SOUTH AFRICAN SHELLFISH MONITORING AND CONTROL PROGRAMME

Branch: Fisheries Management

Chief Directorate: Aquaculture & Economic Development

Directorate: Sustainable Aquaculture Management

Issue 8: January 2021

TITLE

South African Shellfish Monitoring and Control Programme

COMMENCEMENT

This programme comes into force on 1 January 2020.

REVOCATION

This programme issue revokes and replaces South African Molluscan Shellfish Monitoring and Control Programme, Issue 1 as well as the revisions made in Issues 2 to Issue 7 indicated in the Table below.

Issue	Date of issue
1	30 March 2004
2	02 August 2008
3	01 January 2012
4	01 January 2014
5	01 January 2015
6	01 January 2016
7	01 July 2017
8	01 January 2021

This South African Shellfish Monitoring and Control Programme is published by the Deputy Director-General: Fisheries Management as a measure to facilitate compliance with Regulation 73 of the Regulations in terms of the MLRA (Government Notice R1111 in *Government Gazette* 19205 dated 2 September 1998).

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DEPUTY DIRECTOR-GENERAL

FISHERIES MANAGEMENT

DATE:

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1. BACKGROUND

Food safety laws throughout the world give special consideration to shellfish for a number of reasons. 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. Gastropods also accumulate biotoxins, particularly Paralytic Shellfish Toxins (PST) and to a lesser extent Lipophilic Shellfish Toxins as well as numerous other residues. 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 shellfish receive the second highest hazard rating for all foods by the International Commission on Microbial Specification for Foods.

2. PURPOSE

The purpose of this official manual is to identify, monitor, evaluate and manage the risks associated with the commercial growing, harvesting, sorting and transporting of shellfish for human consumption in order to provide the necessary guarantees to foreign buyers and Governments as well as to local consumers that the risk of disease and poisoning through consuming shellfish is adequately managed and minimised.

3. SCOPE AND AUTHORIZATION

1) This manual addresses the public health concerns of shellfish harvested from marine aquaculture production areas and intended for immediate human consumption or for further processing before consumption.

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

3) The manual applies to shellfish as defined under Definition.

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

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 the Department of Environment, Forestry and Fisheries (DEFF) 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 National Regulator for Compulsory Specifications (NRCS) (the appointed body for administering the various Compulsory Specifications for fishery products in South Africa).

6) The functions of this programme are to:

    a) Establish the production area classification system.

    b) Provide data for the annual review of the classification status of the production area.

c) Establish compliance with the requirements of this manual concerning microbiological safety, toxic and hazardous substances, veterinary drug residues and biotoxins in shellfish intended for direct human consumption or for further processing prior to consumption.

d) Provide an early warning system for biotoxin control, where relevant, in the interest of public health.

7) The manual addresses the requirements for the certification and/or issue of permits for the production, harvesting, relaying, wet storage, depuration, feed and drug management, transport and handling of shellfish.

4. DOCUMENT CONTROL

1) This Manual has been prepared by the DEFF in association with the Department of Food and Associated Industries of the NRCS and the shellfish farming industry. The manual will be reviewed as pertinent new information becomes available. The review process will involve consultation with representatives from the Department, NRCS, industry, and the Department of Health, (including provincial and/or municipal health authorities where applicable).

Table 1: Issues of the South African Shellfish Monitoring and Control Programme

Issue	Date of issue
1	30 March 2004
2	02 August 2008
3	01 January 2012
4	01 January 2014
5	01 January 2015
6	01 January 2016
7	01 July 2017
8	01 January 2021

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) A detailed record of all amendments shall be maintained.

4) The latest version will be made available on the Department's website.

5. DEFINITIONS

"Acceptable" means acceptable to the competent authority for the approval and licensing of 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 the Department 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 8.3. 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 the Department.

"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 the Department 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 which 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" refers to the official approval number for a production area and fish processing establishment. The establishment number for packaging and processing is obtained from the Food and Associated Industries Division of the NRCS in Cape Town. This number may also refer to a permit number issued by the Department for a specific cultivation area, relaying area, depuration plant or harvester.

''Fish'' means the marine living resources of the sea and the seashore, including any aquatic plant or animal whether piscine or not, and any mollusc, crustacean, coral, sponge, holothurian or other echinoderm, reptile and marine mammal, and includes their eggs, larvae and all juvenile stages, but does not include sea birds and seals.

"Fish processing establishment'' means any vehicle, vessel, premises or place where fish is processed for sale in or outside the territory of the Republic.

"Harvester" means a person or entity with a marine aquaculture right to harvest 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 the Department, 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 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.

"Shellfish" means for the purposes of this manual, applies to all bivalve molluscs, marine gastropods echinoderms and crustaceans.

"Monitoring and Control Programme" means South African Shellfish Monitoring and Control Programme.

"Non-point source" means any source of pollution that is not a point source; and diffused and dispersed such as agricultural farm runoff, urban runoff or storm water, sewage discharge from vessels, dredging operations or silviculture practices.

"Official Inspector" means any Compliance Officer, Inspector, Environmental Health Practitioner or Health Officer appointed in terms of the Marine Living Resources Act, 1998 (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.

"Open" in relation to a growing area, indicates that the status of the area is open, which means that shellfish may be harvested from the area in accordance with the area's classification.

"Pathogen" means an organism such as a bacterium (e.g. *Salmonella* spp.), a virus (e.g. norovirus) or a protozoon (e.g. Giardia, Cryptosporidium) that may cause disease in humans.

"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.

"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 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 and includes but not limited to any substance or article that is produced from fish by any method, including the work of cutting up, dismembering, separating parts of, cleaning, sorting, lining and preserving of fish, or where fish are canned, packed, dried, gutted, salted, iced, chilled or frozen. Shucking, packing and repacking are also regarded as processing for the purpose of this document.

"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 the Department 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 Section 8.4. Shellfish from restricted areas may be processed (e.g. canning, cooking and freezing as per Section 8.4, paragraph 4) or subjected to an approved depuration process such as relaying or depuration.

"Sanitary Survey" means the evaluation, in accordance with the requirements of Section 8.2 of this manual, by a party approved by the Department, 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 Department, 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.

"Shoreline Survey" means a survey of the shoreline of the production area catchment conducted by an officer authorised by the Department according to requirements in Appendix 1.

"The Department" means the Department of Environment, Forestry and Fisheries.

"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.

6. ABBREVIATIONS

"ADP" means approved depuration process

"AST" means Amnesic Shellfish Toxins

"AZA" means azaspiracid

"BMP" means better management practice

"CITES" means Convention on International Trade in Endangered Species

"DEFF" means Department of Forestry, Fisheries and the Environment

"DTX" means Dinophysis toxins

"E. coli" means *Escherichia coli*

"EC" means European Commission

"FPE" means Fish Processing Establishment

"FSO" means Food Safety Office

"GPS" means global positioning system*

"IATA" means International Air Transport Association

"ILAC" means International Laboratory Accreditation Cooperation

"LC-MS/MS" means Liquid Chromatography Mass Spectrometry/ Mass Spectrometry

"LST" means Lipophilic Shellfish Toxins

"MCP" means Monitoring and Control Programme

"MPN" means Most Probable Number

"MRL" means maximum residue limit

"NRCP" means National Residue Control Programme

"NRCS" means National Regulator for Compulsory Specifications

"NRP" means National Residue Plan

"OA" means okadaic acid

"PST" means Paralytic Shellfish Toxins

"PTX" means Pectenotoxins

"SANAS" means South African National Accreditation System

"SANS" means South African National Standard

"SOP" means Standard Operating Procedure

"WWTW" means waste water treatment works

"YTX" means yessotoxin

7. RULES

1) The definitions in Section 5 apply in this manual unless the context requires otherwise.

2) The Department is the Regulatory Authority authorising the undertaking of aquaculture activities, i.e. farming, harvesting and transporting of 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 granting and issuing of a Marine Aquaculture (mariculture) Rights and permits respectively. Associated activities such as relaying, depuration and wet storage require special authorisation from NRCS and the Department in conjunction with the relevant local health authorities.

3) The NRCS is recognised internationally as the Competent Authority to provide food safety assurances. The NRCS mandate includes the promotion of public health and safety, environmental protections and ensuring fair trade. This mandate is achieved through the administration and maintenance of compulsory specification as well as through market surveillance to ensure compliance with the requirements of the compulsory specifications and technical regulations.

4) Establishments packing or processing molluscs must apply for a marine aquaculture fish processing establishment permit with the Department. Such establishments will be licensed only when the operator can produce a Certificate of Acceptability (CoA) issued by the local municipality or an approval certificate in terms of the relevant Compulsory Specification administered by the NRCS for the establishment, on condition such NRCS approval is valid for at least 3 months before the expiry date. Each establishment must be issued with a CoA by the local municipality or licensed by the NRCS annually (or for the time permissible by a conditional approval obtained from the NRCS).

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

6) The Department, the NRCS or relevant local health authority may appoint official inspectors (e.g. NRCS inspectors, the DEFF 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.

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

8) To enable proper liaison between the Department and other governmental departments/authorities in regard to Section 7, paragraphs 2-5 above, a Memorandum of Understanding must be prepared and signed by all parties concerned.

9) The Department shall keep and maintain a central file containing copies of the records and documents required by this manual including:

   - Copies of permits and other approvals.
   - Official laboratory test reports (certificates).
   - Movement documents.

- Monitoring data and notices.
- Enforcement action reports.
- 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.
- Correspondence with farmers.

10) The officially approved inspector servicing an establishment where 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 Section 7, paragraph 7.

11) 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). The records shall be readily accessible and available for inspection by any authorised person and shall be retrievable within 24 hours. This pertains to each authorised marine farmer including relayer, depuration plant, wet storage facility and establishment packing and/or processing shellfish. Such records shall include:

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

12) 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.

13) Depuration of bivalves in relaying areas or in depuration plants may only take place with a permit obtained from the Department. The permit shall be specific for the particular depuration plant or relaying area.

14) The producers that are exporting shall also comply with the importing country's requirements.

8. CLASSIFICATION OF SHELLFISH PRODUCTION AREAS

8.1. Overview of classification system

1) A production area shall be classified by the Department once a sanitary survey has been conducted by the Department as outlined in Section 8.2.

2) 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.

3) 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 the Department. 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.

4) 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) The sanitary classification status of bivalve shellfish production areas shall be reviewed annually taking into account new potential pollution sources and other developments that could affect water quality. The classification of abalone, echinoderm and crustacean production areas are only reviewed where known contamination risks are introduced to the area or product test reports indicate there may be a necessity to review the sanitary survey.

6) The Department shall maintain a current list of individual farm health status for distribution to the NRCS, relevant health authority and to industry role players.

8.2. Sanitary Surveys

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

2) If a production area is proposed to be classified, the Department must undertake an initial sanitary survey.

3) The Department must review and report on each bivalve growing area on an annual basis to reflect any changes in the growing area catchment and update the monitoring data. Review of the original sanitary survey of an abalone, echinoderm or crustacean production area, is only applicable where known contamination risks are introduced to the area or product test reports indicate there may be a necessity to review the sanitary survey.

4) Every sanitary survey must be done by the Department in accordance with Appendix 1.

8.3. Approved areas

1) Shellfish may be commercially harvested for human consumption from a production area classified as Approved unless the area is closed due to food safety regulatory levels being exceeded.

2) A growing area may be classified as Approved once a sanitary survey has been completed and the production area complies with the following conditions:

   a) The *E. coli* Most Probable Number (MPN) in the shellfish 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.

   b) The shellfish shall not contain hazardous concentrations of toxic substances that exceed the regulatory limits referred to in Section 10.

3) When evaluating the results for the fixed review period for maintenance of an Approved area, the Department may, on the basis of a risk assessment based on an investigation, decide to disregard an anomalous result exceeding the level of 700 *E. coli* per 100 g of flesh and intravalvular liquid

for example but not limited to a sample contamination incident or a sampling error, sample expiring incident, or a laboratory error.

8.4. Restricted areas

1) No shellfish may be harvested for direct human consumption from restricted areas. Shellfish from restricted areas can only be harvested for depuration or relaying if the pollution does not arise from a waste water treatment works (WWTW). If the pollution arises from a WWTW, the shellfish may only be harvested for relay at an approved production area for an extended period of at least 6 months. The depuration of such product, as defined, is not permissible.

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

    a) 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.

3) The Department may approve the harvesting of shellfish of which the *E. coli* MPN are below 4 600/100g flesh and intravalvular fluid, on condition that it is sterilised in hermetically sealed containers or subject to an approved heat treatment and frozen in compliance with Section 8.4, paragraph 5).

4) The permitted treatment methods are:

    a) sterilisation in hermetically sealed containers; and

    b) heat treatments involving:

        i) immersion in boiling water for the period required to raise the internal temperature of the mollusc flesh to not less than 90 °C and maintenance of this minimum temperature for a period of not less than 90 seconds;

        ii) cooking for three to five minutes in an enclosed space where the temperature is between 120 and 160 °C and the pressure is between 2 and 5 kg/cm², followed by shelling and freezing of the flesh to a core temperature of – 20 °C; and

        iii) steaming under pressure in an enclosed space satisfying the requirements relating to cooking time and the internal temperature of the mollusc flesh mentioned under (i). A validated methodology must be used. Procedures based on the HACCP principles must be in place to verify the uniform distribution of heat.

5) Should the *E. coli* MPN exceed the criteria stipulated for limited degree of microbial pollution, the product may only be harvested for relaying on approved production area for extended periods no less than 30 days.

8.5. Prohibited zone

1) The purpose of a prohibited zone is to prevent contaminated, or possibly contaminated, shellfish from being harvested from a part of a production area, while allowing the rest of the production area to be harvested according to its classification.

2) The Department may classify as prohibited zone those areas from which live bivalve molluscs may be collected and placed on the market only after relaying over a long period so as to meet the health standards referred to in Section 8.3.

3) Shellfish shall not be harvested from a prohibited zone for direct human consumption, depuration, relaying or further processing. An area will be classified as a Prohibited zone when any of the following conditions exist:

   a) There is no current sanitary survey or annual evaluation report.

   b) The sanitary survey indicates levels of microbiological pollution exceeding the restricted area limits referred to in Section 8.4.

   c) The sanitary survey or other data indicate contamination of shellfish with heavy metals, radionuclides, pesticides or other hazardous chemicals that exceed the regulatory limits on a regular basis.

   d) Pollution of point or non-point sources that may unpredictably contaminate the shellfish.

4) A prohibited zone must be large enough to provide sufficient time for the Department to close any production area around it before a discharge could travel beyond the prohibited zone.

5) Areas adjacent to sewage outfalls and other waste discharges of public health significance shall be classified as prohibited.

6) For areas around major point source discharges, such as a sewage outfall, the minimum area of the prohibited zone is the area formed by a radius of 500 m around the outfall.

7) The criteria used to determine the size of a prohibited zone must include:

   a) the volume, flow, rate, location of discharge, performance of the wastewater treatment plant and the microbiological quality of the effluent;

   b) the decay rate of the contaminants of public health significance in the wastewater discharged;

   c) the characteristics of the receiving water, including:

      i) bathymetry;

      ii) current velocity;

      iii) net transport velocity;

      iv) water depth and volume;

      v) direction of flow;

      vi) water stratification;

      vii) tidal characteristics;

      viii) dilution rate; and

      ix) likely dispersion;

   d) the wastewater's dispersion and dilution, and the time of waste transport to any area where shellfish may be harvested; and

e) the location of the shellfish resources, classification of adjacent waters and identifiable landmarks or boundaries.

8) 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.

8.6. Conditional areas

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.

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.

3) A management plan shall be developed for Conditional areas that are centred on the predictability of the pollution events (See Appendix 1, paragraph 9).

8.7. Review of classification

1) The Department must review and report on the classification of a growing area if:

a) the area has been closed following an outbreak of illness caused by something in the growing area other than naturally occurring pathogens or biotoxins as referred to in Section 10.3, paragraph 4);

b) the shellfish from the area are implicated in an epidemiologically confirmed foodborne illness outbreak;

c) the area is determined by the Department to be the source of a human pathogen;

d) human pathogens or chemical contaminants are detected in the shellfish and the Department determines, following an investigation that the growing area is or is likely to be the source of the pathogens or chemical contaminants; or

e) the area is found to no longer comply with the conditions of its classification.

2) Any review of classification under this clause must include:

a) a review of the growing area classification file records, including at least the last 3 years water and shellfish bacteriological results;

b) a field review of all existing pollution sources;

c) a review of actual and potential intermittent pollution sources, such as vessel waste discharge and wastewater discharge from treatment plant collection systems; and

d) a review of any related water and shellfish results.

3) Following a review under this clause, the Department may:

a) retain or change the existing classification; and

b) make any changes necessary to the biotoxin management plan and/or the microbiological management plan.

8.8. Extension of production areas

1) If a new production area is proposed to be added to an existing classified production area, the Department must assess any pollution sources that may affect the new area and determine the need for:

   a) further sample stations;

   b) parallel sampling in both the new area and existing growing area for a limited period or an indefinite period; and/ or

   c) additional tests for potentially harmful substances.

2) The Department may adopt the classification status of the new production area referred to in Section 8.8, paragraph 1 once the stipulated criteria have been considered and implemented where relevant.

9. MONITORING OF SHELLFISH PRODUCTION AREAS AFTER CLASSIFICATION

1) 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.

2) It will be the responsibility of the Department 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.

3) The Department must maintain an updated list of farms indicating its classification and current harvesting status i.e. either open or closed to harvest.

4) Should there be conflicting results from two or more methods employed on a test; the test result from the reference method as indicated in this manual will supersede the test results from the other methods.

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

6) No shellfish shall be harvested for direct human consumption if the regulatory limits are exceeded.

10. MICROBIOLOGICAL MONITORING

1) The regulatory limits for microbiological contamination and the recognised test methods are included in the relevant regulations published under the Foodstuffs Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972), Appendix 4 of this document and as per the relevant Compulsory Specifications administered by the NRCS for the relevant packaged products.

2) Microbiological monitoring is mandatory during harvesting periods (See Appendix 6). Farm managers must inform the Department 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.

10.1. Microbiological management plan

1) *E. coli* shall be monitored in each production area in accordance with this programme. Every classified bivalve growing area must have a microbiological management plan prepared by the Department.

2) A microbiological management plan must include all of the following:

   a) a map of the growing area, with the navigational points, showing the location and identification of each farm and, to which the plan applies;

   b) the boundary with the navigational points and the name and number of the growing area;

   c) the species of commercial shellfish within the growing area;

   d) the location and global positioning system (GPS) (or other identification acceptable to the Department) of the primary and any secondary shellfish sample stations allocated by/or in co-operation with the Department;

   e) the routine monitoring programme for shellfish;

   f) the hydrographic details showing predominant currents and circulatory patterns which may affect the movement of contaminated water in or adjacent to the growing area that are included in the Sanitary Survey Reports; and

   g) contingency measures that will apply should the regulatory levels be exceeded.

10.2. Sampling and analysis of samples

1) Sampling will be dictated to a certain extent by the findings of the sanitary survey. 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.

2) Approved and Restricted production areas shall be tested at least monthly for microbial contamination viz. *E. coli*. Conditional production areas as in Section 8.6 shall be tested at least weekly for microbial contamination during harvesting if the production area is considered to exhibit a definite approved status during a particular time of the year. A composite sample of shellfish under harvest or intended for next harvest shall be taken.

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. Pollution-point sampling stations shall be located to provide adequate warning of a potential threat to a production area.

4) Abalone, echinoderm and crustacean production facilities classified as Approved are exempt from the requirements of Section 10.2, paragraph 2 and need only be monitored for microbial contamination during official surveillance of end-of-line product.

5) Should the results from end-product testing above indicate non-compliance of an abalone, echinoderm or crustacean production facility, testing shall be conducted in accordance with Appendix 1, paragraph 2) to ascertain whether re-classification is necessary. Should the test results after 3 months indicate that the classification status of the production facility remains “Approved” Section 10.2 (4) applies.

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.

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

8) Analytical laboratories should strive to provide results to the Department in as short a time as possible from receipt of samples. This period should not exceed 3 days for *E. coli* testing in the majority of cases.

10.3. Contingency measures

1) Where a production area at any time does not comply with the sanitary requirements of its designated classification in terms of the *E. coli* standards stipulated in Appendix 4, the Department in collaboration with the NRCS and/or the relevant Health authorities (see flow diagram, Appendix 6) shall undertake appropriate actions as outlined in an official contingency standard operating procedure.

2) When an end of the line product fails to satisfy the microbiological criteria for human consumption, the relevant Health authority, in consultation with the NRCS and the Department (see flow diagram, Appendix 4) shall undertake appropriate actions as outlined in an official contingency standard operating procedure.

3) 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 association with the Department and the NRCS, shall undertake appropriate actions as outlined in an official contingency standard operating procedure.

4) If an area is closed because an investigation confirms that pathogens in the area (other than those naturally occurring) are responsible for an illness outbreak, the Department shall undertake appropriate actions as outlined in an official contingency standard operating procedure.

5) If the Department reasonably believes that an area has been impacted by a sewage event, the Department must keep the area closed for 28 days from the date of the end of the event, unless the Department determines that a greater or lesser time is required.

6) Microbiologically contaminated shellfish may be canned or cooked and frozen as per requirements in Section 8.4, paragraphs 3 and 4, provided the microbial status meets the Restricted criteria as a minimum (Section 8.4) or the criteria stipulated in Section 8.4, paragraph 2. Such shellfish may also be harvested for relaying or depuration until the animals show compliance with Approved microbial limits (Section 8.3). This option may only be exercised in accordance with special permit conditions issued by the Department.

11. MONITORING OF ENVIRONMENTAL AND VETERINARY DRUG RESIDUES

1) Environmental residues shall be monitored and regulated for the shellfish production areas in terms of a National Residue Plan (NRP) and implemented in terms of a National Residue Control Programme (NRCP).

2) Veterinary drug residues shall be monitored and regulated for the abalone, echinoderm and crustacean production areas in terms of a NRP and implemented in terms of a NRCP.

3) The regulatory limits for environmental contaminants such as heavy metals, radio-active substances (Caesium 134 and 137), polychlorinated biphenyls, dioxins, polycyclic aromatic hydrocarbons and pesticides will be those included in the relevant regulations published under the Foodstuffs Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) and/ or the NRP.

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

5) Should there be conflict in the regulatory limits stipulated in the Foodstuffs , Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) and the NRP, the Foodstuffs , Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) limit will apply to local sales and the NRP will apply to exported products.

11.1. National Residue Plan and National Residue Control Programme

1) Residues monitored shall include, though not limited to those listed in Appendix 10 and where relevant Appendix 11.

2) A NRP shall include all of the following as a minimum:

   a) Compound or marker residue

   b) Matrix to be analysed

   c) Screening method where relevant

   d) Confirmatory method

   e) Screening method level of detection (LOD) where relevant

   f) Confirmatory method LOD

   g) Level of action i.e. Concentration above which a result is deemed non-compliant

   h) Laboratory to be used

3) A NRCP shall include all the following as a minimum:

   a) Farm name and farm code

   b) Sampling date

   c) Sample reference number

   d) Test method

e) Sample condition i.e. frozen or chilled

f) Matric to be tested

g) Laboratory to be used

h) Age cohort to be sampled

i) Sample Size (Flesh mass)

11.2. Sampling and analysis of samples

1) Sampling for environmental and veterinary drug residues will address variation within a production area and will be conducted in accordance with the NRP.

2) Sampling for specific contaminants is recommended when the sanitary survey reveals a potential problem, or if there is concern due to a paucity of data.

3) The sampling and transport of the sample shall be undertaken in accordance with an official standard operating procedure.

4) Non-compliance at any sampling point will require retesting as outlined in Appendix 6. 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.

11.3. Contingency measures

1) Should a residue test result exceed the regulatory limit, the production area will be temporarily closed for harvesting in accordance with an official contingency standard operating procedure.

2) The Department must close a shellfish production area immediately for emergency reasons if in the opinion of the Department any event may pose a food safety risk, such as toxic substance spillage.

3) A production area that has been temporarily closed shall be reopened once the residue concentration in the samples taken fall below the regulatory level and in terms of an official contingency standard operating procedure.

12. BIOTOXIN MONITORING

1) Biotoxin monitoring is mandatory during harvesting periods (See Appendix 7). Farm managers must inform the Department 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.

2) The regulatory limits for biotoxins and the recognised test methods are included in the relevant regulations published under the Foodstuffs Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) and Appendix 3.

12.1. Biotoxin management plan

1) Biotoxins and toxigenic phytoplankton shall be monitored in each production area in accordance with this programme. Every classified bivalve growing area must have a biotoxin management plan prepared by the Department.

2) A biotoxin management plan must include all of the following:

   a) A map of the growing area, showing the location and identification of each production area and, to which the plan applies.

   b) The boundary, name and number of the growing area.

   c) The species of commercial shellfish within the growing area.

   d) The location and GPS (or other identification acceptable to the Department) of the primary and any secondary shellfish and phytoplankton sample stations.

   e) The routine monitoring programme for phytoplankton and biotoxins in shellfish.

   f) The increased sampling to be undertaken, in terms of sites, frequency and shellfish species, when toxigenic phytoplankton or biotoxins in shellfish are detected above background levels.

   g) Hydrographic details showing predominant currents and circulatory patterns which may affect the movement of phytoplankton in or adjacent to the growing area that are included in the Sanitary Survey Reports.

   h) Contingency measures should the regulatory levels be exceeded.

12.2. Sampling and analysis of samples

1) The sampling shall be undertaken in terms of standard operating procedures drafted by the Department.

2) The default testing programme for biotoxins in a growing area with no regular testing of water for toxigenic phytoplankton is for shellfish flesh testing to be carried out weekly.

3) The Department may authorise a reduced programme of shellfish flesh testing on the basis of a review of all shellfish and toxigenic phytoplankton results for the growing area and surrounding areas.

4) Any reduced programme authorised under sub-clause (3) must comply with the following:

   a) If a toxin listed in Appendix 3 has not been detected in shellfish during the review period, then the toxin must be tested for at least monthly.

   b) If a toxin listed in Appendix 3 has been detected in shellfish below the maximum permissible level, then that toxin must be tested for at least every 14 days.

   c) If a toxin listed in Appendix 3 has been detected in shellfish at a level above the maximum permissible, then that toxin must be tested for at least weekly.

   d) In every case, water from the growing area must be tested for the toxigenic phytoplankton listed in Appendix 9 at least weekly.

   e) The Shellfish testing programme must stand on its own, with toxigenic phytoplankton testing being a support system.

5) The Department may decrease the frequency of the testing authorised under Section 12.2 sub-clause 2 for seasonality if, for the growing area and adjacent coastal marine areas, it is demonstrated that there are clear differences in biotoxin activity between the seasons.

6) The Department may authorise a further reduction in the frequency of testing required by this clause if it is satisfied that the risks will be adequately addressed if applying a reduced frequency of testing.

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

8) Toxin levels in the edible portions of shellfish provide the present basis for regulatory action and with regard to bivalves shall include the intravalvular fluid.

9) Harvest closures may be applied selectively to some species and not others from the same production area should testing indicate that certain shellfish species are less susceptible to biotoxin accumulation.

10) The default testing programme for marine biotoxins in a growing area is for shellfish flesh testing to be carried out as outlined in Table 2.

Table 2: Maximum allowable time between routine biotoxin sampling events

Biotoxin group	**West of Cape Point**		**East of Cape Point**	
	Filter feeders	**Non-filter feeders**	**Filter feeders**	**Non-filter feeders**
Paralytic shellfish toxins (PST)	Twice a week for multiple harvesting	2 weeks*	1 month	1 month
Lipophilic shellfish toxins (LST)	1 week	1 month	2 weeks	1 month
Amnesic shellfish toxins (AST)	1 month	N/A[#]	1 month	N/A[#]

* Abalone, echinoderm and crustacean production areas that are closed for live marketing, due to PST concentrations exceeding the regulatory limit, shall be tested for PST at least once a month.

[#] AST testing will be required on a regional basis at least once a month.

11) Analytical laboratories should strive to provide results to the Department in as short a time as possible from receipt of samples. This period should not exceed 3 days for PST, 4 days for LST and 5 days for AST in the majority of cases.

12.3. Contingency measures

1) Should a biotoxin test result exceed the regulatory limit, the production area will be temporarily closed for harvesting in accordance with an official contingency standard operating procedure.

2) Abalone production areas that are closed due to PST concentrations exceeding the regulatory limit may apply for an exemption from the Department to process the abalone for marketing. The processing and related testing shall be undertaken in accordance with an official contingency standard operating procedure.

3) A production area that is closed due to biotoxin concentrations exceeding the regulatory limit shall be reopened for marketing once the toxin concentration in two consecutive samples taken over a period of three days are below the regulatory limit and show a declining trend in the toxin concentration.

4) The intensive biotoxin monitoring is to be initiated following detection of biotoxins in shellfish in excess of the thresholds given in Appendix 5, though still below regulatory limits.

5) Intensive sampling may also be initiated when toxic phytoplankton are present in the absence of shellfish intoxication in accordance with an official contingency standard operating procedure.

6) Following intensive sampling, routine sampling will be re-instated in a specified production area once the biotoxin concentration in all official samples in the production area have returned to below the threshold limits stipulated in Appendix 5.

7) Should an abalone production area that had been temporarily closed, due to exceeding the regulatory limit for PST, be reopened to market live abalone, the production area is required to be tested for PST weekly for 1 month after re-opening.

8) The Department must close an area immediately for emergency reasons if an investigation confirms that biotoxins from the growing area are responsible for an illness outbreak.

13. PHYTOPLANKTON MONITORING

13.1. Sampling and analysis of samples

1) Phytoplankton samples shall be taken at least once a week and the toxigenic species identified and enumerated. Samples shall be taken at least 3 times a week should toxic species be found in the previous 3 months.

2) The sampling frequency and sampling points shall be clearly stipulated in a biotoxin management plan.

3) The Department shall draft standard operating procedures on how the phytoplankton samples are to be taken and analysed.

4) Phytoplankton samples shall be analysed by an officially recognised phytoplankton laboratory within 24 hours of being sampled. Samples from outlying low risk areas may be analysed within 48 hours.

14. REQUIREMENTS FOR HARVESTING AND TRANSPORT OF LIVE SHELLFISH

This section deals with the requirements for harvesting and transport of live shellfish to a dispatch centre, depuration facility or area, or processing plant.

14.1. Harvesting requirements

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 the Department.

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

2) 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.

3) Where necessary, shellfish 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.

4) Containers for the transport or storage of shellfish must be clean and made from impervious, easily cleanable materials.

5) 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.

14.2. Transport and Vessels

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

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.

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

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.

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

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

14.3. Temperature control

1) All shellfish harvested for human consumption, other than shellfish intended for wet storage or depuration, must be temperature controlled. Temperature control must be put in place within 20 hours of harvest or removal from a wet storage facility.

2) Live bivalves that are temperature controlled must be kept in an environment that is 7°C or cooler. The provision of adequate quantities of visible ice in or on a shellfish container is sufficient compliance with the requirement to continuously maintain the temperature at 7°C or cooler.

3) Live abalone, echinoderms and crustaceans that are temperature controlled shall be kept at a suitable temperature that will not cause physiological stress to the shellfish or pose a food safety risk.

4) At any point of transfer shellfish must not remain continuously out of temperature control for more than 2 hours.

5) If a transportation unit provides the means by which shellfish are refrigerated, the unit must be designed, constructed and equipped to ensure that the required temperatures are achieved and maintained throughout transportation.

6) Temperature measuring devices used to measure temperatures in transportation units must be calibrated and be located to measure the internal temperature of the unit at its warmest point.

7) If mechanical refrigeration units are used, the units must be:

   a) equipped with automatic temperature controls; and

   b) capable of maintaining the ambient air temperature in the loaded transportation unit at the required temperature.

14.4. Documentation and records

1) A movement document issued by the Department 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 (see Appendix 8). 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

2) The original (white copy) of the movement document shall be given to the FPE for filing at their registered office. The duplicate blue carbon copy of the movement document shall be submitted to the Department within 30 days and the pink carbon copy shall be kept in the book by the production facility. The completed and cancelled documents shall be scanned and emailed to the Food Safety Office on a weekly basis.

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.

4) If harvesting is carried out by the same staff members that operate the dispatch centre, processing plant, relaying area, depuration plant or wet storage facility of destination, the Department 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.

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

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) The Department shall keep a copy on file of all completed movement documents issued indefinitely.

15. SAMPLING AND TRANSPORT OF SAMPLES

1) The procedures and requirements for the sampling and transport of samples for food safety testing shall be compiled in a standard operating procedure.

2) The sampling and transport of samples shall be implemented in terms of the SOP referred to in Section 15, paragraph 1.

16. 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.

16.1. Conditions

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.

2) Relaying operations must be supervised by a Compliance Officer or duly authorised official inspector.

3) Relaying areas must be authorised by the Department as for a marine aquaculture operation. Harvesting of shellfish for relaying may only be undertaken with authorisation from the Department.

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

5) Relaying areas shall be monitored as for other approved production areas.

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

16.2. Source of shellfish

1) No shellfish that exceed the contaminant levels for restricted areas (Section 8.4) 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.

2) Live shellfish must be gathered and transported in accordance with Section14.

3) Shellfish intended for relaying must be accompanied by a movement document (Section 14.4) unless the conditions of Section 14.4, paragraph 4) apply.

16.3. Relaying areas

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.

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

16.4. Operating procedures

1) Each relayer must develop, in consultation with the Department, 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.

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.

3) The microbiological concentrations in the shellfish shall meet the approved criteria (Section 8.3), and biotoxins limits given in Appendix 3, at the end of the relaying process.

4) A minimum period of 28 days is recommended when conditions are suitable at the relay site.

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

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.

7) Batches of live shellfish harvested in a relaying area must be accompanied by a movement document (Section 14.4) during transport to a dispatch centre or processing plant unless the conditions of Section 14.4, paragraph 4) apply.

16.5. Records

1) Relayers shall be required to keep complete and accurate records for inspection by the Department 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.

2) The Department 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.

17. DEPURATION

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

17.1. Conditions

1) Depuration is the process whereby filter-feeding shellfish are biologically cleansed in a purified and controlled seawater environment such as on-shore tanks. 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.

2) All operations harvesting shellfish for delivery to a depuration plant must be issued with a separate permit by the Department.

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 638 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.

4) The operator shall be responsible for verifying the depuration process.

5) Certified depuration plants are to be inspected at least monthly to ensure compliance with Regulation 638 published under the Foodstuffs , Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972).

6) The Department 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.

17.2. Process verification

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 Section 8.4).
- 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.

17.3. Source of shellfish

2) Only shellfish that meet the requirements for restricted areas (Section 8.4), at a minimum, may be harvested for depuration. The acceptable pre-depuration levels of faecal contamination shall be established as part of the ADP.

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

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

5) Shellfish intended for depuration must be accompanied by a movement document (Section 14.4) unless the conditions of Section 14.4, paragraph 4) apply.

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

17.4. Structural requirements

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 638 published under the Foodstuffs , Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972).

2) Vermin control shall be implemented in accordance with Regulation 638 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.

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.

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.

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

17.5. Process water quality and operation

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.

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

   a) 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.

   b) pH must be in the range pH 7.0 – 8.4.

   c) 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.

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.

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.

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.

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

7) Process water used in the tanks should be changed continuously or at suitable intervals or, if recirculated be treated properly.

17.6. Cleaning and Sanitizing of facilities, utensils and equipment

1) All facilities utensils and equipment on the premises shall be kept clean and sanitized in accordance with Regulation 638 published under the Foodstuffs , Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972).

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

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

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

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

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

17.7. Quality assurance

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.

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 (Section 8.3).

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

4) In the event of a process batch failing to meet the release criteria, the operator shall notify the Department 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

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

6) Batches of depurated shellfish must be accompanied by a movement document during transport to a dispatch centre or processing plant.

17.8. Records

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 shellfish 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.

18. WET STORAGE

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.

18.1. Conditions

1) Wet storage is not intended for depuration therefore all controls pertaining to shellfish for direct human consumption should be applied.

2) The premises and hygienic standards must comply with Regulation 638 published under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972). Wet storage facilities must undergo an annual evaluation by the relevant local health authority.

3) The water microbiological quality monitoring shall be conducted by the NRCS in accordance with Section 15.

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

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

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

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

    a) 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.

    b) The water quality requirements stipulated in Section 17.5 are met.

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

    a) 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.

    b) 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 Appendix 3.

18.2. Source of shellfish

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.

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.

3) Shellfish from different production 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.

4) Shellfish intended for wet storage must be accompanied by a movement document (Section 14.4) unless the conditions of Section 14.4, paragraph 4 apply.

18.3. Structural and design requirements

1) As for depuration.

18.4. Water quality

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

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.

3) Near-shore areas for wet storage must meet the approved (Section 8.3) or conditionally approved (Section 8.6) criteria.

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.

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, echinoderms and crustaceans are exempt from this provision.

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 (Section 17.5) The following conditions apply:

    a) 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.

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

    c) 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.

    d) If compliance is demonstrated for consecutive samples taken for a week, then routine testing to be re-instated.

e) 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.

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).

8) The following requirements are applicable to wet storage facilities in areas that are prone to toxic phytoplankton blooms and that have a filtration system to remove phytoplankton species:

a) The operator of the facility shall conduct a study on the effectiveness of the filtration system as assurance that the system is capable of excluding toxic phytoplankton (see Appendix 9) cells except for Pseudo-nitzschia species for which the concentration in the incoming water shall be less than 100 cells/litre.

b) 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.

18.5. Records

1) The following records shall be maintained by the operator:

- Information that will enable each lot of shellfish 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.

2) Live shellfish shall be labelled as described in Section 19.2 during transport and distribution until retail sale.

19. REQUIREMENTS FOR DISPATCH CENTRES

19.1. Receiving and storage

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

2) The premises and hygienic standards must comply with the Regulation 638 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 and/or relevant local health authority as is applicable. 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).

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.

4) Only batches of live shellfish accompanied by a movement document (Section 14.4) shall be accepted at a dispatch centre unless the conditions of Section 14.4, paragraph 4 apply. Shellfish must have been harvested and transported according to the requirements of this manual (Section 14).

5) In any sorting or dry storage area, live shellfish must comply with the temperature control requirements stipulated in Section 14.3.

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

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

8) Shellfish from different production sites must be kept sorted and packed separately to maintain identity. Should it be impractical to sort and pack separately, the traceability system shall record the origin of the shellfish in a particular consignment and all associated production sites shall be managed together during the implementation of contingency measures.

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

19.2. Marking of consignments and records

1) All packages 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 labelling requirements specified in the relevant regulations published under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972), Legal Metrology Act, 2014 (Act No 9 of 2014), Compulsory Specifications in terms of the National Regulator for Compulsory Specifications Act, 2008 (No. 5 of 2008) and importing country regulations where relevant.

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

3) 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.

4) If shellfish are unwrapped and subsequently re-wrapped, handled or further processed in another establishment, the latter establishment must apply its own label to the product and maintain adequate records of origin and destination for 5 years. The label must include, in addition to that set out in Section 19.2, details of the original dispatch centre and re-packaging details.

19.3. Transport from a dispatch centre

1) The transport of live shellfish intended for human consumption must comply with the relevant provisions of Regulation 638 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 packages until offered for sale to the retailer, restaurant or end consumer.

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

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 bivalves intended for the market in a live, chilled state must be brought to a temperature of 7°C or less before leaving the centre. Abalone, echinoderms and crustaceans shall be maintained at

an appropriate temperature as indicated in Section 14.3. This temperature shall not be so cold as to affect the viability of the shellfish. This temperature shall be maintained during transport and storage.

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.

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

19.4. Export

1) Export requirements are published in the applicable Compulsory Specifications in terms of the National Regulator for Compulsory Specifications Act, 2008 (Act No. 5 of 2008).

2) Health guarantees are issued by the relevant authorities officially authorised by the Department 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.

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

20. FEED MANAGEMENT AND MONITORING

20.1. Feed testing

1) Formulated feed fed to abalone, echinoderms and crustaceans shall be tested in accordance with the National Residue Control Programme for residues.

20.2. Farm manager responsibility

1) 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, veterinary drugs or any other feed ingredient that are permitted for shellfish by the Department and/or relevant legislation. Substances prohibited in terms of relevant legislation shall not be used.

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

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

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

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

6) Farm managers shall follow manufacturer instructions on the use of medicated feeds.

7) 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.

8) Feed shall comply with the requirements stipulated in the relevant legislation and sourced from a supplier approved by the Department.

9) 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

10) Feed shall be handled on a first-in-first-out basis and each batch shall be kept separately and used by the expiry date.

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

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

14) Regarding the control of pests refer to Section 17.4, paragraph 2).

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

16) Veterinary drugs and other chemical treatments shall be authorised for use by the South African Health Products Regulatory Authority (SAHPRA) Medicines Control Council and shall be administered in accordance with recommended practices and comply with national regulations.

17) The addition of veterinary drugs in the feed shall only be undertaken under the supervision of a registered vet.

18) Feeds medicated after procurement shall be clearly identified on the package.

19) Medicated feed shall be store separately form the non-medicated feed.

20.3. Feed producer responsibility

1) Feeds and feed nutritional information shall be properly labelled with an expiry date and production date. Their composition must fit the declaration on the label.

2) Feed ingredients shall be made available when required by the Department.

3) Labelling shall comply with relevant legislation.

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

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

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

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

8) Veterinary drug and other chemical treatments shall be authorised for use by the SAHPRA Medicines Control Council and shall be administered in accordance with recommended practices and comply with national regulations.

9) Medicated feeds shall be clearly identified on the package.

10) Medicated feed shall be store separately form the non-medicated feed.

21. DRUG MANAGEMENT

1) For on-label uses, the withdrawal times specified for the product MUST be adhered to and no treated product shall be sent for processing for human consumption until that withdrawal period has elapsed.

2) For off-label uses, the veterinarian in charge of the animals shall stipulate a withdrawal period that shall be adhered to and no treated product shall be sent for processing for human consumption until that withdrawal period has elapsed. Where drugs are used off-label the shellfish shall not be harvested for human consumption for at least 500 degree days prior to harvesting. The 500 degree days is calculated by adding the ambient water temperature to which the treated shellfish are exposed to on a daily basis, after treatment is completed, until at least 500 degree days is achieved.

3) Only 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) may be used and shall only be administered by veterinarians registered with the South African Veterinary Council, (SAVC) and / or on prescription by such a veterinarian.

4) Veterinary drugs listed in Appendix 10 shall not be used and shall be monitored for in the shellfish.

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

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

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

8) 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.

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

10) 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.

11) 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

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

13) 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

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

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

16) Should shellfish be transferred from one production facility to another for further on-growing or holding, a movement register shall be kept by both production facilities. The register shall include at least the following information:

- Date of movement
- Name and facility code of the production facility receiving the shellfish and /or origin of the shellfish
- Quantity (mass) of shellfish transferred.
- Note any chemical or drug treatment of the shellfish at least 200 degree days prior to movement.

22. SAMPLES AND SAMPLE TAKING

22.1. Sampling requirements

1) The responsibility of the FSO includes:

a) ensuring that all sampling required by this manual is performed in accordance with the requirements;

b) compiling sampling plans relevant to this manual; and

c) identifying required sampling activities to be included in the marine biotoxin management plan and microbiological management plan.

2) The responsibility of the competent authority responsible for sampling includes:

   a) training, certifying and listing samplers;

   b) checking the suitability of equipment used by the samplers; and

   c) conducting an annual review of the sampling activity, including a review of the receipt of samples at a laboratory.

3) The sampling shall be undertaken in terms of a standard operating procedures drafted by the Department. The SOP shall include:

   a) Sample size

   b) Sampling method

   c) Sampling equipment

   d) Tissue to be sampled

   e) Temperature control

22.2. Training of samplers

1) Samplers must be:

   a) trained and audited by or under the supervision of the relevant competent authority; and

   b) certified by the competent authority.

2) A person must not be trained as a sampler unless the competent authority is satisfied that the person:

   a) has adequate educational qualifications and training in scientific principles;

   b) is trustworthy, reliable and self-motivated; and

   c) has declared whether the person has any actual or potential conflicts of interest and, if any, these are acceptable to the competent authority.

3) Samplers must be trained in all of the following where relevant:

   a) legal requirements relating to sampling and the harvest of shellfish;

   b) the sampling requirements of the MCP, including the public health rationale for the sampling;

   c) the consequences of errors in sampling for public health and for growers and harvesters;

   d) the care and use of instruments and equipment used in sampling activities;

   e) the correct method for taking water and shellfish samples aseptically for microbiological analyses;

   f) the correct method for taking water and shellfish samples for biotoxin analysis;

   g) the significance of the number of shellfish to be collected including the variation in microbiological, marine biotoxin and heavy metal levels between individual shellfish;

h) the correct method for taking shellfish samples for heavy metal and other toxic substance analyses;

i) the correct method for completing the sample submission form and the sample label;

j) the correct method for the storage and dispatch of samples to the laboratory;

k) the significance of following correct procedures;

l) the classification and status of growing areas;

m) marine biotoxin management;

n) the patchiness of harmful algae blooms;

o) the significance of toxigenic phytoplankton monitoring;

p) the nature and whereabouts of pollution sources identified in the sanitary survey report;

q) the significance of timing in MCP strategy sampling;

r) the significance of monthly sampling under adverse pollution conditions;

s) the significance of routine sampling;

t) the amount of chilling material required to effectively chill the samples;

u) the organisation and management of sampling runs; and

v) occupational health and safety requirements.

22.3. Responsibilities of samplers

1) Every sampler must:

   a) follow the direction of the regional sampling manager in relation to sampling;

   b) ensure that the equipment used during sampling is adequately calibrated and does not contaminate the sample; and

   c) ensure that the sampling procedure does not result in contamination of the sample.

2) Samplers must follow all of the following procedures when taking samples:

   a) identify, package and store samples without delay after the sample has been taken;

   b) on becoming aware that an unsuitable sample has been taken, notify the laboratory and FSO within 24 hours by phone, followed up within 3 working days in writing;

   c) mark or clearly identify each sample package at the time of sampling in a manner that;

      i) maintains the identity of the sample in a durable and legible manner;

      ii) allows clear and correct matching to any relevant records; and

      iii) clearly identifies the place from which the sample was taken;

   d) individually pack each sample in packaging so that the sample does not contaminate any other sample or packaging material, and to prevent any error in identification of the sample;

e) double bag the sample (unless it is a sample of water) and pack the sample using packaging that is durable, leak proof and free from contaminants;

f) place samples for microbiological and biotoxin analyses promptly into a chilled container at a temperature of cooler than 10°C;

g) complete the sample submission form in writing and sign it:

i) as soon as practicable after taking the sample; and

ii) before dispatching the sample to the laboratory; and

h) promptly dispatch the sample to the laboratory in such a manner that the required times between sample collection and commencement of analysis as stated in relevant sampling and transport SOP can be complied with.

22.4. Sample submission forms

1) Samplers must ensure that a sample submission form accompanies each sample submitted to a laboratory.

2) The sample submission form must set out all of the following:

a) the name and contact details of the sampler;

b) the date and time the sample was taken;

c) the type of sample taken and the part of the sample to be tested;

d) the sample station code, name and where applicable the nearest corresponding marine farm number; and

e) the type of tests to be carried out.

22.5. Labels of samples

1) Samplers must ensure that each sample is labelled.

2) The label must:

a) clearly identify the sample to which it relates;

b) include a unique sample number;

c) the name or number or sample station from which the sample was taken;

d) the sample type; and

e) the date and time of sampling.

23. LABORATORY RESPONSIBILITY

1) South African laboratories used in terms of the MCP must be accredited under the South African National Accreditation System (SANAS) rules. International laboratories must be accredited under the International Laboratory Accreditation Cooperation (ILAC) rules.

2) Only validated test method shall be used.

3) The sample must be processed anonymously by the laboratory.

4) The test results shall be submitted to the relevant authorities within 10 working days for National Residue Control Programme (NRCP) Category A substances and no more than 30 working days for Category B substances.

5) The laboratory shall not accept official samples where:

- The containers are not sealed
- The containers are broken
- The sample has leaked out
- The sampling report is missing
- The sampling report is incorrect or incomplete

23.1. Receipt of samples

1) When a laboratory receives a sample, it must check the following:

   a) that the sample is clearly marked or identified to allow it to be traced back to the sample submission form;

   b) that the information on the sample submission form is consistent with the sample;

   c) the sample provided is suitable for the particular test required;

   d) the sample packaging is intact;

   e) there are no visible signs of contamination of the sample;

   f) that the sample was received:

      i) within 24 hours after sample collection; or

      ii) if delivery was delayed, within 48 hours after sample collection, but only if the sample is determined to be still suitable for analysis by the laboratory.

   g) the sample temperature for marine biotoxin and microbiological samples is less than 10°C, unless:

      i) sampling occurred on the same day; and

      ii) the sample has not had adequate time if placed in a chilled container to reach a temperatures cooler than 10°C.

2) If any of the requirements of this clause are not met, or if the laboratory considers the sample may not be suitable for testing, the laboratory must:

   a) decide whether to analyse the sample or seek direction from the FSO;

   b) record the details of the defect;

   c) notify the FSO within 1 working day of sample receipt; and

   d) analyse as a priority any replacement sample.

3) The laboratory must keep records of all notifications given to FSO under this clause.

4) The FSO must keep records of action taken as a result of reported laboratory non-compliances.

23.2. Tracking systems

1) A recognised laboratory must ensure that there are written procedures detailing the laboratory sample tracking system, including details of sample transfer to laboratories that are subcontracted to perform analyses where applicable.

23.3. Sample temperature and storage

1) Marine biotoxin and microbiological samples at a recognised laboratory must be maintained at a temperature of less than 4°C until analysis is started.

2) Samples that may be involved with an official investigation must be stored until the FSO notifies the laboratory in writing that the samples may be discarded.

23.4. Method performance

1) The laboratory must have in place corrective actions and procedures to deal with, or remedy, the situation where a method fails to perform within the requirements of the method.

2) The laboratory must ensure that samples in the batch are re-analysed where:

   a) batch control values are outside the limits or requirements of the method performance standards; and

   b) the laboratory considers this may affect the results.

3) If there is an unidentified test response for marine biotoxin methods, the laboratory must:

   a) notify the FSO within 24 hours;

   b) investigate the response; and

   c) if possible, identify the unknown compound.

4) The laboratory must provide the FSO with a report of all unidentified test response findings once the investigation is complete.

5) The FSO may direct a laboratory to:

   a) undertake independent confirmation, at the laboratory or at another laboratory determined by the FSO; or

   b) repeat the test of a sample, as long as the remainder of the sample is sufficient for that process.

24. REFERENCES

1) AOAC 1990. Paralytic shellfish poisoning. Biological method. Final action. In: Hellrich, K. (Ed). Official Methods of Analysis. 15th Edition, pp 881-882, sec 959.08. Association of Official Analytical Chemists, Arlington, Virginia, USA.

2) Canadian Shellfish Sanitation Program. Manual of Operations. 1992.

3) Codex 2008. Standard for Live and Raw Bivalve Molluscs. CODEX STAN 292 P1-7

4) Commission Regulation (EC) No 1021/2008. Controls on products of animal origin intended for human consumption

5) Commission Regulation (EC) No 1441/2007. Microbiological criteria for foodstuffs amendment.

6) Commission Regulation (EC) No 15/2011. Detection methods for marine biotoxins.

7) Commission Regulation (EC) No 1664/2006. Implementing measures for certain products amendment

8) Commission Regulation (EC) No 1881/2006. Contaminant limits in foodstuffs

9) Commission Regulation (EC) No 2073/2005. Microbiological criteria for foodstuff

10) Commission Regulation (EC) No 2074/2005. Implementing measures for certain products

11) Commission Regulation (EC) No 420/2011. Contaminant limits in foodstuffs amendment.

12) Commission Regulation (EC) No 558/2010. Hygiene rules for food of animal origin

13) Commission Regulation (EC) No 852/2004. On the hygiene of foodstuffs.

14) Commission Regulation (EC) No 853/2004. Laying down specific hygiene rules for food of animal origin.

15) Commission Regulation (EU) 2017/625 on Official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare

16) Commission Regulation (EU) 2017/644 on Methods of Sampling and analysis for the control of levels of dioxins, dioxin-like PCB's and non-dioxin-like PCB's

17) Donovan TJ, Gallacher s, Andrews NJ, Greenwood MH, Graham j, Russel JE and R Lee (1998) Modification of the standard method used in the United Kingdom for counting Escherichia coli in live bivalve molluscs. Communicable Disease and Public Health 1: 188-196.

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

19) Guide to regulatory requirements and examination procedures for fish and fish products exported from Canada to the European Union. Canadian Food Inspection Agency, Fish Seafood and Production Division. Sept 25, 2000.

20) Hannah DJ, Till DG, Deverall T, Jones PD and JM Fry 1995 Extraction of lipid-soluble marine toxins. Journal of AOAC International 78: 480-483.

21) ISO 16140 (2004) Microbiology of food and animal feeding stuffs – Protocol for the validation of alternative methods.

22) ISO 6579 (2002) Microbiology of food and animal feeding stuffs – Horizontal method for the detection of Salmonella spp.

23) ISO/TS 16649-3 (2005) Microbiology of food and animal feeding stuffs – Horizontal method for the enumeration of beta-glucuronidase-positive Escherichia coli Part 3. Most probable number technique using 5-bromo-4-chloro-3-indolyl-D-glucuronide.

24) National Shellfish Sanitation Program. Manual of Operations. Part 1. Sanitation of Shellfish Growing Areas. 1995 Revision. US-FDA.

25) National Shellfish Sanitation Program. Manual of Operations. Part 2. Sanitation of the Harvesting, Processing and Distribution of Shellfish. 1995 Revision. US-FDA.

26) New Zealand Fishing Industry Agreed Implementation Standards IAIA 001, 1: Shellfish Quality Assurance Circular 1995.

27) New Zealand Regulated Control Scheme: Bivalve Molluscan Shellfish for Human Consumption, 2018

28) NRCS Manual 570 MAN 005. Basic Requirements for Inspection Purposes Pertaining to the Implementation of HACCP Principles for Fishery Products. 2009.

29) Operations Manual of the Australian Shellfish Sanitation and Control Program. First Edition 1997.

30) Quilliam MA, Xie M and WR Hardstaff 1995 Rapid extraction and clean up for liquid chromatographic determination of domoic acid in unsalted food, Journal of AOAC International 78: 534-554.

31) SANS 241:2001 (NRCS 241:2001) Drinking Water.

32) SANS 5221:2001 (NRCS SM 221:2001) Microbial analysis of water – General test methods.

33) SANS 6196: 2006 Examination for the presence of viable pathogenic Vibrio organisms in Foods

34) Sanz, I. 1999. Imports of fishery products into the EC: Sanitary approval for third countries. EC Fisheries 6 Cooperation Bulletin 12: 4-6.

35) Yasumoto T, Murata M, Oshima, Y, Matsumoto K and J Cardy 1984. Diarrhetic shellfish poisoning. In: EP Ragelis (ed.), Seafood Toxins, ACS Symposium Series, 262, 207-214. American Chemical Society, Washington, DC.

25. SOUTH AFRICAN LEGISLATION

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

1) Marine Living Resources Act, 1998 (Act No. 18 of 1998) and Regulations in terms of the Marine Living Resources Act, 1998 (published in Government Notice R1111 in *Government Gazette* 19205 dated 2 September 1998)
2) Foodstuffs, Disinfectants and Cosmetics Act, 1972 (Act No. 54 of 1972)
3) National Regulator for Compulsory Specifications Act, 2008 (Act No. 5 of 2008) including but not limited to:
    a) VC 8014 Compulsory specification for canned fish, canned marine molluscs and canned crustaceans and products derived therefrom-2018
    b) VC 8017 Compulsory Specification for frozen fish, frozen marine molluscs and frozen products derived therefrom-2015
    c) VC 9001 Compulsory Specification for live aquacultured abalone-2012
    d) VC 9107 Compulsory Specification for aquacultured live and chilled raw bivalve molluscs 2016
4) Municipal Structures Act, 1998 (Act No.117 of 1998)
5) Legal Metrology Act, 2014 (Act No. 9 of 2014)
6) Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies, 1947 (Act No. 36 of 1947)
7) Medicines & Related Substances Control Act, 1965 (Act No. 101 of 1965)
8) Veterinary and Para-veterinary Professions Act, 1982 (Act No. 19 of 1982)

Appendix 1: Sanitary survey

1) Establishing sampling stations

   a) For shore-based aquaculture systems, shellfish samples are to be taken from either within the culture units or, if the production area 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 shellfish species may be used under advisement of the Department.

   b) Water abstracted for onshore cultivation must comply with the requirements for an approved area (Section 8.3). 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 (Section 8.4). Water that does not meet the criteria for an Approved area may not be used for marine aquaculture.

   c) 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.

   d) 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).

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

   f) 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.

2) Frequency of Sampling Required for Classification

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

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

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

   d) 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.

e) The samples are to be taken by the Department sanctioned personnel (Section 7, paragraph 6) at a fixed frequency (determined by the Department) under sufficiently broad environmental conditions to identify possible adverse scenarios. It is expected that 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.

f) 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.

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

h) Should a new farm be developed in the same production area as existing farms producing the same shellfish type such as oysters, abalone, echinoderms or crustaceans; or existing farms producing mussels; or existing farms that have a similar or more stringent microbiological risk profile, the classification status of the production area may be applied to the new farm. Conformance of the new farm with the classification status of the production area shall be confirmed by testing *E. coli* once a month for a period of 12 months.

i) Water samples for phytoplankton identification by the Department sanctioned personnel are to be taken at least monthly.

3) Sampling and analytical protocols for microbiological parameters

a) Live shellfish, including intravalvular fluids is sampled from each station as summarized in SOP Sampling and Transport of Cultured Fish and submitted to an accredited or officially approved microbiology laboratory.

b) The five-tube, three-dilution MPN method of Donovan et al. (1998) is required for enumeration of *E. coli* (Appendix 4). 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).

Appendix 2: 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 8.2. These guidelines act as a checklist and provide a model for the structure of the report.

1) Summary

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

2) Background information

   a) Motivation for the study.

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

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

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

   e) History of production area classification:

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

3) Pollution source (shore line) survey

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

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

   c) 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.
      - Storm-water – 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

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

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

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

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

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

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

   g) River discharges – volumes and seasonality.

   h) 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

   a) Sampling plan, taking potential pollution sources into account.

   b) Map showing sampling stations.

   c) Description of sample collection and analytical procedures.

   d) Microbiological data analysis and presentation. Present data and statistical analyses in table form indicating compliance with criteria given in Section 8 and classification of individual sample stations where applicable.

   e) Assessment of levels of toxic and hazardous substances in shellfish.

   f) Assessment of risk imposed by biotoxin producing phytoplankton.

   g) 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.

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

7) Recommendations.

   a) 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.

   b) Monitoring actions for biotoxins.

c) Monitoring actions for drugs and residues.

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

8) Enforcement action reports

a) Provide details of enforced closure to harvest for public health reasons during the re-classification period. This should include (see also paragraphs 9)d) & 9)e)) 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 farm manager(s).

9) Management plans

a) 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.

b) The plan shall include a description of predictable pollution events that cause closure.

c) Information on wastewater treatment, environmental effects and other events shall be included as relevant:

i) 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.

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

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

d) Implementation of conditional area closures.

i) 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.

ii) 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.

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

e) Criteria for reopening a conditional area after a pollution event. The Department 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.

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

Appendix 3: Analysis methods and regulatory limits for biotoxins

BIOTOXIN	TEST METHODS	STANDARDS
Paralytic Shellfish Toxins (PST)		
Saxitoxin	^Lawrence method (AOAC Official Method 2005.06) (Commission Regulation (EC) No 1664/2006).	≤ 0.8 mg saxitoxin hydrochloride equivalent per kg edible flesh[#] (Regulation (EC) No 853/2004).
Lipophilic Shellfish Toxins (LST)		
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 equivalent per 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 equivalent per 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 equivalent per kg edible flesh[#] (Commission Regulation (EC) No 853/2004).
Amnesic Shellfish Toxins (AST)		
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 equivalent per kg edible flesh[#] (Commission Regulation (EC) No 853/2004).

*European Union Reference Laboratory

^ Reference Method

[#] Includes intravalvular fluid with regard to bivalves

Appendix 4: Analysis methods and regulatory limits for microbiological contaminants

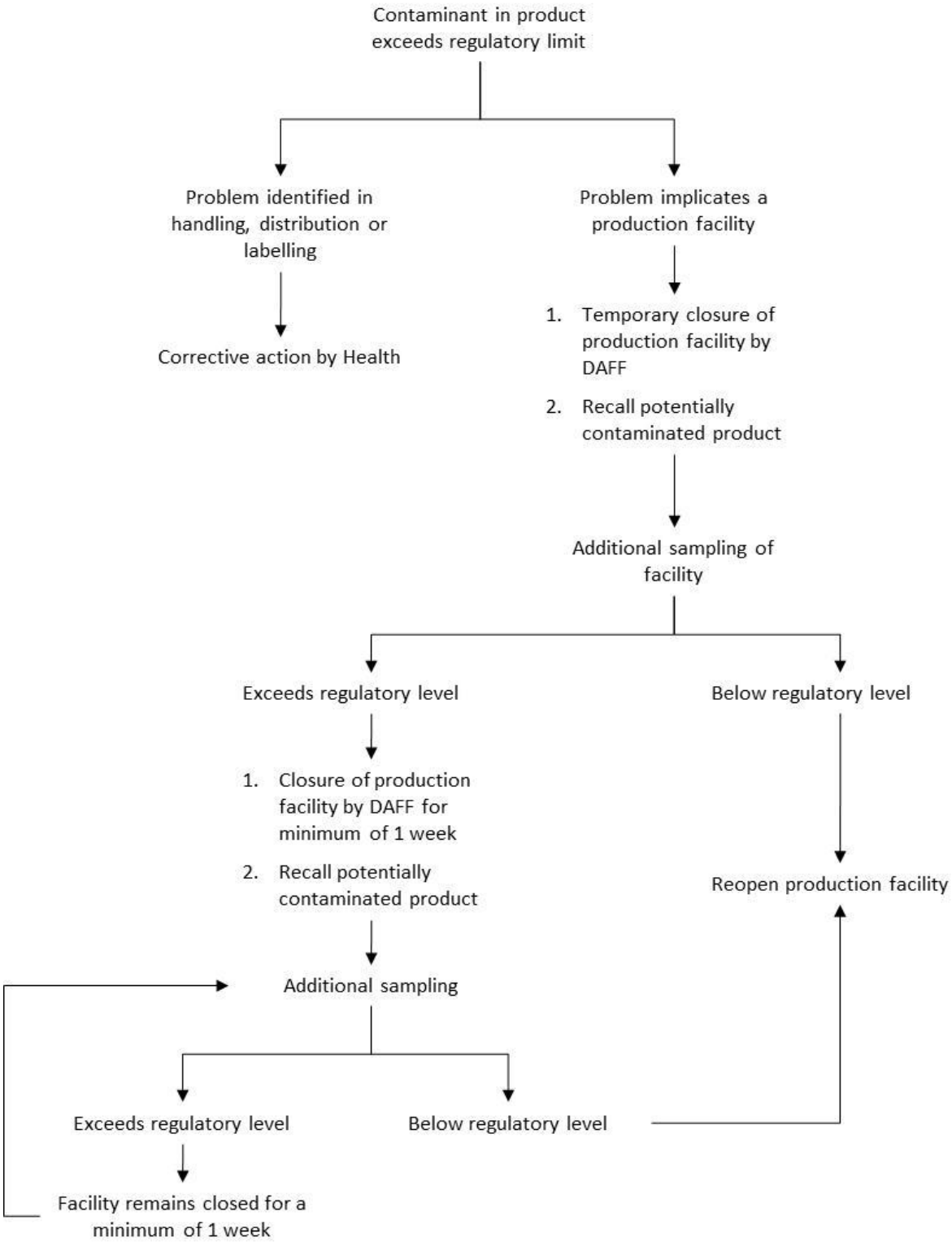
MICROBIAL AGENTS	TEST METHOD	STANDARDS
Escherichia coli	SANS 16649-3:2008/ISO/TS 16649-3:2005 (Donovan *et al*. 1998)	≤230.100g^{-1} edible flesh (Class A) <4 600.100g^{-1} g edible flesh (Class B)
Salmonella	SANS 6579:2003/ISO 6579:2002	Absence in 25 g
Vibrio cholerae & *V. parahaemolyticus*	SANS 6196:2006	Absence in 25 g

Appendix 5: Thresholds that trigger intensive biotoxin testing

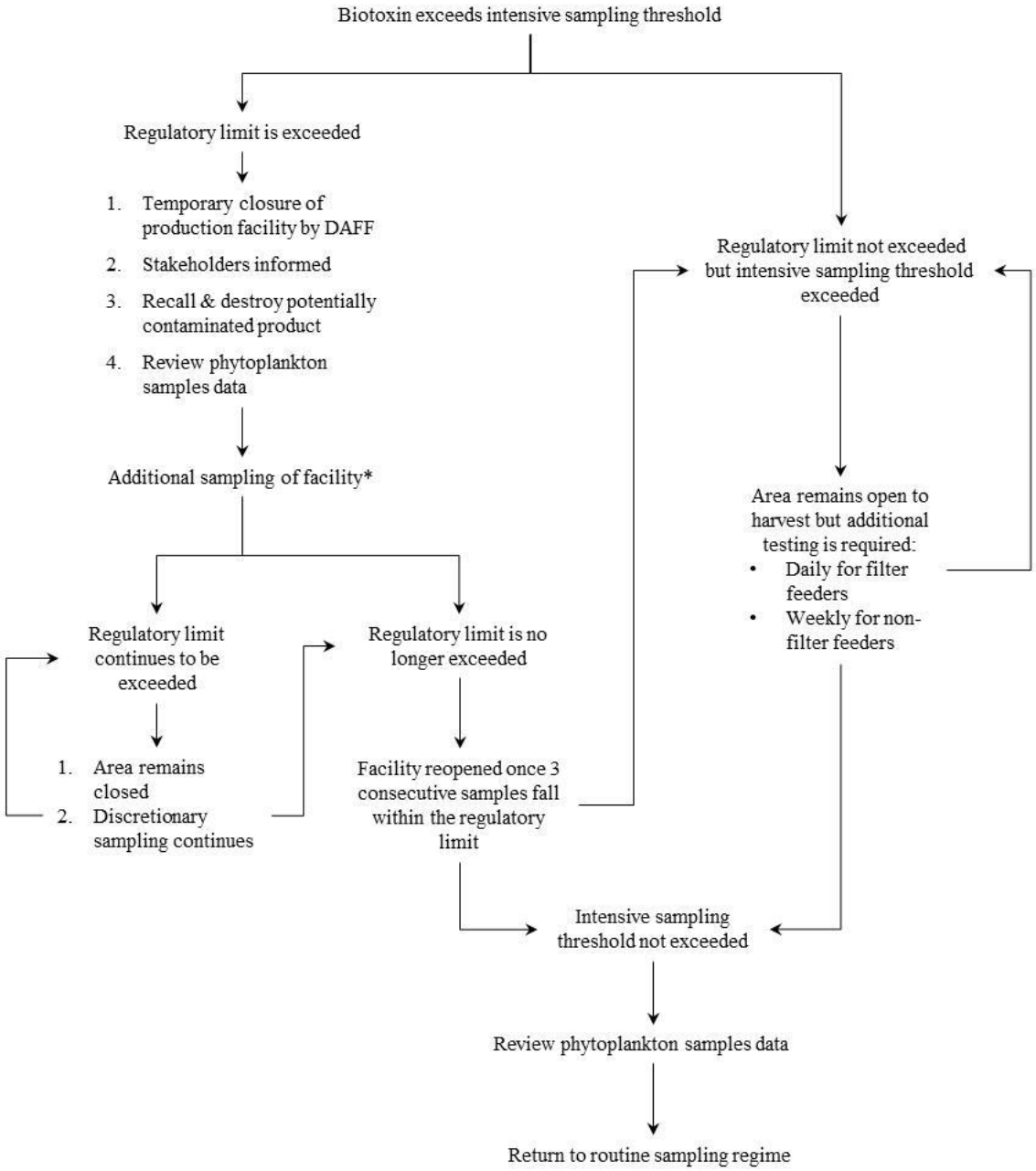
The following biotoxin concentration thresholds shall trigger daily testing for the implicated toxin in filter feeders and weekly testing in abalone, echinoderms or crustaceans if the production area is not temporarily closed for harvesting:

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 6: Microbiological and hazardous substance contingency measures



Appendix 7: Biotoxin contingency measures



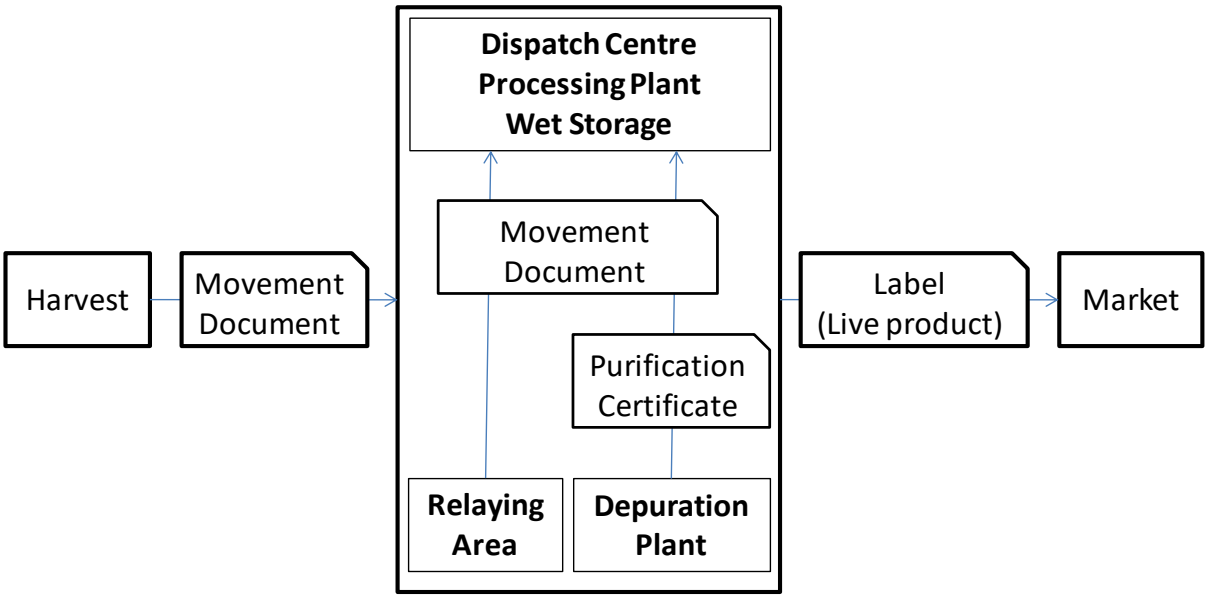
*Frequency of sampling is at farm managers discretion, but no more than one sample may be submitted per day. Multiple samples on the same day will be considered one sample.

Appendix 8: Documentation and labelling requirements during transport of live shellfish

1) A movement document must accompany batches of live shellfish transported prior to placing on the market unless the same staff members operate the facility, relaying site or depuration plant of destination. 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 dispatched from the FPE. 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.



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 - International Air Transport Association (IATA), insurance certificate, veterinary certificate and Convention on International Trade in Endangered Species (CITES) certificate). From a public health perspective, some countries may require that each shipment of seafood product 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 9: Phytoplankton species that are toxic to humans

The following list includes those phytoplankton species found in South African marine environment that are reported to be toxic or potentially toxic to humans:

Dinophyceae

Alexandrium catenella

Alexandrium minutum

Dinophysis acuta

Dinophysis acuminata

Dinophysis fortii

Dinophysis hastata

Dinophysis tripos

Dinophysis rotundata#

Protoceratium reticulatum

Gonyaulax spinifera

Lingulodinium polyedrum

Karenia cristata

Bacillariophyceae

Pseudo-nitzschia spp

Appendix 10: Prohibited substances

The following substances are prohibited during the growing of shellfish:

- Stilbenes
- Steroids
- Chloramphenicol
- Nitrofurans
- Nitroimidazoles

Appendix 11: Controlled substances

The following substances are controlled during the production of shellfish where relevant:

- Biotoxins (Paralytic, Lipophilic and Amnesic Shellfish toxins)
- Pesticides and Polychlorinated Biphenyl
- Heavy metals (lead, mercury, cadmium, arsenic)
- Mycotoxins
- Dioxin, Polycyclic Aromatic Hydrocarbons and Furans
- Radionuclides
- Antibacterial substances
- Anthelmintics