firm's product removals or corrections which the agency determines to be market withdrawals or stock recoveries. The report, which also includes other Food and Drug Administration regulatory actions, e.g., seizures that were affected and injunctions and prosecutions that were filed, is available upon request from the Office of Public Affairs (HFI-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

§ 7.53 Recall status reports.

(a) The recalling firm is requested to submit periodic recall status reports to the appropriate Food and Drug Administration district office so that the agency may assess the progress of the recall. The frequency of such reports will be determined by the relative urgency of the recall and will be specified by the Food and Drug Administration in each recall

case; generally the reporting interval will be between 2 and 4 weeks.

(b) Unless otherwise specified or inappropriate in a given recall case, the recall status report should contain the following information:

(1) Number of consignees notified of the recall, and date and method of notification.

(2) Number of consignees responding to the recall communication and quantity of products on hand at the time it was received.

(3) Number of consignees that did not respond (if needed, the identity of nonresponding consignees may be requested by the Food and Drug Administration).

(4) Number of products returned or corrected by each consignee contacted and the quantity of products accounted for.

(5) Number and results of effectiveness checks that were made.

(6) Estimated time frames for completion of the recall.

(c) Recall status reports are to be discontinued when the recall is terminated by the Food and Drug Administration.

§ 7.55 Termination of a recall.

(a) A recall will be terminated when the Food and Drug Administration determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. Written notification that a recall is terminated will be issued by the appropriate Food and Drug Administration district office to the recalling firm.

(b) A recalling firm may request termination of its recall by submitting a written request to the appropriate Food and Drug Administration district office stating that the recall is effective in accordance with the criteria set forth in paragraph (a) of this section, and by accompanying the request with the most current recall status report and a description of the disposition of the recalled product.

§ 7.59 General industry guidance.

A recall can be disruptive of a firm's operation and business, but there are several steps a prudent firm can take in advance to minimize this disruptive effect. Notwithstanding similar specific requirements for certain products in other parts of this chapter, the following is provided by the Food and Drug Administration as guidance for a firm's consideration:

(a) Prepare and maintain a current written contingency plan for use in initiating and effecting a recall in accordance with §§ 7.40 through 7.49, 7.53, and 7.55.

(b) Use sufficient coding of regulated products to make possible positive lot identification and to facilitate effective recall of all violative lots.

(c) Maintain such product distribution records as are necessary to facilitate location of products that are being recalled. Such records should be maintained for a period of time that exceeds the shelf life and expected use of the product and is at least the length of time specified in other applicable regulations concerning records retention.

PART 101 - FOOD LABELING

Subpart A - General Provisions

Subpart B - Specific Food Labeling Requirements

Subpart C - Specific Nutrition Labeling Requirements and Guidelines

[58 FR 2413, Jan. 6, 1993; 58 FR 17343, Apr. 2, 1993]

Subpart D - Specific Requirements for Nutrient Content Claims

Subpart A - General Provisions

101.1 Principal display panel of package form food.

The term ``principal display panel'' as it applies to food in package form and as used in this part, means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of dis-play for retail sale. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part with clarity and conspicuousness and without obscuring design, vignettes, or crowding. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. For the purpose of obtaining uniform type size in declaring the quantity of contents for all packages of substantially the same size, the term ``area of the principal display panel'' means the area of the side or surface that bears the principal display panel, which area shall be:

(a) In the case of a rectangular package where one entire side properly can be considered to be the principal display panel side, the product of the height times the width of that side;

(b) In the case of a cylindrical or nearly cylindrical container, 40 percent of the product of the height of the container times the circumference;

(c) In the case of any otherwise shaped container, 40 percent of the total surface of the container: Provided, however, that where such container presents an obvious ``principal display panel'' such as the top of a triangular or circular package of cheese, the area shall

consist of the entire top surface. In determining the area of the principal display panel, exclude tops, bottoms, flanges at tops and bottoms of cans, and shoulders and necks of bottles or jars. In the case of cylindrical or nearly cylindrical containers, information required by this part to appear on the principal display panel shall appear within that 40 percent of the circumference which is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

101.2 Information panel of package form food.

(a) The term ``information panel'' as it applies to packaged food means that part of the label immediately contiguous and to the right of the principal display panel as observed by an individual facing the principal display panel with the following exceptions:

(1) If the part of the label immediately contiguous and to the right of the principal display panel is too small to accommodate the necessary information or is otherwise unusable label space, e.g., folded flaps or can ends, the panel immediately contiguous and to the right of this part of the label may be used.

(2) If the package has one or more alternate principal display panels, the information panel is immediately contiguous and to the right of any principal display panel.

(3) If the top of the container is the principal display panel and the package has no alternate principal display panel, the information panel is any panel adjacent to the principal display panel.

(b) All information required to appear on the label of any package of food pursuant to §§ 101.4, 101.5, 101.8, 101.9, 101.17, 101.25 and Part 105 of this chapter shall appear either on the principal display panel or on the information panel, unless otherwise specified by regulations in this chapter.

(c) All information appearing on the principal display panel or the information panel pursuant to this section shall appear prominently and conspicuously, but in no case may the letters and/or numbers be less than one-sixteenth inch in height unless an exemption pursuant to paragraph (f) of this section is established. The requirements for conspicuousness and legibility shall include the specifications of §§ 101.105(h) (1) and (2) and 101.15.

(1) Packaged foods are exempt from the type size requirements of this paragraph: Provided, That:

(i) The package is designed such that it has a surface area that can bear an information panel and/or an alternate principal display panel.

(ii) The area of surface available for labeling on the principal display panel of the package as this term is defined in § 101.1 is less than 10 square inches.

(iii) The label information includes:

(a) Nutrition labeling in accordance with § 101.9.

(b) A full list of ingredients in accordance with regulations in this part and the policy expressed in § 101.6.

(iv) The information required by paragraph (b) of this section appears on the principal display panel or information panel label in accordance with the provisions of this paragraph (c) except that the type size is not less than three sixty-fourths inch in height.

(2) Packaged foods are exempt from the type size requirements of this paragraph: Provided, That:

(i) The package is designed such that it has a single ``obvious principal display panel'' as this term is defined in § 101.1 and has no

other available surface area for an information panel or alternate principal display panel.

(ii) The area of surface available for labeling on the principal display panel of the package as this term is defined in § 101.1 is less than 12 square inches and bears all labeling appearing on the package.

(iii) The label information includes:

(a) Nutrition labeling in accordance with § 101.9.

(b) A full list of ingredients in accordance with regulations in this part and the policy expressed in § 101.6.

(iv) The information required by paragraph (b) of this section appears on the single, obvious principal display panel in accordance with the provisions of this paragraph (c) except that the type size is not less than one thirty-second inch in height.

(3) Packaged foods are exempt from the type size requirements of this paragraph: Provided, That:

(i) The package is designed such that it has a total surface area available to bear labeling of less than 12 square inches.

(ii) The label information includes:

(a) Nutrition labeling in accordance with § 101.9.

(b) A full list of ingredients in accordance with regulations in this part and the policy expressed in § 101.6.

(iii) The information required by paragraph (b) of this section appears on the principal display panel or information panel label in accordance with the provisions of this paragraph (c) except that the type size is not less than one thirty-second inch in height.

(4)(i) Soft drinks packaged in bottles manufactured before October 31, 1975 shall be exempt from the requirements prescribed by this section to the extent that information which is blown, lithographed, or formed onto the surface of the bottle is exempt from the size and placement requirements of this section.

(ii) Soft drinks packaged in bottles shall be exempt from the size and placement requirements prescribed by this section if all of the following conditions are met:

(a) If the soft drink is packaged in a bottle bearing a paper, plastic foam jacket, or foil label, or is packaged in a non-reusable bottle bearing a label lithographed onto the surface of the bottle or is packaged in metal cans, the product shall not be exempt from any requirement of this section other than the exemptions created by § 1.24(a)(5) (ii) and (v) of this chapter and the label shall bear all required information in the specified minimum type size, except the label will not be required to bear the information required by § 101.5 if this information appears on the bottle closure or on the lid of the can in a type size not less than one-sixteenth inch in height, or if embossed on the lid of the can in a type size not less than one-eighth inch in height.

(b) If the soft drink is packaged in a bottle which does not bear a paper, plastic foam jacket or foil label, or is packaged in a reusable bottle bearing a label lithographed onto the surface of the bottle:

(1) Neither the bottle nor the closure is required to bear nutrition labeling in compliance with § 101.9, except that any multiunit retail package in which it is contained shall bear nutrition labeling if required by § 101.9; and any vending machine in which it is contained shall bear nutrition labeling if nutrition labeling is not present on the bottle or closure, if required by § 101.9.

(2) All other information pursuant to this section shall appear on the top of the bottle closure prominently and conspicuously in letters and/or numbers no less than one thirty-second inch in height, except that if the information required by § 101.5 is placed on the side of the closure in accordance with § 1.24(a)(5)(ii) of this chapter, such information shall appear in

letters and/or numbers no less than one-sixteenth inch in height.

(3) Upon the petition of any interested person demonstrating that the bottle closure is too small to accommodate this information, the Commissioner may by regulation establish an alternative method of disseminating such information. Information appearing on the closure shall appear in the following priority:

(i) The warning required by § 100.130 of this chapter.

(ii) The statement of ingredients.

(iii) The name and address of the manufacturer, packer, or distributor.

(iv) The statement of identity.

(5) Individual serving-size packages of food served with meals in restaurants, institutions, and on board passenger carriers, and not intended for sale at retail, are exempt from type-size requirements of this paragraph, provided:

(i) The package has a total area of 3 square inches or less available to bear labeling;

(ii) There is insufficient area on the package available to print all required information in a type size of 1/16 inch in height;

(iii) The label information includes a full list of ingredients in accordance with regulations in this part and the policy expressed in § 101.6 of this chapter; and

(iv) The information required by paragraph (b) of this section appears on the label in accordance with the provisions of this paragraph, except that the type size is not less than 1/32 inch in height.

(d)(1) All information required to appear on the principal display panel or on the information panel pursuant to this section shall appear on the same panel unless there is insufficient space. In determining the sufficiency of the available space, any vignettes, design, and other non-mandatory label information shall not be considered. If there is insufficient space for all of this information to appear on a single panel, it may be divided between these two panels except that the information required pursuant to any given section or part shall all appear on the same panel. A food whose label is required to bear the ingredient statement on the principal display panel may bear all other information specified in paragraph (b) of this section on the information panel.

(2) Any food, not otherwise exempted in this section, if packaged in a container consisting of a separate lid and body, and bearing nutrition labeling pursuant to § 101.9, and if the lid qualifies for and is designed to serve as a principal display panel, shall be exempt from the placement requirements of this section in the following respects:

(i) The name and place of business information required by § 101.5 shall not be required on the body of the container if this information appears on the lid in accordance with this section.

(ii) The nutrition information required by § 101.9 shall not be required on the lid if this information appears on the container body in accordance with this section.

(iii) The statement of ingredients required by § 101.4 shall not be required on the lid if this information appears on the container body in accordance with this section. Further, the statement of ingredients is not required on the container body if this information appears on the lid in accordance with this section.

(e) All information appearing on the information panel pursuant to this section shall appear in one place without other intervening material.

(f) If the label of any package of food is too small to accommodate all of the information required by §§ 101.4, 101.5, 101.8, 101.9, 101.17, and 101.25, and Part

105 of this chapter, the Commissioner may establish by regulation an acceptable alternative method of disseminating such information to the public, e.g., a type size smaller than one-sixteenth inch in height, or labeling attached to or inserted in the package or available at the point of purchase. A petition requesting such a regulation, as an amendment to this paragraph shall be submitted pursuant to Part 10 of this chapter.

[42 FR 14308, Mar. 15, 1977, as amended at 42 FR 15673, Mar. 22, 1977; 42 FR 45905, Sept. 13, 1977; 42 FR 47191, Sept. 20, 1977; 44 FR 16006, Mar. 16, 1979; 49 FR 13339, Apr. 4, 1984; 53 FR 16068, May 5, 1988]

101.3 Identity labeling of food in packaged form.

(a) The principal display panel of a food in package form shall bear as one of its principal features a statement of the identity of the commodity.

(b) Such statement of identity shall be in terms of:

(1) The name now or hereafter specified in or required by any applicable Federal law or regulation; or, in the absence thereof,

(2) The common or usual name of the food; or, in the absence thereof,

(3) An appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food.

(c) Where a food is marketed in various optional forms (whole, slices, diced, etc.), the particular form shall be considered to be a necessary part of the statement of identity and shall be declared in letters of a type size bearing a reasonable relation to the size of the letters forming the other components of the statement of identity; except that if the optional form is visible through the container or is depicted by an appropriate vignette, the particular form need not be included in the statement. This specification does not affect the required declarations of identity under definitions and standards for foods promulgated pursuant to section 401 of the act.

(d) This statement of identity shall be presented in bold type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.

(e) Under the provisions of section 403(c) of the Federal Food, Drug, and Cosmetic Act, a food shall be deemed to be misbranded if it is an imitation of another food unless its label bears, in type of uniform size and prominence, the word ``imitation" and, immediately thereafter, the name of the food imitated.

(1) A food shall be deemed to be an imitation and thus subject to the requirements of section 403(c) of the act if it is a substitute for and resembles another food but is nutritionally inferior to that food.

(2) A food that is a substitute for and resembles another food shall not be deemed to be an imitation provided it meets each of the following requirements:

(i) It is not nutritionally inferior to the food for which it substitutes and which it resembles.

(ii) Its label bears a common or usual name that complies with the provisions of § 102.5 of this chapter and that is not false or misleading, or in the absence of an existing common or usual name, an appropriately descriptive term that is not false or misleading. The label may, in addition, bear a fanciful name which is not false or misleading.

(3) A food for which a common or usual name is established by regulation (e.g., in a standard of identity pursuant to section

401 of the act, in a common or usual name regulation pursuant to Part 102 of this chapter, or in a regulation establishing a nutritional quality guideline pursuant to Part 104 of this chapter), and which complies with all of the applicable requirements of such regulation(s), shall not be deemed to be an imitation.

(4) Nutritional inferiority includes: (i) Any reduction in the content of an essential nutrient that is present in a measurable amount, but does not include a reduction in the caloric or fat content provided the food is labeled pursuant to the provisions of § 101.9, and provided the labeling with respect to any reduction in caloric content complies with the provisions applicable to caloric content in Part 105 of this chapter.

(ii) For the purpose of this section, a measurable amount of an essential nutrient in a food shall be considered to be 2 percent or more of the U.S. RDA of protein or any vitamin or mineral listed under § 101.9(c)(7)(iv) of this chapter per average or usual serving, or where the food is customarily not consumed directly, per average or usual portion, as established in § 101.9.

(iii) If the Commissioner concludes that a food is a substitute for and resembles another food but is inferior to the food imitated for reasons other than those set forth in this paragraph, he may propose appropriate revisions to this regulation or he may propose a separate regulation governing the particular food.

(f) A label may be required to bear the percentage(s) of a characterizing ingredient(s) or information concerning the presence or absence of an ingredient(s) or the need to add an ingredient(s) as part of the common or usual name of the food pursuant to Subpart B of Part 102 of this chapter.

[42 FR 14308, Mar. 15, 1977, as amended at 48 FR 10811, Mar. 15, 1983]

§ 101.4 Food; designation of ingredients.

(a)(1) Ingredients required to be declared on the label of a food, including foods that comply with standards of identity that require labeling in compliance with this Part 101, except those exempted by § 101.100, shall be listed by common or usual name in descending order of pre-dominance by weight on either the principal display panel or the information panel in accordance with the provisions of § 101.2.

(2) The descending order of predominance requirements of paragraph (a)(1) of this section do not apply to ingredients present in amounts of 2 percent or less by weight when a listing of these ingredients is placed at the end of the ingredient statement following an appropriate quantifying statement, e.g., ``Contains ___ percent or less of ___,'' or ``Less than ___ percent of ___.'' The blank percentage within the quantifying statement shall be filled in with a threshold level of 2 percent, or, if desired, 1.5 percent, 1.0 percent, or 0.5 percent, as appropriate. No ingredient to which the quantifying phrase applies may be present in an amount greater than the stated threshold.

(b) The name of an ingredient shall be a specific name and not a collective (generic) name, except that:

(1) Spices, flavorings, colorings and chemical preservatives shall be declared according to the provisions of § 101.22.

(2) An ingredient which itself contains two or more ingredients and which has an established common or usual name, conforms to a standard established pursuant to the Meat Inspection or Poultry Products Inspection Acts by the U.S. Department of Agriculture, or conforms to a definition and standard of identity established pursuant to

section 401 of the Federal Food, Drug, and Cosmetic Act, shall be designated in the statement of ingredients on the label of such food by either of the following alternatives:

(i) By declaring the established common or usual name of the ingredient followed by a parenthetical listing of all ingredients contained therein in descending order of predominance except that, if the ingredient is a food subject to a definition and standard of identity established in this Subchapter B, only the ingredients required to be declared by the definition and standard of identity need be listed; or

(ii) By incorporating into the statement of ingredients in descending order of predominance in the finished food, the common or usual name of every component of the ingredient without listing the ingredient itself.

(3) Skim milk, concentrated skim milk, reconstituted skim milk, and nonfat dry milk may be declared as ``skim milk'' or ``nonfat milk''.

(4) Milk, concentrated milk, reconstituted milk, and dry whole milk may be declared as ``milk''.

(5) Bacterial cultures may be declared by the word ``cultured'' followed by the name of the substrate, e.g., ``made from cultured skim milk or cultured buttermilk''.

(6) Sweet cream buttermilk, concentrated sweet cream buttermilk, reconstituted sweet cream buttermilk, and dried sweet cream buttermilk may be declared as ``buttermilk''.

(7) Whey, concentrated whey, reconstituted whey, and dried whey may be declared as ``whey''.

(8) Cream, reconstituted cream, dried cream, and plastic cream (sometimes known as concentrated milk fat) may be declared as ``cream''.

(9) Butter oil and anhydrous butterfat may be declared as ``butterfat''.

(10) Dried whole eggs, frozen whole eggs, and liquid whole eggs may be declared as ``eggs''.

(11) Dried egg whites, frozen egg whites, and liquid egg whites may be declared as ``egg whites''.

(12) Dried egg yolks, frozen egg yolks, and liquid egg yolks may be declared as ``egg yolks''.

(13) [Reserved]

(14) Each individual fat and/or oil ingredient of a food intended for human consumption shall be declared by its specific common or usual name (e.g., ``beef fat'', ``cottonseed oil'') in its order of predominance in the food except that blends of fats and/or oils may be designated in their order of predominance in the foods as ``-- shortening'' or ``blend of -- oils'', the blank to be filled in with the word ``vegetable'', ``animal'', ``marine'', with or without the terms ``fat'' or ``oils'', or combination of these, whichever is applicable if, immediately following the term, the common or usual name of each individual vegetable, animal, or marine fat or oil is given in parentheses, e.g., ``vegetable oil shortening (soybean and cottonseed oil)''. For products that are blends of fats and/or oils and for foods in which fats and/or oils constitute the predominant ingredient, i.e., in which the combined weight of all fat and/or oil ingredients equals or exceeds the weight of the most predominant ingredient that is not a fat or oil, the listing of the common or usual names of such fats and/or oils in parentheses shall be in descending order of predominance. In all other foods in which a blend of fats and/or oils is used as an ingredient, the listing of the common or usual names in parentheses need not be in descending order of predominance if the manufacturer, because of the use of varying mixtures, is unable to adhere to a constant pattern of fats and/or oils in the product. If the fat or oil is completely hydrogenated, the

name shall include the term ``hydrogenated'', or if partially hydrogenated, the name shall include the term ``partially hydrogenated''. If each fat and/or oil in a blend or the blend is completely hydrogenated, the term ``hydrogenated'' may precede the term(s) describing the blend, e.g., ``hydrogenated vegetable oil (soybean, cottonseed, and palm oils)'', rather than preceding the name of each individual fat and/or oil; if the blend of fats and/or oils is partially hydrogenated, the term ``partially hydrogenated'' may be used in the same manner. Fat and/or oil ingredients not present in the product may be listed if they may sometimes be used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as ``or'', ``and/or'', ``contains one or more of the following:'', e.g., ``vegetable oil shortening (contains one or more of the following: cottonseed oil, palm oil, soybean oil)''. No fat or oil ingredient shall be listed unless actually present if the fats and/or oils constitute the predominant ingredient of the product, as defined in this paragraph (b)(14).(15) When all the ingredients of a wheat flour are declared in an ingredient statement, the principal ingredient of the flour shall be declared by the name(s) specified in §§ 137.105, 137.200, 137.220 and 137.225 of this chapter, i.e., the first ingredient designated in the ingredient list of flour, or bromated flour, or enriched flour, or self-rising flour is ``flour'', ``white flour'', ``wheat flour'', or ``plain flour''; the first ingredient designated in the ingredient list of durum flour is ``durum flour''; the first ingredient designated in the ingredient list of whole wheat flour, or bromated whole wheat flour is ``whole wheat flour'', ``graham flour'', or ``entire wheat flour''; and the first ingredient designated in the ingredient list of whole durum wheat flour is ``whole durum wheat flour''.

(16) Ingredients that act as leavening agents in food may be declared in the ingredient statement by stating the specific common or usual name of each individual leavening agent in parentheses following the collective name ``leavening'', e.g., ``leavening (baking soda, monocalcium phosphate, and calcium carbonate)''. The listing of the common or usual name of each individual leavening agent in parentheses shall be in descending order of predominance: Except, That if the manufacturer is unable to adhere to a constant pattern of leavening agents in the product, the listing of individual leavening agents need not be in descending order of predominance. Leavening agents not present in the product may be listed if they are sometimes used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as ``or'', ``and/or'', ``contains one or more of the following:''.

(17) Ingredients that act as yeast nutrients in foods may be declared in the ingredient statement by stating the specific common or usual name of each individual yeast nutrient in parentheses following the collective name ``yeast nutrients'', e.g., ``yeast nutrients (calcium sulfate and ammonium phosphate)''. The listing of the common or usual name of each individual yeast nutrient in parentheses shall be in descending order of predominance: Except, That if the manufacturer is unable to adhere to a constant pattern of yeast nutrients in the product, the listing of the common or usual names of individual yeast nutrients need not be in descending order of predominance. Yeast nutrients not present in the product may be listed if they are sometimes used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as ``or'', ``and/or'', or ``contains one or more of the following:''.

(18) Ingredients that act as dough conditioners may be declared in the ingredient statement by stating the specific common or usual name of each individual dough conditioner in parentheses following the collective name ``dough conditioner'', e.g., ``dough conditioners (L-cysteine, ammonium sulfate)''. The listing of the common or usual name of each dough conditioner in parentheses shall be in descending order of predominance: *Except*, That if the manufacturer is unable to adhere to a constant pattern of dough conditioners in the product, the listing of the common or usual names of individual dough conditioners need not be in descending order of predominance. Dough conditioners not present in the product may be listed if they are sometimes used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as ``or'', ``and/or'', or ``contains one or more of the following:''.

(19) Ingredients that act as firming agents in food (e.g., salts of calcium and other safe and suitable salts in canned vegetables) may be declared in the ingredient statement, in order of predominance appropriate for the total of all firming agents in the food, by stating the specific common or usual name of each individual firming agent in descending order of predominance in parentheses following the collective name ``firming agents''. If the manufacturer is unable to adhere to a constant pattern of firming agents in the food, the listing of the individual firming agents need not be in descending order of predominance. Firming agents not present in the product may be listed if they are sometimes used in the product. Such ingredients shall be identified by words indicating that they may not be present, such as ``or'', ``and/or'', ``contains one or more of the following:''

(c) When water is added to reconstitute, completely or partially, an ingredient permitted by paragraph (b) of this section to be declared by a class name, the position of the ingredient class name in the ingredient statement shall be determined by the weight of the unreconstituted ingredient plus the weight of the quantity of water added to reconstitute that ingredient, up to the amount of water needed to reconstitute the ingredient to single strength. Any water added in excess of the amount of water needed to reconstitute the ingredient to single strength shall be declared as ``water'' in the ingredient statement.

[42 FR 14308, Mar. 15, 1977, as amended at 43 FR 12858, Mar. 28, 1978; 43 FR 24519, June 6, 1978; 48 FR 8054, Feb. 25, 1983; 55 FR 17433, Apr. 25, 1990]

§ 101.5 Food; name and place of business of manufacturer, packer, or distributor.

(a) The label of a food in packaged form shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor.

(b) The requirement for declaration of the name of the manufacturer, packer, or distributor shall be deemed to be satisfied, in the case of a corporation, only by the actual corporate name, which may be preceded or followed by the name of the particular division of the corporation. In the case of an individual, partnership, or association, the name under which the business is conducted shall be used.

(c) Where the food is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase that reveals the connection such person has with such food; such as ``Manufactured for -------'', ``Distributed by -------'', or any other wording that expresses the facts.

(d) The statement of the place of business shall include the street address, city, State, and ZIP code; however, the street address

may be omitted if it is shown in a current city directory or telephone directory. The requirement for inclusion of the ZIP code shall apply only to consumer commodity labels developed or revised after the effective date of this section. In the case of non-consumer packages, the ZIP code shall appear either on the label or the labeling (including invoice).

(e) If a person manufactures, packs, or distributes a food at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where such food was manufactured or packed or is to be distributed, unless such statement would be misleading.

[Code of Federal Regulations]
[Title 21, Volume 2, Parts 100 to 169]
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[Page 192-193]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES--CONTINUED

PART 109--UNAVOIDABLE CONTAMINANTS IN FOOD FOR HUMAN CONSUMPTION AND FOOD-PACKAGING MATERIAL--Table of Contents

Subpart A--General Provisions

Sec. 109.4 Establishment of tolerances, regulatory limits, and action levels.

(a) When appropriate under the criteria of Sec. 109.6, a tolerance for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in subpart B of this part under the provisions of section 406 of the act. A tolerance may prohibit any detectable amount of the substance in food.

(b) When appropriate under the criteria of Sec. 109.6, and under section 402(a)(1) of the act, a regulatory limit for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in subpart C of this part under the provisions of sections 402(a)(1) and 701(a) of the act. A regulatory limit may prohibit any detectable amount of the substance in food. The regulatory limit established represents the level at which food is adulterated within the meaning of section 402(a)(1) of the act.(c)(1) When appropriate under the criteria of Sec. 109.6, an action level for an added poisonous or deleterious substance, which may be a food additive, may be established to define a level of contamination at which a food may be regarded as adulterated.

(2) Whenever an action level is established or changed, a notice shall be published in the Federal Register as soon as practicable thereafter. The notice shall call attention to the material supporting the action level which shall be on file with the Dockets Management Branch before the notice is published. The notice shall invite public comment on the action level.

[[Page 193]]

(d) A regulation may be established in subpart D of this part to identify a food containing a naturally occurring poisonous or deleterious substance which will be deemed to be adulterated under section 402(a)(1) of the act. These regulations do not constitute a complete list of such foods.

[42 FR 52819, Sept. 30, 1977, as amended at 55 FR 20785, May 21, 1990]

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[Page 193-194]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF

HEALTH AND HUMAN SERVICES--CONTINUED

PART 109--UNAVOIDABLE CONTAMINANTS IN FOOD FOR HUMAN CONSUMPTION AND FOOD-PACKAGING MATERIAL--Table of Contents

Subpart A--General Provisions

Sec. 109.6 Added poisonous or deleterious substances.

(a) Use of an added poisonous or deleterious substance, other than a pesticide chemical, that is also a food additive, will be controlled by a regulation issued under section 409 of the act when possible. When such a use cannot be approved under the criteria of section 409 of the act, or when the added poisonous or deleterious substance is not a food additive, a tolerance, regulatory limit, or action level may be established pursuant to the criteria in paragraphs (b), (c), or (d) of this section. Residues resulting from the use of an added poisonous or deleterious substance that is also a pesticide chemical will ordinarily be controlled by a tolerance established in a regulation issued under sections 406, 408, or 409 of the act by the U.S. Environmental Protection Agency (EPA). When such a regulation has not been issued, an action level for an added poisonous or deleterious substance that is also a pesticide chemical may be established by the Food and Drug Administration. The Food and Drug Administration will request EPA to recommend such an action level pursuant to the criteria established in paragraph (d) of this section.

(b) A tolerance for an added poisonous or deleterious substance in any food may be established when the following criteria are met:

(1) The substance cannot be avoided by good manufacturing practice.

(2) The tolerance established is sufficient for the protection of the public health, taking into account the extent to which the presence of the substance cannot be avoided and the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances.

(3) No technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established. Examples of changes that might affect the appropriateness of the tolerance include anticipated improvements in good manufacturing practice that would change the extent to which use of the substance is unavoidable and anticipated studies expected to provide significant new toxicological or use data.

(c) A regulatory limit for an added poisonous or deleterious substance in any food may be established when each of the following criteria is met:

(1) The substance cannot be avoided by current good manufacturing practices.

(2) There is no tolerance established for the substance in the particular food under sections 406, 408, or 409 of the act.

(3) There is insufficient information by which a tolerance may be established for the substance under section 406 of the act or technological changes appear reasonably possible that may affect the appropriateness of a tolerance. The regulatory limit established represents the level at which food is adulterated within the meaning of section 402(a)(1) of the act.

(d) An action level for an added poisonous or deleterious substance in any food may be established when the criteria in paragraph (b) of this section are met, except that technological or other changes that might affect the appropriateness of the tolerance are foreseeable in the near future.

An action level for an added poisonous or deleterious substance in any food may be established at a level at which the Food and Drug Administration may regard the food as adulterated within the meaning of section 402(a)(1) of the act, without regard to the criteria in paragraph (b) of this section or in section 406 of the act. An action level will be withdrawn when a tolerance or regulatory limit for the same substance and use has been established.

(e) Tolerances will be established under authority appropriate for action levels (sections 306, 402(a), and 701(a) of the act, together with section 408 or 409 of the act, if appropriate) as well as under authority appropriate for tolerances (sections 406 and 701 of the act). In the event the effectiveness of a tolerance is stayed pursuant to section

[[Page 194]]

701(e)(2) of the act by the filing of an objection, the order establishing the tolerance shall be deemed to be an order establishing an action level until final action is taken upon such objection.

[42 FR 52819, Sept. 30, 1977, as amended at 55 FR 20785, May 21, 1990]

PART 110 — CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD

Authority: Secs. 402, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 371, 374); sec. 361 of the Public Health Service Act (42 U.S.C. 264).

Source: 51 FR 24475, June 19, 1986, unless otherwise noted.

Subpart A - General Provisions

§ 110.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) are applicable to such terms when used in this part. The following definitions shall also apply:

(a) ``*Acid foods* or *acidified foods*" means foods that have an equilibrium pH of 4.6 or below.

(b) ``*Adequate*" means that which is needed to accomplish the intended purpose in keeping with good public health practice.

(c) ``*Batter*" means a semi fluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

(d) ``*Blanching*," except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

(e) ``*Critical control point*" means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.

(f) ``*Food*" means food as defined in section 201(f) of the act and includes raw materials and ingredients.

(g) ``*Food-contact surfaces*" are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food

ordinarily occurs during the normal course of operations. ``Food-contact surfaces'' includes utensils and food-contact surfaces of equipment.

(h) ``*Lot*'' means the food produced during a period of time indicated by a specific code.

(i) ``*Microorganisms*'' means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term ``undesirable microorganisms'' includes those micro-organisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of the act. Occasionally in these regulations, FDA used the adjective ``microbial'' instead of using an adjectival phrase containing the word microorganism.

(j) ``*Pest*'' refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.

(k) ``*Plant*'' means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.

(l) ``*Quality control operation*'' means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.

(m) ``*Rework*'' means clean, unadulterated food that has been removed from processing for reasons other than unsanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

(n) ``*Safe-moisture level*'' is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.

(o) ``*Sanitize*'' means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

(p) ``*Shall*'' is used to state mandatory requirements.

(q) ``*Should*'' is used to state recommended or advisory procedures or identify recommended equipment.

(r) ``*Water activity*'' (a_w) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

§ 110.5 Current good manufacturing practice.

(a) The criteria and definitions in this part shall apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of

section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

§ 110.10 Personnel.

The plant management shall take all reasonable measures and precautions to ensure the following:

(a) *Disease control*. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.

(b) *Cleanliness*. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

(1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.

(2) Maintaining adequate personal cleanliness.

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.

(6) Wearing, where appropriate, in an effective manner, hairnets, headbands, caps, beard covers, or other effective hair restraints.

(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

(9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

(c) Education and training. Personnel responsible for identifying sanitation failures or food contamination should have a

background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and unsanitary practices.

(d) Supervision. Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

§ 110.19 Exclusions.

(a) The following operations are not subject to this part: Establishments engaged solely in the harvesting, storage, or distribution of one or more ``raw agricultural commodities,'' as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.

(b) FDA, however, will issue special regulations if it is necessary to cover these excluded operations.

Subpart B — Buildings and Facilities

§ 110.20 Plant and grounds.

(a) *Grounds*. The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a) (1) through (3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(b) *Plant construction and design*. Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.

(2) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is

likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

(3) Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:

(i) Using protective coverings.

(ii) Controlling areas over and around the vessels to eliminate harborages for pests.

(iii) Checking on a regular basis for pests and pest infestation.

(iv) Skimming the fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.

(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.

(7) Provide, where necessary, adequate screening or other protection against pests.

§ 110.35 Sanitary operations.

(a) *General maintenance*. Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

(b) *Substances used in cleaning and sanitizing; storage of toxic materials*. (1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in laboratory testing procedures;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in the plant's operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals

shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products should be followed.

(c) *Pest control*. No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(d) *Sanitation of food-contact surfaces*. All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

(1) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.

(3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.

(4) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.

(5) Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or ma-chine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.

(e) Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

§ 110.37 Sanitary facilities and controls.

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

(a) *Water supply*. The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts food or food-contact surfaces shall be safe

and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b) *Plumbing*. Plumbing shall be of adequate size and design and adequately installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge wastewater or sewage and piping systems that carry water for food or food manufacturing.

(c) *Sewage disposal*. Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

(d) *Toilet facilities*. Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:

(1) Maintaining the facilities in a sanitary condition.

(2) Keeping the facilities in good repair at all times.

(3) Providing self-closing doors.

(4) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive airflow systems).

(e) *Hand-washing facilities*. Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:

(1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.

(2) Effective hand-cleaning and sanitizing preparations.

(3) Sanitary towel service or suitable drying devices.

(4) Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.

(5) Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, of food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.

(6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

(f) *Rubbish and offal disposal*. Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

Subpart C — Equipment

§ 110.40 Equipment and utensils.

(a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.

(c) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual open-ration.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact sure-faces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

Subpart D — [Reserved]

Subpart E — Production and Process Controls

§ 110.80 Processes and controls.

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more

competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the act shall be rejected, or if permissible, treated or processed to eliminate the contamination.

(a) *Raw materials and other ingredients*. (1) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

(2) Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations, guidelines, and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.

(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Food and Drug Administration regulations, guidelines, and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination.

(5) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the act. Material scheduled for rework shall be identified as such.

(6) Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and

other ingredients from becoming adulterated within the meaning of the act.

(7) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

(b) *Manufacturing operations*. (1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(2) All food manufacturing, includng packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, a_w, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.

(3) Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act. Compliance with this requirement may be accomplished by any effective means, including:

(i) Maintaining refrigerated foods at 45 EF (7.2 EC) or below as appropriate for the particular food involved.

(ii) Maintaining frozen foods in a frozen state.

(iii) Maintaining hot foods at 140 EF (60 EC) or above.

(iv) Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

(4) Measures such as sterilizing, irradiating, pasteurizing, freezing, re-rigerating, controlling pH or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act.

(5) Work-in-process shall be handled in a manner that protects against contamination.

(6) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary.

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination.

(8) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.

(9) Food, raw materials, and other ingredients that are adulterated within the

meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reonditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food.

(10) Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.

(11) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.

(12) Batters, breading, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:

(i) Using ingredients free of contamination.

(ii) Employing adequate heat processes where applicable.

(iii) Using adequate time and temperature controls.

(iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.

(v) Cooling to an adequate temperature during manufacturing.

(vi) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.

(13) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including:

(i) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.

(ii) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.

(iii) Using materials for food containers and food-packaging materials that are safe and suitable, as defined in § 130.3(d) of this chapter.

(iv) Providing physical protection from contamination, particularly airborne contamination.

(v) Using sanitary handling procedures.

(14) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a_w for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this

requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the a_w of food.

(ii) Controlling the soluble solids-water ratio in finished food.

(iii) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the a_w of the food does not increase to an unsafe level.

(15) Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the pH of raw materials, food in process, and finished food.

(ii) Controlling the amount of acid or acidified food added to low-acid food.

(16) When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

(17) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

§ 110.93 Warehousing and distribution.

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

Subpart F — [Reserved]

Subpart G — Defect Action Levels

§ 110.110 Natural or unavoidable defects in food for human use that present no health hazard.

(a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.

(b) Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.

(c) Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the act that food not be prepared, packed, or held under unsanitary conditions or the requirements in this part that food manufacturers, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(d) The mixing of a food containing defects above the current defect action level

with another lot of food is not permitted and renders the final food adulterated within the meaning of the act, regardless of the defect level of the final food.

(e) A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Industry Programs Branch (HFF-326), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

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[Page 240-248]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES--CONTINUEPART 123--FISH AND FISHERY PRODUCTS

Subpart A--General Provisions

Sec.

Authority: Secs. 201, 402, 403, 406, 409, 701, 704, 721, 801, 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393); secs. 301, 307, 361 of the Public Health Service Act (42 U.S.C. 241, 242l, 264).

Subpart B--Smoked and Smoke-Flavored Fishery Products

Subpart C--Raw Molluscan Shellfish

Source: 60 FR 65197, Dec. 18, 1995, unless otherwise noted.

Effective Date Note: At 60 FR 65197, Dec. 18, 1995, part 123 was added, effective December 18, 1997.

Subpart A--General Provisions

Sec. 123.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) and in part 110 of this chapter are applicable to such terms when used in this part, except where they are herein redefined. The following definitions shall also apply:

(a) Certification number means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.

(b) Critical control point means a point, step, or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels.

(c) Critical limit means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

[[Page 241]]

(d) Fish means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.

(e) Fishery product means any human food product in which fish is a characterizing ingredient.

(f) Food safety hazard means any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

(g) Importer means either the U.S. owner or consignee at the time of entry into the United States, or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States, who is responsible for ensuring that goods being offered for entry into the United States are in compliance with all laws affecting the importation. For the purposes of this definition, ordinarily the importer is not the custom house broker, the freight forwarder, the carrier, or the steamship representative.

(h) Molluscan shellfish means any edible species of fresh or frozen oysters, clams, mussels, or scallops, or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.

(i) Preventive measure means physical, chemical, or other factors that can be used to control an identified food safety hazard.

(j) Process-monitoring instrument means an instrument or device used to indicate conditions during processing at a critical control point.

(k)(1) Processing means, with respect to fish or fishery products:
Handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding.

(2) The regulations in this part do not apply to:

(i) Harvesting or transporting fish or fishery products, without otherwise engaging in processing.

(ii) Practices such as heading, eviscerating, or freezing intended solely to prepare a fish for holding on board a harvest vessel.

(iii) The operation of a retail establishment.

(l) Processor means any person engaged in commercial, custom, or institutional processing of fish or fishery products, either in the United States or in a foreign country. A processing includes any person engaged in the production of foods that are to be used in market or consumer tests.

(m) Scombroid toxin-forming species means tuna, bluefish, mahi mahi, and other species, whether or not in the family Scombridae, in which
significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that permit the growth of mesophilic bacteria.

(n) Shall is used to state mandatory requirements.

(o) Shellfish control authority means a Federal, State, or foreign agency, or sovereign tribal government, legally responsible for the administration of a program that includes activities such as

classification of molluscan shellfish growing areas, enforcement of molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.

(p) Shellstock means raw, in-shell molluscan shellfish.

(q) Should is used to state recommended or advisory procedures or to identify recommended equipment.

(r) Shucked shellfish means molluscan shellfish that have one or both shells removed.

(s) Smoked or smoke-flavored fishery products means the finished food prepared by:

(1) Treating fish with salt (sodium chloride), and

(2) Subjecting it to the direct action of smoke from burning wood, sawdust, or similar material and/or imparting to it the flavor of smoke by a means such as immersing it in a solution of wood smoke.

(t) Tag means a record of harvesting information attached to a container of shellstock by the harvester or processor.

[[Page 242]]

Sec. 123.5 Current good manufacturing practice.

(a) Part 110 of this chapter applies in determining whether the facilities, methods, practices, and controls used to process fish and fishery products are safe, and whether these products have been processed under sanitary conditions.

(b) The purpose of this part is to set forth requirements specific to the processing of fish and fishery products.

Sec. 123.6 Hazard Analysis and Hazard Analysis Critical Control Point (HACCP) plan.

(a) Hazard analysis. Every processor shall conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed by that processor and to identify the preventive measures that the processor can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest. A food safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls.

(b) The HACCP plan. Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, as described in paragraph (a) of this section. A HACCP plan shall be specific to:

(1) Each location where fish and fishery products are processed by that processor; and

(2) Each kind of fish and fishery product processed by the processor. The plan may group kinds of fish and fishery products together, or group kinds of production methods together, if the food safety hazards, critical control points, critical limits, and procedures required to

be identified and performed in paragraph (c) of this section are identical for all fish and fishery products so grouped or for all production methods so grouped.

(c) The contents of the HACCP plan. The HACCP plan shall, at a minimum:

(1) List the food safety hazards that are reasonably likely to occur, as identified in accordance with paragraph (a) of this section, and that thus must be controlled for each fish and fishery product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:

(i) Natural toxins;

(ii) Microbiological contamination;

(iii) Chemical contamination;

(iv) Pesticides;

(v) Drug residues;

(vi) Decomposition in scombroid toxin-forming species or in any other species where a food safety hazard has been associated with decomposition;

(vii) Parasites, where the processor has knowledge or has reason to know that the parasite-containing fish or fishery product will be consumed without a process sufficient to kill the parasites, or where the processor represents, labels, or intends for the product to be so consumed;

(viii) Unapproved use of direct or indirect food or color additives; and

(ix) Physical hazards;

(2) List the critical control points for each of the identified food safety hazards, including as appropriate:

(i) Critical control points designed to control food safety hazards that could be introduced in the processing plant environment; and

(ii) Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest;

(3) List the critical limits that must be met at each of the critical control points;

(4) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include any corrective action plans that have been developed in accordance with Sec. 123.7(b), to be followed

[[Page 243]]

in response to deviations from critical limits at critical control points;

(6) List the verification procedures, and frequency thereof, that the processor will use in accordance with Sec. 123.8(a);

(7) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(d) Signing and dating the HACCP plan.

(1) The HACCP plan shall be signed and dated, either by the most responsible individual onsite at the processing facility or by a higher level official of the processor. This signature shall signify that the HACCP plan has been accepted for implementation by the firm.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) Upon verification of the plan in accordance with Sec. 123.8(a)(1).

(e) Products subject to other regulations. For fish and fishery products that are subject to the requirements of

part 113 or 114 of this chapter, the HACCP plan need not list the food safety hazard associated with the formation of *Clostridium botulinum* toxin in the finished, hermetically sealed container, nor list the controls to prevent that food safety hazard. A HACCP plan for such fish and fishery products shall address any other food safety hazards that are reasonably likely to occur.

(f) Sanitation. Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with Sec. 123.11(b) they need not be included in the HACCP plan, and vice versa.

(g) Legal basis. Failure of a processor to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary, otherwise operate in accordance with the requirements of this part, shall render the fish or fishery products of that processor adulterated under section 402(a)(4) of the act. Whether a processor's actions are consistent with ensuring the safety of food will be determined through an evaluation of the processors overall implementation of its HACCP plan, if one is required.

Sec. 123.7 Corrective actions.

(a) Whenever a deviation from a critical limit occurs, a processor shall take corrective action either by:

(1) Following a corrective action plan that is appropriate for the particular deviation, or

(2) Following the procedures in paragraph (c) of this section.

(b) Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with Sec. 123.6(c)(5), by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

(1) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and

(2) The cause of the deviation is corrected.

(c) When a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (c)(2) and (c)(3) of this section are met;

(2) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review. Adequate training may or may not include training in accordance with Sec. 123.10;

(3) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;

(4) Take corrective action, when necessary, to correct the cause of the deviation;

(5) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with Sec. 123.10, to

determine whether the [[Page 244]] HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.

(d) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with Sec. 123.8(a)(3)(ii) and the record keeping requirements of Sec. 123.9.

Sec. 123.8 Verification.

(a) Overall verification. Every processor shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented. Verification shall include, at a minimum:

(1) Reassessment of the HACCP plan. A reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. Such changes may include changes in the following: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with Sec. 123.10. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of Sec. 123.6(c).

(2) Ongoing verification activities. Ongoing verification activities including:

(i) A review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;

(ii) The calibration of process-monitoring instruments; and,

(iii) At the option of the processor, the performing of periodic end product or in-process testing.

(3) Records review. A review, including signing and dating, by an individual who has been trained in accordance with Sec. 123.10, of the records that document:

(i) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within 1 week of the day that the records are made;

(ii) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with Sec. 123.7. This review shall occur within 1 week of the day that the records are made; and

(iii) The calibrating of any process control instruments used at critical control points and the performing of any periodic end-product or in process testing that is part of the processor's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made.

(b) Corrective actions. Processors shall immediately follow the procedures in Sec. 123.7 whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

(c) Reassessment of the hazard analysis. Whenever a processor does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes that could reasonably affect whether a food safety hazard now exists. Such changes may include, but are not limited to changes in: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with Sec. 123.10.

(d) Record keeping. The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with paragraphs (a)(2)(ii) through (iii) of this section shall be

[[Page 245]]

documented in records that are subject to the record keeping requirements of Sec. 123.9.

Sec. 123.9 Records.

(a) General requirements. All records required by this part shall include:

(1) The name and location of the processor or importer;

(2) The date and time of the activity that the record reflects;

(3) The signature or initials of the person performing the operation; and

(4) Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed.

(b) Record retention. (1) All records required by this part shall be retained at the processing facility or importer's place of business in the United States for at least 1 year after the date they were prepared in the case of refrigerated products and for at least 2 years after the date they were prepared in the case of frozen, preserved, or shelf-stable products.

(2) Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility or the importer's place of business in the United States for at least 2 years after their applicability to the product being produced at the facility.

(3) If the processing facility is closed for a prolonged period between seasonal packs, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack but shall be immediately returned for official review upon demand.

(c) Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying at reasonable times.

(d) Public disclosure. (1) Subject to the limitations in paragraph (d)(2) of this section, all plans and records required by this part are not available for public disclosure unless they have been previously disclosed to the public as defined in Sec. 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in Sec. 20.61 of this chapter.

(2) However, these records and plans may be subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic-type HACCP plans that reflect standard industry practices.

(e) Tags. Tags as defined in Sec. 123.3(t) are not subject to the requirements of this section unless they are used to fulfill the requirements of Sec. 123.28(c).

(f) Records maintained on computers. The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

Sec. 123.10 Training.

At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to fish and fishery product processing at least equivalent to that received under standardized curriculum recognized as adequate by the U.S. Food and Drug Administration or who is otherwise qualified through job experience to perform these functions. Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum.

(a) Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan, that is appropriate for a specific processor, in order to meet the requirements of Sec. 123.6(b);

(b) Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in Sec. 123.7(c)(5), the HACCP plan in accordance with the verification activities specified in Sec. 123.8(a)(1), and the hazard analysis in accordance with the verification activities specified in Sec. 123.8(c); and

[[Page 246]]

(c) Performing the record review required by Sec. 123.8(a)(3); The trained individual need not be an employee of the processor.

Sec. 123.11 Sanitation control procedures.

(a) Sanitation SOP. Each processor should have and implement a written sanitation standard operating procedure (herein referred to as SSOP) or similar document that is specific to each location where fish and fishery products are produced. The SSOP should specify how the processor will meet those sanitation conditions and practices that are to be monitored in accordance with paragraph (b) of this section.

(b) Sanitation monitoring. Each processor shall monitor the conditions and practices during processing with

sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 of this chapter that are both appropriate to the plant and the food being processed and relate to the following:

(1) Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice;

(2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;

(3) Prevention of cross-contamination from unsanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product;

(4) Maintenance of hand washing, hand sanitizing, and toilet facilities;

(5) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;

(6) Proper labeling, storage, and use of toxic compounds;

(7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and

(8) Exclusion of pests from the food plant.

The processor shall correct in a timely manner, those conditions and practices that are not met.

(c) Sanitation control records. Each processor shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b) of this section. These records are subject to the requirements of Sec. 123.9.

(d) Relationship to HACCP plan. Sanitation controls may be included in the HACCP plan, required by Sec. 123.6(b). However, to the extent that they are monitored in accordance with paragraph (b) of this section they need not be included in the HACCP plan, and vice versa.

Sec. 123.12 Special requirements for imported products.

This section sets forth specific requirements for imported fish and fishery products.

(a) Importer verification. Every importer of fish or fishery products shall either:

(1) Obtain the fish or fishery product from a country that has an active memorandum of understanding (MOU) or similar agreement with the Food and Drug Administration, that covers the fish or fishery product and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system, accurately reflects the current situation between the signing parties, and is functioning and enforceable in its entirety; or

(2) Have and implement written verification procedures for ensuring that the fish and fishery products that they offer for import into the United States were processed in accordance with the requirements of this part. The procedures shall list at a minimum:

(i) Product specifications that are designed to ensure that the product is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act because it may be injurious to health or

have been processed under unsanitary conditions, and,

(ii) Affirmative steps that may include any of the following:

(A) Obtaining from the foreign processor the HACCP and sanitation monitoring records required by this part

[[Page 247]]

that relate to the specific lot of fish or fishery products being offered for import;

(B) Obtaining either a continuing or lot-by-lot certificate from an appropriate foreign government inspection authority or competent third party certifying that the imported fish or fishery product is or was processed in accordance with the requirements of this part;

(C) Regularly inspecting the foreign processor's facilities to ensure that the imported fish or fishery product is being processed in accordance with the requirements of this part;

(D) Maintaining on file a copy, in English, of the foreign processor's HACCP plan, and a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of the part;

(E) Periodically testing the imported fish or fishery product, and maintaining on file a copy, in English, of a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of this part or,

(F) Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.

(b) Competent third party. An importer may hire a competent third party to assist with or perform any or all of the verification activities specified in paragraph (a)(2) of this section, including writing the importer's verification procedures on the importer's behalf.

(c) Records. The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in paragraph (a)(2)(ii) of this section. These records shall be subject to the applicable provisions of Sec. 123.9.

(d) Determination of compliance. There must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with this part. If assurances do not exist that the imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors under this part, the product will appear to be adulterated and will be denied entry.

Subpart B--Smoked and Smoke-Flavored Fishery Products

Sec. 123.15 General.

This subpart augments subpart A of this part by setting forth specific requirements for processing smoked and smoke-flavored fishery products.

Sec. 123.16 Process controls.

In order to meet the requirements of subpart A of this part, processors of smoked and smoke-flavored fishery products, except those subject to the requirements of part 113 or 114 of this chapter, shall include in their HACCP plans how they are controlling the food

safety hazard associated with the formation of toxin by Clostridium botulinum for at least as long as the shelf life of the product under normal and moderate abuse conditions.

Subpart C--Raw Molluscan Shellfish

Sec. 123.20 General.

This subpart augments subpart A of this part by setting forth specific requirements for processing fresh or frozen molluscan shellfish, where such processing does not include a treatment that ensures the destruction of vegetative cells of microorganisms of public health concern.

Sec. 123.28 Source controls.

(a) In order to meet the requirements of subpart A of this part as they apply to microbiological contamination, chemical contamination, natural toxins, and related food safety hazards, processors shall include in their HACCP plans how they are controlling the origin of the molluscan shellfish they process to ensure that the conditions of paragraphs (b), (c), and (d) of this section are met.

(b) Processors shall only process molluscan shellfish harvested from growing waters approved for harvesting by a shellfish control authority. In the case of molluscan shellfish harvested from U.S. Federal waters, the requirements of this paragraph will be met so [[Page 248]] long as the shellfish have not been harvested from waters that have been closed to harvesting by an agency of the Federal government.

(c) To meet the requirements of paragraph (b) of this section, processors who receive shellstock shall accept only shellstock from a harvester that is in compliance with such licensor requirements as may apply to the harvesting of molluscan shellfish or from a processor that is certified by a shellfish control authority, and that has a tag affixed to each container of shellstock. The tag shall bear, at a minimum, the information required in Sec. 1240.60(b) of this chapter. In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the information required in Sec. 1240.60(b) of this chapter. Processors shall maintain records that document that all shellstock have met the requirements of this section. These records shall document:

(1) The date of harvest;

(2) The location of harvest by State and site;

(3) The quantity and type of shellfish;

(4) The date of receipt by the processor; and

(5) The name of the harvester, the name or registration number of the harvester's vessel, or an identification number issued to the harvester by the shellfish control authority.

(d) To meet the requirements of paragraph (b) of this section, processors who receive shucked molluscan shellfish shall accept only containers of shucked molluscan shellfish that bear a label that complies with Sec. 1240.60(c) of this chapter. Processors shall maintain records that document that all shucked molluscan shellfish have met the requirements of this section. These records shall document:

(1) The date of receipt;

(2) The quantity and type of shellfish; and

(3) The name and certification number of the packer or repacker of the product.

PART 161 - FISH AND SHELLFISH

Subpart A — General Provisions

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

Source: 42 FR 14464, Mar. 15, 1977, unless otherwise noted.

Subpart A —- General Provisions

§ 161.30 Declaration of quantity of contents on labels for canned oysters.

(a) For many years packers of canned oysters in the Gulf area of the United States have labeled their output with a declaration of the drained weight of oysters in the containers. Packers in other areas have marketed canned oysters with a declaration of the total weight of the contents of the container. Investigation reveals that under present-day practice consumers generally do not discard the liquid packing medium, but use it as a part of the food. Section 403(e)(2) of the Federal Food, Drug, and Cosmetic Act and the regulations there under require food in package form to bear an accurate label statement of the quantity of food in the container.

(b) It is concluded that compliance with the label declaration of quantity of contents requirement will be met by an accurate declaration of the total weight of the contents of the can. The requirements of § 161.145(c), establishing a standard of fill of container for canned oysters and specifying the statement of substandard fill

Subpart B - Requirements for Specific Standardized Fish and Shellfish

§ 161.130 Oysters.

(a) Oysters, raw oysters, shucked oysters, are the class of foods each of which is obtained by shucking shell oysters and preparing them in accordance with the procedure prescribed in paragraph (b) of this section. The name of each such food is the name specified in the applicable definition and standard of identity prescribed in §§ 161.131 to 161.140, inclusive.

(b) If water, or salt water containing less than 0.75 percent salt, is used in any vessel into which the oysters are shucked the combined volume of oysters and liquid when such oysters are emptied from such vessel is not less than four times the volume of such water or salt water. Any liquid accumulated with the oysters is removed. The oysters are washed, by blowing or otherwise, in water or salt water, or both. The total time that the oysters are in contact with water or salt water after leaving the shucker, including the time of washing, rinsing, and any other contact with water or salt water is not more than 30 minutes. In computing the time of contact with water or salt water, the length of time that oysters are in contact with water or salt water that is agitated

by blowing or otherwise, shall be calculated at twice its actual length. Any period of time that oysters are in contact with salt water containing not less than 0.75 percent salt before contact with oysters, shall not be included in computing the time that the oysters are in contact with water or salt water. Before packing into the containers for shipment or other delivery for consumption the oysters are thoroughly drained and are packed without any added substance.

(c) For the purposes of this section:

(1) ``Shell oysters'' means live oysters of any of the species, *Ostrea virginica*, *Ostrea gigas*, *Ostrea lurida*, in the shell, which, after removal from their beds, have not been floated or otherwise held under conditions which result in the addition of water.

(2) ``Thoroughly drained'' means one of the following:

(i) The oysters are drained on a strainer or skimmer which has an area of not less than 300 square inches per gallon of oysters, drained, and has perforations of at least 1/4 of an inch in diameter and not more than 1 1/4 inches apart, or perforations of equivalent areas and distribution. The oysters are distributed evenly over the draining surface of the skimmer and drained for not less than 5 minutes; or

(ii) The oysters are drained by any method other than that prescribed by paragraph (c)(2)(i) of this section whereby liquid from the oysters is removed so that when the oysters are tested within 15 minutes after packing by draining a representative gallon of oysters on a skimmer of the dimensions and in the manner described in paragraph (c)(2)(i) of this section for 2 minutes, not more than 5 percent of liquid by weight is removed by such draining.

§ 161.136 Olympia oysters.

Olympia oysters, raw Olympia oysters, shucked Olympia oysters, are of the species *Ostrea lurida* and conform to the definition and standard of identity prescribed for oysters in § 161.130.

§ 161.145 Canned oysters.

(a) *Identity*. (1) Canned oysters is the food prepared from one or any mixture of two or all of the forms of oysters specified in paragraph (a)(2) of this section, and a packing medium of water, or the watery liquid draining from oysters before or during processing, or a mixture of such liquid and water. The food may be seasoned with salt. It is sealed in containers and so processed by heat as to prevent spoilage.

(2) The forms of oysters referred to in paragraph (a)(1) of this section are prepared from oysters which have been removed from their shells and washed and which may be steamed while in the shell or steamed or blanched or both after removal there from, and are as follows:

(i) Whole oysters with such broken pieces of oysters as normally occur in removing oysters from their shells, washing, and packing.

(ii) Pieces of oysters obtained by segregating pieces of oysters broken in shucking, washing, or packing whole oysters.

(iii) Cut oysters obtained by cutting whole oysters.

(3)(i) When the form of oysters specified in paragraph (a)(2)(i) of this section is used, the name of the food is ``Oysters'' or ``Cove oysters'', if of the species *Ostrea virginica*; ``Oysters'' or ``Pacific oysters'', if of the species

Ostrea gigas; ``Oysters'' or ``Olympia oysters'', if of the species *Ostrea lurida*.

(ii) When the form of oysters specified in paragraph (a)(2)(ii) of this section is used, the name of the food is ``Pieces of ----'', the blank being filled in with the name ``Oysters'' or ``Cove oysters'', if of the species *Ostrea virginica*; ``Oysters'' or ``Pacific oysters'', if of the species *Ostrea gigas*; ``Oysters'' or ``Olympia oysters'', if of the species *Ostrea lurida*.

(iii) When the form of oysters specified in paragraph (a)(2)(iii) of this section is used, the name of the food is ``Cut --'', the blank being filled in with the name ``Oysters'' or ``Cove oysters'', if of the species *Ostrea virginica*; ``Oysters'' or ``Pacific oysters'', if of the species *Ostrea gigas*; ``Oysters'' or ``Olympia oysters'', if of the species *Ostrea lurida*.

(iv) In case a mixture of two or all such forms of oysters is used, the name is a combination of the names specified in this paragraph (a)(3) of the forms of oysters used, arranged in order of their predominance by weight.

(4) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(b) [Reserved]

(c) *Fill of container*. (1) The standard of fill of container for canned oysters is a fill such that the drained weight of oysters taken from each container is not less than 59 percent of the water capacity of the container.

(2) Water capacity of containers is determined by the general method provided in § 130.12(a) of this chapter.

(3) Drained weight is determined by the following method: Keep the unopened canned oyster container at a temperature of not less than 68E or more than 95E Fahrenheit for at least 12 hours immediately preceding the determination. After opening, tilt the container so as to distribute its contents evenly over the meshes of a circular sieve which has been previously weighed. The diameter of the sieve is 8 inches if the quantity of the contents of the container is less than 3 pounds, and 12 inches if such quantity is 3 pounds or more. The bottom of the sieve is woven-wire cloth that complies with the specifications for such cloth set forth under ``2.38 mm (No. 8)'' in ``Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Ed. (1980), Table 1, ``Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series),'' under the heading ``Definitions of Terms and Explanatory Notes,'' which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists, 2200 Wilson Blvd., Suite 400, Arlington, VA 22201-3301, or may be examined at the Office of the Federal Register, 1100 L St. NW. Washington, DC 20408. Without shifting the material on the sieve, so incline the sieve as to facilitate drainage. Two minutes from the time drainage begins, weigh the sieve and the drained oysters. The weight so found, less the weight of the sieve, shall be considered to be the drained weight of the oysters.

(4) If canned oysters fall below the standard of fill of container prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter in the manner and form therein specified, followed by the statement, ``A can of this size should

contain --- oz. of oysters. This can contains only --- oz.", the blanks being filled in with the applicable figures.

[42 FR 14464, Mar. 15, 1977, as amended at 47 FR 11832, Mar. 19, 1982; 49 FR 10102, Mar. 19, 1984; 54 FR 24895, June 12, 1989; 58 FR 2884, Jan 6, 1993]

[Code of Federal Regulations]
[Title 21, Volume 6, Parts 500 to 599]
[Revised as of April 1, 1997]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR509.3]

[Page 33]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES--(Continued)

PART 509--UNAVOIDABLE CONTAMINANTS IN ANIMAL FOOD AND FOOD-PACKAGING MATERIAL--Table of Contents

Subpart A--General Provisions

Sec. 509.3 Definitions and interpretations.

(a) Act means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms contained in section 201 of the act are applicable to such terms when used in this part unless modified in this section.

(c) A naturally occurring poisonous or deleterious substance is a poisonous or deleterious substance that is an inherent natural constituent of a food and is not the result of environmental, agricultural, industrial, or other contamination.

(d) An added poisonous or deleterious substance is a poisonous or deleterious substance that is not a naturally occurring poisonous or deleterious substance. When a naturally occurring poisonous or deleterious substance is increased to abnormal levels through mishandling or other intervening acts, it is an added poisonous or deleterious substance to the extent of such increase.

(e) Food includes pet food, animal feed, and substances migrating to food from food-contact articles.

[Code of Federal Regulations]
[Title 21, Volume 6, Parts 500 to 599]
[Revised as of April 1, 1997]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR509.4]

[Page 33-34]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES-- (Continued)

PART 509--UNAVOIDABLE CONTAMINANTS IN ANIMAL FOOD AND FOOD-PACKAGING MATERIAL--Table of Contents

Subpart A--General Provisions

Sec. 509.4 Establishment of tolerances, regulatory limits, and action levels.

(a) When appropriate under the criteria of Sec. 509.6, a tolerance for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in subpart B of this part under the provisions of section 406 of the act. A tolerance may [[Page 34]] prohibit any detectable amount of the substance in food.

(b) When appropriate under the criteria of Sec. 509.6, and under section 402(a)(1) of the act, a regulatory limit

for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in subpart C of this part under the provisions of sections 402(a)(1) and 701(a) of the act. A regulatory limit may prohibit any detectable amount of the substance in food. The regulatory limit established represents the level at which food is adulterated within the meaning of section 402(a)(1) of the act.

(c)(1) When appropriate under the criteria of Sec. 509.6, an action level for an added poisonous or deleterious substance, which may be a food additive, may be established to define a level of contamination at which a food may be regarded as adulterated.

(2) Whenever an action level is established or changed, a notice shall be published in the Federal Register as soon as practicable thereafter. The notice shall call attention to the material supporting the action level which shall be on file with the Dockets Management Branch before the notice is published. The notice shall invite public comment on the action level.

(d) A regulation may be established in subpart D of this part to identify a food containing a naturally occurring poisonous or deleterious substance which will be deemed to be adulterated under section 402(a)(1) of the act. These regulations do not constitute a complete list of such foods.

[42 FR 52821, Sept. 30, 1977, as amended at 55 FR 20786, May 21, 1990]

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VIII. FDA MANUAL OF INTERPRETATIONS

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National Shellfish Sanitation Program
U.S. Food and Drug Administration
Shellfish Safety Team
Division of Cooperative Programs
Office of Compliance

MANUAL OF INTERPRETATIONS CODIFICATION SYSTEM

Date: December 8, 2002

The Manual of Interpretation Codification System consists of nine subject areas. The nine areas are **Interpretation Number**, **Date**, **National Shellfish Sanitation Guide for the Control of Molluscan Shellfish**, reference hereon known as **"Model Ordinance Reference"**, **Key Words**, **Question**, **Interpretation**, **Rationale, Other References,** and **Contact.**

Interpretation Number:

The interpretation number consists of four fields:
(1) primary
(2) secondary
(3) tertiary and
(4) quaternary.

Each identified field is related to a particular section of the Model Ordinance and a chronological number is assigned for the interpretation. The following is an example:

For example: **Interpretation Number: 01-III-@.02-100**

01- The primary field corresponds to the last published Guide for the Control of Molluscan Shellfish revision date; in this case it is "2001."

III- The secondary field corresponds to a chapter in the Guide; in this case it is "Chapter III - Laboratory."

@.02- The third field corresponds to the chronological numerical sequence for a subparagraph under a particular section in a chapter.

100- The fourth field is a chronological number for each interpretation issued under a particular section. **Note**: All interpretations issued for the first time for each Guide section will start with the number 100.

Date: This is the actual date when the interpretation was issued.

Model Ordinance Reference This refers to the particular chapters, paragraphs and subparagraphs in the guide. For example "**Chapter III, section @.02A"**

Keywords: These are words that serve to provide significant or memorable statements for systematic index entry.

Question: This is the particular question of concern that needs to be interpreted.

Interpretation: The FDA written response to clarify the particular area of concern in a specific chapter or section of the **NSSP Guide for the Control of Molluscan Shellfish**.

Rationale: This explains the reason for the interpretation. This area will cover existing policy, regulations, laws, and public health reasons.

Other References: This includes other documents used to issue the interpretation such as laws, regulations, model codes, scientific literature, etc.

Contact: This is the office responsible for issuing the interpretation. Any questions or comments should be in writing and addressed to:

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway (HFS-628)
College Park, MD 20740

ISSC Program Interpretations

The Interpretations found in the 1997 version of the NSSP Guide have been converted to Model Ordinance language. The conversion eliminated the need for four of the original interpretations. The chart below lists the Guide Interpretations that replaced the previous Manual Interpretations.

Manual Interpretation	Guide Interpretation
II-A-2-101	01-I-@.02-100
I-B-1-100	01-III-@.02-100
I-C-1-100	01-IV-@.02-100
99-IV@.02-101	01-IV-@.02-101
II-A-2-100	Deleted
II-B-1-100	01-VIII-.03-100
II-B-1-101	01-VIII-.03-101
II-I-8-100	Deleted
II-D-20-100	Deleted
II-D-9-100	Deleted
97-XI-01.B-100	01-XI-.01-100
97-XI-02-100	01-XI-.02-100
97-XI-02.B-100	01-XI-.02-101
99-XV-03L-101	01-XV-.03-100

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National Shellfish Sanitation Program
U.S. Food and Drug Administration
Shellfish Safety Team
Division of Cooperative Programs

MANUAL OF INTERPRETATIONS

Office of Compliance

Interpretation Number: 01-I-@.02-100

Date: July 15, 1994
Revised: December 8, 2002

Model Ordinance Reference: Chapter I@.02A(1)
NSSP Guidance Document –
Shellfish Plant Inspection Standardization Procedures

Key Words: Standardization, Limited, Officers

Question: What procedures are to be used to standardize a State Shellfish Standardization Officer in jurisdictions which have less than five (5) dealers to certify for the ICSSL?

Interpretation:

OPTIONS FOR STANDARDIZING STATE SHELLFISH STANDARDIZATION OFFICERS WITHIN JURISDICTIONS WITH FEWER THAN 5 CERTIFIED DEALERS

1. Determine the number of intrastate shellfish dealers not listed on the ICSSL and include as many as necessary to obtain the minimum 5 inspections. All certified dealers must be included in the sample.
2. Arrange to conduct standardization inspections in another jurisdiction, using as many certified dealers as necessary to complete the exercise. All certified dealers within the candidate's home state must be included in the sample. This exercise must be conducted with an FDA Standardization Officer.

3. If options 1 or 2 are possible, they must be selected before pursuing option 3. When the Regional Shellfish Specialist agrees that option 1 or 2 cannot be utilized, the FDA Standardization Officer and the State Candidate will inspect all interstate and intrastate dealers within the state. If this number of dealers equals less than 5, the standardization exercise will be based upon the inspection of the number of available plants. However, the Candidate must achieve 80% agreement on EACH inspection. The FDA Standardization Officer shall review annually the number of dealers available within the jurisdiction and standardize the State Shellfish Officer using 5 dealers whenever they become available. The State Shellfish Officer shall make every effort to achieve standardization using 5 dealers. If a State Shellfish Standardization Officer standardized under this option relocates to another state with five (5) or more dealers, that Officer must be restandardized by the Regional FDA Shellfish Specialist through field standardization using 5 dealers.

IN ALL OF THE ABOVE OPTION CASES, THE STATE SHELLFISH STANDARDIZATION OFFICER CANDIDATE MUST SUCCESSFULLY COMPLETE THE FDA CLASSROOM TRAINING PORTION OF THE STANDARDIZATION PROCESS.

4. A state may choose to contract with another state which has a recognized State Standardization Officer to conduct routine and pre-certification inspections.

Rationale:

NSSP Guidance Document – Shellfish Plant Inspection Standardization Procedures, in the Guide for the Control of Molluscan Shellfish, establishes the procedures for measuring the training and performance of an applicant to become a standardized State Shellfish Officer or Plant Inspector. NSSP Guidance Document – Shellfish Plant Inspection Standardization Procedures requires that, during the plant inspection phase of standardization, a minimum of 8 plants be jointly inspected by the FDA Standardization Officer and the candidate for State Shellfish Officer. Three of the 8 plant inspections are considered to be a review or warm-up inspections, and 5 inspections are counted as the official number of inspections for the standardization process.

However, several states and foreign countries that participate in the ISSC and want to list firms on the ICSSL have fewer than 5 plants within their jurisdiction. Therefore, they are unable to follow the procedures set forth in NSSP Guidance Document – Shellfish Plant Inspection Standardization Procedures to standardize a State official. NSSP Guidance Document – Shellfish Plant Inspection Standardization Procedures addresses this issue vaguely, stating that, "For states that do not have 8 plants, all of the available plants must be inspected with the Standard determining the appropriate review number."

To clarify this issue, FDA offers the above options. Election of any option will:

* Meet the intent of the standardization procedures;
* Maintain uniform requirements for Standardized State Officers; and
* Uphold the criteria for listing dealers on the ISSCL.

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National Shellfish Sanitation Program
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Manual of Interpretations

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Model Ordinance Reference: Chapter III@.02A
NSSP Guidance Document - Approved NSSP Laboratory Tests
NSSP Guidance Document - Shellfish Laboratory Evaluation Checklist

Key Words: Single Dilution, MPN, Classification, Sampling, Seawater

Question: What are the options for use of a 12-tube single dilution (no dilution) most probable number (MPN) test for growing area water samples?

Interpretation:

The 12-tube single dilution MPN test may be used to survey and classify shellfish growing waters in the Approved classification in accordance with the conditions specified in this interpretation. Table 1 is a summary of the applicable criteria.

Table 1 - Applicable Criteria for use of the 12-Tube Single Dilution Test

12-tube, single dilution Approved Areas		
Use	**Total Coliforms For routine monitoring and survey**	**Fecal Coliforms For routine monitoring, and survey**
Sample inocula:	1 ml per tube	5 ml per tube
Count range:	9 to 248 MPN	2 to 50 MPN
Standard:	70 MPN/100 ml	14 MPN/100 ml
Allowed 90th percentile:	140 MPN	28 MPN

Background:

The use of a single dilution MPN test for sampling shellfish growing waters emerged from the 8th National Shellfish Sanitation Workshop in 1974. At that Workshop, it was recognized that the single dilution MPN test is a simpler approach than either the five or 3-tube, multiple dilution MPN test because it requires fewer tubes than the 5-tube multiple dilution MPN test, media of one strength, no diluent, quicker inoculation, less incubator and/or waterbath space, fewer pipets, and, generally yields better data. The conventional MPN procedure simply uses multiple dilutions to expand the range of determinate counts that can be obtained by the single dilution test procedure. In their deliberations, Workshop conferees agreed:

1. That the number of tubes in each dilution for the multiple tube test may vary from standard published tables to suit the purposes of a particular sampling program provided the confidence limits of the test shall not exceed the upper confidence limits of a 3-tube, three dilution MPN test.

2. That a 12-tube single dilution series can be used to routinely monitor closure lines and, where appropriate classify areas within the limits of the test.

3. That the volume used for the 12-tube single dilution test should be such that when half of the tubes are positive, the MPN value would correspond to the median value of the microbiological standard.

Requirements for dilution volumes and numbers of tubes

Although there is no limit to the number of tubes that could be used in a single dilution MPN test, Workshop conferees agreed to the use of the 12 tube single dilution test as an alternative to the three and 5-tube, multiple dilution test. Specific criteria for determining sample volume were developed to meet the requirement to maintain the median value for the microbiological standard at 70 MPN/100 ml for total coliform organisms and 14 MPN/100 ml for fecal coliform organisms when six of the 12 tubes in the single dilution series were positive. The inoculum volumes required for the 12-tube, single dilution test have been calculated as 1 ml per tube and 5 ml per tube for total and fecal coliform organisms, respectively. The total inoculum is 12 ml for the total coliform test and 60 ml for the fecal coliform test. The range of determinate values for each sample volume is shown in Table 2.

Table 2 - MPN Table 12-tube, single dilution

1 ml sample inoculum			5 ml sample inoculum	
Number of Positive Tubes	**MPN/100 ml**		**Number of Positive Tubes**	**MPN/100 ml**
0	<9		0	<2
1	9		1	2
2	18		2	4
3	29		3	6
4	41		4	8
5	54		5	11
6	70		6	14
7	88		7	18
8	110		8	22
9	139		9	28
10	179		10	32
11	248		11	50
12	>248		12	>50
Range 9 to 248			Range 2 to 50	

Similar calculations for the use of the 12-tube single dilution MPN test to meet the Restricted area classification result in sample inocula of 0.1 ml per tube for the total coliform test and 0.8 ml per tube for the fecal coliform test. The total inoculum is 1.2 ml for total coliforms and 9.6 ml for fecal coliforms. The range of determinate values for each sample volume is shown in Table 3. However, it is not recommended that the 12-tube single dilution MPN test be used for monitoring total coliforms from restricted areas because of the potential for errors in pipetting such small volumes as 0.1 ml.

Table 3 - MPN Table 12-tube, single dilution

0.1 ml sample inoculum			0.8 ml sample inoculum	
Number of Positive Tubes	**MPN/100 ml**		**Number of Positive Tubes**	**MPN/100 ml**
0	<87		0	<11
1	87		1	11
2	182		2	23
3	288		3	36
4	406		4	51
5	539		5	67
6	700		6	88
7	875		7	109
8	1099		8	137
9	1386		9	173
10	1792		10	224
11	2485		11	311
12	>2485		12	>311
Range 87 to 2485			Range 11 to 311	

Potential classification impact - NSSP variability criteria

The water quality criteria of the National Shellfish Sanitation Program consists of two parts: the measure of central tendency (median or geometric mean) and the measure of variability (the 90th percentile or upper ten percent). For simplicity, the measure of central tendency will be referred to as the median, and the variability as the 90th percentile. The median value of the classification criteria was required to remain at the level of both the three and 5-tube tests (70 MPN/100 ml for total coliforms and 14 MPN/100 ml for fecal coliform organisms). The variability of the data depends on the sampling variability of the test itself and other factors related to changing conditions in the water being sampled. The NSSP has addressed this by using the upper two-sided 95% confidence limit for the median value of the microbiological standard and designating it as the

allowed 90th percentile.
For a 3-tube, multiple dilution MPN test, the upper two-sided 95% confidence limit for a median value of 70 MPN/100 ml is 330 MPN/100 ml; for a 5-tube multiple dilution MPN test, the upper two-sided 95% confidence limit for a median value of 70 is 230 MPN/100 ml. For a 12-tube single dilution test, the upper two-sided 95% confidence limit for a median of 70 MPN/100 ml is 140 MPN/100 ml. For a median value of 14 MPN/100 ml, the upper two-sided 95% confidence limits for three and 5-tube, multiple dilution tests are approximately 49 MPN/100 ml and 43 MPN/100 ml respectively. For the 12-tube single dilution test, the upper two-sided 95% confidence limit for a median value of 14 MPN/100 ml is 28 MPN/100 ml. Hence, the criteria for the 12-tube, single dilution test for total coliforms is a median of 70 MPN per 100 ml with not more than 10% of the samples exceeding 140 MPN/100 ml; for fecal coliforms, the criteria are a median of 14 MPN per 100 ml with not more than 10% of the samples exceeding 28 MPN/100 ml.

The 5-tube, multiple dilution MPN test is more precise than the 3-tube, multiple dilution test; and, the greater precision is reflected in the reduced value of the allowed 90th percentile. Notwithstanding the difference in numerical value, each of these criteria represent an equal probability that the waters being sampled are of the same sanitary quality. Since the 12-tube, single dilution test has been found to be more precise than the 5-tube, multiple dilution test over two-thirds of its range (from three to 11 tubes positive), the difference in the magnitude of the values (28 versus 43) between the 12-tube and 5-tube tests is merely a function of the relative precision of the two tests and represents an equal probability that the waters being sampled are of the same sanitary quality. Thus, the impact on the water sampling program from the use of the 12-tube, single dilution test should be negligible if properly applied.

Restricted Areas

By extending the guidelines developed by Workshop conferees, the 12-tube, single dilution test MPN table (Table 3) could be used with medians of 700 MPN/100 ml for total coliforms and 88 MPN/100 ml for fecal coliforms. For these 12-tube, single dilution tests, the allowed 90th percentiles would be an MPN of 1386/100 ml for total coliforms and an MPN of 173/100 ml for fecal coliforms.

Calculation

This method limits the range of determinate values obtainable, and indeterminate values must be treated mathematically to ensure that they receive proper consideration. Refer to Guidance Document A.7 - Estimating the 90^{th} Percentile for the procedure.

Other References:
U.S. DHEW/PHS/FDA Shellfish Sanitation Branch, “Proceedings Eighth National Shellfish Sanitation Workshop,” January 16-18, 1974, New Orleans, LA

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Manual of Interpretations

Interpretation Number:	01-IV-@.02-100	**Date:**	January 4, 1995
		Reissued:	January 19, 2001
		Revised:	December 8, 2002

Model Ordinance Reference: Chapter IV@.02D(3)(a)
Chapter IV@.02E(3)(a)

Key Words: Water Samples; Time Interval; Adverse Pollution Conditions; Remote Areas

Question: What is the acceptable time interval between water quality samples collected from approved growing areas when using adverse pollution condition monitoring (IV@.02E(3)(a)), or an approved area designated as remote (IV@.02D(3)(a))?

Interpretation:

In accordance with Chapter IV@.02E(3)(a) and Chapter IV@.02F(6)(a), approved areas monitored under adverse pollution conditions shall have a minimum of five (5) samples collected annually from each station in the growing area. Samples shall be collected at intervals, which distribute them over a twelve (12) month period unless it can be demonstrated through data analysis that adverse pollution conditions are represented by a shorter time period. In this case, sampling may be limited to the reduced time period and shall include a minimum of five (5) samples representative of the adverse pollution condition. Sample collection shall be timed to distribute samples over the entire reduced monitoring period.

In accordance with Chapter IV@.02D(3)(a), approved areas designated as remote shall have a minimum of two (2) samples collected annually from each station in the area. Ideally, sample collection shall be timed to distribute samples over a twelve (12) month period. If the two-sample minimum is incorporated by the SSCA, then sample collection shall occur at a frequency of one (1) sample every six (6) months.

It is always the option of the SSCA to collect more than the minimum number of samples required by theModel Ordinance. When the SSCA elects to collect more than the minimum requirement, it is recommended that additional samples be distributed over a twelve (12) month period.

The Model Ordinance neither intends nor implies that sample collection be performed in a manner which results in multiple samples per sampling station visit or multiple samples over several consecutive days or weeks.

Rationale:

Although the Model Ordinance is not specific concerning the time interval between sample collection for adverse pollution condition monitoring in approved areas, or for approved areas designated as remote, it is a basic premise of the NSSP to coordinate sample collection to provide data representative of water quality over time. Collection of multiple samples on the same day or over brief time intervals negates the intent of the Model Ordinance and the SSCA's ability to evaluate data associated with changing environmental conditions.

Supportive documentation is found in Chapter IV@.03C(3)(b)(ii), which states that for conditionally approved areas, “monthly water samples are required when the growing area is in the open status of its conditional classification.” Here, emphasis is placed on the need to sample monthly, qualifying the Model Ordinance intent to sample at discrete time intervals necessary to provide representative temporal data. Chapter IV@.02F(6)(b)(iii), specifies the requirements for systematic random sampling, stating, "A minimum of six (6) random water samples shall be collected annually from each sample station in the growing area” and Chapter IV@.02F(6)(b)(ii) states that "Sample collection shall be scheduled sufficiently far in advance to support random collection with respect to environmental conditions." By design, this strategy provides for the sampling of an area over a twelve (12) month period to ensure collection under varying environmental conditions.

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Manual of Interpretations

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Revised: December 8, 2002

Model Ordinance Reference: Chapter IV @.02 D, E, F ,G and H

Key Words: Weighted 90th Percentile, Adverse Pollution Condition, Systematic Random Sampling, Estimated 90th Percentile

Question: What is the procedure for determining the value of the 90th percentile to be used in the analysis of sample data derived from different MPN procedures?

Interpretation:

A weighted 90th percentile value is calculated for each set of samples derived from different MPN procedures.

Rationale:

A number of states have availed themselves of the advantages afforded by the action of the 8th National Shellfish Sanitation Workshop in allowing the use of a virtual limitless combination of tubes and dilutions in MPN procedures used in support of the National Shellfish Sanitation Program (NSSP). A change in the combination of tubes and/or dilutions from those traditionally used in the NSSP alters the precision or variability of the test and thus its associated 90th percentile. When a change in MPN procedures is instituted, new data with a different 90th percentile must be phased into the existing sample database. During this phase-in period a "hybrid" 90th percentile value must be calculated and used as the variability component of the bacteriological standard against which the variability of sample data is to be compared. This "hybrid" 90th percentile value is calculated by

weighting the relative contributions of each MPN method to the sample database. The resulting value is known as the weighted 90th percentile. Weighted 90th percentile values can be used equally effectively with either Adverse Pollution Condition (APC) or Systematic Random Sampling (SRS) regimes.

Calculations:

The value of the weighted 90th percentile from a data set derived from different MPN procedures is calculated in the following manner:

a. Convert the 90th percentile values for both MPN procedures to their respective base 10 logarithmic values.

b. Multiply the logarithmic values for each MPN procedure by the number of samples in the database examined by that procedure.

c. Add these logarithmic values, and then divide by the total number of samples examined.

d. Take the antilog of this value.

e. Round off conventionally to the nearest whole number.

f. This value is the weighted 90th percentile against which sample data is compared.

g. Recalculate the weighted 90th percentile when new data is added to the database.

h. Once all accumulated data is from the same MPN procedure and the transition in methodologies is complete, the corresponding 90th percentile value for this MPN procedure is then used for comparing sample data.

Example 1

Data was gathered for a sampling station under the APC sampling regime. The growing area which encompasses this sampling station is in the approved classification. The first ten samples in the database were examined by the traditional 5-tube, decimal dilution MPN test for fecal coliforms. The remaining five samples required under APC sampling were analyzed by the 12-tube, single dilution MPN test for fecal coliforms. The 90th percentile value for the 5-tube, decimal dilution MPN test for **fecal coliforms** is 43. The 90th percentile value for the 12-tube, single dilution MPN test is 28. The weighted 90th percentile value which results from this data will lie somewhere between the 90th percentile values of the MPN procedures used. Its proximity to either method's 90th percentile value will depend on the relative number of samples analyzed from each method. Since most of the samples in this example were derived from the 5-tube MPN test, the 90th percentile value calculated will be weighted toward 43.

To calculate the weighted 90th percentile for this data set:

a. The 90th percentile values of 43 for the 5-tube decimal dilution MPN test and 28 for the 12-tube, single dilution MPN test are converted to base 10 logarithms. This gives base 10 log values of 1.633 and 1.447 respectively.

b. The base 10 log values are then multiplied by the number of samples in the database examined by each MPN procedure used. Ten of 15 samples were analyzed by the 5-tube, decimal dilution MPN test. The remaining 5 of 15 were examined by the 12-tube, single dilution test. This gives 1.633 for the 5-tube test x 10 samples = 16.330 and 1.447 for the 12-tube, single dilution test x 5 samples = 7.235.

c. These values are added together and the resultant divided by the total number of samples in the database being used. Thus, 16.330 + 7.235 = 23.565, 23.565/15 = 1.571.

d. The antilog of this value is taken. In this example, the antilog of 1.571 is 37.239.

e. The antilog value is rounded off to the nearest whole number which in this example is 37.

f. The weighted 90th percentile for this data set is 37. Thirty-seven (37) is the 90th percentile value which cannot be exceeded more than 10% of the time by the sample station data in this data set under the APC sampling regime for this station to remain in the approved classification status. When new data is added to the database of this sampling station, the value of the weighted 90th percentile would have to be recalculated until the transition in methodologies is completed and all the data from this sampling station is derived from the same MPN procedure. At this time, the corresponding 90th percentile value of 28 for the 12-tube, single dilution MPN procedure in use will be employed in comparisons with sample data.

Example 2

Data was derived from a sampling station under the SRS sampling regime. The growing area which encompasses this sampling station is also in the approved classification for **fecal coliforms**. The first 18 of 30 samples were analyzed using the 3-tube, decimal dilution MPN test. The remaining 12 of 30 samples were examined using a 12-tube, single dilution MPN test. The 90th percentile values for the 3-tube, decimal dilution test in the approved classification status is 49. That for the 12-tube, single dilution MPN test is 28. Again the value for the weighted 90th percentile will be somewhere between the respective 90th percentile values of both MPN methods. Its proximity to either is a function of the number of samples in the data set contributed by each MPN procedure. In this example, a somewhat greater number of samples were derived from use of the 3-tube, decimal dilution MPN test; so that, the value of the 90th percentile will be weighted in that direction also.

To calculate the weighted 90th percentile for this data set:

a. The 90th percentile values of 49 for the 3-tube, decimal dilution MPN test for **fecal**

coliforms and 28 for the 12-tube, single dilution MPN test for **fecal coliforms** are converted to base 10 logs. This gives base 10 log values of 1.690 for the 3-tube, decimal dilution test and 1.447 for the 12-tube, single dilution MPN test.

b. These base 10 log values are then multiplied by the number of samples in the database analyzed by each MPN procedure. In this example, 18 of 30 samples were examined by the 3-tube, decimal dilution MPN test; and, 12 of 30 samples were analyzed by the 12-tube, single dilution MPN test. This gives 1.690 for the 3-tube, decimal dilution MPN test x 18 samples = 30.420 and 1.447 for the 12-tube, single dilution MPN test x 12 samples = 17.364.

c. These values are added together and the resultant divided by the total number of samples in the database being used. Thus, 30.420 + 17.364 = 47.784, 47.784/30 = 1.593.

d. The antilog of this value is determined. In this example, the antilog of 1.593 is 39.174.

e. This antilog value is rounded to the nearest whole number, which in this example is 39.

f. The weighted 90^{th} percentile value for this data set is 39. Thirty-nine (39) is the value of the 90^{th} percentile which will be compared to the estimated 90^{th} percentile calculated from the data in the sample data set collected under the SRS sampling regime and examined using the two different MPN methods. To remain in the approved status, the estimated 90^{th} percentile calculated from this data set must be less than or equal to the value determined for the weighted 90^{th} percentile of the data set. Again, the weighted 90^{th} percentile will have to be recalculated as new data becomes available. This recalculation must continue until the transition in methodologies is completed and all the data from this sampling station has been derived from the same MPN procedure. At this time, the corresponding 90^{th} percentile of 28 for the 12-tube, single dilution MPN procedure in use will be employed in comparisons to the estimated 90^{th} percentiles calculated directly from the sampling data.

Example 3

Data in this example was collected from a sampling station under the SRS sampling regime. This sampling station is in an area classified as restricted. The first 24 of the 30 samples collected were analyzed by the 5-tube, decimal dilution MPN test for **fecal coliforms**. The remaining 6 samples of the 30 collected were analyzed using a 5-tube, fivefold dilution MPN test for **fecal coliforms**. The 90^{th} percentiles value for each of these MPN procedures is 260 and 190 respectively. The value of the weighted 90^{th} percentile for this data set will be somewhere between 190 and 260. The proximity to either value will depend on the respective number of samples analyzed by each MPN method. In this example, most of the samples were derived from the 5-tube, decimal dilution MPN test. Consequently, the 90^{th} percentile value will be heavily weighted in that direction.

To calculate the weighted 90^{th} percentile for this data set:

a. The 90th percentile values of 260 for the 5-tube, decimal dilution MPN test for **fecal coliforms** and 190 for the 5-tube, fivefold dilution MPN test for **fecal coliforms** are converted to base 10 logs. This gives a base 10 logarithmic value of 2.415 for the 5-tube, decimal dilution MPN test and 2.279 for the 5-tube, fivefold MPN test.

b. These base 10 values are then multiplied by the number of samples in the database analyzed by each MPN procedure. In this example, the 5-tube, decimal dilution MPN was used in the analysis of 24 of the 30 samples while the 5-tube, fivefold dilution MPN was used to test the remaining 6 samples. Hence, 2.415, the log 90th percentile value for the 5-tube, decimal dilution MPN test is multiplied by 24, the number of samples tested by this MPN procedure to give 57.960; and, 2.279, the log 90th percentile value for the 5-tube, fivefold dilution MPN test is multiplied by 6, the number of samples obtained using this MPN procedure to give 13.674.

c. These values are added together and subsequently divided by the total number of samples analyzed by both methods. In this example, 57.960 + 13.674 = 71.634, 71.634/30 = 2.388.

d. The antilog of this value is determined. In this example the antilog of 2.388 is 244.343.

e. This antilog is conventionally rounded to the nearest whole number, which in this example is 244.

f. The weighted 90th percentile value for the data set is 244. Two hundred forty- four (244) is the value of the 90th percentile which will be compared to the estimated 90th percentile calculated from the data in the sample data set collected under the SRS sampling regime and examined using the two MPN methods. To remain in the restricted classification, the estimated 90th percentile calculated from the data set will have to be less than or equal to the value of the weighted 90th percentile obtained from the data set. This weighted 90th percentile value will need to be recalculated as more data becomes available and until such time as all the transition in methodologies is completed and all the samples have been derived from the same MPN procedure. When this occurs, the corresponding 90th percentile for the MPN procedure in use will be employed in comparisons to the estimated 90th percentile calculated directly from the sampling data.

Example 4

Data in this example was collected from a sampling station under the APC sampling regime. This sampling station is in the approved classification and 5 of 15 samples in the database were tested by the 5-tube, decimal dilution MPN test for **total coliforms**. The remaining 10 samples in the database were analyzed by the 3-tube, decimal dilution MPN test for **total coliforms**. The 90th percentile value for each of these MPN tests is 230 and 330 respectively. The value of the weighted 90th percentile will be somewhere between 230 and 330. Its proximity to either value depends on the respective number of samples analyzed by each MPN procedure. In this example, the preponderance of samples were tested by the 3-tube MPN procedure. As a result, the value of the 90th percentile

will be weighted more heavily toward 330.

To calculate the weighted 90th percentile for this data:

a. The 90th percentile values of 230 for the 5-tube, decimal dilution MPN test for **total coliforms** and 330 for the 3-tube, decimal dilution MPN test for **total coliforms** are converted to base 10 logarithms. This gives base 10 log values of 2.362 and 2.519 respectively.

b. These base 10 log values are then multiplied by the number of samples in the database analyzed by each MPN procedure. In this example, 5 of 15 samples in the database were analyzed by the 5-tube, decimal dilution MPN test. The remaining 10 of 15 samples were examined by the 3-tube, decimal dilution test. Thus, the base 10 log value of 2.362, the 90th percentile of the 5-tube MPN procedure for **total coliforms** is multiplied by the 5 samples tested by this MPN method to give 11.810. In addition, the base 10 log value of 2.519, the 90th percentile of the 3-tube MPN test for **total coliforms** is multiplied by the 10 samples examined by this MPN procedure to give 25.190.

c. These values are added together and the resultant divided by the total number of samples in the database being analyzed. In this example, 11.810 + 25.190 = 37.000, 37.000/15 = 2.467.

d. The antilog of this value is determined. For this example, the antilog of 2.467 is 293.089.

e. This antilog is rounded off to the nearest whole number, which in this case is 293.

f. The weighted 90th percentile for this data set is 293. Two hundred ninety three (293) is the value for the 90th percentile that cannot be exceeded more than 10% of the time by this sampling station under APC for it to remain in approved classification status. The value for the weighted 90th percentile must be recalculated as more data becomes available. This will continue until the transition in methodologies is completed and all samples in the database have been analyzed using the same MPN procedure. When this happens, the corresponding 90th percentile of 330 for the 3-tube, decimal dilution MPN procedure in use will be employed in comparisons with the sample data.

Other References:

1. *Schaum's Outline Series Theory and Problems of Statistics,* Second Edition, 1994, McGraw Hill, Inc.

2. U.S. DHEW/PHS/FDA Shellfish Sanitation Branch, *Proceedings Eight National Shellfish Sanitation Workshop*, January 16-18, 1974, New Orleans, LA.

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Manual of Interpretations

Interpretation Number: 01-VIII-.03-100

Date: March 20, 1996
Revised: December 8, 2002

Model Ordinance Reference: Chapter VIII.03

Key Words: *Vibrio vulnificus*, matrix, AMMWT

Question: What is the procedure for calculating the average monthly maximum water temperature (AMMWT) used in applying the *Vibrio vulnificus* control matrix?

Interpretation:

The state shellfish control authority shall determine, for each shellfish growing area, the AMMWT for each month using historical water temperature data for each of the previous five (5) years.

The procedure for calculating the AMMWT for each shellfish growing area is as follows:

1. List the maximum water temperature recorded for each day of the month.

2. Calculate the average maximum water temperature for the month using the daily water temperatures listed in step 1. **NOTE:** If water temperature data are not available for each day of the month, then use temperature data for those days it is available. These data shall be representative of water temperatures observed throughout the month.

3. Perform steps 1 and 2 for each month for each of the previous five years.

4. Determine the AMMWT by calculating the mean of the five (5) average maximum water temperatures from step 3 for each month.

Rationale:

The procedure outlined above is consistent with the intent of the 1995 ISSC to calculate the AMMWT using maximum **daily** water temperatures, not the single warmest water temperature recorded during the month. This procedure is identical to that used to calculate average maximum monthly air temperatures (AMMAT) required under Chapter VIII.03.

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Manual of Interpretations

Interpretation Number: 01-VIII-.03-101 **Date:** May 15, 1996
Revised: December 8, 2002

Model Ordinance Reference: Chapter VIII.03, Chapter IX.02.C(2)

Key Words: Shellstock Shippers, Temperature, Transport

Question: Once harvested, what is the maximum time shellstock can be held outside temperature control? Once brought to shore, what is the maximum time before certified dealers must place shellstock in temperature control?

Interpretation:

All shellstock (not intended for wet storage or depuration) must be placed under temperature in accordance with the temperature matrices in Chapter VIII.03. Shellfish harvested from areas not implicated in *Vibrio vulnificus* or *Vibrio parahaemolyticus* illnesses must comply with the time-temperature matrix in Option 3 of Chapter VIII.03. Once the shellstock is removed from the water the time begins in determining when the shellstock must be placed under temperature control. This includes the time the shellstock are on the boat, beach, flat, etc., during transport to a dealer or processor; and any processing or storage by the dealer.

This minimum criteria does not preclude an SSCA from requiring stricter requirements. FDA recommends refrigerating shellfish as soon as possible after harvest.

Shellfish harvested from areas implicated in *Vibrio vulnificus* or *Vibrio parahaemolyticus* illnesses must comply with the requirements as specified in Options 1 and 2, respectively, of Chapter VIII.03. As above, the maximum time before shellstock must be placed under temperature control begins when the shellstock are removed from the water.

Once placed under temperature control, shellstock shall not be permitted to remain without ice, mechanical refrigeration, or other approved means of lowering the internal body temperature of the shellstock to 50°F or less for more than 2 hours at points of transfer such as loading docks (Chapter IX.02.C(2).

Rationale:

Shellstock deterioration and bacteriological growth occurs after harvest. Studies of shellstock handling have also shown that inadequate refrigeration can accelerate the growth of bacteriological pathogens, spoilage organisms, as well as Vibrio species.

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MANUAL OF INTERPRETATIONS

Interpretation Number 01-XI-.01-100 **Date:** October 26, 1998
Revised: December 8, 2002

Model Ordinance Reference:
Chapter I @.02 H.(2)(c)-(e)
Chapter XI 01.B.(2) and 01.C and 01.D
Chapter XII 01.B and 01.C
Chapter XIII 01.B.(2)
Chapter XIV 01.B and 01.C

Key Words: Time/Temperature abuse, Enforcement Follow-up, Microbiological testing

Question: Is microbiological testing by the shellfish control authority a suitable means of determining whether a critical deficiency exists when a dealer fails to control shellstock or shucked product time/temperature exposure during storage or processing as specified in the above referenced sections of Chapters XI, XII, XIII, and XIV. If such a critical deficiency exists, is microbiological testing (i.e. where the product may be released if no microbiological contaminants are found at or above levels of concern) a suitable enforcement follow-up?

Interpretation:

Failure to comply with the time/temperature exposure conditions specified in the referenced sections of the Guide for the Control of Molluscan Shellfish Chapters XI, XII, XIII, and XIV constitutes a critical deficiency. Chapter X.0l.C(2)and(3) states that, even if processors choose to select critical limits other than those specified in these referenced sections, they must meet the conditions as components of good manufacturing practice.

Violation of the temperature control requirements is a critical deficiency. When a critical deficiency is observed, product must be controlled to prevent contaminated or adulterated shellfish from reaching consumers. Microbiological testing is not a suitable means of determining whether the deficiency is a critical deficiency. There are no provisions in the NSSP for any rating other than critical for such deficiencies.

The referenced sections of Chapter I state that when a critical deficiency is detected during an inspection, the dealer must correct the deficiency during the inspection and must cease production affected by the deficiency until the deficiency is corrected. Failing that, the Shellfish Control Authority must immediately begin certification suspension or revocation proceedings. Additionally the Authority is required to ensure that contaminated or adulterated product does not reach the consumer.

A suitable correction for a time/temperature abused product is destruction or processing the product in such a way that the microbiological hazard is eliminated (e.g. thermal processing) and modifying plant operations in such a way that a reoccurrence of the deficiency is not likely (e.g. pre-chilling product, reducing the size of the shucking or finished product containers, adding ice to the product during processing, making adjustments to or repairs to mechanical cooling systems). If these kinds of corrections are not enacted during the course of the inspection, the Shellfish Control Authority must immediately initiate certification revocation or suspension proceedings.

Microbiological testing (i.e. where the product may be released if microbiological contaminants are not found at or above levels of concern) is not a suitable means of ensuring that contaminated or adulterated product does not reach the consumer. The sample size necessary to ensure that any one microbiological contaminant is not present is prohibitively large, especially considering the low levels of organisms of concern and the typically high variability of the lot. Additionally, microbiological analysis will only provide information on the pathogen for which analysis was performed, and low levels of indicator organisms is not a reliable assurance that pathogens are not present in the product.

Where the dealer fails to take the appropriate corrective action as outlined above and required by I.@.02 H.(2)(c), the shellfish Control Authority must initiate decertification procedures, as required by I.@.02 H.(2)(d), and must ensure that the product is removed from commerce or is processed to eliminate the hazard, consistent with I.@.02 H.(2)(e).

Rationale:

Shellfish is a potentially hazardous food, particularly since it is frequently consumed raw. Consequently, controls must be in place to prevent the growth of naturally occurring pathogens as well as pathogens that may be introduced into the product during processing. Rapid chilling and holding the product at refrigeration temperature are two of the most practical and effective means of

controlling the microbial hazards in raw molluscan shellfish.

Naturally occurring Vibrio sp., such as *Vibrio vulnificus* and *Vibrio parahaemolyticus,* are human pathogens found in shellfish. During periods of warm water temperature, the number of these organisms may increase to high levels and further bioaccumulate in the shellfish during processing and storage. These organisms grow rapidly at temperatures of 70 degrees F or above (one log increase in 2 hrs). Conversely, little or no growth occurs at temperatures at or below 45 degrees F. Therefore, it is critical for shellfish products to be rapidly chilled to and held at 45 degrees F or less. Further, enteric pathogens may be introduced into the shellfish through improper handling during post harvest practices (e.g. use of contaminated water for shellstock washing or wet storage) or during shucking and repacking operations. Growth of these pathogenic organisms may also be prevented by rapidly chilling the product to 45 degrees F or less.

Other References:

1) 21 Code of Federal Regulations, Part 123 - Fish and Fishery Products, Government Printing Office, Washington , DC
2) 21 Code of Federal Regulations, Part 110 - Current Good manufacturing Practice in Manufacturing, Packing, or Holding Human Food, Government Printing Office, Washington , DC

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MANUAL OF INTERPRETATIONS

Interpretation Number: 01-XI-.02-100

Date: October 26, 1998
Revised: December 8, 2002

Model Ordinance Reference:
Chapter I.@.02.H.(2).(c)-(e)
Chapter XI.02.A.(2)
Chapter XI.02.E. (4)

Keywords: Ice, sanitary quality, stored, protected, adulteration

Question: What are the factors affecting the sanitary quality of ice and actions that should be taken when ice is improperly stored, protected or subject to adulteration?

Interpretation:

Ice is a regulated food which is used or intended for use on molluscan shellfish either in-shell or shucked for human consumption. Ice must be protected from adulteration as defined in the Food, Drug and Cosmetic Act §402.

In accordance with the Guide for the Control of Molluscan Shellfish any ice used in the processing, storage or transport of shellstock or shucked shellfish shall be made on-site from potable water in a commercial machine; or received from a facility sanctioned by the appropriate regulatory authority. Ice must be stored in a safe and sanitary manner to prevent its contamination.

The dealer shall use only equipment and utensils, including approved plastic ware which are: (1) constructed in a manner and with materials that can be cleaned, sanitized, maintained or replaced in a manner to prevent contamination of ice and shellfish products; and, (2) free from any exposed screws, bolts, or rivet heads on food contact surfaces. The dealer shall assure that all joints on food contact surfaces: (1) have smooth easily cleanable surfaces; and (2) for stainless steel, are welded. "Item 12 - Ice: approved source, sanitary, protected" is designated as a Swing item and identified as either a Key or Critical deficiency (NSSP Standardized Shellfish Processing Plant Inspection Form (ISSC Form 93-01(A))

Key Deficiency: Applies when conditions may lead to adulteration of ice.
Critical Deficiency: Applies when the ice is visibly adulterated.

Key Conditions:

The following conditions are representative of Key deficiencies:

Improperly constructed, maintained, cleaned, and sanitized walk-in coolers, insulated rooms, or other storage containers;

- Improperly constructed, cleaned, sanitized and stored totes, scoops, shovels, or other utensils used in handling ice;
- Ice making machines not maintained or protected (reservoir).

Corrective Actions:

Ice storage unit:

- Discontinue the use;
- Set a correction schedule for cleaning, repair, or replacement

Ice handling equipment:

- Discontinue use, clean and sanitize; or
- Replace with approved equipment

Ice machines:

- Shut down and initiate cleaning and/or repair.

Critical Conditions:

The following conditions are representative of Critical conditions:

- Dirt or other debris such as insulation, or paint chips observed in the ice;
- Ice is observed to be exposed to mold, slim, rust, condensate from cooler evaporator units, or other sources of adulteration.
- Ice exposed to foot traffic and observed to be used in direct contact with product;
- Stored food items in the ice.

Critical deficiency corrective action:

1. Discard ice;
2. Repair or replace ice storage units and equipment which caused the ice to be adulterated, or obtain ice from another source;
3. Destroy all product exposed to ice produced under conditions of adulteration

Where the dealer fails to take the appropriate corrective action as outlined above and required by Chapter I.@02.H(2)(a), the shellfish Control Authority must initiate decertification procedures, as required by Chapter I.@02.H(2)(b), and must ensure that the product is removed from commerce or is processed to eliminate the hazard, consistent with Chapter I.@02.H(2)(c).

Rationale:

Ice is considered a food when used in direct contact with shellfish. As a food ice must be stored and handled in the same sanitary manner as any other food product. No food product shall enter into commerce that is either injurious to health or is otherwise adulterated. Contaminated ice used in direct contact with shellfish will cause the shellfish to be adulterated. Each shellfish dealer must protect molluscan bivalves and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate and other chemical, physical and biological contaminants.

All materials used in equipment, utensils, walk in coolers, or rooms used to make or store ice must meet food contact surface requirements. A preventive or corrective measure should be used to control an identified food safety hazard to ensure that no product shall enter into commerce that is either injurious to health or is otherwise adulterated.

Other References:

1. Food and Drug Administration, “Federal Food, Drug and Cosmetic Act”, Government Printing Office, Washington, DC
2. Food and Drug Administration, “1997 Food Code”, Washington, DC.
3. 21 Code of Federal Regulations, Part 123 - Fish and Fishery Products, Government Printing Office, Washington, DC
4. 21 Code of Federal Regulations, Part 110 - Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, Government Printing Office, Washington, DC

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MANUAL OF INTERPRETATIONS

Interpretation Number: 01-XI-.02 -101 **Date:** January 15, 1999
Revised: December 8, 2002

Model Ordinance Reference: Chapter XI.02.B(1)
Chapter XI.02.B(2)

Key Words: Food contact surfaces, cleaning, sanitizing, equipment construction

Question:
1) What is a **food contact surface**?
2) What constitutes effective cleaning and sanitizing of a food contact surface?
3) What constitutes acceptable construction of shellstock grinders and parts thereof are considered food contact surfaces?

Interpretation:

1) A **"food contact surface"** means a surface of equipment or a utensil with which food normally comes into contact; or a surface of equipment or a utensil from which food or liquid may drain, drip, or splash into a food; or onto a surface normally in contact with food. Food contact surfaces include, but are not limited to, equipment and utensils such as; shucking knives and handles, shucking hammers and handles, shucking blocks, ice scoops and shovels, ice bins, skimmers, blower tanks, shucking pails, shellstock grinders.

2) Food-contact surface shall be clean to sight and touch. Cleaning and sanitizing shall occur prior to use each day and any time during use when contamination may have occurred. At a minimum, food contact surfaces shall be cleaned and sanitized every four hours. More frequent cleaning may be necessary depending on the characteristics of the equipment and its use and the amount of food residue accumulation. At the end of each day, food contact equipment and utensils shall be washed and rinsed.

Food contact surfaces shall be effectively washed to remove or completely loosen soils by manual or mechanical means such as the application of detergents; hot water; brushes; or high pressure sprays. If washing in sink compartments is impractical such as when equipment is fixed or utensils are too large, washing shall be done using an alternative manual procedure. In such instances, washing shall be facilitated by 1) disassembling equipment as necessary to allow access of the detergent solution to all parts and equipment components and 2) utensils shall be scraped or rough cleaned to remove food particle accumulation.

The cleaning of food contact surfaces shall occur prior to sanitizing in order for the sanitizer to be effective in destroying vegetative bacteria. Sanitizers may be applied by immersion, spraying or brushing. Sanitizer concentration shall be in accordance with the manufacturer's directions on the label.

3) Parts of a shellstock grinder which are considered food contact surfaces include; the blade, the area behind the blade including the motor shaft from the blade to the motor housing, and the inside surface of the housing or cover surrounding the blade. These food contact parts shall be manufactured from high impact materials that are easily cleanable and non-corrosive. The grinder must be constructed to be easily disassembled and assembled to facilitate inspection, maintenance, cleaning, and sanitizing.

Guidelines for grinder construction:

1) The motor shaft should be of corrosion resistant material.
2) Juncture point where the motor shaft enters the blade chamber must be sealed to reduce dirt and detritus deposition around the shaft.
3) The blade must be made from a single piece of high impact non-corrosive material. Blade teeth must be an integral part of the blade, or if grinding surfaces are used instead of teeth, they must be welded to the face of the blade with all welds ground smooth.
4) The housing around the blade assembly must be constructed of material that is corrosion resistant.
5) Bolts or screws must be constructed of corrosion resistant material to prevent rust and corrosion.
6) The inside surface of the blade housing must be smooth, and if welded ground smooth for easy cleaning.

7) The blade housing must be designed with an easily removable cover that will open up the **entire blade assembly area** to facilitate inspection, cleaning, sanitizing, and maintenance.

Rationale:

Each shellfish dealer is responsible for assuring that all food contact equipment and utensils meet the design, construction, repair, and cleaning requirements of the NSSP, Guide for the Control of Molluscan Shellfish. Food contact surfaces must be cleaned and sanitized at a minimum frequency and in accordance with proper procedures to prevent contamination of shellfish by microbial pathogens and chemicals. Consistent with the FDA Food Code, cleaning and sanitizing shall occur at least every four hours and where necessary more often, depending on the accumulation of food debris or exposure to other contaminants. Under the NSSP Guide for the Control of Molluscan Shellfish and 21 CFR, Part 123, shellfish dealers are responsible for monitoring and maintaining records of the cleaning and sanitizing of food contact surfaces.

Other References:

1. 21 Code of Federal Regulations, Part 110 - Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, U.S. Food and Drug Administration
2. 21 Code of Federal Regulations, Part 123 - Fish and Fishery Products, U.S. Food and Drug Administration
3. 1997 Food Code, U.S. Food and Drug Administration
4. Food Equipment American National Standard NSF International Standard ANSI/NSF, NSF International, Ann Arbor, MI, 48113

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MANUAL OF INTERPRETATIONS

Interpretation Number: 01-XV-.03-100

Date: February 14, 2001
Revised: December 8, 2002

Model Ordinance Reference: Chapter XV.03.L.(1)(c)
NSSP Guidance Documents
Approved NSSP Laboratory Tests

Key Words: Sample Volume, Fecal Coliform Counts, MPN Table and Count Range

Question: What sample volume is inoculated in the 12-tube, single dilution MPN test for end product depurated shellfish samples?

How are fecal coliform counts determined using the 12-tube, single dilution MPN test for end product depurated shellfish?

Interpretation:

Two (2) mls (1 gram) of a 1:1 dilution of shellfish homogenate is inoculated into each tube of single strength lauryl tryptose presumptive broth in the 12-tube, single dilution MPN test for end product depurated shellfish samples. Inoculated tubes are incubated in an air incubator at 35°C for 24 hours. Any gas positive presumptive broth tubes are then subcultured to EC medium and incubated in a water bath at 44.5°C for 24 hours. The presence of any amount of gas or effervescence in the EC tubes constitutes a positive test. Fecal coliform counts are read from the MPN Table below and reported as MPN/100 grams.

MPN Table for End-product Depurated Shellfish Samples	
Number of Positive Tubes	**MPN/100 grams**
0	**< 9.0**
1	**9.0**
2	**18**
3	**29**
4	**41**
5	**54**
6	**70**
7	**88**
8	**110**
9	**139**
10	**179**
11	**248**
12	**>248**
Count range 9 to 248	

Rationale:

The use of the 12-tube, single dilution MPN test for end-product depurated shellfish was established as an acceptable method of analysis with the ISSC's adoption of the rewrite of *Model Ordinance*, Chapter XV, the Depuration Chapter in 1998. However, no specific guidance was provided on sample volumes to be examined or how fecal coliform counts were to be determined. Since the volume of sample inoculated in a single dilution MPN test controls the range of counts that can be determined, it is essential that an appropriate volume be inoculated to encompass the count range prescribed as the critical limits for depuration plant performance listed for all shellfish species encountered.

The inoculation of two (2) ml (yielding 1 gram) of sample from an initial 1:1 dilution of shellfish homogenate into each tube of the 12-tube, single dilution MPN produces a range of counts from 9 to 248. This range is sufficient to cover the critical limits of performance of all shellfish types listed in Chapter XV.03.L(1)(c).

Remarks:

Comments received from the review of the draft version of Interpretation 01-XV.03-100 indicated that the content of the Interpretation was too broad to be dealt with effectively in a single Interpretation. For this reason, this second Interpretation was developed from information presented in the first concerning the correct application of the single dilution MPN test to end product depurated shellfish.

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IX. HISTORY OF THE NATIONAL SHELLFISH SANITATION PROGRAM

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HISTORY OF THE NATIONAL SHELLFISH SANITATION PROGRAM

Introduction

The National Shellfish Sanitation Program (NSSP) was developed in 1925 when the U. S. Public Health Service responded to a request for assistance from local and state public health officials in controlling disease associated with the consumption of raw shellfish (oysters, clams, and mussels).

The public health control procedures established by the Public Health Service were dependent on the cooperative and voluntary efforts of State regulatory agencies. These efforts were augmented by the assistance and advice of the Public Health Service (now the Food and Drug Administration) and the voluntary participation of the shellfish industry. These three parties combined to form a tripartite cooperative program. The guidelines of the program have evolved into the NSSP Handbook which is managed and updated by the Interstate Shellfish Sanitation Conference (ISSC).

A Declaration of Principles

Oysters, clams and mussels are unique foods which have been enjoyed by consumers for many years. The popularity of shellfish as a food can be traced through several centuries of American history. To early settlers, the food resources of the sea were one of the most valuable and readily usable of the natural resources, particularly from the estuaries. It is not surprising that shellfish were foremost among their staple food items.

The value of these renewable natural resources to the early settlers was reflected in colonial legislation designed to encourage their wise use. Over 300 years ago in 1658, the Dutch Council of New Amsterdam passed an ordinance regulating the taking of oysters from the East River. Other early legislation, including that of New York (1715), New Jersey (1730), and Rhode Island (1734), was designed to regulate harvesting, presumably as conservation measures to guarantee a continuing supply.

Public health controls of shellfish became a national concern in the U.S. in the late nineteenth and early twentieth century when public health authorities noted a large number of illnesses associated with consuming raw oysters, clams, and mussels. These shellfish-associated outbreaks were also medically recorded in other parts of the world, most notably in European countries. During the winter of 1924, there occurred a widespread typhoid fever outbreak, with cases in New York, Chicago, and Washington, D.C., which was finally traced to sewage polluted oysters. Local and state public health officials, and the shellfish industry became sufficiently alarmed over this outbreak to request that the Surgeon General of the United States Public Health

Service develop necessary control measures to ensure a safe shellfish supply to the consuming public.

In accordance with this request, the Surgeon General called a conference of representatives from state and municipal health authorities, state conservation commissions, the Public Health Service and its Bureau of Chemistry (later to become the Food and Drug Administration), the Bureau of Commercial Fisheries (now National Marine Fisheries Service) and the shellfish industry. This historic conference was held in Washington, D.C. on February 19, 1925.

The members of the conference recommended eight resolutions for the sanitary control of the oyster industry. These included:

> "The beds on which shellfish are grown must be determined, inspected, and controlled by some official state agency and the U.S. Public Health Service."
>
> "The plants in which shellfish are shucked or otherwise prepared or packed by the shipper must be inspected and controlled by some official state agency and the U.S. Public Health Service."
>
> "There must be such governmental supervision and such trade organization as will make plain the source of shellfish and will prevent shellfish from one source being substituted for those from another source. This will be chiefly a problem of the individual state."
>
> "The methods of shipping must be supervised, inspected, controlled and approved by the proper official federal and state agency."
>
> "The product must conform to an established bacterial standard and must meet federal, state, and local laws and regulations relative to salinity, water content, food proportion and conform to the Pure Food Laws standards."

The conference also established a committee to develop further necessary guidelines to recommend control practices for the sanitary control of the shellfish industry.

The basic concepts in formulating a program of national public health controls were reiterated by the Surgeon General in his letter of August 12, 1925, to state health officers and all others concerned. This letter set forth the following understandings:

1. "The Public Health Service considers that the responsibility for the sanitary control of the shellfish industry rests chiefly upon the individual states; and that the requisite coordination and uniformity of control may best be achieved

by mutual agreement among the states, with the assistance and cooperation of the Public Health Service..."

2. "In accordance with this principle, it is considered that each producing state is directly responsible for the effective regulation of all production and handling of shellfish within its confines, not merely for the protection of its own citizens, but equally for safeguarding such of its product as goes to other states..."

3. "In order that each state may have full information concerning the measures carried out in other states, the Public Health Service will undertake systematic surveys of the machinery and efficiency of sanitary control as actually established in each producing state, and will report thereon for the information of the authorities of other states. It is believed that, in addition to furnishing valuable information, these reports will have an important influence in stimulating the development of better sanitary control and in promoting substantial uniformity on a higher plane."

4. "The officers of the Public Health Service assigned to this survey work will assist the state agencies in determining their sanitary problems, in formulating plans for adequate sanitary control, and in making actual sanitary surveys as far as practicable."

5. "In addition to the above, the Public Health Service will continue to extend the services which it is already rendering, especially in conducting scientific investigations of fundamental importance to control, and in serving as a clearinghouse for the interchange of information and the discussion of policies between state authorities."

To implement this program, the members of the 1925 conference agreed that the producing states would issue "Certificates," i.e., a permit to operate, to shellfish shippers that meet agreed upon sanitary standards. The Public Health Service would serve as a clearinghouse for information on the effectiveness of the state control programs. This clearinghouse responsibility was met initially through issuance of a periodic "Progress Report on Shellfish Sanitation" describing the shellfish sanitation program in each state. This procedure was subsequently abandoned in favor of a "program endorsement" concept. Under this concept, the Public Health Service made a continuing appraisal of each state's shellfish sanitation program to determine if the control measures were in substantial accord with the provisions of the current "Manual of Recommended Practice for Sanitary Control of the Shellfish Industry." The Public Health Service also published a list of all shellfish shippers certified by those states that maintained "satisfactory" control programs.

The procedures used by the Public Health Service in fulfillment of its obligations under the Public Heath Service Act resulted from an understanding that implementation and enforcement of the necessary public health controls could best be accomplished under state laws with federal technical support and industry participation. The National Shellfish Sanitation Program, now the Interstate Shellfish Sanitation Program, is dependent entirely upon the states adopting the recommended requirements and the cooperative and voluntary efforts of state regulatory agencies and the shellfish industry.

NATIONAL SHELLFISH SANITATION PROGRAM

The National Shellfish Sanitation Program (NSSP) developed from public health principles and Program controls formulated at the original conference on shellfish sanitation called by the Surgeon General of the United States Public Health Service in 1925. These fundamental components were described in a supplement to ***Public Health Reports***, ***Report of Committee on Sanitary Control of the Shellfish Industry in the United States*** (Frost, 1925)

The public health control procedures established by the Public Health Service were dependent on the cooperative and voluntary efforts of state regulatory agencies. These efforts were augmented by the assistance and advice of the Public Health Service (replaced by the Food and Drug Administration) and the voluntary participation of the shellfish industry. These three parties combined to form a tripartite cooperative program.

To carry out this cooperative control program, each partner accepted responsibility for certain procedures.

Each shellfish shipping state adopted adequate laws and regulations for sanitary control of the shellfish industry, completed sanitary surveys of harvest areas, delineated and patrolled restricted areas, inspected shellfish plants, and conducted such additional inspections, laboratory investigations, and control measures as were necessary to insure that the shellfish reaching the consumer had been grown, harvested and processed in a sanitary manner. The state annually issued numbered certificates to shellfish dealers who complied with the agreed-upon sanitary standards, and forwarded copies of the interstate certificates to the Food and Drug Administration (FDA).

The FDA made an annual review of each state shellfish control program including the inspection of a representative number of shellfish processing plants. On the basis of the information thus obtained, the FDA determined the degree of conformity the state control program had with the NSSP. For the information of health authorities and others concerned, the FDA published a monthly list of valid interstate shellfish shipper certificates.

The shellfish industry cooperated by obtaining shellfish from safe sources, by providing plants which met the agreed upon sanitary standards, by maintaining sanitary operating conditions, by

placing the proper certificate number on each package of shellfish, and by keeping and making available to the control authorities records which showed the origin and disposition of all shellfish.

Although the basic public health principles of the NSSP have remained unchanged, program procedures have been updated and improved upon at periodic intervals. The original 1925 "Report of Committee on Sanitary Control of the Shellfish Industry in the United States" was revised and reissued in 1937 and again in 1946. The document was then divided into two parts Part II entitled "Sanitation of Harvesting and Processing of Shellfish" was issued in 1957 and in 1959, Part I, "Sanitation of Shellfish Growing Areas." The need for a specialized program of this nature was reaffirmed by the cooperating members at the First National Shellfish Sanitation Workshop held in Washington, D.C., (Jensen, 1954) and at subsequent National Shellfish Sanitation Workshops (Jensen,1956, 1958, 1961; Houser, 1964). A more complete summary of the history and evolution of the NSSP and its early approaches to resolution of shellfish sanitation issues can be found in David Clem' s historical overview (Clem, 1994).

In the 1940's, the NSSP moved beyond its original 1925 objective of insuring that shellfish shipped in interstate commerce were safe for human consumption. Paralytic shellfish poison became a matter of public health concern and requirements were added to address this public health hazard. In 1957, when it was determined that shellfish could concentrate certain radionuclides, the procedures were revised to include public health controls for the pollutant. In the 1960's and 1970's, the program was again revised to address public health concern associated with heavy metals and pesticides.

Additional recommendations from the states and industry resulted in the 1965 revision of the shellfish sanitation manual. This revision was prepared in cooperation with the shellfish control authorities in all coastal states, food control authorities in the inland states, interested federal agencies, Canadian federal departments, the Oyster Institute of North America, the Pacific Coast Oyster Growers Association, and the Oyster Growers and Dealers Association of North America.

In 1968, the Sixth National Shellfish Sanitation Workshop was held (Morrison, 1969). Recommendations for further revisions to the 1965 Manual were made and accepted by Workshop participants. This Workshop was structured around 12 task forces that were assigned specific topics to examine and develop recommendations for discussion by all workshop participants. This approach to examining and discussing large numbers of issues was proved successful and was recommended for use in future Workshops.

The shellfish sanitation program responsibilities assigned to the Assistant Secretary for Health, Department of Health, Education and Welfare were delegated to the Commissioner of Food and Drugs in late 1968. The FDA continued to sponsor the National Shellfish Sanitation Workshops (Ratcliffe, 1971; Wilt, 1974, 1975 and 1977) Proceedings from these Workshops contained additional recommendations for revisions to the 1965 Manual of Operations.

On June 19, 1975, the FDA proposed National Shellfish Safety Program Regulations in the ***Federal Register*** (FDA, 1975). There was considerable discussion at the 1975 and 1977 Workshops concerning these proposed regulations. After evaluation of the comments received as a result of the proposed rules, the FDA determined that promulgating federal regulations would not likely achieve NSSP goals. Subsequently, FDA decided revision of the 1965 Manual of Operations was the best approach for strengthening the NSSP. (See Federal Register of February 26, 1985, 50 F.R. 7797)

During this period, many state shellfish control agencies began questioning the uniformity and effectiveness of shellfish programs in other states. These states and FDA began exploring methods for strengthening the NSSP that would not involve federal regulations. In reviewing other approaches, it was noted that since 1950 the National Conference of Interstate Milk Shippers (NCIMS), a successful voluntary public health program, has been successful in assuring a nationwide safe and wholesome milk supply. The NCIMS was consulted for direction and advice.

The success of the NCIMS program prompted state shellfish control officials and FDA to select the NCIMS program as a model for developing a shellfish organization. In 1982, a delegation of state officials from 22 states met in Annapolis, Maryland and formed the Interstate Shellfish Sanitation Conference (ISSC). The ISSC is composed of state shellfish regulatory officials, industry officials, FDA, and other federal agencies.

The ISSC organization provides the forum for state regulatory officials to establish uniform national guidelines and to exchange information regarding sources of safe shellfish. The first annual meeting was held in New Orleans, Louisiana in August 1983. At this conference, the ISSC adopted the 1965 NSSP Manuals of Operation, as well as formal procedures for adopting changes to the Manuals. These documents provided the basis for an Interstate Shellfish Sanitation Program (ISSP). In March 1984, FDA entered into a Memorandum of Understanding (MOU) with the ISSC. The MOU formalized the FDA's relationship with the ISSC and established the ISSC as a federal-state-industry cooperative body. The ISSP, acknowledged in the 1984 MOU, is a set of guidelines for the sanitary control of shellfish, adequate to insure that shellfish will be safe and sanitary.

At its second annual meeting in Orlando, Florida in August 1984, the ISSC accepted for review a revision of Part I of the 1965 NSSP Manual of Operations. At the third annual meeting in Cherry Hill, New Jersey, in August, 1985, the ISSC adopted an updated Part I of the NSSP Manual of Operations (published in 1986), and accepted for review a revision of Part II of the 1965 NSSP Manual.

In preparing the draft revision of the 1965 NSSP Manual of Operations, FDA relied principally on the following sources:

(1) The draft revision of the Proposed National Shellfish Safety Program Regulations, Part 951;

(2) The 1965 NSSP ***Manual of Operations, Part I, Sanitation of Growing Waters; Part II, Sanitation of the Harvesting and Processing of Shellfish***; and ***Part III, Appraisal of State Shellfish Sanitation Programs***, U.S. Department of Health, Education, and Welfare, Public Health Service Publication No. 33;

(3) The National Shellfish Sanitation Program Workshop Proceedings for 1968, 1971, 1973, 1974, and 1977;

(4) The Environmental Protection Agency rules and regulations (40 CFR Parts 400, et seq.) concerning water pollution control and shellfish waters;

(5) Other federal laws and regulations concerning quality of shellfish and shellfish growing areas;

(6) Existing state rules and regulations concerning shellfish growing area control and water quality criteria;

(7) Analytical methods accepted by the American Public Health Association, Association of Official Analytical Chemists, American Society of Testing Materials, and other voluntary standard-setting organizations relating to shellfish and shellfish waters; and

(8) Recommendations from the Interstate Shellfish Sanitation Conference.

Developing the updated Manual was a cooperative effort between FDA and the ISSC. Initial drafts were prepared by FDA and presented to the ISSC and other interested parties for review and comment. Comments were incorporated into drafts after consultation with the ISSC, and the final revision was presented to the ISSC for formal endorsement in 1986. In updating the 1965 Manual, the harvesting and the processing of shellfish continued to be recognized as two distinct phases of operation in the shellfish industry. Therefore, the updated Manual was published in two parts; Part I: ***Sanitation of Shellfish Growing Areas*** (1986); and Part II: ***Sanitation of the Harvesting, Processing and Distribution of Shellfish*** (1987). Part I of the Manual continued as a guide for preparing state shellfish laws and regulations pertaining to sanitary control of shellfish harvest area classification, laboratory procedures, relaying, patrol operations and marine biotoxin. Part II of the Manual continued as a guide for operating, inspecting and certifying shellfish shippers, processors and depuration facilities; and for controlling interstate shipments of shellfish. Part III: *Public Health Service Appraisal of State Shellfish Sanitation Programs* was discontinued by the FDA.

In addition to setting forth the principles and requirements for the sanitary control of shellfish produced and shipped in interstate commerce in the U.S., the updated Manual was intended to be used by the states to control the harvesting and handling of shellfish for recreational and intrastate commercial use. Most coastal states believe that consumers residing in their state should be provided equal public health protection, as are consumers in other states under the interstate certification program. To accomplish this, states may apply the same water quality and harvesting restrictions on non-interstate shellfish activities as on interstate activities. Having uniform intra and interstate programs also greatly facilitates the effective implementation and regulation of all shellfish harvesting activities, and results in the most efficient utilization of public health resources.

The updated Manual was also to be used by FDA as the basis for evaluating foreign shellfish sanitation programs. To accomplish this, FDA seeks to establish international MOUs with official agencies in those foreign countries that wish to export shellfish to the U.S. An MOU is established after the foreign government demonstrates to FDA that the government has laws or regulations equivalent to those published in the Manual, and that the foreign program was supported by trained personnel, laboratory facilities, and other resources as may be necessary to exercise control over the export shellfish industry. Once a country has an effective MOU, the shellfish control authority submits certificates of their certified shellfish dealers to the FDA. The FDA publishes the names of these certified shellfish shippers in the Interstate Certified Shellfish Shippers List as an approved source of shellfish.

In the years 1986 through 1995, under its 1984 Memorandum of Understanding with the Interstate Shellfish Sanitation Conference (ISSC), the FDA published seven revisions of the Manual. Between 1995 and 2003, the ISSC/FDA has published two revisions of the NSSP Guide for the Control of Molluscan Shellfish. The revisions were the result of the findings and recommendations from the annual meetings of the ISSC and reflected mutual FDA and ISSC concurrence. A full listing of all editions of the Manual of Operations for the National Shellfish Sanitation Program can be found in the reference portion of this section.

The intent in establishing the ISSP Program was to modify the manuals into a model ordinance format and include the ordinance with other shellfish related documents and procedures into an ISSP Handbook.

INTERSTATE SHELLFISH SANITATION PROGRAM

During development of the ISSC, FDA, state regulatory officials and the industry worked diligently to establish uniform guidelines and to exchange reliable information on sources of safe shellfish, and to provide revisions to the NSSP Manual as necessary through formal ISSC procedures. These efforts have been conducted under the umbrella of the March 1984 Memorandum of Understanding (MOU) between the FDA and the ISSC. The Memorandum formally established a FDA cooperative relationship with both the states and shellfish industry. The ISSC continues to play an important role in assuring that uniform shellfish control measures are adopted, and that those measures are enforced consistently by state regulatory authorities.

One of the foremost goals of the ISSC has been the adoption of a Model Ordinance which would embody the principles and requirements of the ISSP. Adoption of the Model Ordinance by each of the ISSC participating states implies commitment by each state to provide the necessary legal authority and resources to implement these regulatory requirements. Adoption also ensures uniformity across state boundaries and enhances public confidence in shellfish product.

Development of the Model Ordinance began in 1987 with the establishment of the ISSC Model Ordinance Committee, which included representatives of the FDA, the states and the industry. The Model Ordinance Committee worked to incorporate the NSSP Manual into the format of regulation and to resolve inconsistencies within the Manual. The initial draft Ordinance was presented to and adopted by the ISSC at its 1992 meeting. The FDA responded with comments and requested development of a strategy for the transition from the NSSP Manual to the Model Ordinance as the basis for the National Shellfish Sanitation Program and for use by FDA in reviewing state shellfish sanitation programs.

The ISSC recognized the importance of retaining many of the elements of the NSSP Manual that should not be incorporated into an ordinance. To accomplish this, the Model Ordinance Committee recommended development of the Interstate Shellfish Sanitation Program Handbook which would include, in addition to the Model Ordinance, guidance documents concerning important components of the NSSP, references, public health reasons for NSSP requirements, and procedures which support or are used in the NSSP. The ISSC Constitution, By-laws and Procedures were revised to recognize an Interstate Shellfish Sanitation Program (ISSP) and its Model Ordinance as replacing the NSSP on January 1, 1998 as the effective rules governing participation in the ISSC. However, further discussions by the ISSC Executive Board and FDA regarding recognition and identify of the Program have resulted in retention of the National Shellfish Sanitation Program title hereafter referred to as the National Shellfish Sanitation Program (NSSP).

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Annex IV

Section VII of
REGULATION (EC) No 853/2004 OF THE EUROPEAN PARLIAMENT

AND OF THE COUNCIL

of 29 April 2004

laying down specific hygiene rules for food of animal origin

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SECTION VII: LIVE BIVALVE MOLLUSCS

1. This Section applies to live bivalve molluscs. With the exception of the provisions on purification, it also applies to live echinoderms, tunicates and marine gastropods.
2. Chapters I to VIII apply to animals harvested from production areas that the competent authority has classified in accordance with Regulation (EC) No …/2004 *. Chapter IX applies to pectinidae harvested outside those areas.
3. Chapters V, VI, VIII and IX, and paragraph 3 of Chapter VII, apply to retail.
4. The requirements of this Section supplement those laid down in Regulation (EC) No …/2004 **.
(a) In the case of operations that take place before live bivalve molluscs arrive at a dispatch or purification centre, they supplement the requirements of Annex I to that Regulation.
(b) In the case of other operations, they supplement the requirements of Annex II to that Regulation.
* Official Publications Office is to insert the official number of Regulation on the organisation of official controls.
** Official Publications Office is to insert the official number of Regulation on the hygiene of foodstuffs.

CHAPTER I: GENERAL REQUIREMENTS FOR THE PLACING ON THE MARKET OF LIVE BIVALVE MOLLUSCS

1. Live bivalve molluscs may not be placed on the market for retail sale otherwise than via a dispatch centre, where an identification mark must be applied in accordance with Chapter VII.
2. Food business operators may accept batches of live bivalve molluscs only if the documentary requirements set out in paragraphs 3 to 7 have been complied with.
3. Whenever a food business operator moves a batch of live bivalve molluscs between establishments, up to and including the arrival of the batch at a dispatch centre or processing establishment, a registration document must accompany the batch.
4. The registration document must be in at least one official language of the Member State in which the receiving establishment is located and contain at least the information specified below.
(a) In the case of a batch of live bivalve molluscs sent from a production area, the registration document must contain at least the following information:
(i) the gatherer's identity and address;
(ii) the date of harvesting;
(iii) the location of the production area described in as precise detail as is practicable or by a code number;
(iv) the health status of the production area;
(v) the shellfish species and quantity; and
(vi) the destination of the batch.
(b) In the case of a batch of live bivalve molluscs sent from a relaying area, the registration document must contain at least the information referred to in (a) and the following information:
(i) the location of the relaying area; and
(ii) the duration of relaying.

(c) In the case of a batch of live bivalve molluscs sent from a purification centre, the registration document must contain at least the information referred to in (a) and the following information:
(i) the address of the purification centre;
(ii) the duration of purification; and
(iii) the dates on which the batch entered and left the purification centre.
5. Food business operators sending batches of live bivalve molluscs must complete the relevant
sections of the registration document so that they are easy to read and cannot be altered. Food business operators receiving batches must date-stamp the document on receipt of the batch or record the date of receipt in another manner.
6. Food business operators must keep a copy of the registration document relating to each batch sent and received for at least twelve months after its dispatch or receipt (or such longer period as the competent authority may specify).
7. However, if:
(a) the staff gathering live bivalve molluscs also operate the dispatch centre, purification centre, relaying area or processing establishment receiving the live bivalve molluscs; and
(b) a single competent authority supervises all the establishments concerned, registration documents are not necessary if that competent authority so permits.

CHAPTER II: HYGIENE REQUIREMENTS FOR THE PRODUCTION AND HARVESTING OF LIVE BIVALVE MOLLUSCS

A. REQUIREMENTS FOR PRODUCTION AREAS

1. Gatherers may only harvest live bivalve molluscs from production areas with fixed locations and boundaries that the competent authority has classified – where appropriate, in cooperation with food business operators – as being of class A, B or C in accordance with Regulation (EC) No …/2004 *.
2. Food business operators may place live bivalve molluscs collected from class A production areas on the market for direct human consumption only if they meet the requirements of Chapter V.
3. Food business operators may place live bivalve molluscs collected from class B production areas on the market for human consumption only after treatment in a purification centre or after relaying.
4. Food business operators may place live bivalve molluscs collected from class C production areas on the market for human consumption only after relaying over a long period in accordance with Part C of this Chapter.
* Official Publications Office is to insert the official number of Regulation on the organisation of official controls.

5. After purification or relaying, live bivalve molluscs from class B or C production areas must meet all of the requirements of Chapter V. However, live bivalve molluscs from such areas that have not been submitted for purification or relaying may be sent to a processing establishment, where they must undergo treatment to eliminate pathogenic microorganisms (where appropriate, after removal of sand, mud or slime in the same or another establishment). The permitted treatment methods are:
(a) sterilisation in hermetically sealed containers; and
(b) heat treatments involving:
(i) immersion in boiling water for the period required to raise the internal temperature of the mollusc flesh to not less than 90°C and maintenance of this minimum temperature for a period of not less than 90 seconds;
(ii) cooking for three to five minutes in an enclosed space where the temperature is between 120 and 160°C and the pressure is between 2 and 5 kg/cm2, followed by shelling and freezing of the flesh to a core temperature of -20°C; and

(iii) steaming under pressure in an enclosed space satisfying the requirements relating to cooking time and the internal temperature of the mollusc flesh mentioned under (i). A validated methodology must be used. Procedures based on the HACCP principles must be in place to verify the uniform distribution of heat.

6. Food business operators must not produce live bivalve molluscs in, or harvest them from, areas that the competent authority has not classified, or which are unsuitable for health reasons. Food business operators must take account of any relevant information concerning areas' suitability for production and harvesting, including information obtained from own-checks and the competent authority. They must use this information, particularly information on environmental and weather conditions, to determine the appropriate treatment to apply to harvested batches.

B. REQUIREMENTS FOR HARVESTING AND HANDLING FOLLOWING HARVESTING

Food business operators harvesting live bivalve molluscs, or handling them immediately after harvesting, must ensure compliance with the following requirements.
1. Harvesting techniques and further handling must not cause additional contamination or excessive damage to the shells or tissues of the live bivalve molluscs or result in changes significantly affecting their suitability for treatment by purification, processing or relaying.
Food business operators must in particular:
(a) adequately protect live bivalve molluscs from crushing, abrasion or vibration;
(b) not expose live bivalve molluscs to extreme temperatures;
(c) not re-immerse live bivalve molluscs in water that could cause additional contamination; and
(d) if carrying out conditioning in natural sites, use only areas that the competent authority has classified as being of class A.

2. Means of transport must permit adequate drainage, be equipped to ensure the best survival conditions possible and provide efficient protection against contamination.

C. REQUIREMENTS FOR RELAYING LIVE BIVALVE MOLLUSCS

Food business operators relaying live bivalve molluscs must ensure compliance with the following requirements.
1. Food business operators may use only those areas that the competent authority has approved for relaying live bivalve molluscs. Buoys, poles or other fixed means must clearly identify the boundaries of the sites. There must be a minimum distance between relaying areas, and also between relaying areas and production areas, so as to minimise any risk of the spread of contamination.
2. Conditions for relaying must ensure optimal conditions for purification. In particular, food business operators must:
(a) use techniques for handling live bivalve molluscs intended for relaying that permit the resumption of filter-feeding activity after immersion in natural waters;
(b) not relay live bivalve molluscs at a density that prevents purification;
(c) immerse live bivalve molluscs in seawater at the relaying area for an appropriate period, fixed depending on the water temperature, which period must be of at least two months' duration unless the competent authority agrees to a shorter period on the basis of the food business operator's risk analysis; and
(d) ensure sufficient separation of sites within a relaying area to prevent mixing of batches; the "all in, all out" system must be used, so that a new batch cannot be brought in before the whole of the previous batch has been removed.

3. Food business operators managing relaying areas must keep permanent records of the source of live bivalve molluscs, relaying periods, relaying areas used and the subsequent destination of the batch after relaying, for inspection by the competent authority.

CHAPTER III: STRUCTURAL REQUIREMENTS FOR DISPATCH AND PURIFICATION CENTRES

1. The location of premises on land must not be subject to flooding by ordinary high tides or run-off from surrounding areas.
2. Tanks and water storage containers must meet the following requirements:
(a) Internal surfaces must be smooth, durable, impermeable and easy to clean.
(b) They must be constructed so as to allow complete draining of water.
(c) Any water intake must be situated in a position that avoids contamination of the water supply.
3. In addition, in purification centres, purification tanks must be suitable for the volume and type of products to be purified.

CHAPTER IV: HYGIENE REQUIREMENTS FOR PURIFICATION AND DISPATCH CENTRES

A. REQUIREMENTS FOR PURIFICATION CENTRES

Food business operators purifying live bivalve molluscs must ensure compliance with the following requirements.
1. Before purification commences, live bivalve molluscs must be washed free of mud and accumulated debris using clean water.
2. Operation of the purification system must allow live bivalve molluscs rapidly to resume and to maintain filter-feeding activity, to eliminate sewage contamination, not to become re-contaminated and to be able to remain alive in a suitable condition after purification for wrapping, storage and transport before being placed on the market.
3. The quantity of live bivalve molluscs to be purified must not exceed the capacity of the purification centre. The live bivalve molluscs must be continuously purified for a period sufficient to achieve compliance with allow the health standards of Chapter V and microbiological criteria adopted in accordance with Regulation (EC) No …/2004 *.
4. Should a purification tank contain several batches of live bivalve molluscs, they must be of the same species and the length of the treatment must be based on the time required by the batch needing the longest period of purification.
* Official Publications Office is to insert the official number of Regulation on the hygiene of foodstuffs.

5. Containers used to hold live bivalve molluscs in purification systems must have a construction that allows clean seawater to flow through. The depth of layers of live bivalve molluscs must not impede the opening of shells during purification.
6. No crustaceans, fish or other marine species may be kept in a purification tank in which live bivalve molluscs are undergoing purification.
7. Every package containing purified live bivalve molluscs sent to a dispatch centre must be provided with a label certifying that all molluscs have been purified.

B. REQUIREMENTS FOR DISPATCH CENTRES

Food business operators operating dispatch centres must ensure compliance with the following requirements.
1. Handling of live bivalve molluscs, particularly conditioning, calibration, wrapping and packing, must not cause contamination of the product or affect the viability of the molluscs.

2. Before dispatch, the shells of live bivalve molluscs must be washed thoroughly with clean water.
3. Live bivalve molluscs must come from:
(a) a class A production area;
(b) a relaying area;
(c) a purification centre; or
(d) another dispatch centre.
4. The requirements laid down in points 1 and 2 also apply to dispatch centres situated on board vessels. Molluscs handled in such centres must come from a class A production area or a relaying area.

CHAPTER V: HEALTH STANDARDS FOR LIVE BIVALVE MOLLUSCS

In addition to ensuring compliance with microbiological criteria adopted in accordance with
Regulation (EC) No …/2004 *, food business operators must ensure that live bivalve molluscs placed on the market for human consumption meet the standards laid down in this Chapter.
1. They must have organoleptic characteristics associated with freshness and viability, including shells free of dirt, an adequate response to percussion and normal amounts of intravalvular liquid.
2. They must not contain marine biotoxins in total quantities (measured in the whole body or any part edible separately) that exceed the following limits:
(a) for Paralytic Shellfish Poison (PSP), 800 micrograms per kilogram;
(b) for Amnesic Shellfish Poison (ASP), 20 milligrams of domoic acid per kilogram;
* Official Publications Office is to insert the official number of Regulation on the hygiene of foodstuffs.
(c) for okadaic acid, dinophysistoxins and pectenotoxins together, 160 micrograms of okadaic acid equivalents per kilogram;
(d) for yessotoxins, 1 milligram of yessotoxin equivalent per kilogram; and
(e) for azaspiracids, 160 micrograms of azaspiracid equivalents per kilogram.

CHAPTER VI: WRAPPING AND PACKAGING OF LIVE BIVALVE MOLLUSCS

1. Oysters must be wrapped or packaged with the concave shell downwards.
2. Individual consumer-size packages of live bivalve molluscs must be closed and remain closed after leaving the dispatch centre and until presented for sale to the final consumer.

CHAPTER VII: IDENTIFICATION MARKING AND LABELLING

1. The label, including the identification mark, must be waterproof.
2. In addition to the general requirements for identification marks contained in Annex II, Section I, the following information must be present on the label:
(a) the species of bivalve mollusc (common name and scientific name); and
(b) the date of packaging, comprising at least the day and the month.
By way of derogation from Directive 2000/13/EC, the date of minimum durability may be replaced by the entry "these animals must be alive when sold".

3. The retailer must keep the label attached to the packaging of live bivalve molluscs that are not in individual consumer-size packages for at least 60 days after splitting up the contents.

CHAPTER VIII: OTHER REQUIREMENTS

1. Food business operators storing and transporting live bivalve molluscs must ensure that they are kept at a temperature that does not adversely affect food safety or their viability.
2. Live bivalve molluscs must not be re-immersed in, or sprayed with, water after they have been packaged for retail sale and left the dispatch centre.

CHAPTER IX: SPECIFIC REQUIREMENTS FOR PECTINIDAE HARVESTED OUTSIDE CLASSIFIED PRODUCTION AREAS

Food business operators harvesting pectinidae outside classified production areas or handling such pectinidae must comply with the following requirements.
1. Pectinidae may not be placed on the market unless they are harvested and handled in accordance with Chapter II, Part B, and meet the standards laid down in Chapter V, as proved by a system of own-checks.
2. In addition, where data from official monitoring programmes enable the competent authority to classify fishing grounds – where appropriate, in cooperation with food business operators – the provisions of Chapter II, Part A, apply by analogy to pectinidae.

3. Pectinidae may not be placed on the market for human consumption otherwise than via a fish auction, a dispatch centre or a processing establishment. When they handle pectinidae, food business operators operating such establishments must inform the competent authority and, as regards dispatch centres, comply with the relevant requirements of Chapters III and IV.
4. Food business operators handling pectinidae must comply:
(a) with the documentary requirements of Chapter I, points 3 to 7, where applicable. In this case, the registration document must clearly indicate the location of the area where the pectinidae were harvested; or
(b) as regards packaged pectinidae, and wrapped pectinidae if the wrapping provides protection equivalent to that of packaging, with the requirements of Chapter VII concerning identification marking and labelling.

Annex V

United States National Shellfish Sanitation Biotoxin Laboratory Checklist, 2001

PUBLIC HEALTH SERVICE
U.S. FOOD AND DRUG ADMINISTRATION
DIVISION OF COOPERATIVE PROGRAMS
200 "C" STREET, SW (HFS-628)
WASHINGTON, DC 20204
TEL. 202-205-8703 FAX 202-205-5560

SHELLFISH LABORATORY EVALUATION CHECKLIST

LABORATORY:		
ADDRESS:		
TELEPHONE:	FAX No.	Email:
DATE OF EVALUATION	DATE OF REPORT	LAST EVALUATION

LABORATORY REPRESENTED BY:	TITLE:
LABORATORY EVALUATION OFFICER:	SHELLFISH SPECIALIST: REGION:
OTHER OFFICIALS PRESENT:	TITLE:

Items which do not conform are noted by:

C - Critical K - Key O - Other NA - Not Applicable Conformity is noted by a **"T"**

FDA Shellfish Laboratory Evaluation Checklist - PSP Component

PART I – QUALITY ASSURANCE			
Code	**Item Description**		
	1.1. Quality Assurance (QA) Plan		
K		1. Written Plan adequately covers all of the following: (check / those that apply)	
			a. Organization of the laboratory.
			b. Staff training requirements.
			c. Standard operating procedures.
			d. Internal quality control measures for equipment, calibration, maintenance, repair and performance.
			e. Laboratory safety.
			f. Quality assessment.
			g. Proper animal care.
C		**2. QA plan implemented.**	
	1.2. Work Area		
O		1. Adequate for workload and storage.	
O		2. Clean and well lighted.	
O		3. Adequate temperature control.	
O		4. All work surfaces are nonporous and easily cleaned.	
C		**5. A separate, quiet area with adequate temperature control for mice acclimation and injection is maintained.**	
	1.3. Laboratory Equipment		
O		1. The pH meter has a standard accuracy of 0.1 unit.	
K		2. pH paper in the appropriate range (ie. 1-4) is used with minimum accuracy of 0.5 pH unit.	
K		3. pH electrodes consist of pH half cell and reference half cell or equivalent combination electrode (free from Ag/AgCl or contains an ion exchange barrier to prevent passage of Ag ions into the medium which may result in inaccurate pH readings).	
K		4. pH meter is calibrated daily or with each use. Records maintained.	
K		5. Effect of temperature has been compensated for by an ATC probe or by manual adjustment.	
K		6. A minimum of two standard buffer solutions (2 & 7) are used to calibrate the pH meter. Standard buffer solutions are used once and discarded.	

Code		Item Description
K		7. Electrode efficiency is determined daily or with each use following either slope or millivolt procedure.
K		8. The balance provides a sensitivity of at least 0.1 g at a load of 150 g.
K		9. The balance calibration is checked monthly using NIST Class S or ASTM Class 1 or 2 weights or equivalent. Records maintained.
K		10. Refrigerator temperature is maintained between 0E and 4EC.
K		11. Refrigerator temperature is monitored at least once daily. Records maintained.
K		12. Freezer temperature maintained at -20EC or below.
O		13. Freezer temperature monitored at least once daily. Records maintained.
O		14. All glassware is clean.
O		15. Once during each day of washing, several pieces of glassware from each batch washed are tested for residual detergent with aqueous 0.04% bromthymol blue solution. Records maintained.
	1.4.	**Reagent and Reference Solution Preparation and Storage**
C		**1. Opened PSP reference standard solution (100 Fg/ml) is not stored.**
K		2. PSP working standard solution (1 Fg/ml) and all dilutions are prepared with dilute HCl, pH 3 water, using “Class A” volumetric glassware (flask and pipettes) or prepared gravimetrically.
K		3. Refrigerated storage of PSP working standard solution (1 Fg/ml) does not exceed 6 months and is checked gravimetrically for evaporation loss.
K		4. PSP working dilutions are discarded after use.
K		5. Make up water is distilled or deionized (circle one) and exceeds 0.5 megohm resistance or is less than 2 FSiemens/cm conductivity at 25EC to be tested and recorded monthly for resistance or conductivity (circle the appropriate).
O		6. Make up water is analyzed for residual chlorine monthly and is at a nondetectable level (#0.1 ppm). Records maintained.
K		7. Make up water is free from trace (<0.5 mg/l) dissolved metals specifically Cd, Cr, Cu, Ni, Pb, and Zn as determined annually with total heavy metal content #1.0 mg/l. Records maintained.
O		8. Make up water contains < 1000 CFU/ml as determined monthly using the heterotrophic plate count method. Records maintained.
	1.5.	**Collection and Transportation of Samples**
O		1. Shellstock are collected in clean, waterproof, puncture resistant containers.
K		2. Samples are appropriately labeled with the collector’s name, harvest area, and time and date of collection.
K		3. Immediately after collection, shellstock samples are placed in dry storage for transport (e.g. cooler) which is maintained between 0E and 10E C. Upon receipt at the lab, samples are placed under refrigeration.

Code		Item Description
K		4. The time from collection to completion of the bioassay should not exceed 24 hours. However, if there are significant transportation delays, then shellstock samples are processed immediately as follows (circle the appropriate choice);
		a. washed, shucked, drained, frozen until extracted;
		b. washed, shucked, drained, homogenized and frozen;
		c. washed, shucked, drained, extracted, the supernatant decanted and refrigerated (**this is best approach**); or
		d. the lab has an appropriate contingency plan in place to handle samples which can't be analyzed within 24 hours due to transportation issues.
K		5. Frozen shucked product or homogenates are allowed to thaw completely and all liquid is included as part of the sample before being processed further.
PART II – EXAMINATION OF SHELLFISH TISSUE FOR PSP TOXIN		
	2.1.	**Preparation of Sample**
C		1. **At least 12 animals are used per sample, or the lab has an appropriate contingency plan for dealing with non-typical species of shellfish.**
O		2. The outside of the shell is thoroughly cleaned with fresh water.
O		3. Shellstock are opened by cutting adductor muscles.
O		4. The inside of the shell is rinsed with fresh water to remove sand or other foreign material.
O		5. Shellfish meats are removed from the shell by separating adductor muscles and tissue connecting at the hinge.
K		6. Damage to the body of the mollusk is minimized in the process of opening.
O		7. Shucked shellfish are drained on a #10 mesh sieve (or equivalent) without layering for 5 minutes.
K		8. Pieces of shell and drainings are discarded.
C		9. **Drained meats or thawed homogenates are blended at high speed until homogenous** (60-120 seconds).
	2.2.	**Extraction**
K		1. 100 g of homogenized sample is weighed into a beaker.
K		2. An equal amount of 0.1N/0.18N HCl is added to the homogenate and thoroughly mixed (circle the appropriate normality).
C		**3. pH is checked and, if necessary adjusted to between pH 2.0 and 4.0.**
C		**4. Adjustment of the pH is made by the dropwise addition of either the acid (5N HCl) or base (0.1N NaOH) while constantly stirring the mixture.**

Code		Item Description
C		**5. The homogenate/acid mixture is promptly brought to a boil, 100EC ± 1EC, then gently boiled for 5 minutes.**
O		6. The homogenate/acid mixture is boiled under adequate ventilation (i.e. fume hood).
O		7. The extract is cooled to room temperature.
C		**8. The pH of the extract is determined and adjusted, if necessary, to between pH 2 and 4, preferably to pH 3, with the stirred dropwise addition of 5N HCl to lower the pH or 0.1N NaOH to raise the pH.**
K		9. The extract volume (or mass) is adjusted to 200 mls (or grams) with dilute HCl, pH 3 water.
K		10. The extract is returned to the beaker, stirred to homogeneity and allowed to settle to remove particulates; or, if necessary, an aliquot of the stirred supernatant is centrifuged at 3,000 RPM for 5 minutes before injection.
K		11. If mice cannot be injected immediately then the supernatant should be removed from the centrifuge tubes and refrigerated for up to 24 hours.
K		12. Refrigerated extracts are allowed to reach ambient temperature before being bioassayed.
	2.3	**Bioassay**
O		1. A 26-gauge hypodermic needle is used for injection.
K		2. Healthy mice in the weight range of 17-23 grams (19 to 21 grams preferable) from a stock colony are used for routine assays. Mice are not reused for bioassay.
		Stock strain used? Source of mice?
C		**3. Mice are allowed to acclimate for at least 24 hours prior to injection. In some cases up to 48 hours may be required.**
C		**4 A conversion factor (CF) has been determined as?**
		Month and year when current CF determined?
C		**5. CF value is checked weekly if assays are done on several days during the week, or, once each day that assays are performed if they are performed less than once per week.** **Date of most recent CF check?** **Results CF verified/CF not verified?** (Circle appropriate choice).
C		**6. If the CF is not verified, 5 ADDITIONAL mice are injected with the dilution used in the CF check to complete a group of 10 mice. TEN ADDITIONAL mice are also injected with this dilution to produce a second group of 10 mice. The CF is calculated for each group of 10 mice and averaged to give the CF to be used in sample toxicity calculations for the DAY'S OR WEEK'S WORK ONLY. All subsequent work must make use of the original laboratory CF value unless this value continues to fail to be verified by routine CF checks.**
C		**7. If the CF fails to be verified, the cause is investigated and the situation corrected. If the cause cannot be determined with reasonable certainty and fails > 3 times per year, the bioassay is restandardized.**

Code		Item Description
O		8. Mice are weighed to the nearest 0.5 gram.
C		**9. Mice are injected intraperitoneally with 1 ml of the acid extract.**
K		10. For the CF check, at least 5 mice are used.
C		**11. At least 3 mice are used per sample in routine assays.**
C		**12. Elapsed time is accurately determined and recorded.**
K		13. If death occurs, the time of death to the nearest second is noted by the last gasping breath.
O		14. Mice are carefully observed for up to 20 minutes after injection with periodic checks for a total of 60 minutes.
C		**15. If median death time (2 out of 3 mice injected die) is <5 minutes, a dilution is made with dilute HCl, pH 3 water, to obtain a median death time in the range of 5 to 7 minutes.**
	2.4	**Calculation of Toxicity**
C		**1. The death time of each mouse is converted to mouse units (MU) using Sommer's Table (Table 6 Recommended Procedures, 4th edition). The death time of mice surviving beyond 60 minutes is considered to be <0.875 MU.**
K		2. A weight correction in MU is made for each mouse injected using Table 7 in Recommended Procedures, 4th edition.
C		**3. The death time for each mouse in MU is multiplied by a weight correction in MU to give the corrected mouse unit (CMU) for each mouse.**
C		**4. The median value of the array of corrected mouse units (CMU) is determined to give the median corrected mouse unit (MCMU).**
C		**5. The concentration of toxin is determined by the formula: MCMU x CF x Dilution Factor x 200.**
C		**6. Any value greater than 80 Fg/100 grams of meat is actionable.**

REFERENCES

1. Adams & Furfari, Evaluation of laboratory performance of the AOAC method for PSP toxin in shellfish, 1984. *J. Assoc. Off. Anal. Chem.* Vol. **67**, 6:1147-1148.
2. American Public Health Association. Recommended Procedures for the Examination of Sea Water and Shellfish, 4th Edition, 1970.
3. American Public Health Association. Standard Methods for the Examination of Dairy Products, 16th Edition, 1992.
4. AOAC International. Methods of Analysis, 15th Edition, 1990.
5. APHA/WEF/AWWA. Standard Methods for the Examination of Water and Wastewater, 18th Edition, 1992.
6. Good laboratory practice.
7. National Research Council. Guide for the Care and Use of Laboratory Animals. 1996. National Academy Press.
8. Personal communication with USFDA Washington Seafood Laboratory Branch, Office of Seafood, CFSAN, 1998-1999.

Laboratory:			**Date:**
SHELLFISH LABORATORY EVALUATION CHECKLIST SUMMARY OF NONCONFORMITIES			
Page	**Item**	**Observation**	**Corrective Action/ Documentation Required**

LABORATORY STATUS

Laboratory:	**Date:**

PARALYTIC SHELLFISH POISON COMPONENT: (PART I-II)

A. RESULTS

Total # of Critical (C) Nonconformities in Parts I through II _____

Total # of Key (K) Nonconformities in Parts I through II _____

Total # of Critical, Key & Other (O) Nonconformities in Parts I-II _____

B. Criteria for Determining Laboratory Status of the Paralytic Shellfish Poison Component

1. Does Not Conform Status: The PSP component of this laboratory is not in conformity with NSSP requirements if:
   A. The total # of Critical nonconformities is $ 3 or
   B. The total # of Key nonconformities is $ 6 or
   C. The total # of Critical, Key, and Other is $ 10 (Not to exceed the Critical and Key criteria)
2. Provisionally Conforms Status: The PSP component of this laboratory is determined to be provisionally conforming to the NSSP requirements if the number of critical nonconformities is 1 but less than 3 (Not to exceed Key and Total criteria)

C. Laboratory Status (circle appropriate)

Does Not Conform Provisionally Conforms Conforms

D. Acknowledgment by Laboratory Director/Supervisor:

All corrective action will be implemented and verifying substantiating documentation received by the Laboratory Evaluation Officer on or before

Laboratory Signature: _____ Date: _____

LEO Signature: _____ Date: _____

Annex VI

Article 1 of Decision 2002/225/EC

COMMISSION DECISION

of 15 March 2002

laying down detailed rules for the implementation of Council Directive 91/492/EEC as regards the maximum levels and the methods of analysis of certain marine biotoxins in bivalve molluscs, echinoderms, tunicates and marine gastropods

(notified under document number C(2002) 1001)

(Text with EEA relevance)

(2002/225/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/492/EEC of 15 July 1991 laying down the health conditions for the production and the placing on the market of live bivalve molluscs [1], as last amended by Directive 97/79/EC [2], and in particular Chapter V, paragraphs 3 and 5, of the Annex thereto,

Whereas:

(1) Chapter V, point 7, of the Annex to Directive 91/492/EEC provides that the customary biological testing methods must not give a positive result to the presence of diarrhetic shellfish poisoning (DSP) in the edible parts of molluscs (the whole body or any part edible separately).

(2) It has been scientifically proven that certain marine biotoxins such as those of the diarrhetic shellfish poisoning (DSP) complex (okadaic acid (OA) and dinophysistoxins (DTXs)) and also yessotoxins (YTXs), pectenotoxins (PTXs) and azaspiracids (AZAs), pose a serious hazard to human health when present above certain limits in bivalve molluscs, echinoderms, tunicates or marine gastropods.

(3) In the light of recent scientific studies it is now possible to establish maximum levels and methods of analysis for those biotoxins.

(4) Maximum levels and methods of analysis should be harmonised and be implemented by the Member States in order to protect human health.

(5) In addition to biological testing methods, alternative detection methods such as chemical methods and *in vitro* assays should be accepted if it is demonstrated that the performance of the chosen methods is not less effective than the performance of the biological method and that their implementation provides an equivalent level of public health protection.

(6) The proposed maximum levels are based on provisional data and should be re-evaluated when new scientific evidence becomes available.

(7) The measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

Article 1

This Decision lays down the maximum levels for the marine biotoxins of the diarrhetic shellfish poisoning (DSP) complex (okadaic acid and dinophysistoxins), yessotoxins, pectenotoxins and azaspiracids and the methods of analysis to be used for their detection. It applies to bivalve molluscs, echinoderms, tunicates and marine gastropods that are intended for immediate human consumption or for further processing before consumption.

Article 2

The maximum level of okadaic acid, dinophysistoxins and pectenotoxins together in the animals referred to in Article 1 (the whole body or any part edible separately) shall be 160 µg of okadaic acid equivalents/kg. The methods of analysis are set out in the Annex.

Article 3

The maximum level of yessotoxins in the animals referred to in Article 1 (the whole body or any part edible separately) shall be 1 mg of yessotoxin equivalent/kg. The methods of analysis are set out in the Annex.

Article 4

The maximum level of Azaspiracids in the animals referred to in Article 1 (the whole body or any part edible separately) shall be 160 µg of azaspiracid equivalents/kg. The methods of analysis are set out in the Annex.

[1] OJ L 268, 24.9.1991, p. 1.
[2] OJ L 24, 30.1.1998, p. 31.

Article 5

When the results of the analyses performed demonstrate discrepancies between the different methods, the mouse bioassay should be considered as the reference method.

Article 6

This Decision is addressed to the Member States.

Done at Brussels, 15 March 2002.

For the Commission

David BYRNE

Member of the Commission

ANNEX

Detection methods

Biological methods

A series of mouse bioassay procedures, differing in the test portion (hepatopancreas or whole body) and in the solvents used for the extraction and purification steps, can be used for detection of the toxins mentioned in Article 1. Sensitivity and selectivity depend on the choice of the solvents used for the extraction and purification steps and this should be taken into account when making a decision on the method to be used, in order to cover the full range of toxins.

A single mouse bioassay involving acetone extraction can be used to detect okadaic acid, dinophysistoxins, pectenotoxins and yessotoxins. This assay may be complemented if necessary with liquid/liquid partition steps with ethyl acetate/water or dichloromethane/water to remove potential interferences. Azaspiracids detection at the regulatory levels by means of this procedure requires the use of the whole body as the test portion.

Three mice should be used for each test. The death of two out of three mice within 24 hours after inoculation into each of them of an extract equivalent to 5 g of hepatopancreas or 25 g whole body should be considered as a positive result for the presence of one or more of the toxins mentioned in Article 1 at levels above those established in Article 2, 3 and 4.

A mouse bioassay with acetone extraction followed by liquid/liquid partition with diethylether can be used to detect okadaic acid, dinophysistoxins, pectenotoxins and azaspiracids but it cannot be used to detect yessotoxins as losses of these toxins may take place during the partition step. Three mice should be used for each test. The death of two out of three mice within 24 hours after inoculation into each of them of an extract equivalent to 5 g of hepatopancreas or 25 g whole body should be considered as a positive result for the presence of okadaic acid, dinophysistoxins, pectenotoxins and azaspiracids at levels above those established in Article 2 and 4.

The rat bioassay can detect okadaic acid, dinophysistoxins and azaspiracids. Three rats should be used for each test. A diarrhetic response in any of the three rats is considered a positive result for the presence of okadaic acid, dinophysistoxins and azaspiracids at levels above those mentioned in Article 2 and 4.

Alternative detection methods

A series of methods such as high performance liquid chromatography (HPLC) with fluorimetric detection, liquid chromatography (LC)-mass spectrometry (MS), inmunoassays and functional assays such as the phosphatase inhibition assay can be used as alternative or complementary methods to the biological testing methods, provided that either alone or combined they can detect at least the following analogues, that they are not less effective than the biological methods and that their implementation provides an equivalent level of public health protection:

— okadaic acid and dinophysistoxins: an hydrolysis step may be required in order to detect the presence of DTX3,

— pectenotoxins: PTX1 and PTX2,

— yessotoxins: YTX, 45 OH YTX, homo YTX, and 45 OH homo YTX,

— azaspiracids: AZA1, AZA2 and AZA3.

If new analogues of public health significance are discovered they should be included in the analysis. Standards will have to be available before chemical analysis will be possible. Total toxicity will be calculated using conversion factors based on the toxicity data available for each toxin.

The performance characteristics of these methods should be defined after validation following an internationally agreed protocol.

Annex VII

United States National Shellfish Sanitation Laboratory Evaluation Microbiology Checklist

PUBLIC HEALTH SERVICE
U.S. FOOD AND DRUG ADMINISTRATION
DIVISION OF COOPERATIVE PROGRAMS
200 "C" STREET, SW (HFS-628)
WASHINGTON, DC 20204
TEL. 202-205--8703 FAX 202-205-5560

SHELLFISH LABORATORY EVALUATION CHECKLIST

LABORATORY:		
ADDRESS:		
TELEPHONE:	FAX:	Email:
DATE OF EVALUATION	DATE OF REPORT	LAST EVALUATION

LABORATORY REPRESENTED BY:	TITLE:
LABORATORY EVALUATION OFFICER:	SHELLFISH SPECIALIST: REGION:
OTHER OFFICIALS PRESENT:	TITLE:

Items which do not conform are noted by:

C - Critical K - Key O - Other NA - Not Applicable Conformity is noted by a **"T"**

	Check the applicable analytical methods:
	Multiple Tube Fermentation Technique for Seawater (APHA) [PART II]
	Multiple Tube Fermentation Technique for Seawater using MA-1 [PART II]
	Multiple Tube Fermentation Technique for Shellfish Meats (APHA) [PART III]
	Standard Plate Count for Shellfish Meats [PART III]
	Elevated Temperature Coliform Plate Method for Shellfish Meats [PART III]

PART I - QUALITY ASSURANCE			
CODE	**REF.**		**ITEM**
K	8, 11		**Quality Assurance Plan**
			1. Written Plan (*Check **T** those items which apply.*)
			a. Organization of the laboratory
			b. Staff training requirements.
			c. Standard operating procedures.
			d. Internal quality control measures for equipment calibration, maintenance, repair and for performance checks.
			e. Laboratory safety
			f. Internal performance assessment.
			g. External performance assessment
C	8		2. QA Plan Implemented
K	11		3. Participates in a proficiency testing program annually.
			Specify Program(s) _____

CODE	REF.		Work Area
O	8,11		1. Adequate for workload and storage.
K	11		2. Clean, well lighted.
K	11		3. Adequate temperature control.
O	11		4. All work surfaces are nonporous, easily cleaned and disinfected.
K	11		5. Microbiological quality and density of air is < 15 colonies/plate in a 15 minute exposure determined monthly and results recorded.
O	11		6. Pipet aid used, mouth pipetting not permitted.

CODE	REF.		Equipment
O	9		1. To determine the pH of prepared media, the pH meter has a standard accuracy of 0.1 pH unit.
O	14		2. pH electrodes, consisting of pH half cell and reference half cell or equivalent combination electrode (free from Ag/AgCl or contains an ion exchange barrier preventing passage of Ag ions into the medium which may effect the accuracy of the pH reading).
K	11		3. The effect of temperature on the pH is compensated for by an ATC probe or by manual adjustment.
K	8		4. pH meter is calibrated daily or with each use and records are maintained.
K	11		5. A minimum of two standard buffer solutions are used to calibrate the pH meter. The first must be near the electrode isopotential point (pH7). The second near the expected sample pH (i.e. pH 4 or pH 10). (Standard buffer solutions are used once daily and discarded).
O	8,15		6. Electrode effectiveness is determined daily or with each use.
			Method of determination_____.
K	9		7. Balance provides a sensitivity of at least 0.1g at a load of 150g.
K	11,13		8. Balance checked monthly using NIST Class S or ASTM Class 1 or 2 weights or equivalent and records are maintained.
K	11		9. Refrigerator temperature(s) monitored at least once daily and recorded.
K	1		10. Refrigerator temperature maintained at 0E to 4EC.
C	9		**11. The temperature of the incubator is maintained at 35E ± 0.5EC.**
C	11		**12. Thermometers used in the air incubator(s) are graduated at no greater than 0.5EC increments.**
K	9		13. Working thermometer located on top and bottom shelves of use in the air incubator(s).
C	11		**14. Temperature of the waterbath is maintained at 44.5E ± 0.2EC under any loading capacity.**
C	9		**15. The thermometers used in the waterbath are graduated in 0.1EC increments.**
O	13		16. The waterbath has adequate capacity for workload.
K	9		17. The level of water in the waterbath covers the level of liquid in the incubating tubes.
K	8, 11		18. Air incubator/waterbath temperatures are taken twice daily and recorded.
K	13		19. Working thermometers are tagged with identification, date of calibration, calibrated temperature and correction factor.
K	4		20. All working thermometers are appropriately immersed.
K	11		21. A standards thermometer has been calibrated by NIST or one of equivalent accuracy at the points 0E, 35E and 44.5EC (45.5EC for ETCP). Calibration records maintained.
K	4		22. Standards thermometer is checked annually for accuracy by ice point determination. Results recorded and maintained.
			Date of most recent determination._____
K	13		23. Incubator and waterbath working thermometers are checked annually against the standards thermometer at the temperatures at which they are used. Records maintained.

CODE	REF.		Labware and Glassware Washing
0	9		1. Utensils and containers are clean borosilicate glass, stainless steel or other noncorroding material.
K	9		2. Culture tubes are of a suitable size to accommodate the volume for nutritive ingredients and samples.
K	9		3. Sample containers are made of glass or some other inert material (i.e. polypropylene).
0	9		4. Dilution bottles and tubes are made of borosilicate glass or plastic and closed with rubber stoppers, caps or screw caps with nontoxic liners.
K	9		5. Graduations are indelibly marked on dilution bottles and tubes or an acceptable alternative method is used to ensure appropriate volumes.
K	9		6. Pipets used to inoculate the sample deliver accurate aliquots, have unbroken tips and are appropriately graduated. Pipets larger than 10 ml are not used to deliver 1 ml; nor, are pipets larger than 1 ml used to deliver 0.1 ml.
K	9		7. Reusable sample containers are capable of being properly washed and sterilized.
K	9		8. In washing reusable pipets, a succession of at least three fresh water rinses plus a final rinse of distilled/deionized water is used to thoroughly rinse off all the detergent.
C	9		**9. In washing reusable sample containers, glassware and plasticware, the effectiveness of the rinsing procedure is established annually or when detergent (brand or lot) is changed by the Inhibitory Residue Test as described in the current edition of Standard Methods for the Examination of Water and Wastewater. Records are kept.** **Date of most recent testing**_____ **Average difference between Groups A and B**_____ **Average difference between Groups B and D**_____ **Detergent brand**_____ **Lot #**_____
K	11		10. Once during each day of washing several pieces of glassware (pipets, sample bottles, etc.) from one batch are tested for residual acid or alkali w/aqueous 0.04% bromthymol blue. Records are maintained.

CODE	REF.		Sterilization and Decontamination
O	9		1. Autoclave(s) are of sufficient size to accommodate the workload.
O	8		2. Routine autoclave maintenance performed (e.g. pressure relief values, exhaust trap, chamber drain) and records maintained.
O	8		3. Autoclave(s) and/or steam generators serviced annually or as needed by a qualified technician and records maintained.
C	11		**4. Autoclave(s) provides a sterilizing temperature of 121EC (tolerance 121 ± 2EC) as determined weekly using a calibrated working maximum registering thermometer or equivalent (thermocouples, platinum resistance thermometers).**
K	11		5. An autoclave standards thermometer has been calibrated by the National Institute of Standards and Technology (NIST) or its equivalent at 121EC.

K	16		6. The autoclave standards thermometer is checked every five years for accuracy at either 121EC or at the steam point. Date of most recent determination_____
K	1		7. Working autoclave thermometers are checked against the autoclave standards thermometer at 121EC yearly. Date of last check _____ Method _____
K	11		8. Spore suspensions are used monthly to evaluate the effectiveness of the autoclave sterilization process. Results are recorded.
O	11		9. Heat sensitive tape is used with each autoclave batch.
K	11,13		10. Autoclave sterilization records including length of sterilization, total exposure time and chamber temperature are maintained. Type of record: autoclave log, computer printout or chart recorder tracings (***circle appropriate type or types***).
K	11		11. For dry heat sterilized materials, the hot-air sterilizing oven provides heating and sterilizing temperature in the range of 160E to 180EC.
K	9		12. A thermometer capable of determining temperatures accurately in the range of 160E to 180EC is used to monitor the operation of the hot-air sterilizing oven when in use.
K	13		13. Records of temperatures and exposure times are maintained for the operation of the hot-air sterilizing oven during use.
K	11		14. Spore strips are used quarterly to evaluate the effectiveness of the sterilization process in the hot-air oven. Records are maintained.
K	11		15. Reusable sample containers are sterilized for 60 minutes at 170EC in a hot-air sterilizing oven or autoclaved for 15 minutes at 121EC.
0	1		16. The sterility of reusable/disposable sample containers is determined for each batch/lot.
K	9		17. Reusable pipets are stored and sterilized in aluminum or stainless steel canisters or equivalent alternative.
K	9		18. Reusable pipets (in canisters) are sterilized in a hot-air oven at 170EC for 2 hours.
O	2		19. The sterility of reusable/disposable pipets is determined with each batch/lot. Results are recorded and maintained.
K	18		20. Hardwood applicator transfer sticks are properly sterilized.
O	13		21. Spent broth cultures and agar plates are decontaminated by autoclaving for at least 30 minutes before conventional disposal.

CODE	REF.		Media Preparation
K	3,5		1. Media is commercially dehydrated except in the case of medium A-1 which is prepared from the individual components and modified MacConkey Agar which may be prepared from its components.
O	11		2. Dehydrated media and media components properly stored in cool, clean, dry place.
O	11		3. Dehydrated media are labeled with date of receipt and date opened.
C	12		4. Caked or expired media are discarded.
C	11		**5. Make-up water is distilled or deionized (circle one) and exceeds 0.5 megohm resistance or is less than 2µ Siemens/cm conductivity at 25EC to be tested and recorded monthly for resistance or conductivity (*circle the appropriate*)**

C	11		**6. Make-up water is analyzed for residual chlorine monthly and is at a nondetectable level (< 0.1ppm). Records are maintained.**
			Specify method of determination_____
K	11		7. Make-up water is free from trace (< 0.05mg/L) dissolved metals specifically Cd, Cr, Cu, Ni, Pb, and Zn as determined annually with total heavy metal content < or equal to 1.0mg/L and records are maintained.
K	11		8. Make-up water contains < 1000 CFU/ml as determined monthly using the heterotrophic plate count method and record are maintained.
K	11		9. Media are sterilized according to the manufacturer's instructions.
K	9		10. Volume and concentration of media in the tube are suitable for the amount of sample inoculated.
C	11		**11. Total time of exposure of sugar broths to autoclave temperatures does not exceed 45 minutes.**
C	1		**12. Media sterility and positive and negative controls are run with each lot of commercially prepared media or run with each batch of media prepared from its components as a check of media productivity. Results recorded and records maintained.**
O	9		13. Sterile phosphate buffered dilution water or 0.5% peptone water is used as the sample diluent. **(*circle appropriate choice*)**
K	11		14. pH is determined after sterilization to ensure that it is consistent with manufacturer's requirements and records are maintained.

CODE	REF.		Storage of Prepared Culture Media
O	9		1. Prepared culture media are stored in a cool, clean, dry space where excessive evaporation and the danger of contamination are minimized.
K	5,11		2. Brilliant green bile 2% broth and A-1 are stored in the dark.
K	13		3. Stored media are labeled with expiration date or sterilization date.
O	9		4. Storage of prepared culture media at room temperature does not exceed 7 days.
O	2		5. Storage under refrigeration of prepared media with loose fitting closures shall not exceed 1 month.
O	11		6. Storage under refrigeration of prepared media with screw-cap closures does not exceed 3 months.
K	17		7. All prepared media stored under refrigeration are held at room temperature overnight prior to use. Culture tubes containing any type of precipitate or Durham tubes containing air bubbles are discarded.

PART II - SEAWATER SAMPLES			
CODE	**REF.**		**ITEM**
			Collection and Transportation of Samples
C	11		**1. Containers are of suitable size to contain at least 100 ml and to allow head space for shaking. Seawater samples are collected in clean, sterile, water tight, properly labeled sample containers.**
K	1		2. Sample identified with collectors name, harvest area, time and date of collection.
C	9		**3. After collection, seawater samples shall be kept at a temperature between 0E and 10EC until examined.**
K	1		4. A temperature blank is used to determine the temperature of samples upon receipt at the laboratory. Results are recorded and maintained.
C	9		**5. Examination of the sample is initiated as soon as possible after collection. However, seawater samples are not tested if they are held beyond 30 hours regardless of refrigeration.**

CODE	REF.		Bacteriological Examination of Seawater by the APHA MPN
C	9		**1. Lactose broth or lauryl tryptose broth is used as the presumptive medium. (*circle appropriate one*)**
C	9		**2. Sample and dilutions of sample are mixed vigorously (25 times in a 12" arc in 7 seconds) before inoculation.**
C	9		**3. In a multiple dilution series not less than 3 tubes per dilution are used (5 tubes are recommended).**
C	6		**4. In a single dilution series not less than 12 tubes are used (for depuration at least 5 tubes are used).**
K	6		5. In a single dilution series, the volumes examined are adequate to meet the needs of routine monitoring. Sample volume inoculated _____ Range of MPN _____ Strength of media used _____
K	9		6. Inoculated media are placed in an air incubator at 35E ± 0.5EC for up to 48 ± 3 hours.
K	2		7. Positive and negative control cultures accompany samples throughout the procedure. Records are maintained. Positive Control_____ Negative Control_____
K	9		8. Inoculated media are read after 24 ± 2 hours and 48 ± 3 hours of incubation and transferred at both intervals if positive for gas.

CODE	REF.		Confirmed Test for Seawater by APHA MPN
C	9		**1. Brilliant green bile 2% broth (BGB) is used as the confirmatory medium for total coliforms.**
C	9		**2. EC medium is used as the confirmatory medium for fecal coliforms.**
K	9, 11		3. Transfers are made to BGB/EC by either sterile loop or sterile hardwood applicator stick from positive presumptives incubated for 24 and 48 hours (***circle the method of transfer***).
K	2		4. When the inoculation of both EC and BGB broths is performed using the same loop or transfer stick, the order of inoculation is; EC first followed by BGB.
C	9		**5. BGB tubes are incubated at 35 ± 0.5E C.**
K	9		6. BGB tubes are read after 48 ± 3 hours of incubation.
C	9		**7. EC tubes are incubated in a circulating waterbath at 44.5 ± 0.2E C for 24 ± 2 hours.**
C	9		**8. The presence of any amount of gas or effervescence in the culture tube constitutes a positive test.**

CODE	REF.		Computation of results
K	9		1. Results of multiple dilution tests are read from tables in Recommended Procedures, 4th Edition.
K	7		2. Results from single dilution series are calculated from Hoskins equation or interpolated from figure 1 Public Health Report 1621 entitled "Most Probable Numbers fro Evaluation of Coli aerogenes Tests by Fermentation tube Method.
K	7,9		3. Results are reported as MPN/100 ml of sample.

CODE	REF.		Bacteriological Examination of Seawater by the MA-1 Method
C	5		**1. Medium A-1 sterilized for 10 minutes at 121EC.**
C	9		**2. Sample and dilutions of sample are mixed vigorously (25 times in a 12" arc in 7 seconds) before inoculation.**
C	9		**3. In a multiple dilution series not less than 3 tubes per dilution are used (5 tubes recommended).**
C	6		**4. In a single dilution series at least 12 tubes are used.**
K	6		5. In a single dilution series, the volumes examined are adequate to meet the needs of routine monitoring. Sample volume inoculated _____ Range of the MPN _____ Strength of media used _____
K	2		6. Positive and negative control cultures accompany samples throughout the procedure. Records are maintained. Positive control _____ Negative control _____
C	2,5		**7. Inoculated media are placed in an air incubator at 35 ± 0.5EC for 3 ±0.5 hours of resuscitation.**
C	5		**8. After 3 ±0.5 hours resuscitation at 35EC, inoculated media are incubated at 44.5 ± 0.2EC in a circulating waterbath for the remainder of the 24 ± 2 hours.**
C	5		**9. The presence of any amount of gas or effervescence in the culture tube constitutes a positive test.**

CODE	REF.		Computation of results
K	9		1. Results of multiple dilution tests are read from tables in Recommended Procedures, 4th Edition.
K	7		2. Results from single dilution series are calculated from Hoskins equation or interpolated from figure 1 Public Health Report 1621 entitled "Most Probable Numbers fro Evaluation of Coli aerogenes Tests by Fermentation tube Method.
K	7,9		3. Results are reported as MPN/100 ml of sample.

PART III - SHELLFISH SAMPLES			
CODE	**REF.**		**ITEM**
			Collection and Transportation of Samples
C	9		**1. A representative sample of shellstock is collected.**
K	9		2. Shellstock is collected in clean, waterproof, puncture resistant containers.
K	9		3. Shellstock labeled with collector's name, type of shellstock, the source, the harvest area, time, date and place (if market sample) of collection.
C	9		**4. Shellstock samples are maintained in dry storage between 0E and 10E C until examined.**
C	1		**5. Examination of the sample is initiated as soon as possible after collection. However, shellfish samples are not examined if the time interval between collection and examination exceeds 24 hours.**

CODE	**REF.**		**Preparation of Shellstock for Examination**
K	2,11		1. Shucking knives, scrub brushes, and blender jars are (autoclave) sterilized for 15 minutes prior to use.
O	2		2. Blades of shucking knives are not corroded.
O	9		3. Prior to scrubbing and rinsing debris off shellstock, the hands of the analyst are thoroughly washed with soap and water.
O	2		4. The faucet used to provide the potable water for rinsing the shellstock does not contain an aerator.
K	9		5. Shellstock are scrubbed with a stiff, sterile brush and rinsed under water of drinking water quality.
O	9		6. Shellstock are allowed to drain in a clean container or on clean towels prior to opening.
K	9		7. Prior to opening, the hands (or gloved hands) of the analyst are thoroughly washed with soap and water and rinsed in 70% alcohol.
K	9		8. Shellstock are not shucked directly through the hinge.
C	9		**9. Contents of shellstock (liquor and meat) are shucked into a sterile, tared blender jar or other sterile container.**
K	9		10. At least 200 grams of shellfish meat is used for analysis.
K	2,19		11. The sample is weighed to the nearest 0.1 gram and an equal amount by weight of (tempered for ETCP) diluent is added.
O	9		12. Sterile phosphate buffered dilution water or 0.5% peptone water is used as the sample diluent **(*circle appropriate choice*)**
K	3		13. Sterile phosphate buffered saline is used as a sample diluent for ETCP procedure
C	9		**14. Samples are blended at high speed for 60 to 120 seconds.**
K	9		15. For other than shellstock, APHA Recommended Procedures are followed for the examination of freshly shucked and frozen shellfish meats.

CODE	REF.		MPN Analysis for Fecal Coliform Organisms, Presumptive Test APHA
C	9		**1. Appropriate strength lactose or lauryl tryptose broth is used as presumptive media in the analysis. *(circle appropriate choice*)**
K	9		2. Immediately (within 2 minutes) after blending, the ground sample is diluted and inoculated into tubes of presumptive media.
C	9		**3. No fewer than 5 tubes per dilution are used in a multiple dilution MPN series.**
C	9		**4. Allowing for the initial 1:1 dilution of the sample, appropriate portions are inoculated (i.e., 2 ml of original 1:1 dilution for the 1 g portion) and diluted for subsequent inoculation (i.e., 22 ml of 1:1 diluted sample to 88 ml of diluent or the equivalent for 0.1 g portion).**
K	6		5. In a single dilution series, the volumes examined are adequate to meet the needs of routine monitoring. Sample volume inoculated _____ Range of MPN _____ Strength of media used _____
C	2		**6. Positive and negative control cultures accompany samples throughout the procedure. Records maintained.** **Positive control**_____ **Negative control**_____
K	9		7. Inoculated media are incubated at 35E ± 0.5EC.
K	10		8. Presumptive tubes are read at 24 ± 2 hours of incubation and transferred if positive.

CODE	REF.		Confirmed Test For Fecal Coliform - APHA
C	9		**1. EC medium is used as the confirmatory medium.**
K	9,11		2. Transfers are made to EC medium by either sterile loop or hardwood sterile applicator sticks from positive presumptives incubated for 24 hours (***circle the method of transfer***).
C	9		**3. EC tubes are incubated in a circulating waterbath at 44.5E ± 0.2EC. for 24 ± 2 hours.**
K	9		4. EC tubes are read for gas production after 24 ± 2 hours of incubation.
C	9		**5. The presence of any amount of gas or effervescence in the Durham tube constitutes a positive test.**

CODE	REF.		Computation of Results - for MPN analyses
K	9		1. Results of multiple dilution tests are read from tables in Recommended Procedures, 4th Edition and multiplied by the appropriate dilution factor.
K	7		2. Results from single dilution series are calculated from Hoskins equation or interpolated from Figure 1, Public Health Report Reprint 1621 entitled Most Probable Numbers for Evaluation of Coli Aerogenes Tests by Fermentation Tube Method.
K	9		3. Results are reported as MPN/100 grams of sample.

CODE	REF.		Standard Plate Count Method
O	20		1. A standard plate count analysis is performed in conjunction with the analysis for fecal coliform organisms.
K	9		2. In the standard plate count procedure at least four plates, duplicates of two dilutions are used to provide 30 to 300 colonies per plate.
K	2		3. Fifteen to 20 mls of tempered sterile plate count agar is used.
K	9		4. Agar tempering bath maintains the agar at 44E to 46EC.
O	9		5. Temperature control of the plate count agar is used in the tempering bath.
K	9		6. Not more than 1 ml nor less than 0.1 ml of sample or sample dilution is plated.
C	9		**7. Samples or sample dilutions to be plated are mixed vigorously (25 times in a 12" arc in 7 seconds) before plating.**
K	11		8. Control plates are used to check the sterility of the air, agar and the diluent.
K	9,21		9. Solidified plates are incubated at 35 ± 0.5E for 48 ± 3 hours inverted and stacked not more than 4 high.
K	9		10. Quebec Colony Counter or its equivalent is used to provide the necessary magnification and visibility for counting plates.
K	1		11. A hand tally or its equivalent is used for accuracy in counting.

CODE	REF.		Computation of Results
K	9		1. Colony counts determined in accordance with Part III, A, Sections 4.31 through 4.33 Recommended Procedures, 4th Edition.
O	19		2. Colony counts reported as APC/g of sample.

CODE	REF.		Bacteriological Examination of Shellfish Using the ETCP
K	9		1. Sample homogenate is cultured within 2 minutes of blending.
K	3		2. Double strength Modified MacConkey Agar is used.
C	3		**3. Hydrated double strength Modified MacConkey Agar is heated to boiling, removed from the heat, and boiled again. This agar is never autoclaved.**
K	2,3		4. Twice boiled, double strength Modified MacConkey Agar and sterile phosphate buffered saline are maintained in a tempering bath at 45E to 50EC until used. Prepared Modified MacConkey Agar is used on the day it is made.
C	2,3		**5. The equivalent of 6 grams of the homogenate is placed into a sterile container and the contents brought up to 60 ml with tempered, sterile phosphate buffered saline.**
K	3		6. Sixty (60) ml of tempered, twice boiled double strength Modified MacConkey Agar is added.
K	2,3, 22		7. Container is gently swirled or rotated to mix contents which are then distributed uniformly over 6 to 8 petri plates.
C	1		**8. Media and diluent sterility is determined with each use. Results recorded and records maintained.**
C	1		**9. To determine media productivity, positive and negative control cultures are pour plated in an appropriate concentration to accompany samples throughout the procedure**.
			Positive control _____ **Negative control** _____
C	3,13		**10. Plates are incubated inverted within 3 hours of plating in air at 45.5E ± 0.5EC for 18 to 30 hours. Plates are stacked not more than four high.**
C	3		**11. Incubator temperature maintained at 45.5E ± 0.5EC.**

CODE	REF.		Expression of Results
K	11		1. Quebec Colony Counter or its equivalent is used to provide the necessary magnification and visibility.
O	1		2. A hand tally or its equivalent is used to aid in counting.
C	3,6		**3. All brick red colonies greater than 0.5 mm in diameter are totaled over all the plates and multiplied by a factor of 16.7 to report results as CFU/100 grams of sample.**

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LABORATORY:	DATE OF EVALUATION

SHELLFISH LABORATORY EVALUATION CHECKLIST

SUMMARY OF NONCONFORMITIES

Page	Item	Observation	Documentation Required

Page _____ of _____

LABORATORY STATUS

LABORATORY:	DATE:
LABORATORY REPRESENTATIVE:	

MICROBIOLOGICAL COMPONENT: (PART I-III)

A. Results

Total # of Critical (C) Nonconformities in Parts I through III _____

Total # of Key (K) Nonconformities in Parts I through III _____

Total # of Critical, Key & Other (O) Nonconformities in Parts I through III _____

B. Criteria for Determining Laboratory Status of the Microbiological Component

1. Does Not Conform Status: The microbiological component of this laboratory is not in conformity with NSSP requirements if:

   A. The total # of Critical nonconformities is $4 or

   B. The total # of Key nonconformities is $13 or

   C. The total # of Critical, Key, and Other is $18 (not to exceed the Critical and Key Criteria)

2. Provisionally Conforms Status: The microbiological component of this laboratory is determined to be provisionally conforming to NSSP requirements if the number of critical nonconformities is $ 1 but # 3 (not to exceed Key and Total criteria.

C. Laboratory Status (*circle appropriate*)

Does Not Conform Provisionally Conforms Conforms

Acknowledgment by Laboratory Director/Supervisor:

All corrective Action will be implemented and verifying substantiating documentation received by the Laboratory Evaluation Officer on or before _____

Laboratory Signature: _____ Date _____

LEO Signature: _____ Date _____

Annex VIII

Donovan Method for the Examination of shellfish for *Escherichia coli*

Donovan Method for the Examination of shellfish for *Escherichia coli*

The numbers of *Escherichia coli* in live bivalve mollusks are estimated as a marker of fecal contamination in shellfish flesh. This allows harvesting areas to be classified and is used to monitor the quality of the marketed product.

1.1 Sample size
Oysters and clams 10 - 15
Mussels 15 - 30
Cockles 30 - 50

1.2 Sample transport

Deliver samples to the laboratory as soon as possible. Use a cool box with freezer packs to keep temperature near 4°C, but do not allow direct contact between samples and freezer packs. No more than 24 h should elapse between sample collection and start of tests.

Store samples at 4°C during this time; do not freeze.

1.3 Sample preparation

(i) Wear gloves during sample preparation; use a separate pair for each sample.
(ii) Discard any gaping shellfish and those with obvious signs of damage.
(iii) Select at least ten oysters or clams, 15 mussels, or 30 cockles.
(iv) Scrub shellfish clean under cold, running tap water of potable quality.
(v) Dry with clean paper towels.
(vi) Open shellfish with a sterile shucking knife (flamed and cooled), as follows.
* Another 25 g of homogenate may be removed at this stage for detection of salmonella.

1.3.1 Oysters/clams

Insert the knife between the two shells towards the hinge end of the shellfish. Push the knife further into the shellfish and prise open the upper shell, allowing any liquor to drain into a sterile weighed bag or beaker. Push the blade through the shellfish and sever the muscle attachments by slicing across. Remove the upper shell and scrape the contents of the lower shell into the bag or beaker. Repeat for ten oysters/clams and collect in the same bag or beaker.

1.3.2 Mussels/cockles

Insert the knife between the shells through the byssal opening of the shellfish and separate the shells by twisting the knife. Collect the liquor in a weighed sterile bag or beaker. Cut the muscle between the two shells and scrape the contents into the sterile bag or beaker. Repeat for at least 15 mussels or 30 cockles and collect in the same bag or beaker.

1.4 Homogenization and dilution of sample

1.4.1 Dilution fluid 0.1% peptone in water, pH 7.2 ± 0.2

1.4.2 Homogenization in stomacher

Place the bag containing shellfish flesh and liquor inside two more bags; this will prevent small pieces of shell from puncturing the bag. Remove excess air and place in the stomacher. Operate stomacher for 2-3 minutes (min).

Remove 50g* of homogenate to another stomacher bag. From a measured 450 mL volume of sterile dilution fluid, add about 100 mL to the 50 g sample. Homogenize in the stomacher for –3 min. Then add the remainder of the dilution fluid and mix well. This forms the master 1 in 10 dilution.

Prepare a 1 in 100 dilution by adding 10 mL of the 1 in 10 dilution to 90 mL dilution fluid. If levels of *E. coli* are expected to be high, - e.g., for category C and prohibited harvesting areas - prepare 1 in 1000 and 1 in 10 000 dilutions in the same way. Store remainder of the sample homogenate at 1-4°C until testing is completed.

1.4.3 Homogenization in blender (homogenizer) Weigh beaker containing shellfish flesh and liquor and subtract the weight of the beaker to obtain the weight of sample. Add two parts by weight of sterile dilution fluid. Transfer to a sterile blender, replace lid, and homogenize at high speed (about 12 000 rev/min) for a total of 60 seconds (s) (four sessions of 15 s blending with 15 s intervals). Stand for 30 s, swirl briefly, and transfer 30 mL of homogenate to 70 mL of sterile dilution fluid. This forms the master 1 in 10 dilution.

Prepare further decimal dilutions as described in 1.4.1.

1.5 Examination

1.5.1 Media

Minerals modified glutamate broth (MMGB), e.g. Oxoid CM607 (base) and L124 sodium glutamate. Equivalent formulations from other suppliers may be used.
This medium is prepared as single and double strength and dispensed in quantities of 10 mL in bottles or tubes.

Double strength: Dissolve 5 g ammonium chloride in 1 L of distilled water. Add 22.7 g minerals modified medium base and 12.7 g sodium glutamate.

Single strength: Dissolve 2.5 g ammonium chloride in 1 L of distilled water. Add 11.4 g minerals modified medium base and 6.4 g sodium glutamate.

Mix to dissolve completely. Adjust pH to 6.7 after autoclaving. Dispense in 10 mL. Sterilize in the autoclave for 10 min at 116°C.
5-bromo-4-chloro-3-indolyl-β-D-glucuronide agar (BCIG) tryptone bile agar containing 75 mg/l 5-bromo- 4-chloro-3-indolyl-β-D-glucuronide, e.g. Oxoid CM 945
(TBX agar), Lab M LAB 162 (tryptone bile glucuronide agar).

1.5.2 First stage tests

1.5.2.1 Inoculation

(a) Inoculate 10 mL of 1 in 10 homogenate to each of five tubes containing 10 mL of double strength MMGB. Each tube contains the equivalent of 1 g of tissue.

(b) Inoculate 1 mL of the 1 in 10 homogenate to each of five tubes containing 10 mL of single strength MMGB. Each tube contains the equivalent of 0.1 g of tissue.

(c) Inoculate 1 mL of the 1 in 100 dilution to each of five tubes containing 10 mL of single strength MMGB. Each tube contains the equivalent of 0.01 g of tissue.

(d) If further dilutions have been prepared, inoculate 1 mL aliquots of each dilution to each of five tubes containing 10 mL of single strength MMGB.

1.5.2.2 Incubation

(e) Incubate the inoculated tubes at 37 ± 1°C for 24 ± 2 h.

(f) At the end of the incubation period, examine the tubes for the presence of acid, denoted by a yellow coloration of the medium. Note that the presence of any acid, regardless of quantity, is regarded as a positive result.

Absence of acid denotes a negative result for *E. coli*.

1.5.3.1 Second stage tests

(g) At the time of detection, subculture all tubes showing the presence of acid to a section of BCIG agar and streak to separate colonies.

Do not refrigerate tubes before subculture.

Note that up to five sections per plate may be used.

(h) Incubate BCIG agar plates at 44 ± 1°C for 20-24 h.

(i) Examine the plates for the presence of bluegreen colonies, which signify b-glucuronidase activity. Tubes of MMGB that grow blue-green colonies are deemed to contain *E. coli*. Absence

b) Blender used for E. coli

Weigh out a separate 25 g amount into a sterile beaker.

Add about 50 mL from a measured 225 mL volume of BPW and homogenise at high speed for a total of 60 s (see Section 1.4.2). Add remainder of BPW and mix well. Incubate at 37 ± 1°C for 18-24 h.

2.1.4 Selective enrichment

Transfer 0.1 mL of incubated BPW to 10 mL sterile Rappaport Vassiliadis soya (RVS) peptone broth.

Incubate at 41- 42°C for 48 ± 2 h.

2.1.5 Subculture

Subculture the incubated RVS broth after 18 to 24 h and again after 48 h. Using a loop of 2-3 mm diameter, subculture to plates of XLD agar and brilliant green agar (BGA) and streak to obtain isolated colonies. Incubate the XLD and BGA plates at 37 ± 1°C for 18-24 h. At the end of incubation examine the plates for suspect salmonella colonies. Investigate suspect colonies using standard biochemical and serological methods.

2.2 Method for Salmonella typhi

2.2.1 Media

Buffered peptone water – e.g., Oxoid CM 509 Selenite F broth – e.g., Oxoid CM 399 with sodium biselenite L121 to give 0.4% concentration.

Caution: sodium biselenite is hazardous.

Desoxycholate citrate agar (Hynes modification) –e.g., Oxoid CM227, Lab M LAB65 Bismuth sulphite agar - e.g., Lab M LAB13A andLAB13B.

2.2.2 Sample preparation

See Section 2.1.2.

2.2.3 Sample homogenisation and pre-enrichment

See Section 2.1.3.

2.2.4 Selective enrichment

Transfer 10 mL of incubated BPW to 100 mL of sterile selenite F broth. Incubate at 37 ± 1°C for 24 ± 2 h.

2.2.5 Subculture

At the end of the incubation period, subculture the selenite F broth to desoxycholate citrate agar (DCA) and bismuth sulphite agar. Use a loopful 2-3 mm in diameter and streak to obtain isolated colonies.

Incubate the plates at 37°C for 18 to 24 h. Examine the plates for suspect salmonella colonies. Reincubate the plates for a further 24 h (48 ± 2 h in total) and examine again at the end of incubation. Investigate suspect salmonella colonies using standard biochemical and serological methods. of blue-green colonies denotes a negative result for *E. coli*.

Control cultures

NCTC 9001 *Escherichia coli* (β-glucuronidase positive)
NCTC 9528 *Klebsiella aerogenes* (β-glucuronidase negative)

1.5.4 Calculation of E. coli count

(j) After completing the second stage tests, determine the number of MMGB tubes/bottles positive for *E. coli*. Compute the most probable number (MPN) by reference to the MPN table for the appropriate dilution range. Report the results as the number of *E. coli* per 100 g shellfish. If the positive tube combination obtained is not shown in the MPN tables, either report the test as void or repeat the test from the sample homogenate stored at 1-4°C.

2 Examination of shellfish for Salmonella spp.

Tests for salmonellas are required to be applied only to shellfish for immediate human consumption (final product) and not for the classification of harvesting areas. In certain circumstances it may be necessary to test for the presence of *S. typhi*. A general method for salmonella, which will recover a wide range of serotypes, is given below. This method is not suitable for the specific isolation of *S. typhi*, however, and an additional method for its isolation is also described.

2.1 General method for salmonella

2.1.1 Media

The use of commercially available dehydrated media is advised. Equivalent formulations from other suppliers may be used.

Buffered peptone water - e.g., Oxoid CM 509.
Rappaport Vassiliadis Soya (RVS) peptone broth –e.g., Oxoid CM 866. XLD agar - e.g., Oxoid CM 469.
Brilliant green agar (BGA) – e.g., Oxoid CM 329 (modified).

2.1.2 Sample preparation

See Section 1.3.

2.1.3 Sample homogenization and pre-enrichment

a) Stomacher used for E. coli

Remove 25 g of bulk homogenate prepared as in section 1.4.1 to a 250 mL or larger container. Add 225 mL of buffered peptone water (BPW). Mix well.

Incubate at 37 ± 1°C for 18-24 h.

(TJ Donovan, S Gallacher, NJ Andrews, MH Greenwood, J Graham, JE Russell, D Roberts,R Lee*Vol1 No. 3 1998)

TABLE A1 Most probable number (MPN) of organisms: tables for multiple tube methods using 5×1 g, 5×0.1 g, 5×0.01 g[16]

1 g	0.1 g	0.01 g	MPN/100g	
0	0	0	<20	
0	0	1	20	
0	1	0	20	
1	0	0	20	
1	0	1	40	
1	1	0	40	
1	2	0	50	
2	0	0	40	
2	0	1	50	
2	1	0	50	
2	1	1	70	
2	2	0	70	
2	3	0	110	
3	0	0	70	
3	0	1	90	
3	1	0	90	
3	1	1	130	
3	2	0	130	
3	2	1	160	
3	3	0	160	
4	0	0	110	
4	0	1	140	
4	1	0	160	
4	1	1	200	
4	2	0	200	Category A
5	0	0	220	(<230 E. coli)
4	2	1	250	Category B
4	3	0	250	(>230 E. coli)
4	3	1	310	(<4600 E. coli)
4	4	0	320	

TABLE A2 Most probable number (MPN) of organisms: tables for multiple tube methods using 5×0.1 g, 3×0.01 g, 5×0.001g[16]

0.1 g	0.01 g	0.001 g	MPN/100g	
0	0	1	200	
0	1	0	200	Category A
1	0	0	200	(<230 E. coli)
1	0	1	400	Category B
1	1	0	400	(>230 E. coli)
1	2	0	500	(<4600 E. coli)
2	0	0	400	
2	0	1	500	
2	1	0	500	
2	1	1	700	
2	2	0	700	
2	3	0	1100	
3	0	0	700	
3	0	1	900	
3	1	0	900	
3	1	1	1300	
3	2	0	1300	
3	2	1	1600	
3	3	0	1600	
4	0	0	1100	
4	0	1	1400	
4	1	0	1600	
4	1	1	2000	
4	2	0	2000	
4	2	1	2500	
4	3	0	2500	
4	3	1	3100	
4	4	0	3200	
4	4	1	3800	
5	0	0	2200	

4	4	1	380	5	0	1	2900	
5	0	1	290	5	0	2	4100	
5	0	2	410	5	1	0	3100	
5	1	0	310	5	1	1	4300	
5	1	1	430					
5	1	2	600	5	1	2	6000	Category C
5	1	3	850	5	1	3	8500	(>4600 E. coli)
5	2	0	500	5	2	0	5000	(<46000 E. coli)
5	2	1	700	5	2	1	7000	
5	2	2	950	5	2	2	9500	
5	2	3	1200	5	2	3	12000	
5	3	0	750	5	3	0	7500	
5	3	1	1100	5	3	1	11000	
5	3	2	1400	5	3	2	14000	
5	3	3	1750	5	3	3	17500	
5	3	4	2100	5	3	4	21000	
5	4	0	1300	5	4	0	13000	
5	4	1	1700	5	4	1	17000	
5	4	2	2200	5	4	2	22000	
5	4	3	2800	5	4	3	28000	
5	4	4	3450	5	4	4	34500	
5	5	0	2400	Category B 5	5	0	24000	
5	5	1	3500	(<4600 E. coli) 5	5	1	35000	
5	5	2	5400	Category C 5	5	2	54000	Prohibited
5	5	3	9100	(>4600 E. coli) 5	5	3	91000	(>46000 E. coli)
5	5	4	16000	(<46000 E. coli) 5	5	4	160000	
5	5	5	>18000*	5	5	5	>180000	

* needs further dilutions to clarify classification

TABLE A3 Most probable number (MPN) of organisms: tables for multiple tube methods using 5×0.01 g, 3×0.001 g, 5×0.0001g ^{16}

0.01 g	0.001 g	0.0001 g	MPN/100g	
0	0	1	2000	
0	1	0	2000	
1	0	0	2000	
1	0	1	4000	Category B
1	1	0	4000	(>230 E. coli)
2	0	0	4000	(<4600 E. coli)
1	2	0	5000	Category C
2	0	1	5000	(>4600 E. coli)
2	1	0	5000	(<46 000 E. coli)
2	1	1	7000	
2	2	0	7000	
2	3	0	11000	
3	0	0	7000	
3	0	1	9000	
3	1	0	9000	
3	1	1	13000	
3	2	0	13000	
3	2	1	16000	
3	3	0	16000	
4	0	0	11000	
4	0	1	14000	
4	1	0	16000	
4	1	1	20000	
4	2	0	20000	
4	2	1	25000	
4	3	0	25000	
4	3	1	31000	
4	4	0	32000	
4	4	1	38000	
5	0	0	22000	
5	0	1	29000	
5	0	2	41000	Category C
5	1	0	31000	(>4600 E. coli)
5	1	1	43000	(<46000 E. coli)
5	1	2	60000	Prohibited
5	1	3	85000	(>46000 E. coli)
5	2	0	50000	
5	2	1	70000	
5	2	2	95000	
5	2	3	120000	

5	3	0	75000
5	3	1	110000
5	3	2	140000
5	3	3	175000
5	3	4	210000
5	4	0	130000
5	4	1	170000
5	4	2	220000
5	4	3	280000
5	4	4	345000
5	5	0	240000
5	5	1	350000
5	5	2	540000
5	5	3	910000
5	5	4	160000
			0

Annex IX

REGULATION (EC) No 853/2004 OF THE

EUROPEAN PARLIAMENT

AND OF THE COUNCIL

of 29 April 2004

laying down specific hygiene rules for the hygiene of foodstuffs

REGULATION (EC) No 853/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004

laying down specific hygiene rules for on the hygiene of foodstuffs

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(b) thereof,

Having regard to the proposal from the Commission [*],

Having regard to the Opinion of the European Economic and Social Committee [†],

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty [‡],

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[*] OJ C 365 E, 19.12.2000, p. 58.

[†] OJ C 155, 29.5.2001, p. 39.

[‡] Opinion of the European Parliament of 15 May 2002 (OJ C 180 E, 31.7.2003, p. 288), Council Common Position of 27 October 2003 (OJ C 48 E, 24.2.2004, p. 23), Position of the European Parliament of 30 March 2004 (not yet published in the Official Journal) and Council Decision of 16 April 2004.

Whereas:

(1) By Regulation (EC) No /2004 [*], the European Parliament and the Council laid down general rules for food business operators on the hygiene of foodstuffs.

(2) Certain foodstuffs may present specific hazards to human health, requiring the setting of specific hygiene rules. This is particularly the case for food of animal origin, in which microbiological and chemical hazards have frequently been reported.

(3) In the context of the common agricultural policy, many Directives have been adopted to establish specific health rules for the production and placing on the market of the products listed in Annex I to the Treaty. These health rules have reduced trade barriers for the products concerned, contributing to the creation of the internal market while ensuring a high level of protection of public health.

(4) With regard to public health, these rules contain common principles, in particular in relation to the manufacturers' and competent authorities' responsibilities, structural, operational and hygiene requirements for establishments, procedures for the approval of establishments, requirements for storage and transport and health marks.

(5) These principles constitute a common basis for the hygienic production of food of animal origin, permitting the simplification of the existing Directives.

(6) It is desirable to achieve further simplification by applying the same rules wherever appropriate to all products of animal origin.

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[*] Page … of this Official Journal.

(7) The requirement in Regulation (EC) No /2004 * whereby food business operators carrying out any stage of production, processing and distribution of food after primary production and associated operations must put in place, implement and maintain procedures based on hazard analysis and critical control point (HACCP) principles also permits simplification.

(8) Taken together, these elements justify a recasting of the specific hygiene rules contained in existing Directives.

(9) The principal objectives of the recasting are to secure a high level of consumer protection with regard to food safety, in particular by making food business operators throughout the Community subject to the same rules, and to ensure the proper functioning of the internal market in products of animal origin, thus contributing to the achievement of the objectives of the common agricultural policy.

(10) It is necessary to maintain and, where required to ensure consumer protection, to tighten detailed hygiene rules for products of animal origin.

(11) Community rules should not apply either to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption. Moreover, where small quantities of primary products or of certain types of meat are supplied directly by the food business operator producing them to the final consumer or to a local retail establishment, it is appropriate to protect public health through national law, in particular because of the close relationship between the producer and the consumer.

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* Official Publications Office is to insert official number of Regulation on the hygiene of foodstuffs (as in recital 1).

(12) The requirements of Regulation (EC) No /2004 * are generally sufficient to ensure food safety in establishments carrying out retail activities involving the direct sale or supply of food of animal origin to the final consumer. This Regulation should generally apply to wholesale activities (that is, when a retail establishment carries out operations with a view to supplying food of animal origin to another establishment). Nevertheless, with the exception of the specific temperature requirements laid down in this Regulation, the requirements of Regulation (EC) No /2004 * should suffice for wholesale activities consisting only of storage or transport.

(13) Member States should have some discretion to extend or to limit the application of the requirements of this Regulation to retail under national law. However, they may limit their application only if they consider that the requirements of Regulation (EC) No /2004 * are sufficient to achieve food hygiene objectives and when the supply of food of animal origin from a retail establishment to another establishment is a marginal, localised and restricted activity. Such supply should therefore be only a small part of the establishment's business; the establishments supplied should be situated in its immediate vicinity; and the supply should concern only certain types of products or establishments.

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* Official Publications Office is to insert official number of Regulation on the hygiene of foodstuffs (as in recital 1).

(14) In accordance with Article 10 of the Treaty, Member States are to take all appropriate measures to ensure that food business operators comply with the obligations laid down in this Regulation.

(15) The traceability of food is an essential element in ensuring food safety. In addition to complying with the general rules of Regulation (EC) No 178/2002 [*], food business operators responsible for establishments that are subject to approval in accordance with this Regulation should ensure that all products of animal origin that they place on the market bear either a health mark or an identification mark.

(16) Food imported into the Community is to comply with the general requirements laid down in Regulation (EC) No 178/2002 or to satisfy rules that are equivalent to Community rules. This Regulation defines specific hygiene requirements for food of animal origin imported into the Community.

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[*] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1). Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p.4).

(17) The adoption of this Regulation should not reduce the level of protection provided by the additional guarantees agreed for Finland and Sweden on their accession to the Community and confirmed by Decisions 94/968/EC [*], 95/50/EC [†], 95/160/EC [‡], 95/161/EC [§], 95/168/EC [**], 95/409/EC [††], 95/410/EC [‡‡] and 95/411/EC [§§]. It should establish a procedure for the granting, for a transitional period, of guarantees to any Member State that has an approved national control programme which, for the food of animal origin concerned, is equivalent to those approved for Finland and Sweden. Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents [***] provides for a similar procedure in respect of live animals and hatching eggs.

(18) It is appropriate for the structural and hygiene requirements laid down in this Regulation to apply to all types of establishments, including small businesses and mobile slaughterhouses.

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[*] OJ L 371, 31.12.1994, p. 36.
[†] OJ L 53, 9.3.1995, p. 31.
[‡] OJ L 105 9.5.1995, p. 40.
[§] OJ L 105, 9.5.1995, p. 44.
[**] OJ L 109, 16.5.1995, p. 44.
[††] OJ L 243, 11.10.1995, p. 21.
[‡‡] OJ L 243, 11.10.1995, p. 25.
[§§] OJ L 243, 11.10.1995, p. 29.
[***] OJ L 325, 12.12.2003, p. 1.

(19) Flexibility is appropriate to enable the continued use of traditional methods at any of the stages of production, processing or distribution of food and in relation to structural requirements for establishments. Flexibility is particularly important for regions that are subject to special geographical constraints, including the outermost regions referred to in Article 299(2) of the Treaty. However, flexibility should not compromise food hygiene objectives. Moreover, since all food produced in accordance with the hygiene rules will normally be in free circulation throughout the Community, the procedure allowing Member States to exercise flexibility should be fully transparent. It should provide, where necessary to resolve disagreements, for discussion within the Standing Committee on the Food Chain and Animal Health established by Regulation (EC) No 178/2002 and for the Commission to coordinate the process and take appropriate measures.

(20) The definition of mechanically separated meat (MSM) should be a generic one covering all methods of mechanical separation. Rapid technological developments in this area mean that a flexible definition is appropriate. The technical requirements for MSM should differ, however, depending on a risk assessment of the product resulting from different methods.

(21) There are interactions between food business operators, including the animal feed sector, and connections between animal health, animal welfare and public health considerations at all stages of production, processing and distribution. This requires adequate communication between the different stakeholders along the food chain from primary production to retail.

(22) In order to ensure proper inspection of hunted wild game placed on the Community market, bodies of hunted animals and their viscera should be presented for official post-mortem inspection at a game-handling establishment. However, to preserve certain hunting traditions without prejudicing food safety, it is appropriate to provide for training for hunters who place wild game on the market for human consumption. This should enable hunters to undertake an initial examination of wild game on the spot. In these circumstances, it is not necessary to require trained hunters to deliver all viscera to the game-handling establishment for post-mortem examination, if they carry out this initial examination and identify no anomalies or hazards. However, Member States should be allowed to establish stricter rules within their territories to take account of specific risks.

(23) This Regulation should establish criteria for raw milk pending the adoption of new requirements for its placing on the market. These criteria should be trigger values, implying that, in the event of any overshooting, food business operators are to take corrective action and to notify the competent authority. The criteria should not be maximum figures beyond which raw milk cannot be placed on the market. This implies that, in certain circumstances, raw milk not fully meeting the criteria can safely be used for human consumption, if appropriate measures are taken. As regards raw milk and raw cream intended for direct human consumption, it is appropriate to enable each Member State to maintain or establish appropriate health measures to ensure the achievement of the objectives of this Regulation on its territory.

(24) It is appropriate for the criterion for raw milk used to manufacture dairy products to be three times as high as the criterion for raw milk collected from the farm. The criterion for milk used to manufacture processed dairy products is an absolute value, whereas for raw milk collected from the farm it is an average. Compliance with the temperature requirements laid down in this Regulation will not halt all bacterial growth during transport and storage.

(25) The present recasting means that the existing hygiene rules can be repealed. Directive 2004/.../EC of the European Parliament and of the Council of ..... repealing certain Directives on food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption [*] achieves this.

(26) In addition, the rules of this Regulation on eggs replace those of Council Decision 94/371/EC of 20 June 1994 laying down specific public health conditions for the putting on the market of certain types of eggs [†], which the repeal of Annex II to Council Directive 92/118/EEC [‡] renders void.

(27) Scientific advice should underpin Community legislation on food hygiene. To this end, the European Food Safety Authority should be consulted whenever necessary.

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[*] Page … of this Official Journal.

[†] OJ L 168, 2.7.1994, p. 34.

[‡] Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC (OJ L 62, 15.3.1993, p. 49). Directive as last amended by Commission Regulation (EC) No 445/2004 (OJ L 72, 11.3.2004, p. 60).

(28) To take account of technical and scientific progress, close and effective cooperation should be ensured between the Commission and the Member States within the Standing Committee on the Food Chain and Animal Health.

(29) The requirements of this Regulation should not apply until all parts of the new legislation on food hygiene have entered into force. It is also appropriate to provide for at least 18 months to elapse between entry into force and the application of the new rules, to allow the industries affected time to adapt.

(30) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [*],

[*] OJ L 184, 17.7.1999, p. 23.

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

1. This Regulation lays down specific rules on the hygiene of food of animal origin for food business operators. These rules supplement those laid down by Regulation (EC) No /2004 [*]. They shall apply to unprocessed and processed products of animal origin.

2. Unless expressly indicated to the contrary, this Regulation shall not apply to food containing both products of plant origin and processed products of animal origin. However, processed products of animal origin used to prepare such food shall be obtained and handled in accordance with the requirements of this Regulation.

3. This Regulation shall not apply in relation to:

(a) primary production for private domestic use;

(b) the domestic preparation, handling or storage of food for private domestic consumption;

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[*] Official Publications Office is to insert official number of Regulation on the hygiene of foodstuffs.

(c) the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer;

(d) the direct supply, by the producer, of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer as fresh meat;

(e) hunters who supply small quantities of wild game or wild game meat directly to the final consumer or to local retail establishments directly supplying the final consumer.

4. Member States shall establish, under national law, rules governing the activities and persons referred to in paragraph 3(c), (d) and (e). Such national rules shall ensure the achievement of the objectives of this Regulation.

5. (a) Unless expressly indicated to the contrary, this Regulation shall not apply to retail.

(b) However, this Regulation shall apply to retail when operations are carried out with a view to the supply of food of animal origin to another establishment, unless:

(i) the operations consist only of storage or transport, in which case the specific temperature requirements laid down in Annex III shall nevertheless apply; or

(ii) the supply of food of animal origin from the retail establishment is to other retail establishments only and, in accordance with national law, is a marginal, localised and restricted activity.

(c) Member States may adopt national measures to apply the requirements of this Regulation to retail establishments situated on their territory to which it would not apply pursuant to subparagraphs (a) or (b).

6. This Regulation shall apply without prejudice to:

(a) relevant animal and public health rules, including more stringent rules laid down for the prevention, control and eradication of certain transmissible spongiform encephalopathies;

(b) animal welfare requirements; and

(c) requirements concerning the identification of animals and the traceability of products of animal origin.

Article 2

Definitions

The following definitions shall apply for the purposes of this Regulation:

1) the definitions laid down in Regulation (EC) No 178/2002;

2) the definitions laid down in Regulation (EC) No /2004 *;

3) the definitions laid down in Annex I; and

4) any technical definitions contained in Annexes II and III.

* Official Publications Office is to insert official number of Regulation on the hygiene of foodstuffs.

CHAPTER II

FOOD BUSINESS OPERATORS' OBLIGATIONS

Article 3

General obligations

1. Food business operators shall comply with the relevant provisions of Annexes II and III.

2. Food business operators shall not use any substance other than potable water – or, when Regulation (EC) No /2004 * or this Regulation permits its use, clean water – to remove surface contamination from products of animal origin, unless use of the substance has been approved in accordance with the procedure referred to in Article 12(2). Food business operators shall also comply with any conditions for use that may be adopted under the same procedure. The use of an approved substance shall not affect the food business operator's duty to comply with the requirements of this Regulation.

Article 4

Registration and approval of establishments

1. Food business operators shall place products of animal origin manufactured in the Community on the market only if they have been prepared and handled exclusively in establishments:

(a) that meet the relevant requirements of Regulation (EC) No /2004 *, those of Annexes II and III of this Regulation and other relevant requirements of food law; and

* Official Publications Office is to insert official number of Regulation on the hygiene of foodstuffs.

(b) that the competent authority has registered or, where required in accordance with paragraph 2, approved.

2. Without prejudice to Article 6(3) of Regulation (EC) No /2004 [*], establishments handling those products of animal origin for which Annex III to this Regulation lays down requirements shall not operate unless the competent authority has approved them in accordance with paragraph 3 of this Article, with the exception of establishments carrying out only:

(a) primary production;

(b) transport operations;

(c) the storage of products not requiring temperature-controlled storage conditions; or

(d) retail operations other than those to which this Regulation applies pursuant to Article 1(5)(b).

3. An establishment subject to approval in accordance with paragraph 2 shall not operate unless the competent authority has, in accordance with Regulation (EC) No /2004 of the European Parliament and of the Council of ..... laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption [*]:

(a) granted the establishment approval to operate following an on-site visit; or

(b) provided the establishment with conditional approval.

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[*] Page … of this Official Journal.

* Official Publications Office is to insert official number of Regulation on the hygiene of foodstuffs.

4. Food business operators shall cooperate with the competent authorities in accordance with Regulation (EC) No /2004 [*]. In particular, food business operators shall ensure that an establishment ceases to operate if the competent authority withdraws its approval or, in the case of conditional approval, fails to prolong it or to grant full approval.

5. This Article shall not prevent an establishment from placing food on the market between the date of application of this Regulation and the first subsequent inspection by the competent authority, if the establishment:

(a) is subject to approval in accordance with paragraph 2 and placed products of animal origin on the market in accordance with Community legislation immediately prior to the application of this Regulation; or

(b) is of a type in respect of which there was no requirement for approval before the application of this Regulation.

[*] Official Publications Office is to insert official number of Regulation on the organisation of official controls (see Article 4(3)).

Article 5

Health and identification marking

1. Food business operators shall not place on the market a product of animal origin handled in an establishment subject to approval in accordance with Article 4(2) unless it has either:

(a) a health mark applied in accordance with Regulation (EC) No /2004 *; or

(b) when that Regulation does not provide for the application of a health mark, an identification mark applied in accordance with Annex II, Section I, of this Regulation.

2. Food business operators may apply an identification mark to a product of animal origin only if the product has been manufactured in accordance with this Regulation in establishments meeting the requirements of Article 4.

3. Food business operators may not remove a health mark applied in accordance with Regulation (EC) No /2004 * from meat unless they cut or process it or work upon it in another manner.

* Official Publications Office is to insert official number of Regulation on the organisation of official controls.

Article 6

Products of animal origin from outside the Community

1. Food business operators importing products of animal origin from third countries shall ensure that importation takes place only if:

(a) the third country of dispatch appears on a list, drawn up in accordance with Article 11 of Regulation (EC) No [*]/2004, of third countries from which imports of that product are permitted;

(b) (i) the establishment from which that product was dispatched, and in which it was obtained or prepared, appears on a list, drawn up in accordance with Article 12 of Regulation (EC) No [*]/2004, of establishments from which imports of that product are permitted, when applicable,

(ii) in the case of fresh meat, minced meat, meat preparations, meat products and MSM, the product was manufactured from meat obtained in slaughterhouses and cutting plants appearing on lists drawn up and updated in accordance with Article 12 of Regulation (EC) No [*]/2004 or in approved Community establishments, and

(iii) in the case of live bivalve molluscs, echinoderms, tunicates and marine gastropods, the production area appears on a list drawn up in accordance with Article 13 of that Regulation, when applicable;

* Official Publications Office is to insert the official number of the Regulation on the organisation of official controls.

(c) the product satisfies:

(i) the requirements of this Regulation, including the requirements of Article 5 on health and identification marking;

(ii) the requirements of Regulation (EC) No [*]/2004; and

(iii) any import conditions laid down in accordance with Community legislation governing import controls for products of animal origin, and

(d) the requirements of Article 14 of Regulation (EC) No [**]/2004 concerning certificates and documents are satisfied, when applicable.

2. By way of derogation from paragraph 1, the importation of fishery products may also take place in accordance with the special provisions laid down in Article 15 of Regulation (EC) No [**]/2004.

3. Food business operators importing products of animal origin shall ensure that:

(a) products are made available for control upon importation in accordance with Directive 97/78/EC *;

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* Official Publications Office is to insert the official number of the Regulation on the hygiene of foodstuffs.

** Official Publications Office is to insert the official number of the Regulation on the organisation of official controls.

* Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 24, 30.1.1998, p. 9). Directive amended by the Act of Accession 2003.

(b) importation complies with the requirements of Directive 2002/99/EC [*]; and

(c) operations under their control that take place after importation are carried out in accordance with the requirements of Annex III.

4. Food business operators importing food containing both products of plant origin and processed products of animal origin shall ensure that the processed products of animal origin contained in such food satisfy the requirements of paragraphs 1 to 3. They must be able to demonstrate that they have done so (for example, through appropriate documentation or certification, which need not be in the format specified in paragraph 1(d)).

CHAPTER III

TRADE

Article 7

Documents

1. When required in accordance with Annex II or III, food business operators shall ensure that certificates or other documents accompany consignments of products of animal origin.

2. In accordance with the procedure referred to in Article 12(2):

(a) model documents may be established; and

(b) provision may be made for the use of electronic documents.

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[*] Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption (OJ L 18, 23.1.2003, p. 11).

Article 8

Special guarantees

1. Food business operators intending to place the following food of animal origin on the market in Sweden or Finland shall comply with the rules set out in paragraph 2 in respect of salmonella:

(a) meat from bovine and porcine animals, including minced meat but excluding meat preparations and MSM;

(b) meat from poultry of the following species: domestic fowl, turkeys, guinea-fowl, ducks and geese, including minced meat but excluding meat preparations and MSM; and

(c) eggs.

2.(a) In the case of meat from bovine and porcine animals and meat from poultry, samples of consignments shall have been taken in the dispatching establishment and been subjected to a microbiological test with negative results in accordance with Community legislation.

(b) In the case of eggs, packing centres shall provide a guarantee that consignments originate from flocks that have been subjected to a microbiological test with negative results in accordance with Community legislation.

(c) In the case of meat from bovine and porcine animals, the test provided for in subparagraph (a) need not be carried out for consignments intended for an establishment for the purposes of pasteurisation, sterilisation or treatment having a similar effect. In the case of eggs, the test provided for in subparagraph (b) need not be carried out for consignments intended for the manufacture of processed products by a process that guarantees the elimination of salmonella.

(d) The tests provided for in subparagraphs (a) and (b) need not be carried out for foodstuffs originating in an establishment that is subject to a control programme recognised, in respect of the food of animal origin concerned and in accordance with the procedure referred to in Article 12(2), as equivalent to that approved for Sweden and Finland.

(e) In the case of meat from bovine and porcine animals and meat from poultry, a trade document or certificate conforming to a model laid down by Community legislation shall accompany the food and state that:

(i) the checks referred to in subparagraph (a) have been carried out with negative results; or

(ii) the meat is intended for one of the purposes referred to in subparagraph (c); or

(iii) the meat comes from an establishment covered by subparagraph (d).

(f) In the case of eggs, a certificate stating that the tests referred to in subparagraph (b) have been carried out with negative results, or that the eggs are destined to be used in the manner referred to in subparagraph (c), must accompany consignments.

3. In accordance with the procedure referred to in Article 12(2):

(a) the requirements of paragraphs 1 and 2 may be updated to take account in particular of changes to Member States' control programmes or the adoption of microbiological criteria in accordance with Regulation (EC) No /2004 [*]; and

(b) the rules laid down in paragraph 2 in respect of any of the foodstuffs referred to in paragraph 1 may be extended, in whole or in part, to any Member State, or any region of a Member State, that has a control programme recognised as equivalent to that approved for Sweden and Finland in respect of the food of animal origin concerned.

4. For the purposes of this Article, "control programme" means a control programme approved in accordance with Regulation (EC) No 2160/2004 .

CHAPTER IV

FINAL PROVISIONS

Article 9

Implementing measures and transitional measures

Implementing measures and transitional arrangements may be laid down in accordance with the procedure referred to in Article 12(2).

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[*] Official Publications Office is to insert the official number of the Regulation on the hygiene of foodstuffs.

Article 10

Amendment and adaptation of Annexes II and III

1. Annexes II and III may be adapted or updated in accordance with the procedure referred to in Article 12(2), taking into account:

(a) the development of guides to good practice;

(b) the experience gained from the implementation of HACCP-based systems pursuant to Article 5 of Regulation (EC) No /2004*;

(c) the technological developments and their practical consequences and consumer expectations with regard to food composition;

(d) scientific advice, particularly new risk assessments;

(e) microbiological and temperature criteria for foodstuffs;

(f) changes in patterns of consumption.

2. Exemptions from Annex II and III may be granted in accordance with the procedure referred to in Article 12(2), provided that they do not affect the achievement of the objectives of this Regulation.

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* Official Publications Office is to insert the official number of the Regulation on the hygiene of foodstuffs.

3. Member States may, without compromising achievement of the objectives of this Regulation, adopt, in accordance with paragraphs 4 to 8, national measures adapting the requirements laid down in Annex III.

4. (a) The national measures referred to in paragraph 3 shall have the aim of:

(i) enabling the continued use of traditional methods at any of the stages of production, processing or distribution of food; or

(ii) accommodating the needs of food businesses situated in regions that are subject to special geographic constraints.

(b) In other cases, they shall apply only to the construction, layout and equipment of establishments.

5. Any Member State wishing to adopt national measures as referred to in paragraph 3 shall notify the Commission and other Member States. Each notification shall:

(a) provide a detailed description of the requirements that that Member State considers need to be adapted and the nature of the adaptation sought;

(b) describe the foodstuffs and establishments concerned;

(c) explain the reasons for the adaptation, including, where relevant, by providing a summary of the hazard analysis carried out and any measures to be taken to ensure that the adaptation will not compromise the objectives of this Regulation; and

(d) give any other relevant information.

6. The other Member States shall have three months from the receipt of a notification referred to in paragraph 5 to send written comments to the Commission. In the case of adaptations arising from paragraph 4(b), this period shall, at the request of any Member State, be extended to four months. The Commission may, and when it receives written comments from one or more Member States shall, consult Member States within the committee referred to in Article 12(1). The Commission may decide, in accordance with the procedure referred to in Article 12(2), whether the envisaged measures may be implemented, subject, if necessary, to appropriate amendments. Where appropriate, the Commission may propose general measures in accordance with paragraph 1 or 2 of this Article.

7. A Member State may adopt national measures adapting the requirements of Annex III only:

(a) in compliance with a decision adopted in accordance with paragraph 6;

(b) if, one month after the expiry of the period referred to in paragraph 6, the Commission has not informed Member States that it has received written comments or that it intends to propose the adoption of a decision in accordance with paragraph 6; or

(c) in accordance with paragraph 8.

8. A Member State may, of its own initiative and subject to the general provisions of the Treaty, maintain or establish national rules:

(a) prohibiting or restricting the placing on the market within its territory of raw milk or raw cream intended for direct human consumption; or

(b) permitting the use, with the authorisation of the competent authority, of raw milk not meeting the criteria laid down in Annex III, Section IX, as regards plate count and somatic cell count of the manufacture of cheeses with an ageing or ripening period of at least 60 days, and dairy products obtained in connection with the manufacture of such cheeses, provided that this does not prejudice the achievement of the objectives of this Regulation.

Article 11

Specific decisions

Without prejudice to the generality of Article 9 and Article 10(1), implementing measures may be laid down, or amendments to Annex II or III adopted, in accordance with the procedure referred to in Article 12(2):

1) to lay down rules for the transport of meat while it is warm;

2) to specify, in respect of MSM, which calcium content is not significantly higher than that of minced meat;

3) to lay down other treatments that may be applied in a processing establishment to live bivalve molluscs from class B or C production areas that have not been submitted to purification or relaying;

4) to specify recognised testing methods for marine biotoxins;

5) to lay down additional health standards for live bivalve molluscs in cooperation with the relevant Community Reference Laboratory, including:

   (a) limit values and analysis methods for other marine biotoxins;

   (b) virus testing procedures and virological standards; and

   (c) sampling plans and the methods and analytical tolerances to be applied to check compliance with the health standards;

6) to lay down health standards or checks, where there is scientific evidence indicating that they are necessary to protect public health;

7) to extend Annex III, Section VII, Chapter IX, to live bivalve molluscs other than pectinidae;

8) to specify criteria for determining when epidemiological data indicate that a fishing ground does not present a health hazard with regard to the presence of parasites and, consequently, for determining when the competent authority may authorise food business operators not to freeze fishery products in accordance with Annex III, Section VIII, Chapter III, Part D;

9) to lay down freshness criteria and limits with regard to histamine and total volatile nitrogen for fisheries products;

10) to permit the use for the manufacture of certain dairy products of raw milk not meeting the criteria laid down in Annex III, Section IX, as regards its plate count and somatic cell count;

11) without prejudice to Directive 96/23/EC [*], to fix a maximum permitted value for the combined total of residues of antibiotic substances in raw milk; and

12) to approve equivalent processes for the production of gelatine or collagen.

Article 12

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period provided for in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

[*] Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products (OJ L 125, 23.5.1996, p. 10). Directive as amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

Article 13

Consultation of the European Food Safety Authority

The Commission shall consult the European Food Safety Authority on any matter falling within the scope of this Regulation that could have a significant impact on public health and, in particular, before proposing to extend Annex III, Section III, to other animal species.

Article 14

Report to the European Parliament and to the Council

1. The Commission shall, not later than ... [*], submit a report to the European Parliament and the Council reviewing the experience gained from the implementation of this Regulation.

2. The Commission shall, if appropriate, accompany the report with relevant proposals.

Article 15

This Regulation shall enter into force twenty days after the date of its publication in the Official Journal of the European Union.

It shall apply 18 months after the date on which all of the following acts have entered into force:

(a) Regulation (EC) No…/2004 [**];

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[*] Five years after the entry into force of this Regulation.

[**] Official Publications Office is to insert the official number of the Regulation on the hygiene of foodstuffs.

(b) Regulation (EC) No…/2004 [*]; and

(c) Directive 2004/…/EC [**].

However, it shall apply no earlier than 1 January 2006.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strsbourg, 29.4.2004.

For the European Parliament	For the Council
The President	The President
P. COX	M. McDOWELL

[*] Official Publications Office is to insert here the official number of the Regulation referred to in Article 4(3).

[**] Official Publications Office is to insert here the official number of the Directive referred to in recital 25.

ANNEX I

DEFINITIONS

For the purpose of this Regulation:

1. MEAT

1.1. "Meat" means edible parts of the animals referred to in points 1.2 to 1.8, including blood.

1.2. "Domestic ungulates" means domestic bovine (including Bubalus and Bison species), porcine, ovine and caprine animals, and domestic solipeds.

1.3. "Poultry" means farmed birds, including birds that are not considered as domestic but which are farmed as domestic animals, with the exception of ratites.

1.4. "Lagomorphs" means rabbits, hares and rodents.

1.5. "Wild game" means:

– wild ungulates and lagomorphs, as well as other land mammals that are hunted for human consumption and are considered to be wild game under the applicable law in the Member State concerned, including mammals living in enclosed territory under conditions of freedom similar to those of wild game; and

– wild birds that are hunted for human consumption.

1.6. "Farmed game" means farmed ratites and farmed land mammals other than those referred to in point 1.2.

1.7. "Small wild game" means wild game birds and lagomorphs living freely in the wild.

1.8. "Large wild game" means wild land mammals living freely in the wild that do not fall within the definition of small wild game.

1.9. "Carcase" means the body of an animal after slaughter and dressing.

1.10. "Fresh meat" means meat that has not undergone any preserving process other than chilling, freezing or quick-freezing, including meat that is vacuum-wrapped or wrapped in a controlled atmosphere.

1.11. "Offal" means fresh meat other than that of the carcase, including viscera and blood.

1.12. "Viscera" means the organs of the thoracic, abdominal and pelvic cavities, as well as the trachea and oesophagus and, in birds, the crop.

1.13. "Minced meat" means boned meat that has been minced into fragments and contains less than 1% salt.

1.14. "Mechanically separated meat" or "MSM" means the product obtained by removing meat from flesh-bearing bones after boning or from poultry carcases, using mechanical means resulting in the loss or modification of the muscle fibre structure.

1.15. "Meat preparations" means fresh meat, including meat that has been reduced to fragments, which has had foodstuffs, seasonings or additives added to it or which has undergone processes insufficient to modify the internal muscle fibre structure of the meat and thus to eliminate the characteristics of fresh meat.

1.16. "Slaughterhouse" means an establishment used for slaughtering and dressing animals, the meat of which is intended for human consumption.

1.17. "Cutting plant" means an establishment used for boning and/or cutting up meat.

1.18. "Game-handling establishment" means any establishment in which game and game meat obtained after hunting are prepared for placing on the market.

2. LIVE BIVALVE MOLLUSCS

2.1. "Bivalve molluscs" means filter-feeding lamellibranch molluscs.

2.2. "Marine biotoxins" means poisonous substances accumulated by bivalve molluscs, in particular as a result of feeding on plankton containing toxins.

2.3. "Conditioning" means the storage of live bivalve molluscs coming from class A production areas, purification centres or dispatch centres in tanks or any other installation containing clean seawater, or in natural sites, to remove sand, mud or slime, to preserve or to improve organoleptic qualities and to ensure that they are in a good state of vitality before wrapping or packaging.

2.4. "Gatherer" means any natural or legal person who collects live bivalve molluscs by any means from a harvesting area for the purpose of handling and placing on the market.

2.5. "Production area" means any sea, estuarine or lagoon area, containing either natural beds of bivalve molluscs or sites used for the cultivation of bivalve molluscs, and from which live bivalve molluscs are taken.

2.6. "Relaying area" means any sea, estuarine or lagoon area with boundaries clearly marked and indicated by buoys, posts or any other fixed means, and used exclusively for the natural purification of live bivalve molluscs.

2.7. "Dispatch centre" means any on-shore or off-shore establishment for the reception, conditioning, washing, cleaning, grading, wrapping and packaging of live bivalve molluscs fit for human consumption.

2.8. "Purification centre" means an establishment with tanks fed by clean seawater in which live bivalve molluscs are placed for the time necessary to reduce contamination to make them fit for human consumption.

2.9. "Relaying" means the transfer of live bivalve molluscs to sea, lagoon or estuarine areas for the time necessary to reduce contamination to make them fit for human consumption. This does not include the specific operation of transferring bivalve molluscs to areas more suitable for further growth or fattening.

3. FISHERY PRODUCTS

3.1. "Fishery products" means all seawater or freshwater animals (except for live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods, and all mammals, reptiles and frogs) whether wild or farmed and including all edible forms, parts and products of such animals.

3.2. "Factory vessel" means any vessel on board which fishery products undergo one or more of the following operations followed by wrapping or packaging and, if necessary, chilling or freezing: filleting, slicing, skinning, shelling, shucking, mincing or processing.

3.3. "Freezer vessel" means any vessel on board which freezing of fishery products is carried out, where appropriate after preparatory work such as bleeding, heading, gutting and removal of fins and, where necessary, followed by wrapping or packaging.

3.4. "Mechanically separated fishery product" means any product obtained by removing flesh from fishery products using mechanical means resulting in the loss or modification of the flesh structure.

3.5. "Fresh fishery products" means unprocessed fishery products, whether whole or prepared, including products packaged under vacuum or in a modified atmosphere, that have not undergone any treatment to ensure preservation other than chilling.

3.6. "Prepared fishery products" means unprocessed fishery products that have undergone an operation affecting their anatomical wholeness, such as gutting, heading, slicing, filleting, and chopping.

4. MILK

4.1. "Raw milk" means milk produced by the secretion of the mammary gland of farmed animals that has not been heated to more than 40ºC or undergone any treatment that has an equivalent effect.

4.2. "Milk production holding" means an establishment where one or more farmed animals are kept to produce milk with a view to placing it on the market as food.

5. EGGS

5.1. "Eggs" means eggs in shell – other than broken, incubated or cooked eggs – that are produced by farmed birds and are fit for direct human consumption or for the preparation of egg products.

5.2. "Liquid egg" means unprocessed egg contents after removal of the shell.

5.3. "Cracked eggs" means eggs with damaged shell and intact membranes.

5.4. "Packing centre" means an establishment where eggs are graded by quality and weight.

6. FROGS' LEGS AND SNAILS

6.1. "Frogs' legs" means the posterior part of the body divided by a transverse cut behind the front limbs, eviscerated and skinned, of the species RNA (family Ranidae).

6.2. "Snails" means terrestrial gastropods of the species Helix pomatia Linné, Helix aspersa Muller, Helix lucorum and species of the family Achatinidae.

7. PROCESSED PRODUCTS

7.1. "Meat products" means processed products resulting from the processing of meat or from the further processing of such processed products, so that the cut surface shows that the product no longer has the characteristics of fresh meat.

7.2. "Dairy products" means processed products resulting from the processing of raw milk or from the further processing of such processed products.

7.3. "Egg products" means processed products resulting from the processing of eggs, or of various components or mixtures of eggs, or from the further processing of such processed products.

7.4. "Processed fishery products" means processed products resulting from the processing of fishery products or from the further processing of such processed products.

7.5. "Rendered animal fat" means fat derived from rendering meat, including bones, and intended for human consumption.

7.6. "Greaves" means the protein-containing residue of rendering, after partial separation of fat and water.

7.7. "Gelatine" means natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals.

7.8. "Collagen" means the protein-based product derived from animal bones, hides, skins and tendons manufactured in accordance with the relevant requirements of this Regulation.

7.9. "Treated stomachs, bladders and intestines" means stomachs, bladders and intestines that have been submitted to a treatment such as salting, heating or drying after they have been obtained and after cleaning.

8. OTHER DEFINITIONS

8.1. "Products of animal origin" means:

- food of animal origin, including honey and blood;

- live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods intended for human consumption; and

- other animals destined to be prepared with a view to being supplied live to the final consumer.

8.2. "Wholesale market" means a food business that includes several separate units which share common installations and sections where foodstuffs are sold to food business operators.

ANNEX II

REQUIREMENTS CONCERNING SEVERAL PRODUCTS OF ANIMAL ORIGIN

SECTION I: IDENTIFICATION MARKING

When required in accordance with Article 5 or 6, and subject to the provisions of Annex III, food business operators must ensure that products of animal origin have an identification mark applied in compliance with the following provisions.

A. APPLICATION OF THE IDENTIFICATION MARK

1. The identification mark must be applied before the product leaves the establishment.

2. However, a new mark need not be applied to a product unless its packaging and/or wrapping is removed or it is further processed in another establishment, in which case the new mark must indicate the approval number of the establishment where these operations take place.

3. An identification mark is not necessary for eggs in respect of which Regulation (EC) No 1907/90 * lays down requirements concerning labelling or marking.

4. Food business operators must, in accordance with Article 18 of Regulation (EC) No 178/2002, have in place systems and procedures to identify food business operators from whom they have received, and to whom they have delivered, products of animal origin.

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* Council Regulation (EEC) No 1907/90 of 26 June 1990 on certain marketing standards for eggs (OJ L 173, 6.7.1990, p. 5). Regulation as last amended by Regulation (EC) No 2052/2003 (OJ L 305, 22.11.2003, p.1).

B. FORM OF THE IDENTIFICATION MARK

5. The mark must be legible and indelible, and the characters easily decipherable. It must be clearly displayed for the competent authorities.

6. The mark must indicate the name of the country in which the establishment is located, which may be written out in full or shown as a two-letter code in accordance with the relevant ISO standard.

   In the case of Member States, however, these codes are AT, BE, DE, DK, ES, FI, FR, GR, IE, IT, LU, NL, PT, SE and UK.

   Food business operators may continue to use stocks and equipment that they ordered before the entry into force of this Regulation until they are exhausted or require replacement.

7. The mark must indicate the approval number of the establishment. If an establishment manufactures both food to which this Regulation applies and food to which it does not, the food business operator may apply the same identification mark to both types of food.

8. When applied in an establishment located within the Community, the mark must be oval in shape and include the abbreviation CE, EC, EF, EG, EK or EY.

C. METHOD OF MARKING

9. The mark may, depending on the presentation of different products of animal origin, be applied directly to the product, the wrapping or the packaging, or be printed on a label affixed to the product, the wrapping or the packaging. The mark may also be an irremovable tag made of a resistant material.

10. In the case of packaging containing cut meat or offal, the mark must be applied to a label fixed to the packaging, or printed on the packaging, in such a way that it is destroyed when the packaging is opened. This is not necessary, however, if the process of opening destroys the packaging. When wrapping provides the same protection as packaging, the label may be affixed to the wrapping.

11. For products of animal origin that are placed in transport containers or large packages and are intended for further handling, processing, wrapping or packaging in another establishment, the mark may be applied to the external surface of the container or packaging.

12. In the case of liquid, granulate and powdered products of animal origin carried in bulk, and fishery products carried in bulk, an identification mark is not necessary if accompanying documentation contains the information specified in paragraphs 6, 7 and, where appropriate, 8.

13. When products of animal origin are placed in a package destined for direct supply to the final consumer, it is sufficient to apply the mark to the exterior of that package only.

14. When the mark is applied directly to products of animal origin, the colours used must be authorised in accordance with Community rules on the use of colouring substances in foodstuffs.

SECTION II: OBJECTIVES OF HACCP-BASED PROCEDURES

1. Food business operators operating slaughterhouses must ensure that the procedures that they have put in place in accordance with the general requirements of Article 5 of Regulation (EC) No …/2004 * meet the requirements that the hazard analysis shows to be necessary and the specific requirements listed in paragraph 2.

2. The procedures must guarantee that each animal or, where appropriate, each lot of animals accepted onto the slaughterhouse premises:

   (a) is properly identified;

   (b) is accompanied by the relevant information from the holding of provenance referred to in Section III;

   (c) does not come from a holding or an area subject to a movement prohibition or other restriction for reasons of animal or public health, except when the competent authority so permits;

   (d) is clean;

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* Official Publications Office is to insert the official number of Regulation on the hygiene of foodstuffs.

(e) is healthy, as far as the food business operator can judge; and

(f) is in a satisfactory state as regards welfare on arrival at the slaughterhouse.

3. In the event of failure to comply with any of the requirements listed under paragraph 2, the food business operator must notify the official veterinarian and take appropriate measures.

SECTION III: FOOD CHAIN INFORMATION

Food business operators operating slaughterhouses must, as appropriate, request, receive, check and act upon food chain information as set out in this Section in respect of all animals, other than wild game, sent or intended to be sent to the slaughterhouse.

1. Slaughterhouse operators must not accept animals onto the slaughterhouse premises unless they have requested and been provided with relevant food safety information contained in the records kept at the holding of provenance in accordance with Regulation (EC) No …/2004 *.

2. Slaughterhouse operators must be provided with the information no less than 24 hours before the arrival of animals at the slaughterhouse, except in the circumstances mentioned in point 7.

3. The relevant food safety information referred to in point 1 is to cover, in particular:

(a) the status of the holding of provenance or the regional animal health status;

(b) the animals' health status;

* Official Oublications Office is to insert the official number of Regulation on the hygiene of foodstuffs.

(c) veterinary medicinal products or other treatments administered to the animals within a relevant period and with a withdrawal period greater than zero, together with their dates of administration and withdrawal periods;

(d) the occurrence of diseases that may affect the safety of meat;

(e) the results, if they are relevant to the protection of public health, of any analysis carried out on samples taken from the animals or other samples taken to diagnose diseases that may affect the safety of meat, including samples taken in the framework of the monitoring and control of zoonoses and residues;

(f) relevant reports about previous ante- and post-mortem inspections of animals from the same holding of provenance including, in particular, reports from the official veterinarian;

(g) production data, when this might indicate the presence of disease; and

(h) the name and address of the private veterinarian normally attending the holding of provenance.

4. (a) However, it is not necessary for the slaughterhouse operator to be provided with:

(i) the information referred to in point 3(a), (b), (f) and (h), if the operator is already aware of this information (for example, through a standing arrangement or a quality assurance scheme); or

(ii) the information referred to in point 3(a), (b), (f) and (g), if the producer declares that there is no relevant information to report.

(b) The information need not be provided as a verbatim extract from the records of the holding of provenance. It may be provided through electronic data exchange or in the form of a standardised declaration signed by the producer.

5. Food business operators deciding to accept animals onto the slaughterhouse premises after evaluating the relevant food chain information must make it available to the official veterinarian without delay and, except in the circumstances mentioned in point 7, no less than 24 hours before the arrival of the animal or lot. The food business operator must notify the official veterinarian of any information that gives rise to health concerns before ante-mortem inspection of the animal concerned.

6. If any animal arrives at the slaughterhouse without food chain information, the operator must immediately notify the official veterinarian. Slaughter of the animal may not take place until the official veterinarian so permits.

7. If the competent authority so permits, food chain information may accompany the animals to which it relates to the slaughterhouse, rather than arriving at least 24 hours in advance, in the case of:

(a) porcine animals, poultry or farmed game that have undergone ante-mortem inspection at the holding of provenance, if a certificate that the veterinarian has signed stating that he or she examined the animals at the holding and found them to be healthy accompanies them;

(b) domestic solipeds;

(c) animals that have undergone emergency slaughter, if a declaration, that the veterinarian has signed recording the favourable outcome of the ante-mortem inspection accompanies them; and

(d) animals that are not delivered directly from the holding of provenance to the slaughterhouse.

Slaughterhouse operators must evaluate the relevant information. If they accept the animals for slaughter, they must give the documents mentioned in subparagraphs (a) and (c) to the official veterinarian. Slaughter or dressing of the animals may not take place until the official veterinarian so permits.

8. Food business operators must check passports accompanying domestic solipeds to ensure that the animal is intended for slaughter for human consumption. If they accept the animal for slaughter, they must give the passport to the official veterinarian."

ANNEX III

SPECIFIC REQUIREMENTS

SECTION I: MEAT OF DOMESTIC UNGULATES

CHAPTER I: TRANSPORT OF LIVE ANIMALS TO THE SLAUGHTERHOUSE

Food business operators transporting live animals to slaughterhouses must ensure compliance with the following requirements.

1. During collection and transport, animals must be handled carefully without causing unnecessary distress.

2. Animals showing symptoms of disease or originating in herds known to be contaminated with agents of public health importance may only be transported to the slaughterhouse when the competent authority so permits.

CHAPTER II: REQUIREMENTS FOR SLAUGHTERHOUSES

Food business operators must ensure that the construction, layout and equipment of slaughterhouses in which domestic ungulates are slaughtered meet the following requirements.

1. (a) Slaughterhouses must have adequate and hygienic lairage facilities or, climate permitting, waiting pens that are easy to clean and disinfect. These facilities must be equipped for watering the animals and, if necessary, feeding them. The drainage of the wastewater must not compromise food safety.

(b) They must also have separate lockable facilities or, climate permitting, pens for sick or suspect animals with separate draining and sited in such a way as to avoid contamination of other animals, unless the competent authority considers that such facilities are unnecessary.

(c) The size of the lairage facilities must ensure that the welfare of the animals is respected. Their layout must facilitate ante-mortem inspections, including the identification of the animals or groups of animals.

2. To avoid contaminating meat, they must:

(a) have a sufficient number of rooms, appropriate to the operations being carried out;

(b) have a separate room for the emptying and cleaning of stomachs and intestines, unless the competent authority authorises the separation in time of these operations within a specific slaughterhouse on a case-by-case basis;

(c) ensure separation in space or time of the following operations:

(i) stunning and bleeding;

(ii) in the case of porcine animals, scalding, depilation, scraping and singeing;

(iii) evisceration and further dressing;

(iv) handling clean guts and tripe;

(v) preparation and cleaning of other offal, particularly the handling of skinned heads if it does not take place at the slaughter line;

(vi) packaging offal; and

(vii) dispatching meat;

(d) have installations that prevent contact between the meat and the floors, walls and fixtures; and

(e) have slaughter lines (where operated) that are designed to allow constant progress of the slaughter process and to avoid cross-contamination between the different parts of the slaughter line. Where more than one slaughter line is operated in the same premises, there must be adequate separation of the lines to prevent cross-contamination.

3. They must have facilities for disinfecting tools with hot water supplied at not less than 82ºC, or an alternative system having an equivalent effect.

4. The equipment for washing hands used by the staff engaged in handling exposed meat must have taps designed to prevent the spread of contamination.

5. There must be lockable facilities for the refrigerated storage of detained meat and separate lockable facilities for the storage of meat declared unfit for human consumption.

6. There must be a separate place with appropriate facilities for the cleaning, washing and disinfection of means of transport for livestock. However, slaughterhouses need not have these places and facilities if the competent authority so permits and official authorised places and facilities exist nearby.

7. They must have lockable facilities reserved for the slaughter of sick and suspect animals. This is not essential if this slaughter takes place in other establishments authorised by the competent authority for this purpose, or at the end of the normal slaughter period.

8. If manure or digestive tract content is stored in the slaughterhouse, there must be a special area or place for that purpose.

9. They must have an adequately equipped lockable facility or, where needed, room for the exclusive use of the veterinary service.

CHAPTER III: REQUIREMENTS FOR CUTTING PLANTS

Food business operators must ensure that cutting plants handling meat of domestic ungulates:

1) are constructed so as to avoid contamination of meat, in particular by:

   (a) allowing constant progress of the operations; or

   (b) ensuring separation between the different production batches;

2) have rooms for the separate storage of packaged and exposed meat, unless stored at different times or in such a way that the packaging material and the manner of storage cannot be a source of contamination for the meat;

3) have cutting rooms equipped to ensure compliance with the requirements laid down in Chapter V;

4) have equipment for washing hands with taps designed to prevent the spread of contamination, for use by staff engaged in handling exposed meat; and

5) have facilities for disinfecting tools with hot water supplied at not less than 82ºC, or an alternative system having an equivalent effect.

CHAPTER IV: SLAUGHTER HYGIENE

Food business operators operating slaughterhouses in which domestic ungulates are slaughtered must ensure compliance with the following requirements.

1. After arrival in the slaughterhouse, the slaughter of the animals must not be unduly delayed. However, where required for welfare reasons, animals must be given a resting period before slaughter.

2. (a) Meat from animals other than those referred to in subparagraphs (b) and (c) must not be used for human consumption if they die otherwise than by being slaughtered in the slaughterhouse.

(b) Only live animals intended for slaughter may be brought into the slaughter premises, with the exception of:

(i) animals that have undergone emergency slaughter outside the slaughterhouse in accordance with Chapter VI;

(ii) animals slaughtered at the place of production in accordance with Section III; and

(iii) wild game, in compliance with Section IV, Chapter II.

(c) Meat from animals that undergo slaughter following an accident in a slaughterhouse may be used for human consumption if, on inspection, no serious lesions other than those due to the accident are found.

3. The animals or, where appropriate, each batch of animals sent for slaughter must be identified so that their origin can be traced.

4. Animals must be clean.

5. Slaughterhouse operators must follow the instructions of the veterinarian appointed by the competent authority in accordance with Regulation (EC) No…/2004 * to ensure that ante-mortem inspection of every animal to be slaughtered is carried out under suitable conditions.

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6. Animals brought into the slaughter hall must be slaughtered without undue delay.

7. Stunning, bleeding, skinning, evisceration and other dressing must be carried out without undue delay and in a manner that avoids contaminating the meat. In particular:

    (a) the trachea and oesophagus must remain intact during bleeding, except in the case of slaughter according to a religious custom;

    (b) during the removal of hides and fleece:

        (i) contact between the outside of the skin and the carcase must be prevented; and

        (ii) operators and equipment coming into contact with the outer surface of hides and fleece must not touch the meat;

    (c) measures must be taken to prevent the spillage of digestive tract content during and after evisceration and to ensure that evisceration is completed as soon as possible after stunning; and

    (d) removal of the udder must not result in contamination of the carcase with milk or colostrum.

8. Complete skinning of the carcase and other parts of the body intended for human consumption must be carried out, except for porcine animals and the heads and feet of ovine and caprine animals and calves. Heads and feet must be handled so as to avoid contamination of other meat.

9. When not skinned, porcine animals must have their bristles removed immediately. The risk of contamination of the meat with scalding water must be minimised. Only approved additives may be used for this operation. Porcine animals must be thoroughly rinsed afterwards with potable water.

10. The carcases must not contain visible faecal contamination. Any visible contamination must be removed without delay by trimming or alternative means having an equivalent effect.

11. Carcases and offal must not come into contact with floors, walls or work stands.

12. Slaughterhouse operators must follow the instructions of the competent authority to ensure that post-mortem inspection of all slaughtered animals is carried out under suitable conditions in accordance with Regulation (EC) No…/2004 *.

13. Until post-mortem inspection is completed, parts of a slaughtered animal subject to such inspection must:

    (a) remain identifiable as belonging to a given carcase; and

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(b) come into contact with no other carcase, offal or viscera, including those that have already undergone post-mortem inspection.

However, provided that it shows no pathological lesion, the penis may be discarded immediately.

14. Both kidneys must be removed from their fatty covering. In the case of bovine and porcine animals, and solipeds, the peri-renal capsule must also be removed.

15. If the blood or other offal of several animals is collected in the same container before completion of post-mortem inspection, the entire contents must be declared unfit for human consumption if the carcase of one or more of the animals concerned has been declared unfit for human consumption.

16. After post-mortem inspection:

(a) the tonsils of bovine animals and solipeds must be removed hygienically;

(b) parts unfit for human consumption must be removed as soon as possible from the clean sector of the establishment;

(c) meat detained or declared unfit for human consumption and inedible by-products must not come into contact with meat declared fit for human consumption; and

(d) viscera or parts of viscera remaining in the carcase, except for the kidneys, must be removed entirely and as soon as possible, unless the competent authority authorises otherwise.

17. After completion of slaughter and post-mortem inspection, the meat must be stored in accordance with the requirements laid down in Chapter VII.

18. When destined for further handling:

(a) stomachs must be scalded or cleaned;

(b) intestines must be emptied and cleaned; and

(c) heads and feet must be skinned or scalded and depilated.

19. Where establishments are approved for the slaughter of different animal species or for the handling of carcases of farmed game and wild game, precautions must be taken to prevent cross-contamination by separation either in time or in space of operations carried out on the different species. Separate facilities for the reception and storage of unskinned carcases of farmed game slaughtered at the farm and for wild game must be available.

20. If the slaughterhouse does not have lockable facilities reserved for the slaughter of sick or suspect animals, the facilities used to slaughter such animals must be cleaned, washed and disinfected under official supervision before the slaughter of other animals is resumed.

CHAPTER V: HYGIENE DURING CUTTING AND BONING

Food business operators must ensure that cutting and boning of meat of domestic ungulates takes place in accordance with the following requirements.

1. Carcases of domestic ungulates may be cut into half-carcases or quarters, and half carcases into no more than three wholesale cuts, in slaughterhouses. Further cutting and boning must be carried out in a cutting plant.

2. The work on meat must be organised in such a way as to prevent or minimise contamination. To this end, food business operators must ensure in particular that:

   (a) meat intended for cutting is brought into the workrooms progressively as needed;

   (b) during cutting, boning, trimming, slicing, dicing, wrapping and packaging, the meat is maintained at not more than 3ºC for offal and 7ºC for other meat, by means of an ambient temperature of not more than 12ºC or an alternative system having an equivalent effect; and

   (c) where the premises are approved for the cutting of meat of different animal species, precautions are taken to avoid cross-contamination, where necessary by separation of the operations on the different species in either space or time.

3. However, meat may be boned and cut before it reaches the temperature referred to in point 2(b) in accordance with Chapter VII, point 3.

4. Meat may also be boned and cut prior to reaching the temperature referred to in point 2(b) when the cutting room is on the same site as the slaughter premises. In this case, the meat must be transferred to the cutting room either directly from the slaughter premises or after a waiting period in a chilling or refrigerating room. As soon as it is cut and, where appropriate, packaged, the meat must be chilled to the temperature referred to in point 2(b).

CHAPTER VI: EMERGENCY SLAUGHTER OUTSIDE THE SLAUGHTERHOUSE

Food business operators must ensure that meat from domestic ungulates that have undergone emergency slaughter outside the slaughterhouse may be used for human consumption only if it complies with all the following requirements.

1. An otherwise healthy animal must have suffered an accident that prevented its transport to the slaughterhouse for welfare reasons.

2. A veterinarian must carry out an ante-mortem inspection of the animal.

3. The slaughtered and bled animal must be transported to the slaughterhouse hygienically and without undue delay. Removal of the stomach and intestines, but no other dressing, may take place on the spot, under the supervision of the veterinarian. Any viscera removed must accompany the slaughtered animal to the slaughterhouse and be identified as belonging to that animal.

4. If more than two hours elapse between slaughter and arrival at the slaughterhouse, the animal must be refrigerated. Where climatic conditions so permit, active chilling is not necessary.

5. A declaration by the food business operator who reared the animal, stating the identity of the animal and indicating any veterinary products or other treatments administered to the animal, dates of administration and withdrawal periods, must accompany the slaughtered animal to the slaughterhouse.

6. A declaration issued by the veterinarian recording the favourable outcome of the ante-mortem inspection, the date and time of, and reason for, emergency slaughter, and the nature of any treatment administered by the veterinarian to the animal, must accompany the slaughtered animal to the slaughterhouse.

7. The slaughtered animal must be fit for human consumption following post-mortem inspection carried out in the slaughterhouse in accordance with Regulation (EC) No…/2004 *, including any additional tests required in the case of emergency slaughter.

8. Food business operators must follow any instructions that the official veterinarian may give after post-mortem inspection concerning the use of the meat.

9. Food business operators may not place meat from animals having undergone emergency slaughter on the market unless it bears a special health mark which cannot be confused either with the health mark provided for in Regulation (EC) No…/2004 * or with the identification mark provided for in Annex II, Section I to this Regulation. Such meat may be placed on the market only in the Member State where slaughter takes place and in accordance with national law.

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CHAPTER VII: STORAGE AND TRANSPORT

Food business operators must ensure that the storage and transport of meat of domestic ungulates takes place in accordance with the following requirements.

1. (a) Unless other specific provisions provide otherwise, post-mortem inspection must be followed immediately by chilling in the slaughterhouse to ensure a temperature throughout the meat of not more than 3ºC for offal and 7ºC for other meat along a chilling curve that ensures a continuous decrease of the temperature. However, meat may be cut and boned during chilling in accordance with Chapter V, point 4.

   (b) During the chilling operations, there must be adequate ventilation to prevent condensation on the surface of the meat.

2. Meat must attain the temperature specified in point 1 and remain at that temperature during storage.

3. Meat must attain the temperature specified in point 1 before transport, and remain at that temperature during transport. However, transport may also take place if the competent authority so authorises to enable the production of specific products, provided that:

   (a) such transport takes place in accordance with the requirements that the competent authority specifies in respect of transport from one given establishment to another; and

   (b) the meat leaves the slaughterhouse, or a cutting room on the same site as the slaughter premises, immediately and transport takes no more than two hours.

4. Meat intended for freezing must be frozen without undue delay, taking into account where necessary a stabilisation period before freezing.

5. Exposed meat must be stored and transported separately from packaged meat, unless stored or transported at different times or in such a way that the packaging material and the manner of storage or transport cannot be a source of contamination for the meat.

SECTION II: MEAT FROM POULTRY AND LAGOMORPHS

CHAPTER I: TRANSPORT OF LIVE ANIMALS TO THE SLAUGHTERHOUSE

Food business operators transporting live animals to slaughterhouses must ensure compliance with the following requirements.

1. During collection and transport, animals must be handled carefully without causing unnecessary distress.

2. Animals showing symptoms of disease or originating in flocks known to be contaminated with agents of public-health importance may only be transported to the slaughterhouse when permitted by the competent authority.

3. Crates for delivering animals to the slaughterhouse and modules, where used, must be made of non-corrodible material and be easy to clean and disinfect. Immediately after emptying and, if necessary, before re-use, all equipment used for collecting and delivering live animals must be cleaned, washed and disinfected.

CHAPTER II: REQUIREMENTS FOR SLAUGHTERHOUSES

Food business operators must ensure that the construction, layout and equipment of slaughterhouses in which poultry or lagomorphs are slaughtered meet the following requirements.

1. They must have a room or covered space for the reception of the animals and for their inspection before slaughter.

2. To avoid contaminating meat, they must:

    (a) have a sufficient number of rooms, appropriate to the operations being carried out;

    (b) have a separate room for evisceration and further dressing, including the addition of seasonings to whole poultry carcases, unless the competent authority authorises separation in time of these operations within a specific slaughterhouse on a case-by-case basis;

    (c) ensure separation in space or time of the following operations:

        (i) stunning and bleeding;

        (ii) plucking or skinning, and any scalding; and

        (iii) dispatching meat;

(d) have installations that prevent contact between the meat and the floors, walls and fixtures; and

(e) have slaughter lines (where operated) that are designed to allow a constant progress of the slaughter process and to avoid cross-contamination between the different parts of the slaughter line. Where more than one slaughter line is operated in the same premises, there must be adequate separation of the lines to prevent cross-contamination.

3. They must have facilities for disinfecting tools with hot water supplied at not less than 82ºC, or an alternative system having an equivalent effect.

4. The equipment for washing hands used by the staff engaged in handling exposed meat must have taps designed to prevent the spread of contamination.

5. There must be lockable facilities for the refrigerated storage of detained meat and separate lockable facilities for the storage of meat declared unfit for human consumption.

6. There must be a separate place with appropriate facilities for the cleaning, washing and disinfection of:

(a) transport equipment such as crates; and

(b) means of transport.

These places and facilities are not compulsory for (b) if officially authorised places and facilities exist nearby.

7. They must have an adequately equipped lockable facility or, where needed, room for the exclusive use of the veterinary service.

CHAPTER III: REQUIREMENTS FOR CUTTING PLANTS

1. Food business operators must ensure that cutting plants handling meat from poultry or lagomorphs:

   (a) are constructed so as to avoid contamination of meat, in particular by:

      (i) allowing constant progress of the operations; or

      (ii) ensuring separation between the different production batches;

   (b) have rooms for the separate storage of packaged and exposed meat, unless stored at different times or in such a way that the packaging material and the manner of storage cannot be a source of contamination for the meat;

   (c) have cutting rooms equipped to ensure compliance with the requirements laid down in Chapter V;

   (d) have equipment for washing hands used by staff handling exposed meat with taps designed to prevent the spread of contamination; and

   (e) have facilities for disinfecting tools with hot water supplied at not less than 82ºC, or an alternative system having an equivalent effect.

2. If the following operations are undertaken in a cutting plant:

(a) the evisceration of geese and ducks reared for the production of "foie gras", which have been stunned, bled and plucked on the fattening farm; or

(b) the evisceration of delayed eviscerated poultry,

food business operators must ensure that separate rooms are available for that purpose.

CHAPTER IV: SLAUGHTER HYGIENE

Food business operators operating slaughterhouses in which poultry or lagomorphs are slaughtered must ensure compliance with the following requirements.

1. (a) Meat from animals other than those referred to in (b) must not be used for human consumption if they die otherwise than by being slaughtered in the slaughterhouse.

(b) Only live animals intended for slaughter may be brought into the slaughter premises, with the exception of:

(i) delayed eviscerated poultry, geese and ducks reared for the production of "foie gras" and birds that are not considered as domestic but which are farmed as domestic animals, if slaughtered at the farm in accordance with Chapter VI;

(ii) farmed game slaughtered at the place of production in accordance with Section III; and

(iii) small wild game in accordance with Section IV, Chapter III.

2. Slaughterhouse operators must follow the instructions of the competent authority to ensure that ante-mortem inspection is carried out under suitable conditions.

3. Where establishments are approved for the slaughter of different animal species or for the handling of farmed ratites and small wild game, precautions must be taken to prevent cross contamination by separation either in time or in space of the operations carried out on the different species. Separate facilities for the reception and storage of carcases of farmed ratites slaughtered at the farm and for small wild game must be available.

4. Animals brought into the slaughter room must be slaughtered without undue delay.

5. Stunning, bleeding, skinning or plucking, evisceration and other dressing must be carried out without undue delay in such a way that contamination of the meat is avoided. In particular, measures must be taken to prevent the spillage of digestive tract contents during evisceration.

6. Slaughterhouse operators must follow the instructions of the competent authority to ensure that the post-mortem inspection is carried out under suitable conditions, and in particular that slaughtered animals can be inspected properly.

7. After post-mortem inspection:

   (a) parts unfit for human consumption must be removed as soon as possible from the clean sector of the establishment;

   (b) meat detained or declared unfit for human consumption and inedible by-products must not come into contact with meat declared fit for human consumption; and

   (c) viscera or parts of viscera remaining in the carcase, except for the kidneys, must be removed entirely, if possible, and as soon as possible, unless otherwise authorised by the competent authority.

8. After inspection and evisceration, slaughtered animals must be cleaned and chilled to not more than 4ºC as soon as possible, unless the meat is cut while warm.

9. When carcases are subjected to an immersion chilling process, account must be taken of the following.

   (a) Every precaution must be taken to avoid contamination of carcases, taking into account parameters such as carcase weight, water temperature, volume and direction of water flow and chilling time.

   (b) Equipment must be entirely emptied, cleaned and disinfected whenever this is necessary and at least once a day.

10. Sick or suspect animals, and animals slaughtered in application of disease eradication or control programmes, must not be slaughtered in the establishment except when permitted by the competent authority. In that event, slaughter must be performed under official supervision and steps taken to prevent contamination; the premises must be cleaned and disinfected before being used again.

CHAPTER V: HYGIENE DURING AND AFTER CUTTING AND BONING

Food business operators must ensure that cutting and boning of meat of poultry and lagomorphs takes place in accordance with the following requirements.

1. The work on meat must be organised in such a way as to prevent or minimise contamination. To this end, food business operators must ensure in particular that:

   (a) meat intended for cutting is brought into the workrooms progressively as needed;

   (b) during cutting, boning, trimming, slicing, dicing, wrapping and packaging, the temperature of the meat is maintained at not more than 4ºC by means of an ambient temperature of 12ºC or an alternative system having an equivalent effect; and

   (c) where the premises are approved for the cutting of meat of different animal species, precautions are taken to avoid cross-contamination, where necessary by separation of the operations on the different species in either space or time.

2. However, meat may be boned and cut prior to reaching the temperature referred to in point 1(b) when the cutting room is on the same site as the slaughter premises, provided that it is transferred to the cutting room either:

   (a) directly from the slaughter premises; or

   (b) after a waiting period in a chilling or refrigerating room.

3. As soon as it is cut and, where appropriate, packaged, the meat must be chilled to the temperature referred to in point 1(b).

4. Exposed meat must be stored and transported separately from packaged meat, unless stored or transported at different times or in such a way that the packaging material and the manner of storage or transport cannot be a source of contamination for the meat.

CHAPTER VI: SLAUGHTER ON THE FARM

Food business operators may slaughter poultry referred to in Chapter IV, point 1(b)(i), on the farm only with the authorisation of the competent authority and in compliance with the following requirements.

1. The farm must undergo regular veterinary inspection.

2. The food business operator must inform the competent authority in advance of the date and time of slaughter.

3. The holding must have facilities for concentrating the birds to allow an ante-mortem inspection of the group to be made.

4. The holding must have premises suitable for the hygienic slaughter and further handling of the birds.

5. Animal welfare requirements must be complied with.

6. The slaughtered birds must be accompanied to the slaughterhouse by a declaration by the food business operator who reared the animal indicating any veterinary products or other treatments administered to the animal, dates of administration and withdrawal periods, and the date and time of slaughter.

7. The slaughtered animal must be accompanied to the slaughterhouse by a certificate issued by the official veterinarian or approved veterinarian in accordance with Regulation (EC) No …/2004 *.

8. In the case of poultry reared for the production of "foie gras", the uneviscerated birds must be transported immediately and, if necessary, refrigerated to a slaughterhouse or cutting plant. They must be eviscerated within 24 hours of slaughter under the supervision of the competent authority.

9. Delayed eviscerated poultry obtained at the farm of production may be kept for up to 15 days at a temperature of not more than 4ºC. It must then be eviscerated in a slaughterhouse or in a cutting plant located in the same Member State as the farm of production.

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SECTION III: MEAT OF FARMED GAME

1. The provisions of Section I apply to the production and placing on the market of meat from even-toed farmed game mammals (Crevice and Suede), unless the competent authority considers them inappropriate.

2. The provisions of Section II apply to the production and placing on the market of meat from ratites. However, those of Section I apply where the competent authority considers them appropriate. Appropriate facilities must be provided, adapted to the size of the animals.

3. Notwithstanding points 1 and 2, food business operators may slaughter farmed ratites and farmed ungulates referred to in point 1 at the place of origin with the authorisation of the competent authority if:

   (a) the animals cannot be transported, to avoid any risk for the handler or to protect the welfare of the animals;

   (b) the herd undergoes regular veterinary inspection;

   (c) the owner of the animals submits a request;

   (d) the competent authority is informed in advance of the date and time of slaughter of the animals;

   (e) the holding has procedures for concentrating the animals to allow an ante-mortem inspection of the group to be made;

(f) the holding has facilities suitable for the slaughter, bleeding and, where ratites are to be plucked, plucking of the animals;

(g) animal welfare requirements are complied with;

(h) slaughtered and bled animals are transported to the slaughterhouse hygienically and without undue delay. If transport takes more than two hours, the animals are, if necessary, refrigerated. Evisceration may take place on the spot, under the supervision of the veterinarian;

(i) a declaration by the food business operator who reared the animals, stating their identity and indicating any veterinary products or other treatments administered, dates of administration and withdrawal periods, accompanies the slaughtered animals to the slaughterhouse; and

(j) during transport to the approved establishment, a certificate issued and signed by the official veterinarian or approved veterinarian, attesting to a favourable result of the ante-mortem inspection, correct slaughter and bleeding and the date and time of slaughter, accompanies the slaughtered animals.

4. Food business operators may also slaughter bison on the farm in accordance with paragraph 3 in exceptional circumstances.

SECTION IV: WILD GAME MEAT

CHAPTER I: TRAINING OF HUNTERS IN HEALTH AND HYGIENE

1. Persons who hunt wild game with a view to placing it on the market for human consumption must have sufficient knowledge of the pathology of wild game, and of the production and handling of wild game and wild game meat after hunting, to undertake an initial examination of wild game on the spot.

2. It is however enough if at least one person of a hunting team has the knowledge referred to in paragraph 1. References in this Section to a "trained person" are references to that person.

3. The trained person could also be the gamekeeper or the game manager if he or she is part of the hunting team or located in the immediate vicinity of where hunting is taking place. In the latter case, the hunter must present the wild game to the gamekeeper or game manager and inform them of any abnormal behaviour observed before killing.

4. Training must be provided to the satisfaction of the competent authority to enable hunters to become trained persons. It should cover at least the following subjects:

   (a) the normal anatomy, physiology and behaviour of wild game;

   (b) abnormal behaviour and pathological changes in wild game due to diseases, environmental contamination or other factors which may affect human health after consumption;

(c) the hygiene rules and proper techniques for the handling, transportation, evisceration etc. of wild game animals after killing; and

(d) legislation and administrative provisions on the animal and public health and hygiene conditions governing the placing on the market of wild game.

5. The competent authority should encourage hunters' organisations to provide such training.

CHAPTER II: HANDLING OF LARGE WILD GAME

1. After killing, large wild game must have their stomachs and intestines removed as soon as possible and, if necessary, be bled.

2. The trained person must carry out an examination of the body, and of any viscera removed, to identify any characteristics that may indicate that the meat presents a health risk.
The examination must take place as soon as possible after killing.

3. Meat of large wild game may be placed on the market only if the body is transported to a game-handling establishment as soon as possible after the examination referred to in point 2.
The viscera must accompany the body as specified in point 4. The viscera must be identifiable as belonging to a given animal.

4. (a) If no abnormal characteristics are found during the examination referred to in paragraph 2, no abnormal behaviour was observed before killing, and there is no suspicion of environmental contamination, the trained person must attach to the animal body a numbered declaration stating this. This declaration must also indicate the date, time and place of killing. In this case, the head and the viscera need not accompany the body, except in the case of species susceptible to Trichinosis (porcine animals, solipeds and others), whose head (except for tusks) and diaphragm must accompany the body. However, hunters must comply with any additional requirements imposed in the Member State where hunting takes place, in particular to permit the monitoring of certain residues and substances in accordance with Directive 96/23/EC;

(b) In other circumstances, the head (except for tusks, antlers and horns) and all the viscera except for the stomach and intestines must accompany the body. The trained person who carried out the examination must inform the competent authority of the abnormal characteristics, abnormal behaviour or suspicion of environmental contamination that prevented him or her from making a declaration in accordance with (a);

(c) If no trained person is available to carry out the examination referred to in paragraph 2 in a particular case, the head (except for tusks, antlers and horns) and all the viscera except for the stomach and the intestines must accompany the body.

5. Chilling must begin within a reasonable period of time after killing and achieve a temperature throughout the meat of not more than 7°C. Where climatic conditions so permit, active chilling is not necessary.

6. During transport to the game-handling establishment, heaping must be avoided.

7. Large wild game delivered to a game-handling establishment must be presented to the competent authority for inspection.

8. In addition, unskinned large wild game may be skinned and placed on the market only if:

   (a) before skinning, it is stored and handled separately from other food and not frozen; and

   (b) after skinning, it undergoes a final inspection in accordance with Regulation (EC) No …/2004 *.

9. The rules laid down in Section I, Chapter V, apply to the cutting and boning of large wild game.

CHAPTER III: HANDLING OF SMALL WILD GAME

1. The trained person must carry out an examination to identify any characteristics that may indicate that the meat presents a health risk. The examination must take place as soon as possible after killing.

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2. If abnormal characteristics are found during the examination, abnormal behaviour was observed before killing, or environmental contamination is suspected, the trained person must inform the competent authority.

3. Meat of small wild game may be placed on the market only if the body is transported to a game-handling establishment as soon as possible after the examination referred to in point 1.

4. Chilling must begin within a reasonable period of time of killing and achieve a temperature throughout the meat of not more than 4°C. Where climatic conditions so permit, active chilling is not necessary.

5. Evisceration must be carried out, or completed, without undue delay upon arrival at the game-handling establishment, unless the competent authority permits otherwise.

6. Small wild game delivered to a game-handling establishment must be presented to the competent authority for inspection.

7. The rules laid down in Section II, Chapter V, apply to the cutting and boning of small wild game.

SECTION V: MINCED MEAT, MEAT PREPARATIONS AND MECHANICALLY SEPARATED MEAT (MSM)

CHAPTER I: REQUIREMENTS FOR PRODUCTION ESTABLISHMENTS

Food business operators operating establishments producing minced meat, meat preparations or MSM must ensure that they:

1) are constructed so as to avoid contamination of meat and products, in particular by:

   (a) allowing constant progress of the operations; or

   (b) ensuring separation between the different production batches;

2) have rooms for the separate storage of packaged and exposed meat and products, unless stored at different times or in such a way that the packaging material and the manner of storage cannot be a source of contamination for the meat or products;

3) have rooms equipped to ensure compliance with the temperature requirements laid down in Chapter III;

4) have equipment for washing hands used by staff handling exposed meat and products with taps designed to prevent the spread of contamination; and

5) have facilities for disinfecting tools with hot water supplied at not less than 82ºC, or an alternative system having an equivalent effect.

CHAPTER II: REQUIREMENTS FOR RAW MATERIAL

Food business operators producing minced meat, meat preparations or MSM must ensure that the raw materials used satisfy the following requirements.

1. The raw material used to prepare minced meat must meet the following requirements.

    (a) It must comply with the requirements for fresh meat;

    (b) It must derive from skeletal muscle, including adherent fatty tissues;

    (c) It must not derive from:

        (i) scrap cuttings and scrap trimmings (other than whole muscle cuttings);

        (ii) MSM;

        (iii) meat containing bone fragments or skin; or

        (iv) meat of the head with the exception of the masseters, the non-muscular part of the linea alba, the region of the carpus and the tarsus, bone scrapings and the muscles of the diaphragm (unless the serosa has been removed).

2. The following raw material may be used to prepare meat preparations:

    (a) fresh meat;

(b) meat meeting the requirements of point 1; and

(c) if the meat preparation is clearly not intended to be consumed without first undergoing heat treatment:

(i) meat derived from the mincing or fragmentation of meat meeting the requirements of point 1 other than point 1(c)(i); and

(ii) MSM meeting the requirements of Chapter III, point 3(d).

3. The raw material used to produce MSM must meet the following requirements.

(a) It must comply with the requirements for fresh meat;

(b) The following material must not be used to produce MSM:

(i) for poultry, the feet, neckskin and head; and

(ii) for other animals, the bones of the head, feet, tails, femur, tibia, fibula, humerus, radius and ulna.

CHAPTER III: HYGIENE DURING AND AFTER PRODUCTION

Food business operators producing minced meat, meat preparations or MSM must ensure compliance with the following requirements.

1. The work on meat must be organised in such a way as to prevent or minimise contamination. To this end, food business operators must ensure in particular that the meat used is:

    (a) at a temperature of not more than 4ºC for poultry, 3ºC for offal and 7ºC for other meat; and

    (b) brought into the preparation room progressively as needed.

2. The following requirements apply to the production of minced meat and meat preparations.

    (a) Unless the competent authority authorises boning immediately before mincing, frozen or deep-frozen meat used for the preparation of minced meat or meat preparations must be boned before freezing. It may be stored only for a limited period.

    (b) When prepared from chilled meat, minced meat must be prepared:

        (i) in the case of poultry, within no more than 3 days of their slaughter;

        (ii) in the case of animal other than poultry, within no more than 6 days of their slaughter; or

(iii) within no more than 15 days from the slaughter of the animals in the case of boned, vacuum-packed beef and veal.

(c) Immediately after production, minced meat and meat preparations must be wrapped or packaged and be:

(i) chilled to an internal temperature of not more than 2ºC for minced meat and 4°C for meat preparations; or

(ii) frozen to an internal temperature of not more than -18°C.

These temperature conditions must be maintained during storage and transport.

3. The following requirements apply to the production and use of MSM produced using techniques that do not alter the structure of the bones used in the production of MSM and the calcium content of which is not significantly higher than that of minced meat.

(a) Raw material for deboning from an on-site slaughterhouse must be no more than 7 days old; otherwise, raw material for deboning must be no more than 5 days old. However, poultry carcases must be no more than 3 days old.

(b) Mechanical separation must take place immediately after deboning.

(c) If not used immediately after being obtained, MSM must be wrapped or packaged and then chilled to a temperature of not more than 2°C or frozen to an internal temperature of not more than -18°C. These temperature requirements must be maintained during storage and transport.

(d) If the food business operator has carried out analyses demonstrating that MSM complies with the microbiological criteria for minced meat adopted in accordance with Regulation (EC) No…/2004 * it may be used in meat preparations that are clearly not intended to be consumed without first undergoing heat treatment and in meat products.

(e) MSM not shown to comply with the criteria referred to in (d) may be used only to manufacture heat-treated meat products in establishments approved in accordance with this Regulation.

4. The following requirements apply to the production and use of MSM produced using techniques other than those mentioned in point 3.

(a) Raw material for deboning from an on-site slaughterhouse must be no more than 7 days old; otherwise, raw material for deboning must be no more than 5 days old. However, poultry carcases must be no more than 3 days old.

(b) If mechanical separation does not take place immediately after deboning the flesh-bearing bones must be stored and transported at a temperature of not more than 2°C or, if frozen, at a temperature of not more than -18°C.

(c) Flesh-bearing bones obtained from frozen carcases must not be refrozen.

(d) If not used within one hour of being obtained, MSM must be chilled immediately to a temperature of not more than 2°C.

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* Official Publications Office is to insert the official number of Regulation on the hygiene of foodstuffs.

(e) If, after chilling, MSM is not processed within 24 hours, it must be frozen within 12 hours of production and reach an internal temperature of not more than -18°C within six hours.

(f) Frozen MSM must be wrapped or packaged before storage or transport, must not be stored for more than three months and must be maintained at a temperature of not more than –18ºC during storage and transport.

(g) MSM may be used only to manufacture heat-treated meat products in establishments approved in accordance with this Regulation.

5. Minced meat, meat preparations and MSM must not be re-frozen after thawing.

CHAPTER IV: LABELLING

1. In addition to the requirements of Directive 2000/13/EC [*], food business operators must ensure compliance with the requirement of point 2 if, and to the extent that, national rules in the Member State in the territory of which the product is placed on the market so require.

2. Packages intended for supply to the final consumer containing minced meat from poultry or solipeds or meat preparations containing MSM must bear a notice indicating that such products should be cooked before consumption.

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[*] Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ L 109, 6.5.2000, p. 29). Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2001, p. 15).

SECTION VI: MEAT PRODUCTS

1. Food business operators must ensure that the following items are not used in the preparation of meat products:

   (a) genital organs of either female or male animals, except testicles;

   (b) urinary organs, except the kidneys and the bladder;

   (c) the cartilage of the larynx, the trachea and the extra-lobular bronchi;

   (d) eyes and eyelids;

   (e) the external auditory meatus;

   (f) horn tissue; and

   (g) in poultry, the head – except the comb and the ears, the wattles and caruncles – the oesophagus, the crop, the intestines and the genital organs.

2. All meat, including minced meat and meat preparations, used to produce meat product must meet the requirements for fresh meat. However, minced meat and meat preparations used to produce meat products need not satisfy other specific requirements of Section V.

SECTION VII: LIVE BIVALVE MOLLUSCS

1. This Section applies to live bivalve molluscs. With the exception of the provisions on purification, it also applies to live echinoderms, tunicates and marine gastropods.

2. Chapters I to VIII apply to animals harvested from production areas that the competent authority has classified in accordance with Regulation (EC) No …/2004 [*]. Chapter IX applies to pectinidae harvested outside those areas.

3. Chapters V, VI, VIII and IX, and paragraph 3 of Chapter VII, apply to retail.

4. The requirements of this Section supplement those laid down in Regulation (EC) No …/2004 [**].

   (a) In the case of operations that take place before live bivalve molluscs arrive at a dispatch or purification centre, they supplement the requirements of Annex I to that Regulation.

   (b) In the case of other operations, they supplement the requirements of Annex II to that Regulation.

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[*] Official Publications Office is to insert the official number of Regulation on the organisation of official controls.

[**] Official Publications Office is to insert the official number of Regulation on the hygiene of foodstuffs.

CHAPTER I: GENERAL REQUIREMENTS FOR THE PLACING ON THE MARKET OF LIVE BIVALVE MOLLUSCS

1. Live bivalve molluscs may not be placed on the market for retail sale otherwise than via a dispatch centre, where an identification mark must be applied in accordance with Chapter VII.

2. Food business operators may accept batches of live bivalve molluscs only if the documentary requirements set out in paragraphs 3 to 7 have been complied with.

3. Whenever a food business operator moves a batch of live bivalve molluscs between establishments, up to and including the arrival of the batch at a dispatch centre or processing establishment, a registration document must accompany the batch.

4. The registration document must be in at least one official language of the Member State in which the receiving establishment is located and contain at least the information specified below.

   (a) In the case of a batch of live bivalve molluscs sent from a production area, the registration document must contain at least the following information:

      (i) the gatherer's identity and address;

      (ii) the date of harvesting;

(iii) the location of the production area described in as precise detail as is practicable or by a code number;

(iv) the health status of the production area;

(v) the shellfish species and quantity; and

(vi) the destination of the batch.

(b) In the case of a batch of live bivalve molluscs sent from a relaying area, the registration document must contain at least the information referred to in (a) and the following information:

(i) the location of the relaying area; and

(ii) the duration of relaying.

(c) In the case of a batch of live bivalve molluscs sent from a purification centre, the registration document must contain at least the information referred to in (a) and the following information:

(i) the address of the purification centre;

(ii) the duration of purification; and

(iii) the dates on which the batch entered and left the purification centre.

5. Food business operators sending batches of live bivalve molluscs must complete the relevant sections of the registration document so that they are easy to read and cannot be altered. Food business operators receiving batches must date-stamp the document on receipt of the batch or record the date of receipt in another manner.

6. Food business operators must keep a copy of the registration document relating to each batch sent and received for at least twelve months after its dispatch or receipt (or such longer period as the competent authority may specify).

7. However, if:

(a) the staff gathering live bivalve molluscs also operate the dispatch centre, purification centre, relaying area or processing establishment receiving the live bivalve molluscs; and

(b) a single competent authority supervises all the establishments concerned,

registration documents are not necessary if that competent authority so permits.

CHAPTER II: HYGIENE REQUIREMENTS FOR THE PRODUCTION AND HARVESTING OF LIVE BIVALVE MOLLUSCS

A. REQUIREMENTS FOR PRODUCTION AREAS

1. Gatherers may only harvest live bivalve molluscs from production areas with fixed locations and boundaries that the competent authority has classified – where appropriate, in cooperation with food business operators – as being of class A, B or C in accordance with Regulation (EC) No …/2004 *.

2. Food business operators may place live bivalve molluscs collected from class A production areas on the market for direct human consumption only if they meet the requirements of Chapter V.

3. Food business operators may place live bivalve molluscs collected from class B production areas on the market for human consumption only after treatment in a purification centre or after relaying.

4. Food business operators may place live bivalve molluscs collected from class C production areas on the market for human consumption only after relaying over a long period in accordance with Part C of this Chapter.

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* Official Publications Office is to insert the official number of Regulation on the organisation of official controls.

5. After purification or relaying, live bivalve molluscs from class B or C production areas must meet all of the requirements of Chapter V. However, live bivalve molluscs from such areas that have not been submitted for purification or relaying may be sent to a processing establishment, where they must undergo treatment to eliminate pathogenic microorganisms (where appropriate, after removal of sand, mud or slime in the same or another establishment). The permitted treatment methods are:

(a) sterilisation in hermetically sealed containers; and

(b) heat treatments involving:

(i) immersion in boiling water for the period required to raise the internal temperature of the mollusc flesh to not less than 90°C and maintenance of this minimum temperature for a period of not less than 90 seconds;

(ii) cooking for three to five minutes in an enclosed space where the temperature is between 120 and 160°C and the pressure is between 2 and 5 kg/cm^2, followed by shelling and freezing of the flesh to a core temperature of -20°C; and

(iii) steaming under pressure in an enclosed space satisfying the requirements relating to cooking time and the internal temperature of the mollusc flesh mentioned under (i). A validated methodology must be used. Procedures based on the HACCP principles must be in place to verify the uniform distribution of heat.

6. Food business operators must not produce live bivalve molluscs in, or harvest them from, areas that the competent authority has not classified, or which are unsuitable for health reasons. Food business operators must take account of any relevant information concerning areas' suitability for production and harvesting, including information obtained from own-checks and the competent authority. They must use this information, particularly information on environmental and weather conditions, to determine the appropriate treatment to apply to harvested batches.

B. REQUIREMENTS FOR HARVESTING AND HANDLING FOLLOWING HARVESTING

Food business operators harvesting live bivalve molluscs, or handling them immediately after harvesting, must ensure compliance with the following requirements.

1. Harvesting techniques and further handling must not cause additional contamination or excessive damage to the shells or tissues of the live bivalve molluscs or result in changes significantly affecting their suitability for treatment by purification, processing or relaying. Food business operators must in particular:

   (a) adequately protect live bivalve molluscs from crushing, abrasion or vibration;

   (b) not expose live bivalve molluscs to extreme temperatures;

   (c) not re-immerse live bivalve molluscs in water that could cause additional contamination; and

   (d) if carrying out conditioning in natural sites, use only areas that the competent authority has classified as being of class A.

2. Means of transport must permit adequate drainage, be equipped to ensure the best survival conditions possible and provide efficient protection against contamination.

C. REQUIREMENTS FOR RELAYING LIVE BIVALVE MOLLUSCS

Food business operators relaying live bivalve molluscs must ensure compliance with the following requirements.

1. Food business operators may use only those areas that the competent authority has approved for relaying live bivalve molluscs. Buoys, poles or other fixed means must clearly identify the boundaries of the sites. There must be a minimum distance between relaying areas, and also between relaying areas and production areas, so as to minimise any risk of the spread of contamination.

2. Conditions for relaying must ensure optimal conditions for purification. In particular, food business operators must:

   (a) use techniques for handling live bivalve molluscs intended for relaying that permit the resumption of filter-feeding activity after immersion in natural waters;

   (b) not relay live bivalve molluscs at a density that prevents purification;

   (c) immerse live bivalve molluscs in seawater at the relaying area for an appropriate period, fixed depending on the water temperature, which period must be of at least two months' duration unless the competent authority agrees to a shorter period on the basis of the food business operator's risk analysis; and

(d) ensure sufficient separation of sites within a relaying area to prevent mixing of batches; the "all in, all out" system must be used, so that a new batch cannot be brought in before the whole of the previous batch has been removed.

3. Food business operators managing relaying areas must keep permanent records of the source of live bivalve molluscs, relaying periods, relaying areas used and the subsequent destination of the batch after relaying, for inspection by the competent authority.

CHAPTER III: STRUCTURAL REQUIREMENTS FOR DISPATCH AND PURIFICATION CENTRES

1. The location of premises on land must not be subject to flooding by ordinary high tides or run-off from surrounding areas.

2. Tanks and water storage containers must meet the following requirements:

(a) Internal surfaces must be smooth, durable, impermeable and easy to clean.

(b) They must be constructed so as to allow complete draining of water.

(c) Any water intake must be situated in a position that avoids contamination of the water supply.

3. In addition, in purification centres, purification tanks must be suitable for the volume and type of products to be purified.

CHAPTER IV: HYGIENE REQUIREMENTS FOR PURIFICATION AND DISPATCH CENTRES

A. REQUIREMENTS FOR PURIFICATION CENTRES

Food business operators purifying live bivalve molluscs must ensure compliance with the following requirements.

1. Before purification commences, live bivalve molluscs must be washed free of mud and accumulated debris using clean water.

2. Operation of the purification system must allow live bivalve molluscs rapidly to resume and to maintain filter-feeding activity, to eliminate sewage contamination, not to become re-contaminated and to be able to remain alive in a suitable condition after purification for wrapping, storage and transport before being placed on the market.

3. The quantity of live bivalve molluscs to be purified must not exceed the capacity of the purification centre. The live bivalve molluscs must be continuously purified for a period sufficient to achieve compliance with allow the health standards of Chapter V and microbiological criteria adopted in accordance with Regulation (EC) No …/2004 *.

4. Should a purification tank contain several batches of live bivalve molluscs, they must be of the same species and the length of the treatment must be based on the time required by the batch needing the longest period of purification.

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* Official Publications Office is to insert the official number of Regulation on the hygiene of foodstuffs.

5. Containers used to hold live bivalve molluscs in purification systems must have a construction that allows clean seawater to flow through. The depth of layers of live bivalve molluscs must not impede the opening of shells during purification.

6. No crustaceans, fish or other marine species may be kept in a purification tank in which live bivalve molluscs are undergoing purification.

7. Every package containing purified live bivalve molluscs sent to a dispatch centre must be provided with a label certifying that all molluscs have been purified.

B. REQUIREMENTS FOR DISPATCH CENTRES

Food business operators operating dispatch centres must ensure compliance with the following requirements.

1. Handling of live bivalve molluscs, particularly conditioning, calibration, wrapping and packing, must not cause contamination of the product or affect the viability of the molluscs.

2. Before dispatch, the shells of live bivalve molluscs must be washed thoroughly with clean water.

3. Live bivalve molluscs must come from:

   (a) a class A production area;

   (b) a relaying area;

(c) a purification centre; or

(d) another dispatch centre.

4. The requirements laid down in points 1 and 2 also apply to dispatch centres situated on board vessels. Molluscs handled in such centres must come from a class A production area or a relaying area.

CHAPTER V: HEALTH STANDARDS FOR LIVE BIVALVE MOLLUSCS

In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) No …/2004 *, food business operators must ensure that live bivalve molluscs placed on the market for human consumption meet the standards laid down in this Chapter.

1. They must have organoleptic characteristics associated with freshness and viability, including shells free of dirt, an adequate response to percussion and normal amounts of intravalvular liquid.

2. They must not contain marine biotoxins in total quantities (measured in the whole body or any part edible separately) that exceed the following limits:

(a) for Paralytic Shellfish Poison (PSP), 800 micrograms per kilogram;

(b) for Amnesic Shellfish Poison (ASP), 20 milligrams of domoic acid per kilogram;

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(c) for okadaic acid, dinophysistoxins and pectenotoxins together, 160 micrograms of okadaic acid equivalents per kilogram;

(d) for yessotoxins, 1 milligram of yessotoxin equivalent per kilogram; and

(e) for azaspiracids, 160 micrograms of azaspiracid equivalents per kilogram.

CHAPTER VI: WRAPPING AND PACKAGING OF LIVE BIVALVE MOLLUSCS

1. Oysters must be wrapped or packaged with the concave shell downwards.

2. Individual consumer-size packages of live bivalve molluscs must be closed and remain closed after leaving the dispatch centre and until presented for sale to the final consumer.

CHAPTER VII: IDENTIFICATION MARKING AND LABELLING

1. The label, including the identification mark, must be waterproof.

2. In addition to the general requirements for identification marks contained in Annex II, Section I, the following information must be present on the label:

(a) the species of bivalve mollusc (common name and scientific name); and

(b) the date of packaging, comprising at least the day and the month.

By way of derogation from Directive 2000/13/EC, the date of minimum durability may be replaced by the entry "these animals must be alive when sold".

3. The retailer must keep the label attached to the packaging of live bivalve molluscs that are not in individual consumer-size packages for at least 60 days after splitting up the contents.

CHAPTER VIII: OTHER REQUIREMENTS

1. Food business operators storing and transporting live bivalve molluscs must ensure that they are kept at a temperature that does not adversely affect food safety or their viability.

2. Live bivalve molluscs must not be re-immersed in, or sprayed with, water after they have been packaged for retail sale and left the dispatch centre.

CHAPTER IX: SPECIFIC REQUIREMENTS FOR PECTINIDAE HARVESTED OUTSIDE CLASSIFIED PRODUCTION AREAS

Food business operators harvesting pectinidae outside classified production areas or handling such pectinidae must comply with the following requirements.

1. Pectinidae may not be placed on the market unless they are harvested and handled in accordance with Chapter II, Part B, and meet the standards laid down in Chapter V, as proved by a system of own-checks.

2. In addition, where data from official monitoring programmes enable the competent authority to classify fishing grounds – where appropriate, in cooperation with food business operators – the provisions of Chapter II, Part A, apply by analogy to pectinidae.

3. Pectinidae may not be placed on the market for human consumption otherwise than via a fish auction, a dispatch centre or a processing establishment. When they handle pectinidae, food business operators operating such establishments must inform the competent authority and, as regards dispatch centres, comply with the relevant requirements of Chapters III and IV.

4. Food business operators handling pectinidae must comply:

   (a) with the documentary requirements of Chapter I, points 3 to 7, where applicable. In this case, the registration document must clearly indicate the location of the area where the pectinidae were harvested; or

   (b) as regards packaged pectinidae, and wrapped pectinidae if the wrapping provides protection equivalent to that of packaging, with the requirements of Chapter VII concerning identification marking and labelling.

SECTION VIII: FISHERY PRODUCTS

1. This Section does not apply to bivalve molluscs, echinoderms, tunicates and marine gastropods when placed on the market live. With the exception of Chapters I and II, it applies to such animals when not placed on the market live, in which case they must have been obtained in accordance with Section VII.

2. Chapter III, Parts A, C and D, Chapter IV and Chapter V apply to retail.

3. The requirements of this Section supplement those laid down in Regulation (EC) No …/2004 *.

(a) In the case of establishments, including vessels, engaged in primary production and associated operations they supplement the requirements of Annex I to that Regulation.

(b) In the case of other establishments, including vessels, they supplement the requirements of Annex II to that Regulation.

4. In relation to fishery products:

(a) primary production covers the farming, fishing and collection of live fishery products with a view to their being placed on the market; and

(b) associated operations cover any of the following operations, if carried out on board fishing vessels: slaughter, bleeding, heading, gutting, removing fins, refrigeration and wrapping; they also include:

(1) the transport and storage of fishery products the nature of which has not been substantially altered, including live fishery products, within fish farms on land and,

(2) the transport of fishery products the nature of which has not been substantially altered, including live fishery products, from the place of production to the first establishment of destination.

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* Official Publications Office is to insert the official number of Regulation on the hygiene of foodstuffs.

CHAPTER I: REQUIREMENTS FOR VESSELS

Food business operators must ensure that:

1. vessels used to harvest fishery products from their natural environment, or to handle or process them after harvesting, comply with the structural and equipment requirements laid down in Part I; and

2. operations carried out on board vessels take place in accordance with the rules laid down in Part II.

I. STRUCTURAL AND EQUIPMENT REQUIREMENTS

A. Requirements for all vessels

1. Vessels must be designed and constructed so as not to cause contamination of the products with bilge-water, sewage, smoke, fuel, oil, grease or other objectionable substances.

2. Surfaces with which fishery products come into contact must be of suitable corrosion-resistant material that is smooth and easy to clean. Surface coatings must be durable and non-toxic.

3. Equipment and material used for working on fishery products must be made of corrosion-resistant material that is easy to clean and disinfect.

4. When vessels have a water intake for water used with fishery products, it must be situated in a position that avoids contamination of the water supply.

B. Requirements for vessels designed and equipped to preserve fresh fishery products for more than twenty-four hours

1. Vessels designed and equipped to preserve fishery products for more than twenty-four hours must be equipped with holds, tanks or containers for the storage of fishery products at the temperatures laid down in Chapter VII.

2. Holds must be separated from the engine compartments and from the crew quarters by partitions which are sufficient to prevent any contamination of the stored fishery products. Holds and containers used for the storage of fishery products must ensure their preservation under satisfactory conditions of hygiene and, where necessary, ensure that melt water does not remain in contact with the products.

3. In vessels equipped for chilling fishery products in cooled clean seawater, tanks must incorporate devices for achieving a uniform temperature throughout the tanks. Such devices must achieve a chilling rate that ensures that the mix of fish and clean seawater reaches not more than 3ºC 6 hours after loading and not more than 0 °C after 16 hours and allow the monitoring and, where necessary, recording of temperatures.

C. Requirements for freezer vessels

Freezer vessels must:

1. have freezing equipment with sufficient capacity to lower the temperature rapidly so as to achieve a core temperature of not more than -18ºC;

2. have refrigeration equipment with sufficient capacity to maintain fishery products in the storage holds at not more than -18ºC. Storage holds must be equipped with a temperature-recording device in a place where it can be easily read. The temperature sensor of the reader must be situated in the area where the temperature in the hold is the highest; and

3. meet the requirements for vessels designed and equipped to preserve fishery products for more than 24 hours laid down in Part B, paragraph 2.

D. Requirements for factory vessels

1. Factory vessels must have at least:

(a) a receiving area reserved for taking fishery products on board, designed to allow each successive catch to be separated. This area must be easy to clean and designed so as to protect the products from the sun or the elements and from any source of contamination;

(b) a hygienic system for conveying fishery products from the receiving area to the work area;

(c) work areas that are large enough for the hygienic preparation and processing of fishery products, easy to clean and disinfect and designed and arranged in such a way as to prevent any contamination of the products;

(d) storage areas for the finished products that are large enough and designed so that they are easy to clean. If a waste-processing unit operates on board, a separate hold must be designated for the storage of such waste;

(e) a place for storing packaging materials that is separate from the product preparation and processing areas;

(f) special equipment for disposing waste or fishery products that are unfit for human consumption directly into the sea or, where circumstances so require, into a watertight tank reserved for that purpose. If waste is stored and processed on board with a view to its sanitation, separate areas must be allocated for that purpose;

(g) a water intake situated in a position that avoids contamination of the water supply; and

(h) hand-washing equipment for use by the staff engaged in handling exposed fishery products with taps designed to prevent the spread of contamination.

2. However, factory vessels on board which crustaceans and molluscs are cooked, chilled and wrapped, need not meet the requirements of paragraph 1 if no other form of handling or processing takes place on board such vessels.

3. Factory vessels that freeze fishery products must have equipment meeting the requirements for freezer vessels laid down in Part C, points 1 and 2.

II. HYGIENE REQUIREMENTS

1. When in use, the parts of vessels or containers set aside for the storage of fishery products must be kept clean and maintained in good repair and condition. In particular, they must not be contaminated by fuel or bilge water.

2. As soon as possible after they are taken on board, fishery products must be protected from contamination and from the effects of the sun or any other source of heat. When they are washed, the water used must be either potable water or, where appropriate, clean water.

3. Fishery products must be handled and stored so as to prevent bruising. Handlers may use spiked instruments to move large fish or fish which might injure them, provided that the flesh of the products suffers no damage.

4. Fishery products other than those kept alive must undergo chilling as soon as possible after loading. However, when chilling is not possible, fishery products must be landed as soon as possible.

5. Ice used to chill fishery products must be made from potable water or clean water.

6. Where fish are headed and/or gutted on board, such operations must be carried out hygienically as soon as possible after capture, and the products must be washed immediately and thoroughly with potable water or clean water. In that event, the viscera and parts that may constitute a danger to public health must be removed as soon as possible and kept apart from products intended for human consumption. Livers and roes intended for human consumption must be preserved under ice, at a temperature approaching that of melting ice, or be frozen.

7. Where freezing in brine of whole fish intended for canning is practised, a temperature of not more than -9 °C must be achieved for the product. The brine must not be a source of contamination for the fish.

CHAPTER II: REQUIREMENTS DURING AND AFTER LANDING

1. Food business operators responsible for the unloading and landing of fishery products must:

   (a) ensure that unloading and landing equipment that comes into contact with fishery products is constructed of material that is easy to clean and disinfect and maintained in a good state of repair and cleanliness; and

   (b) avoid contamination of fishery products during unloading and landing, in particular by:

      (i) carrying out unloading and landing operations rapidly;

      (ii) placing fishery products without delay in a protected environment at the temperature specified in Chapter VII; and

      (iii) not using equipment and practices that cause unnecessary damage to the edible parts of the fishery products.

2. Food business operators responsible for auction and wholesale markets or parts thereof where fishery products are displayed for sale must ensure compliance with the following requirements.

   (a) (i) There must be lockable facilities for the refrigerated storage of detained fishery products and separate lockable facilities for the storage of fishery products declared unfit for human consumption.

(ii) If the competent authority so requires, there must be an adequately equipped lockable facility or, where needed, room for the exclusive use of the competent authority.

(b) At the time of display or storage of fishery products:

(i) the premises must not be used for other purposes;

(ii) vehicles emitting exhaust fumes likely to impair the quality of fishery products must not have access to the premises;

(iii) persons having access to the premises must not introduce other animals; and

(iv) the premises must be well lit to facilitate official controls.

3. When chilling was not possible on board the vessel, fresh fishery products, other than those kept alive, must undergo chilling as soon as possible after landing and be stored at a temperature approaching that of melting ice.

4. Food business operators must cooperate with relevant competent authorities so as to permit them to carry out official controls in accordance with Regulation (EC) No…/2004 *, in particular as regards any notification procedures for the landing of fishery products that the competent authority of the Member State the flag of which the vessel is flying or the competent authority of the Member State where the fishery products are landed might consider necessary.

* Official Publications Office is to insert the official number of Regulation on the organisation of official controls.

CHAPTER III: REQUIREMENTS FOR ESTABLISHMENTS, INCLUDING VESSELS, HANDLING FISHERY PRODUCTS

Food business operators must ensure compliance with the following requirements, where relevant, in establishments handling fishery products.

A. REQUIREMENTS FOR FRESH FISHERY PRODUCTS

1. Where chilled, unpackaged products are not distributed, dispatched, prepared or processed immediately after reaching an establishment on land, they must be stored under ice in appropriate facilities. Re-icing must be carried out as often as necessary. Packaged fresh fishery products must be chilled to a temperature approaching that of melting ice.

2. Operations such as heading and gutting must be carried out hygienically. Where gutting is possible from a technical and commercial viewpoint, it must be carried out as quickly as possible after the products have been caught or landed. The products must be washed thoroughly with potable water or, on board vessels, clean water immediately after these operations.

3. Operations such as filleting and cutting must be carried out so as to avoid contamination or spoilage of fillets and slices. Fillets and slices must not remain on the worktables beyond the time necessary for their preparation. Fillets and slices must be wrapped and, where necessary, packaged and must be chilled as quickly as possible after their preparation.

4. Containers used for the dispatch or storage of unpackaged prepared fresh fishery products stored under ice must ensure that melt water does not remain in contact with the products.

5. Whole and gutted fresh fishery products may be transported and stored in cooled water on board vessels. They may also continue to be transported in cooled water after landing, and be transported from aquaculture establishments, until they arrive at the first establishment on land carrying out any activity other than transport or sorting.

B. REQUIREMENTS FOR FROZEN PRODUCTS

Establishments on land that freeze fishery products must have equipment that satisfies the requirements laid down for freezer vessels in Chapter I, Part I.C, points 1 and 2.

C. REQUIREMENTS FOR MECHANICALLY SEPARATED FISHERY PRODUCTS

Food business operators manufacturing mechanically separated fishery products must ensure compliance with the following requirements.

1. The raw materials used must satisfy the following requirements.

   (a) Only whole fish and bones after filleting may be used to produce mechanically separated fishery products;

   (b) All raw materials must be free from guts.

2. The manufacturing process must satisfy the following requirements:

(a) Mechanical separation must take place without undue delay after filleting;

(b) If whole fish are used, they must be gutted and washed beforehand;

(c) After production, mechanically separated fishery products must be frozen as quickly as possible or incorporated in a product intended for freezing or a stabilising treatment.

D. REQUIREMENTS CONCERNING PARASITES

1. The following fishery products must be frozen at a temperature of not more than -20 °C in all parts of the product for not less than 24 hours; this treatment must be applied to the raw product or the finished product:

(a) fishery products to be consumed raw or almost raw;

(b) fishery products from the following species, if they are to undergo a cold smoking process in which the internal temperature of the fishery product is not more than 60 °C:

(i) herring;

(ii) mackerel;

(iii) sprat;

(iv) (wild) Atlantic and Pacific salmon; and

(c) marinated and/or salted fishery products, if the processing is insufficient to destroy nematode larvae.

2. Food business operators need not carry out the treatment required under paragraph 1 if:

(a) epidemiological data are available indicating that the fishing grounds of origin do not present a health hazard with regard to the presence of parasites; and

(b) the competent authority so authorises.

3. A document from the manufacturer, stating the type of process they have undergone, must accompany fishery products referred to in paragraph 1 when placed on the market, except when supplied to the final consumer.

CHAPTER IV: REQUIREMENTS FOR PROCESSED FISHERY PRODUCTS

Food business operators cooking crustaceans and molluscs must ensure compliance with the following requirements.

1. Rapid cooling must follow cooking. Water used for this purpose must be potable water or, on board vessels, clean water. If no other method of preservation is used, cooling must continue until a temperature approaching that of melting ice is reached.

2. Shelling or shucking must be carried out hygienically, avoiding contamination of the product. Where such operations are done by hand, workers must pay particular attention to washing their hands.

3. After shelling or shucking, cooked products must be frozen immediately, or be chilled as soon as possible to the temperature laid down in Chapter VII.

CHAPTER V: HEALTH STANDARDS FOR FISHERY PRODUCTS

In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) No …/2004 *, food business operators must ensure, depending on the nature of the product or the species, that fishery products placed on the market for human consumption meet the standards laid down in this Chapter.

A. ORGANOLEPTIC PROPERTIES OF FISHERY PRODUCTS

Food business operators must carry out an organoleptic examination of fishery products.
In particular, this examination must ensure that fishery products comply with any freshness criteria.

B. HISTAMINE

Food business operators must ensure that the limits with regard to histamine are not exceeded.

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* Official Publications Office is to insert the official number of Regulation on the hygiene of foodstuffs.

C. TOTAL VOLATILE NITROGEN

Unprocessed fishery products must not be placed on the market if chemical tests reveal that the limits with regard to TVB-N or TMA-N have been exceeded.

D. PARASITES

Food business operators must ensure that fishery products have been subjected to a visual examination for the purpose of detecting visible parasites before being placed on the market. They must not place fishery products that are obviously contaminated with parasites on the market for human consumption.

E. TOXINS HARMFUL TO HUMAN HEALTH

1. Fishery products derived from poisonous fish of the following families must not be placed on the market: Tetraodontidae, Molidae, Diodontidae and Canthigasteridae.

2. Fishery products containing biotoxins such as ciguatoxin or muscle-paralysing toxins must not be placed on the market. However, fishery products derived from bivalve molluscs, echinoderms, tunicates and marine gastropods may be placed on the market if they have been produced in accordance with Section VII and comply with the standards laid down in Chapter V, point 2, of that Section.

CHAPTER VI: WRAPPING AND PACKAGING OF FISHERY PRODUCTS

1. Receptacles in which fresh fishery products are kept under ice must be water-resistant and ensure that melt water does not remain in contact with the products.

2. Frozen blocks prepared on board vessels must be adequately wrapped before landing.

3. When fishery products are wrapped on board fishing vessels, food business operators must ensure that wrapping material:

    (a) is not a source of contamination;

    (b) is stored in such a manner that it is not exposed to a risk of contamination;

    (c) intended for re-use is easy to clean and, where necessary, to disinfect.

CHAPTER VII: STORAGE OF FISHERY PRODUCTS

Food business operators storing fishery products must ensure compliance with the following requirements.

1. Fresh fishery products, thawed unprocessed fishery products, and cooked and chilled products from crustaceans and molluscs, must be maintained at a temperature approaching that of melting ice.

2. Frozen fishery products must be kept at a temperature of not more than -18ºC in all parts of the product; however, whole frozen fish in brine intended for the manufacture of canned food may be kept at a temperature of not more than -9ºC.

3. Fishery products kept alive must be kept at a temperature and in a manner that does not adversely affect food safety or their viability.

CHAPTER VIII: TRANSPORT OF FISHERY PRODUCTS

Food business operators transporting fishery products must ensure compliance with the following requirements.

1. During transport, fishery products must be maintained at the required temperature.
   In particular:

   (a) fresh fishery products, thawed unprocessed fishery products, and cooked and chilled products from crustaceans and molluscs, must be maintained at a temperature approaching that of melting ice;

(b) frozen fishery products, with the exception of frozen fish in brine intended for the manufacture of canned food, must be maintained during transport at an even temperature of not more than -18ºC in all parts of the product, possibly with short upward fluctuations of not more than 3°C.

2. Food business operators need not comply with point 1(b) when frozen fishery products are transported from a cold store to an approved establishment to be thawed on arrival for the purposes of preparation and/or processing, if the journey is short and the competent authority so permits.

3. If fishery products are kept under ice, melt water must not remain in contact with the products.

4. Fishery products to be placed on the market live must be transported in such a way as not adversely to affect food safety or their viability.

SECTION IX: RAW MILK AND DAIRY PRODUCTS

CHAPTER I: RAW MILK – PRIMARY PRODUCTION

Food business operators producing or, as appropriate, collecting raw milk must ensure compliance with the requirements laid down in this Chapter.

I. HEALTH REQUIREMENTS FOR RAW MILK PRODUCTION

1. Raw milk must come from animals:

   (a) that do not show any symptoms of infectious diseases communicable to humans through milk;

   (b) that are in a good general state of health, present no sign of disease that might result in the contamination of milk and, in particular, are not suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever, or a recognisable inflammation of the udder;

   (c) that do not have any udder wound likely to affect the milk;

   (d) to which no unauthorised substances or products have been administered and that have not undergone illegal treatment within the meaning of Directive 96/23/EC; and

   (e) in respect of which, where authorised products or substances have been administered, the withdrawal periods prescribed for these products or substances have been observed.

2. (a) In particular, as regards brucellosis, raw milk must come from:

(i) cows or buffaloes belonging to a herd which, within the meaning of Directive 64/432/EEC [*], is free or officially free of brucellosis;

(ii) sheep or goats belonging to a holding officially free or free of brucellosis within the meaning of Directive 91/68/EEC [†]; or

(iii) females of other species belonging, for species susceptible to brucellosis, to herds regularly checked for that disease under a control plan that the competent authority has approved.

(b) As regards tuberculosis, raw milk must come from:

(i) cows or buffaloes belonging to a herd which, within the meaning of Directive 64/432/EEC, is officially free of tuberculosis; or

(ii) females of other species belonging, for species susceptible to tuberculosis, to herds regularly checked for this disease under a control plan that the competent authority has approved.

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[*] Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ 121, 29.7.1964, p. 1977/64). Directive as last amended by the 2003 Act of Accession.

[†] Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals (OJ L 46, 19.2.1991, p. 19). Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p.1).

(c) If goats are kept together with cows, such goats must be inspected and tested for tuberculosis.

3. However, raw milk from animals that do not meet the requirements of point 2 may be used with the authorisation of the competent authority:

(a) in the case of cows or buffaloes that do not show a positive reaction to tests for tuberculosis or brucellosis, nor any symptoms of these diseases, after having undergone a heat treatment such as to show a negative reaction to the phosphatase test;

(b) in the case of sheep or goats that do not show a positive reaction to tests for brucellosis, or which have been vaccinated against brucellosis as part of an approved eradication programme, and which do not show any symptom of that disease, either:

(i) for the manufacture of cheese with a maturation period of at least two months; or

(ii) after having undergone heat treatment such as to show a negative reaction to the phosphatase test; and

(c) in the case of females of other species that do not show a positive reaction to tests for tuberculosis or brucellosis, nor any symptoms of these diseases, but belong to a herd where brucellosis or tuberculosis has been detected after the checks referred to in point 2(a)(iii) or 2(b)(ii), if treated to ensure its safety.

4. Raw milk from any animal not complying with the requirements of points 1 to 3 – in particular, any animal showing individually a positive reaction to the prophylactic tests vis-à-vis tuberculosis or brucellosis as laid down in Directive 64/432/EEC and Directive 91/68/EEC – must not be used for human consumption.

5. The isolation of animals that are infected, or suspected of being infected, with any of the diseases referred to in point 1 or 2 must be effective to avoid any adverse effect on other animals' milk.

II. HYGIENE ON MILK PRODUCTION HOLDINGS

A. Requirements for premises and equipment

1. Milking equipment, and premises where milk is stored, handled or cooled must be located and constructed so as to limit the risk of contamination of milk.

2. Premises for the storage of milk must be protected against vermin, have adequate separation from premises where animals are housed and, where necessary to meet the requirements laid down in Part B, have suitable refrigeration equipment.

3. Surfaces of equipment that are intended to come into contact with milk (utensils, containers, tanks, etc. intended for milking, collection or transport) must be easy to clean and, where necessary, disinfect and be maintained in a sound condition. This requires the use of smooth, washable and non-toxic materials.

4. After use, such surfaces must be cleaned and, where necessary, disinfected. After each journey, or after each series of journeys when the period of time between unloading and the following loading is very short, but in all cases at least once a day, containers and tanks used for the transport of raw milk must be cleaned and disinfected in an appropriate manner before re-use.

B. Hygiene during milking, collection and transport

1. Milking must be carried out hygienically, ensuring in particular:

(a) that, before milking starts, the teats, udder and adjacent parts are clean;

(b) that milk from each animal is checked for organoleptic or physico-chemical abnormalities by the milker or a method achieving similar results and that milk presenting such abnormalities is not used for human consumption;

(c) that milk from animals showing clinical signs of udder disease is not used for human consumption otherwise than in accordance with the instructions of a veterinarian;

(d) the identification of animals undergoing medical treatment likely to transfer residues to the milk, and that milk obtained from such animals before the end of the prescribed withdrawal period is not used for human consumption; and

(e) that teat dips or sprays are used only if the competent authority has approved them and in a manner that does not produce unacceptable residue levels in the milk.

2. Immediately after milking, milk must be held in a clean place designed and equipped to avoid contamination. It must be cooled immediately to not more than 8 °C in the case of daily collection, or not more than 6 °C if collection is not daily.

3. During transport the cold chain must be maintained and, on arrival at the establishment of destination, the temperature of the milk must not be more than 10ºC.

4. Food business operators need not comply with the temperature requirements laid down in points 2 and 3 if the milk meets the criteria provided for in Part III and either:

(a) the milk is processed within 2 hours of milking; or

(b) a higher temperature is necessary for technological reasons related to the manufacture of certain dairy products and the competent authority so authorises.

C. Staff hygiene

1. Persons performing milking and/or handling raw milk must wear suitable clean clothes.

2. Persons performing milking must maintain a high degree of personal cleanliness. Suitable facilities must be available near the place of milking to enable persons performing milking and handling raw milk to wash their hands and arms.

III. CRITERIA FOR RAW MILK

1. The following criteria for raw milk apply pending the establishment of standards in the context of more specific legislation on the quality of milk and dairy products.

2. A representative number of samples of raw milk collected from milk production holdings taken by random sampling must be checked for compliance with points 3 and 4.

The checks may be carried out by, or on behalf of:

(a) the food business operator producing the milk;

(b) the food business operator collecting or processing the milk;

(c) a group of food business operators; or

(d) in the context of a national or regional control scheme.

3. (a) Food business operators must initiate procedures to ensure that raw milk meets the following criteria:

(i) for raw cows' milk:

Plate count at 30 °C (per ml)	≤ 100 000 (*)
Somatic cell count (per ml)	≤ 400 000 (**)

(ii) for raw milk from other species:

Plate count at 30 °C (per ml)	≤ 1 500 000 (*)

(b) However, if raw milk from species other than cows is intended for the manufacture of products made with raw milk by a process that does not involve any heat treatment, food business operators must take steps to ensure that the raw milk used meets the following criterion.

Plate count at 30 °C (per ml)	≤ 500 000 (*)

(*) Rolling geometric average over a two-month period, with at least two samples per month.

(**) Rolling geometric average over a three-month period, with at least one sample per month, unless the competent authority specifies another methodology to take account of seasonal variations in production levels.

4. Without prejudice to Directive 96/23/EC, food business operators must initiate procedures to ensure that raw milk is not placed on the market if either:

   (a) it contains antibiotic residues in a quantity that, in respect of any one of the substances referred to in Annexes I and III to Regulation (EEC) No 2377/90 [*], exceeds the levels authorised under that Regulation; or

   (b) the combined total of residues of antibiotic substances exceeds any maximum permitted value.

5. When raw milk fails to comply with point 3 or 4, the food business operator must inform the competent authority and take measures to correct the situation.

CHAPTER II: REQUIREMENTS CONCERNING DAIRY PRODUCTS

I. TEMPERATURE REQUIREMENTS

1. Food business operators must ensure that, upon acceptance at a processing establishment, milk is quickly cooled to not more than 6 °C and kept at that temperature until processed.

2. However, food business operators may keep milk at a higher temperature if:

   (a) processing begins immediately after milking, or within 4 hours of acceptance at the processing establishment; or

[*] Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ L 224, 18.8.1990, p. 1). Regulation as last amended by Commission Regulation (EC) No 324/2004 (OJ L 58, 26.2.2004, p. 16).

(b) the competent authority authorises a higher temperature for technological reasons concerning the manufacture of certain dairy products.

II. REQUIREMENTS FOR HEAT TREATMENT

1. When raw milk or dairy products undergo heat treatment, food business operators must ensure that this satisfies the requirements of Regulation (EC) No …/2004 *, Annex II, Chapter XI.

2. When considering whether to subject raw milk to heat treatment, food business operators must:

(a) have regard to the procedures developed in accordance with the HACCP principles pursuant to Regulation (EC) No ..../2004 *; and

(b) comply with any requirements that the competent authority may impose in this regard when approving establishments or carrying out checks in accordance with Regulation (EC) No …/2004 **.

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* Official Publications Office is to insert official number of Regulation on the hygiene of foodstuffs.

** Official Publications Office is to insert official number of Regulation on the organisation of official controls.

III. CRITERIA FOR RAW COWS' MILK

1. Food business operators manufacturing dairy products must initiate procedures to ensure that, immediately before processing:

   (a) raw cows' milk used to prepare dairy products has a plate count at 30ºC of less than 300 000 per ml; and

   (b) processed cows' milk used to prepare dairy products has a plate count at 30ºC of less than 100 000 per ml.

2. When milk fails to meet the criteria laid down in paragraph 1, the food business operator must inform the competent authority and take measures to correct the situation.

CHAPTER III: WRAPPING AND PACKAGING

Sealing of consumer packages must be carried out immediately after filling in the establishment where the last heat treatment of liquid dairy products takes place, by means of sealing devices that prevent contamination. The sealing system must be designed in such a way that, after opening, the evidence of its opening remains clear and easy to check.

CHAPTER IV: LABELLING

1. In addition to the requirements of Directive 2000/13/EC, except in the cases envisaged in Article 13(4) and (5) of that Directive, labelling must clearly show:

   (a) in the case of raw milk intended for direct human consumption, the words "raw milk";

   (b) in the case of products made with raw milk, the manufacturing process for which does not include any heat treatment or any physical or chemical treatment, the words "made with raw milk".

2. The requirements of paragraph 1 apply to products destined for retail trade. The term "labelling" includes any packaging, document, notice, label, ring or collar accompanying or referring to such products.

CHAPTER V: IDENTIFICATION MARKING

By way of derogation from the requirements of Annex II, Section I:

1. rather than indicating the approval number of the establishment, the identification mark may include a reference to where on the wrapping or packaging the approval number of the establishment is indicated;

2. in the case of the reusable bottles, the identification mark may indicate only the initials of the consigning country and the approval number of the establishment.

SECTION X: EGGS AND EGG PRODUCTS

CHAPTER I: EGGS

1. At the producer's premises, and until sale to the consumer, eggs must be kept clean, dry, free of extraneous odour, effectively protected from shocks and out of direct sunshine.

2. Eggs must be stored and transported at a temperature, preferably constant, that is best suited to assure optimal conservation of their hygiene properties.

3. Eggs must be delivered to the consumer within a maximum time limit of 21 days of laying.

CHAPTER II: EGG PRODUCTS

I. REQUIREMENTS FOR ESTABLISHMENTS

Food business operators must ensure that establishments for the manufacture of egg products are constructed, laid out and equipped so as to ensure separation of the following operations:

1) washing, drying and disinfecting dirty eggs, where carried out;

2) breaking eggs, collecting their contents and removing parts of shells and membranes; and

3) operations other than those referred to in points 1 and 2.

II. RAW MATERIALS FOR THE MANUFACTURE OF EGG PRODUCTS

Food business operators must ensure that raw materials used to manufacture egg products comply with the following requirements.

1. The shells of eggs used in the manufacture of egg products must be fully developed and contain no breaks. However, cracked eggs may be used for the manufacture of egg products if the establishment of production or a packing centre delivers them directly to a processing establishment, where they must be broken as soon as possible.

2. Liquid egg obtained in an establishment approved for that purpose may be used as raw material. Liquid egg must be obtained in accordance with the requirements of points 1, 2, 3, 4 and 7 of Part III.

III. SPECIAL HYGIENE REQUIREMENTS FOR THE MANUFACTURE OF EGG PRODUCTS

Food business operators must ensure that all operations are carried out in such a way as to avoid any contamination during production, handling and storage of egg products, in particular by ensuring compliance with the following requirements.

1. Eggs must not be broken unless they are clean and dry.

2. Eggs must be broken in a manner that minimises contamination, in particular by ensuring adequate separation from other operations. Cracked eggs must be processed as soon as possible.

3. Eggs other than those of hens, turkeys or guinea fowl must be handled and processed separately. All equipment must be cleaned and disinfected before processing of hens', turkeys' and guinea fowls' eggs is resumed.

4. Egg contents may not be obtained by the centrifuging or crushing of eggs, nor may centrifuging be used to obtain the remains of egg whites from empty shells for human consumption.

5. After breaking, each particle of the egg product must undergo processing as quickly as possible to eliminate microbiological hazards or to reduce them to an acceptable level.
A batch that has been insufficiently processed may immediately undergo processing again in the same establishment, if this processing renders it fit for human consumption. When a batch is found to be unfit for human consumption, it must be denatured so as to ensure that it is not used for human consumption.

6. Processing is not required for egg white intended for the manufacture of dried or crystallised albumin destined subsequently to undergo heat treatment.

7. If processing is not carried out immediately after breaking, liquid egg must be stored either frozen or at a temperature of not more than 4 °C. The storage period before processing at 4 °C must not exceed 48 hours. However, these requirements do not apply to products to be de-sugared, if de-sugaring process is performed as soon as possible.

8. Products that have not been stabilised so as to be kept at room temperature must be cooled to not more than 4 °C. Products for freezing must be frozen immediately after processing.

IV. ANALYTICAL SPECIFICATIONS

1. The concentration of 3-OH-butyric acid must not exceed 10 mg/kg in the dry matter of the unmodified egg product.

2. The lactic acid content of raw material used to manufacture egg products must not exceed 1 g/kg of dry matter. However, for fermented products, this value must be the one recorded before the fermentation process.

3. The quantity of eggshell remains, egg membranes and any other particles in the processed egg product must not exceed 100 mg/kg of egg product.

V. LABELLING AND IDENTIFICATION MARKING

1. In addition to the general requirements for identification marking laid down in Annex II, Section I, consignments of egg products, destined not for retail but for use as an ingredient in the manufacture of another product, must have a label giving the temperature at which the egg products must be maintained and the period during which conservation may thus be assured.

2. In the case of liquid eggs, the label referred to in paragraph 1 must also bear the words: "non-pasteurised egg products - to be treated at place of destination" and indicate the date and hour of breaking.

SECTION XI: FROGS' LEGS AND SNAILS

Food business operators preparing frogs' legs or snails for human consumption must ensure compliance with the following requirements.

1. Frogs and snails must be killed in an establishment constructed, laid out and equipped for that purpose.

2. Establishment in which frogs' legs are prepared must have a room reserved for the storage and washing of live frogs, and for their slaughter and bleeding. This room must be physically separate from the preparation room.

3. Frogs and snails that die otherwise than by being killed in the establishment must not be prepared for human consumption.

4. Frogs and snails must be subjected to an organoleptic examination carried out by sampling. If that examination indicates that they might present a hazard, they must not be used for human consumption.

5. Immediately following preparation, frogs' legs must be washed fully with running potable water and immediately chilled to a temperature approaching that of melting ice, frozen or processed.

6. After killing, snails' hepato-pancreas must, if it might present a hazard, be removed and not be used for human consumption.

SECTION XII: RENDERED ANIMAL FATS AND GREAVES

CHAPTER I: REQUIREMENTS APPLICABLE TO ESTABLISHMENTS COLLECTING OR PROCESSING RAW MATERIALS

Food business operators must ensure that establishments collecting or processing raw materials for the production of rendered animal fats and greaves comply with the following requirements.

1. Centres for the collection of raw materials and further transport to processing establishments must be equipped with facilities for the storage of raw materials at a temperature of not more than 7°C.

2. Each processing establishment must have:

    (a) refrigeration facilities;

(b) a dispatch room, unless the establishment dispatches rendered animal fat only in tankers; and

(c) if appropriate, suitable equipment for the preparation of products consisting of rendered animal fats mixed with other foodstuffs and/or seasonings.

3. However, the refrigeration facilities required under points 1 and 2(a) are not necessary if the arrangements for the supply of raw materials ensure that they are never stored or transported without active refrigeration otherwise than as provided for in Chapter II, point 1(d).

CHAPTER II: HYGIENE REQUIREMENTS FOR THE PREPARATION OF RENDERED ANIMAL FAT AND GREAVES

Food business operators preparing rendered animal fats and greaves must ensure compliance with the following requirements.

1. Raw materials must:

(a) derive from animals which have been slaughtered in a slaughterhouse, and which have been found fit for human consumption following ante-mortem and post-mortem inspection;

(b) consist of adipose tissues or bones, which are reasonably free from blood and impurities;

(c) come from establishments registered or approved under Regulation (EC) No …/2003 * or under this Regulation; and

(d) be transported, and stored until rendering, in hygienic conditions and at an internal temperature of not more than 7 °C. However, raw materials may be stored and transported without active refrigeration if rendered within 12 hours after the day on which they were obtained.

2. During rendering the use of solvents is prohibited.

3. When the fat for refining meets the standards laid down in point 4, rendered animal fat prepared in accordance with points 1 and 2 may be refined in the same establishment or in another establishment with a view to improving its physico-chemical quality.

* Official Publications Office is to insert official number of Regulation on the hygiene of foodstuffs.

4. Rendered animal fat, depending on type, must meet the following standards:

	Ruminants			Porcine animals			Other animal fat	
	Edible tallow		Tallow for refining	Edible fat		Lard and other fat for refining	Edible	For refining
	Premier jus [(1)]	Other		Lard [(2)]	Other			
FFA (m/m% oleic acid) maximum	0.75	1.25	3.0	0.75	1.25	2.0	1.25	3.0
Peroxide maximum	4 meq/kg	4 meq/kg	6 meq/kg	4 meq/kg	4 meq/kg	6 meq/kg	4 meq/kg	10 meq/kg
Total insoluble impurities	Maximum 0.15%			Maximum 0.5%				
Odour, taste, colour	Normal							

(1) Rendered animal fat obtained by low-temperature rendering of fresh fat from the heart, caul, kidneys and mesentery of bovine animals, and fat from cutting rooms.

(2) Rendered animal fat obtained from the adipose tissues of porcine animals.

5. Greaves intended for human consumption must be stored in accordance with the following temperature requirements.

(a) When greaves are rendered at a temperature of not more than 70°C, they must be stored:

(i) at a temperature of not more than 7°C for a period not exceeding 24 hours; or

(ii) at a temperature of not more than –18°C.

(b) When greaves are rendered at a temperature of more than 70°C and have a moisture content of 10% (m/m) or more, they must be stored:

(i) at a temperature of not more than 7°C for a period not exceeding 48 hours or a time/temperature ratio giving an equivalent guarantee; or

(ii) at a temperature of not more than -18°C.

(c) When greaves are rendered at a temperature of more than 70°C and have a moisture content of less than 10% (m/m), there are no specific requirements.

SECTION XIII: TREATED STOMACHS, BLADDERS AND INTESTINES

Food business operators treating stomachs, bladders and intestines must ensure compliance with the following requirements.

1. Animal intestines, bladders and stomachs may be placed on the market only if:

(a) they derive from animals which have been slaughtered in a slaughterhouse, and which have been found fit for human consumption following ante-mortem and post-mortem inspection;

(b) they are salted, heated or dried; and

(c) after the treatment referred to in (b), effective measures are taken to prevent re-contamination.

2. Treated stomachs, bladders and intestines that cannot be kept at ambient temperature must be stored chilled using facilities intended for that purpose until their dispatch. In particular, products that are not salted or dried must be kept at a temperature of not more than 3°C.

SECTION XIV: GELATINE

1. Food business operators manufacturing gelatine must ensure compliance with the requirements of this Section.

2. For the purpose of this Section, "tanning" means the hardening of hides, using vegetable tanning agents, chromium salts or other substances such as aluminium salts, ferric salts, silicic salts, aldehydes and quinones, or other synthetic hardening agents.

CHAPTER I: REQUIREMENTS FOR RAW MATERIALS

1. For the production of gelatine intended for use in food, the following raw materials may be used:

   (a) bones;

   (b) hides and skins of farmed ruminant animals;

   (c) pig skins;

   (d) poultry skin;

(e) tendons and sinews;

(f) wild game hides and skins; and

(g) fish skin and bones.

2. The use of hides and skins is prohibited if they have undergone any tanning process, regardless of whether this process was completed.

3. Raw materials listed in point 1(a) to (e) must derive from animals which have been slaughtered in a slaughterhouse and whose carcases have been found fit for human consumption following ante-mortem and post-mortem inspection or, in the case of hides and skins from wild game, found fit for human consumption.

4. Raw materials must come from establishments registered or approved under Regulation (EC) No …/2004 * or under this Regulation.

5. Collection centres and tanneries may also supply raw material for the production of gelatine intended for human consumption if the competent authority specifically authorises them for this purpose and they fulfil the following requirements.

(a) They must have storage rooms with hard floors and smooth walls that are easy to clean and disinfect and, where appropriate, provided with refrigeration facilities.

* Official Publications Office is to insert official number of Regulation on the hygiene of foodstuffs.

(b) The storage rooms must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the raw materials.

(c) If raw material not in conformity with this Chapter is stored and/or processed in these premises, it must be segregated from raw material in conformity with this Chapter throughout the period of receipt, storage, processing and dispatch.

CHAPTER II: TRANSPORT AND STORAGE OF RAW MATERIALS

1. In place of the identification mark provided for in Annex II, Section I, a document indicating the establishment of origin and containing the information set out in the Appendix to this Annex must accompany raw materials during transport, when delivered to a collection centre or tannery and when delivered to the gelatine-processing establishment.

2. Raw materials must be transported and stored chilled or frozen unless they are processed within 24 hours after their departure. However, degreased and dried bones or ossein, salted, dried and limed hides, and hides and skins treated with alkali or acid may be transported and stored at ambient temperature.

CHAPTER III: REQUIREMENTS FOR THE MANUFACTURE OF GELATINE

1. The production process for gelatine must ensure that:

   (a) all ruminant bone material derived from animals born, reared or slaughtered in countries or regions classified as having a low incidence of BSE in accordance with Community legislation is subjected to a process which ensures that all bone material is finely crushed and degreased with hot water and treated with dilute hydrochloric acid (at minimum concentration of 4% and pH < 1.5) over a period of at least two days, followed by an alkaline treatment of saturated lime solution (pH > 12.5) for a period of at least 20 days with a sterilisation step of 138-140 °C during four seconds or by any approved equivalent process; and

   (b) other raw material is subjected to a treatment with acid or alkali, followed by one or more rinses. The pH must be adjusted subsequently. Gelatine must be extracted by heating one or several times in succession, followed by purification by means of filtration and sterilisation.

2. If a food business operator manufacturing gelatine complies with the requirements applying to gelatine intended for human consumption in respect of all the gelatine that it produces, it may produce and store gelatine not intended for human consumption in the same establishment.

CHAPTER IV: REQUIREMENTS FOR FINISHED PRODUCTS

Food business operators must ensure that gelatine complies with the residue limits set out in the following table.

Residue	Limit
As	1 ppm
Pb	5 ppm
Cd	0.5 ppm
Hg	0.15 ppm
Cr	10 ppm
Cu	30 ppm
Zn	50 ppm
SO_2 (Reith Williams)	50 ppm
H_2O_2 (European Pharmacopoeia 1986 (V_2O_2))	10 ppm

SECTION XV: COLLAGEN

1. Food business operators manufacturing collagen must ensure compliance with the requirements of this Section.

2. For the purpose of this Section, "tanning" means the hardening of hides, using vegetable tanning agents, chromium salts or other substances such as aluminium salts, ferric salts, silicic salts, aldehydes and quinones, or other synthetic hardening agents.

CHAPTER I: REQUIREMENTS FOR RAW MATERIALS

1. For the production of collagen intended for use in food, the following raw materials may be used:

   (a) hides and skins of farmed ruminant animals;

   (b) pig skins and bones;

   (c) poultry skin and bones;

   (d) tendons;

   (e) wild game hides and skins; and

   (f) fish skin and bones.

2. The use of hides and skins is prohibited if they have undergone any tanning process, regardless of whether this process was completed.

3. Raw materials listed in point 1(a) to (d) must derive from animals which have been slaughtered in a slaughterhouse and whose carcases have been found fit for human consumption following ante-and post-mortem inspection or, in the case of hides and skins from wild game, found fit for human consumption.

4. Raw materials must come from establishments registered or approved under Regulation (EC) No …/2004 * or under this Regulation.

5. Collection centres and tanneries may also supply raw material for the production of collagen intended for human consumption if the competent authority specifically authorises them for this purpose and they fulfil the following requirements.

   (a) They must have storage rooms with hard floors and smooth walls that are easy to clean and disinfect and, where appropriate, provided with refrigeration facilities.

   (b) The storage rooms must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the raw materials.

   (c) If raw material not in conformity with this Chapter is stored and/or processed in these premises, it must be segregated from raw material in conformity with this Chapter throughout the period of receipt, storage, processing and dispatch.

CHAPTER II: TRANSPORT AND STORAGE OF RAW MATERIALS

1. In place of the identification mark provided for in Annex II, Section I, a document indicating the establishment of origin and containing the information set out in the Appendix to this Annex must accompany raw materials during transport, when delivered to a collection centre or tannery and when delivered to the collagen-processing establishment.

* Official Publications Office is to insert official number of Regulation on the hygiene of foodstuffs.

2. Raw materials must be transported and stored chilled or frozen unless they are processed within 24 hours after their departure. However, degreased and dried bones or ossein, salted, dried and limed hides, and hides and skins treated with alkali or acid may be transported and stored at ambient temperature.

CHAPTER III: REQUIREMENTS FOR THE MANUFACTURE OF COLLAGEN

1. Collagen must be produced by a process that ensures that the raw material is subjected to a treatment involving washing, pH adjustment using acid or alkali followed by one or more rinses, filtration and extrusion or by an approved equivalent process.

2. After having been subjected to the process referred to in paragraph 1 above, collagen may undergo a drying process.

3. If a food business operator manufacturing collagen complies with the requirements applying to collagen intended for human consumption in respect of all the collagen that it produces, it may produce and store collagen not intended for human consumption in the same establishment.

CHAPTER IV: REQUIREMENTS FOR FINISHED PRODUCTS

Food business operators must ensure that collagen complies with the residue limits set out in the following table.

Residue	Limit
As	1 ppm
Pb	5 ppm
Cd	0,5 ppm
Hg	0,15 ppm
Cr	10 ppm
Cu	30 ppm
Zn	50 ppm
SO_2 (Reith Williams)	50 ppm
H_2O_2 (European Pharmacopoeia 1986 (V_2O_2))	10 ppm

CHAPTER V: LABELLING

Wrapping and packaging containing collagen must bear the words "collagen fit for human consumption" and indicate the date of preparation.

Appendix to ANNEX III

MODEL DOCUMENT TO ACCOMPANY RAW MATERIAL
DESTINED FOR THE PRODUCTION OF GELATINE OR COLLAGEN

I. Identification of raw material

Type of products: .....
Date of manufacture: .....
Type of packaging: .....
Number of packages: .....
Guaranteed storage period: .....
Net weight (kg): .....

II. Origin of raw material

Address(es) and registration number(s) of the approved production establishment(s): .....
.....

III. Destination of raw material

The raw material will be sent:
from: .....
(place of loading)
to: .....
(country and place of destination)

by the following means of transport: .....
Name and address of consignor: .....
Name and address of consignee: .....

Annex X

REGULATION (EC) No 854/2004 OF THE EUROPEAN PARLIAMENT

AND OF THE COUNCIL of 29 April 2004

Laying down specific rules for the organization of official controls on products of animal origin intended for human consumption.

REGULATION (EC) No 854/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004

laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(b) thereof,

Having regard to the proposal from the Commission [1],

Having regard to the Opinion of the European Economic and Social Committee [2],

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty [3],

[1] OJ C 262 E , 29.10.2002, p. 449.
[2] OJ C 95, 23.4.2003, p. 22.
[3] Opinion of the European Parliament of 5 June 2003 (not yet published in the Official Journal), Council Common Position of 27 October 2003 (OJ C 48 E, 24.2.2004, p. 82), Position of the European Parliament of 30 March 2004 (not yet published in the Official Journal) and Council Decision of 16 April 2004.

Whereas:

(1) Regulation (EC) No .../2004 of the European Parliament and of the Council [1] lays down general hygiene rules applying to all foodstuffs and Regulation (EC) No …/2004 of the European Parliament and of the Council [2] lays down specific hygiene rules for products of animal origin.

(2) Specific rules for official controls on products of animal origin are necessary to take account of specific aspects associated with such products.

(3) The scope of the specific control rules should mirror the scope of the specific hygiene rules for food business operators laid down in Regulation (EC) No …/2004 *. However, Member States should also carry out appropriate official controls to enforce national rules established in accordance with Article 1(4) of that Regulation. They may do so by extending the principles of this Regulation to such national rules.

(4) Official controls on products of animal origin should cover all aspects that are important for protecting public health and, where appropriate, animal health and animal welfare. They should be based on the most recent relevant information available and it should therefore be possible to adapt them as relevant new information becomes available.

(5) Community legislation on food safety should have a sound scientific basis. To that end, the European Food Safety Authority should be consulted whenever necessary.

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[1] Page … of this Official Journal.

[2] Page … of this Official Journal.

* Note for the Official Journal: insert number of Regulation laying down specific hygiene rules for food of animal origin (see recital 1, 2nd Regulation).

(6) The nature and intensity of the official controls should be based on an assessment of public health risks, animal health and welfare, where appropriate, the type and throughput of the processes carried out and the food business operator concerned.

(7) It is appropriate to provide for the adaptation of certain specific control rules, through the transparent procedure provided for in Regulation (EC) No …/2004 [*] and Regulation (EC) No …/2004 [**], to provide flexibility in order to accommodate the specific needs of establishments which use traditional methods, have a low throughput or are located in regions that are subject to special geographical constraints. The procedure should also allow pilot projects to take place in order to try out new approaches to hygiene controls on meat. However, such flexibility should not compromise food hygiene objectives.

(8) Official controls on the production of meat are necessary to verify that food business operators comply with hygiene rules and respect criteria and targets laid down in Community legislation. These official controls should comprise audits of food business operators' activities and inspections, including checks on food business operators' own controls.

(9) In view of their specific expertise, it is appropriate for official veterinarians to carry out audits and inspections of slaughterhouses, game handling establishments and certain cutting plants. Member States should have discretion to decide which are the most appropriate staff for audits and inspections of other types of establishments.

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[*] Note for the Official Journal: insert number of Regulation on the hygiene of foodstuffs (see recital 1, 1st Regulation).

[**] Note for the Official Journal: insert number of Regulation laying down specific hygiene rules for food of animal origin (see recital 1, 2nd Regulation).

(10) Official controls on the production of live bivalve molluscs and on fishery products are necessary to check for compliance with the criteria and targets laid down in Community legislation. Official controls on the production of live bivalve molluscs should in particular target relaying and production areas for bivalve molluscs and the end product.

(11) Official controls on the production of raw milk are necessary to check for compliance with criteria and targets laid down in Community legislation. Such official controls should in particular target milk production holdings and raw milk upon collection.

(12) The requirements of this Regulation should not apply until all parts of the new legislation on food hygiene have entered into force. It is also appropriate to provide for at least 18 months to elapse between entry into force and the application of the new rules, to allow competent authorities and the industries affected time to adapt.

(13) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1],

HAVE ADOPTED THIS REGULATION:

[1] OJ L 184, 17.7.1999, p. 23.

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

1. This Regulation lays down specific rules for the organisation of official controls on products of animal origin.

2. It shall apply only in respect of activities and persons to which Regulation (EC) No …/2004 * applies.

3. The performance of official controls pursuant to this Regulation shall be without prejudice to food business operators' primary legal responsibility for ensuring food safety, as laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council, of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety [1], and any civil or criminal liability arising from the breach of their obligations.

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* Note for the OJ: insert number of Regulation laying down specific hygiene rules for food of animal origin (see recital 1, 2nd Regulation).

[1] OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p.4).

Article 2

Definitions

1. For the purposes of this Regulation, the following definitions shall apply:

(a) "official control" means any form of control that the competent authority performs for the verification of compliance with food law, including animal health and animal welfare rules;

(b) "verification" means checking, by examination and the provision of objective evidence, whether specified requirements have been fulfilled;

(c) "competent authority" means the central authority of a Member State competent to carry out veterinary checks or any authority to which it has delegated that competence;

(d) "audit" means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives;

(e) "inspection" means the examination of establishments, of animals and food, and the processing thereof, of food businesses, and their management and production systems, including documents, finished product testing and feeding practices, and of the origin and destination of production inputs and outputs, in order to verify compliance with the legal requirements in all cases;

(f) "official veterinarian" means a veterinarian qualified, in accordance with this Regulation, to act in such a capacity and appointed by the competent authority;

(g) "approved veterinarian" means a veterinarian designated by the competent authority to carry out specific official controls on holdings on its behalf;

(h) "official auxiliary" means a person qualified, in accordance with this Regulation, to act in such a capacity, appointed by the competent authority and working under the authority and responsibility of an official veterinarian; and

(i) "health mark" means a mark indicating that, when it was applied, official controls had been carried out in accordance with this Regulation.

2. The definitions laid down in the following Regulations shall also apply as appropriate:

(a) Regulation (EC) No 178/2002;

(b) the definitions of "animal by-products", "TSEs" (transmissible spongiform encephalopathies) and "specified risk material" laid down in Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption [1];

(c) Regulation (EC) No …/2004 [*], except for the definition of "competent authority"; and

(d) Regulation (EC) No …/2004 [**].

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[1] OJ L 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 813/2003 (OJ L 117, 13.5.2003, p. 22).

[*] Note for the Official Journal: insert number of Regulation on the hygiene of foodstuffs (see recital 1, 1st Regulation).

[**] Note for the Official Journal: insert number of Regulation laying down specific hygiene rules for food of animal origin (see recital 1, 2nd Regulation).

CHAPTER II

OFFICIAL CONTROLS IN RELATION TO
COMMUNITY ESTABLISHMENTS

Article 3

Approval of establishments

1.(a) When Community legislation requires the approval of establishments, the competent authority shall make an on-site visit. It shall approve an establishment for the activities concerned only if the food business operator has demonstrated that it meets the relevant requirements of Regulations (EC) No …/2004 * and No …/2004 ** and other relevant requirements of food law.

(b) The competent authority may grant conditional approval if it appears from the on-site visit that the establishment meets all the infrastructure and equipment requirements. It shall grant full approval only if it appears from a new on-site visit carried out within three months of the granting of conditional approval that the establishment meets the other requirements referred to in (a). If clear progress has been made but the establishment still does not meet all of these requirements, the competent authority may prolong conditional approval. However, conditional approval shall not exceed a total of six months.

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* Note for the Official Journal: insert number of Regulation on the hygiene of foodstuffs (see recital 1, 1st Regulation).

** Note for the Official Journal: insert number of Regulation laying down specific hygiene rules for food of animal origin (see recital 1, 2nd Regulation).

2. In the case of factory and freezer vessels flying the flag of Member States, the maximum periods of three and six months applying to the conditional approval of other establishments may be extended, if necessary. However, conditional approval shall not exceed a total of 12 months. Inspections of such vessels shall take place as specified in Annex III.

3. The competent authority shall give each approved establishment, including those with conditional approval, an approval number, to which codes may be added to indicate the types of products of animal origin manufactured. For wholesale markets, secondary numbers indicating units or groups of units selling or manufacturing products of animal origin may be added to the approval number.

4. (a) The competent authority shall keep the approval of establishments under review when carrying out official controls in accordance with Articles 4 to 8.

(b) If the competent authority identifies serious deficiencies or has to stop production at an establishment repeatedly and the food business operator is not able to provide adequate guarantees regarding future production, the competent authority shall initiate procedures to withdraw the establishment's approval. However, the competent authority may suspend an establishment's approval if the food business operator can guarantee that it will resolve deficiencies within a reasonable time.

(c) In the case of wholesale markets, the competent authority may withdraw or suspend approval in respect of certain units or groups of units.

5. Paragraphs 1, 2 and 3 shall apply both:

(a) to establishments that begin placing products of animal origin on the market on or after the date of application of this Regulation; and

(b) to establishments already placing products of animal origin on the market but in respect of which there was previously no requirement for approval. In the latter case, the competent authority's on-site visit required under paragraph 1 shall take place as soon as possible.

Paragraph 4 shall also apply to approved establishments that placed products of animal origin on the market in accordance with Community legislation immediately prior to the application of this Regulation.

6. Member States shall maintain up-to-date lists of approved establishments, with their respective approval numbers and other relevant information, and make them available to other Member States and to the public in a manner that may be specified in accordance with the procedure referred to in Article 19(2).

Article 4

General principles for official controls in respect of all products of animal origin falling within the scope of this Regulation

1. Member States shall ensure that food business operators offer all assistance needed to ensure that official controls carried out by the competent authority can be performed effectively

They shall in particular:

– give access to all buildings, premises, installations or other infrastructures;

– make available any documentation and record required under the present regulation or considered necessary by the competent authority for judging the situation.

2. The competent authority shall carry out official controls to verify food business operators' compliance with the requirements of:

(a) Regulation (EC) No …/2004*;

* Note for the Official Journal: insert number of Regulation on the hygiene of foodstuffs (see recital 1, 1st Regulation).

(b) Regulation (EC) No …/2004 [*]; and

(c) Regulation (EC) No 1774/2002.

3. The official controls referred to in paragraph 1 shall include:

(a) audits of good hygiene practices and hazard analysis and critical control point (HACCP)-based procedures;

(b) the official controls specified in Articles 5 to 8; and

(c) any particular auditing tasks specified in the Annexes.

4. Audits of good hygiene practices shall verify that food business operators apply procedures continuously and properly concerning at least:

(a) checks on food-chain information;

(b) the design and maintenance of premises and equipment;

(c) pre-operational, operational and post-operational hygiene;

(d) personal hygiene;

(e) training in hygiene and in work procedures;

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[*] Note for the Official Journal: insert number of Regulation laying down specific hygiene rules for food of animal origin (see recital 1, 2nd Regulation).

(f) pest control;

(g) water quality;

(h) temperature control; and

(i) controls on food entering and leaving the establishment and any accompanying documentation.

5. Audits of HACCP-based procedures shall verify that food business operators apply such procedures continuously and properly, having particular regard to ensuring that the procedures provide the guarantees specified in Section II of Annex II to Regulation (EC) No …/2004 [*]. They shall, in particular, determine whether the procedures guarantee, to the extent possible, that products of animal origin:

(a) comply with microbiological criteria laid down under Community legislation;

(b) comply with Community legislation on residues, contaminants and prohibited substances; and

(c) do not contain physical hazards, such as foreign bodies.

When, in accordance with Article 5 of Regulation (EC) No …/2004 [**], a food business operator uses procedures set out in guides to the application of HACCP principles rather than establishing its own specific procedures, the audit shall cover the correct use of these guides.

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[*] Note for the Official Journal: insert number of Regulation laying down specific hygiene rules for food of animal origin (see recital 1, 2nd Regulation).

[**] Note for the Official Journal: insert number of Regulation on the hygiene of foodstuffs (see recital 1, 1st Regulation).

6. Verification of compliance with the requirements of Regulation (EC) No …/2004 * concerning the application of identification marks shall take place in all establishments approved in accordance with that Regulation, in addition to verification of compliance with other traceability requirements.

7. In the case of slaughterhouses, game handling establishments and cutting plants placing fresh meat on the market, an official veterinarian shall carry out the auditing tasks referred to in paragraphs 3 and 4.

8. When carrying out auditing tasks, the competent authority shall take special care:

(a) to determine whether staff and staff activities in the establishment at all stages of the production process comply with the relevant requirements of the Regulations referred to in paragraph 1(a) and (b). To support the audit, the competent authority may carry out performance tests, in order to ascertain that staff performance meets specified parameters;

(b) to verify the food business operator's relevant records;

(c) to take samples for laboratory analysis whenever necessary; and

(d) to document elements taken into account and the findings of the audit.

9. The nature and intensity of auditing tasks in respect of individual establishments shall depend upon the assessed risk. To this end, the competent authority shall regularly assess:

(a) public and, where appropriate, animal health risks;

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* Note for the Official Journal: insert number of the Regulation laying down specific hygiene rules for food of animal origin (see recital 1,2nd Regulation).

(b) in the case of slaughterhouses, animal welfare aspects;

(c) the type and throughput of the processes carried out; and

(d) the food business operator's past record as regards compliance with food law.

Article 5

Fresh meat

Member States shall ensure that official controls with respect to fresh meat take place in accordance with Annex I.

(1) The official veterinarian shall carry out inspection tasks in slaughterhouses, game handling establishments and cutting plants placing fresh meat on the market in accordance with the general requirements of Section I, Chapter II, of Annex I, and with the specific requirements of Section IV, in particular as regards:

(a) food chain information;

(b) ante-mortem inspection;

(c) animal welfare;

(d) post-mortem inspection;

(e) specified risk material and other animal by-products; and

(f) laboratory testing.

(2) The health marking of carcasses of domestic ungulates, farmed game mammals other than lagomorphs, and large wild game, as well as half-carcasses, quarters and cuts produced by cutting half-carcasses into three wholesale cuts, shall be carried out in slaughterhouses and game-handling establishments in accordance with Section I, Chapter III, of Annex I. Health marks shall be applied by, or under the responsibility of, the official veterinarian when official controls have not identified any deficiencies that would make the meat unfit for human consumption.

(3) After carrying out the controls mentioned in points 1 and 2, the official veterinarian shall take appropriate measures as set out in Annex I, Section II, in particular as regards:

(a) the communication of inspection results;

(b) decisions concerning food chain information;

(c) decisions concerning live animals;

(d) decisions concerning animal welfare; and

(e) decisions concerning meat.

(4) Official auxiliaries may assist the official veterinarian with official controls carried out in accordance with Sections I and II of Annex I as specified in Section III, Chapter I. In that case, they shall work as part of an independent team.

(5) (a) Member States shall ensure that they have sufficient official staff to carry out the official controls required under Annex I with the frequency specified in Section III, Chapter II.

(b) A risk-based approach shall be followed to assess the number of official staff that need to be present on the slaughter line in any given slaughterhouse. The number of official staff involved shall be decided by the competent authority and shall be such that all the requirements of this Regulation can be met.

(6) (a) Member States may allow slaughterhouse staff to assist with official controls by carrying out certain specific tasks, under the supervision of the official veterinarian, in relation to the production of meat from poultry and lagomorphs in accordance with Annex I, Section III, Chapter III, Part A. If they do so, they shall ensure that staff carrying out such tasks:

(i) are qualified and undergo training in accordance with those provisions;

(ii) act independently from production staff; and

(iii) report any deficiency to the official veterinarian.

(b) Member States may also allow slaughterhouse staff to carry out specific sampling and testing tasks in accordance with Annex I, Section III, Chapter III, Part B.

(7) Member States shall ensure that official veterinarians and official auxiliaries are qualified and undergo training in accordance with Annex I, Section III, Chapter IV.

Article 6

Live bivalve molluscs

Member States shall ensure that the production and placing on the market of live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods undergo official controls as described in Annex II.

Article 7

Fishery products

Member States shall ensure that official controls with respect to fishery products take place in accordance with Annex III.

Article 8

Raw milk and dairy products

Member States shall ensure that official controls with respect to raw milk and dairy products take place in accordance with Annex IV.

Article 9

Action in the case of non-compliance

1. When the competent authority identifies non-compliance with the Regulations referred to in Article 4(2)(a) and (b), it shall take action to ensure that the food business operator remedies the situation. When deciding which action to take, the competent authority shall take account of the nature of the non-compliance and the food business operator's past record with regard to non-compliance.

2. Such action shall include, where appropriate, the following measures:

(a) the imposition of sanitation procedures or any other corrective action deemed necessary to ensure the safety of products of animal origin or compliance with the relevant legal requirements;

(b) the restriction or prohibition of the placing on the market, import or export of products of animal origin;

(c) monitoring or, if necessary, ordering the recall, withdrawal and/or destruction of products of animal origin;

(d) authorisation to use products of animal origin for purposes other than those for which they were originally intended;

(e) the suspension of operations or closure of all or part of the food business concerned for an appropriate period of time;

(f) the suspension or withdrawal of the establishment's approval;

(g) in the case of consignments from third countries, seizure followed by destruction or re-dispatch;

(h) any other measure that the competent authority deems appropriate.

3. The competent authority shall provide the food business operator concerned, or a representative, with:

(a) written notification of its decision concerning the action to be taken in accordance with paragraph 1, together with the reasons for the decision; and

(b) information on rights of appeal against such decisions and of the applicable procedure and time limits.

Where appropriate, the competent authority shall also notify the competent authority of the Member State of dispatch of its decision.

CHAPTER III

PROCEDURES CONCERNING IMPORTS

Article 10

General principles and conditions

To ensure the uniform application of the principles and conditions laid down in Article 11 of Regulation (EC) No 178/2002 the procedures laid down in this Chapter shall apply.

Article 11

Lists of third countries and parts of third countries from which imports of specified products of animal origin are permitted

1. Products of animal origin shall be imported only from a third country or a part of third country that appears on a list drawn up and updated in accordance with the procedure referred to in Article 19(2).

2. A third country shall appear on such lists only if a Community control in that country has taken place and demonstrates that the competent authority provides appropriate guarantees as specified in paragraph 4. However, a third country may appear on such lists without a Community control having taken place there if:

(a) the risk determined in accordance with Article 18, point 18 does not warrant it; and

(b) it is determined, when deciding to add a particular third country to a list in accordance with paragraph 1, that other information indicates that the competent authority provides the necessary guarantees.

3. Lists drawn up in accordance with this Article may be combined with other lists drawn up for public and animal health purposes.

4. When lists are drawn up or updated, particular account shall be taken of the following criteria:

(a) the legislation of the third country on:

(i) products of animal origin,

(ii) the use of veterinary medicinal products, including rules on their prohibition or authorisation, their distribution, their placing on the market and the rules covering administration and inspection, and

(iii) the preparation and use of feedingstuffs, including the procedures for using additives and the preparation and use of medicated feedingstuffs, as well as the hygiene quality of the raw materials used for preparing feedingstuffs and of the final product;

(b) the organisation of the third countries' competent authorities, their powers and independence, the supervision to which they are subject and the authority that they have effectively to enforce the applicable legislation;

(c) the training of staff in the performance of official controls;

(d) the resources, including diagnostic facilities available to competent authorities;

(e) the existence and operation of documented control procedures and control systems based on priorities;

(f) where applicable, the situation regarding animal health and procedures for notifying the Commission and relevant international bodies of outbreaks of animal diseases;

(g) the extent and operation of official controls on imports of animals and products of animal origin;

(h) the assurances which the third country can give regarding compliance with, or equivalence to, Community requirements;

(i) the hygiene conditions of production, manufacture, handling, storage and dispatch actually applied to products of animal origin destined for the Community;

(j) any experience of marketing of the product from the third country and the results of any import controls carried out;

(k) the results of Community controls carried out in the third country, in particular the results of the assessment of the competent authorities, and the action that competent authorities have taken in the light of any recommendations addressed to them following a Community control;

(l) the existence, implementation and communication of an approved zoonoses control programme; and

(m) the existence, implementation and communication of an approved residue control programme.

5. The Commission shall arrange for up-to-date versions of all lists drawn up or updated in accordance with this Article to be available to the public.

Article 12

List of establishments from which imports of specified products of animal origin are permitted

1. Products of animal origin may be imported into the Community only if they have been dispatched from, and obtained or prepared in, establishments that appear on lists drawn up and updated in accordance with this Article, except:

(a) when, on a case-by-case basis, it is decided, in accordance with the procedure referred to in Article 19(2), that the guarantees that a specified third country provides in respect of imports of specified products of animal origin are such that the procedure provided for in this Article is unnecessary to ensure compliance with the requirements of paragraph 2; and

(b) in the cases specified in Annex V.

In addition, fresh meat, minced meat, meat preparations, meat products and mechanically separated meat (MSM) may be imported into the Community only if they have been manufactured from meat obtained in slaughterhouses and cutting plants appearing on lists drawn up and updated in accordance with this Article or in approved Community establishments.

2. An establishment may be placed on such a list only if the competent authority of the third country of origin guarantees that:

(a) that establishment, together with any establishments handling raw material of animal origin used in the manufacture of the products of animal origin concerned, complies with relevant Community requirements, in particular those of Regulation (EC) No …/2004 *, or with requirements that were determined to be equivalent to such requirements when deciding to add that third country to the relevant list in accordance with Article 11;

(b) an official inspection service in that third country supervises the establishments and makes available to the Commission, where necessary, all relevant information on establishments furnishing raw materials; and

(c) it has real powers to stop the establishments from exporting to the Community in the event that the establishments fail to meet the requirements referred to under (a).

3. The competent authorities of third countries appearing on lists drawn up and updated in accordance with Article 11 shall guarantee that lists of the establishments referred to in paragraph 1 are drawn up, kept up-to-date and communicated to the Commission.

4. (a) The Commission shall provide the contact points that Member States have designated for this purpose with regular notifications concerning new or updated lists that it has received from the competent authorities of third countries concerned in accordance with paragraph 3.

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* Note for the OJ: insert number of Regulation laying down specific hygiene rules for food of animal origin (see recital 1, 2nd Regulation).

(b) If no Member State objects to the new or updated list within 20 working days of the Commission's notification, imports shall be authorised from establishments appearing on the list 10 working days after the day on which the Commission makes it available to the public.

(c) The Commission shall, whenever at least one Member State makes written comments, or whenever it considers that the modification of a list is necessary in the light of relevant information such as Community inspection reports or a notification under the rapid alert system, inform all Member States and include the point on agenda of the next meeting of the relevant section of the Standing Committee on the Food Chain and Animal Health for decision, where appropriate, in accordance with the procedure referred to in Article 19(2).

5. The Commission shall arrange for up-to-date versions of all lists to be available to the public.

Article 13

Live bivalve molluscs, echinoderms, tunicates and marine gastropods

1. Notwithstanding Article 12(1)(b), live bivalve molluscs, echinoderms, tunicates and marine gastropods shall come from production areas in third countries that appear on lists drawn up and updated in accordance with Article 12.

2. The requirement of paragraph 1 shall not apply to pectinidae harvested outside classified production areas. However, official controls with respect to pectinidae shall take place in accordance with Annex II, Chapter III.

3. (a) Before the lists referred to in paragraph 1 are drawn up, particular account shall be taken of the guarantees that the competent authority of the third country can give concerning compliance with the requirements of this Regulation on the classification and control of production zones.

(b) A Community inspection visit on-the-spot shall take place before such lists are drawn up unless:

(i) the risk determined in accordance with Article 18, point 18 does not warrant it; and

(ii) it is determined, when deciding to add a particular production area to a list in accordance with paragraph 1, that other information indicates that the competent authority provides the necessary guarantees.

4. The Commission shall arrange for up-to-date versions of all lists drawn up or updated in accordance with this Article to be available to the public.

Article 14

Documents

1. A document meeting the requirements set out in Annex VI shall accompany consignments of products of animal origin when they are imported into the Community.

2. The document shall certify that the products satisfy:

(a) the requirements laid down for such products under Regulation (EC) No …/2004 * and Regulation (EC) No …/2004 ** or provisions that are equivalent to those requirements; and

(b) any special import conditions established in accordance with Article 18, point 19.

3. Documents may include details required in accordance with other Community legislation on public and animal health matters.

4. Exemptions from paragraph 1 may be granted in accordance with the procedure referred to in Article 19(2) when it is possible to obtain the guarantees referred to in paragraph 2 of this Article in another manner.

Article 15

Special provisions for fishery products

1. The procedures laid down in this Chapter do not apply to fresh fishery products landed in the Community directly from a fishing vessel flying the flag of a third country.

Official controls with respect to such fishery products shall take place in accordance with Annex III.

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* Note for the OJ: insert number of Regulation on the hygiene of foodstuffs (see recital 1, 1st Regulation).

** Note for the OJ: insert number of Regulation laying down specific hygiene rules for food of animal origin (see recital 1, 2nd Regulation).

2. (a) Fishery products imported from a factory or freezer vessel flying the flag of a third country shall come from vessels that appear on a list drawn up and updated in accordance with the procedure set out in Article 12(4).

(b) However, by way of exemption from Article 12(2)(b), a vessel may also be included on such lists:

(i) on the basis of a joint communication from the competent authority of the third country the flag of which the vessel is flying and from the competent authority of another third country to which the former competent authority has delegated responsibility for the inspection of the vessel concerned, on condition that:

– that third country appears on the list of third countries, drawn up in accordance with Article 11, from which imports of fisheries products are permitted,

– all fishery products from the vessel concerned that are destined for placing on the market in the Community are landed directly in that third country,

– the competent authority of that third country has inspected the vessel and has declared that it complies with Community requirements, and

– the competent authority of that third country has declared that it will regularly inspect the vessel to ensure that it continues to comply with Community requirements;

or

(ii) on the basis of a joint communication from the competent authority of the third country the flag of which the vessel is flying and from the competent authority of a Member State, to which the former competent authority has delegated responsibility for the inspection of the vessel concerned, on condition that:

– all fishery products from the vessel concerned that are destined for placing on the market in the Community are landed directly in that Member State,

– the competent authority of that Member State has inspected the vessel and has declared that it complies with Community requirements, and

– the competent authority of that Member State has declared that it will regularly inspect the vessel to ensure that it continues to comply with Community requirements.

(c) The Commission shall arrange for up-to-date versions of all lists drawn up or updated in accordance with this Article to be available to the public.

3. When fishery products are imported directly from a fishing or freezer vessel, a document signed by the captain may replace the document required under Article 14.

4. Detailed rules for the implementation of this Article may be laid down in accordance with the procedure referred to in Article 19(2).

CHAPTER IV

FINAL PROVISIONS

Article 16

Implementing measures and transitional measures

Implementing measures and transitional arrangements may be laid down in accordance with the procedure referred to in Article 19(2).

Article 17

Amendment and adaptation of the Annexes

1. Annexes I, II, III, IV, V and VI may be amended or supplemented to take account of scientific and technical progress in accordance with the procedure referred to in Article 19(2).

2. Exemptions from Annexes I, II, III, IV, V and VI may be granted in accordance with the procedure referred to in Article 19(2), provided that they do not affect the achievement of the objectives of this Regulation.

3. Member States may, without compromising achievement of the objectives of this Regulation, adopt, in accordance with paragraphs 4 to 7, national measures adapting the requirements laid down in Annex I.

4. The national measures referred to in paragraph 3 shall:

(a) have the aim of:

(i) enabling the continued use of traditional methods at any of the stages of production, processing or distribution of food;

(ii) accommodating the needs of food businesses with a low throughput or that are situated in regions that are subject to special geographic constraints; or

(iii) permitting pilot projects to take place in order to try out new approaches to hygiene controls on meat;

(b) concern in particular the following elements of Annex I:

(i) food chain information;

(ii) the presence of the competent authority in establishments.

5. Any Member State wishing to adopt national measures as referred to in paragraph 3 shall notify the Commission and other Member States. Each notification shall:

(a) provide a detailed description of the requirements that that Member State considers need to be adapted and the nature of the adaptation sought;

(b) describe the establishments concerned;

(c) explain the reasons for the adaptation, including, where relevant, by providing a summary of the hazard analysis carried out and any measures to be taken to ensure that the adaptation will not compromise the objectives of this Regulation; and

(d) give any other relevant information.

6. The other Member States shall have three months from the receipt of a notification referred to in paragraph 5 to send written comments to the Commission. The Commission may, and when it receives written comments from one or more Member States shall, consult Member States within the committee referred to in Article 19(1). The Commission may decide, in accordance with the procedure referred to in Article 19(2), whether the envisaged measures may be implemented subject, if necessary, to appropriate amendments. Where appropriate, the Commission may propose general measures in accordance with paragraphs 1 or 2 of this Article.

7. A Member State may adopt national measures adapting the requirements of Annex I only:

(a) in compliance with a decision adopted in accordance with paragraph 6;

(b) if, one month after the expiry of the period referred to in paragraph 6, the Commission has not informed Member States that it has received written comments or that it intends to propose the adoption of a decision in accordance with paragraph 6.

8. When a Member State adopts national measures implementing a pilot project to try out new approaches to hygiene controls on meat in accordance with paragraphs 3 to 7, the Member State shall communicate the results to the Commission as soon as they are available. The Commission shall then consider proposing general measures in accordance with paragraph 1.

Article 18

Specific decisions

Without prejudice to the generality of Article 16 and Article 17(1), implementing measures may be laid down, or amendments to Annexes I, II, III, IV, V or VI adopted, in accordance with the procedure referred to in Article 19(2), to specify:

1) tests to assess the performance of food business operators and their staff;

2) the method of communicating inspection results;

3) criteria to determine when, on the basis of a risk analysis, the official veterinarian need not be present in slaughterhouses and game handling establishments throughout ante-mortem and post-mortem inspection;

4) rules concerning the content of tests for official veterinarians and official auxiliaries;

5) microbiological criteria for process control in relation to hygiene in establishments;

6) alternative procedures, serological or other laboratory tests that provide guarantees at least equivalent to specific post-mortem inspection procedures described in Annex I, Section IV, and may therefore replace them, if the competent authority so decides;

7) circumstances in which certain of the specific post-mortem inspection procedures described in Annex I, Section IV, are not necessary, having regard to the holding, region or country of origin and to the principles of risk analysis,

8) rules for laboratory testing;

9) the cold treatment to be applied to meat in relation to cysticercosis and trichinosis;

10) conditions under which holdings and regions can be certified as officially free of cysticercus or trichinae;

11) methods to be applied when examining for the conditions referred to in Annex I, Section IV, Chapter IX;

12) for fattening pigs, criteria for controlled housing conditions and integrated production systems;

13) criteria for the classification of production and relaying areas for live bivalve molluscs in cooperation with the relevant Community Reference Laboratory, including:

   (a) limit values and analysis methods for marine biotoxins,

   (b) virus testing procedures and virological standards, and

   (c) sampling plans and the methods and analytical tolerances to be applied to check compliance with the criteria;

14) organoleptic criteria for the evaluation of the freshness of fishery products;

15) analytical limits, methods of analysis and sampling plans for the official controls on fishery products required under Annex III, including with regard to parasites and environmental contaminants;

16) the method by which the Commission will make lists of third countries and establishments in third countries available to the public pursuant to Articles 11, 12, 13 and 15;

17) models for documents and criteria for the use of electronic documents;

18) criteria for determining the risk that particular products of animal origin imported into the Community present;

19) special import conditions for particular products of animal origin, taking account of the associated risks, information that relevant third countries have provided and, where necessary, the results of Community controls carried out in such third countries. These special import conditions may be established for a single product of animal origin or for group of products. They may apply to a single third country, to regions of a third country, or to a group of third countries; and

20) the conditions governing imports of products of animal origin from a third country or a region of a third country pursuant to the implementation of an equivalence agreement, or to a satisfactory audit, recognising that measures applied in that third country or region offer guarantees equivalent to those applied in the Community, if the third country supplies objective proof in this respect.

Article 19

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Article 58 of Regulation (EC) No 178/2002.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

Article 20

Consultation of the European Food Safety Authority

The Commission shall consult the European Food Safety Authority on matters falling within the scope of this Regulation whenever necessary and, in particular:

1) before proposing to modify the specific requirements concerning post-mortem inspection procedures laid down in Section IV of Annex I;

2) before proposing to modify the rules of Annex I, Section IV, Chapter IX, on meat from animals in which post-mortem inspection has revealed lesions indicating infection with brucellosis or tuberculosis; and

3) before proposing implementing measures on the matters referred to in Article 18, points (5) to (15).

Article 21

Report to the European Parliament and to the Council

1. The Commission shall, not later than....., [*] submit a report to the European Parliament and the Council reviewing the experience gained from the application of this Regulation.

2. The Commission shall, if appropriate, accompany the report with relevant proposals.

Article 22

Entry into force

This Regulation shall enter into force twenty days after the date of its publication in the Official Journal of the European Union.

[*] Five years after the entry into force of this Regulation.

It shall apply 18 months after the date on which all of the following acts have entered into force:

(a) Regulation (EC) No …/2004 *;

(b) Regulation (EC) No …/2004 ** and

(c) Directive 2004/…/EC of the European Parliament and of the Council of ..... repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption [1].

However, it shall apply no earlier than 1 January 2006.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 29 April 2004.

For the European Parliament	For the Council
The President	The President
P. COX	M. McDOWELL

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* Note for the Official Journal: insert number of Regulation on the hygiene of foodstuffs (see recital 1, 1st Regulation).

** Note for the Official Journal: insert number of Regulation laying down specific hygiene rules for food of animal origin (see recital 1, 2nd Regulation).

[1] See p. of this Official Journal.

ANNEX I

FRESH MEAT

SECTION I: TASKS OF THE OFFICIAL VETERINARIAN

CHAPTER I: AUDITING TASKS

1. In addition to the general requirements of Article 4(4) concerning audits of good hygiene practices, the official veterinarian is to verify continuous compliance with food business operators' own procedures concerning any collection, transport, storage, handling, processing and use or disposal of animal by-products, including specified risk material, for which the food business operator is responsible.

2. In addition to the general requirements of Article 4(5) concerning audits of HACCP-based principles, the official veterinarian is to check that the operators' procedures guarantee, to the extent possible, that meat:

   (a) does not contain patho-physiological abnormalities or changes;

   (b) does not bear faecal or other contamination; and

   (c) does not contain specified risk material, except as provided for under Community legislation, and has been produced in accordance with Community legislation on TSEs.

When carrying out inspection tasks in accordance with this Chapter, the official veterinarian is to take account of the results of the auditing tasks carried out in accordance with Article 4 and Chapter I of this Annex. Where appropriate he or she is to target inspection tasks accordingly.

A. Food chain information

1. The official veterinarian is to check and analyse relevant information from the records of the holding of provenance of animals intended for slaughter and to take account of the documented results of this check and analysis when carrying out ante- and post-mortem inspection.

2. When carrying out inspection tasks, the official veterinarian is to take account of official certificates accompanying animals, and any declarations made by veterinarians carrying out controls at the level of primary production, including official veterinarians and approved veterinarians.

3. When food business operators in the food chain take additional measures to guarantee food safety by implementing integrated systems, private control systems, independent third party certification or by other means, and when these measures are documented and animals covered by these schemes clearly identifiable, the official veterinarian may take this into account when carrying out inspection tasks and reviewing the HACCP-based procedures.

B. Ante-mortem inspection

1. Subject to paragraphs 4 and 5:

(a) the official veterinarian is to carry out an ante-mortem inspection of all animals before slaughter;

(b) that inspection must take place within 24 hours of arrival at the slaughterhouse and less than 24 hours before slaughter.

In addition, the official veterinarian may require inspection at any other time.

2. Ante-mortem inspection must in particular determine whether, as regards the particular animal inspected, there is any sign:

(a) that welfare has been compromised; or

(b) of any condition which might adversely affect human or animal health, paying particular attention to the detection of zoonotic diseases and diseases on List A or, where appropriate, List B of the Office International des Epizooties (World organisation for animal health, OIE).

3. In addition to routine ante-mortem inspection, the official veterinarian is to carry out a clinical inspection of all animals that the food business operator or an official auxiliary may have put aside.

4. In the case of emergency slaughter outside the slaughterhouse and of hunted wild game, the official veterinarian at the slaughterhouse or game handling establishment is to examine the declaration accompanying the body of the animal issued by the veterinarian or the trained person in accordance with Regulation (EC) No …/2004 [*].

5. Where provided for in Section III, Chapter II, or in Section IV, ante-mortem inspection may be carried out at the holding of provenance. In such cases, the official veterinarian at the slaughterhouse need carry out ante-mortem inspection only when and to the extent specified.

C. Animal welfare

The official veterinarian is to verify compliance with relevant Community and national rules on animal welfare, such as rules concerning the protection of animals at the time of slaughter and during transport.

D. Post-mortem inspection

1. Carcases and accompanying offal are to be subjected without delay after slaughter to post-mortem inspection. All external surfaces are to be viewed. Minimal handling of the carcase and offal or special technical facilities may be required for that purpose. Particular attention is to be paid to the detection of zoonotic diseases and diseases on OIE List A and, where appropriate, OIE List B. The speed of the slaughter line and the number of inspection staff present are to be such as to allow for proper inspection.

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[*] Note for Official Journal: Insert No of Regulation laying down specific hygiene rules for food of animal origin (see recital 1, 2nd Regulation).

2. Additional examinations are to take place, such as palpation and incision of parts of the carcase and offal and laboratory tests, whenever considered necessary:

(a) to reach a definitive diagnosis; or

(b) to detect the presence of:

(i) an animal disease,
(ii) residues or contaminants in excess of the levels laid down under Community legislation,
(iii) non-compliance with microbiological criteria, or
(iv) other factors that might require the meat to be declared unfit for human consumption or restrictions to be placed on its use,

particularly in the case of animals having undergone emergency slaughter.

3. The official veterinarian is to require carcases of domestic solipeds, bovine animals over six months old, and domestic swine over four weeks old to be submitted for post-mortem inspection split lengthways into half carcases down the spinal column. If the inspection so necessitates, the official veterinarian may also require any head or any carcase to be split lengthways. However, to take account of particular eating habits, technological developments or specific sanitary situations, the competent authority may authorise the submission for inspection of carcases of domestic solipeds, bovine animals over six months old, and domestic swine over four weeks old, not split in half.

4. During the inspection, precautions must be taken to ensure that contamination of the meat by actions such as palpation, cutting or incision is kept to a minimum.

5. In the event of an emergency slaughter, the carcass shall be subjected to post-mortem examination as soon as possible in accordance with paragraphs 1 to 4 before it is released for human consumption.

E. Specified risk material and other animal by-products

In accordance with specific Community rules on specified risk material and other animal by-products, the official veterinarian is to check the removal, separation and, where appropriate, marking of such products. The official veterinarian is to ensure that the food business operator takes all necessary measures to avoid contaminating meat with specified risk material during slaughter (including stunning) and removal of specified risk material.

F. Laboratory testing

1. The official veterinarian is to ensure that sampling takes place and that samples are appropriately identified and handled and sent to the appropriate laboratory within the framework of:

(a) the monitoring and control of zoonoses and zoonotic agents;

(b) specific laboratory testing for the diagnosis of TSEs in accordance with Regulation (EC) No 999/2001 of the European Parliament and of the Council [1];

[1] OJ L 147, 31.5.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 2245/2003 (OJ L 133, 20.12.2003, p. 28).

(c) the detection of unauthorised substances or products and the control of regulated substances, in particular within the framework of the National Residue Plans referred to in Council Directive 96/23/EC [1]; and

(d) the detection of OIE List A and, where appropriate, OIE List B diseases.

2. The official veterinarian is also to ensure that any other necessary laboratory testing takes place.

CHAPTER III: HEALTH MARKING

1. The official veterinarian is to supervise health marking and the marks used.

2. The official veterinarian is to ensure, in particular, that:

(a) the health mark is applied only to animals (domestic ungulates, farmed game mammals other than lagomorphs, and large wild game) having undergone ante-mortem and post-mortem inspection in accordance with this Regulation and when there are no grounds for declaring the meat unfit for human consumption. However, the health mark may be applied before the results of any examination for trichinosis is available, if the official veterinarian is satisfied that meat from the animal concerned will be placed on the market only if the results are satisfactory; and

[2] OJ L 125, 23.5.1996, p. 10. Directive as amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

(b) health-marking takes place on the external surface of the carcase, by stamping the mark in ink or hot branding, and in such a manner that, if carcases are cut into half carcases or quarters, or half carcases are cut into three pieces, each piece bears a health mark.

3. The health mark must be an oval mark at least 6,5 cm wide by 4,5 cm high bearing the following information in perfectly legible characters:

(a) the mark must indicate name of the country in which the establishment is located, which may be written out in full in capitals or shown as a two-letter code in accordance with the relevant ISO standard.

In the case of Member States, however, these codes are AT, BE, DE, DK, ES, FI, FR, GR, IE, IT, LU, NL, PT, SE and UK;

(b) the mark must indicate the approval number of the slaughterhouse; and

(c) when applied in a slaughterhouse within the Community, the mark must include the abbreviation CE, EC, EF, EG, EK or EY.

4. Letters must be at least 0,8 cm high and figures at least 1 cm high. The dimensions and characters of the mark may be reduced for health marking of lamb, kids and piglets.

5. The colours used for health marking must be authorised in accordance with Community rules on the use of colouring substances in foodstuffs.

6. The health mark may also include an indication of the official veterinarian who carried out the health inspection of the meat. Competent authorities and food business operators may continue to use equipment that they ordered before entry into force of this Regulation until it is exhausted or requires replacement.

7. Meat from animals having undergone emergency slaughter outside the slaughterhouse must bear a special health mark, which cannot be confused either with the health mark provided for in this Chapter or with the identification mark provided for in Annex II, Section I, to Regulation (EC) No …/2004 [*].

8. Meat from unskinned wild game cannot bear a health mark unless, after skinning in a game handling establishment, it has undergone post-mortem inspection and been declared fit for human consumption.

9. This Chapter is to apply without prejudice to animal health rules on health marking.

SECTION II: ACTION FOLLOWING CONTROLS

CHAPTER I: COMMUNICATION OF INSPECTION RESULTS

1. The official veterinarian is to record and to evaluate the results of inspection activities.

2. (a) If inspections reveal the presence of any disease or condition that might affect public or animal health, or compromise animal welfare, the official veterinarian is to inform the food business operator.

[*] Note for Official Journal: Insert No of Regulation laying down specific hygiene rules for food of animal origin (see recital 1, 2nd Regulation).

(b) When the problem identified arose during primary production, the official veterinarian is to inform the veterinarian attending the holding of provenance, the food business operator responsible for the holding of provenance (provided that such information would not prejudice subsequent legal proceedings) and, where appropriate, the competent authority responsible for supervising the holding of provenance or the hunting area.

(c) If the animals concerned were raised in another Member State or in a third country, the official veterinarian is to inform to the competent authority of the Member State where the establishment is located. That competent authority is to take appropriate measures in accordance with applicable Community legislation.

3. The results of inspections and tests are to be included in relevant databases.

4. When the official veterinarian, while carrying out ante-mortem or post-mortem inspection or any other inspection activity, suspects the presence of an infectious agent mentioned on OIE List A or, where appropriate, OIE List B, the official veterinarian must immediately notify the competent authority and both must take all necessary measures and precautions to prevent the possible spread of the infectious agent in accordance with applicable Community legislation.

CHAPTER II: DECISIONS CONCERNING FOOD CHAIN INFORMATION

1. The official veterinarian is to verify that animals are not slaughtered unless the slaughterhouse operator has been provided with and checked relevant food chain information.

2. However, the official veterinarian may allow animals to undergo slaughter in the slaughterhouse even if the relevant food chain information is not available. In this case, all relevant food chain information must be supplied before the carcase is approved for human consumption. Pending a final judgement, such carcases and related offal must be stored separately from other meat.

3. Notwithstanding paragraph 2, when relevant food chain information is not available within 24 hours of an animal's arrival at the slaughterhouse, all meat from the animal is to be declared unfit for human consumption. If the animal has not yet been slaughtered, it is to be killed separately from other animals.

4. When the accompanying records, documentation or other information shows that:

(a) animals come from a holding or an area subject to a movement prohibition or other restriction for reasons of animal or public health;

(b) rules on the use of veterinary medicinal products have not been complied with; or

(c) any other condition which might adversely affect human or animal health is present, animals may not be accepted for slaughter other than in accordance with procedures laid down under Community legislation to eliminate human or animal health risks.

If the animals are already present at the slaughterhouse, they must be killed separately and declared unfit for human consumption, taking precautions to safeguard animal and public health where appropriate. Whenever the official veterinarian considers it necessary, official controls are to be carried out on the holding of provenance.

5. The competent authority is to take appropriate action if it discovers that the accompanying records, documentation or other information do not correspond with the true situation on the holding of provenance or the true condition of the animals or aim deliberately to mislead the official veterinarian. The competent authority is to take action against the food business operator responsible for the holding of provenance of the animals, or any other person involved. This action may consist in particular of extra controls. The food business operator responsible for the holding of provenance or any other person involved are to bear the costs of such extra controls.

1. The official veterinarian is to verify compliance with the food business operator's duty under Regulation (EC) No …/2004 * to ensure that animals accepted for slaughter for human consumption are properly identified. The official veterinarian is to ensure that animals whose identity is not reasonably ascertainable are killed separately and declared unfit for human consumption. Whenever the official veterinarian considers it necessary, official controls are to be carried out on the holding of provenance.

2. When there are overriding animal welfare considerations, horses may undergo slaughter at the slaughterhouse even if the legally required information concerning their identity has not been supplied. However, this information must be supplied before the carcase may be declared fit for human consumption. These requirements also apply in the case of emergency slaughter of horses outside the slaughterhouse.

3. The official veterinarian is to verify compliance with the food business operator's duty under Regulation (EC) No …/2004 * to ensure that animals that have such hide, skin or fleece conditions that there is an unacceptable risk of contamination of the meat during slaughter are not slaughtered for human consumption unless they are cleaned beforehand.

4. Animals with a disease or condition that may be transmitted to animals or humans through handling or eating meat and, in general, animals showing clinical signs of systemic disease or emaciation, are not to be slaughtered for human consumption. Such animals must be killed separately, under conditions such that other animals or carcases can not be contaminated, and declared unfit for human consumption.

* Note for Official Journal: Insert No of Regulation laying down specific hygiene rules for food of animal origin (see recital 1, 2nd Regulation).

5. The slaughter of animals suspected of having a disease or condition that may adversely affect human or animal health is to be deferred. Such animals are to undergo detailed ante-mortem examination in order to make a diagnosis. In addition, the official veterinarian may decide that sampling and laboratory examinations are to take place to supplement post-mortem inspection. If necessary, the animals are to be slaughtered separately or at the end of normal slaughtering, taking all necessary precautions to avoid contamination of other meat.

6. Animals that might contain residues of veterinary medicinal products in excess of the levels laid down in accordance with Community legislation, or residues of forbidden substances, are to be dealt with in accordance with Directive 96/23/EC.

7. The official veterinarian is to impose the conditions under which animals are to be dealt with under a specific scheme for the eradication or control of a specific disease, such as brucellosis or tuberculosis, or zoonotic agents such as salmonella, under his/her direct supervision. The competent authority is to determine the conditions under which such animals may be slaughtered. These conditions must have the aim of minimising contamination of other animals and the meat of other animals.

8. Animals that are presented to a slaughterhouse for slaughter must as a general rule be slaughtered there. However, in exceptional circumstances, such as a serious breakdown of the slaughter facilities, the official veterinarian may allow direct movements to another slaughterhouse.

CHAPTER IV: DECISIONS CONCERNING ANIMAL WELFARE

1. When the rules concerning the protection of animals at the time of slaughter or killing are not respected, the official veterinarian is to verify that the food business operator immediately takes necessary corrective measures and prevents recurrence.

2. The official veterinarian is to take a proportionate and progressive approach to enforcement action, ranging from issuing directions to slowing down and stopping production, depending on the nature and gravity of the problem.

3. Where appropriate, the official veterinarian is to inform other competent authorities of welfare problems.

4. When the official veterinarian discovers that rules concerning the protection of animals during transport are not being respected, he or she is to take necessary measures in accordance with the relevant Community legislation.

5. When:

(a) an official auxiliary is carrying out checks on animal welfare pursuant to Sections III or IV; and

(b) those checks identify non-compliance with the rules on the protection of animals,

the official auxiliary is immediately to inform the official veterinarian and, if necessary in cases of urgency, is to take the necessary measures referred to in paragraphs 1 to 4 pending the arrival of the official veterinarian.

1. Meat is to be declared unfit for human consumption if it:

(a) derives from animals that have not undergone ante-mortem inspection, except for hunted wild game;

(b) derives from animals the offal of which has not undergone post-mortem inspection, unless otherwise provided for under this Regulation or Regulation (EC) No .../2004 [*];

(c) derives from animals which are dead before slaughter, stillborn, unborn or slaughtered under the age of 7 days;

(d) results from the trimming of sticking points;

(e) derives from animals affected by an OIE List A or, where appropriate, OIE List B disease, unless otherwise provided for in Section IV;

(f) derives from animals affected by a generalised disease, such as generalised septicaemia, pyaemia, toxaemia or viraemia;

(g) is not in conformity with microbiological criteria laid down under Community legislation to determine whether food may be placed on the market;

(h) exhibits parasitic infestation, unless otherwise provided for in Section IV;

[*] Note for Official Journal: Insert No of Regulation laying down specific hygiene rules for food of animal origin (see recital 1, 2nd Regulation).

(i) contains residues or contaminants in excess of the levels laid down in Community legislation. Any overshooting of the relevant level should lead to additional analyses whenever appropriate;

(j) without prejudice to more specific Community legislation, derives from animals or carcases containing residues of forbidden substances or from animals that have been treated with forbidden substances;

(k) consists of the liver and kidneys of animals more than two years old from regions where implementation of plans approved in accordance with Article 5 of Directive 96/23/EC has revealed the generalised presence of heavy metals in the environment;

(l) has been treated illegally with decontaminating substances;

(m) has been treated illegally with ionising or UV-rays;

(n) contains foreign bodies (except, in the case of wild game, material used to hunt the animal);

(o) exceeds the maximum permitted radioactivity levels laid down under Community legislation;

(p) indicates patho-physiological changes, anomalies in consistency, insufficient bleeding (except for wild game) or organoleptic anomalies, in particular a pronounced sexual odour;

(q) derives from emaciated animals;

(r) contains specified risk material, except as provided for under Community legislation;

(s) shows soiling, faecal or other contamination;

(t) consists of blood that may constitute a risk to public or animal health owing to the health status of any animal from which it derives or contamination arising during the slaughter process;

(u) in the opinion of the official veterinarian, after examination of all the relevant information, it may constitute a risk to public or animal health or is for any other reason not suitable for human consumption.

2. The official veterinarian may impose requirements concerning the use of meat derived from animals having undergone emergency slaughter outside the slaughterhouse.

SECTION III: RESPONSIBILITIES AND FREQUENCY OF CONTROLS

CHAPTER I: OFFICIAL AUXILIARIES

Official auxiliaries may assist the official veterinarian with all tasks, subject to the following restrictions and to any specific rules laid down in Section IV:

1. in relation to auditing tasks, official auxiliaries may only collect information regarding good hygienic practices and HACCP-based procedures;

2. in relation to ante-mortem inspection and checks concerning the welfare of animals, official auxiliaries may only make an initial check of animals and help with purely practical tasks; and

3. in relation to post-mortem inspection, the official veterinarian must regularly check the work of official auxiliaries and, in the case of animals having undergone emergency slaughter outside the slaughterhouse, carry out the inspection personally.

CHAPTER II: FREQUENCY OF CONTROLS

1. The competent authority is to ensure that at least one official veterinarian is present:

(a) in slaughterhouses, throughout both ante-mortem and post-mortem inspection; and

(b) in game handling establishments, throughout post-mortem inspection.

2. However, the competent authority may adapt this approach in certain slaughterhouses and game handling establishments identified on the basis of a risk analysis and in accordance with criteria laid down in accordance with Article 18, point 3, if there are any. In such cases:

(a) The official veterinarian need not be present at the time of ante-mortem inspection in the slaughterhouse if:

(i) an official veterinarian or an approved veterinarian carried out ante-mortem inspection at the holding of provenance, checked the food chain information and communicated the results of the check to the official auxiliary at the slaughterhouse,

(ii) the official auxiliary at the slaughterhouse is satisfied that the food chain information does not point to any possible problem for food safety and that the animal's general state of health and welfare is satisfactory, and

(iii) the official veterinarian regularly satisfies himself/herself that the official auxiliary is carrying out such checks properly;

(b) the official veterinarian need not be present at all times during post-mortem inspection if:

(i) an official auxiliary carries out post-mortem inspection and puts aside meat with abnormalities and all other meat from the same animal,

(ii) the official veterinarian subsequently inspects all such meat, and

(iii) the official auxiliary documents his/her procedures and findings in a manner that allows the official veterinarian to be satisfied that standards are being met.

However, in the case of poultry and lagomorphs, the official auxiliary may discard meat with abnormalities and, subject to Section IV, the official veterinarian need not systematically inspect all such meat.

3. The flexibility provided for in paragraph 2 does not apply:

(a) to animals that have undergone emergency slaughter;

(b) to animals suspected of having a disease or condition that may adversely affect human health;

(c) to bovine animals from herds that have not been declared officially free of tuberculosis;

(d) to bovine, ovine and caprine animals from herds that have not been declared officially free of brucellosis;

(e) in the case of an outbreak of a disease listed on OIE List A or, where appropriate, OIE List B. This concerns animals susceptible to the particular disease in question that come from the particular region as defined in Article 2 of Council Directive 64/432/EEC [1];

(f) when stricter controls are necessary to take account of emerging diseases or particular OIE List B diseases.

4. In cutting plants, the competent authority is to ensure that an official veterinarian or an official auxiliary is present when meat is being worked on with a frequency appropriate to achieving the objectives of this Regulation.

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[1] OJ L 121, 29.7.1964, p. 1977/64. Directive as last amended by Commission Regulation (EC) No 21/2004 (OJ L 5, 9.1.2004, p. 8).

CHAPTER III: INVOLVEMENT OF SLAUGHTERHOUSE STAFF

A. SPECIFIC TASKS CONCERNING THE PRODUCTION OF MEAT FROM POULTRY AND LAGOMORPHS

The Member States may permit slaughterhouse staff to take over the activities of the official auxiliaries in controlling the production of poultry and rabbit meat under the following conditions:

(a) Where the establishment has used good hygiene practice in accordance with Article 4, paragraph 4 of this Regulation and the HACCP procedure for at least twelve months, the competent authority may authorise staff of the establishment who have been trained in the same way as the official assistants and have passed the same examination to carry out tasks of the official auxiliaries and form part of the competent authority's independent inspection team, under the supervision, direction and responsibility of the official veterinarian. In these circumstances, the official veterinarian shall be present at anti-mortem and post-mortem examinations, shall supervise these activities and carry out regular performance tests to ensure that the performance of the slaughterhouse tasks meets the specific criteria laid down by the competent authority, and shall document the results of those performance tests. Detailed rules for the performance tests shall be laid down in accordance with the procedure set out in Article 18. Where the level of hygiene of the establishment is affected by the work of this staff, where this staff does not carry out the tasks properly or where in general this staff carries out its work in a manner that the competent authority considers unsatisfactory, this staff shall be replaced by official auxiliaries.

Responsibilities for production and inspection in the establishment must be kept separate and any establishment wishing to use the establishment's own inspectors must possess internationally recognised certification.

(b) The competent authority of the Member State shall decide, in principle and on a case-by-case basis, whether to permit the implementation of the system described above. Where the Member State decides in principle in favour of this system, it shall inform the Commission of that decision and its associated conditions. For food business operators in a Member State implementing the system, the actual use of the system is optional. Food business operators shall not be forced by the competent authority to introduce the system described here. Where the competent authority is not convinced that the food business operator satisfies the requirements, the system shall not be implemented in that establishment. In order to assess this, the competent authority shall carry out an analysis of the production and inspection records, the type of activities undertaken in the establishment, the history of compliance with rules, the expertise, professional attitude and sense of responsibility of the slaughterhouse staff in regard to food safety, together with other relevant information.

B. SPECIFIC SAMPLING AND TESTING TASKS

Slaughterhouse staff who have received specific training, under the supervision of the official veterinarian, may, under the responsibility and the supervision of the official veterinarian, carry out specific sampling and testing tasks in respect of animals of all species.

CHAPTER IV: PROFESSIONAL QUALIFICATIONS

A. OFFICIAL VETERINARIANS

1. The competent authority may appoint only veterinarians who have passed a test meeting the requirements of paragraph 2 as official veterinarians.

2. The competent authority must make arrangements for the test. The test is to confirm knowledge of the following subjects to the extent necessary depending on the veterinarian's background and qualifications:

(a) national and Community legislation on veterinary public health, food safety, animal health, animal welfare and pharmaceutical substances;

(b) principles of the Common Agricultural Policy, market measures, export refunds and fraud detection (including the global context: WTO, SPS, Codex Alimentarius, OIE);

(c essentials of food processing and food technology;

(d) principles, concepts and methods of good manufacturing practice and quality management;

(e) pre-harvest quality management (good farming practices);

(f) promotion and use of food hygiene, food related safety (good hygiene practices);

(g) principles, concepts and methods of risk-analysis;

(h) principles, concepts and methods of HACCP, use of HACCP throughout the food production food chain;

(i) prevention and control of food-borne hazards related to human health;

(j) population dynamics of infection and intoxication;

(k) diagnostic epidemiology;

(l) monitoring and surveillance systems;

(m) auditing and regulatory assessment of food safety management systems;

(n) principles and diagnostic applications of modern testing methods;

(o) information and communication technology as related to veterinary public health;

(p) data-handling and applications of biostatistics;

(q) investigations of outbreaks of food-borne diseases in humans;

(r) relevant aspects concerning TSEs;

(s) animal welfare at the level of production, transport and slaughter;

(t) environmental issues related to food production (including waste management);

(u) precautionary principle and consumer concerns; and

(v) principles of training of personnel working in the production chain.

Candidates may acquire the required knowledge as part of their basic veterinary training, or through training undertaken, or professional experience acquired, after qualifying as veterinarians. The competent authority may arrange for different tests to take account of candidates' background. However, when the competent authority is satisfied that a candidate has acquired all the required knowledge as part of a university degree, or through continuing education resulting in a post-graduate qualification, it may waive the requirement for a test.

3. The veterinarian is to have aptitude for multidisciplinary cooperation.

4. In addition, each official veterinarian is to undergo practical training for a probationary period of at least 200 hours before starting to work independently. During this period the probationer is to work under the supervision of existing official veterinarians in slaughterhouses, cutting plants, inspection posts for fresh meat and on holdings. The training is to concern the auditing of food safety management systems in particular.

5. The official veterinarian is to maintain up-to-date knowledge and to keep abreast of new developments through regular continuing education activities and professional literature. The official veterinarian is, wherever possible, to undertake annual continuing education activities.

6. Veterinarians already appointed as official veterinarians must have adequate knowledge of the subjects mentioned in paragraph 2. Where necessary, they are to acquire this knowledge through continuing education activities. The competent authority is to make adequate provision in this regard.

(7)Notwithstanding paragraphs 1 to 6, Member States may lay down specific rules for official veterinarians working on a part-time basis who are responsible for inspecting small businesses

B. OFFICIAL AUXILIARIES

1. The competent authority may appoint as official auxiliaries only persons who have undergone training and passed a test in accordance with the following requirements.

2. The competent authority must make arrangements for such tests. To be eligible for these tests, candidates must prove that they have received:

(a) at least 500 hours of theoretical training and at least 400 hours of practical training, covering the areas specified in paragraph 5; and

(b) such additional training as is required to enable official auxiliaries to undertake their duties competently.

3. The practical training referred to in paragraph 2(a) is to take place in slaughterhouses and cutting plants, under the supervision of an official veterinarian, and on holdings and in other relevant establishments.

4. Training and tests are to concern principally red meat or poultry meat. However, persons who undergo training for one of the two categories and passed the test, need only undergo abridged training to pass the test for the other category. Training and test should cover wild game, farmed game and lagomorphs, where appropriate.

5. Training for official auxiliaries is to cover, and tests are to confirm knowledge of, the following subjects:

(a) in relation to holdings:

(i) theoretical part:

- familiarity with the farming industry organisation, production methods, international trade etc.,
- good livestock husbandry practices,
- basic knowledge of diseases, in particular zoonoses-viruses, bacteria, parasites etc.,
- monitoring for disease, use of medicines and vaccines, residue testing,
- hygiene and health inspection,
- animal welfare on the farm and during transport,
- environmental requirements - in buildings, on farms and in general,
- relevant laws, regulations and administrative provisions,
- consumer concerns and quality control;

(ii) practical part:

- visits to holdings of different types and using different rearing methods,
- visits to production establishments,
- observation of the loading and unloading of animals,
- laboratory demonstrations,
- veterinary checks,
- documentation;

(b) in relation to slaughterhouses and cutting plants:

(i) theoretical part:

- familiarity with the meat industry organisation, production methods, international trade and slaughter and cutting technology,
- basic knowledge of hygiene and good hygienic practices, and in particular industrial hygiene, slaughter, cutting and storage hygiene, hygiene of work,
- HACCP and the audit of HACCP-based procedures,
- animal welfare on unloading after transport and at the slaughterhouse,
- basic knowledge of the anatomy and physiology of slaughtered animals,
- basic knowledge of the pathology of slaughtered animals,
- basic knowledge of the pathological anatomy of slaughtered animals,
- relevant knowledge concerning TSEs and other important zoonoses and zoonotic agents,
- knowledge of methods and procedures for the slaughter, inspection, preparation, wrapping, packaging and transport of fresh meat,
- basic knowledge of microbiology,
- ante-mortem inspection,
- examination for trichinosis,
- post-mortem inspection,
- administrative tasks,
- knowledge of the relevant laws, regulations and administrative provisions,
- sampling procedure,
- fraud aspects;

(ii) practical part:

- animal identification,
- age checks,
- inspection and assessment of slaughtered animals,
- post-mortem inspection in a slaughterhouse,
- examination for trichinosis,
- identification of animal species by examination of typical parts of the animal,
- identifying and commenting on parts of slaughtered animals in which changes have occurred,
- hygiene control, including the audit of the good hygiene practices and the HACCP-based procedures,
- recording the results of ante-mortem inspection,
- sampling,
- traceability of meat,
- documentation.

6. Official auxiliaries are to maintain up-to-date knowledge and to keep abreast of new developments through regular continuing education activities and professional literature. The official auxiliary is, wherever possible, to undertake annual continuing education activities.

7. Persons already appointed as official auxiliaries must have adequate knowledge of the subjects mentioned in paragraph 5. Where necessary, they are to acquire this knowledge through continuing education activities. The competent authority is to make adequate provision in this regard.

8. However, when official auxiliaries carry out only sampling and analysis in connection with examinations for trichinosis, the competent authority need only ensure that they receive training appropriate to these tasks.

SECTION IV: SPECIFIC REQUIREMENTS

CHAPTER I: DOMESTIC BOVINE ANIMALS

A. BOVINE ANIMALS UNDER SIX WEEKS OLD

Carcases and offal of bovine animals under six weeks old are to undergo the following post-mortem inspection procedures:

1. visual inspection of the head and throat; incision and examination of the retropharyngeal lymph nodes (*Lnn retropharyngiales*); inspection of the mouth and fauces; palpation of the tongue; removal of the tonsils;

2. visual inspection of the lungs, trachea and oesophagus; palpation of the lungs; incision and examination of the bronchial and mediastinal lymph nodes (*Lnn. bifucationes, eparteriales and mediastinales*). The trachea and the main branches of the bronchi must be opened lengthwise and the lungs must be incised in their posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption;

3. visual inspection of the pericardium and heart, the latter being incised lengthwise so as to open the ventricles and cut through the interventricular septum;

4. visual inspection of the diaphragm;

5. visual inspection of the liver and the hepatic and pancreatic lymph nodes, (*Lnn portales*); palpation and, if necessary, incision of the liver and its lymph nodes;

6. visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*); palpation and, if necessary, incision of the gastric and mesenteric lymph nodes;

7. visual inspection and, if necessary, palpation of the spleen;

8. visual inspection of the kidneys; incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);

9. visual inspection of the pleura and peritoneum;

10. visual inspection and palpation of the umbilical region and the joints. In the event of doubt, the umbilical region must be incised and the joints opened; the synovial fluid must be examined.

B. BOVINE ANIMALS OVER SIX WEEKS OLD

Carcases and offal of bovine animals over six weeks old are to undergo the following post-mortem inspection procedures:

1. visual inspection of the head and throat; incision and examination of the sub-maxillary, retropharyngeal and parotid lymph nodes (*Lnn retropharyngiales, mandibulares and parotidei*); examination of the external masseters, in which two incisions must be made parallel to the mandible, and the internal masseters (internal pterygoid muscles), which must be incised along one plane. The tongue must be freed to permit a detailed visual inspection of the mouth and the fauces and must itself be visually inspected and palpated. The tonsils must be removed;

2. inspection of the trachea and oesophagus; visual examination and palpation of the lungs; incision and examination of the bronchial and mediastinal lymph nodes (*Lnn. bifucationes, eparteriales and mediastinales*). The trachea and the main branches of the bronchi must be opened lengthways and the lungs must be incised in their posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption;

3. visual inspection of the pericardium and heart, the latter being incised lengthways so as to open the ventricles and cut through the interventricular septum;

4. visual inspection of the diaphragm;

5. visual inspection and palpation of the liver and the hepatic and pancreatic lymph nodes, (*Lnn portales*); incision of the gastric surface of the liver and at the base of the caudate lobe to examine the bile ducts;

6. visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*); palpation and, if necessary, incision of the gastric and mesenteric lymph nodes;

7. visual inspection and, if necessary, palpation of the spleen;

8. visual inspection of the kidneys and incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);

9. visual inspection of the pleura and the peritoneum;

10. visual inspection of the genital organs (except for the penis, if already discarded);

11. visual inspection and, if necessary, palpation and incision of the udder and its lymph nodes (*Lnn. supramammarii*). In cows, each half of the udder must be opened by a long, deep incision as far as the lactiferous sinuses (*sinus lactiferes*) and the lymph nodes of the udder must be incised, except when the udder is excluded from human consumption.

CHAPTER II: DOMESTIC SHEEP AND GOATS

Carcases and offal of sheep and goats are to undergo the following post-mortem inspection procedures:

1. visual inspection of the head after flaying and, in the event of doubt, examination of the throat, mouth, tongue and retropharyngeal and parotid lymph nodes. Without prejudice to animal-health rules, these examinations are not necessary if the competent authority is able to guarantee that the head, including the tongue and the brains, will be excluded from human consumption;

2. visual inspection of the lungs, trachea and oesophagus; palpation of the lungs and the bronchial and mediastinal lymph nodes (*Lnn. bifucationes, eparteriales and mediastinales*); in the event of doubt, these organs and lymph nodes must be incised and examined;

3. visual inspection of the pericardium and heart; in the event of doubt, the heart must be incised and examined;

4. visual inspection of the diaphragm;

5. visual inspection of the liver and the hepatic and pancreatic lymph nodes, (*Lnn portales*); palpation of the liver and its lymph nodes; incision of the gastric surface of the liver to examine the bile ducts;

6. visual inspection of the gastro-intestinal tract, the mesentery and the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*);

7. visual inspection and, if necessary, palpation of the spleen;

8. visual inspection of the kidneys; incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);

9. visual inspection of the pleura and peritoneum;

10. visual inspection of the genital organs (except for the penis, if already discarded);

11. visual inspection of the udder and its lymph nodes;

12. visual inspection and palpation of the umbilical region and joints of young animals. In the event of doubt, the umbilical region must be incised and the joints opened; the synovial fluid must be examined.

CHAPTER III: DOMESTIC SOLIPEDS

Carcases and offal of solipeds are to undergo the following post-mortem inspection procedures:

1. visual inspection of the head and, after freeing the tongue, the throat; palpation and, if necessary, incision of the sub-maxillary, retropharyngeal and parotid lymph nodes (*Lnn retropharyngiales, mandibulares and parotidei*). The tongue must be freed to permit a detailed visual inspection of the mouth and the fauces and must itself be visually examined and palpated. The tonsils must be removed;

2. visual inspection of the lungs, trachea and oesophagus; palpation of the lungs; palpation and, if necessary, incision of the bronchial and mediastinal lymph nodes (*Lnn. bifucationes, eparteriales and mediastinales*). The trachea and the main branches of the bronchi must be opened lengthwise and the lungs must be incised in their posterior third, perpendicular to their main axes; however, these incisions are not necessary where the lungs are excluded from human consumption;

3. visual inspection of the pericardium and the heart, the latter being incised lengthwise so as to open the ventricles and cut through the interventricular septum;

4. visual inspection of the diaphragm;

5. visual inspection, palpation and, if necessary, incision of the liver and the hepatic and pancreatic lymph nodes, (*Lnn portales*);

6. visual inspection of the gastro-intestinal tract, the mesentery and the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*); incision, if necessary, of the gastric and mesenteric lymph nodes;

7. visual inspection and, if necessary, palpation of the spleen;

8. visual inspection and palpation of the kidneys; incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);

9. visual inspection of the pleura and peritoneum;

10. visual inspection of the genital organs of stallions (except for the penis, if already discarded) and mares;

11. visual inspection of the udder and its lymph nodes (*Lnn. supramammarii*) and, if necessary, incision of the supramammary lymph nodes;

12. visual inspection and palpation of the umbilical region and joints of young animals. In the event of doubt, the umbilical region must be incised and the joints opened; the synovial fluid must be examined;

13. all grey or white horses must be inspected for melanosis and melanomata by examination of the muscles and lymph nodes (*Lnn. subrhomboidei*) of the shoulders beneath the scapular cartilage after loosening the attachment of one shoulder. The kidneys must be exposed and examined by incision through the entire kidney.

CHAPTER IV: DOMESTIC SWINE

A. Ante-mortem inspection

1. The competent authority may decide that pigs intended for slaughter are to be submitted to ante-mortem inspection at the holding of provenance. In that case, slaughter of a lot of pigs from a holding may be authorised only if:

(a) the health certificate provided for in Chapter X, Part A, accompanies them; and

(b) the requirements of paragraphs 2 to 5 are complied with.

2. Ante-mortem inspection at the holding of provenance is to comprise:

(a) checks on records or documentation at the holding, including food chain information;

(b) the examination of the pigs to determine whether:

(i) they have a disease or condition which may be transmitted to animals or humans through handling or eating the meat, or are behaving, individually or collectively, in a manner indicating that such a disease may occur,

(ii) they show disturbance of general behaviour or signs of disease which may make the meat unfit for human consumption, or

(iii) there is evidence or reasons to suspect that they may contain chemical residues in excess of the levels laid down in Community legislation, or residues of forbidden substances.

3. An official veterinarian or an approved veterinarian is to carry out ante-mortem inspection at the holding. The pigs are to be sent directly to slaughter and not to be mixed with other pigs.

4. Ante-mortem inspection at the slaughterhouse need cover only:

(a) a control of the animals' identification; and

(b) a screening to ascertain whether animal welfare rules have been complied with and whether signs of any condition which might adversely affect human or animal health are present. An official auxiliary may carry out this screening.

5. When pigs are not slaughtered within three days of the issue of the health certificate provided for in paragraph 1(a):

(a) if the pigs have not left the holding of provenance for the slaughterhouse, they are to be re-examined and a new health certificate issued;

(b) if the pigs are already en route for or at the slaughterhouse, slaughter may be authorised once the reason for the delay has been assessed, provided that the pigs undergo a further veterinary ante-mortem inspection.

B. Post-mortem inspection

1. Carcases and offal of pigs other than those referred to in paragraph 2 are to undergo the following post-mortem inspection procedures:

(a) visual inspection of the head and throat; incision and examination of the submaxillary lymph nodes (*Lnn mandibulares*); visual inspection of the mouth, fauces and tongue;

(b) visual inspection of the lungs, trachea and oesophagus; palpation of the lungs and the bronchial and mediastinal lymph nodes (*Lnn. bifucationes, eparteriales and mediastinales*). The trachea and the main branches of the bronchi must be opened lengthwise and the lungs must be incised in their posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption;

(c) visual inspection of the pericardium and heart, the latter being incised lengthwise so as to open the ventricles and cut through the interventricular septum;

(d) visual inspection of the diaphragm;

(e) visual inspection of the liver and the hepatic and pancreatic lymph nodes, (*Lnn portales*); palpation of the liver and its lymph nodes;

(f) visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*); palpation and, if necessary, incision of the gastric and mesenteric lymph nodes;

(g)visual inspection and, if necessary, palpation of the spleen;

(h)visual inspection of the kidneys; incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);

(i) visual inspection of the pleura and peritoneum;

(j) visual inspection of the genital organs (except for the penis, if already discarded);

(k)visual inspection of the udder and its lymph nodes (*Lnn. supramammarii*); incision of the supramammary lymph nodes in sows;

(l) visual inspection and palpation of the umbilical region and joints of young animals; in the event of doubt, the umbilical region must be incised and the joints opened.

2. The competent authority may decide, on the basis of epidemiological or other data from the holding, that fattening pigs housed under controlled housing conditions in integrated production systems since weaning need, in some or all of the cases referred to in paragraph 1, only undergo visual inspection.

CHAPTER V: POULTRY

A. Ante-mortem inspection

1. The competent authority may decide that poultry intended for slaughter are to be submitted to ante-mortem inspection at the holding of provenance. In that case, slaughter of a flock of birds from a holding may be authorised only if:

(a) the health certificate provided for in Chapter X, Part A, accompanies them; and

(b) the requirements of paragraphs 2 to 5 are complied with.

2. Ante-mortem inspection on the holding of provenance is to comprise:

(a) checks on records or documentation at the holding, including food chain information;

(b) a flock inspection, to determine whether the birds:

(i) have a disease or condition which may be transmitted to animals or humans through handling or eating the meat, or are behaving in a manner indicating that such a disease may occur,

(ii) show disturbance of general behaviour or signs of disease which may make the meat unfit for human consumption, or

(iii) show evidence that they may contain chemical residues in excess of the levels laid down in Community legislation, or residues of forbidden substances.

3. An official veterinarian or an approved veterinarian is to carry out ante-mortem inspection at the holding.

4. Ante-mortem inspection at the slaughterhouse need only cover:

(a) a control of the animals' identification; and

(b) a screening to ascertain whether animal welfare rules have been complied with and whether signs of any condition which might adversely affect human or animal health are present. An official auxiliary may carry out this screening.

5. When birds are not slaughtered within three days of the issue of the health certificate referred to in paragraph 1(a):

(a) if the flock has not left the holding of provenance for the slaughterhouse, it is to be re-examined and a new health certificate issued;

(b) if the flock is already en route for or at the slaughterhouse, slaughter may be authorised once the reason for the delay has been assessed, provided that the flock is re-examined.

6. When ante-mortem inspection is not carried out at the holding, the official veterinarian is to carry out a flock inspection at the slaughterhouse.

7. If the birds show clinical symptoms of a disease, they may not be slaughtered for human consumption. However, killing of these birds on the slaughter line may take place at the end of the normal slaughter process, if precautions are taken to avoid the risk of spreading pathogenic organisms and to clean and disinfect the facilities immediately after killing.

8. In the case of poultry reared for the production of "foie gras" and delayed eviscerated poultry slaughtered at the holding of provenance, ante-mortem inspection is to be carried out in accordance with paragraphs 2 and 3. A certificate conforming to the model set out in Part C is to accompany the uneviscerated carcasses to the slaughterhouse or cutting plant.

B. Post-mortem inspection

1. All birds are to undergo post-mortem inspection in accordance with Sections I and III. In addition, the official veterinarian is personally to carry out the following checks:

(a) daily inspection of the viscera and body cavities of a representative sample of birds;

(b) a detailed inspection of a random sample, from each batch of birds having the same origin, of parts of birds or entire birds declared unfit for human consumption following post-mortem inspection; and

(c) any further investigations necessary when there is reason to suspect that the meat from the birds concerned could be unfit for human consumption.

2. In the case of poultry reared for the production of "foie gras" and delayed eviscerated poultry obtained at the holding of provenance, post-mortem inspection is to include a check on the certificate accompanying the carcases. When such carcases are transported directly from the holding to a cutting plant, post-mortem inspection is to take place at the cutting plant.

C. SPECIMEN HEALTH CERTIFICATE

HEALTH CERTIFICATE

for poultry intended for the production of foie gras and delayed eviscerated poultry slaughtered at the holding of provenance

Competent service: .....
No: .....

1. Identification of uneviscerated carcases

Species: .....
Number: .....

2. Provenance of uneviscerated carcases

Address of holding: .....

3. Destination of uneviscerated carcases

The uneviscerated carcases will be transported to the following cutting plant: .....
.....

4. Declaration

I, the undersigned, declare that:

- the uneviscerated carcases described above are of birds which were examined before slaughter on the above-mentioned holding at ……. (time) on ……. (date) and found to be healthy;
- the records and documentation concerning these animals satisfied the legal requirements and do not prohibit slaughter of the birds.

Done at: ....., (Place)

on: ..... (Date)

Stamp

……..
(Signature of the official or approved veterinarian)

CHAPTER VI: FARMED LAGOMORPHS

The requirements for poultry are to apply to farmed lagomorphs.

CHAPTER VII: FARMED GAME

A. Ante-mortem inspection

1. Ante-mortem inspection may be carried out at the holding of provenance when the requirements of Annex III, Section III, to Regulation (EC) No …/2004 [*] are satisfied. In this case, an official veterinarian or an approved veterinarian is to carry out ante-mortem inspection.

2. Ante-mortem inspection at the holding is to include checks on the records or documentation at the holding, including food chain information.

3. When ante-mortem inspection takes place no more than three days before the arrival of the animals at the slaughterhouse, and animals are delivered to the slaughterhouse live, ante-mortem inspection at the slaughterhouse need only cover:

(a) a control of the animals' identification; and

(b) a screening to ascertain whether animal welfare rules have been complied with and whether signs of any condition which might adversely affect human or animal health are present.

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[*] Note for Official Journal: Insert No of Regulation laying down specific hygiene rules for food of animal origin (see recital 1, 2nd Regulation).

4. A certificate conforming to the specimen in Chapter X, Part A, is to accompany live animals inspected at the holding. A certificate conforming to the specimen in Chapter X, Part B, is to accompany animals inspected and slaughtered at the holding.

B. Post-mortem inspection

1. This inspection is to include palpation and, where judged necessary, incision of those parts of the animal which have undergone any change or are suspect for any other reason.

2. Post-mortem inspection procedures described for bovine and ovine animals, domestic swine and poultry are to be applied to the corresponding species of farmed game.

3. When the animals have been slaughtered at the holding, the official veterinarian at the slaughterhouse is to check the certificate accompanying them.

CHAPTER VIII: WILD GAME

A. Post-mortem inspection

1. Wild game is to be inspected as soon as possible after admission to the game handling establishment.

2. The official veterinarian is to take account of the declaration or information that the trained person involved in hunting the animal has provided in accordance with Regulation (EC) No …/2004 [*].

[*] Note for Official Journal: Insert No of Regulation laying down specific hygiene rules for food of animal origin (see recital 1, 2nd Regulation).

3. During post-mortem inspection, the official veterinarian is to carry out:

(a) a visual examination of the carcase, its cavities and, where appropriate, organs with a view to:

(i) detecting any abnormalities not resulting from the hunting process. For this purpose, the diagnosis may be based on any information that the trained person has provided concerning the behaviour of the animal before killing,

(ii) checking that death was not caused by reasons other than hunting.

If an assessment cannot be made on the basis of visual examination alone, a more extensive inspection must be carried out in a laboratory;

(b) an investigation of organoleptic abnormalities;

(c) palpation of organs, where appropriate;

(d) where there are serious grounds for suspecting the presence of residues or contaminants, an analysis by sampling of residues not resulting from the hunting process, including environmental contaminants. When a more extensive inspection is made on the basis of such suspicions, the veterinarian must wait until that inspection has been concluded before assessing all the game killed during a specific hunt, or those parts suspected of showing the same abnormalities;

(e) examination for characteristics indicating that the meat presents a health risk, including:

(i) abnormal behaviour or disturbance of the general condition of the live animal, as reported by the hunter,

(ii) the generalised presence of tumours or abscesses affecting different internal organs or muscles,

(iii) arthritis, orchitis, pathological changes in the liver or the spleen, inflammation of the intestines or the umbilical region,

(iv) the presence of foreign bodies not resulting from the hunting process in the body cavities, stomach or intestines or in the urine, where the pleura or peritoneum are discoloured (when relevant viscera are present),

(v) the presence of parasites,

(vi) formation of a significant amount of gas in the gastro-intestinal tract with discolouring of the internal organs (when these viscera are present),

(vii) significant abnormalities of colour, consistency or odour of muscle tissue or organs,

(viii) aged open fractures,

(ix) emaciation and/or general or localised oedema,

(x) recent pleural or peritoneal adhesions, and

(xi) other obvious extensive changes, such as putrefaction.

4. Where the official veterinarian so requires, the vertebral column and the head are to be split lengthwise.

5. In the case of small wild game not eviscerated immediately after killing, the official veterinarian is to carry out a post-mortem inspection on a representative sample of animals from the same source. Where inspection reveals a disease transmissible to man or any of the characteristics listed in paragraph 3(e), the official veterinarian is to carry out more checks on the entire batch to determine whether it must be declared unfit for human consumption or whether each carcase must be inspected individually.

6. In the event of doubt, the official veterinarian may perform any further cuts and inspections of the relevant parts of the animals necessary to reach a final diagnosis.

B. Decisions following controls

In addition to the cases provided for in Section II, Chapter V, meat presenting during post-mortem inspection any of the characteristics listed in paragraph 3(e) of Part A are to be declared unfit for human consumption.

CHAPTER IX: SPECIFIC HAZARDS

A. Tranmissible spongiform encephalopathies

Official controls carried out in relation to TSEs are to take account of the requirements of Regulation (EC) No 999/2001 and other relevant Community legislation.

B. Cysticercosis

1. The post-mortem inspection procedures described in Chapters I and IV are the minimum requirements for the examination for cysticercosis in bovine animals over 6 weeks old and swine. In addition, specific serological tests may be used. In the case of bovines over 6 weeks old, incision of the masseters at post-mortem inspection is not compulsory when a specific serological test is used. The same applies when bovine animals over 6 weeks old have been raised on a holding officially certified to be free of cysticercosis.

2. Meat infected with cysticercus is to be declared unfit for human consumption. However, when the animal is not generally infected with cysticercus, the parts not infected may be declared fit for human consumption after having undergone a cold treatment.

C. Trichinosis

1. Carcases of swine (domestic, farmed game and wild game), solipeds and other species susceptible to trichinosis are to be examined for trichinosis in accordance with applicable Community legislation, unless that legislation provides otherwise.

2. Meat from animals infected with trichinae is to be declared unfit for human consumption.

D. Glanders

1. Where appropriate, solipeds are to be examined for glanders. Examination for glanders in solipeds is to include a careful examination of mucous membranes from the trachea, larynx, nasal cavities and sinuses and their ramifications, after splitting the head in the median plane and excising the nasal septum.

2. Meat from horses in which glanders has been diagnosed are to be declared unfit for human consumption.

E. Tuberculosis

1. When animals have reacted positively or inconclusively to tuberculin, or there are other grounds for suspecting infection, they are to be slaughtered separately from other animals, taking precautions to avoid the risk of contamination of other carcases, the slaughter line and staff present in the slaughterhouse.

2. All meat from animals in which post-mortem inspection has revealed localised tuberculous lesions in a number of organs or a number of areas of the carcase is to be declared unfit for human consumption. However, when a tuberculous lesion has been found in the lymph nodes of only one organ or part of the carcase, only the affected organ or part of the carcase and the associated lymph nodes need be declared unfit for human consumption.

F. Brucellosis

1. When animals have reacted positively or inconclusively to a brucellosis test, or there are other grounds for suspecting infection, they are to be slaughtered separately from other animals, taking precautions to avoid the risk of contamination of other carcases, the slaughter line and staff present in the slaughterhouse.

2. Meat from animals in which post mortem inspection has revealed lesions indicating acute infection with brucellosis is to be declared unfit for human consumption. In the case of animals reacting positively or inconclusively to a brucellosis test, the udder, genital tract and blood must be declared unfit for human consumption even if no such lesion is found.

CHAPTER X: SPECIMEN HEALTH CERTIFICATE

A. SPECIMEN HEALTH CERTIFICATE FOR LIVE ANIMALS

HEALTH CERTIFICATE
for live animals transported from the holding to the slaughterhouse

Competent service: .....
No: .....
1. Identification of the animals
Species: .....
Number of animals: .....
Identification marking: .....

2. Provenance of the animals
Address of holding of provenance: .....
Identification of house*: .....

3. Destination of the animals
The animals will be transported to the following slaughterhouse: .....
.....
by the following means of transport: .....

4. Other relevant information
.....

5. Declaration

I, the undersigned, declare that:

- the animals described above were examined before slaughter at the above-mentioned holding at ……. (time) on ……. (date) and were found to be healthy,
- the records and documentation concerning these animals satisfied the legal requirements and do not prohibit slaughter of the animals.
-

Done at: ....., (Place)

on: ..... (Date)

Stamp

……..
(Signature of official or approved veterinarian)

* optional

B. SPECIMEN HEALTH CERTIFICATE FOR ANIMALS SLAUGHTERED AT THE HOLDING

HEALTH CERTIFICATE
for animals slaughtered at the holding

Competent service: .....
No: .....
1. Identification of the animals
Species: .....
Number of animals: .....
Identification marking: .....

2. Provenance of the animals
Address of holding of provenance: .....
Identification of house*: .....

3. Destination of the animals

The animals will be transported to the following slaughterhouse: .....
.....
by the following means of transport: .....

4. Other relevant information

.....

5. Declaration

I, the undersigned, declare that:

- the animals described above were examined before slaughter at the above-mentioned holding at ……. (time) on ……. (date) and were found to be healthy,
- they were slaughtered at the holding at ……. (time) on ……. (date) and slaughter and bleeding were carried out correctly,
- the records and documentation concerning these animals satisfied the legal requirements and did not prohibit slaughter of the animals.
-

Done at: ....., (Place)

on: ..... (Date)

Stamp

…….. (Signature of official or approved veterinarian)

* optional

ANNEX II

LIVE BIVALVE MOLLUSCS

CHAPTER I: SCOPE

This Annex applies to live bivalve molluscs and, by analogy, to live echinoderms, live tunicates and live marine gastropods.

CHAPTER II: OFFICIAL CONTROLS CONCERNING LIVE BIVALVE MOLLUSCS FROM CLASSIFIED PRODUCTION AREAS

A. CLASSIFICATION OF PRODUCTION AND RELAYING AREAS

1. The competent authority must fix the location and boundaries of production and relaying areas that it classifies. It may, where appropriate, do so in cooperation with the food business operator.

2. The competent authority must classify production areas from which it authorises the harvesting of live bivalve molluscs as being of one of three categories according to the level of faecal contamination. It may, where appropriate, do so in cooperation with the food business operator.

3. The competent authority may classify as being of Class A areas from which live bivalve molluscs may be collected for direct human consumption. Live bivalve molluscs taken from these areas must meet the health standards for live bivalve molluscs laid down in Annex III, Section VII, Chapter V, of Regulation (EC) No …/2004 [*].

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[*] Note for Official Journal: Insert No of Regulation laying down specific hygiene rules for food of animal origin (see recital 1, 2nd Regulation).

4. The competent authority may classify as being of Class B areas from which live bivalve molluscs may be collected, but placed on the market for human consumption only after treatment in a purification centre or after relaying so as to meet the health standards referred to in paragraph 3. Live bivalve molluscs from these areas must not exceed the limits of a five-tube, three dilution Most Probable Number (MPN) test of 4 600 *E.coli* per 100 g of flesh and intravalvular liquid.

5. The competent authority may classify as being of Class C areas from which live bivalve molluscs may be collected but placed on the market only after relaying over a long period so as to meet the health standards referred to in paragraph 3. Live bivalve molluscs from these areas must not exceed the limits of a five-tube, three dilution MPN test of 46 000 *E.coli* per 100 g of flesh and intravalvular liquid.

6. If the competent authority decides in principle to classify a production or relaying area, it must:

(a) make an inventory of the sources of pollution of human or animal origin likely to be a source of contamination for the production area;

(b) examine the quantities of organic pollutants which are released during the different periods of the year, according to the seasonal variations of both human and animal populations in the catchment area, rainfall readings, waste water treatment, etc.;

(c) determine the characteristics of the circulation of pollutants by virtue of current patterns, bathymetry and the tidal cycle in the production area; and

(d) establish a sampling programme of bivalve molluscs in the production area which is based on the examination of established data, and with a number of samples, a geographical distribution of the sampling points and a sampling frequency which must ensure that the results of the analysis are as representative as possible for the area considered.

B. MONITORING OF CLASSIFIED RELAYING AND PRODUCTION AREAS

1. Classified relaying and production areas must be periodically monitored to check:

(a) that there is no malpractice with regard to the origin, provenance and destination of live bivalve molluscs;

(b) the microbiological quality of live bivalve molluscs in relation to the production and relaying areas;

(c) for the presence of toxin-producing plankton in production and relaying waters and biotoxins in live bivalve molluscs; and

(d) for the presence of chemical contaminants in live bivalve molluscs.

2. To implement paragraph 1(b), (c) and (d), sampling plans must be drawn up providing for such checks to take place at regular intervals, or on a case-by-case basis if harvesting periods are irregular. The geographical distribution of the sampling points and the sampling frequency must ensure that the results of the analysis are as representative as possible for the area considered.

3. Sampling plans to check the microbiological quality of live bivalve molluscs must take particular account of:

(a) the likely variation in faecal contamination, and

(b) the parameters referred to in paragraph 6 of Part A.

4. Sampling plans to check for the presence of toxin-producing plankton in production and relaying waters and for biotoxins in live bivalve molluscs must take particular account of possible variations in the presence of plankton containing marine biotoxins. Sampling must comprise:

(a) periodic sampling to detect changes in the composition of plankton containing toxins and their geographical distribution. Results suggesting an accumulation of toxins in mollusc flesh must be followed by intensive sampling;

(b) periodic toxicity tests using those molluscs from the affected area most susceptible to contamination.

5. The sampling frequency for toxin analysis in the molluscs is, as a general rule, to be weekly during the periods at which harvesting is allowed. This frequency may be reduced in specific areas, or for specific types of molluscs, if a risk assessment on toxins or phytoplankton occurrence suggests a very low risk of toxic episodes. It is to be increased where such an assessment suggests that weekly sampling would not be sufficient. The risk assessment is to be periodically reviewed in order to assess the risk of toxins occurring in the live bivalve molluscs from these areas.

6. When knowledge of toxin accumulation rates is available for a group of species growing in the same area, a species with the highest rate may be used as an indicator species. This will allow the exploitation of all species in the group if toxin levels in the indicator species are below the regulatory limits. When toxin levels in the indicator species are above the regulatory limits, harvesting of the other species is only to be allowed if further analysis on the other species shows toxin levels below the limits.

7. With regard to the monitoring of plankton, the samples are to be representative of the water column and to provide information on the presence of toxic species as well as on population trends. If any changes in toxic populations that may lead to toxin accumulation are detected, the sampling frequency of molluscs is to be increased or precautionary closures of the areas are to be established until results of toxin analysis are obtained.

8. Sampling plans to check for the presence of chemical contaminants must enable the detection of any overshooting of the levels laid down in Commission Regulation (EC) No 466/2001 [1].

[1] OJ L 77, 16.3.2001, p. 1. Regulation as last amended by Regulation (EC) No 655/2004 (OJ L 104, 8.4.2004, p. 48).

C. DECISIONS AFTER MONITORING

1. Where the results of sampling show that the health standards for molluscs are exceeded, or that there may be otherwise a risk to human health, the competent authority must close the production area concerned, preventing the harvesting of live bivalve molluscs. However, the competent authority may reclassify a production area as being of Class B or C if it meets the relevant criteria set out in Part A and presents no other risk to human health.

2. The competent authority may re-open a closed production area only if the health standards for molluscs once again comply with Community legislation. If the competent authority closes a production because of the presence of plankton or excessive levels of toxins in molluscs, at least two consecutive results below the regulatory limit separated at least 48 hours are necessary to re-open it. The competent authority may take account of information on phytoplankton trends when taking this decision. When there are robust data on the dynamic of the toxicity for a given area, and provided that recent data on decreasing trends of toxicity are available, the competent authority may decide to re-open the area with results below the regulatory limit obtained from one single sampling.

D. ADDITIONAL MONITORING REQUIREMENTS

1. The competent authority is to monitor classified production areas from which it has forbidden the harvesting of bivalve molluscs or subjected harvesting to special conditions, to ensure that products harmful to human health are not placed on the market.

2. In addition to the monitoring of relaying and production zones referred to in paragraph 1 of Part B, a control system must be set up comprising laboratory tests to verify food business operators' compliance with the requirements for the end product at all stages of production, processing and distribution. This control system is, in particular, to verify that the levels of marine biotoxins and contaminants do not exceed safety limits and that the microbiological quality of the molluscs does not constitute a hazard to human health.

E. RECORDING AND EXCHANGE OF INFORMATION

The competent authority must:

(a) establish and keep up to date a list of approved production and relaying areas, with details of their location and boundaries, as well as the class in which the area is classified, from which live bivalve molluscs may be taken in accordance with the requirements of this Annex. This list must be communicated to interested parties affected by this Annex, such as producers, gatherers and operators of purification centres and dispatch centres;

(b) immediately inform the interested parties affected by this Annex, such as producers, gatherers and operators of purification centres and dispatch centres, about any change of the location, boundaries or class of a production area, or its closure, be it temporary or final; and

(c) act promptly where the controls prescribed in this Annex indicate that a production area must be closed or reclassified or can be re-opened.

F. FOOD BUSINESS OPERATORS' OWN-CHECKS

To decide on the classification, opening or closure of production areas, the competent authority may take into account the results of controls that food business operators or organisations representing food business operators have carried out. In that event, the competent authority must have designated the laboratory carrying out the analysis and, if necessary, sampling and analysis must have taken place in accordance with a protocol that the competent authority and the food business operators or organisation concerned have agreed.

CHAPTER III: OFFICIAL CONTROLS CONCERNING PECTINIDAE HARVESTED OUTSIDE CLASSIFIED PRODUCTION AREAS

Official controls on pectinidae harvested outside classified production areas are to be carried out in fish auctions, dispatch centres and processing establishments. Such official controls are to verify compliance with the health standards for live bivalve molluscs laid down in Annex III, Section VII, Chapter V, to Regulation (EC) No .../2004 [*] as well as compliance with other requirements of Annex III, Section VII, Chapter IX, to that Regulation.

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[*] Note for Official Journal: Insert No of Regulation laying down specific hygiene rules for food of animal origin (see recital 1, 2nd Regulation).

ANNEX III

FISHERY PRODUCTS

CHAPTER I: OFFICIAL CONTROLS OF PRODUCTION AND PLACING ON THE MARKET

1. Official controls on the production and placing on the market of fishery products are to include, in particular:

(a) a regular check on the hygiene conditions of landing and first sale;

(b) inspections at regular intervals of vessels and establishments on land, including fish auctions and wholesale markets, to check, in particular:

(i) where appropriate, whether the conditions for approval are still fulfilled,
(ii) whether the fishery products are handled correctly,
(iii) for compliance with hygiene and temperature requirements, and
(iv) the cleanliness of establishments, including vessels, and their facilities and equipment, and staff hygiene; and

(c) checks on storage and transport conditions.

2. However, subject to paragraph 3, official controls of vessels:

(a) may be carried out when vessels call at a port in a Member State;

(b) concern all vessels landing fishery products at ports in the Community, irrespective of flag; and

(c) may, if necessary, when the competent authority of the Member State the flag of which the vessel is flying carries out the official control, be carried out while the vessel is at sea or when it is in a port in another Member State or in a third country.

3. (a) In the case of an inspection of a factory or freezer vessel flying the flag of a Member State carried out with a view to the approval of the vessel, the competent authority of the Member State the flag of which the vessel is flying is to carry out inspections in such a manner as to comply with the requirements of Article 3, particularly the time limits of Article 3(2). If necessary, that competent authority may inspect the vessel while it is at sea or when it is in a port in another Member State or in a third country.

(b) When the competent authority of the Member State the flag of which the vessel is flying has granted the vessel conditional approval in accordance with Article 3, that competent authority may authorise a competent authority of:

(i) another Member State, or

(ii) a third country that appears on a list of third countries from which imports of fishery products are permitted drawn up in accordance with Article 11,

to carry out a follow-up inspection with a view to granting full approval or prolonging conditional approval in accordance with Article 3(1)(b) or to keeping approval under review in accordance with Article 3(4). If necessary, that competent authority may inspect the vessel while it is at sea or when it is in a port in another Member State or in a third country.

4. When the competent authority of a Member State authorises the competent authority of another Member State or of a third country to carry out inspections on its behalf in accordance with paragraph 3, the two competent authorities are to agree on the conditions governing such inspections. These conditions are to ensure, in particular, that the competent authority of the Member State the flag of which the vessel is flying receives reports on the results of inspections and on any suspected non-compliance without delay, so as to enable it to take the necessary measures.

CHAPTER II: OFFICIAL CONTROLS OF FISHERY PRODUCTS

Official controls of fishery products are to include at least the following elements.

A. ORGANOLEPTIC EXAMINATIONS

Random organoleptic checks must be carried out at all stages of production, processing and distribution. One aim of these checks is to verify compliance with the freshness criteria established in accordance with Community legislation. In particular, this includes verifying, at all stages of production, processing and distribution, that fishery products at least exceed the baselines of freshness criteria established in accordance with Community legislation.

B. FRESHNESS INDICATORS

When the organoleptic examination reveals any doubt as to the freshness of the fishery products, samples may be taken and subjected to laboratory tests to determine the levels of total volatile basic nitrogen (TVB-N) and trimethylamine nitrogen (TMA-N).

The competent authority is to use the criteria laid down under Community legislation.

When the organoleptic examination gives cause to suspect the presence of other conditions which may affect human health, appropriate samples are to be taken for verification purposes.

C. HISTAMINE

Random testing for histamine is to be carried out to verify compliance with the permitted levels laid down under Community legislation.

D. RESIDUES AND CONTAMINANTS

Monitoring arrangements are to be set up to control the levels of residues and contaminants in accordance with Community legislation.

E. MICROBIOLOGICAL CHECKS

Where necessary, microbiological checks are to be performed in accordance with the relevant rules and criteria laid down under Community legislation.

F. PARASITES

Random testing is to take place to verify compliance with Community legislation on parasites.

G. POISONOUS FISHERY PRODUCTS

Checks are to take place to ensure that the following fishery products are not placed on the market:

1. poisonous fish of the following families are not placed on the market: Tetraodontidae, Molidae, Diodontidae and Canthigasteridae; and

2. fishery products containing biotoxins such as Ciguatera or other toxins dangerous to human health. However, fishery products derived from bivalve molluscs, echinoderms, tunicates and marine gastropods may be placed on the market if they have been produced in accordance with Section VII of Annex III to Regulation (EC) No…/2004 [*] and comply with the standards laid down in Chapter V, point 2, of that Section.

CHAPTER III: DECISIONS AFTER CONTROLS

Fishery products are to be declared unfit for human consumption if:

1. organoleptic, chemical, physical or microbiological checks or checks for parasites have shown that they are not in compliance with the relevant Community legislation;

2. they contain in their edible parts contaminants or residues in excess of the limits laid down in Community legislation or at levels where the calculated dietary intake would exceed the acceptable daily or weekly intake for humans;

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[*] Note for Official Journal: Insert No of Regulation laying down specific hygiene rules for food of animal origin (see recital 1, 2nd Regulation).

3. they derive from:

(i) poisonous fish,

(ii) fishery products not complying with the requirement of Part G, point 2, of Chapter II concerning biotoxins, or

(iii) bivalve molluscs, echinoderms, tunicates or marine gastropods containing marine biotoxins in total quantities exceeding the limits referred to in Regulation (EC) No …/2004 [*]; or

4. the competent authority considers that they may constitute a risk to public or animal health or are for any other reason not suitable for human consumption.

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[*] Note for Official Journal: Insert No of Regulation laying down specific hygiene rules for food of animal origin (see recital 1, 2nd Regulation).

ANNEX IV

RAW MILK AND DAIRY PRODUCTS

CHAPTER I: CONTROL OF MILK PRODUCTION HOLDINGS

1. Animals on milk production holdings must be subject to official controls to verify that the health requirements for raw milk production, and in particular the health status of the animals and the use of veterinary medicinal products, are being complied with. These controls may take place at the occasion of veterinary checks carried out pursuant to Community provisions on animal or public health or animal welfare and may be carried out by an approved veterinarian.

2. If there are grounds for suspecting that the animal health requirements are not being complied with, the general health status of the animals is to be checked.

3. Milk production holdings are to undergo official controls to verify that hygiene requirements are being complied with. These official controls may involve inspections and/or the monitoring of controls that professional organisations carry out. If it is shown that the hygiene is inadequate, the competent authority is to verify that appropriate steps are taken to correct the situation.

CHAPTER II: CONTROL OF RAW MILK UPON COLLECTION

1. The competent authority is to monitor the checks carried out in accordance with Annex III, Section IX, Chapter I, Part III, to Regulation (EC) No …/2004 [*].

2. If the food business operator has not corrected the situation within three months of first notifying the competent authority of non-compliance with the criteria with regard to plate count and somatic cell count, delivery of raw milk from the production holding is to be suspended or - in accordance with a specific authorisation of, or general instructions from, the competent authority - subjected to requirements concerning its treatment and use necessary to protect public health. This suspension or these requirements are to remain in place until the food business operator has proved that the raw milk again complies with the criteria.

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[*] Note for Official Journal: Insert No of Regulation laying down specific hygiene rules for food of animal origin (see recital 1, 2nd Regulation).

ANNEX V

ESTABLISHMENTS NOT SUBJECT TO THE LISTING REQUIREMENT OF ARTICLE 12(1)

The following third country establishments need not appear on lists drawn up and updated in accordance with Article 12(4):

1. establishments handling products of animal origin for which Annex III to Regulation (EC) No…/2004 * does not lay down requirements;

2. establishments carrying out only primary production;

3. establishments carrying out only transport operations;

4. establishments carrying out only the storage of products of animal origin not requiring temperature-controlled storage conditions.

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* Note for Official Journal: Insert No of Regulation laying down specific hygiene rules for food of animal origin (see recital 1, 2nd Regulation).

ANNEX VI

REQUIREMENTS FOR CERTIFICATES ACCOMPANYING IMPORTS

1. The representative of the competent authority of the third country of dispatch issuing a certificate to accompany a consignment of products of animal origin destined for the Community must sign the certificate and ensure that it bears an official stamp. This requirement applies to each sheet of the certificate if it consists of more than one. In the case of factory vessels, the competent authority may authorise the captain or another ship's officer to sign the certificate.

2. Certificates must be drawn up in the official language or languages of the third country of dispatch and the Member State in which the border inspection takes place, or be accompanied by a certified translation into that language or languages. If the Member State of destination so requests, certificates must also be accompanied by a certified translation into the official language or languages of that Member State. However, a Member State may consent to the use of an official Community language other than its own.

3. The original version of the certificate must accompany consignments on entry into the Community.

4. Certificates must consist of:

(a) a single sheet of paper; or

(b) two or more pages that are part of an integrated and indivisible sheet of paper; or

(c) a sequence of pages numbered so as to indicate that it is a particular page in a finite sequence (for example, "page 2 of 4 pages").

5. Certificates must bear a unique identifying number. Where the certificate consists of a sequence of pages, each page must indicate this number.

6. The certificate must be issued before the consignment to which it relates leaves the control of the competent authority of the third country of dispatch.