Annex 1

List of Attendees

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Annex 2

Workshop Agenda

MULTI-STAKEHOLDER WORKSHOP AGENDA
MINISTRY OF FISHERIES AND MARINE RESOURCES

Alte Brücke Hotel Conference Centre, 1 February 2005

Best implementable management approaches for molluscan shellfish safety in the Benguela region

0830 - 0845	Welcome and Introductions *(B. Currie)*
0845 - 0900	Opening by workshop Chair *(Director, E. Klingelhoeffer)*
0900 - 0930	The need for national shellfish safety programs *(B Currie)* Harmful Algal Blooms *(D. Anderson)* Sanitary and other regulatory requirements *(P. Anderson)*
0930 -1015	Present status of safety programs in South Africa, Namibia, Angola *(T. Probyn, D. Louw, I. Rangel)*
1015 – 1045	Tea
1045 -1130	Perspective from Industry – Angola, Namibia, and South Africa *(Industry representative from each country)*
1130 – 1215	Model Molluscan Shellfish Sanitation Ordinance *(B. Currie)* - Results oriented requirements and roles and responsibilities - The Competent Authority (integrated roles between agencies)
1215 – 1230	*moved to the afternoon: The role of SABS in the fish export program of Namibia *(S Seane)*
1230 – 1315	Questions and identification of critical issues for consensus decisions
1315 – 1415	Lunch (provided)
1415 – 1545	Discussions on identified issues
1545 – 1600	Consensus on best implementable management approaches

Annex 3

Working document for workshop participants

(Note – appendices to the working document are not included here)

WORKING DOCUMENT

MULTISTAKEHOLDER WORKSHOP:

BEST IMPLEMENTABLE MANAGEMENT APPROACHES FOR MOLLUSCAN SHELLFISH SAFETY IN THE BENGUELA REGION

SWAKOPMUND 1 FEBRUARY 2005

Outline of

THE REQUIREMENTS FOR A Proposed MODEL Shellfish Monitoring Programme for the Benguela Region

CONTENTS

Glossary of Terms

ADP	Approved Depuration Process
ASP	Amnesic Shellfish Poisoning
AZP	Azaspiracid Shellfish Poisoning
DSP	Diarrhetic Shellfish Poisoning
HAB	Harmful Algal Bloom
HPLC	High Performance Liquid Chromatography
LC-MS	Liquid Chromatography - Mass Spectrometry
M&CM	Marine and Coastal Management
MFMR	Ministry of Fisheries and Marine Resources
MPN	Most probable number
MSSC	The Molluscan Shellfish Safety Committee
NP	Non-point source of pollution
PCB	Polychlorinated biphenyl
PP	Pollution point
PSP	Paralytic Shellfish Poisoning.
PTX	Pectenotoxin
SABS	South African Bureau of Standards
YTX	Yessotoxin Shellfish Poisoning

1 INTRODUCTION TO SHELLFISH SANITATION PROGRAMMES

1.1 BACKGROUND

As they feed on microscopic plants and animals in the water, molluscan bivalves filter and ingest any particulate matter that happens to be in the growing areas. In coastal areas that are subject to sewage or faecal contamination, shellfish will concentrate bacteria, viruses and other potentially dangerous biological contaminants, and can make the consumer sick. There are many examples where consumers have contracted hepatitis, cholera, Norwalk Virus and other microbial diseases from the consumption of shellfish harvested in polluted waters. There is also strong evidence that shellfish can concentrate pollutants such as heavy metals, PCBs and other toxins when they are subject to the discharges from industrial areas. Since shellfish consumers expect their shellfish to be live and wholesome until they are cooked or ingested, there have been many specific regulations and procedures developed internationally to ensure that shellfish are harvested, handled, processed and shipped under appropriate conditions to ensure consumer safety.

Another risk to shellfish consumers is from blooms of toxic algae (termed harmful algal blooms or HABs) that are filtered from the water by the shellfish which then accumulate the biotoxins. Programmes to monitor for algal toxins in shellfish tissues have now been implemented in most shellfish-producing countries throughout the world, and are underway in the BCLME region. Because of the dual threat to consumers from algal toxins and microbial and other contaminants, HAB monitoring programmes are typically embedded within comprehensive shellfish safety programmes.

This outline has been prepared by the team working on the BCLME project "Harmonization of Regulations for Microalgal Toxins for Application in Countries Bordering the Benguela Current Large Marine Ecosystem" (EV/HAB/02/01) and ""Development of a Shellfish Sanitation Program Model for Application in consort with the Microalgal Toxins Component " (EV/HAB/04 SHELLSAN) as a workshop document for stakeholders in the BCLME region. The procedures outlined potentially provide operators with the necessary guarantees to foreign buyers, Governments and local consumers that the risk of disease and poisoning through consuming molluscan shellfish is adequately managed and minimized. The final guidelines with draft regulations are intended to produce a generic template that can be modified for use by individual countries so that the proposed programme complies with their legislation and government policies.

A shellfish sanitation programme should be internationally acceptable. Several economies around the world, including the EU countries, New Zealand, the US, recently South Africa, and others, have adopted shellfish sanitation programmes which have provided models for this proposed programme for the Benguela Region. The policies and procedures discussed cover the following components:

- Growing area classification for sanitary pollution
- Water quality monitoring
- Marine biotoxin management plans and contingency plans
- Processing, shipping and handling of live shellfish
- Laboratory methods for microbiological contaminants and marine biotoxins
- Enforcement of shellfish safety regulations

A Model Programme outlines:

- How shellfish and phytoplankton samples are to be collected, handled, transported, delivered to the laboratories, and analyzed for biotoxin and sanitary pollution,
- The procedures for reporting of results,
- The procedures for opening/closing production areas,
- The procedures for regulating the harvesting, processing and shipping of live bivalve molluscs.

Additionally (in sections 9 – 13) the procedures required for relaying, depuration and processing of molluscan shellfish, including preparation for sale as frozen of canned product, are outlined. Whilst such treatments may have limited scope or applicability in the Benguela region, provision of such procedures aligns a national programme internationally.

2 SCOPE AND AUTHORIZATION

A model programme addresses the public health concerns of live molluscan shellfish intended for immediate human consumption or for further processing before consumption. By definition the term “molluscan shellfish” as used in this document applies to all bivalve molluscs including Pectinidae as well as marine gastropods but excluding octopus and squid. (Where the word "shellfish" appears in the text, molluscan shellfish is meant).

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

The programme 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, labeling and storing of shellfish.

Included are the monitoring activities required for audit of growing areas and establishments in the interests of public health. These activities will be controlled by the recognized Competent Authority for each country in the BCLME region.

The programme addresses the requirements for the classification of shellfish growing areas and the control of harvesting, relaying, wet storage, depuration, transport and handling of live molluscan shellfish.

3 RULES

3.1 The definitions in Section 14 apply unless the context requires otherwise.

3.2 The Regulatory Authority authorizes the mariculture, harvesting, transport, relaying, depuration and wet storage of molluscan shellfish for wholesale trading in terms of the appropriate legislation. Authorizations are administered through the issue of appropriate permits or licensing of cultured or wild harvest. Land-based wet storage facilities and depuration plants must obtain appropriate approval from the appropriate relevant authority.

3.3 Establishments packing or processing molluscs (live, chilled, canned or frozen products) must also have the license/permit required by the Regulatory Authorities in co-operation with the Competent Authority. Each establishment must be licensed annually.

3.4 The Regulatory Authority may appoint official inspectors (e.g. Competent Authority inspectors, fisheries inspectors, observers, 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. The responsibilities of the inspector/officer need to be delineated in writing.

3.5 Where inter-government guarantees are sought (e.g. health certificate), the Competent Authority must have free access to records kept by the Regulatory Authority.

3.6 To enable proper liaison between the Regulatory Authority 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 The Regulatory Authority 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 and sanitary 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 officially-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 authorized marine farmer and includes as applicable the relayer, depuration plant, wet storage unit and establishment for 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 the Regulatory Authority 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 6.2.3.1 and 6.2.3.2

3.11 It is the Regulatory Authority's 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 microbial pollution will require detailed justification.

3.12 Once a growing area has been shown to conform to the approved area requirements (Paragraph 6.2.3.1) or that it may be utilized under certain conditions (Paragraph 6.2.3.2), a permit/license may be issued to the operator. The conditions for operation, harvesting, transport, relaying and marketing will be controlled through either regulation or permitting. [choose approach suitable for a particular country] All mariculture facilities must provide access and assistance to official staff for monitoring purposes as specified in Section 7.

3.13 Harvesting, handling and transport of molluscan shellfish by licensed operators shall be regulated as given in Section 8.

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 (e.g. prohibited areas) 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 the Regulatory Authority. The permit shall be specific for the particular depuration plant or relaying area. The requirements for the relaying of shellfish are given in Section 9. The layout and water quality required of depuration facilities must comply with the requirements given in Section 10.

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 11.

3.17 Requirements for dispatch centres and processing establishments are given in Sections 12 and 13 respectively.

4 STAKEHOLDERS

Stakeholders include: the Regulatory Authority, The Competent Authority, industry participants, and other government agencies with relevant roles and responsibilities.

Representatives comprise the Molluscan Shellfish Safety Committee (MSSC). The Molluscan Shellfish Safety Committee (MSSC) provides a national forum for all involved in the production and placing on the market of bivalve molluscs to discuss the safety of the product and the management of the industry from a consumer protection

perspective. The lead agencies together with Industry representation compose the Management Cell of the MSSC which will proactively manage the risk presented by marine biotoxins and other sanitary issues. The objective of the Management Cell is to facilitate rapid decision making in non-routine situations. This Management Cell need not be created immediately, but as the programme matures and accumulates data for growing area classification, it is recommended that a Management Cell be organized to assist with the interpretation of anomalous results. A description of the MSSC and the draft terms of reference are provided (as Appendix 1).

5 LEGISLATION

Appropriate legislation relevant to this draft ordinance in the three countries can be referenced in the two previous reports of BCLME project EV/HAB/02/01, report 1: "Review and assessment of existing policies and approaches regarding Harmful Algal Bloom management, marine water quality, and shellfish sanitation in Angola, Namibia and South Africa", and report 2: "A synthesis of requirements of various sectors of Governments and industry relating to microalgal toxins and other sanitary issues".

To summarize briefly: in all three countries legislation exists which in general terms ensures consumer safety for molluscan shellfish. In South Africa a fully fledged molluscan shellfish safety programme is nationally endorsed and run by M&CM, the Regulatory Authority. Compliance to the programme by shellfish producers is enforced through the permitting process. In Namibia the pertinent legislation has been promulgated in the Aquaculture Act. The Regulatory Authority MFMR has over the past year initiated a basic water quality monitoring programme but regulations detailing molluscan shellfish safety procedures are needed. In Angola pertinent legislation is presently contained in the Biological Aquatic Resources Act but specific regulations and monitoring for molluscan shellfish safety are needed.

6 CLASSIFICATION OF SHELLFISH GROWING AREAS

6.1 COMPLIANCE

Compliance with classification objectives shall satisfy the conditions listed below:

6.1.1 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.

6.1.2 The requirements for a sanitary survey apply to both near-shore and shore-based mariculture operations as well as wild harvest areas.

6.1.3 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 the Regulatory Authority shall decide on the sanitary classification of a growing area.

6.1.4 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 identified risks for a particular area and species.

6.1.5 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.

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

6.2 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

6.2.1 Establishing sampling stations:

Officials as specified in Paragraph 3.4 may be appointed by the Regulatory Authority to assist with sampling activities.

6.2.1.1 Land-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 6.2.3.1). If water is to be treated to conform to these requirements the microbial quality of source water, prior to disinfection, and re-circulated water shall meet, at a minimum, the restricted growing area standards (Paragraph 6.2.3.3). Water that does not meet the restricted area standards may not be used for mariculture (see section xx).

The location of sampling sites for phytoplankton or marine biotoxin is as described below (section 6.2.1.2).

6.2.1.2 Ocean-based cultivating/growing areas

The growing area survey in open waters shall take into account the proposed positioning of cultivation structures, or wild harvest sites, and potential pollution sources in accordance with these guidelines:

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.

c) 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.

6.2.2 Frequency of Sampling Required

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 the Regulatory Authority for the monitoring action required to classify the growing area or tank establishment. All points are to be included during one sampling operation.

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 Regulatory Authority-sanctioned personnel (Paragraph 3.4). Samples shall be taken at a fixed frequency (determined by the Regulatory Authority) 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. However, the farmer or harvester 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.

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 described in the sampler's report.

Microbiological samples shall be taken once every two weeks from each sampling point for both provisional and full classification of a growing area.

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.

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 the Regulatory Authority) is not available in a new growing area water samples are analyzed 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.

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 the Regulatory Authority.

6.2.2.1 Sampling protocol for microbiological parameters of production waters and products

Water must be sampled to the satisfaction of the Competent Authority. In South Africa and Namibia this is described in the latest version of SABS 241 (see Appendix II) 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. E..coli (Donovan method) will be required by EU as from 2006

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.

Sampling procedures for microbiological parameters are summarized in Appendix III.

6.2.3 CLASSIFICATION OF GROWING AREAS

6.2.3.1 Approved areas

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.

As a water sampling scheme may miss occasionally excessively polluted events, it is preferable for shellfish (culture species or alternative, see section 6.2.2) 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.

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.

6.2.3.2 Controlled areas (conditionally approved or restricted):

6.2.3.2.1 Conditionally approved area

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.

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.

A management plan shall be developed for conditionally approved areas that addresses the predictability of the pollution events (See Appendix IV).

6.2.3.2.2 Restricted areas

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 unfavorable 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

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, the Regulatory Authority 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.

6.2.3.2.3 Prohibited areas

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 for restricted areas (6000 coliforms/100g. flesh)
- 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.

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.

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.

6.2.4 Toxic and hazardous substance parameters for shellfish products

6.2.4.1 Limits for environmental toxins

The limits for toxins such as heavy metals, radio-active substances (Cesium 134 and 137), polychlorinated biphenyls and pesticides will be those described in terms of the current legislation in each country. These limits apply to the fresh weight, edible portion of the shellfish.

6.2.4.2 Limits for biotoxins

The recommended methods for shellfish toxicity tests are given in Appendix V. 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) and related lipophillic toxins (e.g. AZP, YTX, PTX) - Not detectable using the mouse bioassay (2 out of 3 mice dead within 24 hours) or chemically Okadaic Acid , PTX, DTX - 160 ug/kg; YTX - 1mg/kg; for azaspiracids -160ug/kg.
- Amnesic shellfish poisoning (ASP) - 20 mg domoic acid/kg edible flesh

6.2.4.3 Limits for veterinary drugs

The limits for veterinary medicines must comply with the health regulations of the country. Limits are given in South Africa and Namibia in the current Foodstuffs Cosmetics and Disinfectants Act (No. 54 of 1972)

7 MONITORING OF SHELLFISH PRODUCTION AREAS

7.1 BACKGROUND

A system of sanitary checks will be initiated under the guidance of the Regulatory Authority for each approved and controlled growing area (including both natural and artificial areas used for mariculture, wild harvest 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 regulatory requirements concerning microbiological quality (Section 6.2.3), toxic and hazardous substances (Paragraph 6.2.4) and biotoxins (Paragraph 6.2.4.2) 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).

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.

It will be the responsibility of the Regulatory Authority 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.

The sampling and analysis effort required for classification and monitoring represents a significant commitment of personnel and financial resources. In practice, many countries share these costs and responsibilities between government and industry. For

example, the government may cover the costs of classification of growing areas, but the industry would bear the costs of ongoing monitoring at their facilities (sample collection, transport and laboratory analysis). Alternatively, the industry may need to bear all of the costs of the classification and monitoring phases of the programme. Any final version of this draft ordinance should specify how these sampling and analysis costs are to be apportioned.

7.2 MICROBIOLOGICAL MONITORING

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.

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 6.2.xx). 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.

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 6.2.1.2) stations.

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 the Regulatory Authority, 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
- Conduct appropriate follow-up sampling for biotoxin and sanitary pollution

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.

Where a growing area at any time does not comply with the sanitary requirements of its designated classification (Paragraph 6.2.3.1 or 6.2.3.2) the following actions must be undertaken by the Regulatory Authority in collaboration with the relevant Health authorities:

- 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 of the classification assigned to the growing area is called for when sampling indicates an area continues to exceed its current classification limits.

Where an end of the line product fails to satisfy the microbiological criteria for human consumption, actions must be taken (e.g flow diagram, Appendix IV)

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

If the problem is not identified as related to handling, distribution and labeling, the course of actions given above in this section come into effect for the implicated growing area.

Microbiologically contaminated products may also be canned or cooked and frozen as per requirements in Section 13, 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 the Regulatory Authority.

7.3 MONITORING OF TOXIC AND HAZARDOUS SUBSTANCES

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.

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.

7.4 BIOTOXIN MONITORING

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 Molluscan Shellfish Safety Committee (see Section 4).

7.4.1 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”. Considering the apparent global trend of expanding distributions of toxic algal species, the Regulatory Authority will be actively involved in efforts to fully characterize existing as well as newly emerging toxic species and toxins.

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.

7.4.1.1 Routine monitoring phase

To be conducted uniformly year round unless there is justification (i.e., no harvesting) that a seasonal monitoring plan is sufficient.

In ocean-based harvest areas, water samples for phytoplankton analysis should be collected weekly/biweekly and delivered to the Regulatory Authority for phytoplankton identification and enumeration.

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

Shellfish samples for each species being harvested or intended for next harvest from each growing area will be collected appropriately for toxin analysis. Where justified by historical data, analysis of a sentinel species may sufficient for regulatory decisions for other species in the growing area. A composite sample of a single species of shellstock is to be taken. The frequency of sampling may be reduced in specific areas or for specific species of molluscs if a risk assessment on historical toxin or phytoplankton occurrence suggests a low risk of toxic episodes.

Certain growing areas regarded as high risk may be required to test for biotoxins more frequently than specified.

7.4.1.2 Intensive sampling phase

To be initiated following detection of biotoxins in shellfish meats, though still below regulatory limits (Paragraph 6.2.4.2).

Intensive sampling (intensity determined by the usage of the shellfish) will be determined by various factors:

- history of contamination of the growing area with specific biotoxins

- toxic phytoplankton are present in the absence of shellfish intoxication. With experience it may prove feasible to apply a critical concentration for a particular toxic species as the criterion for initiation of intensive sampling.

Routine sampling will be re-established when biotoxin levels are undetectable for 2 consecutive samples.

7.4.1.3 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 other lipophillic toxins) and ASP are given in Paragraph 6.2.4.2.

The Regulatory Authority will place a ban on harvesting in the area.

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

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

The Regulatory Authority inspectors will ensure the embargo is maintained.

The frequency of testing of shellfish meats will be at the Regulatory Authority's discretion in consultation with the farm managers.

7.4.1.4 Re-opening phase

A shellfish growing area closed due to biotoxins will only be re-opened to harvesting when the Regulatory Authority 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 2 consecutive samples taken at least 48 hours apart. Information regarding detoxification kinetics for individual shellfish species 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 2 consecutive samples.

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

8.1 HARVESTING REQUIREMENTS

No person shall harvest, handle or transport shellfish for human consumption except according to the requirements and conditions stipulated by the Regulatory Authority.

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

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.

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).

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.

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

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.

8.2 TRANSPORT AND VESSELS

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

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

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.

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

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.

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

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

8.3 DOCUMENTATION AND RECORDS

A movement document issued by the Regulatory Authority 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.

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, the Regulatory Authority 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.

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

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.

The Regulatory Authority shall keep a copy on file of all completed movement documents issued for a minimum of 2 years.

9 REQUIREMENTS FOR RELAYING OF SHELLFISH

9.1 CONDITIONS

(DO COUNTRIES OF THE BENGUELA WANT THE OPTION OF DEPURATION AVAILABLE? CONSULT WITH STAKEHOLDERS).

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.

Relaying operations must be supervised by a Regulatory Authority inspector or duly authorized official.

Relaying areas must be authorized by the Regulatory Authority as for a mariculture operation. Harvesting of shellfish for relaying may only be undertaken with authorization from the Regulatory Authority. Permits shall be valid for 1 year.

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

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

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.

9.2 SOURCE OF SHELLFISH

No shellfish that exceed the contaminant levels for restricted areas (Paragraph 6.2.5) may be relayed.

Live shellfish must be gathered and transported in accordance with Section 8.

Shellfish intended for relaying must be accompanied by a movement document (Paragraph 8.3.) The conditions of Section 8.3 apply.

9.3 RELAYING AREAS

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

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

9.4 OPERATING PROCEDURES

Each relayer must develop written operating procedures in consultation with the Regulatory Authority, 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.

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.

The microbiological concentrations in the shellfish shall meet the approved criteria (Paragraph 6.2.4), and biotoxins less than the limits given in Paragraph 6.2.4.2 at the end of the relaying process.

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

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.

Batches of live shellfish harvested in a relaying area must be accompanied by a movement document (Paragraph 8.3) during transport to a dispatch centre or processing plant.

9.5 RECORDS

Relayers shall be required to keep complete and accurate records for inspection by the Regulatory Authority. 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

The Regulatory Authority 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.

10 DEPURATION

(DO COUNTRIES OF THE BENGUELA WANT THE OPTION OF DEPURATION AVAILABLE? CONSULT WITH STAKEHOLDERS).

10.1 CONDITIONS

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.

All operations harvesting shellfish for delivery to a depuration plant must be issued with a separate permit by the Regulatory Authority.

Each depuration plant shall be certified by the local authority as for food premises in terms of [insert appropriate legislation]. Certification of depuration plants shall require:

- Approval of plant design, construction and operation
- Verification of the depuration process by the operator.
- Certified depuration plants are to be inspected at least monthly to assure compliance of operating procedures.

The Regulatory Authority shall analyze plant processing data and other records at least monthly to verify the process and controls are sufficient to meet the end product criteria.

10.2 PROCESS VERIFICATION

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 6.2.xx).
- 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

10.3 SOURCE OF SHELLFISH

Only shellfish that meet the requirements for restricted areas (paragraph 6.2.3.3.2), at a minimum, may be harvested for depuration. The acceptable pre-purification levels of faecal contamination shall be established as part of the ADP.

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

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

Shellfish intended for depuration must be accompanied by a movement document (Paragraph 8.3).

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

Should a purification tank contain several batches of live bivalve molluscs, they must be of the same species and the length of treatment must be based on the time required by the batch needing the longest period of purification.

10.4 STRUCTURAL REQUIREMENTS

The construction of floors, walls, ceilings (where provided) and installation of lighting, plumbing and sewage disposal systems must comply with the provisions of the [insert appropriate legislation].

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

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 sanitizing to prevent contamination of the tanks and water.

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.

The site, facility and plant shall be evaluated and approved annually by the Regulatory Authority in conjunction with the Competent Authority and relevant Health authority, taking into account the records of water officially tested.

10.5 PROCESS WATER QUALITY AND OPERATION

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.
- 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.
- The minimum depuration time is 48 hours.
- Different lots of shellfish must not be mixed in order to preserve identity and integrity.
- After completion of purification, the shells of the live shellfish must be washed with clean seawater or potable water and damaged individuals culled.

10.6 SANITATION OF SYSTEMS

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

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

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

- Process units, trays, containers and racks shall be cleaned, sanitized and rinsed before each depuration operation.
- The process unit including the system piping network shall be cleaned, and where possible, sanitized after each batch.
- The seawater storage tanks shall be cleaned and sanitized on a regular basis.
- The washing, culling, sorting and pre-process storage areas shall be thoroughly washed and sanitized after each use.

10.7 QUALITY ASSURANCE

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.

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 6.2.3.1).

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

In the event of a process batch failing to meet the release criteria, the operator shall notify the Regulatory Authority 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 Competent Authority as relevant:

- Destruction of the shellfish
- Non-food use of the shellfish
- An additional depuration cycle
- Modification of the ADP

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.

10.8 RECORDS

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.

The Regulatory Authority 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.

11 WET STORAGE

11.1 CONDITIONS

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

Wet storage premises must be certified by the local authority as for food premises in terms of [insert appropriate legislation for each of the 3 countries]. Wet storage sites or facilities must undergo an annual evaluation by the relevant Health authority in co-operation with the Regulatory Authority. 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 remodeling.

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.

11.2 SOURCE OF SHELLFISH

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

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

Shellfish from different harvest areas shall be wet stored separately.

Shellfish intended for wet storage must be accompanied by a movement document (Paragraph 8.3)

11.3 STRUCTURAL AND DESIGN REQUIREMENTS

The construction of floors, walls, ceilings (where provided) and installation of lighting, plumbing and sewage disposal systems must comply with the provisions of the [insert appropriate legislation for each country].

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

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 sanitizing to prevent contamination of the tanks and water.

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.

The site, facility and plant shall be evaluated and approved annually by the Regulatory Authority in conjunction with the Competent Authority and relevant Health authority, taking into account the records of water officially tested.

11.4 WATER QUALITY

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

Near-shore areas for wet storage must meet the approved or conditionally approved criteria (Paragraphs 6.2.3.1 or 6.2.3.2.1).

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.

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.

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 6.2.4).

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.

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

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.

The treatment process shall not leave any residues that are not “Generally Recognized As Safe” (GRAS) or that may interfere with the process.

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.

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.

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

11.5 RECORDS

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).

Live shellfish shall be labeled as described in Paragraph 12.2 during transport and distribution until retail sale.

12 REQUIREMENTS FOR DISPATCH CENTRES

12.1 RECEIVING AND STORAGE

Dispatch centres must be certified according to [insert appropriate legislation for each country] and must be inspected at least once annually and approved by a Competent Authority inspector or relevant Health official.

The premises and hygienic standards must comply with the [insert appropriate legislation for each country].

Only batches of live shellfish accompanied by a movement document (Paragraph 8.3) shall be accepted at a dispatch centre. Shellfish must have been harvested and transported according to the requirements outlined in Section 8.

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.

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.

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

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

12.2 MARKING OF CONSIGNMENTS AND RECORDS

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 labeling requirements specified by [insert any appropriate legislation for each country] or importing country regulations:

- Dispatch establishment number, name and address.
- Date of harvest (year, month, day)
- Date of packaging (year, month, day) 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 [insert country of origin].

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

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.

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 this section, details of the original dispatch centre and re-packaging details.

12.3 TRANSPORT FROM A DISPATCH CENTRE

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

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.

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.

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

13 CANNING OR COOKING AND FREEZING

13.1 REQUIREMENTS FOR PROCESSING ESTABLISHMENTS

Processing may only be conducted in establishments issued with a permit by the Regulatory Authority in terms of the [insert appropriate legislation for each country]. Permits are subject to prior certification by the local Health authority or the Competent Authority.

Where any processing is conducted (such as shucking, cooking, freezing, canning, etc.), the premises must comply with the requirements in terms of the [insert appropriate regulations, *e.g. SABS Compulsory Specification for the Manufacture, Production, Processing and Treatment of Canned Fish and Canned Marine Molluscs*].

Only batches of live shellfish accompanied by a movement document (Paragraph 8.3) shall be accepted at a processing establishment. Shellfish must have been harvested and transported according to the requirements of this manual.

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 outlined in Section 8.

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 (IS THIS REASONABLE? CONSULT WITH STAKEHOLDERS).

Abalone shall be kept alive until immediately before processing.

Canning in hermetically sealed containers:

> Shellfish may be subjected to sterilization in hermetically sealed containers at a canning factory approved by the Competent Authority and under supervision of inspectors of that Competent Authority. 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 appropriate legislation in each country (*e.g. SABS Compulsory Specification for the Manufacture, Production, Processing and Treatment of Canned Fish and Canned Marine Molluscs).*

13.2 COOKING, COOLING, PACKING AND FREEZING

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 [insert appropriate specifications, *e.g. SABS Compulsory Specification for the Manufacture, Production, Processing and Treatment of Canned Fish and Canned Marine Molluscs*]. 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.
- 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 [insert appropriate specifications, *e.g. 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 [insert appropriate specifications].
- The product shall comply with the microbiological standards for cooked frozen marine molluscs specified in the [insert appropriate specifications].

14 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 unfavorably 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 the Regulatory Authority 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, authorized by the Regulatory Authority in accordance with paragraph 6.2. An approved area may be temporarily closed to harvesting, e.g. when a flood, storm or marine biotoxin event occurs.

Bioassay:

Measurement of the concentration or potency of a substance by its effect on living cells or tissues.

Central file:

The file system maintained by the persons responsible for management of this programme at the Regulatory Authority.

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.

Competent Authority:

The central authority competent for the organization of official controls or any other authority to which that competence has been conferred.

Conditionally approved area:

The classification by the Regulatory Authority 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 the Regulatory Authority for a specific cultivation area, relaying area, depuration plant or harvester. The establishment number for packaging and processing is obtained from the Competent Authority.

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 [insert appropriate legislation for each country].

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 these guidelines 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 algae or cyanobacteria, or on seawater containing toxins produced by such organisms.

Molluscan Shellfish:

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

Molluscan Shellfish Safety Committee (MSSC):

A group that provides a national forum for all involved in the production and placing on the market of bivalve molluscs to discuss the safety of the product and the management of the industry from a consumer protection perspective.

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.

Product recall:

The removal of unsafe food from the distribution chain extending to food sold to consumers and therefore involving communication with consumers.

Product withdrawal:

The removal of unsafe foodstuff from the distribution chain not extending to food sold to the consumer.

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.

Regulatory Authority:

An independent third party that the Competent Authority has delegated certain control tasks.

Restricted area:

A growing area classified by the Regulatory Authority 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 the Regulatory Authority 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 6.2 of this manual, by a Regulatory Authority-approved party, of all actual and potential pollution sources and environmental factors that may affect shellfish growing water quality.

Shellstock:

Shellfish in the shell.

Shoreline Survey:

A survey of the shoreline of the growing area catchment conducted by an officer authorized by the Regulatory Authority 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.

LIST OF APPENDICES

SPECIFICATIONS FOR SAMPLES

Species: (listed per country, scientific name)

Amount (number/weight)

RESPONSIBILITY & COSTING

Sampling

Transport of samples to analytical laboratory

Analyses

Reporting

Inspecting

Annex 4

Welcome and Introductory remarks

The following text contains some of the comments made by *Eckard Klingelhoeffer*, Director of Aquaculture (Namibia) and Chair of the workshop.

"Good morning.

We are meeting today to discuss issues critical to the future development of the shellfish industry in South Africa, Namibia, and Angola. We have convened a group representing regulators, industry, and academic scientists with the goal of achieving a consensus on actions and policies related to marine biotoxins and the sanitary safety of shellfish.

We all know that the Benguela Current system brings extraordinary richness to our coastal waters, and that there is therefore great potential for a vibrant aquaculture industry in this region, particularly for filter-feeding molluscs. However, there are risks associated with consumption of these shellfish - risks that are recognized throughout the world, and for which many countries have established monitoring and management programs. In the case of Angola and Namibia, these programs are essentially non-existent, whereas South Africa is making rapid strides towards an internationally accepted program.

A shellfish sanitation program has many elements that require close cooperation between government regulators and industry. Some of the actions and policies within a sanitary program will necessitate changes in the way we presently do business. For example, shellfish processing facilities need to meet strict hygiene requirements, and some within this country, at least, presently do not. The regulators will also have to change the way they do business by improvements in inspection, rapid reaction to events, and so forth.

We are talking about programs with significant costs to both industry and government. These include short-term start up costs and long-term monitoring and analysis expenses. It is generally the norm for these costs to be shared in some way between government and industry. One of the issues to be discussed today is the extent to which costs should be shared.

In that context, one must consider the "do nothing" option - i.e., to implement no programs

whatsoever. The cost of such a policy is not zero, however, but could be huge due to the loss of access to markets throughout the world, the possibility of human illness and death at home, and tarnishment of the reputation of the shellfish industry and other seafood related businesses. Even a single poisoning event can have far-reaching negative effects that could devastate a fledgling aquaculture industry.

I can speak for Namibia in stating that the development of a shellfish aquaculture industry is a major national priority, and therefore that the implementation of an internationally accepted shellfish sanitation program is also a priority.

Today's agenda begins with short presentations about harmful algal blooms, shellfish sanitation policies, and the status of national programs within the region. A model molluscan shellfish sanitation ordinance will also be presented. There will be ample opportunity for industry representatives to voice their perspectives and concerns, and to participate in a dialogue about the proposed ordinance. We hope to move from here to a consensus on best-implementable management approaches, harmonized across the three BCLME countries. "

Annex 5

The need for national shellfish safety programs

Bronwen Currie, Ministry of Fisheries and Marine Resources
Swakopmund, Namibia

"Harmonization of Regulations for Microalgal Toxins for Application in Countries Bordering the Benguela Current Large Marine Ecosystem" (EV/HAB/02/01)

"Development of a Shellfish Sanitation Program Model for Application in consort with the Microalgal Toxins Component" (EV/HAB/04 SHELLSAN)

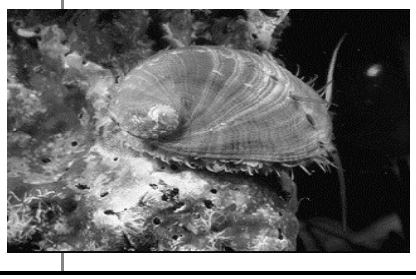
***A* Molluscan shellfish Safety programme provides for a special class of seafood that is normally**

- **sold live**
- **eaten raw**

This class of seafood e.g. mussels, oysters, clams, abalone, and others, have the unfortunate ability to concentrate in their bodies, any harmful substances which may be present in the water where the shellfish are growing.

Oyster production

scallops



Abalone

These harmful substances may occur

- naturally
  e.g. toxic Harmful Algal Blooms
- from pollution of the seawater
  e.g. faecal matter, industrial effluent

CONSUMER SAFETY is therefore a concern for

Domestic harvesting and consumption

Domestic marketing

Regional trade within the Benguela Region

Export to other countries

Legal responsibility of the country

Globally, programmes to protect consumer safety for molluscan shellfish are increasingly implemented

If the countires of the Benguela are to maintain their reputation as top-quality seafod suppliers, a shellfish safety programme which ensures producton of shellfish along healthy and sustainable prodcedures, is called for.

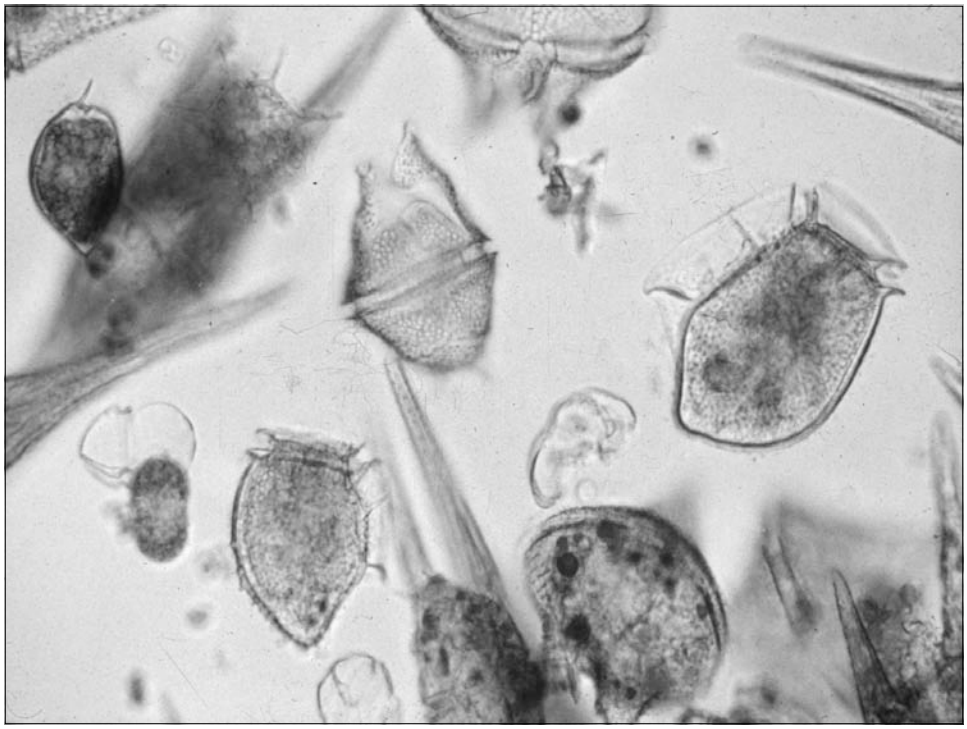
Annex 6

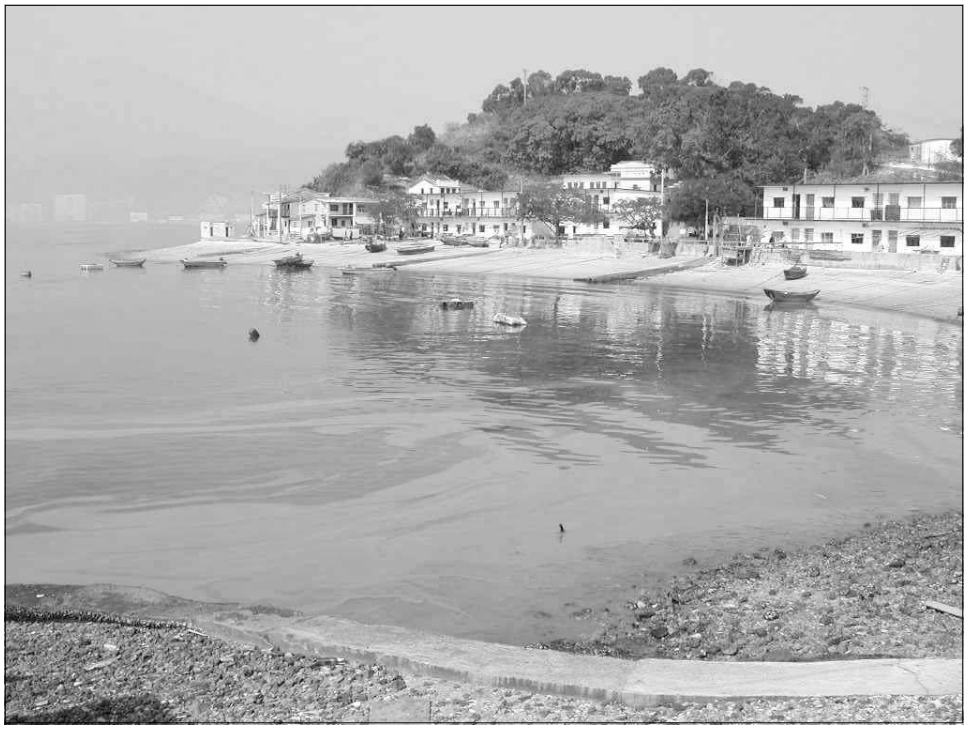
Red Tides and Harmful Algal Blooms (HABs): Issues related to management and monitoring

Donald M. Anderson, Senior Scientist, Biology Department, Woods Hole Oceanographic Institution, Woods Hole, MA, USA

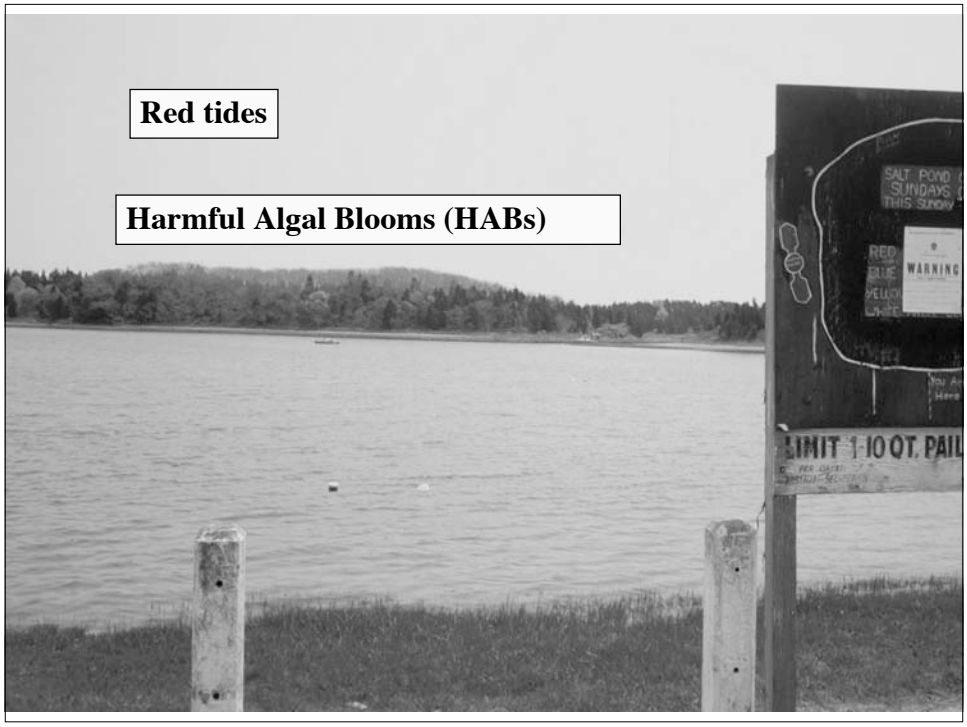
Red Tides and Harmful Algal Blooms (HABs): Issues related to management and monitoring

Donald M. Anderson
Senior Scientist, Biology Department
Woods Hole Oceanographic Institution





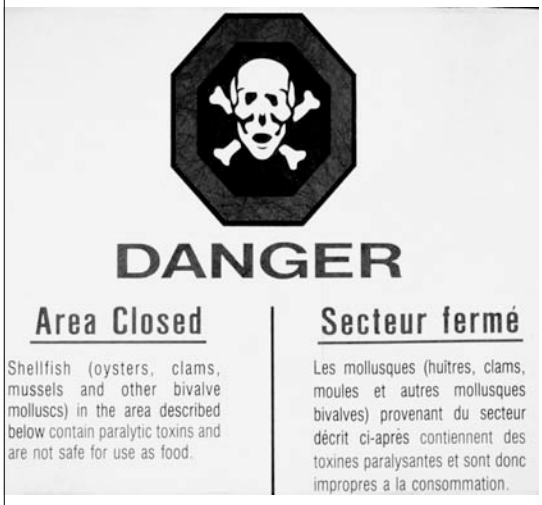

Aloft Inc. Aerial Photography



TYPES OF HAB IMPACTS

- **Paralytic Shellfish Poisoning (PSP)**
- **Neurotoxic Shellfish Poisoning (NSP)**
- **Amnesic Shellfish Poisoning (ASP)**
- **Diarrhetic Shellfish Poisoning (DSP)**
- **Azaspiracid Shellfish Poisoning (AZP)**
- **Ciguatera Fish Poisoning (CFP)**
- **Brown tides**
- **Fish mortalities** (wild and farmed)
- **Pfiesteria** (fish kills & poorly characterized human health effects)
- **Other faunal mortalities** (dissolved oxygen)
- **Noxious blooms** (aesthetics)
- **Macroalgal blooms**
- **Freshwater toxins** (drinking water, recreation)

Paralytic Shellfish Poisoning (PSP)



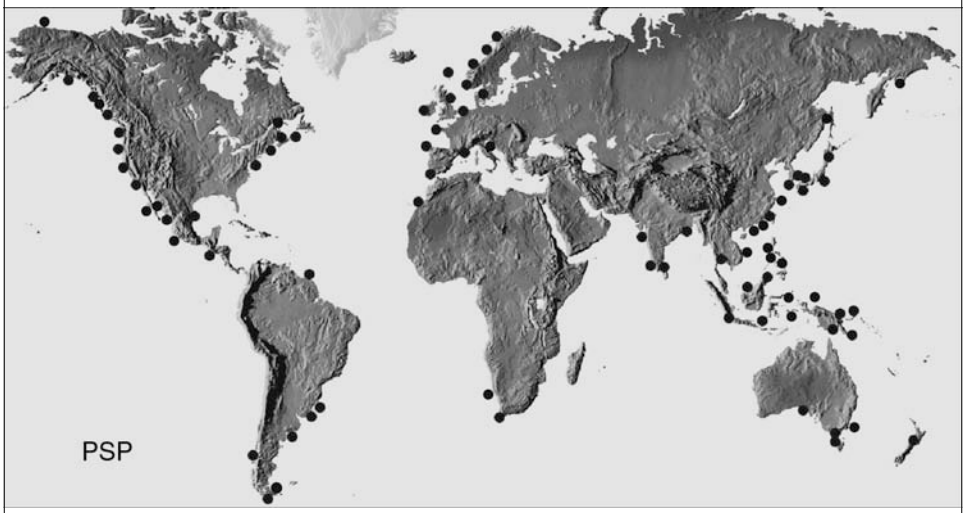
DANGER

Area Closed

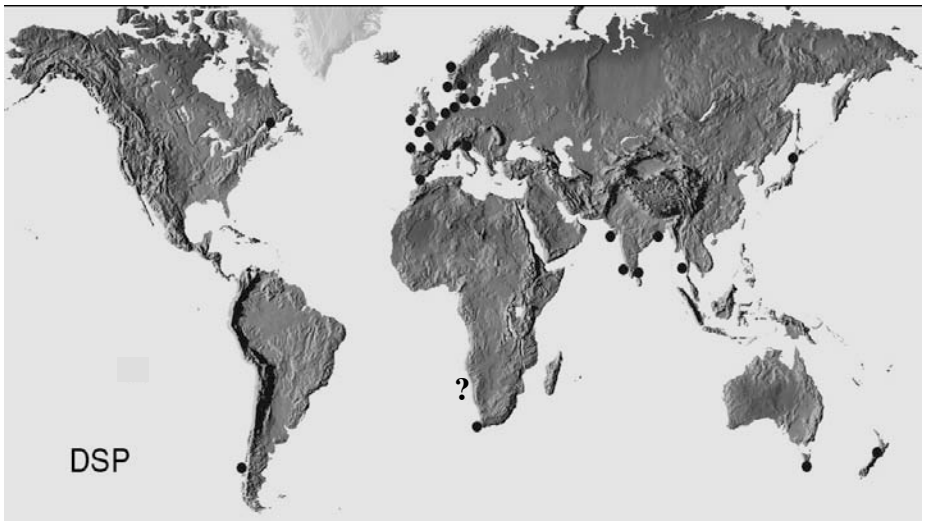
Shellfish (oysters, clams, mussels and other bivalve molluscs) in the area described below contain paralytic toxins and are not safe for use as food.

Secteur fermé

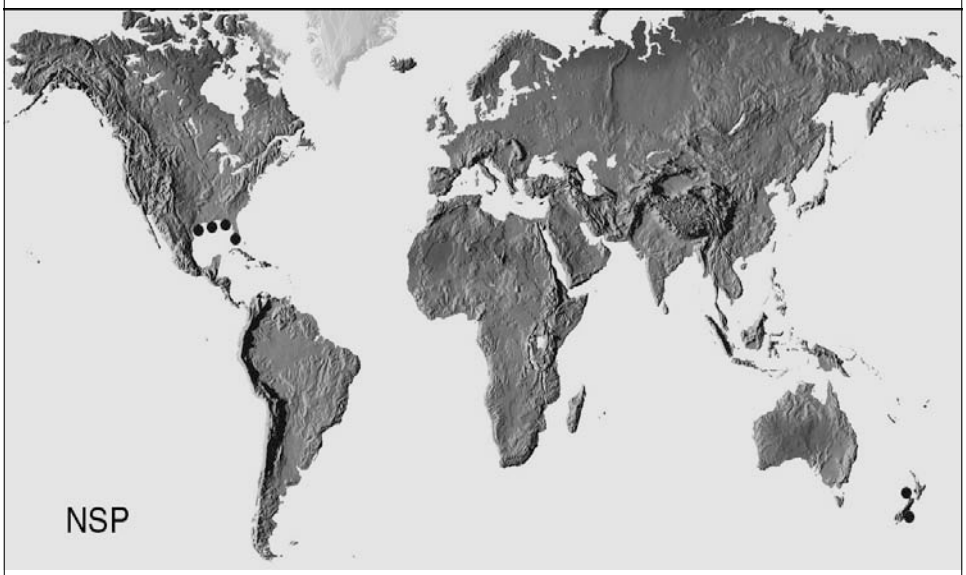
Les mollusques (huîtres, clams, moules et autres mollusques bivalves) provenant du secteur décrit ci-après contiennent des toxines paralysantes et sont donc impropres a la consommation.


PSP

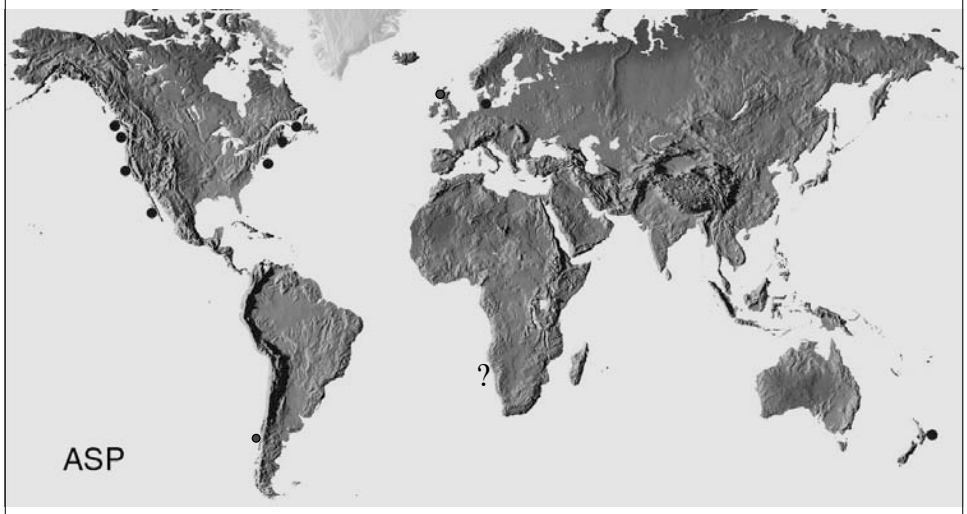
Diarrhetic Shellfish Poisoning (DSP)



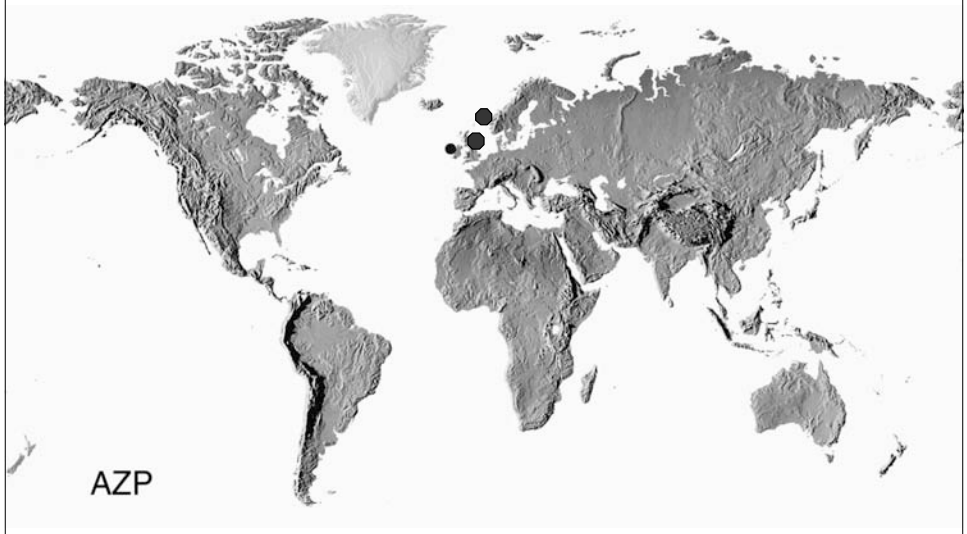
Neurotoxic Shellfish Poisoning (NSP)



Amnesic Shellfish Poisoning (ASP)



Azaspiracid Shellfish Poisoning (AZP)



TYPES OF HAB IMPACTS

- **Paralytic Shellfish Poisoning (PSP)**
- **Neurotoxic Shellfish Poisoning (NSP)**
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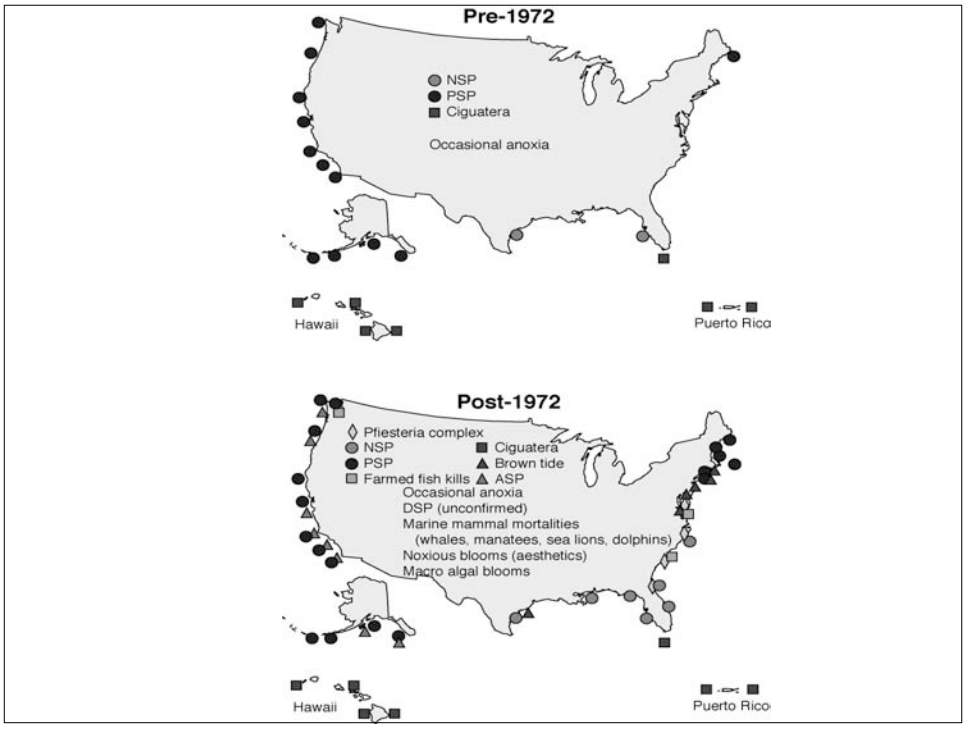
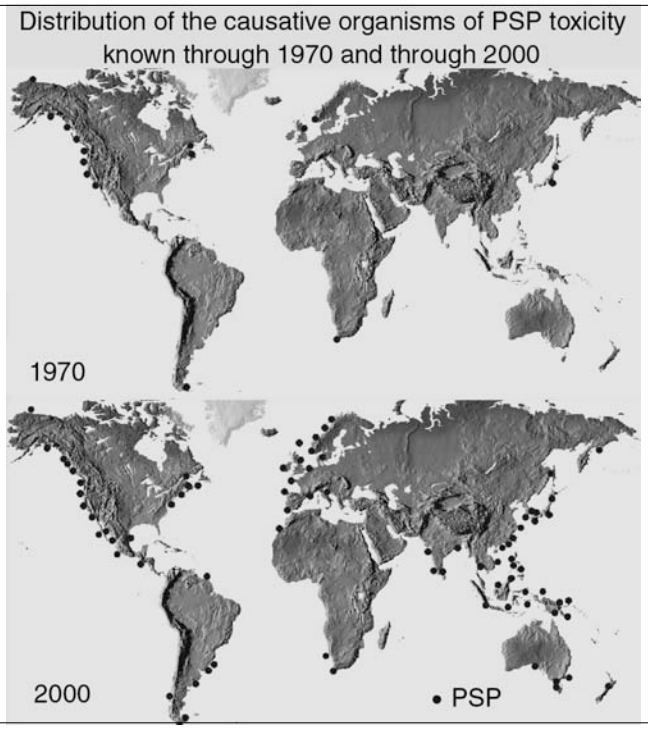
- **Azaspiracid Shellfish Poisoning (AZP)**

Trends in HAB incidence





Monitoring and management challenges

Countries with HAB exposure need to:

1) **Protect public health**
2) **Protect existing and developing fisheries industries (capture and mariculture)**
3) **Protect import and export industries**
4) **Protect tourists, residents, & tourist industry from toxic and noxious blooms**
5) **Protect ecosystem resources**

HAB Monitoring and Management Programs

Necessary elements:

1) Monitoring program for HAB toxins (many vectors, many toxins)

2) Monitoring program for HAB cells

3) Environmental monitoring/sanitation

4) Regulatory legislation (restrict harvesting, prohibit sales, certification of imports & exports, …….)

5) Communications network

6) Action plans for affected sectors, agencies

7) Mitigation strategies

8) Public information campaign

9) Analytical capability

10) HAB research program

Annex 7

Sanitary and other regulatory requirements

Paul Anderson, Maine Sea Grant Program
Orono, ME, USA

Shellfish Safety Programs

Multi-stakeholder Workshop

BEST IMPLEMENTABLE MANAGEMENT APPROACHES FOR MOLLUSCAN SHELLFISH SAFETY IN THE BENGUELA REGION

February 1, 2005
Swakopmund, Namibia

Regulatory programs for shellfish safety General components

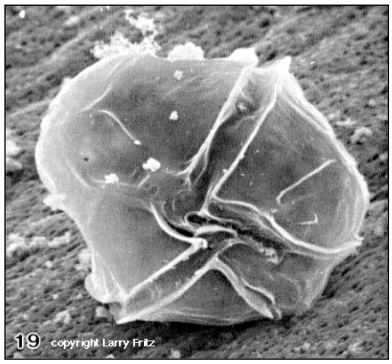
- **Monitoring of growing areas**
- **Laboratory analyses**
- **Data analysis and interpretation**
- **Regulatory action**
- **Surveillance of shellfish market**
- **Sampling for re-opening of areas after HAB event**
- **Tagging or marking of shellfish during shipment**
- **Shipping conditions – sanitary and refrigerated**

Shellfish Sanitation Issues

- Foundation for a HAB monitoring program
- Fecal contamination from sewage and non-point sources
- All harvested growing areas must be monitored
- Shoreline survey for potential pollution sources
- Risk analysis – Sanitary Survey
- Classification of area for harvest
- metals and other toxic pollutants

HAB Monitoring Program

- **Assess known HAB presence in the region**
- Past illnesses
- Historic information
- Oceanographic information

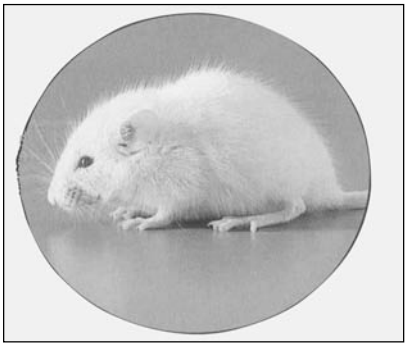


HAB Monitoring Program (cont.)

- **Shellfish toxicity**
- Sample from growing areas (agency or industry)
- Market samples
- Laboratory analysis using approved methods for various target toxins
- Data analysis and determination of regulatory action
- Close harvest areas and/or seize product
- Repeat sampling for re-opening of growing area
- Develop predictive capability if possible

Laboratory Analysis for Biotoxins

- **Biological Methods:** Mouse Bioassay: with various sample preparation and extraction methods for different biotoxin types, Receptor Binding Assays
- **Chemical Methods:** including HPLC,, Phosphatase inhibition assay
- **Immunological Methods:** ELISA, RIA,



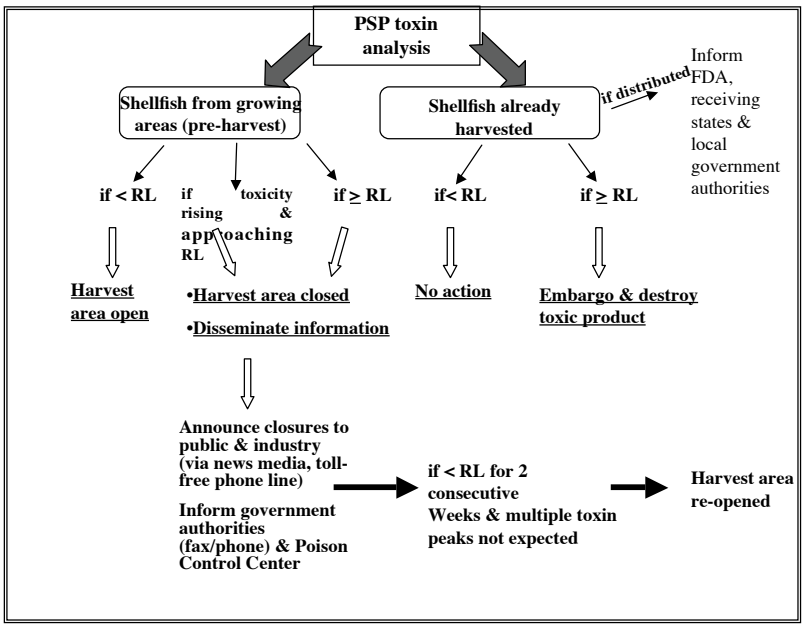
HAB Monitoring Program (cont.)

- **Phytoplankton Monitoring**
- **Agency or industry participation**
- **Weekly samples with plankton nets and microscopic analysis**
- **Species identification to inform shellfish analysis for toxins**
- **Generally qualitative observations rather than quantitative**

Post-harvest Handling

- Shucking
- Handling
- Clean conditions
- Potable water source
- Proper packing
- Time and Temperature
- Transportation
- Wet storage
- Depuration

FIGURE 17. Action plan for the shellfish monitoring program in the state of Maine, Atlantic U.S.A. (see text for details). RL = regulatory safety level = 80μg STXeq100g^{-1}.



Domestic Regulatory authority

- **Authority to close areas to harvest**
- public health or marine resource agency
- **Intention to limit/control pollution**
- environmental agency
- **Enforce closures, seize and embargo product**
- signage, public education
- environmental police or marine resource agency
- **Monitoring of consumer and domestic issues**
- seafood dealers and restaurants
- medical community
- public health agency

Interagency Cooperation

- **Identify cooperating agencies with complementary missions and assign roles formalized with an MOU**
- **Communication of laboratory res from laboratories to regulators a industry**
- **E.g. South Africa:**
  - **Sea Fisheries**
  - **Department of Health**
  - **Food Inspection Division of SABS**
  - **Department of Trade and Industries**

Annex 8

Background to the development of the South African shellfish sanitation programme

Trevor Probyn, Marine and Coastal Management
Cape Town, South Africa

BACKGROUND TO THE DEVELOPMENT OF THE SA SHELLFISH SANITATION PROGRAMME.

- **1994 – A consignment of mussels to Italy was rejected on the basis of biotoxin levels (DSP).**

  Officials from SABS and the Fishing Industry Research Institute (FIRI) visited Italy to investigate and ratify the claim. It was identified that the method employed in SA for testing for DSP was not in accordance with EU recommendations.

- **1995 – Inspectors from the EU Commission in Brussels visited SA to assess the SA system of regulation and inspection. They identified shortcomings in the system of molluscan shellfish sanitation, particularly with regard to:**
  - **i) lack of official regulations.**
  - **ii) Frequency of plankton monitoring.**
  - **iii) Poorly-defined procedures for regulating harvesting during a public health emergency. The situation of self-regulation by the industry was unacceptable.**

- **1996 – Commission Decision 96/607/EC recognized the SABS as the competent authority for verifying and certifying compliance of fishery products with the requirements of Directive 91/493/EEC. This decision authorized the SABS to provide guarantees for fish <u>other than bivalve molluscs (including echinoderms, tunicates and gastropods).</u>**

- **After in-depth discussions between the SABS, the Dept of Agriculture, the Mariculture Association of SA (including AFASA) and M&CM, it was decided that M&CM would be responsible for coordinating the monitoring of water quality in molluscan shellfish growing waters.**

- **1997 – A number of meetings were held with M&CM, SABS, Dept of Health, the DTI, the mariculture industry and Onderstepoort Veterinary Institute. This led to the initiation of the Molluscan Shellfish Monitoring and Control Programme for SA.**
- **Funding application submitted to Sea Fisheries Advisory Committee. The application was not approved on the grounds that such funding should come from the user groups. MASA - Existing exports are to non-subscribers of EU/FDA requirements – hence little interest in providing funding.**

- **1998 – Regulations specific to mariculture were promulgated in terms of the Marine Living Resources Act No. 18. These regulations, however, do not explicitly address public health concerns related to shellfish.**

- **M&CM produced new permit conditions for shellfish mariculture that provided more detail on monitoring requirements for growing waters. M&CM would administer these results and enforce closures when necessary.**

- **2001 - Industry interest in expanding imports to include the EU. Renewed need to have the programme officially sanctioned by the EU and the ban lifted.**

  Funding was sourced from the DTI and industry through the Sector Partnership Fund (Sept 2001) – employed a Shellfish Sanitation Manager and 2 technical assistants.

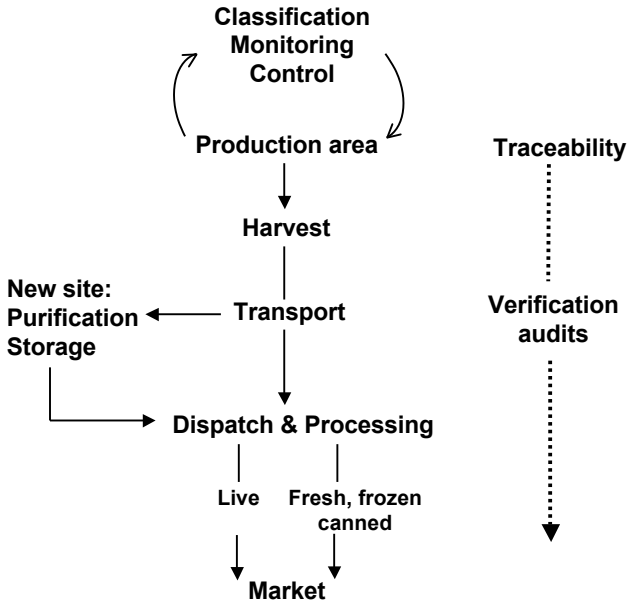
- **Recently 2003 – 2004:**

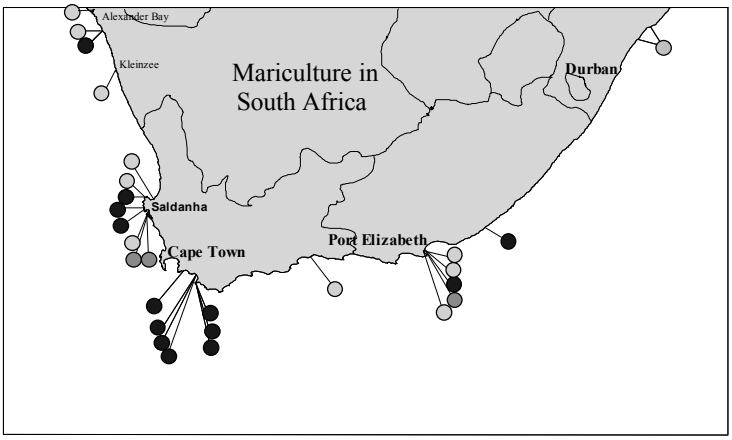
  A MOU between M&CM and the SABS is presently being finalized.

  Number of meetings were held with the local health authorities in the coastal provinces.

  March 2004 - The programme was officially authorized by the DDG of M&CM.

  June 2004 - Programme was submitted by the SABS to the EU. Await comments from the Food and Veterinary Office on the programme document and date for inspection visit.





Present - 15 land-based abalone operations

9 small/medium oyster operations

3 black mussel farms

Annex 9

Present status of the molluscan shellfish safety program in Namibia

Deon Louw, Ministry of Fisheries and Marine Resources
Swakopmund, Namibia

Present status of the molluscan shellfish safety program in Namibia

Content

- Introduction
- Policy and Legislation
- Capacity
- Monitoring program
  - Microbiology
  - Biotoxin
  - Phytoplankton
  - Others
- Results
- The way forward

Introduction

- History – HABs in Namibian water/events
- MFMR – Establish- Aquaculture section
- Aquaculture farms and wild fisheries
- BCLME projects – EV/HAB/02/01, EV/HAB/02/02a and Shellsan
- Policy and Legislations

Capacity

- Staff
  - Aquaculture Director
  - Chief Fisheries Biologist
  - Biologist (1)
  - Technicians (3)
  - TA (1)
  - Others
    - Drivers
    - Phytoplankton section
  - Buildings

Policy and Legislation

- Policy 2001
- Aquaculture Act – 2002
- Namibian Aquaculture Strategic Plan- 2004

Monitoring Program (1)

- **Microbiology**
  - Currently done by SABS in Walvis Bay (Namibia)
  - Aquaculture staff do the sampling and deliver it to SABS within 2-3 hours of sampling
  - This is done twice a month on each farm (other areas are also included)
  - Results are faxed to the Ministry
  - Results are kept on hard copies as well as electronic format
  - Reports are generated and sent to the farms as well as to office of the Minister. This total process can take up to two weeks
    - Extra data are available

Monitoring Program (2)

- **Biotoxin**
  - No biotoxin analysis laboratories exist presently in Namibia
  - Currently Aquaculture staff collect oyster samples from farms
  - One abalone farm collect samples as well
  - All samples are sent to CSIR in Cape Town for analysis
  - Costs are borne totally by the farmers
  - Results are sent to MFMR and farmers
  - "HOT" results are sent by fax to farmers as well as MFMR. MFMR conducts a re-sampling for confirmatory analysis
  - Results are kept on hard copies as well as electronic format
  - Reports are generated and sent to the farms as well as to office of the Minister
  - The initial sampling, analysis and reporting can take approximately one week

Monitoring Program (3)

- **Phytoplankton**
  - Phytoplankton samples are collected and analyzed by MFMR
  - Currently Aquaculture staff collect bottle and net phytoplankton samples from existing farms and other locations
  - Samples are brought to MFMR in Swakopmund for analysis – net samples are examined first
  - Aquaculture staff with phytoplankton staff analyse samples
  - Results are kept on hard copies as well as electronic format
  - Reports are generated and sent to the farms as well as to office of the Minister
  - In the event that high concentrations of a known toxin producing phytoplankton species are detected, voluntary closures will be recommended

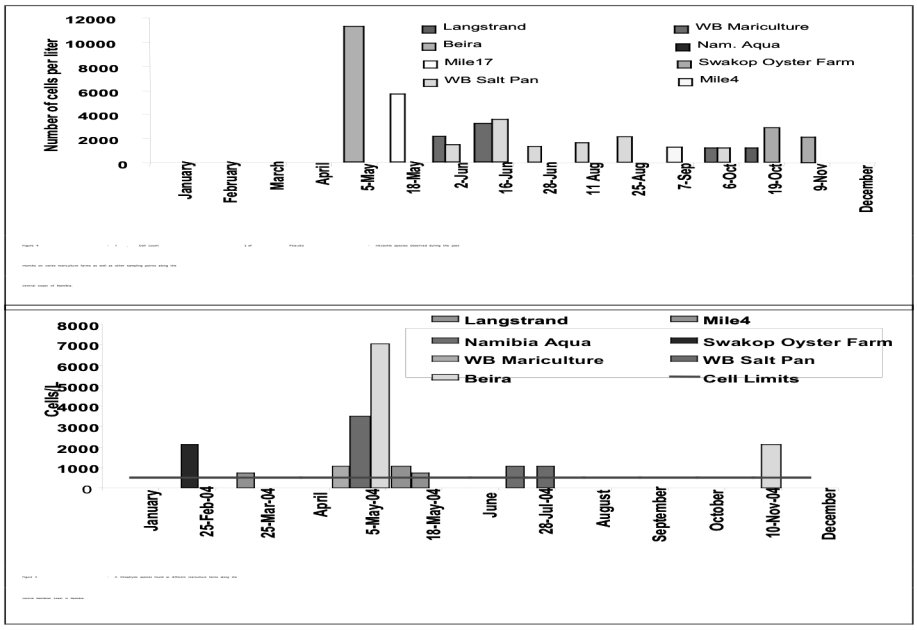
Monitoring Program (4)

- **Others Parameters**
  - Heavy Metals –Mercury, Zinc, Lead, Cadmium, Tin, Chromium, Arsenic and Copper
  - Water and shellfish flesh samples were taken by Aquaculture staff and analyses were paid for by Namport
  - Salmonella tests were done on shellfish– paid by the industry

Results (1)

Months	Medium	Test (MPN)	Swk Salt Pans	Walvis Bay Maricultur e	WB Salt Pans	Beira Aqua.	Nam. Aqua.	Units
March	Water	*E. coli*	0	0	0	0	0	*E.coli*/100ml
April	Water	*E. coli*	0	0	0	0	0	*E.coli*/100ml
May	Water	Total coliforms	0	0	0	0	0	T. colif orms/100ml
June	Flesh/oysters	Total coliforms	0	0	190	0	90	T. coliforms/g
July	Flesh/oysters	Total coliforms	15	0	0	5	90	T. coliforms/g
August	Flesh/oysters	Faecal coliforms	0	0	0	0	0	F.coliforms/g
Septembe r	Flesh/oysters	Faecal coliforms	0	0	0	0	0	F.coliforms/g
October	Flesh/oysters	Faecal coliforms	0	0	0	0	0	F.coliforms/g
November	Flesh/oysters	Faecal coliforms	0	0	0	0	0	F.coliforms/g
December	Flesh/oysters	Faecal coliforms	0	0	0	0	0	F.coliforms/g

Results (2)



The way forward

- Microbiology – use current data and continued sampling for classification; expand sampling to other areas
- Biotoxin – Namibian-based accredited laboratories
  - Transport and customs problems – turn around time is not acceptable (analysis times: DSP-2days, PSP-4days and ASP-5days. Total time 4 – 10 days)
- Include tests for other substances (pesticides, PCBs and radionuclides)
- Need written protocols and checklists to be used by inspectors and farmers
- Competent authorities require shellfish/aquaculture inspectors for farms as well as for processing, transport, etc.
- Farmers need training in terms of requirements for processing, dispatch centers, tagging, labeling, etc.

Annex 10

Present status of the molluscan shellfish safety program for Angola

Isabel Rangel, Marine Research Institute
Luanda, Angola

Present status of the molluscan shellfish safety programme for Angola

Isabel Rangel

The establishment of a detailed programme for the sanitary safety of shellfish in the area of the Benguela Current has the potential to open new shellfish markets for Angolan, Namibian and South African producers.

Angola is working together with Namibia and South Africa to establish shellfish sanitation programmes in the area of Benguela Current through cooperation among the 3 BCLME countries.

For the sanitary safety of seafood (fish and crustaceans) the IIM oversees sanitary control based on chemical and microbiological analyses of the products and respective issuance of sanitary certificates for export.
Routine monitoring for shellfish has not yet been established, mainly because all product is utilized for domestic consumption.

In the event of a clear health problem: Example -

- Cholera (1991-1996)
- Testing done for: potable water, non-potable water, seawater and shellfish by the National Institute of Public Health
- *Vibrio parahaemolyticus* found in Mabanga (a clam) from Luanda Bay in 1994

Microbiological control of water and seafood

There is equipment and trained personel for testing

Water: Faecal coliforms

Sea food: Faecal coliforms, *E. coli, Salmonella*

Through the BCLME projects, some samples will be tested during the next months as a pilot study.

Chemical control for fish and crustaceans

- Determination of heavy metal (cadmium (Cd) and lead (Pb)) content and organoleptic quality of fish and seafood.

However regarding shellfish, there is limited information on catch, consumption and marketing.

We do not have:

Knowledge of the total landings of shellfish
Number of licensed shellfishermen
Sanitary control programme

Steps for control of shellfish :

- The Law for Aquatic Resources was approved in June 2004 and will be published shortly .

-The regulations for the hygiene-sanitary requirements of fisheries and aquaculture products are waiting for approval.

- Introduction of the receptor binding assay (RBA) technique in the detection of PSP toxins in shellfish is awaiting approval of a law on the use of radioactive materials

- A pilot monitoring program in Luanda will soon begin with support from the Angolan government and the BCLME programme.

Annex 11

Angolan shellfish industry

Olivia Torres, Microbiology Laboratory Head
Marine Research Institute, Angola

Angolan shellfish industry

Industry……..?

Wild shellfish beds are exploited in Luanda, Benguela, Namibe.

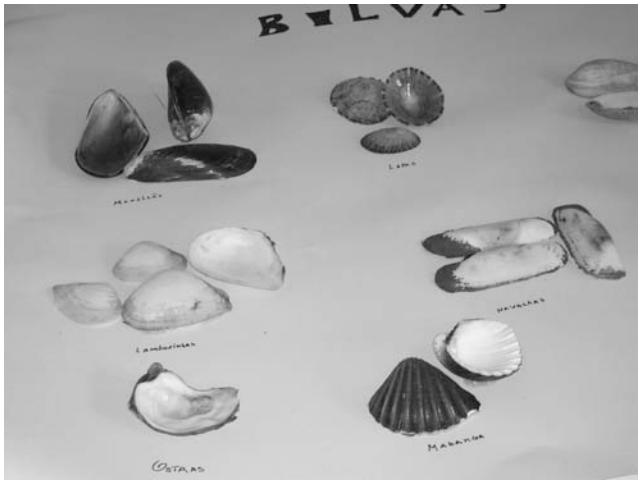
The main exploited site is in Luanda (Benfica / Km 17) . At least 100 woman process shellfish at arrival of the boats. They buy the shellfish from the harvesters.

The bed has been exploited for many years, seven days a week. Harvesting is done manually by divers.

There is no information about the quantities of harvested product.

Pre-processing is done at the beach and the product is sold cooked at the street markets.

Harvested species



Some have been identified at the species level: *Perna perna, Senilia senilis, Donax rugosus*

Gastropods are also harvested and marketed after cooking.

- People involved in this "industry" are not organized or associated.
- Ilda Lucas (Head of the Department: Aquaculture). After the workshop she will recommend to include shellfish harvesting in the study of artisan fisheries statistics.
- It is a priority of the Angolan government to promote bivalve aquaculture in Bahia dos Tigres, the location of the largest natural shellfish bed along the Angolan coast, (mainly oysters and mussels). It is presently exploited at a very low level.

Annex 12

Perspective from industry

James West, Chairman of Aquaculture
NamAqua, Namibia

Perspective from Industry in Namibia

James West, Chairman of the Aquaculture Association of Namibia

Mr. West stressed the importance of the market and in particular the fragility of the Namibian marketing situation due to over-reliance on the South African market, which depends on requirements of the South African import permit.

There are threats to the industry because of remoteness from large markets.

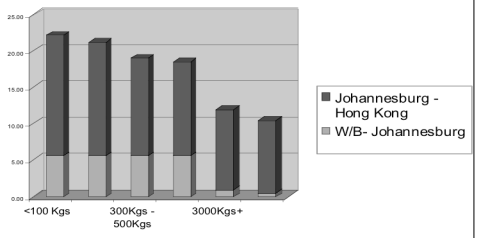
When exporting there are interesting transport costs, as shown by the graphs. A shipment to Hong Kong for example shows that air transport to Johannesburg takes up a disproportionate fraction of the costs. If increased volumes were produced, shipment by truck/other means would be a proposition and would be vastly cheaper. Likewise the profit margin to the producer is greater with higher production.

Therefore in order to overcome these disproportionate costs it will be necessary to produce a far greater volume so that alternate transport can be utilized. This will require a minimum production of 1,2 million per year and this increased production is feasible only if more receiving markets are opened to Namibian producers.

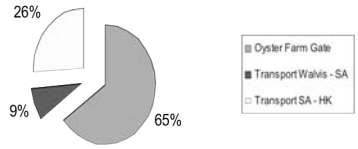
There is the need for harmonised testing programmes to allow access to new markets. There is the likelihood that most new markets will require similar testing of products.

Producers are looking to opening the market of the Far East, and are awaiting a harmonized regulatory programme so that the EU markets will be accessible.

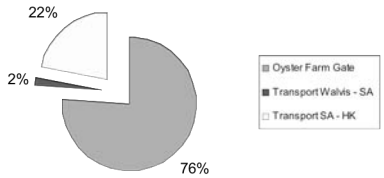
Cost of Transport Walvis Bay -Hong Kong



Transport Costs <100 Kgs



Transport Costs 3000Kg +



Annex 13

Present status of safety programs in South Africa

Wayne R. Barnes, Fisheries and Mariculture Consultant, Montepesca
Fish Hoek, South Africa

PRESENT STATUS OF SAFETY PROGRAMS IN SOUTH AFRICA

Wayne R. Barnes
Fisheries and Mariculture Consultant
Montepesca
Fish Hoek, South Africa

1. SOUTH AFRICAN INDUSTRY PROFILE

The production of the South African cultured abalone industry was some 800 tons live weight to end 2004 and is likely to reach 1,000 tons by the end of this year or early 2006. This at present represents about 5% of international commercial trade in abalone. Almost all of this is produced on 12 farms, most of which are located in the Western Cape. Almost all product is exported to Far Eastern markets in live, canned or frozen form. The abalone farming industry is relatively well organized and is represented by the Abalone Farmers Association of Southern Africa (AFASA).

Mussel and Oyster farming is a much smaller industry. Almost all significant mussel production comes from a single farm situated in Saldanha Bay one of the few areas on the South African coast that enjoys sufficient protected waters. There are some 10 or 12 oyster farms most of which are small and employ only 5 to 6 people per farm. Total production is about 4 million oysters per annum and is sold into the local market. Neither the mussel nor the oyster farming industry has attained the sort of "critical mass" to justify formal representation. It is also geographically scattered which makes for difficult and expensive co-ordination.

2. MONITORING PROGRAMME

Through AFASA the abalone farming industry initiated the shellfish monitoring programme in South Africa as a project, obtaining some government funding through the Sector Partnership Fund. The project objectives were: (a) draughting a suitable programme; (b) implementing the programme; (c) establishing an ASP testing protocol; (d) obtaining EU approval of the programme. The 2 year project has been extended slightly and the final milestones have yet to be achieved, viz. an acceptable ASP protocol and final memoranda of understanding between Marine & Coastal Management, the South African Bureau of Standards and the Department of Health. The abalone farmers, through AFASA, are still effectively carrying the costs of the salaries of those employed on the programme.

Annual costs are approximately R250 000 for salaries and another R250 000 for sampling by the SABS. Analysis costs run to R1 200 per month per farm. Hence for ten farms…another R144 000 per annum…giving a total direct cost of some R644 000 per annum.

3. INDUSTRY PERSPECTIVES AND CONCERNS

3.1 Mussel and Oyster Farmers

The primary concern according to spokesmen for the mussel and oyster sectors is the cost of mandatory monitoring which they calculate at about R7 000 per month per operator and which is at present prohibitive. They therefore feel strongly that any proposed programme that includes them must primarily take cognisance of cost. They support monitoring and would like to see some affordable monitoring in place

rather than no monitoring at all. Their suggestion is thus that a plankton monitoring system be established which:

- provides for daily plankton samples from each farm or immediate farm district for real time qualitative microscopic examination for HAB species;
- will serve as an early warning system, pre-empting the second tier mouse test (which would only be triggered by virtue of the "early warning" results);
- provides for samples to reach examination centres on the same day by courier – mostly for same-day examination – at a fraction of the cost of mouse tests and with close on real time results.

Further points made by the oyster and mussel farmers are:

investigation of other possible qualitative tests prior to mouse bio-assays

taking into account the relative risks of different districts, e.g. does Walvis Bay have the same PSP risk as Saldanha? (To my knowledge, this is in fact already done.)

possibly matching surveillance intensity to the known seasonality of HAB occurrences (I don't think there are any guarantees on this one!)

that each regional government should handle its own safety certification but should strive for harmonisation of methods and practices for all mussel and oyster farmers in the SADEC region.

Quoting a prominent SA aqaculturist: "NO OYSTERS should be allowed into South Africa unless they have been approved by an approved authority in terms of sanitation, toxicity and trace metals. The same standards have to be applied as to the South African farmers because of our CONCERN FOR THE MARKET. The idea that oysters are tested AFTER entering the country is ludicrous! How can it be controlled? There should also be no further grace period to implementation!"

3.2 Abalone Farmers

The viewpoint of the South African abalone farmers is essentially that they have taken the initiative in establishing an internationally acceptable shellfish monitoring programme but, with exchange rates at less than R6 to the US dollar, they simply cannot afford to continue with what is essentially a government function.

AFASA also supports the notion of daily, faster, cheaper monitoring leading to mouse testing when indicated and also recognises the inherent difficulties associated with the spread of farms over a long coastline.

The SA abalone farmers would like to see proper monitoring in each country in the region and strict controls at our international borders.

The immediate areas of concern that AFASA would like to see addressed and solved are:

the establishment of an ASP testing history acceptable to the EU,

the finalisation of the memoranda of agreement between the different SA state departments and agencies,

acceptance of the programme by the EU, and

the complete take-over of the programme by the SA government.

Annex 14

Requirements for a proposed model shellfish monitoring programme for the Benguela region

Bronwen Currie, Ministry of Fisheries and Marine Resources
Swakopmund, Namibia

REQUIREMENTS FOR

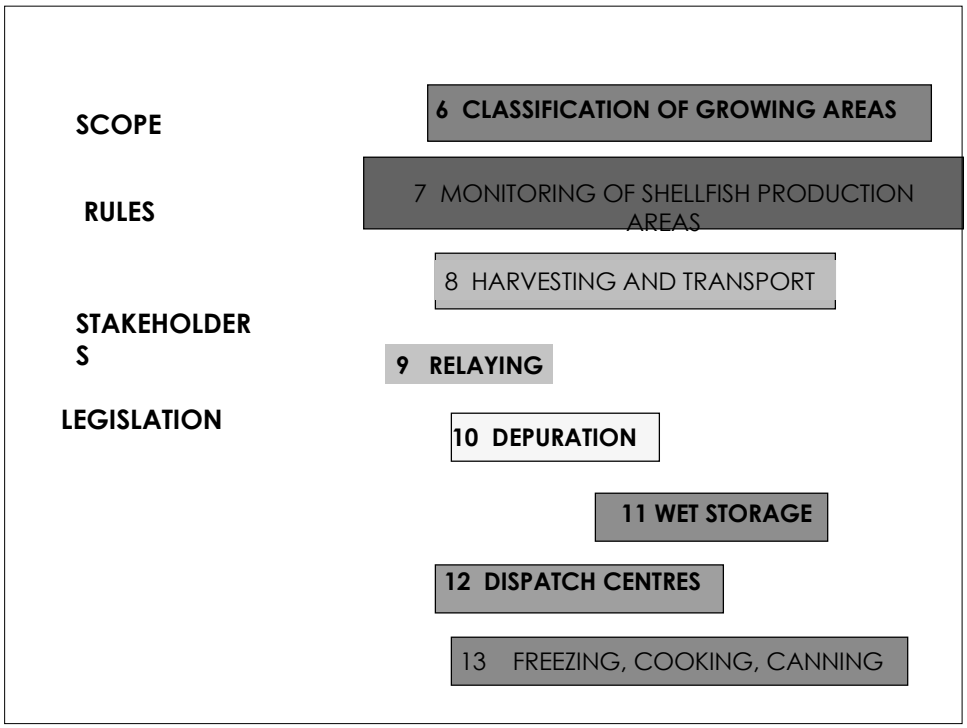
A Proposed

MODEL SHELLFISH MONITORING PROGRAMME

for the Benguela Region

2 SCOPE AND AUTHORIZATION

- Molluscan shellfish: all bivalves and gastropods but excluding cephalopods e.g. squid and octopus
- Commercial farming: all activities including growing, harvesting, wet storage, relaying, depuration, packaging, dispatch, processing, transporting, labeling and storing of shellfish.
    - Recreational harvesting ?
    - Commercial harvesting of natural resources ?



3 RULES

Responsibilities and duties of the Regulatory Authority and the Competent Authority must be clearly defined

The sampling procedure, analysis and interpretation of monitoring data best facilitated by the Regulatory Authority and should remain under its responsibility and control.

Where responsibilities are fragmented , Memoranda of Understanding between the Competent Authority and the responsible agencies must clearly define the scope of the responsibilities.

Records of all required procedures must be kept and made available at any time on request by responsible agencies

4 STAKEHOLDERS

Regulatory Authority, The Competent Authority, industry participants, and other government agencies with relevant roles and responsibilities

Representatives comprise a Molluscan Shellfish Safety Committee (MSSC)

As the coverage of the programme grows, a Management Cell comprising lead agencies plus industry representation, is desirable to take decisions on anomalous results

5 LEGISLATION

If applied solely or primarily to aquaculture activities the shellfish safety programme can be embedded as a set of regulations into Aquaculture legislation.

In all 3 countries legislation presently exists which in general terms enables consumer safety for molluscan shellfish

South Africa:
The present active programme is enforced and controlled by means of permit issue by the Regulatory Authority to farmers

Namibia:
Present monitoring is carried out by the Regulatory Authority but this is not yet formalized into any regulations. The enabling legislation is the Aquaculture Act

Angola:
A monitoring programme could be enabled through the Aquatic Biological Resources Act

In Both South Africa and Angola Aquaculture legislation is being drafted

6 CLASSIFICATION OF GROWING AREAS

Classification of growing areas by the Regulatory Authority using the Sanitary Survey

- **Primarily rely on microbiological records over a one-year period**
- **Monitoring records of other health hazards are taken into consideration e.g. heavy metals, pesticides, algal toxins**

Growing area classification is reviewed annually

6.2 SANITARY SURVEY

1. **Sampling stations**
    1. **For pollution**
        1. **Land-based: 500m on either side of the intake**
        2. **Ocean-based: take into account point-sources and non-point sources**
    2. **For HABs**
       Sampling points should take into account hydrodynamics

6.2.2 FREQUENCY OF SAMPLING

For microbiology:

20 official samples
covering the broad range of environmental conditions experienced by the area.

At least a year 's records are needed.

Shellfish flesh is preferentially tested for faecal coliforms.

Sampling procedure and analytical methodology are specified.

Other hazardous chemicals should be tested twice during the classification period i.e. every 6 months

One sample for radionuclides should be tested

6.2.3 CLASSIFICATION OF GROWING AREA
Water or flesh? *E. coli* or faecal coliforms

APPROVED

CONTROLLED

PROHIBITED

6.2.3 CLASSIFICATION OF GROWING AREA

Water or flesh? *E. coli* or faecal coliforms?

APPROVED areas:

Tolerance levels

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

Flesh + intravalvular fluids: 300 faecal coliforms/100g flesh.
Total absence of *Salmonella* in 25g flesh.
shall not contain hazardous concentrations of toxic substances or biotoxins.

Harvesting may take place

CONTROLLED areas:

Conditionally approved: Harvesting only when growing water/flesh meet the APPROVED requirements. During harvesting samples for microbiological analyses are taken at least once a week to prove the conformance of the water.

A management plan to address the predictability of the pollution events

Restricted: Faecal coliform median MPN of water not 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 < 6000/100g shellfish flesh

Prohibited areas:

Criteria:

There is no current sanitary survey or annual evaluation report.
The sanitary survey indicates levels of microbial pollution exceeding 6000 coliforms/100g flesh

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.
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.

New regulations (EU 2006)

A approved for harvesting < 230 *E. coli*/100g

B must be depurated < 4600 *E. coli*/100g

C must be relayed < 46000 *E. coli*/100g

6.2.4 Limits for hazardous substances

The limits for toxins such as heavy metals, radio-active substances (Cesium 134 and 137), polychlorinated biphenyls and pesticides will be those described in terms of the current legislation in each country. These limits apply to the fresh weight, edible portion of the shellfish.

6.2.4.3 Limits for veterinary drugs

The limits for veterinary medicines must comply with the health regulations of the country.

6.2.4.2 Limits for Biotoxins

Paralytic shellfish poisoning (PSP) - 800 µg STX eq./kg edible flesh.

Diarrhetic shellfish poisoning (DSP) and related lipophillic toxins (e.g. AZP, YTX, PTX) - Not detectable using the mouse bioassay (2 out of 3 mice dead within 24 hours). Chemically Okadaic Acid , PTX, DTX - 160 ug/kg edible flesh; YTX - 1mg/kg edible flesh; for azaspiracids -160ug/kg edible flesh

Amnesic shellfish poisoning (ASP) - 20 mg domoic acid/kg edible

7 MONITORING OF GROWING AREAS

Trained and approved personnel : sample collection and delivery to relevant accredited laboratories for analyses.
Establish compliance with the regulatory requirements concerning microbiological quality, toxic and hazardous substances and biotoxins in shellfish.

Responsibility of the Regulatory Authority 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.

The sampling and analysis effort required for classification and monitoring represents a significant commitment of personnel and financial resources. In practice, many countries share these costs and responsibilities between government and industry.

For example,

- **the government may cover the costs of classification of growing areas, but the industry would bear the costs of ongoing monitoring at their facilities (sample collection, transport and laboratory analysis).**

- **Alternatively, the industry may need to bear all of the costs of the classification and monitoring phases of the programme.**

- **Any final version of this draft ordinance should specify how these sampling and analysis costs are to be apportioned.**

7.2 Microbiological monitoring

Classification of the growing area decides the frequency of testing

e.g. Approved areas require only 12 samples in 12 months,
more frequent resting in controlled areas.
Point source pollution, episodic events all require intensified sampling.
Non-compliance to required levels will result in closure until tests over a week- interval show compliance

7.3 Toxic *and* Hazardous substances

Sampling for heavy metals, PCBs, radionuclides and pesticides on shellfish flesh only

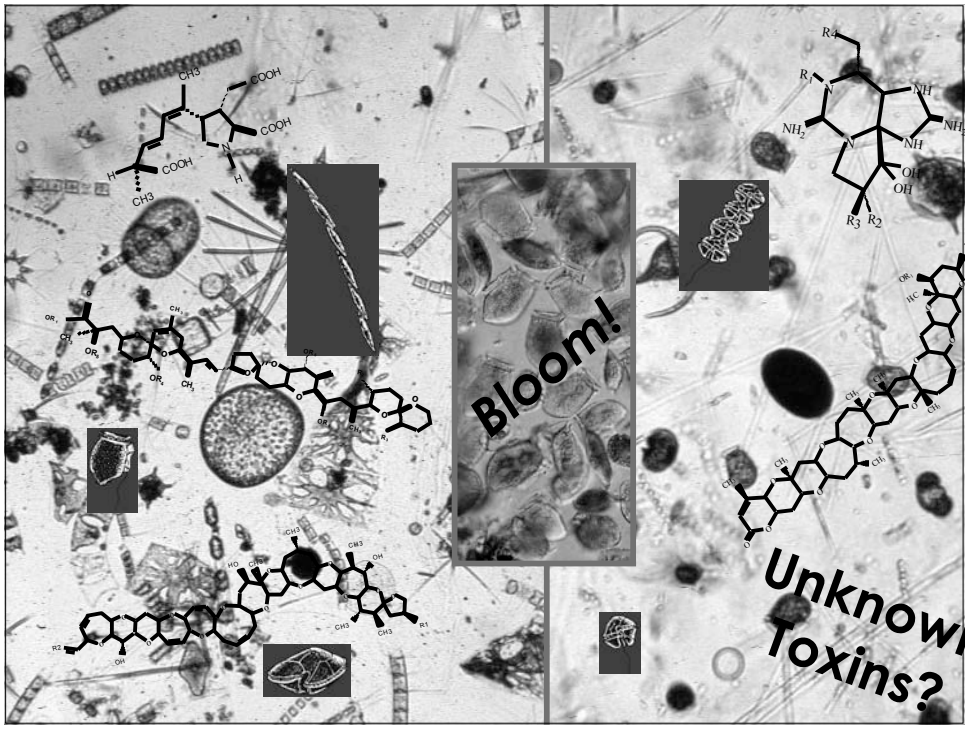
Testing for specific contaminants is recommended ANNUALLY, or only when the sanitary survey reveals a potential problem, or if there is concern due to a paucity of data

Sampling will address variation within a production area and will be conducted annually

7.4 BIOTOXIN MONITORING

A FACTOR IN SHELLFISH PRODUCTION THAT CANNOT

BE CONTROLLED BUT MUST BE MANAGED



Toxic blooms can develop rapidly

Toxicity potential varies

Uptake of toxic algae by shellfish varies and the ultimate level of toxicity in the shellfish flesh varies

7.4.1 BIOTOXIN MANAGEMENT PLAN

Components

Phytopankton monitoring programme
- **warning system of potential toxicity**

Biotoxin testing
- **Toxic shellfish**

Contingency plan
- **No harvesting/consumption of toxic shellfish**
- **Consumer protection, industry protection**

For this reason shellfish must be shown to be safe for human consumption.

Three main classes of microalgal toxins are recognized to be of significant risk in Benguela waters

PSP

Lipophillic group (DSP,AZP,PTX, YTX….)

ASP

Although numerous chemical methods have been shown to satisfactorily determine levels of these toxins in shellfish flesh Standardized levels of toxicity remain dependent on
- **the mouse bioassay for PSP and DSP**
- **HPLC analysis for ASP**

For a model programme it will be necessary for the countries to have quick access to these tests.

In order to provide warning of potential toxicity in shellfish the Biotoxin Management Plan comprises

1. **Routine Monitoring: phytoplankton sampling and biotoxin testing**
   - **Provides farmers and consumers with assurance that the product is safe (for international trade this must be according to criteria of the receiving nation)**

2. **Intensive sampling: suspicious phytoplankton and/or biotoxin detected below regulatory level**

3. **Quarantine conditions: testing indicates that shellfish are not safe for consumption**
   - **Testing shows unacceptable toxin levels in the flesh**

3. **Reopening: testing shows that shellfish are no longer toxic**
   - **Testing shows in 2 consecutive analyses at least 48 hours apart that flesh is below acceptable toxin levels**

The turn around time for results is critical !!!

…….If the test is really going to address consumer safety and not just certification…….

The turn around time has serious implications for the producer:

Wet Storage time
late deliveries - clientele
loss of clients

8 HARVESTING AND TRANSPORT

Harvesting:

- **Temperature control of <7 C within 20 hours of harvesting**
- **When harvested offshore vessel transport time without temperature control limited to 6 hours**

Transport from harvest area to dispatch centre or wet storage:

- **Regulatory Authority must be satisfied that the transfer is efficiently and hygienically carried out, with monitoring checks and records as necessary. Transfer to Wet Storage/ Dispatch Centre etc; these facilities must comply with regulations**

11 WET STORAGE

Wet storage: the temporary storage of shellfish in near-shore waters or onshore tanks prior to preparation for sale.

Wet storage is NOT intended for purification therefore all controls pertaining to shellfish for direct human consumption should be applied.

Wet storage premises must be certified by the local authority as for food premises in terms of appropriate legislation for each country.

Wet storage sites or facilities must undergo an annual evaluation by the relevant Health authority in co-operation with the Regulatory Authority. This evaluation shall consider the following:

- **The sanitary survey (if a 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.**

12 DISPATCH CENTRES

Dispatch centres must be certified according to appropriate legislation for each country and must be inspected at least once annually and approved by a Competent Authority inspector or relevant Health official.

The premises and hygienic standards must comply with the appropriate legislation for each country (e..g..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.

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

In sorting or storage area, 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 Depuration

the process whereby filter-feeding shellfish are naturally cleansed in a purified and controlled seawater environment.

All operations harvesting shellfish for delivery to a depuration plant must be issued with a separate permit by the Regulatory Authority.

There are extensive and detailed regulations governing depuration units and the sale of shellfish therefrom

DEPURATION IS COSTLY AND A DIRECT CONSEQUENCE OF GROWING SHELLFISH IN POLLUTED WATERS.

- Is this desirable?

13 CANNING, COOKING, FREEZING

According to legislation of each country

RESPONSIBILITY & COSTING

Sampling

Transport of samples to analytical laboratory

Analyses

Reporting

Inspecting

Annex 15

The role of SABS in the fish export program of Namibia

SSM Seane, GCS Namibia Acting Managing Director
SABS Holdings, Namibia

SYNOPSIS OF ADDRESS TO Multi-stakeholder Workshop

on

BEST IMPLEMENTABLE MANAGEMENT APPROACHES FOR MOLLUSCAN SHELLFISH SAFETY IN THE BENGUELA REGION

held on 1 February 2005 in SWAKOPMUND

by

Dr Randall Carolissen
GROUP MD: SABS HOLDINGS (PTY) LTD

1. INTRODUCTION

It is my pleasure to introduce the Head of Regulatory, Ms Faiza Salie, as well as the Managing Director of our subsidiary, GCS Namibia, Mr Twedi Seane. Their contact details are as follows:

Ms Salie
tel +27 (0)12 4286158
fax +27(0)12 4286116

Mr Seane
tel +27 (0)12 4287899
fax +27(0)12 4286687

The SABS is designated by an agreement with the Namibian Ministry of Trade and Industry to act as the competent authority for marine exports to the European Union. South African marine exports certification, compliant to EU directives is similarly served by the SABS through its Regulatory division. Presently GCS Namibia, a subsidiary company of the SABS, is executing this Namibian obligation as well as providing supporting laboratory services. This agreement is in the final stages of review and will be signed within the next month by our CEO, Mr Martin Kuscus and the Namibian Minister of Trade & Industry.

2. THE REVISED ROLE OF SABS IN NAMIBIA

To restore alignment of expertise and to give proper effect to government to government agreements, the agreement between SABS and Namibian Trade and Industry will in future be serviced through the SABS Regulatory division. This division will employ the inspectors in Namibian and further provide on oversight function of the Namibian operations. This alignment will also extend the 17025 accreditation to Namibian operations, provide quality assurance audits, interface with the industry to ensure timeous interventions where and when required and liase with Namibia Trade and Industry to give effect to this agreement.

Supplementary laboratory services and certification will continue to reside in GCS Namibia who, in competition with the private sector, provide such services. Attention will be paid to commercial imperatives such as turnaround times and other service delivery related issues. International acceptance of reports through accreditation will also be maintained.

This reorganization of the SABS activities will bring Namibia in line with EU and WTO requirements. It will also ensure that Namibia has access to the internationally recognized expertise of our operations in South Africa at the correct interfaces.

3. FUTURE REQUIREMENTS

This workshop was intended to establish a mollusc export program for Namibia and to this end the Namibia Ministry of Trade & Industry previously approached the SABS for assistance to establish the required testing and monitoring infrastructure. Mr Seane of SABS who in conjunction with Namibia Ministry of Trade & Industry will determine is developing a project plan

a) the EU testing requirements
b) transfer of knowledge programme
c) the CAPEX and HR requirements
d) accreditation requirements
e) environmental assessment programs

It was stressed earlier that this mollusc export program was driven at ministerial level and that strategic, as well as financial considerations must be taken into account when feasibility studies are carried out.

It will also be important that other role players, such as Department of Fisheries and Marine Resources in Namibia, CSIR, as well as other global networks such as WAITRO be brought on board right at the inception of this project.

4. CONCLUSION

We will be meeting individually with our clients over the next day where some of these discussions will be taken forward and as you have requested, I will make a copy of this address available.

Dr Randall Carolissen
GROUP MD: SABS HOLDINGS (PTY) LTD
2005-02-03