forestry, fisheries & the environment

Department:
Forestry, Fisheries and the Environment
REPUBLIC OF SOUTH AFRICA

AQUACULTURED MARINE FISH

FOOD SAFETY PROGRAMME

Branch: Fisheries Management

Chief Directorate: Aquaculture Development and Freshwater Fisheries

Directorate: Sustainable Aquaculture Management

Version 1: March 2024

TITLE
Aquacultured Marine Fish Food Safety Programme (Version 1).

COMMENCEMENT
This programme comes into force on 1 March 2024.

REVOCATION
This programme version revokes and replaces South African Molluscan Shellfish Monitoring and Control Programme, Version 8, as well as previous revisions of the programme as indicated in the table below.

Version	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 programme version furthermore revokes and replaces South African Cultured Marine Fish Monitoring and Control Programme, Version 4, as well as previous revisions of the programme as indicated in the table below.

Version	Date of issue
1	01 September 2013
2	01 January 2015
3	01 January 2016
4	01 May 2022

This Aquacultured Fish Food Safety Programme is published by the Director Sustainable Aquaculture 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).

CHIEF DIRECTOR

AQUACULTURE DEVELOPMENT AND FRESWATER FISHERIES

DATE: 22/02/2024

Contents

Tables

Appendices

DOCUMENT CONTROL

1) This programme has been prepared by the Department in association with the division Food and Associated Industries within the NRCS and the marine aquaculture industry role-players. The programme will be reviewed as new and pertinent 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: Publications of the Aquacultured Marine Fish Food Safety Programme

Version 1	Date of issue
1	1 March 2024

2) Suggestions for alterations that would significantly improve the programme are welcome. These should be submitted to the co-ordinator of this programme, explaining the reasons for the suggested changes.

Co-ordinator: Mr John Foord
Department of Forestry, Fisheries and the Environment
Private Bag X2
Roggebaai
8012
Cape Town
South Africa
Email: JFoord@dffe.gov.za

3) A detailed record of all amendments shall be kept by the Department.

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

1. DEFINITIONS

"Acceptable" means acceptable to the Department and the Competent Authority.

"Accredited laboratory" for the purposes of the Programme means any South African laboratory as contemplated in the Accreditation for Conformity, Assessment, Calibration and Good Laboratory Practice Act, 2006 (Act No. 19 of 2006) or international laboratory accredited under the International Laboratory Accreditation Cooperation (ILAC) rules.

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

"Approved Areas (or 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 9.3. An approved area may temporarily be closed to harvesting, e.g. when a flood, storm or marine biotoxin event occurs.

"Aquaculture" means the farming of aquatic organisms in controlled or selected aquatic environments involving—

(a) a degree of human intervention in the rearing process to enhance production which may include propagation, breeding, regular stocking, feeding, protection from predators and harvesting of cultured aquatic organisms. and

(b) individual or corporate ownership of the stock being farmed.

"Batch" means fish harvested from a particular identifiable area at a particular time (i.e. no more than one day).

"Bivalves" means filter feeders as defined and *Pectinidae*.

"Central File" means the file system maintained by the persons responsible for management of this programme at the Department, which remains in one single location for auditing purposes.

"Certificate of Acceptability" means the certificate referred to in regulation 3 of Regulations Governing General Hygiene Requirements for Food Premises and the Transport of Food and Related Matters published in GN 638 of 22 June 2018 in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972).

"Clean Ice" means ice made from potable water or clean seawater and that has hygienically been stored 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" means a Production Area where the harvesting of fish for human consumption is either temporarily or permanently not permitted.

"Comfort Facilities" includes but is not limited to ablution facilities, catering facilities and staff quarters.

"Competent Authority" means the National Regulator for Compulsory Specifications.

"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.

"Degree Day" degree days are calculated by multiplying the water temperature in degrees centigrade by the number of days following cessation of treatment, for example 500-degree days would represent a withdrawal of 50 days at 10°C or 100 days at 5°C.

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

"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 of sale (i.e. safe in a live, fresh state, if so desired). Also referred to as immediate 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.

"Filter feeders" means species commonly referred to as mussels, oysters and clams.

"Finfish" means the fish in the class Osteichthyes.

"Fish Processing Establishment" means any vehicle, vessel, premises or place where fish are processed for sale.

"Fish" means cultured marine living resources intended human consumption, including filter feeders, non-filter feeders and finfish.

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

"Foodstuffs Act" means the Foodstuffs Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972).

"**GNR 638**" means the regulations governing general hygiene requirements for food premises, the transport of food and related matters published in GNR 638 of 2018 under the Foodstuffs Act.

"Harvester" means a person or entity with a marine aquaculture right to harvest fish 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 with similar characteristics (i.e. no more than one day).

"Management plan" means a plan that is specific to a particular geographic area that outlines procedures that are required to be implemented within the area to achieve a particular objective.

"Marine Aquaculture" means 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.

"Non-filter feeders" means species commonly referred to as gastropods, *Pectinidae*, urchins and crustaceans.

"Non-Point Source (of pollution)" 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 Fishery Control 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, 2003 (Act No.61 of 2003) and regulations promulgated under these Acts.

"Official sample" means any sample taken in accordance with this Programme.

"Official test result" means test result of an official sample.

"Open" in relation to a production 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 is 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.

"Product" means any live or dead aquacultured fish organism or product derived from an aquacultured fish organism that is offered for sale, sold or otherwise traded.

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

"Production facility" means an artificial system that comprises of infrastructure, whether onshore or offshore, that supports or could support the culture of live fish.

"Prohibited Zone" 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 worse than Restricted Class C production areas. 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 (or Class B)" means a Production Area classified by the Department as an area from which shellfish may be harvested only upon written approval from the Department. A restricted area must comply with the microbiological requirements set out in Paragraph 9.4. Shellfish from restricted areas may be processed (e.g. canning, cooking and freezing as per Paragraph 9.4, 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 Paragraph 9.2 of this Programme, 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" means filter feeders and non-filter feeders as defined.

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

"The Programme" means the Aquacultured Marine Fish Food Safety Programme.

"Traceability" means the ability to discern, identify and follow the movement of a food or substance intended to be or expected to be incorporated into a food, through all stages of production, processing and distribution.

"Transaction Record" means a form used to document each purchase or sale of fish 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.

"Wet Storage" means the temporary storage of shellfish in water prior to marketing.

2. ABBREVIATIONS

"ADP" means approved depuration process
"AST" means Amnesic Shellfish Toxins
"AZA" means Azaspiracid
"BMP" means better management practice
"CCP" means Critical Control Point
"CITES" means Convention on International Trade in Endangered Species
"CoA" means Certificate of Acceptability
"DTX" means Dinophysis toxins
"*E. coli*" means *Escherichia coli*
"EC" means European Commission
"FPE" means Fish Processing Establishment
"FSO" means Food Safety Office within the Department
"GPS" means global positioning system
"HACCP" means Hazard Analysis and Critical Control Point
"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
"MLRA" means the Marine Living Resources Act, 1998 (Act No. 18 of 1998)
"MPN" means Most Probable Number
"MRL" means maximum residue limit
"NRCP" means National Residue Control Programme
"NRCS Act" means the National Regulator Compulsory Specifications Act, 2008 (Act No. 5 of 2008)
"NRCS" means National Regulator for Compulsory Specifications
"NRP" means National Residue Plan
"OA" means okadaic acid
"PST" means Paralytic Shellfish Toxins
"PTX" means Pectenotoxins
"SAHPRA" means South African Health Products Regulatory Authority
"SANAS" means South African National Accreditation System
"SANS" means South African National Standard
"SAVC" means South African Veterinary Council
"SOP" means Standard Operating Procedure
"WWTW" means wastewater treatment works
"YTX" means Yessotoxin

3. BACKGROUND

Food safety laws throughout the world give special consideration to fish for several reasons. Some of the fish 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. Non-filter feeder shellfish also accumulate biotoxins, particularly Paralytic Shellfish Toxins (PST) and to a lesser extent Lipophilic Shellfish Toxins (LST) 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 furthermore not eliminated by cooking.

Finfish may also pose a food safety risk as they have the potential to accumulate environmental residues from the aquatic environment in which they are cultured, or through their feed, which may contain hazardous residues. Finfish and shellfish are also at risk of containing veterinary drug residues, including banned substances that may be used to treat fish diseases, or prophylactically to enhance growth and prevent diseases.

The Programme addresses monitoring and control measures applicable to enteric bacteria, marine biotoxins, environmental contaminants and veterinary medicine residues. Enteric bacteria namely *E. coli* is used as an indicator for enteric viruses that may be present in shellfish due to sewage contamination. Marine biotoxins are predominantly produced by toxic phytoplankton species and accumulate in shellfish, predominantly filter feeding bivalve species that filter toxic phytoplankton from the water. Bioaccumulation also occurs to a lesser extent in crustaceans and echinoderms that feed on toxic vectors, and in gastropods for which the mode of toxin accumulation is not clear. Environmental contaminants include heavy metals, pesticides, polychlorinated biphenyls (PCB), dioxins, dioxin like PCB's, polycyclic aromatic hydrocarbons, perfluoroalkyl substances and radionuclides, which are predominantly of anthropogenic origin. Veterinary medicine residues are typically introduced in aquacultured fish through feed (either intentionally or accidentally) or through contaminated or treated water.

4. PURPOSE

The purpose of the Programme is to identify, monitor, evaluate and manage the food safety, environmental and veterinary residue risks associated with the commercial growing, harvesting, sorting and transporting of cultured fish for human consumption to provide the necessary guarantees to local consumers, foreign markets and governments that the risk of disease and poisoning through consuming cultured marine fish is adequately managed and minimised.

5. SCOPE

1) This Programme addresses the public health concerns of fish harvested from marine aquaculture Production Areas that are intended for immediate human consumption or for further processing before consumption.

2) Hatcheries and nurseries are not subject to biotoxin, microbiological, environmental contaminant and controlled veterinary medicine residue monitoring and control provided the product is more than 6 months from minimum market size. Hatcheries and nurseries shall, however, be monitored for banned substances, where relevant.

3) The Programme applies to cultured marine fish. The monitoring and control measures for the various commodities namely finfish, filter feeders and non-filter feeders shall be outlined for each commodity as appropriate considering the food safety risk associated with the commodity.

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

5) The Programme 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 Forestry, Fisheries and the Environment (the Department) under the Marine Living Resources Act, 1998 (Act No. 18 of 1998) in cooperation with the National Regulator for Compulsory Specifications (NRCS), the statutory body responsible for administering the various Compulsory Specifications for fishery products in South Africa.

6) The functions of this Programme are to:

   a) define production areas from which relevant products originate and undertake sanitary surveys of these production areas;

   b) establish the Production Area classification system where relevant and maintain the classification system;

   c) set standards and monitoring requirements to ensure that fish intended for human consumption, or for further processing prior to consumption, meet the safety thresholds in respect of biotoxins, microbiological contamination, environmental residues and veterinary medicine residues where relevant;

   d) provide criteria and procedures for the closure of production areas that do not meet the required standards; and

   e) provide an early warning system for biotoxin and microbiological control, where relevant, in the interest of public health.

7) The Programme addresses the requirements for the certification and/or issuance of permits for the production, harvesting, relaying, wet storage, depuration, feed and veterinary medicine management, transport and handling of shellfish.

6. ROLES AND RESPONSIBILITIES

1) The Department is the regulatory authority responsible for authorising the undertaking of aquaculture activities, i.e. farming, harvesting and transporting of shellfish for wholesale trading in terms of the MLRA and associated Regulations. Authorisations are administered through the granting and issuing of a marine aquaculture (mariculture) rights and permits.

2) The Department is responsible for the following primary production related activities:

   a) determining production areas where relevant;

   b) undertaking sanitary surveys where relevant;

   c) classifying production areas where relevant;

   d) monitoring and controlling the primary production areas in terms of biotoxin, microbiological and environmental food safety risks including the sampling of primary production areas;

   e) monitoring and controlling of relaying areas and depuration facilities;

   f) monitoring and controlling the use of veterinary medicines;

g) monitoring and controlling of the use of feed;

h) determining laboratories that may undertake food safety tests during primary production in terms of official controls.

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

- copies of permits and other approvals;
- official laboratory test reports (certificates);
- movement documents;
- monitoring data and notices;
- enforcement action reports (e.g. contingency notifications, warnings, etc.);
- 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.

4) The Department shall draft or oversee the drafting of official standard operating procedures (SOP) to facilitate the implementation of this Programme. The official SOPs will form part of this Programme.

5) The Department shall draft or oversee the drafting of management plans where appropriate to facilitate the implementation of this Programme. The official management plans will form part of this Programme.

6) The NRCS is recognised internationally as the competent authority to provide food safety assurances. The mandate of the NRCS includes the promotion of public health and safety, environmental protection 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 published under the NRCS Act.

7) The NRCS is responsible for the following post primary production related activities:

a) harvesting of product;

b) handling of product once harvested;

c) wet storage;

d) transporting of product;

e) processing of product and HACCP compliance;

f) labelling;

g) final certification for export;

h) auditing of the Programme to evaluate performance.

8) The local municipality is responsible for issuing a Certificate of Acceptability (CoA) to processing facilities where required.

9) Where required, the Department, the NRCS or relevant local health authority may appoint officials or other appropriately trained personnel to assist with the official survey and sampling activities. Where that official is not employed by a government entity a written appointment is required that defines the responsibilities of the official so appointed.

10) Where inter-governmental guarantees are sought (health certificate), the NRCS must have free access to records kept by the Department.

11) 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 paragraph inspection reports, sample requisition forms and relevant test certificates.

12) To enable proper liaison between the Department and other governmental departments/authorities, a Memorandum of Understanding must be prepared and signed by all parties concerned.

13) The producer is responsible for the following activities:

    a) processing facilities must obtain a Certificate of Acceptability (CoA) issued by the local municipality and an approval certificate in terms of the relevant compulsory specifications administered by the NRCS for the establishment, where relevant;

    b) processing facilities must apply to the Department for a marine aquaculture fish processing establishment permit; Such establishments will be licensed only when the operator can produce a Certificate of Acceptability (CoA) issued by the local municipality and where relevant an approval certificate in terms of the relevant compulsory specifications administered by the NRCS for the establishment, on condition that such NRCS approval has a remaining validity period of least 3 months prior to expiry; Each establishment must be issued with a CoA by the local municipality and where relevant approved by the NRCS annually (or for the time permissible by a conditional approval obtained from the NRCS);

    c) 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 for which the permit is applied;

    d) the producers exporting shall also comply with the importing country's requirements.

14) The producer 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 relay facility operator, depuration plant, wet storage facility and establishment packing and/or processing shellfish. Such records shall include information:

    - 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.

7. APPLICATION

Food safety risks vary depending on the species farmed with and the commodities produced. The relevant sections that apply to each of the product are indicated below (see Table 2 and Table 3).

Table 2: Control system requirements for different commodities and production characteristics

Feeding	Commodity	Area control for microbiology	Biotoxins	Veterinary medicine & environmental residues	Food Safety
Filter Feeder shellfish	Live	✓	✓	✓	✓
	Processed	✓	✓	✓	✓
Non-filter feeder shellfish	Live		✓	✓	✓
	Processed		✓	✓	✓
Finfish	Processed			✓	✓

Live and processed filter feeders shall be monitored in terms of microbiological area control, biotoxins (Appendix 9), veterinary medicine (Appendix 8 and Appendix 9) and environmental residues (Appendix 9) and food safety. The relevant sections in terms of the control system requirements listed above include, though are not limited to:

- Paragraph 9 CLASSIFICATION OF FILTER FEEDER SHELLFISH PRODUCTION AREAS
- Paragraph 10 MICROBIOLOGICAL MONITORING OF FILTER FEEDER PRODUCTION AREAS
- Paragraph 11 BIOTOXIN MONITORING
- Paragraph 12 PHYTOPLANKTON MONITORING
- Paragraph 13 MONITORING OF ENVIRONMENTAL AND VETERINARY MEDICINE RESIDUES

Live and processed non-filter feeders shall be monitored in terms of biotoxins, veterinary medicine and environmental residues and food safety. The commodities will be tested in the end-of-line products for contaminants that pose a food safety risk including but not limited to microbiological contamination. The monitoring of biotoxins and environmental and veterinary medicine residues shall be undertaken during the primary production phase. The relevant sections in terms of the control system requirements listed above include, though are not limited to:

- Paragraph 11 BIOTOXIN MONITORING
- Paragraph 12 PHYTOPLANKTON MONITORING
- Paragraph 13 MONITORING OF ENVIRONMENTAL AND VETERINARY MEDICINE RESIDUES

Finfish shall be monitored in terms of veterinary medicine, environmental residues and food safety. The relevant sections in terms of the control system requirements listed above include, though not limited to:

- Paragraph 13 MONITORING OF ENVIRONMENTAL AND VETERINARY MEDICINE RESIDUES

Aquacultured products shall be monitored for food safety during harvesting and post-harvest. Food safety controls include but are not limited to time-temperature controls and contamination of the product during transport, handling and packaging and traceability.

Table 3: Relevant sections for different commodities

Section	Filter feeders	Non-filter feeders	Finfish
8 Site selection	X	X	X
9 Classification of filter feeder shellfish production areas	X		
10 Microbiological monitoring of filter feeder production areas	X		
11 Biotoxin monitoring	X	X	
12 Phytoplankton monitoring	X	X	
13 Monitoring of environmental and veterinary medicine residues	X	X	X
14 Harvesting and transport of harvested fish	X	X	X
15 Time and temperature control	X	X	X
16 Handling of fish	X	X	X
17 Traceability system	X	X	X
18 Sampling and transport of samples	X	X	X
19 Relaying of filter feeders	X		
20 Depuration of filter feeders	X		
21 Wet storage	X		
22 Requirements for fish processing establishments	X	X	X
23 Feed management and monitoring		X	X
24 Veterinary medicine management	X	X	X
25 Samples and sample taking	X	X	X
26 Payment of food safety monitoring costs	X	X	X

8. SITE SELECTION

1) The siting, design, lay out and construction of fish culture facilities should follow principles of good aquaculture practice appropriate to the species being cultivated.

2) Physical environmental conditions (i.e. temperature, current, salinity and depth) should also be considered as different species have different environmental requirements. Closed recirculation systems shall adapt the physical environment parameters to the environment requirements of the cultured fish species.

3) Fish aquaculture facilities shall be located in areas where the risk of contamination by chemical, physical or microbiological hazards is minimal. Siting of the facilities should ideally be away from sources of pollution to avoid contamination of product.

4) Soil for the construction of earthen ponds and fertilizers, liming materials or other chemicals and biological materials shall not contain concentrations of chemicals and other substances that may lead to the presence of contamination in fish that would exceed the regulatory limits of the contaminants.

5) Ponds and tanks shall be designed and laid out to have separate inlets and discharge channels to ensure that water supplies and effluent are not mixed.

6) All sites shall be operated so as not to cause adverse impacts on human health from the consumption of the cultured fish.

9. CLASSIFICATION OF FILTER FEEDER SHELLFISH PRODUCTION AREAS

9.1. Overview of classification system

1) The classification of Production Areas is only applicable to areas where filter-feeders are cultured.

2) A filter-feeder production area shall be classified by the Department once a sanitary survey has been conducted by the Department as outlined in Paragraph 9.2.

3) 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 consider the risks that were established for a particular area and species.

4) Microbiological classification of Production Areas is based on analysis 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. It may be necessary to place net bags or baskets containing the culture species in the Production Area to provide the shellfish for testing.

5) 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 officially been established. Results of microbiological testing of filter feeder 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.

6) The sanitary classification status of filter feeder Production Areas shall be reviewed annually, taking into account new potential pollution sources and other developments that could affect water quality.

7) 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.

9.2. Sanitary Surveys

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

2) Once the Department is requested to classify a Production Area by a client, the Department must undertake an initial sanitary survey at the farm's cost.

3) The Department must, at the cost of the affected farm(s), review and report on the production areas on a five-year basis to reflect any changes in the production area catchment and update the monitoring data.

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

9.3. Approved Areas

1) Filter-feeders 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 production area may be classified as an Approved Area 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 MPN/100 g of flesh and intravalvular liquid in 80% of the samples. No sample may exceed an *E. coli* concentration of 700 MPN/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 paragraph 10.

3) When evaluating the results for the fixed review period for maintenance of an Approved Area, the Department may, after conducting a risk assessment based on an investigation, disregard an anomalous result which exceeds an *E. coli* concentration of 700 MPN/100 g of flesh and intravalvular

liquid. For example, where a sample contamination incident occurred, due to a sampling error, a sample expiring incident, or a laboratory error.

4) If samples are not taken at the required frequency for an Approved Area, the production area shall be closed until the required samples are taken. Additional testing shall be required once the production area is re-opened for harvesting to account for the missing test results. The production area may need to be temporarily downgraded to a Restricted Area if a risk analysis indicates that there is a significant risk of the *E. coli* concentration exceeding 700 MPN/100g during the period for which the results are not available.

5) The Department may approve the harvesting of shellfish from an Approved Area of which the *E. coli* concentration exceeds 230 MPN/100g but is below or equal to 700 MPN/100g flesh and intravalvular fluid, based on a risk assessment, and only on a temporary and non-recurring basis, on condition that it is sterilised in hermetically sealed containers or subject to an approved heat treatment and frozen.

6) 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; or

      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 as a Critical Control Point (CCP) to ensure the safety of the product.

9.4. Restricted Areas

1) No filter feeders may be harvested for direct human consumption from restricted areas. Filter feeders from restricted areas can only be harvested for depuration or relaying.

2) A Restricted Area is one in which the sanitary survey indicates a limited degree of microbial pollution.

3) Limited pollution is defined as "The *E. coli* concentration may not exceed 4 600 MPN/ 100 g of flesh and intravalvular liquid in 90% of the samples. No sample may exceed an *E. coli* concentration of 14 000 MPN/100 g of flesh and intravalvular liquid".

4) Should the *E. coli* MPN exceed the criteria stipulated for limited degree of microbial pollution, the product may only be harvested for relaying in an approved Production Area or depuration facility for extended periods as described in paragraphs 18 2) and 20 of this Programme.

9.5. Prohibited Zone

1) The purpose of a Prohibited Zone is to prevent contaminated, or possibly contaminated filter feeders 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 filter feeders 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 Paragraph 9.3.

3) Shellfish shall not be harvested from a Prohibited Zone for direct human consumption, depuration 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 that levels of microbiological pollution exceed the Restricted Area limits referred to in Paragraph 9.4;

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

   d) there are point source or non-point sources of pollution that may unpredictably contaminate the shellfish.

4) Areas adjacent to outfalls of wastewater treatment works and other waste discharges of public health significance shall be classified as Prohibited Areas.

5) 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.

6) When determining a Prohibited Zone, regard for the following must be considered:

   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 the following criteria:

      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;

      ix) likely dispersion.

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

   e) the location of the filter feeders, classification of adjacent waters and identifiable landmarks or boundaries.

7) Seed may be taken for on-growing from a Prohibited Zone provided it is cultured in an Approved Area or Restricted Area for a minimum of 6 months prior to harvesting for human consumption or relaying/depuration.

9.6. 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 production area in response to a clearly established set of criteria that can timeously be implemented. For example, opening/ closure criteria might be based on performance standards of wastewater treatment works, 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).

9.7. Review of classification

1) The Department must review and report on the classification of a Production Area if:

   a) the area has been closed following an outbreak of illness caused by factors within the production area other than naturally occurring pathogens or biotoxins as referred to in paragraph 10.3, paragraph 4) for example anthropogenic pollution;

   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 filter feeders and the Department determines, following an investigation that the Production 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 paragraph must include the following criteria:

   a) a review of the production 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;

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

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

   a) retain or change the existing classification; and/or

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

9.8. 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 sampling stations;

   b) parallel sampling in both the new area and existing production 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 paragraph 9.8, paragraph 1 once the stipulated criteria have been considered and implemented where relevant.

10. MICROBIOLOGICAL MONITORING OF FILTER FEEDER PRODUCTION AREAS

1) Filter Feeder production areas shall be routinely monitored for microbiological contamination. Non-filter feeders and finfish production areas are exempted. However, microbiological monitoring shall be undertaken in the end-of-line products by the NRCS.

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 Programme will supersede the test results from the other methods.

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

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

7) The regulatory limits for microbiological contamination and the recognised test methods are included in the relevant regulations published under the Foodstuffs Act, Appendix 4 of this Programme and as per the relevant Compulsory Specifications administered by the NRCS for the relevant packaged products.

8) Microbiological monitoring is mandatory during harvesting periods. 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 paragraph 10.

2) Every classified bivalve production area must have a microbiological management plan prepared by the Department.

3) A microbiological management plan must include all the following:

   a) a map of the production 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 production area;

   c) the species of commercial shellfish within the production 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 filter feeders;

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

   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 and will be detailed in the relevant microbiological management plan described in paragraph 10.1 above. Sampling should consider 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 paragraph 9.6 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) 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 areas and at least the last 30 samples for Restricted Conditional areas. The period evaluated should not be less than the last 12 months.

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

6) 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 most 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, shall undertake appropriate actions as outlined in an official contingency SOP implemented by the Department.

2) When an end-of-line product fails to satisfy the microbiological criteria for human consumption, the relevant health authority, in consultation with the NRCS and the Department shall undertake appropriate actions as outlined in the official contingency SOP.

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 area, in association with the Department and the NRCS, shall undertake appropriate actions as outlined in the official contingency SOP.

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 the official contingency SOP.

5) If the Department reasonably believes that an area has been impacted by a sewage event, the Department must keep the area closed for 7 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 paragraph 9.3 (6), provided the microbial status meets the Approved criteria as a minimum (paragraph 9.3). Such shellfish may also be harvested for relaying or depuration until the animals show compliance with Approved microbial limits (Paragraph 9.3). This option may only be exercised in accordance with special permit conditions issued by the Department.

11. BIOTOXIN MONITORING

1) Biotoxin monitoring shall be implemented for filter feeder and non-filter feeder Production Areas.

2) Biotoxin monitoring is mandatory during harvesting periods. Farm managers must inform the Department of extended periods of non-harvesting and dates when harvesting is to be resumed. Failure to comply will result in temporary closure until testing is reinstated.

3) The regulatory limits for biotoxins and the recognised test methods are included in the relevant regulations published under the Foodstuffs Act and Appendix 3.

11.1. Biotoxin management plan

1) Biotoxins and toxigenic phytoplankton shall be monitored in each shellfish Production Area in accordance with this Programme. Every shellfish production area must have a biotoxin management plan prepared by the Department.

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

   a) a map of the production area, showing the location and identification of each Production Area;

   b) the boundary, name and number of the production area;

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

d) the location and GPS (or other identification acceptable to the Department) of the sentinel sampling stations, any sampling sub-stations and phytoplankton sampling stations;

e) the routine monitoring programme for biotoxins in the shellfish and phytoplankton in the Production Area;

f) contingency measures should the regulatory levels be exceeded.

11.2. Sampling and analysis of samples

1) The sampling frequency for toxin analysis in shellfish shall be weekly during harvesting periods with the following exceptions:

a) the sampling frequency may be reduced in specific production areas if a risk assessment of toxins or phytoplankton occurrence suggests a low risk of toxic episodes;

b) the sampling frequency shall be increased where such an assessment suggests that weekly sampling would not be sufficient.

Table 4: Maximum time between routine biotoxin sampling events for shellfish Production Areas

Biotoxin group	West of Cape Point		East of Cape Point	
	Filter Feeder	Non-Filter Feeders	Filter Feeder	Non-Filter Feeders
Paralytic shellfish toxins	4 days	1 week	1 month	2 weeks
Lipophilic shellfish toxins	1 week	1 month	1 week	1 month
Amnesic shellfish toxins	1 month	1 month	1 month	1 month

2) The sampling frequency for each production area shall be stipulated in an Action Plan for the specific production area drafted by the Department.

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

4) The sampling shall be undertaken in terms of the official SOPs implemented by the Department and in accordance with paragraph 18 below.

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

6) Toxin levels in the edible portions of shellfish provide the present basis for regulatory action, and regarding bivalves shall include the intravalvular fluid.

7) 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.

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 working days for PST, LST and AST in the majority of cases.

11.3. Contingency measures

1) Should a biotoxin test result exceed the regulatory limit, the Production Area will temporarily be closed for harvesting in accordance with the official contingency SOP.

2) 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 at least three days are below the regulatory limit and show a declining trend in the toxin concentration.

3) The intensive biotoxin monitoring is to be initiated when biotoxin concentrations in shellfish reaches the thresholds given in Appendix 5, though still below regulatory limits. Intensive monitoring is daily for filter-feeder and weekly for non-filter feeders, unless otherwise stated by the Department. Intensive biotoxin monitoring for a particular biotoxin is not required for abalone farms that are undergoing weekly routine testing for the relevant biotoxin.

4) Intensive sampling may also be initiated when toxic phytoplankton are present in the absence of shellfish intoxication in accordance with the official contingency SOP.

5) 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.

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

12. PHYTOPLANKTON MONITORING

12.1. Sampling and analysis of samples

1) Phytoplankton samples shall be taken in regulated shellfish Production Areas. However, non-filter shellfish Production Areas, where the shellfish are batch tested and/or processed in such a manner to adequately remove potential toxins, may be exempted from phytoplankton monitoring. The producer is required to apply to the Department for such an exemption.

2) Phytoplankton samples shall be taken, and the toxigenic species analysed at least once a week in low risk Production Areas, in terms of biotoxin accumulation in the shellfish, and three times a week in Production Areas with a significant risk.

3) The Department shall undertake a risk assessment to determine the risk of biotoxin accumulation in shellfish to determine the risk in Production Areas referred to in paragraph 12.1 (2).

4) The sampling frequency and sampling points shall be clearly stipulated in a biotoxin management plan published in terms of paragraph 11.1.

5) Sampling shall be undertaken in accordance with paragraph 18 below.

6) Phytoplankton samples shall be analysed by an officially recognised phytoplankton laboratory within 24 hours of being sampled.

13. MONITORING OF ENVIRONMENTAL AND VETERINARY MEDICINE RESIDUES

1) Environmental residues shall be monitored and regulated for in the Production Areas for all cultured fish in terms of a National Residue Plan (NRP) and implemented in terms of a National Residue Control Programme (NRCP).

2) Veterinary medicine residues shall be monitored and regulated for in the Production Areas for all cultured fish in terms of a National Residue Plan (NRP) and implemented in terms of a National Residue Control Programme (NRCP).

3) The regulatory limits for environmental contaminants such as heavy metals, radio-active substances (Caesium 134 and 137), PCBs, dioxins, dioxin-like PCB's, polycyclic aromatic hydrocarbons, perfluoroalkyl substances and pesticides will be those included in the relevant regulations published under the Foodstuffs Act and/ or included in the NRP.

4) The regulatory limits for veterinary medicines where applicable will be those included in relevant regulations published under the Foodstuffs Act and/ or included the NRP.

5) Should there be conflict in the regulatory limits stipulated in the Foodstuffs Act and the NRP, the Foodstuffs Act limit will apply to local sales and the NRP will apply to exported products.

13.1. National Residue Plan and National Residue Control Programme

1) Residues monitored shall include, though not limited to those substances listed in Appendix 8 and Appendix 9.

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

   a) compound or marker residue;

   b) matrix to be tested;

   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 following criteria 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) matrix to be tested;

   g) laboratory to be used;

   h) age cohort to be sampled;

   i) sample Size (Flesh mass)

13.2. Sampling and analysis of samples

1) Sampling for environmental and veterinary medicine 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 paragraph 25.

4) Non-compliance at any sampling point will require retesting as outlined in the official contingency SOP. 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.

13.3. Contingency measures

1) In the case where non-compliant environmental or veterinary medicine residue test results are confirmed the procedures outlined in the official contingency SOP shall be followed.

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 the official contingency SOP.

14. HARVESTING AND TRANSPORT OF HARVESTED FISH

This paragraph deals with the requirements for harvesting and transport of the harvested fish to a fish processing establishment, depuration facility or wet storage.

14.1. Harvesting requirements

1) No person shall harvest, handle or transport cultured fish for human consumption except according to the requirements of this Programme under conditions stated in an official permit issued by the Department.

2) Harvesting techniques shall be undertaken efficiently and in a humane manner and must not cause excessive damage to the shells where relevant or tissues of the fish and no incisions shall be made into the finfish.

3) Fish harvested and transported on a vessel for more than 6 hours must be shaded from the sun. Finfish shall be chilled with clean ice and shellfish shall be covered with clean wet sacks.

4) 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 reused.

5) The finfish shall be slaughtered humanely (i.e. inflicting the least pain possible) immediately after being harvested, using a suitable anaesthetic that does not pose a food safety risk or a stunning technique prior to slaughter.

6) Once anaesthetised or stunned the finfish shall be placed into ice slurry until the core temperature decreases to below 5°C. The water in the ice slurry shall be of at least the same quality as the water from which the finfish is harvested.

7) Once removed from the ice slurry the finfish shall be placed on ice in bins. The layers of ice between the fish shall be sufficient to ensure that there is sufficient ice between the fish by the time the fish is removed from the bins for processing. There shall furthermore be drainage of the bins to ensure that the water from the melted ice is able to be continuously drained out of the bins, without contaminating bottom bins if the bins are stacked on top of each other.

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

9) Bags or sacks may not be re-used for shellfish unless they are made from a material that can be washed and disinfected prior to re-use.

14.2. Transport and Vessels

1) The transporter must be in possession of a valid transport permit for harvested fish.
2) All harvesting vessels and road transport vehicles must be inspected at least once annually and approved by the NRCS or relevant Health authority.
3) Decks and storage areas on vessels shall be designed and constructed to prevent bilge water or polluted water from coming into contact with the harvested fish.
4) Where the vessel or vehicle deck is not channelled, graded or adequately drained, the fish shall be stored at a minimum height of 100 mm off the deck.
5) 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.
6) Human body wastes (i.e. excreta) shall not be discharged from harvest vessels while in, or adjacent to, Production Areas.
7) All land and water transport vehicles and/ or vessels used for the transport of fish for processing shall comply with the requirements stipulated in the official SOP for vehicles and vessels implemented by the Department. The vehicles and/ or vessels shall be constructed, operated, cleaned and maintained so as to prevent contamination, deterioration or decomposition of the fish transported.

15. TIME AND TEMPERATURE CONTROL

1) Fish shall be kept chilled, processed and distributed with care and minimum delay.
2) All fish harvested for human consumption, other than shellfish intended for wet storage or depuration, must be temperature controlled throughout the value chain. Temperature control must be put in place from the time of harvesting.
3) Ice used for temperature control must have been made from potable water or clean seawater.
4) Live bivalves that are temperature controlled must be kept in an environment that is 7°C or cooler within 20 hours of harvest for direct human consumption or removal from a wet storage facility. The provision of adequate quantities of visible ice in or on a shellfish container is sufficient compliance with the requirement continuously to maintain the temperature at 7°C or cooler.
5) Non-filter feeders that are temperature controlled shall be kept at a suitable minimum temperature that will not cause physiological stress to the shellfish or pose a food safety risk.
6) Finfish shall be cooled with minimum delay. Sufficient and adequate icing or chilled or refrigerated water systems where appropriate, shall be employed to ensure that finfish brought to a temperature of melting ice, with a deviation of not more than 2°C, and as close as possible to .0°C once slaughtered. The finfish shall be stored in shallow layers and surrounded by finely divided melting ice to maximize cooling capacity.
7) At any point of transfer fish must not remain continuously out of temperature control for more than 2 hours.

8) Chilled or refrigerated water systems and/ or cold storage systems should be designed and maintained to provide adequate cooling and/ or freezing capacities throughout the cooling process and during peak loads.

9) 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.

10) 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.

11) A documented control program shall be implemented to guarantee that temperature monitoring is in place and that the requirements stipulated above are complied with.

16. HANDLING OF FISH

Poor handling practices can lead to damage of fish that can accelerate the rate of decomposition and increase unnecessary post-harvest losses.

1) Fish must be handled and conveyed with care particularly during transfer and sorting to avoid physical damage.

2) While fish are on deck, exposure to the adverse effects of the elements should be kept to a minimum to prevent unnecessary dehydration.

3) Fish shall not be trampled, stood upon or handled with excessive force.

4) Where boxes are used for storage of finfish, they should not be overfilled or stacked too deep to prevent damage.

17. TRACEABILITY SYSTEM

1) A traceability stem shall be implemented that will enable the production facility and/ or FPE to identify their immediate supplier(s), where relevant, and their immediate customer(s). The names and addresses of both the supplier of the fish product and the FPE to whom the fish was supplied are needed. The requirement relies on the 'one-step back'-'one-step forward' approach.

2) The Department shall implement an official SOP, which details the procedures and requirements for the traceability of product harvested for human consumption.

3) The production facilities and/ or FPEs shall have a system in place that meets the requirements of the official traceability SOP referred to in paragraph 17 (2) in order to ensure traceability of the product from farm to fork as is applicable. The system shall be designed to ensure rapid recall of any lot of non-compliant fishery product from the market.

4) The traceability system for shellfish shall incorporate the use of movement documents where relevant for the movement of live shellfish from the production area to an FPE as outlined in paragraph 17.1.

17.1. Movement documents and records

1) The use of movement documents is only applicable for the movement of cultured shellfish to a FPE.

2) The Department shall issue to each farm, at that farm's cost, a book containing movement documents.

3) A movement document shall be completed by the harvester and accompany each batch of live shellfish during transport from the Production Area up to, and including, arrival of the batch at a FPE (see Appendix 6).

4) 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), where applicable;
- shellfish identity (common and scientific names) and quantity;
- destination and, if applicable, approval number;
- date and place of receipt

5) 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 of movement of the harvested product and the pink carbon copy shall be kept in the book by the production facility. Should a document be spoiled or no longer used, it shall be cancelled by writing "Cancelled" across it. The completed and cancelled documents shall be scanned and emailed to the Food Safety Office on a weekly basis.

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

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

8) The harvester must keep all the books containing the pink copies of the movement documents issued on file for a period of not less than 5 years.

9) The Department shall keep a copy on file of all completed movement documents issued for a period of 5 years.

10) If harvesting is carried out on the same premises on which the FPE is situated, the Department may, if it is satisfied that the requirements concerning gathering and handling will otherwise be complied with, issue a letter authorising that harvester to operate without utilising movement documents subject to any conditions that may be included. The Department may, at any time, withdraw this authorisation.

18. SAMPLING AND TRANSPORT OF SAMPLES

1) The Department shall implement an official sampling and transport SOP and management plans, which details the procedures and requirements for sampling and transport of samples for food safety testing.

2) The sampling and transport of samples SOP shall include at minimum:

   a) general sampling principles;

   b) sampling and testing requirements for veterinary medicine and environmental residues, microbiological contaminants, marine biotoxins, radionuclides;

   c) equipment requirements for sampling;

d) preparation and packaging of samples;

e) transport of samples;

f) health and safety and biosecurity measures required during sampling.

3) The management plans shall include at minimum:

a) designated official sampling stations;

b) species to be sampled;

c) routine and intensive testing frequency;

d) criteria for the closure of production areas to harvest;

e) criteria for the reopening of production areas to harvest.

19. RELAYING OF FILTER FEEDERS

Relaying is intended to reduce the number of pathogenic microbiological organisms that may be present in filter feeders from moderately polluted waters as those from Production areas that are classified as Restricted to reduce microbiological concentration to safe levels. Relaying is undertaken in a suitable Production Area.

The guidelines presented below are recommendations for the management and control of relaying operations and are based on international recommendations.

19.1. Conditions

1) Relaying refers to the transfer of filter feeders with limited levels of pollution to approved areas where the ambient environment provides the medium for biological depuration.

2) 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 including environmental residues unless studies are conducted that verify depletion of the contaminant(s) of concern to acceptable levels.

3) Relaying operations must be supervised by a Fishery Control Officer or duly authorised official inspector.

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

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

6) Relaying areas shall be monitored as for other approved Production Areas.

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

19.2. Source of filter feeders

1) No filter feeders that exceed the contaminant levels for restricted areas (paragraph 9.4) may be relayed. Filter feeders must not be contaminated with biotoxins to the extent that safe levels cannot be achieved at the end of the relaying period.

2) Live filter feeders must be gathered and transported in accordance with paragraph 14.

3) Filter feeders intended for relaying must be accompanied by a movement document (paragraph 17) unless the conditions of paragraph 17.1(10) apply.

19.3. Relaying areas

1) Relayed filter feeders 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.

19.4. Operating procedures

1) Each relay facility operator must develop, in consultation with the Department, written SOPs that provide assurance of end-product safety. The procedures shall address the following:

- source and species of filter feeders;
- contaminant levels of filter feeders before 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 filter feeders in the relaying area;
- method of holding filter feeders at the relaying site and maintaining identity of individual source lots.

2) Studies shall be undertaken by the relay facility operator to determine the effectiveness of contaminant reduction with due consideration to species and initial degree of contamination of the filter feeders. 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 relay facility operator when it is known that limiting values may be approached.

3) The microbiological concentrations in the filter feeders shall meet the approved criteria (paragraph 9.3), 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 filter feeders may only be harvested from a relaying area following laboratory confirmation of successful purification.

6) The harvester of relayed filter feeders 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 filter feeders harvested in a relaying area must be accompanied by a movement document (paragraph 17) during transport to a FPE unless the conditions of paragraph 17.1(10) apply.

19.5. Records

1) Relay facility operators shall be required to keep complete and accurate records for inspection by the Department for at least 5 years. This should include the following:

- source and species of batches of filter feeders;
- results of microbiological and/or biotoxicity tests of each lot of filter feeders before and during relaying;
- date of harvest and quantity of filter feeders harvested;
- dates and duration of relay;
- records of critical environmental parameters during relaying;

- purchaser and quantity purchased;
- Movement documents where applicable and other records necessary to trace individual batches of filter feeders.

2) The Department shall maintain records of the following:

- 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 relay facility operator;
- Movement documents where applicable.

20. DEPURATION OF FILTER FEEDERS

Depuration is the process whereby filter feeders are biologically cleansed from pathogenic organisms in a purified and controlled seawater environment in a fit-for-purpose land-based facility. Depuration is intended to reduce the number of pathogenic organisms that may be present in filter feeders from moderately polluted areas. Depuration is neither intended to reduce contamination in filter feeders from heavily polluted areas nor to reduce the levels of accumulated toxic substances including environmental residues.

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

20.1. Conditions

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

2) The premises and hygienic standards must comply with the Regulations Governing the General Hygiene Requirements for Food Premises and the Transport of Food, GNR 638 of 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.

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

4) Certified depuration plants are to be inspected at least monthly to ensure compliance with GNR 638.

5) 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.

20.2. 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:

- species to be depurated and source;
- maximum pre-depuration level of faecal contamination to ensure that end point criteria are consistently achieved during normal operations (not to exceed limits given in paragraph 9.4);
- design construction and operation of the plant regarding flow rates, loading rates, tank dimensions and spacing of filter feeders;
- 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.

20.3. Source of filter feeders

1) Only filter feeders that meet the requirements for restricted areas (paragraph 9.4), at a minimum, may be harvested for depuration. The acceptable pre-depuration levels of faecal contamination shall be established as part of the ADP.

2) Filter feeders must be protected from contamination and physiological stress during harvesting and storage.

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

4) Filter feeders intended for depuration must be accompanied by a movement document (paragraph 17) unless the conditions of paragraph 17.1(10) apply.

5) Dead or damaged individuals shall be removed from the batch of filter feeders to be depurated and the remaining filter feeders shall be washed with clean seawater or potable water prior to depuration.

20.4. Structural requirements

1) The construction of floors, walls, ceilings (where provided) and installation of lighting, plumbing and wastewater treatment 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) Filter feeder containers (where used) shall have an impervious mesh-type construction that allows adequate flow of water to all filter feeders in the containers. They must be placed in tanks in such a manner that sufficient clearance is provided between the filter feeders 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.

20.5. Process water quality and operation

1) Source water may be drawn from an Approved or Restricted Production Area prior to treatment. Prohibited Production Areas may not be used as source waters.

2) Process water must meet the requirements for sanitary quality and normal physiological activity of the filter feeder 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 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 filter feeders spacing as established in the process verification study.

4) Only filter feeders of the same species are to undergo depuration in the same depuration unit. Different harvest lots of filter feeders 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 filter feeders 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.

20.6. Cleaning and Sanitising of facilities, utensils and equipment

1) All facilities utensils and equipment on the premises shall be kept clean and sanitised in accordance with GNR 638.

2) All filter feeders 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.

20.7. 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) Filter feeders from single process batches may not be released to market unless laboratory results confirm that the end product meets the microbiological standards for approved areas (paragraph 9.3).

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 filter feeders;
- non-food use of the filter feeders;
- an additional depuration cycle;
- modification of the ADP.

5) Every package of purified filter feeders must be provided with a label certifying that all 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 filter feeders.

6) Batches of depurated filter feeders being transported to a FPE must be accompanied by a movement document (paragraph 17) unless the conditions of paragraph 17.1(10) apply .

20.8. Records

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

- source and species of batches of filter feeders;
- date of harvest and quantity of filter feeders harvested;
- dates and duration of depuration;
- records of critical environmental parameters during depuration;
- results of microbiological tests of each lot of filter feeders before and during depuration;
- current copy of the plant operating procedures;
- dispatch details of batch after depuration;
- movement documents where applicable and other records necessary to trace individual batches of filter feeders.

21. 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.

21.1. 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 paragraph 18.

4) No other marine species may be stored in the same tank with the 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 may be sold from onshore wet storage that has filtration in place to prevent the entry of phytoplankton on the following conditions:

   a) the shellfish shall not be obtained from a Production Area that is closed due to biotoxin accumulation, including shellfish harvested on or after the date that the sample was taken that resulted in the closure of the Production Area;

   b) the last batch to enter the wet storage shall be tested for the implicated biotoxin that resulted in the production area closure; 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;

   c) the water quality requirements stipulated in paragraph 20.5 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 plant 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.

21.2. 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 or approved relaying area.

2) Shellfish delivered to a wet storage plant 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 (paragraph 17) unless the conditions of paragraph 17.1(10) apply.

21.3. Structural and design requirements

1) The structural and design requirement are the same as for depuration (paragraph 20.4).

21.4. 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 (9.3) or Conditionally Approved (paragraph 9.6) open status 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 non-filter feeders 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 (paragraph 20.5) 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; If 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 7) 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 three times a week for phytoplankton until all Production Areas are re-opened.

21.5. 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 were applicable.

22. REQUIREMENTS FOR FISH PROCESSING ESTABLISHMENTS

22.1. Receiving and storage

1) The premises and hygienic standards must comply with the GNR 638 published under the Foodstuffs Act and must be inspected at least once annually and approved by an NRCS inspector and/or relevant local health authority as is applicable. FPEs 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).

2) Fish shall be processed within 24 hours of harvesting.

3) Finfish and non-filter feeders accepted at a FPE must have originated from an authorised production area or an approved FPE. A record should be kept of the condition of each batch received and accepted.

4) Live filter feeder shellfish accepted at a FPE must have originated from an Approved or Conditionally Approved Production Area, a relaying area, a depuration plant or an approved FPE. A record should be kept of the condition of each batch received and accepted.

5) Only batches of live shellfish accompanied by a movement document (paragraph 17) shall be accepted at a FPE unless the conditions of paragraph 17.1(10) apply.

6) In any sorting or dry storage area, fish must comply with the temperature control requirements stipulated in paragraph 15.

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

8) No chemicals that may contaminate the fish may be present in the room used for sorting or storing.

9) Fish 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 fish in a particular consignment and all associated production sites shall be managed together during the implementation of contingency measures.

10) Before dispatch, the shells of shellfish must be washed thoroughly with clean seawater or potable water should there be organic material present on the shell.

22.2. Packaging material

1) Subject to the relevant requirements of the Regulations promulgated under the Foodstuffs Act, packaging and wrapping materials for the unprotected product shall be unused (new), clean, non-toxic, inert and of low moisture-vapour permeability, and shall not contain substances deleterious to the product or harmful to health.

2) No packaging or wrapping material shall impart a flavour to, or in any way cause discoloration of, the product, or be itself discoloured by contact with the product.

3) The fish product shall be packed in a dustproof, liquid-proof and where relevant insulated container.

4) For finfish, the container shall be adequately insulated to maintain the temperature.

22.3. Marking of consignments and records

1) All packages in a consignment of fish shall bear a label so that the original FPE 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) The operator of the FPE 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 fish products 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.

22.4. Transport from a fish processing establishment

1) The transport of fish and fishery products intended for human consumption must comply with the relevant provisions of GNR 638. Consignments of fish and fishery products 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 fish or fishery products must remain sealed after leaving the FPE until presented for sale to the end consumer.

3) Fish and fishery products must be transported and distributed using closed vehicles or containers which maintain the product at the required temperature outlined in paragraph 15.

4) Packages containing fish or fish products must not come into direct contact with the vehicle floor and must not be transported with other products that might contaminate them.

22.5. Export

1) Export requirements are published in the applicable Compulsory Specifications in terms of the NRCS Act.

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 fish and fishery products will be monitored based on a random testing and surveillance programme, in addition to the sampling of the 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).

4) Fish and fishery product exports shall comply with the import requirements of the importing country, at the cost of the producer.

23. FEED MANAGEMENT AND MONITORING

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

2) 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 medicines or any other feed ingredient that are permitted for fish by the relevant regulatory authority and/ or relevant legislation and shall be safe for fish and consumers of the fish and fishery products. Substances prohibited in terms of relevant legislation shall not be used.

3) Veterinary medicine 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.

4) Feed shall comply with the relevant legislation in terms of veterinary and environmental residue contaminants and prohibited substances shall not be incorporated into the feed.

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

23.1. Feed testing

1) Formulated feed fed to fish shall be tested in accordance with the NRCP for residues in feed.

2) The NRCP for residues in feed shall include the prohibited substances indicated in Appendix 8 as a minimum.

23.2. Farm manager responsibility

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

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

3) Each batch procured by the production facility 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;
- identity of any veterinary medicine incorporated into the feed, if applicable;
- prescribed withdrawal period (minimum 500-degree days), if applicable;
- prescribing veterinarian (name), if applicable

4) Feed shall be stored in a storeroom that is dry, well-ventilated and kept clean.

5) Regarding the control of pests refer to paragraph 20.4 (2).

6) There shall be no chemicals stored in the same storeroom or substances that are harmful to fish or humans.

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

8) Dry feeds shall be stored in cool and dry areas to prevent spoilage, mould growth and contamination.

9) Moist feed shall be properly refrigerated according to manufacturer instructions.

10) The feed shall be kept off the ground and away from the walls of the storeroom to allow for ventilation and to reduce contamination.

11) The addition of veterinary medicines in the feed at the production facility shall only be undertaken under the supervision of a registered vet.

12) Feeds medicated after procurement shall be clearly identified on the package. The label shall indicate what medication was used.

13) Medicated feed shall be stored separately from the non-medicated feed to avoid errors when feeding.

23.3. Feed producer responsibility

1) Feed producers which supply feed to the aquaculture industry are required to be registered with the relevant regulatory authority. If, however, the feed producer is an international company, the importer or local distributor would need to register the feed on behalf of the feed producer.
2) The feed importer or local distributor shall ensure that a CoA accompanies the registration forms, and that the product is safe for fish and consumers of the fish.
3) 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.
4) Feed ingredients shall be made available when required by relevant regulatory authorities.
5) Labelling shall comply with relevant legislation.
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) Medicated feeds shall be clearly identified on the package.
9) Medicated feed shall be stored separately from the non-medicated feed.
10) There shall be no cross-contamination of veterinary medicines to non-medicated feed during the production, storage or transport of the feed.

24. VETERINARY MEDICINE MANAGEMENT

1) Veterinary medicines or medicated feeds should be used according to manufacturer instructions.
2) 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.
3) Where veterinary medicines are used off-label the treated fish shall not be harvested for human consumption for at least 500-degree days prior to harvesting, unless otherwise authorised by the veterinarian in charge. 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.
4) Only products registered under the 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.
5) Veterinary medicines listed in Appendix 8 shall not be used and shall be monitored for in the fish and feed.
6) All chemicals used for the treatment of fish or production water shall be adequately labelled.
7) Storage and transportation conditions of the veterinary medicines shall conform to the specifications on the label.
8) Control of diseases with veterinary medicines shall be carried out only based on an accurate diagnosis by a registered vet.

9) The fish and medicated feed shall be monitored for veterinary medicines in terms of the NRCP and required to comply with the maximum regulatory limits (MRL) stipulated in the NRCP and relevant legislation.

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

11) 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.

12) The Veterinary Medicine Procurement Register shall contain at least the following information:

- date purchased;
- suppliers name and contact details;
- name of veterinary medicine;
- quantity purchased;
- batch number;
- expiry date;
- withdrawal period.

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

14) Records shall be maintained for the use of veterinary medicines 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 veterinary medicine;
- amount used;
- withdrawal period;
- date shellfish safe for harvest;
- who administered the veterinary medicine;
- reason for treatment.

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

16) Should fish treated with veterinary medicines be transferred from one production facility to another for further on-growing or holding within 90 days of last treatment:

a) a movement register shall be kept by both production facilities;

b) the fish shall only be transferred after 500-degree days from the day of last treatment, unless a veterinarian has indicated that a shorter withdrawal period will suffice;

c) a copy of the treatment register shall be submitted to the receiving production facility;

d) the register shall include at least the following information:

- date of movement;
- name and facility code of the production facility sending/ receiving the fish;
- quantity (mass) of the fish transferred.

25. SAMPLES AND SAMPLE TAKING

25.1. Sampling requirements

1) The responsibility of the FSO includes the following:
   a) ensuring that all sampling required by this Programme is performed in accordance with the requirements;
   b) compiling sampling plans relevant to this Programme;
   c) identifying required sampling activities to be included in the marine biotoxin management plan and microbiological management plan for filter feeders.
2) The responsibility of the duly authorised sampling service provider includes the following:
   a) sampling of the aquaculture facilities;
   b) training, certifying and listing samplers;
   c) ensuring that the samplers have the required sampling equipment and checking the suitability of equipment used by the samplers;
   d) 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 the official SOPs implemented by the Department. The SOP shall include as a minimum the following:
   a) tissue to be sampled;
   b) sample size;
   c) sampling method;
   d) sampling equipment;
   e) temperature control of the sample;
   f) sample identification

25.2. Training of samplers

1) The official samplers responsible for the sampling of the primary production area must be:
   a) trained and audited by, or under the supervision of the sampling service provider duly authorised by the Department; and
   b) certified by the sampling service provider duly authorised by the Department.
2) A person must be trained as a sampler unless the Department or NRCS as is relevant is satisfied that the person:
   a) has adequate educational qualifications and training in scientific principles;
   b) is trustworthy, reliable and self-motivated;
   c) has declared whether the person has any actual or potential conflicts of interest and, if any, these are acceptable to the Department or NRCS as is relevant.

3) Samplers must be trained in the following criteria where relevant:
   a) legal requirements relating to the sampling and the harvest of fish;
   b) sampling requirements of the Programme, including the public health rationale for the sampling;
   c) consequences of errors in sampling for public health and for growers and harvesters;
   d) care and use of instruments and equipment used in sampling activities;
   e) correct method for taking water and fish samples aseptically for microbiological analyses;
   f) correct method for taking water and fish samples for biotoxin analyses;
   g) significance of the number of fish to be collected including the variation in microbiological, marine biotoxin and heavy metal levels between individual shellfish;
   h) correct method for taking fish samples for residue analyses;
   i) correct method for completing the sample submission form and the sample label;
   j) correct method for the storage and dispatch of samples to the laboratory;
   k) significance of following correct procedures;
   l) classification and status of fish production areas where applicable;
   m) marine biotoxin management;
   n) patchiness of harmful algae blooms;
   o) significance of toxigenic phytoplankton monitoring;
   p) nature and whereabouts of pollution sources identified in the sanitary survey report;
   q) significance of timing in terms of strategy sampling;
   r) significance of sampling under adverse pollution conditions;
   s) significance of routine sampling;
   t) amount of chilling material required to effectively chill the samples;
   u) organisation and management of sampling runs;
   v) Occupational health and safety requirements.

25.3. Responsibilities of samplers

1) Every sampler must:
   a) follow the direction of the sampling manager and the procedures outlined in the official SOP that is implemented by the Department on sampling and transport of samples;
   b) ensure that the equipment used during sampling is adequately calibrated where relevant and does not contaminate the sample; and
   c) ensure that the sampling procedure does not result in contamination of the sample.
2) Samplers must adhere to 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) veterinary medicine residue samples that are not personally delivered to the laboratory by the sampler must be placed into a tamper-proof bag and sealed before the sample is dispatched.

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

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

i) as soon as practicable after taking the sample;

ii) before dispatching the sample to the laboratory; and

iii) the serial number on the tamper-proof container, when used, must be recorded on the sample submission form.

i) 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.

25.4. 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 the following:

a) email address of the Department to which the test results must be submitted;

b) the name and contact details of the sampler;

c) the date and time the sample was taken;

d) official code number of the sample;

e) animal species;

f) sample matrix;

g) number of individual organisms in the sample;

h) the sample station code, name;

i) substances or substance groups for examination;

j) relevant remarks.

25.5. 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) official code number of the sample where applicable;
   c) the facility name and facility number or sample station from which the sample was taken;
   d) the sample type; and
   e) the date and time of sampling.

26. PAYMENT OF FOOD SAFETY MONITORING COSTS

1) Each farm shall be responsible for the costs associated with the sampling and testing required in terms of this Programme and as set out in terms of an applicable plan or SOP published in terms of this Programme.

27. LABORATORY RESPONSIBILITY

1) South African laboratories used for regulatory purposes in terms of the Programme must be ISO 17025 accredited under the South African National Accreditation System (SANAS) rules. International laboratories must be accredited under the International Laboratory Accreditation Cooperation (ILAC) rules.
2) Where relevant, the test methods shall be validated for the sample matrix to be tested, or a suitable substitute matrix.
3) The validated test method shall be either included in the scope of accreditation, or in the process of being included in the scope of accreditation.
4) The sample must be processed anonymously by the laboratory.
5) The test results shall be submitted to the relevant authorities within 20 working days for National Residue Control Programme (NRCP) Category A substances and no more than 30 working days for Category B substances.
6) The laboratory shall not accept official samples where the following conditions are not met:
   - containers are not sealed;
   - containers are broken;
   - sample has leaked out;
   - sampling report is missing; and/or
   - sampling report is incorrect or incomplete.

27.1. Receipt of samples

1) When a laboratory receives a sample, it must check the following:
   a) the sample is clearly marked or identified to allow it to be traced back to the sample submission form;
   b) the information on the sample submission form is consistent with the sample;

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

d) the sample packaging is intact;

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

f) 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 or equal to 10°C, however, microbiological samples may not be frozen. If the sample is delivered within 4 hours of sampling and the temperature was not able to reach 10°C, the temperature should be at least less than the temperature of the water in the production area at the time of sampling.

2) If any of the requirements of this paragraph 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) In the event when the sample arrives in a tamper-proof bag, the tamper-proof bag shall be cut open along the bottom seal of the bag to remove the sample as proof that the seal was not tampered with.

4) Should a sample contained in a tamper-proof bag be transferred from one laboratory to another, the initial laboratory may cut open the tamper-proof bag to verify the content of the sample for logging purposes before transferring the sample.

5) The laboratory is required to record the following on arrival of the sample:

a) temperature of the sample; and

b) number of individual organisms in the sample.

6) The bag and a subsample shall be kept at the laboratory at – 20°C until the Department authorises the laboratory to discard the bag and the sample.

7) The laboratory must keep records of all notifications given to FSO under this paragraph for a period of no less than 5 years.

8) The FSO must keep records of action taken as a result of reported laboratory non-compliances for a period of no less than 5 years.

27.2. Tracking systems

1) The laboratory used for testing in terms of the Programme 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.

27.3. 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. However, biotoxin and residue samples that are stored for longer than 8 hours shall be frozen.

2) Samples taken in terms of the NRCP 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.

27.4. Method performance

1) The laboratory must have corrective actions and procedures in place 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, if the remainder of the sample is sufficient for that process.

28. REFERENCES

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.

Canadian Shellfish Sanitation Program. Manual of Operations. 1992.

Codex Alimentarius. 1995. Codex General Standard for Contaminants and Toxins in Food and Feed. CODEX STAN 193-1995, Rev.13-2020.

Codex Alimentarius. 2003. Code of Practice for Fish and Fishery Products. CAC/RCP 52-2003, Rev.7-2016.

Codex Alimentarius. 2003. Recommended International Code of Practice: General principles of food hygiene. CAC/RCP 1-1969, Rev.4 – 2020.

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

Codex Alimentarius. 2009. Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programme associated with the use of Veterinary medicines in Food Producing Animals. CAC/GL 71-2009, Rev.2-2014.

Codex Alimentarius. 2010. Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood. CAC/GL 73-2010.

Commission Delegated Regulation (EU) 2019/624 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council.

Commission Delegated Regulation (EU) 2021/224 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with specific rules on official controls as regards sampling procedures for pesticides residues in food and feed.

Commission Delegated Regulation (EU) 2021/224 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with specific rules on official controls as regards sampling procedures for pesticides residues in food and feed.

Commission Delegated Regulation (EU) 2022/2292 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of food-producing animals and certain goods intended for human consumption.

Commission Directive 2001/22/EC laying down the sampling methods and the methods of analysis for the official control of the levels of lead, cadmium, mercury and 3-MCPD in foodstuffs.

Commission Regulation (EU) 2004/852 on the hygiene of foodstuffs.

Commission Regulation (EU) 2004/853 Laying down specific hygiene rules for food of animal origin.

Commission Regulation (EU) 2005/2073 Microbiological criteria for foodstuff.

Commission Regulation (EU) 2005/2074 Amending Regulations 852and 853/2004.

Commission Regulation (EU) 2006/1664 Amending Regulation 853/2004.

Commission Regulation (EU) 2006/1881 Contaminant limits in foodstuffs.

Commission Regulation (EU) 2007/333 Laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs.

Commission Regulation (EU) 2009/152 Laying down the methods of sampling and analysis for the official control of feed.

Commission Regulation (EU) 2010/558 Amending Regulation 853/2004.

Commission Regulation (EU) 2011/15 Detection methods for marine biotoxins.

Commission Regulation (EU) 2017/1980 amending Annex III to Regulation (EU) No 2074/2005 as regards paralytic shellfish poison (PSP) detection method.

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.

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.

Commission Regulation (EU) 2019/627 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption and amending Regulations 2074/2005 and 625/2017.

Commission Regulation (EU) 2021/1709 amending Implementing Regulation (EU) 2019/627 as regards uniform practical arrangements for the performance of official controls on products of animal origin.

Commission Regulation (EU) 2021/808 on the performance of analytical methods for residues of pharmacologically active substances used in food-producing animals and on the interpretation of results as well as on the methods to be used for sampling.

Commission Regulation (EU) 2022/1428 Laying down methods of sampling and analysis for the control of perfluoroalkyl substances in certain foodstuffs.

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.

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

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

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.

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

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

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.

National Shellfish Sanitation Program. Manual of Operations. Part 1. Sanitation of Shellfish Production areas. 1995 Revision. US-FDA.

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

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

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

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

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

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.

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

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

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

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

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.

Appendix 1: Sanitary survey for cultured filter feeder production areas

1) Establishing sampling stations

   a) For shore-based aquaculture systems, filter feeder 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 filter feeder 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 (paragraph 9.3). If water is to be treated to conform to these requirements the microbiological quality of source water, prior to disinfection, and recirculated water shall meet, at a minimum, the restricted Production Area standards (paragraph 9.4). 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 consider the proposed positioning of cultivation structures and potential pollution sources. Where a possible pollution Point Source 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) Water sampling positions for phytoplankton identification must take local hydrodynamics into account. A single key station may suffice for a particular Production Area.

   e) Shellfish flesh may be composited from several 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 official samplers appointed by the Department, 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, pesticides, polychlorinated biphenyl and any other hazardous substance deemed to pose a food safety risk. 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. 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 should the new farm be at greater risk of contamination from a known pollution point.

3) Sampling and analytical protocols for microbiological parameters

a) The shellfish shall be sampled as outlined in the official sampling and transport SOP implemented by the Department and submitted to an accredited laboratory that employs validated methods indicated in Appendix 4.

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 for filter feeder shellfish production areas

The following provides an outline of the factors to be considered in performing and reporting on the sanitary survey as required in paragraph 9.2. 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 Production Area under investigation.

2) Background information

   a) Motivation for the study.

   b) General description of the 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 (shoreline) 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 flow) 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 bathymetry.

   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 to 10 years on strength, direction and seasonality.

   g) River discharges – volumes and seasonality.

   h) 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 paragraph 9 and classification of individual sample stations where applicable.

   e) Assessment of levels of toxic and hazardous substances in the shellfish. Marine biotoxins are required to be monitored at least one month before shellfish is harvested for marketing.

   f) Assessment of risk imposed by biotoxin producing phytoplankton shall be initiated at least one before the shellfish is harvested for marketing and continue while the shellfish is harvested for marketing.

   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 demarcated production areas 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 veterinary medicines 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 the Production Areas shall be drafted based on the outcomes of the 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 group toxins	^Lawrence method (AOAC Official Method 2005.06) (Commission Regulation (EU) No 1664/2006).	≤ 0.8 mg saxitoxin hydrochloride equivalent per kg edible flesh# (Regulation (EU) 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 (EU) No 15/2011)	≤ 0.16 mg okadaic acid equivalent per kg edible flesh# (Commission Regulation (EU) 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 (EU) 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 (EU) No 15/2011)	≤ 0.16 mg azaspiracid equivalent per kg edible flesh# (Commission Regulation (EU) 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 (EU) No 2074/2005). Liquid Chromatography Mass Spectrometry (LC-MS/MS method)	≤ 20 mg domoic acid equivalent per kg edible flesh# (Commission Regulation (EU) 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 MPN/100g edible flesh (Class A) <4 600 MPN/100g edible flesh (Class B)

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:

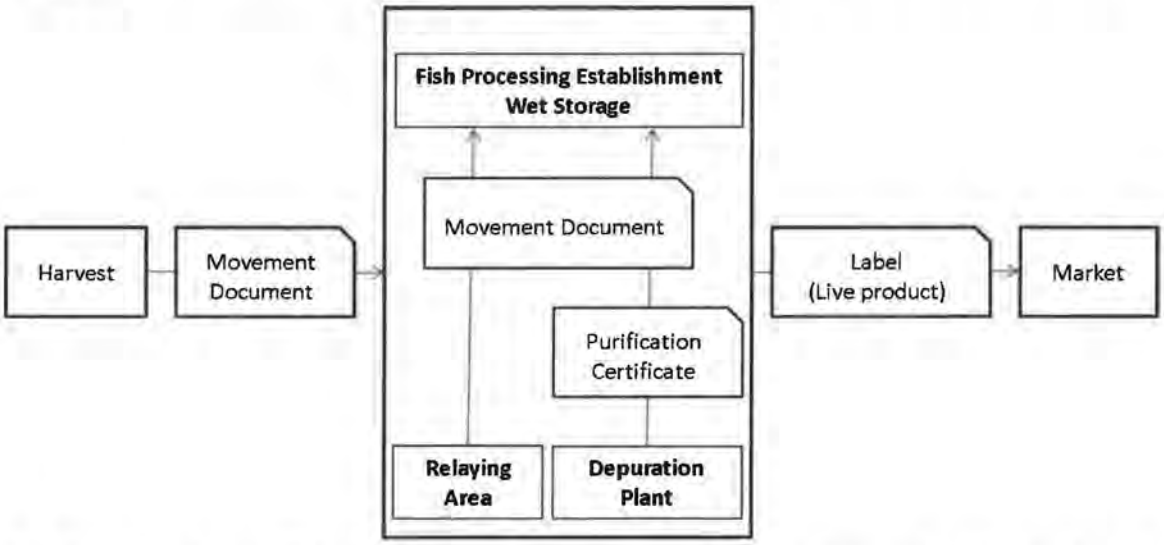
Biotoxin	**Threshold**
Total Saxitoxin	0.4 mg saxitoxin equivalents / kg edible flesh
Sum of OA, DTX 1, DTX 2, DTX 3, PTX 1 & PTX 2	0.08 mg okadaic acid equivalents / kg edible flesh
Sum of YTX, 45 OH YTX, homo YTX, and 45 OH homo YTX	4 mg yessotoxin equivalents / kg edible flesh
Sum of AZA 1, AZA 2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

Appendix 6: Documentation and labelling requirements during transport of filter feeder shellfish

1) A movement document must accompany batches of 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 shellfish dispatched from the FPE. This label allows the FPE of origin to be identified.

3) Depurated and relayed shellfish must be provided with a label certifying that all shellfish have been purified.



4) When exporting shellfish, the requirement for supporting documentation can be extensive (e.g. air waybill, certificate of origin, commercial invoice, shippers export declaration, shipper's 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 that 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 7: 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 acuminata

Dinophysis acuta

Dinophysis fortii

Dinophysis hastata

Dinophysis tripos

Gonyaulax spinifera

Karenia cristata

Lingulodinium polyedrum

Phalacroma rotundatum

Protoceratium reticulatum

Bacillariophyceae

Pseudo-nitzschia spp

Appendix 8: Prohibited substances

The following substances are prohibited during the growing of fish:

- Stilbenes
- Steroids with androgenic, estrogenic or progestagenic activity
- Chloramphenicol
- Nitrofurans
- Nitroimidazoles
- Dyes
- Unauthorised anti-microbials
- Unauthorised anti-inflammatories and sedatives

Appendix 9: Controlled substances

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

- Biotoxins
  - Paralytic shellfish toxins
  - Lipophilic shellfish toxins
  - Amnesic shellfish toxins
- Environmental residues
  - Pesticides
  - Polychlorinated biphenyl
  - Heavy metals (lead, mercury, cadmium, arsenic)
  - Dioxin and dioxin-like polychlorinated biphenyl
  - Polycyclic aromatic hydrocarbons
  - Dioxins
  - Furans
  - Mycotoxins
  - Radionuclides
  - Perfluoroalkyl substances
- Veterinary medicines
  - Antibacterial substances
  - Anthelmintics
  - Sedatives

Appendix 10: South African Legislation

The following South African legislation is applicable to the Programme:

1) Animal Diseases Act, 1984 (Act No. 35 of 1984)
2) Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies, 1947 (Act No. 36 of 1947)
3) Foodstuffs, Disinfectants and Cosmetics Act, 1972 (Act No. 54 of 1972)
4) Legal Metrology Act, 2014 (Act No. 9 of 2014)
5) 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)
6) Medicines & Related Substances Control Act, 1965 (Act No. 101 of 1965)
7) Municipal Structures Act, 1998 (Act No.117 of 1998)
8) National Health Act, 2003 (Act No. 61 of 2003)
9) 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
10) Veterinary and Para-veterinary Professions Act, 1982 (Act No. 19 of 1982)