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SOUTH AFRICAN LIVE MOLLUSCAN SHELLFISH MONITORING AND CONTROL PROGRAMME

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1. BACKGROUND

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

- Some of them are filter feeding shellfish that accumulate hazardous levels of biotoxins and other toxins and pathogenic micro-organisms (viruses, protozoa, bacteria and helminths) in their flesh causing them to become naturally contaminated.
- While filter feeding bivalve molluscs pose by far the greater public health threat from biotoxins, predatory, grazing and scavenging gastropods may accumulate toxins from their prey (e.g. toxic bivalve molluscs), food or if they grow in sea water containing toxin-producing phytoplankton. Often the source of intoxication is not clear for gastropods.
- In many cases no thermal process is applied to shellfish prior to sale to eliminate pathogens and therefore, further microbiological multiplication is likely to occur. The presence of marine biotoxins is also not eliminated by cooking.
- Raw molluscan shellfish receive the second highest hazard rating for all foods by the International Commission on Microbial Specification for Foods.

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

This Manual has been prepared by the Department of Agriculture, Forestry and Fisheries (DAFF) and the Department of Food and Associated Industries of the National Regulator for Compulsory Specifications (NRCS), with the purpose of developing an official manual for South African operators which will provide the necessary guarantees to foreign buyers and Governments as well as to local consumers that the risk of disease and poisoning through consuming molluscan shellfish is adequately managed and minimised.

2. SCOPE AND AUTHORIZATION

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

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

2.3. The manual applies to molluscan shellfish (hereafter referred to as shellfish) as defined under Section 14

2.4. The manual addresses all activities related to the commercial farming of molluscan shellfish prior to placing on the market, including the producing, harvesting, wet storage, relaying, depuration, packaging, dispatch, transporting, labelling and storing of live molluscan shellfish. The freezing and canning of molluscan shellfish is controlled by the relevant Compulsory Specifications published under the NRCS Act, 2008 (Act No. 5 of 2008)

2.5. The manual includes the monitoring activities required for audit of production areas and establishments in the interests of public health. These activities will be managed and controlled by DAFF under the Marine Living Resources Act, 1998 (Act No. 18 of 1998) and the relevant municipal health authorities under the National Health Act, 2003 (Act No. 61 of 2003) and the Municipal Structures Act, 1998 (Act No. 117 of 1998); in cooperation with the NRCS (the appointed body for administering the various Compulsory Standard Specifications for fishery products in South Africa and the recognised competent authority by certain countries for the trade and export of fishery products).

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

3. DOCUMENT CONTROL

3.1. This manual was compiled by DAFF in cooperation with the NRCS and the molluscan shellfish farming industry. The manual will be reviewed as pertinent new information becomes available. The review process will involve consultation with representatives from DAFF, NRCS, industry, and the Department of Health, (including provincial and/or municipal health authorities where applicable), who collectively shall comprise the Shellfish Management Committee.

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

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

3.4. The latest version will be made available on the DAFF website and at NRCS.

4. RULES

4.1. The definitions in Section 14 apply in this manual unless the context requires otherwise.

4.2. DAFF is the Regulatory Authority authorising the aquaculture, harvesting, transport of molluscan shellfish for wholesale trading in terms of the Marine Living Resources Act, 1998 (Act No. 18 of 1998) and associated Regulations. Authorisations are administered through the issue of a marine aquaculture (mariculture) right and permit. Associated activities such as relaying, depuration and wet storage will require special authorisation from DAFF in conjunction with the relevant local health authority. Land-based wet storage facilities and depuration plants must obtain a Certificate of Acceptability for food premises from the local health authority as required by Regulation 962 published under the Foodstuffs , Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972).

4.3. Establishments packing or processing molluscs must also be licensed by DAFF in cooperation with the NRCS (canned or frozen products) and/or local Health authorities (live and chilled products) as is relevant. Such establishments will be licensed only when the operator can produce a Certificate of Acceptability in terms of Regulation 962 published under the Foodstuffs , Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) for the establishment which is not older than 3 months. Each establishment must be licensed annually.

4.4. DAFF, the NRCS or relevant local health authority may appoint official inspectors (e.g. NRCS inspectors, DAFF Compliance Officers, Environmental Health Practitioners) or other appropriately trained personnel to assist with the official survey and sampling activities, and for the inspection of compliance of operators with the requirements of this manual. A written appointment is required that defines the responsibilities of the inspector/officer so appointed.

4.5. Where inter-government guarantees are sought (health certificate), the competent authority officially authorised by DAFF must have free access to records kept by DAFF.

4.6. To enable proper liaison between DAFF and other governmental departments/authorities in regard to Paragraphs 4.2 - 4.4 above, a Memorandum of Understanding must be prepared and signed by all parties concerned.

4.7. DAFF 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.
- Copies of Certificates of Acceptability as referred to in Paragraphs 4.2 and 4.3.
- Official laboratory certificates.
- Movement documents.
- Individual production area reports (e.g. maps of production areas, surveillance records, sanitary surveys, management plans, transport, closure, harvesting criteria adjustments, reclassification of areas and annual evaluation reports).
- Details regarding marine aquaculture operations including reconstruction and remodelling plans.
- Summaries of shellfish food-borne illness reports, where available (from Department of Health).
- Marine biotoxin monitoring data and notices.
- Enforcement action reports.
- Evaluation reports generated by foreign governments or local authorities.
- All data, criteria and protocols relating to the operation of a restricted area such as relaying reports, depuration reports, harvesting permits and harvesting control records.
- All data, procedures and reports on wet storage.
- All approved documentation for licensing of dispatch and processing establishments.
- Correspondence with farmers.

4.8. 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 4.7.

4.9. Industry shall keep complete, accurate and legible shellfish transaction records for at least 5 years in a permanently bound ledger book (or other approved method). This pertains to each authorised marine farmer including relayer, depuration plant, wet storage unit and establishment packing and/or processing shellfish. Such records shall include:

- All information necessary to trace all purchases and sales of molluscan shellfish back to their production 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.

4.10. Permits to cultivate and harvest shellfish for direct human consumption or further processing shall be issued by DAFF subject to a satisfactory classification of the production or relaying area following a sanitary survey. An area shall be classified as suitable for production and harvesting shellfish if it meets the requirements for approved (Class A) or restricted (Class B) areas as specified in Paragraphs 5.3 and 5.4.

4.11. The development of new marine aquaculture operations in waters meeting the approved criteria is to be promoted. In view of the extra demands for the management and control and the greater risk of contamination for shellfish products originating from waters of lesser microbiological status than approved areas, cultivating shellfish in such areas is discouraged. Approval for cultivation in waters with limited microbial pollution will require detailed motivation.

4.12. Once a production area has been shown to conform to the approved area requirements (Paragraph 5.3) or that it may be utilized under certain conditions (Paragraph 5.4), a permit may be issued to the operator stating the conditions for operation, harvesting, transport, relaying and marketing as may be applicable. All marine aquaculture facilities must provide access and assistance to official staff for monitoring purposes as specified in Section 6.

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

4.14. 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 depuration approaches are not intended for heavily microbiologically contaminated shellfish or to reduce the levels of other accumulated toxic substances.

4.15. Depuration of shellfish in relaying areas or in depuration plants may only take place with a permit obtained from DAFF. The permit shall be specific for the particular depuration plant or relaying area. The requirements for the relaying of shellfish are given in Section 8. The layout and water quality required of depuration facilities must comply with the requirements given in Section 9.

4.16. Each sea-based wet storage site for shellfish shall be approved as above (Paragraph 4.10). The general requirements for wet storage, both sea-based and land-based are given in Section 10.

4.17. Requirements for dispatch centres are given in Sections 11.

5. CLASSIFICATION OF SHELLFISH PRODUCTION AREAS

5.1. Compliance

Compliance with classification objectives shall satisfy the conditions listed below.

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

5.1.2. The requirements for a sanitary survey apply to both sea-based and shore-based marine aquaculture operations.

5.1.3. Existing production areas that have not been classified will be assessed on the basis of existing data on shellfish quality and related public health information. Based on this review DAFF shall decide on the sanitary classification of the area.

5.1.4. Production areas are classified primarily according to their microbiological quality. Other health risks such as contamination by heavy metals and pesticides, and occurrence of biotoxin-producing algae, may also be considered. Monitoring actions must take into account the risks that were established for a particular area and species.

5.1.5. Microbiological classification of production areas is based on analyses of shellfish flesh. Where the culture species is not available in a new production area an alternative species may be used as advised by DAFF. In the case of bivalves, it may be necessary to place bags containing the culture species in the production area to provide flesh for testing.

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

5.1.7. The sanitary classification status of production areas shall be reviewed annually taking into account new potential pollution sources and other developments that could affect water quality.

5.1.8. DAFF shall maintain a current list of individual farm health status for distribution to the NRCS and relevant local health authority.

5.2. 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 depuration or further processing, and those waters where harvesting is prohibited.

5.2.1. Establishing sampling stations

Officials as specified in Paragraph 4.4 may be appointed by DAFF to assist with sampling activities.

5.2.1.1. For shore-based aquaculture systems, shellfish samples are to be taken from either within the culture units or, if the farm is not established, from the source coastal waters at the position of the proposed intake and 500m on either side of this point parallel to the coastline. Should the culture species not be present an alternative indicator Molluscan shellfish species may be used under advisement of DAFF.

5.2.1.2. Water abstracted for onshore cultivation must comply with the requirements for an approved area (Paragraph 5.3). If water is to be treated to conform to these requirements the microbiological quality of source water, prior to disinfection, and recirculated water shall meet, at a minimum, the restricted production area standards (Paragraph 5.4). Water that is excessively contaminated may not be used for marine aquaculture.

5.2.1.3. The production area survey in open waters shall take into account the proposed positioning of cultivation structures and potential pollution sources. Where a possible point source of pollution is indicated, a sampling station should be positioned on the boundary of the production area nearest to this point taking the predominant circulation patterns into account. The positioning of other non-

pollution point microbiological sampling stations shall also be dictated by the local hydrodynamics. All sampling points must be fixed and indicated on a chart of the production area. Samples should be collected as close as possible to the nominal positions.

5.2.1.4. Where relevant, sampling should address possible water column gradients that may affect the candidate species (e.g. if culture species is to be grown on ropes or poles) and growth habit (e.g. attached to rock or rope, living in or on the sediment).

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

5.2.1.6. Shellfish flesh may be composited from a number of sampling points for analysis of other toxic and hazardous substances. However, sampling points considered to be near point sources of such contamination must be analysed separately.

5.2.2. Frequency of Sampling Required for Classification

5.2.2.1. A sample or sampling batch for a particular production area is considered to include all points that were established as sampling stations by DAFF.

5.2.2.2. Microbiological samples shall be taken every two weeks from each sampling point for classification of a production area.

5.2.2.3. The samples are to be taken by DAFF sanctioned personnel (Paragraph 4.4) at a fixed frequency (determined by DAFF) 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. All data collected during this period will be used for classification purposes.

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

5.2.2.5. An initial period of no shorter than 3 months may be used for provisional classification. Harvesting for the market may be permitted following provisional classification, providing results to date indicate conformance with microbiological, heavy metal, and other hazardous substances standards. Microbiological sampling shall be conducted weekly in this case.

5.2.2.6. Should a new farm be developed in the same production area as existing farms producing the same shellfish type i.e. mussels, oysters or abalone, the new farm is only required to show conformance with the microbiological standards for the provisional classification, provided that the other farms in the same growing water conforms to heavy metal and other hazardous substances standards.

5.2.2.7. If at any stage during the sampling regime the test results fall outside specifications, weekly sampling shall either be initiated until such time as the problem is identified. More frequent sampling may also be required when environmental conditions indicate a high potential for faecal contamination.

5.2.2.8. 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 DAFF.

5.2.2.9. Water samples for phytoplankton identification by DAFF sanctioned personnel are to be taken at least monthly.

5.2.3. Sampling and analytical protocols for microbiological parameters

5.2.3.1. Live shellstock, including intravalvular fluids is sampled from each station as summarized in Appendix II and submitted to an accredited or officially approved microbiology laboratory.

5.2.3.2. The five-tube, three-dilution MPN method of Donovan *et al.* (1998) is required for enumeration of *E. coli* (Appendix III). Alternative methods for *E. coli*, including other MPN methods, should be validated against the reference method following an internationally accepted protocol (e.g. ISO 16140).

5.3. Approved areas (Class A)

5.3.1. Shellfish harvested from an approved area shall comply with the following conditions:

- The *E. coli* MPN may not exceed 230 *E. coli* per 100 g of flesh and intravalvular liquid in 80% of the samples. No sample may exceed 700 *E. coli* per 100 g of flesh and intravalvular liquid.
- Shall not contain hazardous concentrations of toxic substances that exceed the regulatory limits referred to in Paragraph 5.7.

5.3.2. Harvesting for direct human consumption may take place at any time in an approved area provided a temporary closure is not in effect due to adverse pollution or biotoxin events.

5.4. Restricted areas (Class B)

5.4.1. A restricted area is one in which the sanitary survey indicates a limited degree of microbial pollution.Limited pollution is defined as:

- The *E. coli* MPN may not exceed 4 600 *E. coli* per 100 g of flesh and intravalvular liquid in 90% of the samples. No sample may exceed 14 000 *E. coli* per 100 g of flesh and intravalvular liquid.

5.4.2. No shellfish may be harvested for direct human consumption from restricted areas at any time. Shellfish from restricted areas can only be harvested for depuration or relaying. However, DAFF may consider the issuing of a special permit to harvest shellfish of which the *E. coli* count of the flesh and intravalvular fluids are below 4 600/100g flesh, on condition that it is sterilised in hermetically sealed containers or subject to an approved heat treatment and frozen in compliance with Paragraph 2.4.

5.5. Prohibited areas (Class C)

5.5.1. Shellfish shall not be harvested from prohibited areas for direct human consumption, depuration, relaying or further processing. 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 microbiological pollution exceeding the restricted area limits referred to in Paragraph 5.4.1.
- The sanitary survey or other data indicate contamination of shellfish with heavy metals, radionuclides, pesticides or other hazardous chemicals that exceed the regulatory limits. Petrochemical contamination is also considered a food hazard.
- Pollution sources may unpredictably contaminate the shellfish.

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

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

5.6. Conditional areas (Temporarily Class A or B)

5.6.1. Conditional areas are subject to intermittent microbiological pollution events but may be classified as conditionally approved or conditionally restricted if they meet the relevant criteria for a reasonable and predictable period.

5.6.2. The conditional category allows for a change in classification status of a growing area in response to a clearly established set of criteria that can be timeously implemented. For example, opening/closure criteria might be based on performance standards of sewage treatment plants, seasonal activities affecting water quality, meteorological events, etc.

5.6.3. A management plan shall be developed for Conditional areas that are centred on the predictability of the pollution events (See Appendix I, Paragraph 9).

5.7. Toxic and other hazardous substances parameters for shellfish products

5.7.1. Limits for environmental contaminants

The limits for contaminants such as heavy metals, radio-active substances (Caesium 134 and 137), polychlorinated biphenyls and pesticides will be those included in the relevant regulations published under the Foodstuffs Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972). These limits apply to the fresh weight, edible portion of the shellfish.

5.7.2. Limits for biotoxins

5.7.2.1. No shellfish shall be harvested for direct human consumption if the regulatory limits included in the relevant regulations published under the Foodstuffs Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) and APPENDIX III are exceeded.

5.7.2.2. The recognised methods for shellfish toxicity tests are given in APPENDIX III. Alternatives to biological methods such as the mouse bioassay may be employed on condition that they can be shown to provide an equivalent level of public health protection according to an internationally acceptable validation protocol.

5.7.2.3. Should there be conflicting results from two or more methods employed on a test; the test result from the reference method as indicated in APPENDIX III will supersede the test results from the other methods.

5.7.2.4. Given the appropriate analytical capability, separate limits may be applied to the various sub-groups of lipophilic toxins (formerly diarrhetic shellfish toxins).

5.7.3. Limits for veterinary drugs

The limits for veterinary drugs will be those included in the relevant regulations published under the Foodstuffs Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972).

5.7.4. Export

Where shellfish are intended for export, the official limits applicable to the destination country shall be adhered to.

6. MONITORING OF SHELLFISH PRODUCTION AREAS AFTER CLASSIFCATION

6.1. Background

6.1.1. A system of sanitary checks will be initiated under the guidance of DAFF for each production area (including both natural and artificial areas used for marine aquaculture or relaying and depuration) to promote public safety for both local and international markets. The functions of this programme are to:

- Establish compliance with the requirements of this manual concerning microbiological quality (Paragraph 5.3 and 5.4), toxic and hazardous substances (Paragraph 5.7.1) and biotoxins (Paragraph 5.7.2) 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 (Class A), Restricted (Class B) etc.
- Provide an early warning system for biotoxin control, where relevant, in the interest of public health (and shellfish health and survival in certain cases).

6.1.2. Trained and approved personnel shall assist with sample collection and delivery to accredited or officially approved laboratories for analyses. A system of sample coding will be implemented.

6.1.3. It will be the responsibility of DAFF 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.

6.1.4. DAFF must maintain an updated list of farms indicating its classification and current harvesting status i.e. either open or closed to harvest.

6.2. Microbiological monitoring

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

6.2.2. Approved (Class A) and Restricted production areas shall be tested at least monthly for microbial contamination *viz. E. coli*. Conditional production areas shall be tested at least weekly for microbial contamination during harvesting. A composite sample of shellstock under harvest or intended for next harvest shall be taken.

6.2.3. If the initial sanitary survey indicated a production area could potentially be affected by point sources of faecal contamination, additional, fixed pollution-point sampling station(s) shall be established (Paragraph 5.2.1.3). Pollution-point sampling stations shall be located to provide adequate warning of a potential threat to a production area.

6.2.4. Abalone production facilities classified as Approved are exempt from the requirements of paragraph 6.2.2 and need only be monitored for microbial contamination during official surveillance of end-of-line product. If, however, the end-of-line product is not monitored on a routine basis, the Paragraph 6.2.2 still applies.

6.2.5. Should the results from end-product testing above indicate non-compliance of an abalone production facility, testing shall be conducted in accordance with Paragraphs 5.2.2.5 and 5.2.2.7 to ascertain whether re-classification is necessary. Should the test results after 3 months indicate that the classification status of the abalone production facility remains Approved Paragraph 6.2.4 shall apply.

6.2.6. A minimum of 12 samples must be collected from each station over a 12 month period in approved and restricted areas. 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 and Restricted areas and at least the last 30 samples for Conditional areas. The period evaluated should not be less than the last 12 months.

6.2.7. Production areas must be sampled for shellfish flesh microbiological parameters at least monthly for annual classification purposes, even if not harvesting.

6.2.8. Where a production area at any time does not comply with the sanitary requirements of its designated classification (Paragraph 5.3 or 5.4) in terms of the *E. coli* standards stipulated in Appendix III, the following

actions must be undertaken by DAFF in collaboration with the relevant Health authorities and/or the NRCS (see flow diagram, Appendix IV):

- Review all necessary documentation to trace and recall potentially contaminated shellfish products that are in the distribution system.
- Effect an immediate temporary closure to harvest from the production area being monitored.
- Where *E. coli* concentrations exceed the regulatory limit, conduct confirmatory *E. coli* tests on representative flesh samples taken from at least 5 sampling points (n=5) for farms in an open water system e.g. bays, spread out over the production area to be monitored or in the case of land based tanks systems, from 5 baskets of the next batch to be marketed.
- Re-open to harvest if the results are within regulatory limits (i.e. *E. coli* n=5, C=1, m=230/100g and M=700/100g (see CODEX STAN 292-2008) as in paragraph 5.4). If the confirmatory test results are not within the regulatory limits, the farm is closed until at least 3 different batches of 5 samples each, taken over a minimum period of 3 consecutive days are within regulatory limits.
- Should the *E. coli* concentration in the shellfish exceed the initial trigger limit of <230/100g and fall within the regulatory limit n=5, C=1, m=230/100g and M=700/100g the shellfish may be marketed if pasteurized at 70°C for 2 minutes (Codex Code of Practice for Fish and Fishery Products No. 53 of 2003).
- Where the *E. coli* regulatory limit, n=5, C=1, m=230/100g and M=700/100g has been exceeded but remains below the *E. coli* MPN value of 6000/100g in all raw samples tested, the product may be canned or cooked to a core temperature of 90°C held for at least 90 seconds.
- Furthermore the shellfish shall be tested for *Salmonella* and pathogenic *Vibrio* contamination (see GNR 692 in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972)).
- Where *Salmonella* or *Vibrio cholera* (or other pathogenic *Vibrio*) positives are encountered, conduct confirmatory tests for that organism on representative flesh samples taken from at least 5 sampling points (n=5) for farms in an open water system e.g. bays, spread out over the production area to be monitored, or from 5 baskets in case of tanks systems of the next batch to be marketed.
- Re-open to harvest if the results are within regulatory limits (absence of *Salmonella* or pathogenic *Vibrio* in all 5 samples (see CODEX STAN 292-2008)). If the confirmatory test results are not within the regulatory limits, the farm is closed until the test results of at least 3 different batches of 5 samples each, taken over a minimum period of 3 consecutive days are within regulatory limits.
- Review the classification assigned to the production area when sampling indicates an area continues to exceed its current classification limits.

6.2.9. When an end of the line product fails to satisfy the microbiological criteria for human consumption, the following actions must be undertaken by the relevant Health authority, in consultation with the NRCS and DAFF (see flow diagram, Appendix IV):

- Investigate the possibility of a problem with handling, distribution and labelling and instigate appropriate corrective actions as required.
- Instigate the course of actions given in Paragraph 6.2.8 for the implicated production area if the problem is not identified as related to handling, distribution and labelling.

6.2.10. When an epidemiologically confirmed shellfish-borne illness is reported involving two or more persons and implicating a shellfish production area, the Health authority responsible for the particular area, in consultation with DAFF and the NRCS, shall promptly:

- Place a temporary ban on harvest from the implicated production area.
- Detain and recall any remaining shellfish that are in the distribution system.
- Investigate the possibility of a problem with handling, distribution and labelling and instigate appropriate corrective actions as required.
- Remove the ban on harvesting and re-instate the original classification category if it is determined that the production area is not the source of the outbreak, i.e. problem caused in handling or distribution,

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

6.2.11. Microbiologically contaminated shellfish may be canned or cooked and frozen as per requirements in Paragraph 2.4, provided the microbial status meets the Restricted criteria as a minimum (Paragraph 5.4) or the criteria stipulated in Paragraph 6.2.8. Such shellfish may also be harvested for relaying or depuration until the animals show compliance with Approved microbial limits (Paragraph 5.3). This option may only be exercised in accordance with special permit conditions issued by DAFF.

6.3. Monitoring of environmental contaminants

6.3.1. Sampling will address variation within a production area and will be conducted annually for heavy metals, polychlorinated biphenyls (PCBs) and pesticides. Tests for radionuclides should be conducted every three years or more frequently if there is reason to suspect contamination. 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.

6.3.2. The test sample shall comprise that portion of the shellfish generally recognised as the edible portion, i.e. the whole animal for oysters and mussels, the muscular foot for abalone and the adductor muscle (including roe) for scallops. Test specimens of marketable size and condition should be used for these analyses.

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

6.4. Biotoxin monitoring

6.4.1. Background

Historical data collected by DAFF around the South African coastline indicate that harmful algal blooms, some of which may be toxic, are clearly more prevalent in the west coast upwelling system with relatively few events recorded east of Cape Agulhas. The most likely candidate toxic species are *Alexandrium catenella*, which is responsible for paralytic shellfish poisoning on the west coast and the diarrhetic shellfish poisoning species, *Dinophysis acuminata* and *D. fortii* around the coastline. Other species of *Dinophysis* namely; *D. hastata, D. rotundata* and *D. tripos* also occur in the region. *Alexandrium catenella* has not been recorded east of Cape Point but another species of *Alexandrium* has been isolated from the Western Agulhas Bank. However, substantial blooms have not been observed to date and the cell toxin quota is low; thus it does not appear to render shellfish toxic. In both *D. fortii* and *D. acuminata*, cell toxin quota data indicate that they are only moderately toxic with okadaic acid the primary toxin. *Protoceratium reticulatum* has been implicated in the accumulation of yessotoxins in black mussels on the west coast. Cysts of another species associated with yessotoxins, *Lingulodinium polyedrum,* have been found in low numbers in sediments on the west coast. *Pseudonitzschia* spp are frequently encountered, in particular, *P. australis*. Although a known producer of domoic acid from other parts of the world, results to date indicate that blooms of *P. australis* on the west coast of South Africa are not associated with amnesic shellfish poisoning events. A number of *Karenia* spp (formerly *Gymnodinium* spp) are found around the coast though none have been implicated in shellfish poisoning to date. One species, *K. cristata*, appears to release an aerosol toxin responsible for skin and respiratory disorders of bathers, similar to *K. brevis* and *K. brevisulcata*. (NOTE: Considering the apparent global trend of expanding distributions of toxic algal species, DAFF personnel are actively involved in research on phytoplankton distribution and ecology and attempt to investigate all reported incidences of blooms).

Biotoxins and biotoxin-producing algae shall be monitored in each production 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 DAFF.

6.4.2. Biotoxin Management Plan (See APPENDIX VII)

Biotoxin monitoring is mandatory during harvesting periods. Farm managers must inform DAFF of extended periods of no harvest and dates when harvesting is to be resumed. Failure to comply will result in temporary closure until testing is reinstated.

Abalone farms that are closed for the marketing of live abalone due to PSP toxin levels are required to test the abalone on the farm for PSP on a monthly basis. Each batch of processed product, however, shall be tested to ensure compliance with the regulatory limits.

Each production 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".

In open-water systems, sampling should be undertaken at sites where present knowledge indicates biotoxins are most likely to appear first.

Filter-feeding shellfish most susceptible to rapid biotoxin accumulation (e.g. black mussels) may be used as sentinel species as advised by DAFF.

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

Under certain circumstances, as determined by DAFF, joint biotoxin monitoring programmes may be established for farms in close proximity to each other. A farm selected by DAFF shall be used to monitor the biotoxin status. Should the selected farm be closed due to regulatory limits being exceeded, all the farms that are part of the programme will also be closed. Each farm would then be required to carry out its own tests for each species farmed to be reopened in accordance with Section 6.2.8 for biotoxins, unless otherwise stated in a joint biotoxin agreement signed by the programme manager.

When testing indicates certain shellfish species do not constitute a biotoxin risk, harvest closures may be applied selectively to some species and not others from the same production area.

Sampling at production areas 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, geographic position, presence of biotoxin producing phytoplankton and level of contamination of shellfish flesh.

6.4.2.1. Routine monitoring phase

The routine monitoring phase is to be conducted year round as described below:

- In open water systems, a composite sample of the upper water column will be taken from DAFF selected sites daily, where possible, or at least 3 days a week and delivered to DAFF for phytoplankton identification and enumeration.
- In land-based systems, a water sample representative of the broad hydrographic regime from which intake water is drawn will be used for phytoplankton analyses. Where this is not feasible, a sample of the inflow prior to screening or filtration shall suffice.
- These water samples will be composited on a weekly basis for microscope counting.
- Shellfish samples for biotoxin analyses will be collected in accordance with Table 1.
- A composite sample of shellstock currently being harvested or intended for next harvest is to be taken.

- The sampling schedule given in Table 1 provides the minimum sampling requirements for shellfish flesh.
- Routine testing for biotoxins may be required to be performed more frequently than specified in Table 1 for certain production areas regarded as high risk.

Table 1: Maximum allowable time between biotoxin test and shellfish harvesting

Biotoxin group	West of Cape Point		East of Cape Point	
	Filter feeders	Non-filter feeders	Filter feeders	Non-filter feeders
Paralytic shellfish poisons (PSP)	48h or twice a week for multiple harvesting	2 weeks*	1 month	1 month
Lipophilic shellfish poisons (LSP)	1 week	1 month	2 weeks	1 month
Amnesic shellfish poison (ASP)	1 month	N/A	1 month	N/A

* Farms that are closed for live marketing, due to PSP toxins concentrations exceeding the regulatory limit, shall test the shellfish on the farm once a month and each processed batch shall be tested for PSP toxins. Should an abalone farm to the west of Cape Point that has been temporarily closed for the marketing of live abalone, due to PSP toxin concentrations exceeding the regulatory limit, be reopened in accordance with Paragraph 6.4.2.2, the farm is required to test for PSP weekly for 6 months after re-opening.

- Should an abalone farm to the west of Cape Point be temporarily closed for the marketing of live abalone due to PSP for a period of more than three months, the maximum time between biotoxin tests for PSP in live abalone can extend to 1 month if an exemption is issued to process the abalone in such a way that the PSP is reduced to below the regulatory limit. Each batch of processed abalone shall be tested for PSP.

6.4.2.2. Intensive sampling phase

The intensive sampling phase is to be initiated following detection of biotoxins in shellfish meats in excess of the trigger limits given in APPENDIX V, though still below regulatory limits (Paragraph 5.7.2). Intensive sampling may also be initiated when toxic phytoplankton are present in the absence of shellfish intoxication. DAFF is in the process of investigating whether threshold concentrations for certain toxic phytoplankton species can be correlated with shellfish toxicity and hence used to trigger intensive sampling.

Should a test result exceed the regulatory limit the farm will be temporarily closed for harvesting (Section 6.4.2) and a retest undertaken.

Should the retest result exceed the regulatory limit the farm will be temporarily closed for harvesting and the procedure outlined below in this Section shall be initiated.

In the event that more sample is required for a confirmatory test, the procedure outlined below in this section shall be initiated.

The intensive sampling phase shall be carried out as described below:

- Daily testing of filter-feeder shellfish and weekly testing of non-filter feeders for the relevant biotoxin(s) will be initiated - at an increased number of sampling points, as deemed necessary.
- Should the presence of toxic algae be indicated in the water or in shellfish flesh, the individual daily phytoplankton samples around the event will be counted.
- Supplementary phytoplankton samples may be collected from the implicated production area.

Routine sampling will be re-instated once the biotoxin concentration has returned to non-detectable levels for 3 consecutive samples. A maximum of one sample per day may be submitted for testing.

6.4.2.3. Quarantine phase

The quarantine phase is to be brought into effect immediately following detection of biotoxins in shellfish meats at a level sufficient to cause a public health hazard. The limits for the various groups of biotoxins are given in Paragraph 5.7.2. The quarantine phase is to be carried out as described below:

- DAFF will place a ban on harvesting in the area.
- DAFF Compliance Officers will ensure the embargo is maintained.
- The closed status of the area will be communicated to Industry, the NRCS, the relevant Health authority and other affected parties in writing, with confirmation of receipt.
- The producer shall ensure that any stock marketed from the day that a representative sample of the stock was taken, and the biotoxin concentration in the sample was shown to exceed the regulatory limit, is recalled.
- The producer shall ensure that any operator (packer, processor, retailer), holding stock/s supplied by the farm that has been closed for biotoxins that has not been tested between the particular date that a farm exceeded the regulatory limit and the last date at which the farm tested below the regulatory limit, shall test such stock/s in their possession to ensure compliance with the biotoxin regulatory limits.
- Contaminated products will be recalled, embargoed and destroyed under the supervision of the local Health authority or NRCS inspector responsible for the area. Shellfish that are still alive may be placed back into the production facility.
- The frequency of testing of shellfish will be at the farm managers' discretion in consultation with DAFF. A maximum of one sample per day may be submitted for testing.

6.4.2.4. Re-opening phase

During the re-opening phase a shellfish production area closed due to biotoxins will only be re-opened to harvesting when DAFF has determined that the criteria justifying this action are met. Areas will only be re-opened when biotoxin levels are below the regulatory limit for 3 consecutive samples taken over a period not exceeding two weeks. Information regarding detoxification curves will assist in adjusting these criteria in the future. The re-opening phase is to be carried out as described below:

- The re-opened status will be communicated to all relevant parties.
- Sampling intensity following re-opening to harvest will be dictated by shellfish toxin levels. This would involve intensive sampling in the continued presence of biotoxins in the flesh even though the shellfish have attained sub-quarantine levels of biotoxins.
- Routine sampling will be re-instated once the biotoxin concentration has returned to non-detectable levels for 3 consecutive samples.

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

7.1. Harvesting requirements

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

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, sprayed with clean seawater, 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.

7.1.2. Where necessary, shellstock shall be washed using clean seawater or potable water under pressure to remove mud, bottom sediments or attached biota 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 re-used for shellfish unless they are made from impervious material that can be washed and disinfected prior to re-use.

7.2. Transport and Vessels

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

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

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

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

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

7.2.6. 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 transport permit.

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

7.3. Documentation and records

7.3.1. A movement document issued by DAFF shall accompany each batch of live shellfish during transport from the production area up to, and including, arrival of the batch at a dispatch centre or processing establishment. The movement document must be completed in full and contain the following information:

- Document number
- Identity of harvester, address and signature
- Date of harvesting
- Harvest site and official registration number of production area
- Classification of production area (e.g. Approved – Class A)
- Shellfish identity (common and scientific names) and quantity

- Destination and, if applicable, approval number
- Date and place of receipt

7.3.2. The original (white copy) of the movement document shall be kept by the Permit Holder at their registered office. The duplicate (pink copy) of the movement document shall be kept by the authorised Fish Processing Establishment (FPE) and the duplicate (blue copy) of the movement document shall be submitted to the Department within 30 days.

7.3.3. In the case of a batch of live shellfish that have been subject to a depuration process, the movement document must include, in addition to the above, the location/address of the relaying area or depuration plant and the duration and dates of purging.

7.3.4. 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, DAFF 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.

7.3.5. The facility receiving a movement document must keep it available for inspection for a period of at least 5 years.

7.3.6. 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 5 years.

7.3.7. DAFF shall keep a copy on file of all completed movement documents issued indefinitely.

8. REQUIREMENTS FOR RELAYING SHELLFISH

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

8.1. Conditions

8.1.1. Relaying refers to the transfer of shellfish with limited levels of pollution to approved areas where the ambient environment provides the medium for biological depuration. 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 unless studies are conducted that verify depletion of the contaminant(s) of concern to acceptable levels.

8.1.2. Relaying operations must be supervised by a DAFF Compliance Officer or duly authorised official inspector.

8.1.3. Relaying areas must be authorised by DAFF as for a marine aquaculture operation. Harvesting of shellfish for relaying may only be undertaken with authorisation from DAFF.

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

8.1.5. Relaying areas shall be monitored as for other approved production areas.

8.1.6. Caution must be exercised in relaying of shellfish from marine aquaculture operations to prevent the potential spread of animal diseases.

8.2. Source of shellfish

8.2.1. No shellfish that exceed the contaminant levels for restricted areas (Paragraph 5.4) may be relayed. Shellfish must not be contaminated with biotoxins to the extent that safe levels cannot be achieved at the end of the relaying period.

8.2.2. Live shellfish must be gathered and transported in accordance with Section 7.

8.2.3. Shellfish intended for relaying must be accompanied by a movement document (Paragraph 7.3.1). The conditions of Paragraph 7.3.4 apply.

8.3. Relaying areas

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

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

8.4. Operating procedures

8.4.1. Each relayer must develop in consultation with DAFF, written standard operating procedures that provide assurance of end-product safety. The procedures shall address the following:

- Source and species of shellfish.
- Contaminant levels of source shellfish and after depuration.
- 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.

8.4.2. Studies shall be undertaken by the relayer to determine the effectiveness of contaminant reduction with due consideration to species and initial shellfish degree of contamination. Water temperature and other critical parameters for effective depuration 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.

8.4.3. The microbiological concentrations in the shellfish shall meet the approved criteria (Paragraph 5.3), and biotoxins limits given in Paragraph 8.4.2, at the end of the relaying process.

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

8.4.5. Batches of shellfish may only be harvested from a relaying area following laboratory confirmation of successful purification.

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

8.4.7. Batches of live shellfish harvested in a relaying area must be accompanied by a movement document (Paragraph 7.3.1) during transport to a dispatch centre or processing plant. The conditions of Paragraph 7.3.4 apply.

8.5. Records

8.5.1. Relayers shall be required to keep complete and accurate records for inspection by DAFF for at least 5 years. This should include the following:

- The source and species of batches of shellfish.
- Results of microbiological and/or biotoxicity tests of each lot of shellfish before and during relaying.
- The date of harvest and quantity of shellfish harvested.
- The dates and duration of relay.
- Records of critical environmental parameters during relaying.
- The purchaser and quantity purchased.
- Movement documents and other records necessary to trace individual batches of shellfish.

8.5.2. DAFF 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
- Movement documents

9. DEPURATION

The guidelines presented below are recommendations for the management and control of depuration centres and are based on international experience.

9.1. Conditions

9.1.1. Depuration is the process whereby filter-feeding shellfish are biologically 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.

9.1.2. All operations harvesting shellfish for delivery to a depuration plant must be issued with a separate permit by DAFF.

9.1.3. The premises and hygienic standards must comply with the Regulations Governing the General Hygiene Requirements for Food Premises and the Transport of Food, Regulation 962 published under the Foodstuffs , Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972). Certification of depuration plants shall require:

- Approval of plant design, construction and operation including remodelling.

9.1.4. The operator shall be responsible for verifying the depuration process.

9.1.5. Certified depuration plants are to be inspected at least monthly to ensure compliance with Regulation 962 published under the Foodstuffs , Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972).

9.1.6. DAFF shall analyse plant processing data and other records at least monthly to verify if the process and controls are sufficient to meet the end product criteria.

9.2. Process verification

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

- Shellfish species and source
- Maximum pre-depuration level of faecal contamination to ensure that end point criteria are consistently achieved during normal operations (not to exceed limits given in paragraph 5.4.1).
- 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

9.3. Source of shellfish

9.3.1. Only shellfish that meet the requirements for restricted areas (paragraph 5.4.1), at a minimum, may be harvested for depuration. The acceptable pre-depuration levels of faecal contamination shall be established as part of the ADP.

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

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

9.3.4. Shellfish intended for depuration must be accompanied by a movement document (Paragraph 7.3.1) unless the conditions of Paragraph 7.3.3 apply.

9.3.5. Shellfish should be culled of dead or damaged individuals and washed with clean seawater or potable water prior to depuration.

9.4. Structural requirements

9.4.1. The construction of floors, walls, ceilings (where provided) and installation of lighting, plumbing and sewage disposal systems must comply with the provisions of the Regulation 962 published under the Foodstuffs , Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972).

9.4.2. Vermin control shall be implemented in accordance with Regulation 962 published under the Foodstuffs , Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972). Effective barriers shall be provided to prevent the entry of vermin, animals and birds into the area and above the storage tanks.

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

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

9.4.5. The site, facility and plant shall be evaluated and approved annually by DAFF in conjunction with the NRCS and relevant local health authority, taking into account the records of water officially tested.

9.5. Process water quality and operation

9.5.1. Source water may be drawn from an approved or restricted production area prior to treatment. Prohibited growing areas may not be used as source waters.

9.5.2. 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 E. coli. Water must be sampled as described in the latest version of SANS 241 and analysed according to SANS 5221. 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 when UV disinfection is employed.

9.5.3. 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 l/min/m^3 of shellfish is recommended.

9.5.4. Only shellfish of the same species are to undergo depuration in the same depuration unit. Different harvest lots of shellfish must not be mixed and shall be maintained as identifiable batches throughout the depuration process and final packaging.

9.5.5. The minimum depuration time is based on the batch in a depuration tank requiring the longest period of depuration and should be no shorter than 48 hours.

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

9.6. Cleaning and Sanitizing of facilities, utensils and equipment

9.6.1. All facilities utensils and equipment on the premises shall be kept clean and sanitized in accordance with Regulation 962 published under the Foodstuffs , Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972).

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

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

- The process unit including the system piping network shall be cleaned, and where possible, sanitised after each batch.
- The seawater storage tanks shall be cleaned and sanitised on a regular basis.
- The washing, culling, sorting and pre-process storage areas shall be thoroughly washed and sanitised after each use.

9.7. Quality assurance

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

9.7.2. Shellfish from single process batches may not be released to market unless laboratory results confirm that the end product meets the microbiological standards for approved areas (Paragraph 5.3).

9.7.3. Water disinfection systems should be sampled frequently to monitor effectiveness of the treatment units.

9.7.4. In the event of a process batch failing to meet the release criteria, the operator shall notify DAFF 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 NRCS as relevant:

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

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

- Name of depuration plant and identity of operator
- Depuration cycle number and date
- Identity of production area
- Type and quantity of shellfish

9.7.6. Batches of depurated shellfish must be accompanied by a movement document during transport to a dispatch centre or processing plant (Paragraphs 7.3.1 and 7.3.4).

9.8. Records

9.8.1. Operators shall be required to keep the following complete and accurate records for at least 5 years:

- Information that will allow a package of depurated shellstock to be traced back to the process batch, production area, harvest date and harvester and corresponding movement documents.
- Results of product sampling and critical parameters (maintained for at least 5 years).
- Current copy of the plant operating procedures.
- Dispatch details of consignments after depuration.

10. WET STORAGE

10.1. Conditions

10.1.1. Wet storage refers to the holding of live shellfish in near-shore waters or onshore tanks for temporary storage or conditioning purposes prior to processing/packaging for sale. Wet storage is not intended for depuration therefore all controls pertaining to shellfish for direct human consumption should be applied.

10.1.2. The premises and hygienic standards must comply with Regulation 962 published under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972). Wet storage sites or facilities must undergo an annual evaluation by the relevant local health authority in co-operation with DAFF. This evaluation shall consider the following:

- The sanitary survey of the near-shore site and monitoring records.
- The design and operating procedures for the onshore storage facility including the quality of source water and details of any water treatment system.
- Plans for remodelling.

10.1.3. No other marine species may be stored in the same tank with shellfish.

10.1.4. Caution must be exercised in wet storing shellfish from marine aquaculture operations to prevent the potential spread of animal diseases.

10.1.5. Filtration may be used to mitigate against contamination from biotoxin producing phytoplankton in shore-based wet storage systems

10.1.6. Shellfish can be sold from onshore wet storage that has filtration in place to prevent the entry of phytoplankton on the following conditions:

- Should a production area supplying the wet storage be closed due to the biotoxin concentration in the shellfish exceeding the regulatory limit, the last batch to enter the wet storage shall be tested for the implicated biotoxin. Should the test result for the last batch be below the regulatory limit, the last batch and any prior batches contained in the wet storage may be placed on the market.
- The water quality requirements stipulated in Section 10.4.8 are met.

10.1.7. The following conditions apply to wet storage that has no filtration in place to prevent the entry of phytoplankton:

- Should the production area from which the wet storage plant draws its water be closed for biotoxins, the wet storage facility shall also be closed.
- Should there not be a biotoxin monitoring programme for the source waters of the wet storage plant, the shellfish shall be tested as stipulated in Table 1

10.2. Source of shellfish

10.2.1. Shellfish for wet storage shall be harvested only from approved or conditionally approved production areas in open status or taken from a certified depuration plant.

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

10.2.3. Shellfish from different harvest areas shall be wet stored separately. If multiple harvest lots are wet stored simultaneously, the identity of each lot shall be maintained throughout the process.

10.2.4. Shellfish intended for wet storage must be accompanied by a movement document (Paragraph 7.3.1) unless the conditions of Paragraph 7.3.4 apply.

10.3. Structural and design requirements

As for depuration (Paragraph 9.4).

10.4. Water quality

10.4.1. Shellfish shall be washed with clean seawater or potable water and culled of dead or damaged animals prior to wet storage.

10.4.2. 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.

10.4.3. Near-shore areas for wet storage must meet the approved or conditionally approved criteria (Paragraphs 0 or 5.6).

10.4.4. Water of approved production 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.

10.4.5. In-water or land-based wet storage facilities that meet the approved criteria must conduct monthly microbiological testing or secure the services of an outside laboratory to provide confirmation of approved water status. Wet storage facilities for abalone are exempt from this provision.

10.4.6. Re-circulating systems or systems using water of a quality inferior to the approved water criteria must be treated. Treated water entering wet storage tanks shall have no detectable levels *E. coli*, as for depuration (Paragraph 9.5.2) The following conditions apply:

- 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 *E. coli* 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 shall be taken daily of untreated source water. Any positive sample for *E. coli* 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 Recognised As Safe 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 *E. coli*, 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

10.4.7. Salt added to increase salinity or produce synthetic seawater must be food-grade salt as defined under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972)

10.4.8. The following requirement is applicable to wet storage that has a filtration system to remove phytoplankton species:

- The operator of the facility shall conduct a study on the effectiveness of the filtration system as assurance that the no toxic phytoplankton (see APPENDIX IX) cells shall be found in the facility except for Pseudo-nitzchia species for which the concentration in the incoming water shall be less than 100 cells/litre. Samples of filtered water entering the storage system shall be taken at a minimum frequency of 3/day over a period of 5 days for analysis.
- Should any production areas in the vicinity be closed for biotoxins, the incoming filtered water shall be analysed once a week for phytoplankton until all production areas are re-opened.

10.5. Records

10.5.1. The following records shall be maintained by the operator:

- Information that will enable each lot of shellstock to be traced to the wet storage facility and classified production area
- Records of water sampling and other tests as may be required (minimum of 2 years)
- Movement documents

10.5.2. Live shellfish shall be labelled as described in Paragraph 11.2.1 during transport and distribution until retail sale.

11. REQUIREMENTS FOR DISPATCH CENTRES

11.1. Receiving and storage

11.1.1. A dispatch centre is any installation for the reception, handling and packaging of live shellfish fit for human consumption.

11.1.2. The premises and hygienic standards must comply with the Regulation 962 published under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) and must be inspected at least once annually and approved by an NRCS inspector or relevant local health authority. Dispatch centres must be issued with a permit as for a processing establishment in terms of the Marine Living Resources Act, 1998 (Act No. 18 of 1998).

11.1.3. Live shellfish accepted at a dispatch centre must have originated from an approved or conditionally approved production area, a relaying area, a depuration plant, or another dispatch centre. A record should be kept of the condition of each batch received and accepted.

11.1.4. Only batches of live shellfish accompanied by a movement document (Paragraph 7.3.1) shall be accepted at a dispatch centre unless the conditions of Paragraph 7.3.4 apply. Shellfish must have been harvested and transported according to the requirements of this manual (Section 7).

11.1.5. In any sorting or dry 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, though not so cold as to affect viability. Temperature control must be put in place within 20 hours of harvest.

11.1.6. The room must be vermin proof and have impermeable floors. Shellstock should be held in a protected location away from direct contact with the floor or from foot splash.

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

11.1.8. Shellfish from different production areas must be kept sorted and packed separately to maintain identity.

11.1.9. Before dispatch, the shells of live shellfish must be washed thoroughly with clean seawater or potable water.

11.2. 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 labelling requirements specified in the relevant regulations published under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972), where applicable, Trade Metrology Act, 1973 (Act No77 of 1973), Compulsory Technical Standards as applied in terms of the National Regulator for Compulsory Specifications Act, 2008 (No. 5 of 2008), or importing country regulations:

- Dispatch establishment number, name and address.
- Date of harvest (day, month, year)
- Date of packaging (day, month, year) and batch code reflecting origin of product.
- Production method, commercial designation and species name (e.g. cultivated abalone – *Haliotis midae*).
- Requirements for storage prior to use by consumer (on main panel) and the warning: These animals must be alive when sold (or date of durability).
- Net mass in kilograms.
- Product of the Republic of South Africa.

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

11.2.2. A person operating the dispatch centre must keep a record of each consignment for a period of not less than 5 years to enable products to be traced and recalled if necessary.

11.2.3. 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 5 years. The label must include, in addition to that set out in Paragraph 11.2.1, details of the original dispatch centre and re-packaging details.

11.3. Transport from a dispatch centre

11.3.1. The transport of live shellfish intended for human consumption must comply with the relevant provisions of Regulation 962 published under the Foodstuffs , Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972). Consignments of live shellfish intended for human consumption must be transported wrapped in sealed parcels until offered for sale to the consumer or retailer.

11.3.2. Individual consumer-size packages of live shellfish must remain sealed after leaving the dispatch centre until presented for sale to the end consumer.

11.3.3. Live shellfish must be transported and distributed using closed vehicles or containers which maintain the product at a temperature that 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 not be so cold as to affect the viability of the shellfish. This temperature shall be maintained during transport and storage.

11.3.4. 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.

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

11.4. Export

11.4.1. Health guarantees are issued by the relevant authorities officially authorised by DAFF in accordance with the requirements of the country of destination. As required, finally prepared and packaged live shellfish will be monitored on the basis of a random testing and surveillance programme, in addition to the sampling of live product prior to dispatch.

11.4.2. Exporters are to copy their request for health certification from the issuing office to their area NRCS inspector (for sampling purposes)

12. Feed management and monitoring

Feed that is compounded industrially or at the aquaculture facility shall contain only such additives, growth promoting substances, flesh colouring agents; anti-oxidizing agents, caking agents or veterinary drugs that are permitted for shellfish by DAFF.

Storage and transportation conditions shall conform to the specifications on the label.

12.1. Farmer responsibility

12.1.1. Feed and feed ingredients shall be supplied by feed manufacturers which are registered with the regulatory body.

12.1.2. Ingredients shall meet acceptable, and where applicable, statutory standards for levels of undesirable substances that may give rise to human health hazards.

12.1.3. Medicated feed shall be stored separately, in order to avoid errors.

12.1.4. Farmers shall follow manufacturer instructions on the use of medicated feeds.

12.1.5. The feed and the ingredients of the feed shall be fully traceable to source and product tracing of all feed ingredients shall be assured by proper record-keeping.

12.1.6. Feed shall be registered with DAFF and sourced from a supplier approved by DAFF.

12.1.7. Each batch procured shall be recorded on Feed Batch Register, which is to be filed and be available for inspection. The register shall include at least:

- Brand name
- Batch Date (Date of manufacture)
- Date In
- Date Out of last bag
- Period in storage
- Supplier

12.1.8. Feed shall be handled on a first-in-first-out basis and each batch shall be kept separately and used by the expiry date. If the expiry date is exceeded the producer shall ensure that the feed is safe for intended use.

12.1.9. Dry feeds shall be stored in cool and dry areas to prevent spoilage, mould growth and contamination. Moist feed shall be properly refrigerated according to manufacturer instructions.

12.1.10. The feed shall be kept off the ground to allow for ventilation to reduce contamination.

12.1.11. The store room shall be dry, well ventilated and kept clean.

12.1.12. Regarding the control of pests refer to Section 9.4.2.

12.1.13. There shall be no chemicals stored in the same store room or substances that are harmful to shellfish or humans.

12.2. Feed producer responsibility

12.2.1. Feeds and feed ingredients shall be properly labelled with an expiry date and production date. Their composition must fit the declaration on the label.

12.2.2. Labelling shall comply with relevant legislation.

12.2.3. Feed shall comply with the relevant legislation in terms of hazardous substances and shall be safe for fish consumption.

12.2.4. Only approved additives and approved flesh colouring agents of the correct concentration shall be included in the feed.

12.2.5. Moist feed or feed ingredients shall be fresh and of adequate chemical and microbiological quality.

12.2.6. Fish silage and offal from fish, if used, shall be properly cooked or treated to eliminate potential hazards to human health.

12.2.7. Veterinary drug and other chemical treatments shall be authorised for use by the medicines control council and shall be administered in accordance with recommended practices and comply with national regulations.

12.2.8. Medicated feeds shall be clearly identified on the package.

13. Drug management

13.1. Prior to administering veterinary drugs, a system shall be in place to monitor the application of the drug to ensure that the withdrawal time for the batch of treated shellfish can be verified.

13.2. Products registered under Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947) and Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965) shall only be administered by veterinarians registered with the South African Veterinary Council, (SAVC) and / or on prescription by such a veterinarian.

13.3. Drugs listed in APPENDIX X shall not be used and shall be monitored for in the shellfish.

13.4. All chemicals used for the treatment of shellfish or production water shall be adequately labelled.

13.5. Storage and transportation conditions shall conform to the specifications on the label.

13.6. Control of diseases with drugs shall be carried out only on the basis of an accurate diagnosis by a registered vet.

13.7. If aquacultured shellfish are monitored for drug residues and drug residue concentrations are found to be above the maximum residue limit (MRL) or the withdrawal limits have not been observed as indicated on the drug label, harvest of the batch shall be postponed until the batch complies with the MRL. After an assessment of the better management practices (BMP) regarding pre-harvest measures, appropriate steps shall be taken to modify the drug residue control system.

13.8. A post harvest control shall reject all shellfish that do not comply with the requirements set for MRL.

13.9. Products registered under Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (act No. 36 of 1947) and Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965) shall only be procured from a registered veterinarian.

13.10. The Drug Procurement Register shall contain at least the following information:

- Date purchased
- Suppliers name and contact details
- Name of drug
- Quantity purchased
- Batch number
- Expiry date
- Withholding period

13.11. The treatment of shellfish or production water shall only be undertaken under the supervision of a registered vet.

13.12. Records shall be maintained for the use of veterinary drugs in aquaculture production. A Treatment Register shall be maintained and shall include at least the following information:

- Date administered
- Batch of shellfish treated
- Name of the drug
- Amount used
- Withholding period
- Date shellfish safe for harvest
- Who administered the drug
- Reason for treatment

13.13. Withdrawal times shall be observed before shellfish is harvested for human consumption.

13.14. The Treatment Register shall be properly filed and available for inspection.

14. DEFINITIONS

"**Acceptable**" means acceptable to the competent authority for the approval and licensing of molluscan shellfish production and harvesting waters and for the competent authority inspecting and certifying such product for export.

"**Adverse pollution conditions**" means conditions determined by changes in meteorological, hydrographic, seasonal and point source pollution conditions that have been historically demonstrated to unfavourably impact on a particular production 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 (Class A)**" means the classification by DAFF of a production area where shellfish may be harvested for sale for direct human consumption at any time outside of temporary closures. An approved area must meet the microbiological requirements set out in Paragraph 5.3. An approved area may be temporarily closed to harvesting, e.g. when a flood, storm or marine biotoxin event occurs.

"**Central file**" means the file system maintained by the persons responsible for management of this programme at DAFF.

"**Clean ice**" means ice made from potable water or clean seawater and that has been stored hygienically prior to use.

"**Clean seawater**" means 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**" means a production area where the harvesting of shellfish is temporarily or permanently not permitted.

"**Compliance Officer**" means any person appointed as such in terms of the Marine Living Resources Act, 1998 (Act No. 18 of 1998).

"**Conditional areas**" means the classification by DAFF of a production area that meets either the approved or restricted area criteria for a predictable period. The period is conditional upon established performance standards specified in a management plan.

"**Conditioning**" means the storage in clean seawater of live shellfish meeting the approved area criteria for the purpose of improving palatability and/or vitality.

"**Depuration plant**" means a licensed establishment comprising one or more depuration units that are used for purifying shellfish according to an approved depuration process. A depuration unit is a tank or series of tanks fed by a single process water system.

"**Depuration**" means the process of using a controlled clean sea water system to reduce to levels of microbial contaminants in live shellfish.

"**Direct human consumption**" means live shellfish intended for direct human consumption are regarded as ready to eat at the point sale, i.e. safe in the live, fresh state, if so desired. Also referred to as immediate human consumption.

"**Dispatch centre**" means any installation for the reception, conditioning, washing, cleaning, grading and packaging of live shellfish fit for human consumption.

"**Establishment number**" means refers to the official approval number for a production or harvesting area and packaging or processing facility. The establishment number for packaging and processing is obtained from the Food Standards Division of the NRCS in Cape Town. This number may also refer to a permit number issued by DAFF for a specific cultivation area, relaying area, depuration plant or harvester.

"**Harvester**" means a person who takes shellfish by any means from a production area.

"**Health authority**" means the relevant local authorities responsible for municipal health services as defined in the National Health Act, 2003 (Act No. 61 of 2003) as amended, read in conjunction with the Municipal Structures Act, 1998 (Act No. 117 of 1998).

"**Intensive sampling**" means the taking of samples at a greater frequency, as prescribed by DAFF, than required for routine sampling.

"**Lot of shellfish (or batch)**" means shellfish harvested from a particular identifiable area at a particular time (i.e. no more than one day).

"**Marine aquaculture**" means for the purposes of this manual, the controlled production of molluscan shellfish in natural and artificial seawater systems destined for the market as a foodstuff.

"**Marine biotoxins**" means poisonous compounds that accumulate in shellfish generally by feeding on toxin-producing dinoflagellates or diatoms, though other means of toxification could occur.

"**Molluscan Shellfish**" means for the purposes of this manual, applies to all bivalve molluscs and including Pectinidae and marine gastropods but excluding octopus and squid. ("shellfish" in the text refers to molluscan shellfish).

"**Official Inspector**" means any Compliance Officer, Inspector, Environmental Health Practitioner or Health Officer appointed in terms of the Marine Living Resources Act, (Act No. 18 of 1998), National Regulator for Compulsory Specifications Act, 2008 (Act No. 5 of 2008) or National Health Act, 1998 (Act No.61 of 2003) and regulations promulgated under these Acts.

"**Person**" means an individual, partnership, corporation, association or other legal entity.

"**Point source** (of pollution)" means a discernible single source such as any pipe, ditch, channel, tunnel or conduit that carries pollution.

"**Potable water**" means water that is safe for human consumption and that complies with the requirements of SANS 241 (NRCS 241).

"**Process batch**" means a quantity of shellfish used to fill each separate depuration unit.

"**Process water**" means seawater in depuration tanks during the time that the shellfish are 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 are being wet stored.

"**Processing**" means the physical or chemical treatment of shellfish that substantially alters the initial product. Shucking, packing and repacking are also regarded as processing.

"**Processor**" means a person who processes shellfish.

"**Production area**" means an artificial or natural seawater or estuarine system that supports or could support the propagation of live shellfish.

"**Prohibited area**" means a production area where there is no current sanitary survey or where the sanitary survey or other monitoring programme indicates that faecal material (*E. coli*), pathogens or toxic substances may reach the area in excessive concentrations. Any taking of shellfish for human consumption from such area is prohibited.

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

"**Restricted area (Class B)"** means a production area classified by DAFF as an area from which shellfish may be harvested only by special permit. A restricted area must comply with the microbiological requirements set out in Paragraph 5.4. Shellfish from restricted areas may be processed (e.g. canning, cooking and freezing) or subjected to an approved depuration process such as relaying or depuration.

"**Sanitary Survey**" means the evaluation, in accordance with the requirements of Paragraph 5.2 of this manual, by a DAFF approved party, of all actual and potential pollution sources and environmental factors that may affect shellfish production water quality.

"**Shellfish Management Committee**" means the board of management of the DAFF, in co-operation with the Department of Health, NRCS, and Industry, whose primary role it is to review the management actions proposed in this manual with regard to public health on an annual or more frequent basis.

"**Shellstock**" means shellfish in the shell.

"**Shoreline Survey**" means a survey of the shoreline of the production area catchment conducted by an officer authorised by DAFF according to requirements in Appendix I.

"**Transaction Record**" means a form used to document each purchase or sale of shellfish at the wholesale level.

"**Treated water**" means seawater used in a depuration or wet storage facility that has been disinfected by either UV, ozone, chlorine/hypochlorite, iodophor, or other appropriate treatment. Treated water must contain no detectable *E. coli* after treatment.

"**Wet Storage**" means the temporary storage of shellfish harvested from Approved or Conditional production areas open to harvesting.

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16. SOUTH AFRICAN LEGISLATION

The following South African legislation is applicable to the South African Molluscan Shellfish Monitoring and Control Programme:

- Marine Living Resources Act, 1998 (Act No. 18 of 1998)
- Foodstuffs, Disinfectants and Cosmetics Act, 1972 (Act No. 54 of 1972) and relevant regulations
- National Regulator for Compulsory Specifications Act, 2008 (Act No. 5 of 2008)
    - Compulsory Specification for the Manufacture, Production, Processing and Treatment of Canned Fish, Canned Marine Molluscs and Canned Crustaceans. Regulation 790, 1 9 July 2004, in terms of the NRCS Act (Act No. 5 of 2008).
    - Compulsory Specification for Frozen Fish, Frozen Marine Molluscs and Frozen Products derived there from. Regulation 979, 4 July 2003, in terms of the NRCS Act, 2008 (Act No. 5 of 2008).
- Municipal Structures Act, 1998 (Act No.117 of 1998)
- Trade Metrology Act, 1973 (Act No. 77 of 1973)
- Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies, 1947 (Act No. 36 of 1947)
- Medicines & Related Substances Control Act, 1965 (Act No. 101 of 1965)
- Veterinary and Para- veterinary Professions Act, 1982 (Act No. 19 of 1982)

APPENDIX I: MINIMUM REQUIREMENTS OF THE SANITARY SURVEY REPORT

The following provides an outline of the many factors to be considered in performing and reporting on the sanitary survey as required in Section 5.2. These guidelines act as a checklist and provide a model for the structure of the report.

1. Summary

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

2. Background information

2.1 Motivation for the study.

2.2 General description of production area – including maps and, where available, aerial photographs.

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

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

2.5 History of production area classification:

- Summary of sanitary survey history
- Previous classification – including maps and photographs, where appropriate.

3. Pollution source (shore line) survey

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

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

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

- Domestic wastes – include maps and discussion on use of septic tanks in the catchment area and sewage treatment facilities and outfalls
- Stormwater – information on the nature (combined) and conduiting (drainage ditches, pipes and runoff)
- Agricultural waste from farms, feedlots and slaughterhouses
- Industrial wastes
- Wildlife areas – unfenced access of animals to production areas
- Radionuclides
- Marinas
- Minor sources such as boats, birds and seals

4. Hydrographic and meteorological characteristics

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

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

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

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

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

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

4.7 River discharges – volumes and seasonality.

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

5. Water quality studies

5.1 Sampling plan, taking potential pollution sources into account.

5.2 Map showing sampling stations.

5.3 Description of sample collection and analytical procedures.

5.4 Microbiological data analysis and presentation. Present data and statistical analyses in table form indicating compliance with criteria given in Section 6 and classification of individual sample stations where applicable.

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

5.6 Assessment of risk imposed by biotoxin producing phytoplankton.

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

- Effects of meteorological and hydrodynamic factors on pollution sources.
- Causes of adverse pollution conditions.
- Potential pollution associated with seasonal events such as holidays, festivals etc.
- Explanation for the variability in the data.

6. Recommended classification.

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

7. Recommendations.

7.1 Details of monitoring schedule for microbiological indicators and toxic and hazardous substances that will be used in the annual re-assessment of production area classification.

7.2 Monitoring actions for biotoxins.

7.3 Provide suggestions for future work and improvements in the above programmes from previous years.

8. Enforcement action reports

Provide details of enforced closure to harvest for public health reasons during the re-classification period. This should include (see also Paragraphs 9.3 and 9.4 of this Appendix):

- Reasons for closure and duration (dates)
- Management actions taken (harvest closures, recall, embargo, policing) and response times from sampling to the specific responses.
- Details regarding the roles of the different agencies involved in the emergency response,
- Re-opening criteria and re-classification status if applicable.
- Information relevant to cooperation received from the affected harvester(s) or farmer(s).

9. Management plans

9.1 Management plans for areas classified as conditionally approved or conditionally restricted shall be included in the initial sanitary survey and updated as necessary during the annual evaluations. Because of the burden on the public resource, a conditional classification option should only be considered in special cases.

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

9.2.1 Wastewater treatment facility - performance standards based on:

- Peak effluent flow
- Bacteriological, chemical and physical quality of the effluent

- Bypasses
- Design, construction and maintenance to minimise mechanical failure or overloading
- Monitoring of wastewater treatment efficacy and feedback system in the case of inadequate treatment

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

9.2.3 Other events - marina openings and closures, bird migrations, holiday seasons etc.

9.3 Implementation of conditional area closures.

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

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

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

9.4 Criteria for reopening a conditional area after a pollution event. DAFF shall establish the following control elements to define re-opening criteria:

- Procedures to determine that the pollution event has ended
- Physical flushing time, i.e., time for area to exchange a sufficient volume of water to disperse/assimilate the pollutant load
- Shellfish feeding activity is sufficient to promote natural cleansing
- Time after flushing required for shellfish to naturally cleanse themselves

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

APPENDIX II: SAMPLING OF SHELLFISH AND WATER

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

Shellfish samples for microbiological and biotoxin analyses should comprise shellstock close to market size. Juvenile shellfish should not be used as a proxy.

1 **Shore-based marine aquaculture systems**

1.1 Filter feeders - samples for microbiological examination are to be taken of shellstock within the grow-out units.

1.2 Non-filter feeders - samples for microbiological examination are to be taken of shellstock within the grow-out units, as well as the intake water to the farm.

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

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

2 **Production (cultivation) areas in the open-water environment**

2.1 Filter feeders - samples for microbiological examination are to be taken from shellstock within the production area.

2.2 Non-filter feeders - samples for microbiological examination are to be taken of shellstock within the production area, as well as ambient water.

2.3 Water samples for algal identification shall be taken from positions that provide adequate early warning of the presence of harmful algal species. DAFF will advise on sample station positioning and method of collection. Where feasible, an integrated sample of the upper water column shall be taken using a Lund tube.

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

3 **Shellfish samples**

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

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

3.2 Shellstock is collected in clean, waterproof, puncture resistant containers. Sample containers for microbiological analyses must be sterile.

3.3 Separate samples are to be collected for biotoxin and microbiological analyses.

3.4 Shellfish should be cleaned of dirt, sediment and other organisms, and then rinsed in clean seawater and drained before being placed in storage containers.

3.5 The sample is labelled with the collector's name, type of shellfish, the source or production area code, station position or other identifier as relevant, time and date, and intended analysis (e.g. *E. coli*, PSP etc.). An official sample submission form should be used for this purpose.

3.6 Samples for microbial testing are maintained in dry storage between 0° and 7°C until examined - as soon as possible after collection but not exceeding 24 hours. Coolers containing ice packs, not in direct contact with the sample, offer a convenient system. Samples should not be frozen.

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

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

4. **Seawater samples for microbial examination**

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

4.2 Samples are identified with the collector's name, source or production area identifier, position, time and date of collection, and intended analysis. An official laboratory submission form should be used for this purpose.

4.3 Samples shall be maintained at 0° - 7°C until examined - as soon as possible after collection but not exceeding 24 hours.

5. **Seawater samples for algal identification**

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

5.2 Samples are identified with the collector's name, production area or other identifier, position, and time and date. Supplementary environmental data should be supplied as requested by DAFF

5.3 Samples are preserved with buffered formalin to a final concentration of 2.5%.

6 **Receipt of samples by the laboratory**

6.1 Samples should be accompanied by an official submission form.

6.2 For microbiological analyses, the receiving laboratory must record:

- the condition and number of individuals in the sample
- sample temperature
- time of sample collection and receipt at the laboratory

6.3 Shellfish intended for microbiological analysis must be alive on receipt by the laboratory and stored at between 0 and 7°C prior to analysis.

6.4 For biotoxin analyses, the receiving laboratory must record the condition (freshness) and number of individuals in the sample.

APPENDIX III: STANDARDS AND METHODS FOR THE ANALYSES OF BIOTOXINS AND MICROBIAL CONTAMINANTS

BIOTOXIN	TEST METHODS	STANDARDS
Paralytic Shellfish Poisons (PSP)		
Saxitoxin	Mouse bioassay (AOAC official method 959.08 1990) (Commission Regulation (EC) 2074/2005). Lawrence method (AOAC Official Method 2005.06) (Commission Regulation (EC) No 1664/2006).	≤ 0.8 mg total PSP / kg edible flesh (Regulation (EC) No 853/2004).
Lipophilic Shellfish Poisons (LSP)		
Okadaic acid, dinophysistoxins, azaspiracids, pectenotoxins and yessotoxins	Mouse bioassay (Yasumoto *et al.* 1984) using acetone extraction and liquid-liquid partitioning with dichloromethane (Hannah *et al.* 1995) (Commission Regulation (EC) No 15/2011).	Death of 2 out of 3 mice in 24 hours is considered a positive result (Regulation (EC) No 2074/2005).
Okadaic acid group toxins: OA, DTX 1, DTX 2 & DTX 3 and Pectenotoxins group toxins: PTX 1 & PTX 2	**^**Liquid Chromatography Mass Spectrometry (EU-RL* LC-MS/MS method) (Commission Regulation (EC) No 15/2011)	≤ 0.16 mg okadaic acid equivalents / kg edible flesh (Commission Regulation (EC) No 853/2004).
Yessotoxins group toxins: YTX, 45 OH YTX, homo YTX, and 45 OH homo YTX	**^**Liquid Chromatography Mass Spectrometry (EU-RL LC-MS/MS method) (Commission Regulation (EC) No 15/2011)	≤ 8 mg yessotoxin equivalents / kg edible flesh (Codex).
Azaspiracids group toxins: AZA1, AZA2 and AZA3.	**^**Liquid Chromatography Mass Spectrometry (EU-RL LC-MS/MS method) (Commission Regulation (EC) No 15/2011)	≤ 0.16 mg azaspiracid equivalents / kg edible flesh (Commission Regulation (EC) No 853/2004).
Amnesic Shellfish Poisons (ASP)		
Domoic acid	**^**High Performance Liquid Chromatography with UV detection after methanolic extraction and SAX-cleanup (Quilliam *et al.* 1995) (Commission Regulation (EC) No 2074/2005). Liquid Chromatography Mass Spectrometry (LC-MS/MS method)	≤ 20 mg domoic acid eq / kg edible flesh (Commission Regulation (EC) No 853/2004).

*European Union Reference Laboratory

^ Reference Method

APPENDIX IV: MICROBIOLOGICAL REGULATORY LIMITS

MICROBIAL AGENTS	TEST METHOD	STANDARDS
Escherichia coli	SANS 16649-3:2008/ISO/TS 16649-3:2005 (Donovan *et al*. 1998)	<230/100 g edible flesh (Class A). <4 600/100 g edible flesh (Class B).
Salmonella	SANS 6579:2003/ISO 6579:2002	Absence in 25 g
Vibrio cholerae & *V. parahaemolyticus*	SANS 6196:2006	Absence in 25 g

Analytical laboratories should strive to provide results to DAFF in as short a time as possible from receipt of samples. This period should not exceed 3 days for PSP, 3 days for DSP, and 3 days for *E. coli* in the majority of cases. As ASP is only tested on a monthly basis due to low risk the requirement for reporting of test results is less critical. Should the biotoxin or microbiological concentrations exceed the regulatory limit, the laboratory is to inform DAFF via a Red Alert immediately after the results are obtained.

Relevant legislation

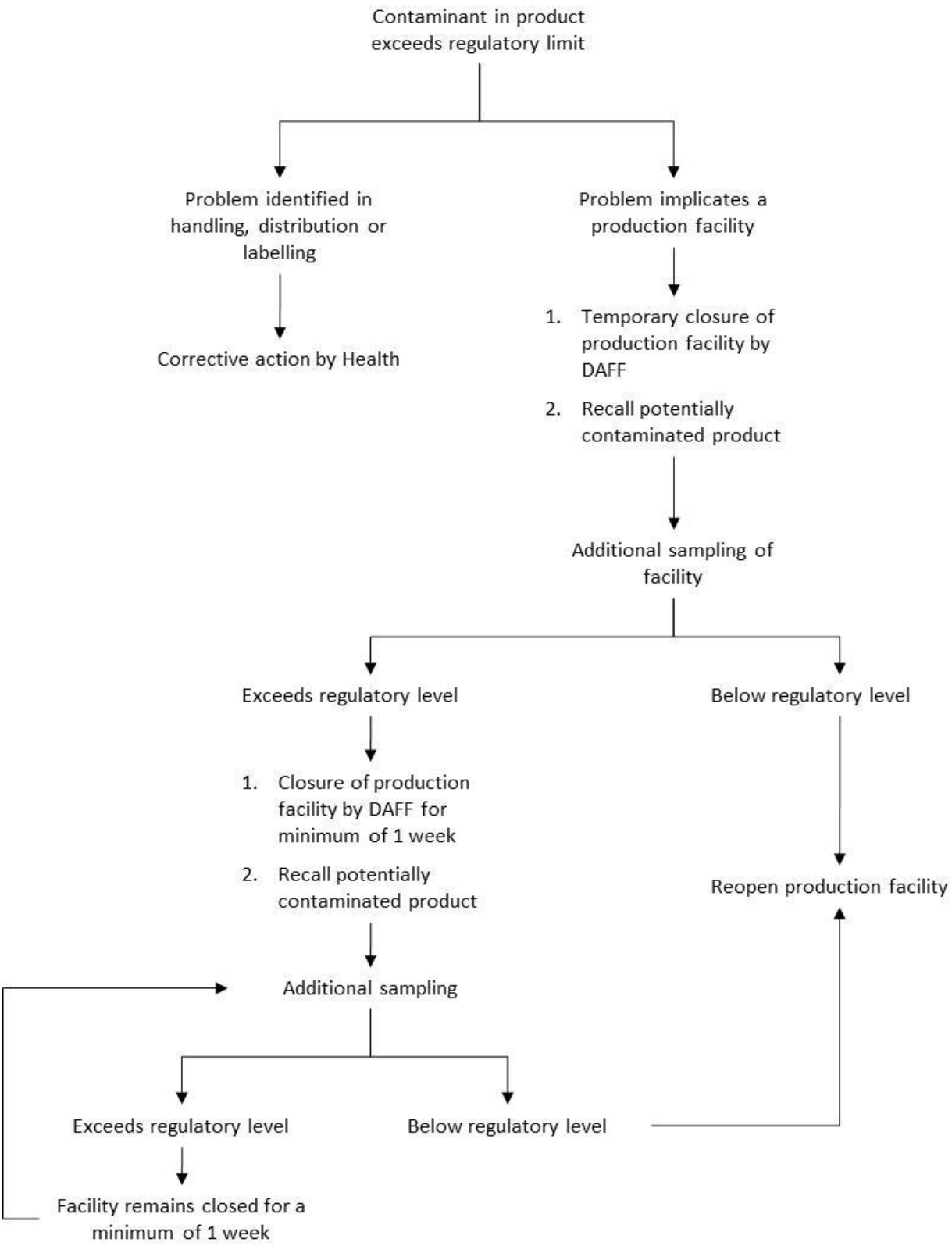
Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) - Regulation 692 of 1997: Regulations governing microbiological standards for foodstuffs and related matters

APPENDIX V: THRESHOLDS THAT TRIGGER INTENSIVE BIOTOXIN TESTING

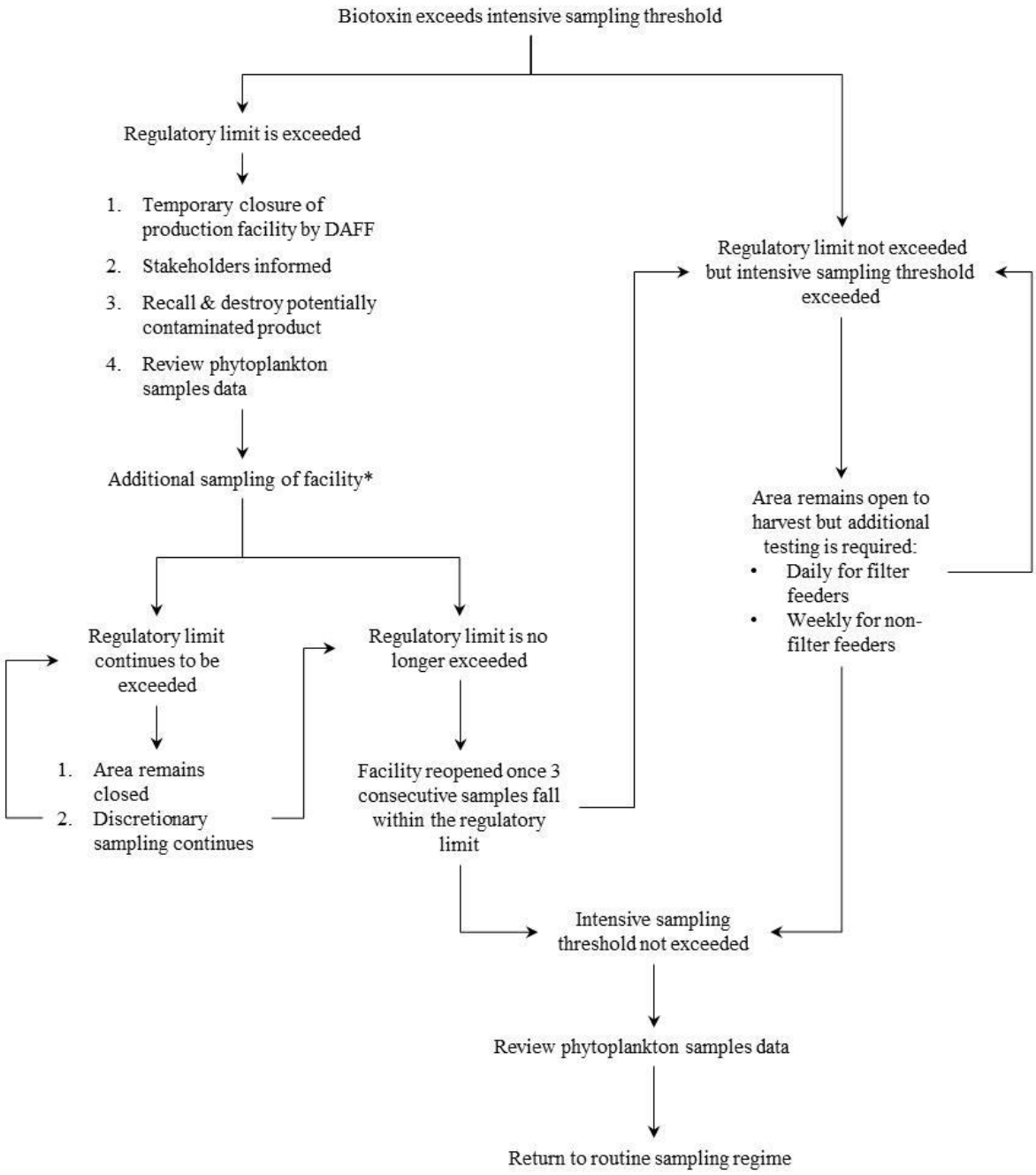
The following biotoxin concentration thresholds shall trigger daily testing for the implicated toxin in filter feeders and weekly testing in abalone if the production area is not temporarily closed for harvesting:

Biotoxin	Threshold
Total Saxitoxin	0.4 mg saxitoxin equivalents / kg edible flesh
Sum of OA, DTX 1, DTX 2, DTX 3, PTX 1 & PTX 2	0.08 mg okadaic acid equivalents / kg edible flesh
Sum of YTX, 45 OH YTX, homo YTX, and 45 OH homo YTX	4 mg yessotoxin equivalents / kg edible flesh
Sum of AZA 1, AZA 2 & AZA 3	0.08 mg azaspiracid equivalents / kg edible flesh
Total Domoic acid	5 mg domoic acid eq / kg edible flesh

APPENDIX VI: MICROBIOLOGICAL AND HAZARDOUS SUBSTANCE CONTINGENCY MEASURES



APPENDIX VII: BIOTOXIN CONTINGENCY MEASURES



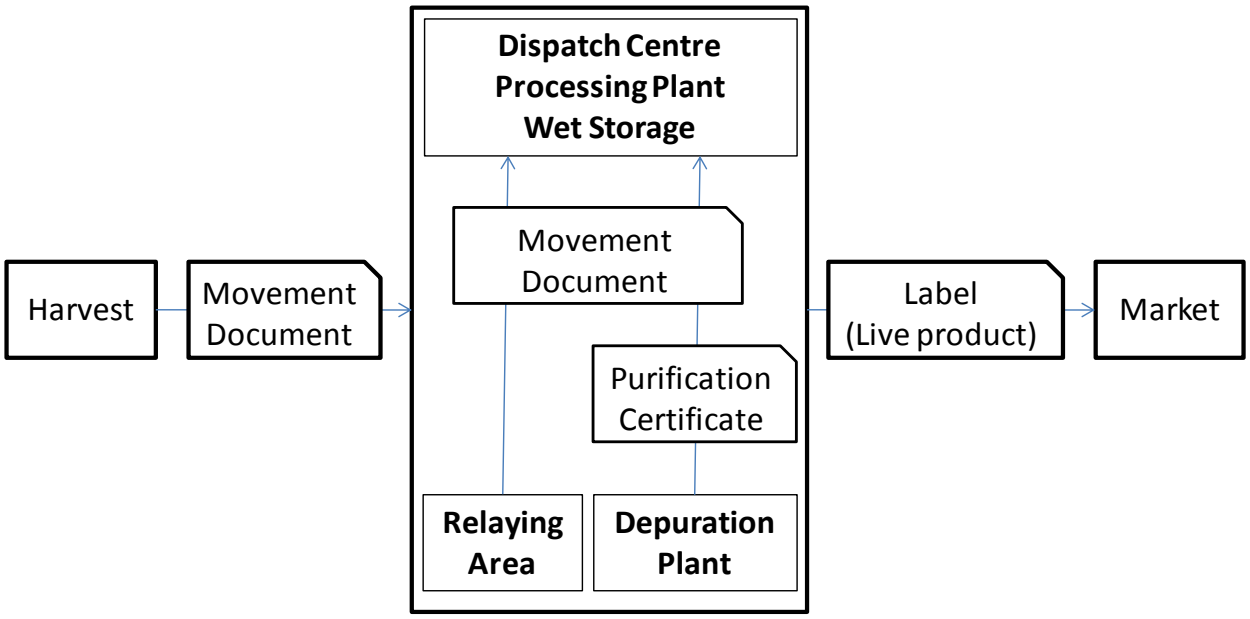
*Frequency of sampling is at farm managers discretion, but no more than one sample may be submitted per day. Multiple samples on the same day will be considered one sample.

APPENDIX VIII: DOCUMENTATION AND LABELLING REQUIREMENTS DURING TRANSPORT OF LIVE SHELLFISH

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

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

3 Depurated shellfish must be provided with a label certifying that all live shellfish have been purified (Paragraph 8.7.5).



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

APPENDIX IX: HARMFUL ALGAL SPECIES FOUND IN SOUTH AFRICAN MARINE ENVIRONMENT

The following list includes those phytoplankton species reported to form blooms and/or to be toxic or potentially toxic:

Dinophyceae

*Alexandrium catenella+**
Alexandrium minutum
Ceratium dens+
Ceratium furca+
Ceratium lineatum+
*Dinophysis acuta**
*Dinophysis acuminata**
*Dinophysis fortii**
*Dinophysis hastata**
*Dinophysis tripos**
Dinophysis rotundata#
*Protoceratium reticulatum+**
Gonyaulax polygramma+
Gonyaulax spinifera+
*Karenia cristata+**
Gymnodinium sanguineum+
Heterocapsa triqueta+
Noctiluca scintillas+
Prorocentrum balticum+
Prorocentrum micans+
Prorocentrum rostratum
Prorocentrum triestinum+
Polykrikos schwartzii+
Scrippsiella trochoidea+

Bacillariophyceae

Chaetoceros convolutus#
Pseudo-nitzschia spp *#*

Raphidophyceae

Chattonella spp*#*
Heterosigma akashiwo+#

Pelagophyceae

Aureococcus anophagefferens+

Haptophyceae

Chrysochromulina spp#
Emiliania huxley+
Gephyrocapsa oceanica+
Phaeocystis pouchetii#
Syracosphaera pulchra+

Euglenophyceae

Eutreptiella sp+

Ciliates

Mesodinium rubrum+

+ Bloom
*Toxic
Potentially harmful or toxic

APPENDIX X: PROHIBITED DRUGS

List of pharmacologically active substances for which no maximum levels can be fixed:

- Stilbenes, stilbene derivatives, and their salts and esters
- Steroids
- Aristolochia spp. and preparations thereof
- Chloramphenicol
- Chloroform
- Chlorpromazine
- Colchicine
- Dapsone
- Dimetridazole
- Metronidazole
- Nitrofurans (including furazolidone)
- Ronidazole