forestry, fisheries & the environment

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

INVITATION TO BID

BID REFERENCE NUMBER: MLRF189/22

THE APPOINTMENT OF A SERVICE PROVIDER TO UNDERTAKE SAMPLING OF MARINE FISH FARMS LOCATED IN THE NORTHERN CAPE, WESTERN CAPE AND EASTERN CAPE FOR A PERIOD OF THIRTY-SIX (36) MONTHS.

Contact person:

Name: Ms Talitha Bikani/ Mr Lwandisa Hoza

Office Telephone No: (021) 402 3260

E-Mail: MLRFTENDERS@DFFE.GOV.ZA

NATIONAL TREASURY CENTRAL SUPPLIER DATABASE (CSD) REGISTRATION INFORMATION

Company name	Supplier registration number	Unique reference number	
			Main contractor
			Sub-contracted/ joint venture comp 1
			Sub-contracted/ joint venture comp 2

CLOSING DATE OF THE BID: 14th OF OCTOBER 2022 AT 11H00

Briefing session:

Compulsory briefing session will be held on the 30th of September 2022 (Friday) at 10h00. Link can be requested from MLRFTENDERS@DFFE.GOV.ZA

Drop off Address:

The location of the drop off is: Tender Box, Ground Floor, Foretrust Building, 2 Martin Hammerschlag Way, Foreshore, Cape Town, 8001.

PART A
INVITATION TO BID

YOU ARE HEREBY INVITED TO BID FOR REQUIREMENTS OF THE *(NAME OF DEPARTMENT/ PUBLIC ENTITY)*					
BID NUMBER:	**MLRF189/22**	CLOSING DATE:	**14 October 2022**	CLOSING TIME:	**11:00**
DESCRIPTION	**THE APPOINTMENT OF A SERVICE PROVIDER TO UNDERTAKE SAMPLING OF MARINE FISH FARMS LOCATED IN THE NORTHERN CAPE, WESTERN CAPE AND EASTERN CAPE FOR A PERIOD OF THIRTY-SIX (36) MONTHS**				

BID RESPONSE DOCUMENTS MAY BE DEPOSITED IN THE BID BOX SITUATED AT *(STREET ADDRESS)*
GROUND FLOOR, FORETRUST BUILDING
MARTIN HAMMERSCHLAG WAY
FORESHORE, CAPE TOWN, 8001

BIDDING PROCEDURE ENQUIRIES MAY BE DIRECTED TO		**TECHNICAL ENQUIRIES MAY BE DIRECTED TO:**	
CONTACT PERSON	**Ms. Talitha Bikani**	CONTACT PERSON	**Mr Lwandisa Hoza**
TELEPHONE NUMBER	**021-402 3260**	TELEPHONE NUMBER	**021-402 3708**
FACSIMILE NUMBER		FACSIMILE NUMBER	
E-MAIL ADDRESS	**MLRFtenders@dffe.gov.za**	E-MAIL ADDRESS	**MLRFtenders@dffe.gov.za**

SUPPLIER INFORMATION					
NAME OF BIDDER					
POSTAL ADDRESS					
STREET ADDRESS					
TELEPHONE NUMBER	CODE		NUMBER		
CELLPHONE NUMBER					
FACSIMILE NUMBER	CODE		NUMBER		
E-MAIL ADDRESS					
VAT REGISTRATION NUMBER					
SUPPLIER COMPLIANCE STATUS	TAX COMPLIANCE SYSTEM PIN:		**OR**	CENTRAL SUPPLIER DATABASE No:	MAAA
B-BBEE STATUS LEVEL VERIFICATION CERTIFICATE	TICK APPLICABLE BOX] ☐ Yes ☐ No		B-BBEE STATUS LEVEL SWORN AFFIDAVIT		[TICK APPLICABLE BOX] ☐ Yes ☐ No

[A B-BBEE STATUS LEVEL VERIFICATION CERTIFICATE/ SWORN AFFIDAVIT (FOR EMES & QSEs) MUST BE SUBMITTED IN ORDER TO QUALIFY FOR PREFERENCE POINTS FOR B-BBEE]

ARE YOU THE ACCREDITED REPRESENTATIVE IN SOUTH AFRICA FOR THE GOODS /SERVICES /WORKS OFFERED?	☐Yes ☐No [IF YES ENCLOSE PROOF]	ARE YOU A FOREIGN BASED SUPPLIER FOR **THE GOODS /SERVICES /WORKS OFFERED?**	☐Yes ☐No [IF YES, ANSWER THE QUESTIONNAIRE BELOW]

QUESTIONNAIRE TO BIDDING FOREIGN SUPPLIERS	
IS THE ENTITY A RESIDENT OF THE REPUBLIC OF SOUTH AFRICA (RSA)?	☐ YES ☐ NO
DOES THE ENTITY HAVE A BRANCH IN THE RSA?	☐ YES ☐ NO
DOES THE ENTITY HAVE A PERMANENT ESTABLISHMENT IN THE RSA?	☐ YES ☐ NO
DOES THE ENTITY HAVE ANY SOURCE OF INCOME IN THE RSA?	☐ YES ☐ NO

IS THE ENTITY LIABLE IN THE RSA FOR ANY FORM OF TAXATION? ☐ YES ☐ NO

IF THE ANSWER IS "NO" TO ALL OF THE ABOVE, THEN IT IS NOT A REQUIREMENT TO REGISTER FOR A TAX COMPLIANCE STATUS SYSTEM PIN CODE FROM THE SOUTH AFRICAN REVENUE SERVICE (SARS) AND IF NOT REGISTER AS PER 2.3 BELOW.

PART B
TERMS AND CONDITIONS FOR BIDDING

1.	**BID SUBMISSION:**
1.1.	BIDS MUST BE DELIVERED BY THE STIPULATED TIME TO THE CORRECT ADDRESS. LATE BIDS WILL NOT BE ACCEPTED FOR CONSIDERATION.
1.2.	**ALL BIDS MUST BE SUBMITTED ON THE OFFICIAL FORMS PROVIDED–(NOT TO BE RE-TYPED) OR IN THE MANNER PRESCRIBED IN THE BID DOCUMENT.**
1.3.	THIS BID IS SUBJECT TO THE PREFERENTIAL PROCUREMENT POLICY FRAMEWORK ACT, 2000 AND THE PREFERENTIAL PROCUREMENT REGULATIONS, 2017, THE GENERAL CONDITIONS OF CONTRACT (GCC) AND, IF APPLICABLE, ANY OTHER SPECIAL CONDITIONS OF CONTRACT.
1.4.	**THE SUCCESSFUL BIDDER WILL BE REQUIRED TO FILL IN AND SIGN A WRITTEN CONTRACT FORM (SBD7).**
2.	**TAX COMPLIANCE REQUIREMENTS**
2.1	BIDDERS MUST ENSURE COMPLIANCE WITH THEIR TAX OBLIGATIONS.
2.2	BIDDERS ARE REQUIRED TO SUBMIT THEIR UNIQUE PERSONAL IDENTIFICATION NUMBER (PIN) ISSUED BY SARS TO ENABLE THE ORGAN OF STATE TO VERIFY THE TAXPAYER'S PROFILE AND TAX STATUS.
2.3	APPLICATION FOR TAX COMPLIANCE STATUS (TCS) PIN MAY BE MADE VIA E-FILING THROUGH THE SARS WEBSITE WWW.SARS.GOV.ZA.
2.4	BIDDERS MAY ALSO SUBMIT A PRINTED TCS CERTIFICATE TOGETHER WITH THE BID.
2.5	IN BIDS WHERE CONSORTIA / JOINT VENTURES / SUB-CONTRACTORS ARE INVOLVED, EACH PARTY MUST SUBMIT A SEPARATE TCS CERTIFICATE / PIN / CSD NUMBER.
2.6	WHERE NO TCS PIN IS AVAILABLE BUT THE BIDDER IS REGISTERED ON THE CENTRAL SUPPLIER DATABASE (CSD), A CSD NUMBER MUST BE PROVIDED.
2.7	NO BIDS WILL BE CONSIDERED FROM PERSONS IN THE SERVICE OF THE STATE, COMPANIES WITH DIRECTORS WHO ARE PERSONS IN THE SERVICE OF THE STATE, OR CLOSE CORPORATIONS WITH MEMBERS PERSONS IN THE SERVICE OF THE STATE."

NB: FAILURE TO PROVIDE / OR COMPLY WITH ANY OF THE ABOVE PARTICULARS MAY RENDER THE BID INVALID.

SIGNATURE OF BIDDER: .....

CAPACITY UNDER WHICH THIS BID IS SIGNED: .....
(Proof of authority must be submitted e.g. company resolution)

DATE: .....

SARS

TAX CLEARANCE

TCC 001

Application for a Tax Clearance Certificate

Purpose

Select the applicable option ..... Tenders ☐ Good standing ☐

If "Good standing", please state the purpose of this application

Particulars of applicant

Name/Legal name (Initials & Surname or registered name)

Trading name (if applicable)

ID/Passport no

Company/Close Corp. registered no

Income Tax ref no

PAYE ref no 7

VAT registration no 4

SDL ref no L

Customs code

UIF ref no U

Telephone no

Fax no

E-mail address

Physical address

Postal address

Particulars of representative (Public Officer/Trustee/Partner)

Surname

First names

ID/Passport no

Income Tax ref no

Telephone no

Fax no

E-mail address

Physical address

Particulars of tender (If applicable)

Tender number

Estimated Tender amount R ,

Expected duration of the tender year(s)

Particulars of the 3 largest contracts previously awarded

Date started	Date finalised	Principal	Contact person	Telephone number	Amount

Audit

Are you currently aware of any Audit investigation against you/the company? YES NO

If "YES" provide details

Appointment of representative/agent (Power of Attorney)

I the undersigned confirm that I require a Tax Clearance Certificate in respect of Tenders or Goodstanding.

I hereby authorise and instruct to apply to and receive from SARS the applicable Tax Clearance Certificate on my/our behalf.

Signature of representative/agent

Date

Name of representative/ agent

Declaration

I declare that the information furnished in this application as well as any supporting documents is true and correct in every respect.

Signature of applicant/Public Officer

Date

Name of applicant/ Public Officer

Notes:

1. It is a serious offence to make a false declaration.
2. Section 75 of the Income Tax Act, 1962, states: Any person who
   (a) fails or neglects to furnish, file or submit any return or document as and when required by or under this Act; or
   (b) without just cause shown by him, refuses or neglects to-
      (i) furnish, produce or make available any information, documents or things;
      (ii) reply to or answer truly and fully, any questions put to him ...

   As and when required in terms of this Act ... shall be guilty of an offence ...
3. **SARS will, under no circumstances, issue a Tax Clearance Certificate unless this form is completed in full.**
4. Your Tax Clearance Certificate will only be issued on presentation of your South African Identity Document or Passport (Foreigners only) as applicable.

PRICING SCHEDULE
(Professional Services)

NAME OF BIDDER: .....BID NO.: **MLRF189/22**

CLOSING TIME **11:00** CLOSING DATE: **14 OCTOBER 2022**

OFFER TO BE VALID FOR **120 DAYS** FROM THE CLOSING DATE OF BID.

ITEM NO	DESCRIPTION	BID PRICE IN RSA CURRENCY **(ALL APPLICABLE TAXES INCLUDED)

THE APPOINTMENT OF A SERVICE PROVIDER TO UNDERTAKE SAMPLING OF MARINE FISH FARMS LOCATED IN THE NORTHERN CAPE, WESTERN CAPE, AND EASTERN CAPE FOR A PERIOD OF THIRTY-SIX (36) MONTHS.

1. The accompanying information must be used for the formulation of proposals.

2. Bidders are required to indicate a ceiling price based on the total estimated time for completion of all phases and including all expenses inclusive of all applicable taxes for the project. R.....

3. PERSONS WHO WILL BE INVOLVED IN THE PROJECT AND RATES APPLICABLE (CERTIFIED INVOICES MUST BE RENDERED IN TERMS HEREOF)

4. PERSON AND POSITION	HOURLY RATE	DAILY RATE
----------	R----------	----------
----------	R----------	----------
----------	R----------	----------
----------	R----------	----------
----------	R----------	----------

5. PHASES ACCORDING TO WHICH THE PROJECT WILL BE COMPLETED, COST PER PHASE AND MAN-DAYS TO BE SPENT

----------	R----------	---------- days
----------	R----------	---------- days
----------	R----------	---------- days
----------	R----------	---------- days

5.1 Travel expenses (specify, for example rate/km and total km, class of airtravel, etc). Only actual costs are recoverable. Proof of the expenses incurred must accompany certified invoices.

DESCRIPTION OF EXPENSE TO BE INCURRED	RATE	QUANTITY	AMOUNT
----------	.....	.....	R.....
----------	.....	.....	R.....
----------	.....	.....	R.....
----------	.....	.....	R.....

TOTAL: R.....

Name of Bidder: .....

** "all applicable taxes" includes value- added tax, pay as you earn, income tax, unemployment insurance contributions and skills development levies.

5.2 Other expenses, for example accommodation (specify, eg. Three star hotel, bed and breakfast, telephone cost, reproduction cost, etc.). On basis of these particulars, certified invoices will be checked for correctness. Proof of the expenses must accompany invoices.

DESCRIPTION OF EXPENSE TO BE INCURRED	RATE	QUANTITY	AMOUNT
----------	.....	.....	R.....
----------	.....	.....	R.....
----------	.....	.....	R.....
----------	.....	.....	R.....

TOTAL: R.....

6. Period required for commencement with project after acceptance of bid .....

7. Estimated man-days for completion of project .....

8. Are the rates quoted firm for the full period of contract? *YES/NO

9. If not firm for the full period, provide details of the basis on which adjustments will be applied for, for example consumer price index. .....

.....

.....

.....

***[DELETE IF NOT APPLICABLE]**

Any enquiries regarding bidding procedures may be directed to the –

DEPARTMENT OF FORESTRY, FISHERIES AND THE ENVIRONMENT – THE MARINE LIVING RESOURCE FUND

Contact person: Ms Talitha Bikani
Contact Number: 021 402 3260
E-mail: MLRFTENDERS@DFFE.GOV.ZA

OR

Contact person: Mr Lwandisa Hoza
Contact Number: 021 402 3708
E-mail: MLRFTENDERS@DFFE.GOV.ZA

BIDDER'S DISCLOSURE

1. PURPOSE OF THE FORM

Any person (natural or juristic) may make an offer or offers in terms of this invitation to bid. In line with the principles of transparency, accountability, impartiality, and ethics as enshrined in the Constitution of the Republic of South Africa and further expressed in various pieces of legislation, it is required for the bidder to make this declaration in respect of the details required hereunder.

Where a person/s are listed in the Register for Tender Defaulters and / or the List of Restricted Suppliers, that person will automatically be disqualified from the bid process.

2. Bidder's declaration

2.1 Is the bidder, or any of its directors / trustees / shareholders / members / partners or any person having a controlling interest1 in the enterprise, employed by the state? **YES/NO**

2.1.1 If so, furnish particulars of the names, individual identity numbers, and, if applicable, state employee numbers of sole proprietor/ directors / trustees / shareholders / members/ partners or any person having a controlling interest in the enterprise, in table below.

Full Name	Identity Number	Name of State institution

2.2 Do you, or any person connected with the bidder, have a relationship

---

1 the power, by one person or a group of persons holding the majority of the equity of an enterprise, alternatively, the person/s having the deciding vote or power to influence or to direct the course and decisions of the enterprise.

with any person who is employed by the procuring institution? **YES/NO**

2.2.1 If so, furnish particulars:

.....

.....

2.3 Does the bidder or any of its directors / trustees / shareholders / members / partners or any person having a controlling interest in the enterprise have any interest in any other related enterprise whether or not they are bidding for this contract? **YES/NO**

2.3.1 If so, furnish particulars:

.....

.....

3 DECLARATION

I, the undersigned, (name)..... in submitting the accompanying bid, do hereby make the following statements that I certify to be true and complete in every respect:

3.1 I have read and I understand the contents of this disclosure;

3.2 I understand that the accompanying bid will be disqualified if this disclosure is found not to be true and complete in every respect;

3.3 The bidder has arrived at the accompanying bid independently from, and without consultation, communication, agreement or arrangement with any competitor. However, communication between partners in a joint venture or consortium2 will not be construed as collusive bidding.

3.4 In addition, there have been no consultations, communications, agreements or arrangements with any competitor regarding the quality, quantity, specifications, prices, including methods, factors or formulas used to calculate prices, market allocation, the intention or decision to submit or not to submit the bid, bidding with the intention not to win the bid and conditions or delivery particulars of the products or services to which this bid invitation relates.

3.4 The terms of the accompanying bid have not been, and will not be, disclosed by the bidder, directly or indirectly, to any competitor, prior to the date and time of the official bid opening or of the awarding of the contract.

3.5 There have been no consultations, communications, agreements or arrangements made by the bidder with any official of the procuring

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2 Joint venture or Consortium means an association of persons for the purpose of combining their expertise, property, capital, efforts, skill and knowledge in an activity for the execution of a contract.

institution in relation to this procurement process prior to and during the bidding process except to provide clarification on the bid submitted where so required by the institution; and the bidder was not involved in the drafting of the specifications or terms of reference for this bid.

3.6 I am aware that, in addition and without prejudice to any other remedy provided to combat any restrictive practices related to bids and contracts, bids that are suspicious will be reported to the Competition Commission for investigation and possible imposition of administrative penalties in terms of section 59 of the Competition Act No 89 of 1998 and or may be reported to the National Prosecuting Authority (NPA) for criminal investigation and or may be restricted from conducting business with the public sector for a period not exceeding ten (10) years in terms of the Prevention and Combating of Corrupt Activities Act No 12 of 2004 or any other applicable legislation.

I CERTIFY THAT THE INFORMATION FURNISHED IN PARAGRAPHS 1, 2 and 3 ABOVE IS CORRECT.
I ACCEPT THAT THE STATE MAY REJECT THE BID OR ACT AGAINST ME IN TERMS OF PARAGRAPH 6 OF PFMA SCM INSTRUCTION 03 OF 2021/22 ON PREVENTING AND COMBATING ABUSE IN THE SUPPLY CHAIN MANAGEMENT SYSTEM SHOULD THIS DECLARATION PROVE TO BE FALSE.

.....	.....
Signature	Date
.....	.....
Position	Name of bidder

PREFERENCE POINTS CLAIM FORM IN TERMS OF THE PREFERENTIAL PROCUREMENT REGULATIONS 2017

This preference form must form part of all bids invited. It contains general information and serves as a claim form for preference points for Broad-Based Black Economic Empowerment (B-BBEE) Status Level of Contribution

NB: BEFORE COMPLETING THIS FORM, BIDDERS MUST STUDY THE GENERAL CONDITIONS, DEFINITIONS AND DIRECTIVES APPLICABLE IN RESPECT OF B-BBEE, AS PRESCRIBED IN THE PREFERENTIAL PROCUREMENT REGULATIONS, 2017.

---

1. GENERAL CONDITIONS

1.1 The following preference point systems are applicable to all bids:

- the 80/20 system for requirements with a Rand value of up to R50 000 000 (all applicable taxes included); and
- the 90/10 system for requirements with a Rand value above R50 000 000 (all applicable taxes included).

1.2

a) The value of this bid is estimated to not exceed R50 000 000 (all applicable taxes included) and therefore the 80/20 preference point system shall be applicable;

1.3 Points for this bid shall be awarded for:

(a) Price; and

(b) B-BBEE Status Level of Contributor.

1.4 The maximum points for this bid are allocated as follows:

	POINTS
PRICE	80
B-BBEE STATUS LEVEL OF CONTRIBUTOR	20
Total points for Price and B-BBEE must not exceed	100

1.5 Failure on the part of a bidder to submit proof of B-BBEE Status level of contributor together with the bid, will be interpreted to mean that preference points for B-BBEE status level of contribution are not claimed.

1.6 The purchaser reserves the right to require of a bidder, either before a bid is adjudicated or at any time subsequently, to substantiate any claim in regard to preferences, in any manner required by the purchaser.

2. DEFINITIONS

(a) **"B-BBEE"** means broad-based black economic empowerment as defined in section 1 of the Broad-Based Black Economic Empowerment Act;

(b) **"B-BBEE status level of contributor"** means the B-BBEE status of an entity in terms of a code of good practice on black economic empowerment, issued in terms of section 9(1) of the Broad-Based Black Economic Empowerment Act;

(c) **"bid"** means a written offer in a prescribed or stipulated form in response to an invitation by an organ of state for the provision of goods or services, through price quotations, advertised competitive bidding processes or proposals;

(d) **"Broad-Based Black Economic Empowerment Act"** means the Broad-Based Black Economic Empowerment Act, 2003 (Act No. 53 of 2003);

(e) **"EME"** means an Exempted Micro Enterprise in terms of a code of good practice on black economic empowerment issued in terms of section 9 (1) of the Broad-Based Black Economic Empowerment Act;

(f) **"functionality"** means the ability of a tenderer to provide goods or services in accordance with specifications as set out in the tender documents.

(g) **"price"** includes all applicable taxes less all unconditional discounts;

(h) **"proof of B-BBEE status level of contributor"** means:

1) B-BBEE Status level certificate issued by an authorized body or person;

2) A sworn affidavit as prescribed by the B-BBEE Codes of Good Practice;

3) Any other requirement prescribed in terms of the B-BBEE Act;

(i) **"QSE"** means a qualifying small business enterprise in terms of a code of good practice on black economic empowerment issued in terms of section 9 (1) of the Broad-Based Black Economic Empowerment Act;

(j) **"rand value"** means the total estimated value of a contract in Rand, calculated at the time of bid invitation, and includes all applicable taxes;

3. FORMULAE FOR PROCUREMENT OF GOODS AND SERVICES

4. POINTS AWARDED FOR PRICE

4.1 THE 80/20 OR 90/10 PREFERENCE POINT SYSTEMS

A maximum of 80 or 90 points is allocated for price on the following basis:

80/20 **or** **90/10**

$$Ps = 80\left(1 - \frac{Pt - P\,min}{P\,min}\right) \text{ or } \qquad Ps = 90\left(1 - \frac{Pt - P\,min}{P\,min}\right)$$

Where

Ps = Points scored for price of bid under consideration

Pt = Price of bid under consideration

Pmin = Price of lowest acceptable bid

4.2 FORMULAE FOR DISPOSAL OR LEASING OF STATE ASSETS AND INCOME-GENERATING PROCUREMENT

4.3 POINTS AWARDED FOR PRICE

A maximum of 80 or 90 points is allocated for price on the following basis:

80/20 **or** **90/10**

$$Ps = 80\left(1 + \frac{Pt - P\,max}{P\,max}\right) \text{ or } \quad Ps = 90\left(1 + \frac{Pt - P\,max}{Pmax}\right)$$

Where

Ps = Points scored for price of bid under consideration

Pt = Price of bid under consideration

Pmax = Price of highest acceptable bid

5. POINTS AWARDED FOR B-BBEE STATUS LEVEL OF CONTRIBUTOR

5.1 In terms of Regulation 6 (2) and 7 (2) of the Preferential Procurement Regulations, preference points must be awarded to a bidder for attaining the B-BBEE status level of contribution in accordance with the table below:

B-BBEE Status Level of Contributor	Number of points (90/10 system)	Number of points (80/20 system)
1	10	20
2	9	18
3	6	14
4	5	12
5	4	8
6	3	6
7	2	4
8	1	2
Non-compliant contributor	0	0

6. BID DECLARATION

6.1 Bidders who claim points in respect of B-BBEE Status Level of Contribution must complete the following:

7. B-BBEE STATUS LEVEL OF CONTRIBUTOR CLAIMED IN TERMS OF PARAGRAPHS 1.4 AND 4.1

7.1 B-BBEE Status Level of Contributor: . = ...(maximum of 10 or 20 points)

(Points claimed in respect of paragraph 7.1 must be in accordance with the table reflected in paragraph 4.1 and must be substantiated by relevant proof of B-BBEE status level of contributor.

8. SUB-CONTRACTING

8.1 Will any portion of the contract be sub-contracted?

(***Tick applicable box***)

YES		NO	

8.1.1 If yes, indicate:

i) What percentage of the contract will be subcontracted.....%
ii) The name of the sub-contractor.....
iii) The B-BBEE status level of the sub-contractor.....
iv) Whether the sub-contractor is an EME or QSE
(Tick applicable box)

YES		NO	

v) Specify, by ticking the appropriate box, if subcontracting with an enterprise in terms of Preferential Procurement Regulations,2017:

Designated Group: An EME or QSE which is at last 51% owned by:	**EME √**	**QSE √**
Black people		
Black people who are youth		
Black people who are women		
Black people with disabilities		
Black people living in rural or underdeveloped areas or townships		
Cooperative owned by black people		
Black people who are military veterans		
OR		
Any EME		
Any QSE		

9. DECLARATION WITH REGARD TO COMPANY/FIRM

9.1 Name of company/firm:.....

9.2 VAT registration number:.....

9.3 Company registration number:.....

9.4 TYPE OF COMPANY/ FIRM

Partnership/Joint Venture / Consortium
One person business/sole propriety
Close corporation
Company
(Pty) Limited
[TICK APPLICABLE BOX]

9.5 DESCRIBE PRINCIPAL BUSINESS ACTIVITIES

.....
.....
.....
.....

9.6 COMPANY CLASSIFICATION

Manufacturer
Supplier
Professional service provider
Other service providers, e.g. transporter, etc.
[*TICK APPLICABLE BOX*]

9.7 Total number of years the company/firm has been in business:.....

9.8 I/we, the undersigned, who is / are duly authorised to do so on behalf of the company/firm, certify that the points claimed, based on the B-BBE status level of contributor indicated in paragraphs 1.4 and 6.1 of the foregoing certificate, qualifies the company/ firm for the preference(s) shown and I / we acknowledge that:

i) The information furnished is true and correct;

ii) The preference points claimed are in accordance with the General Conditions as indicated in paragraph 1 of this form;

iii) In the event of a contract being awarded as a result of points claimed as shown in paragraphs 1.4 and 6.1, the contractor may be required to furnish documentary proof to the satisfaction of the purchaser that the claims are correct;

iv) If the B-BBEE status level of contributor has been claimed or obtained on a fraudulent basis or any of the conditions of contract have not been fulfilled, the purchaser may, in addition to any other remedy it may have –

(a) disqualify the person from the bidding process;

(b) recover costs, losses or damages it has incurred or suffered as a result of that person's conduct;

(c) cancel the contract and claim any damages which it has suffered as a result of having to make less favourable arrangements due to such cancellation;

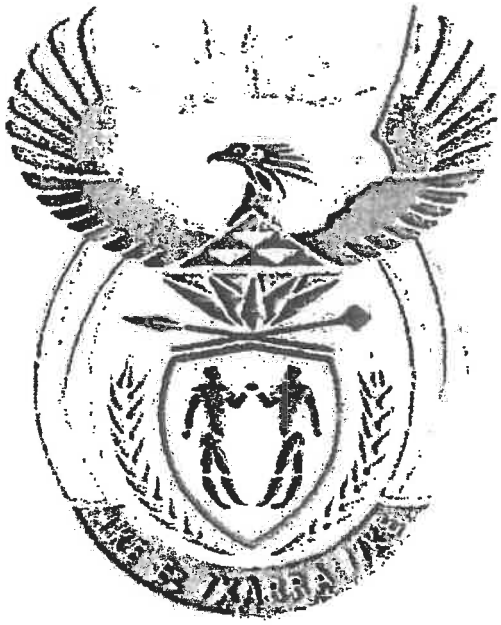
(d) recommend that the bidder or contractor, its shareholders and directors, or only the shareholders and directors who acted on a fraudulent basis, be restricted by the National Treasury from obtaining business from any organ of state for a period not exceeding 10 years, after the *audi alteram partem* (hear the other side) rule has been applied; and

(e) forward the matter for criminal prosecution.

WITNESSES 1. ..... 2.	..... SIGNATURE(S) OF BIDDERS(S) DATE: ..... ADDRESS ....

THE NATIONAL TREASURY

Republic of South Africa



GOVERNMENT PROCUREMENT:

GENERAL CONDITIONS OF CONTRACT

July 2010

GOVERNMENT PROCUREMENT

GENERAL CONDITIONS OF CONTRACT
July 2010

NOTES

The purpose of this document is to:

(i) Draw special attention to certain general conditions applicable to government bids, contracts and orders; and

(ii) To ensure that clients be familiar with regard to the rights and obligations of all parties involved in doing business with government.

In this document words in the singular also mean in the plural and vice versa and words in the masculine also mean in the feminine and neuter.

- The General Conditions of Contract will form part of all bid documents and may not be amended.

- Special Conditions of Contract (SCC) relevant to a specific bid, should be compiled separately for every bid (if (applicable) and will supplement the General Conditions of Contract. Whenever there is a conflict, the provisions in the SCC shall prevail.

TABLE OF CLAUSES

General Conditions of Contract

1. Definitions

1. The following terms shall be interpreted as indicated:

1.1 "Closing time" means the date and hour specified in the bidding documents for the receipt of bids.

1.2 "Contract" means the written agreement entered into between the purchaser and the supplier, as recorded in the contract form signed by the parties, including all attachments and appendices thereto and all documents incorporated by reference therein.

1.3 "Contract price" means the price payable to the supplier under the contract for the full and proper performance of his contractual obligations.

1.4 "Corrupt practice" means the offering, giving, receiving, or soliciting of any thing of value to influence the action of a public official in the procurement process or in contract execution.

1.5 "Countervailing duties" are imposed in cases where an enterprise abroad is subsidized by its government and encouraged to market its products internationally.

1.6 "Country of origin" means the place where the goods were mined, grown or produced or from which the services are supplied. Goods are produced when, through manufacturing, processing or substantial and major assembly of components, a commercially recognized new product results that is substantially different in basic characteristics or in purpose or utility from its components.

1.7 "Day" means calendar day.

1.8 "Delivery" means delivery in compliance of the conditions of the contract or order.

1.9 "Delivery ex stock" means immediate delivery directly from stock actually on hand.

1.10 "Delivery into consignees store or to his site" means delivered and unloaded in the specified store or depot or on the specified site in compliance with the conditions of the contract or order, the supplier bearing all risks and charges involved until the supplies are so delivered and a valid receipt is obtained.

1.11 "Dumping" occurs when a private enterprise abroad market its goods on own initiative in the RSA at lower prices than that of the country of origin and which have the potential to harm the local industries in the

RSA.

1.12 "Force majeure" means an event beyond the control of the supplier and not involving the supplier's fault or negligence and not foreseeable. Such events may include, but is not restricted to, acts of the purchaser in its sovereign capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions and freight embargoes.

1.13 "Fraudulent practice" means a misrepresentation of facts in order to influence a procurement process or the execution of a contract to the detriment of any bidder, and includes collusive practice among bidders (prior to or after bid submission) designed to establish bid prices at artificial non-competitive levels and to deprive the bidder of the benefits of free and open competition.

1.14 "GCC" means the General Conditions of Contract.

1.15 "Goods" means all of the equipment, machinery, and/or other materials that the supplier is required to supply to the purchaser under the contract.

1.16 "Imported content" means that portion of the bidding price represented by the cost of components, parts or materials which have been or are still to be imported (whether by the supplier or his subcontractors) and which costs are inclusive of the costs abroad, plus freight and other direct importation costs such as landing costs, dock dues, import duty, sales duty or other similar tax or duty at the South African place of entry as well as transportation and handling charges to the factory in the Republic where the supplies covered by the bid will be manufactured.

1.17 "Local content" means that portion of the bidding price which is not included in the imported content provided that local manufacture does take place.

1.18 "Manufacture" means the production of products in a factory using labour, materials, components and machinery and includes other related value-adding activities.

1.19 "Order" means an official written order issued for the supply of goods or works or the rendering of a service.

1.20 "Project site," where applicable, means the place indicated in bidding documents.

1.21 "Purchaser" means the organization purchasing the goods.

1.22 "Republic" means the Republic of South Africa.

1.23 "SCC" means the Special Conditions of Contract.

1.24 "Services" means those functional services ancillary to the supply of the goods, such as transportation and any other incidental services, such as installation, commissioning, provision of technical assistance, training, catering, gardening, security, maintenance and other such

obligations of the supplier covered under the contract.

1.25 "Written" or "in writing" means handwritten in ink or any form of electronic or mechanical writing.

2. Application

2.1 These general conditions are applicable to all bids, contracts and orders including bids for functional and professional services, sales, hiring, letting and the granting or acquiring of rights, but excluding immovable property, unless otherwise indicated in the bidding documents.

2.2 Where applicable, special conditions of contract are also laid down to cover specific supplies, services or works.

2.3 Where such special conditions of contract are in conflict with these general conditions, the special conditions shall apply.

3. General

3.1 Unless otherwise indicated in the bidding documents, the purchaser shall not be liable for any expense incurred in the preparation and submission of a bid. Where applicable a non-refundable fee for documents may be charged.

3.2 With certain exceptions, invitations to bid are only published in the Government Tender Bulletin. The Government Tender Bulletin may be obtained directly from the Government Printer, Private Bag X85, Pretoria 0001, or accessed electronically from www.treasury.gov.za

4. Standards

4.1 The goods supplied shall conform to the standards mentioned in the bidding documents and specifications.

5. Use of contract documents and information; inspection.

5.1 The supplier shall not, without the purchaser's prior written consent, disclose the contract, or any provision thereof, or any specification, plan, drawing, pattern, sample, or information furnished by or on behalf of the purchaser in connection therewith, to any person other than a person employed by the supplier in the performance of the contract. Disclosure to any such employed person shall be made in confidence and shall extend only so far as may be necessary for purposes of such performance.

5.2 The supplier shall not, without the purchaser's prior written consent, make use of any document or information mentioned in GCC clause 5.1 except for purposes of performing the contract.

5.3 Any document, other than the contract itself mentioned in GCC clause 5.1 shall remain the property of the purchaser and shall be returned (all copies) to the purchaser on completion of the supplier's performance under the contract if so required by the purchaser.

5.4 The supplier shall permit the purchaser to inspect the supplier's records relating to the performance of the supplier and to have them audited by auditors appointed by the purchaser, if so required by the purchaser.

6. Patent rights

6.1 The supplier shall indemnify the purchaser against all third-party claims of infringement of patent, trademark, or industrial design rights arising from use of the goods or any part thereof by the purchaser.

7. Performance security

7.1 Within thirty (30) days of receipt of the notification of contract award, the successful bidder shall furnish to the purchaser the performance security of the amount specified in SCC.

7.2 The proceeds of the performance security shall be payable to the purchaser as compensation for any loss resulting from the supplier's failure to complete his obligations under the contract.

7.3 The performance security shall be denominated in the currency of the contract, or in a freely convertible currency acceptable to the purchaser and shall be in one of the following forms:

(a) a bank guarantee or an irrevocable letter of credit issued by a reputable bank located in the purchaser's country or abroad, acceptable to the purchaser, in the form provided in the bidding documents or another form acceptable to the purchaser; or

(b) a cashier's or certified cheque

7.4 The performance security will be discharged by the purchaser and returned to the supplier not later than thirty (30) days following the date of completion of the supplier's performance obligations under the contract, including any warranty obligations, unless otherwise specified in SCC.

8. Inspections, tests and analyses

8.1 All pre-bidding testing will be for the account of the bidder.

8.2 If it is a bid condition that supplies to be produced or services to be rendered should at any stage during production or execution or on completion be subject to inspection, the premises of the bidder or contractor shall be open, at all reasonable hours, for inspection by a representative of the Department or an organization acting on behalf of the Department.

8.3 If there are no inspection requirements indicated in the bidding documents and no mention is made in the contract, but during the contract period it is decided that inspections shall be carried out, the purchaser shall itself make the necessary arrangements, including payment arrangements with the testing authority concerned.

8.4 If the inspections, tests and analyses referred to in clauses 8.2 and 8.3 show the supplies to be in accordance with the contract requirements, the cost of the inspections, tests and analyses shall be defrayed by the purchaser.

8.5 Where the supplies or services referred to in clauses 8.2 and 8.3 do not comply with the contract requirements, irrespective of whether such supplies or services are accepted or not, the cost in connection with these inspections, tests or analyses shall be defrayed by the supplier.

8.6 Supplies and services which are referred to in clauses 8.2 and 8.3 and which do not comply with the contract requirements may be rejected.

8.7 Any contract supplies may on or after delivery be inspected, tested or

analyzed and may be rejected if found not to comply with the requirements of the contract. Such rejected supplies shall be held at the cost and risk of the supplier who shall, when called upon, remove them immediately at his own cost and forthwith substitute them with supplies which do comply with the requirements of the contract. Failing such removal the rejected supplies shall be returned at the suppliers cost and risk. Should the supplier fail to provide the substitute supplies forthwith, the purchaser may, without giving the supplier further opportunity to substitute the rejected supplies, purchase such supplies as may be necessary at the expense of the supplier.

8.8 The provisions of clauses 8.4 to 8.7 shall not prejudice the right of the purchaser to cancel the contract on account of a breach of the conditions thereof, or to act in terms of Clause 23 of GCC.

9. Packing

9.1 The supplier shall provide such packing of the goods as is required to prevent their damage or deterioration during transit to their final destination, as indicated in the contract. The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt and precipitation during transit, and open storage. Packing, case size and weights shall take into consideration, where appropriate, the remoteness of the goods' final destination and the absence of heavy handling facilities at all points in transit.

9.2 The packing, marking, and documentation within and outside the packages shall comply strictly with such special requirements as shall be expressly provided for in the contract, including additional requirements, if any, specified in SCC, and in any subsequent instructions ordered by the purchaser.

10. Delivery and documents

10.1 Delivery of the goods shall be made by the supplier in accordance with the terms specified in the contract. The details of shipping and/or other documents to be furnished by the supplier are specified in SCC.

10.2 Documents to be submitted by the supplier are specified in SCC.

11. Insurance

11.1 The goods supplied under the contract shall be fully insured in a freely convertible currency against loss or damage incidental to manufacture or acquisition, transportation, storage and delivery in the manner specified in the SCC.

12. Transportation

12.1 Should a price other than an all-inclusive delivered price be required, this shall be specified in the SCC.

13. Incidental services

13.1 The supplier may be required to provide any or all of the following services, including additional services, if any, specified in SCC:

(a) performance or supervision of on-site assembly and/or commissioning of the supplied goods;

(b) furnishing of tools required for assembly and/or maintenance of the supplied goods;

(c) furnishing of a detailed operations and maintenance manual for each appropriate unit of the supplied goods;

(d) performance or supervision or maintenance and/or repair of the supplied goods, for a period of time agreed by the parties, provided that this service shall not relieve the supplier of any warranty obligations under this contract; and

(e) training of the purchaser's personnel, at the supplier's plant and/or on-site, in assembly, start-up, operation, maintenance, and/or repair of the supplied goods.

13.2 Prices charged by the supplier for incidental services, if not included in the contract price for the goods, shall be agreed upon in advance by the parties and shall not exceed the prevailing rates charged to other parties by the supplier for similar services.

14. Spare parts

14.1 As specified in SCC, the supplier may be required to provide any or all of the following materials, notifications, and information pertaining to spare parts manufactured or distributed by the supplier:

(a) such spare parts as the purchaser may elect to purchase from the supplier, provided that this election shall not relieve the supplier of any warranty obligations under the contract; and

(b) in the event of termination of production of the spare parts:

(i) Advance notification to the purchaser of the pending termination, in sufficient time to permit the purchaser to procure needed requirements; and

(ii) following such termination, furnishing at no cost to the purchaser, the blueprints, drawings, and specifications of the spare parts, if requested.

15. Warranty

15.1 The supplier warrants that the goods supplied under the contract are new, unused, of the most recent or current models, and that they incorporate all recent improvements in design and materials unless provided otherwise in the contract. The supplier further warrants that all goods supplied under this contract shall have no defect, arising from design, materials, or workmanship (except when the design and/or material is required by the purchaser's specifications) or from any act or omission of the supplier, that may develop under normal use of the supplied goods in the conditions prevailing in the country of final destination.

15.2 This warranty shall remain valid for twelve (12) months after the goods, or any portion thereof as the case may be, have been delivered to and accepted at the final destination indicated in the contract, or for eighteen (18) months after the date of shipment from the port or place of loading in the source country, whichever period concludes earlier, unless specified otherwise in SCC.

15.3 The purchaser shall promptly notify the supplier in writing of any claims arising under this warranty.

15.4 Upon receipt of such notice, the supplier shall, within the period specified in SCC and with all reasonable speed, repair or replace the defective goods or parts thereof, without costs to the purchaser.

15.5 If the supplier, having been notified, fails to remedy the defect(s) within the period specified in SCC, the purchaser may proceed to take

such remedial action as may be necessary, at the supplier's risk and expense and without prejudice to any other rights which the purchaser may have against the supplier under the contract.

16. Payment

16.1 The method and conditions of payment to be made to the supplier under this contract shall be specified in SCC.

16.2 The supplier shall furnish the purchaser with an invoice accompanied by a copy of the delivery note and upon fulfillment of other obligations stipulated in the contract.

16.3 Payments shall be made promptly by the purchaser, but in no case later than thirty (30) days after submission of an invoice or claim by the supplier.

16.4 Payment will be made in Rand unless otherwise stipulated in SCC.

17. Prices

17.1 Prices charged by the supplier for goods delivered and services performed under the contract shall not vary from the prices quoted by the supplier in his bid, with the exception of any price adjustments authorized in SCC or in the purchaser's request for bid validity extension, as the case may be.

18. Contract amendments

18.1 No variation in or modification of the terms of the contract shall be made except by written amendment signed by the parties concerned.

19. Assignment

19.1 The supplier shall not assign, in whole or in part, its obligations to perform under the contract, except with the purchaser's prior written consent.

20. Subcontracts

20.1 The supplier shall notify the purchaser in writing of all subcontracts awarded under this contracts if not already specified in the bid. Such notification, in the original bid or later, shall not relieve the supplier from any liability or obligation under the contract.

21. Delays in the supplier's performance

21.1 Delivery of the goods and performance of services shall be made by the supplier in accordance with the time schedule prescribed by the purchaser in the contract.

21.2 If at any time during performance of the contract, the supplier or its subcontractor(s) should encounter conditions impeding timely delivery of the goods and performance of services, the supplier shall promptly notify the purchaser in writing of the fact of the delay, its likely duration and its cause(s). As soon as practicable after receipt of the supplier's notice, the purchaser shall evaluate the situation and may at his discretion extend the supplier's time for performance, with or without the imposition of penalties, in which case the extension shall be ratified by the parties by amendment of contract.

21.3 No provision in a contract shall be deemed to prohibit the obtaining of supplies or services from a national department, provincial department, or a local authority.

21.4 The right is reserved to procure outside of the contract small quantities or to have minor essential services executed if an emergency arises, the

supplier's point of supply is not situated at or near the place where the supplies are required, or the supplier's services are not readily available.

21.5 Except as provided under GCC Clause 25, a delay by the supplier in the performance of its delivery obligations shall render the supplier liable to the imposition of penalties, pursuant to GCC Clause 22, unless an extension of time is agreed upon pursuant to GCC Clause 21.2 without the application of penalties.

21.6 Upon any delay beyond the delivery period in the case of a supplies contract, the purchaser shall, without canceling the contract, be entitled to purchase supplies of a similar quality and up to the same quantity in substitution of the goods not supplied in conformity with the contract and to return any goods delivered later at the supplier's expense and risk, or to cancel the contract and buy such goods as may be required to complete the contract and without prejudice to his other rights, be entitled to claim damages from the supplier.

22. Penalties

22.1 Subject to GCC Clause 25, if the supplier fails to deliver any or all of the goods or to perform the services within the period(s) specified in the contract, the purchaser shall, without prejudice to its other remedies under the contract, deduct from the contract price, as a penalty, a sum calculated on the delivered price of the delayed goods or unperformed services using the current prime interest rate calculated for each day of the delay until actual delivery or performance. The purchaser may also consider termination of the contract pursuant to GCC Clause 23.

23. Termination for default

23.1 The purchaser, without prejudice to any other remedy for breach of contract, by written notice of default sent to the supplier, may terminate this contract in whole or in part:

(a) if the supplier fails to deliver any or all of the goods within the period(s) specified in the contract, or within any extension thereof granted by the purchaser pursuant to GCC Clause 21.2;

(b) if the Supplier fails to perform any other obligation(s) under the contract; or

(c) if the supplier, in the judgment of the purchaser, has engaged in corrupt or fraudulent practices in competing for or in executing the contract.

23.2 In the event the purchaser terminates the contract in whole or in part, the purchaser may procure, upon such terms and in such manner as it deems appropriate, goods, works or services similar to those undelivered, and the supplier shall be liable to the purchaser for any excess costs for such similar goods, works or services. However, the supplier shall continue performance of the contract to the extent not terminated.

23.3 Where the purchaser terminates the contract in whole or in part, the purchaser may decide to impose a restriction penalty on the supplier by prohibiting such supplier from doing business with the public sector for a period not exceeding 10 years.

23.4 If a purchaser intends imposing a restriction on a supplier or any

person associated with the supplier, the supplier will be allowed a time period of not more than fourteen (14) days to provide reasons why the envisaged restriction should not be imposed. Should the supplier fail to respond within the stipulated fourteen (14) days the purchaser may regard the intended penalty as not objected against and may impose it on the supplier.

23.5 Any restriction imposed on any person by the Accounting Officer / Authority will, at the discretion of the Accounting Officer / Authority, also be applicable to any other enterprise or any partner, manager, director or other person who wholly or partly exercises or exercised or may exercise control over the enterprise of the first-mentioned person, and with which enterprise or person the first-mentioned person, is or was in the opinion of the Accounting Officer / Authority actively associated.

23.6 If a restriction is imposed, the purchaser must, within five (5) working days of such imposition, furnish the National Treasury, with the following information:

(i) the name and address of the supplier and / or person restricted by the purchaser;
(ii) the date of commencement of the restriction
(iii) the period of restriction; and
(iv) the reasons for the restriction.

These details will be loaded in the National Treasury's central database of suppliers or persons prohibited from doing business with the public sector.

23.7 If a court of law convicts a person of an offence as contemplated in sections 12 or 13 of the Prevention and Combating of Corrupt Activities Act, No. 12 of 2004, the court may also rule that such person's name be endorsed on the Register for Tender Defaulters. When a person's name has been endorsed on the Register, the person will be prohibited from doing business with the public sector for a period not less than five years and not more than 10 years. The National Treasury is empowered to determine the period of restriction and each case will be dealt with on its own merits. According to section 32 of the Act the Register must be open to the public. The Register can be perused on the National Treasury website.

24. Anti-dumping and countervailing duties and rights

24.1 When, after the date of bid, provisional payments are required, or anti-dumping or countervailing duties are imposed, or the amount of a provisional payment or anti-dumping or countervailing right is increased in respect of any dumped or subsidized import, the State is not liable for any amount so required or imposed, or for the amount of any such increase. When, after the said date, such a provisional payment is no longer required or any such anti-dumping or countervailing right is abolished, or where the amount of such provisional payment or any such right is reduced, any such favourable difference shall on demand be paid forthwith by the contractor to the State or the State may deduct such amounts from moneys (if any) which may otherwise be due to the contractor in regard to supplies or services which he delivered or rendered, or is to deliver or render in terms of the contract or any other contract or any other amount which

may be due to him

25. Force Majeure

25.1 Notwithstanding the provisions of GCC Clauses 22 and 23, the supplier shall not be liable for forfeiture of its performance security, damages, or termination for default if and to the extent that his delay in performance or other failure to perform his obligations under the contract is the result of an event of force majeure.

25.2 If a force majeure situation arises, the supplier shall promptly notify the purchaser in writing of such condition and the cause thereof. Unless otherwise directed by the purchaser in writing, the supplier shall continue to perform its obligations under the contract as far as is reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the force majeure event.

26. Termination for insolvency

26.1 The purchaser may at any time terminate the contract by giving written notice to the supplier if the supplier becomes bankrupt or otherwise insolvent. In this event, termination will be without compensation to the supplier, provided that such termination will not prejudice or affect any right of action or remedy which has accrued or will accrue thereafter to the purchaser.

27. Settlement of Disputes

27.1 If any dispute or difference of any kind whatsoever arises between the purchaser and the supplier in connection with or arising out of the contract, the parties shall make every effort to resolve amicably such dispute or difference by mutual consultation.

27.2 If, after thirty (30) days, the parties have failed to resolve their dispute or difference by such mutual consultation, then either the purchaser or the supplier may give notice to the other party of his intention to commence with mediation. No mediation in respect of this matter may be commenced unless such notice is given to the other party.

27.3 Should it not be possible to settle a dispute by means of mediation, it may be settled in a South African court of law.

27.4 Mediation proceedings shall be conducted in accordance with the rules of procedure specified in the SCC.

27.5 Notwithstanding any reference to mediation and/or court proceedings herein,

(a) the parties shall continue to perform their respective obligations under the contract unless they otherwise agree; and
(b) the purchaser shall pay the supplier any monies due the supplier.

28. Limitation of liability

28.1 Except in cases of criminal negligence or willful misconduct, and in the case of infringement pursuant to Clause 6;

(a) the supplier shall not be liable to the purchaser, whether in contract, tort, or otherwise, for any indirect or consequential loss or damage, loss of use, loss of production, or loss of profits or interest costs, provided that this exclusion shall not apply to any obligation of the supplier to pay penalties and/or damages to the purchaser; and

(b) the aggregate liability of the supplier to the purchaser, whether under the contract, in tort or otherwise, shall not exceed the total contract price, provided that this limitation shall not apply to the cost of repairing or replacing defective equipment.

29. Governing language

29.1 The contract shall be written in English. All correspondence and other documents pertaining to the contract that is exchanged by the parties shall also be written in English.

30. Applicable law

30.1 The contract shall be interpreted in accordance with South African laws, unless otherwise specified in SCC.

31. Notices

31.1 Every written acceptance of a bid shall be posted to the supplier concerned by registered or certified mail and any other notice to him shall be posted by ordinary mail to the address furnished in his bid or to the address notified later by him in writing and such posting shall be deemed to be proper service of such notice

31.2 The time mentioned in the contract documents for performing any act after such aforesaid notice has been given, shall be reckoned from the date of posting of such notice.

32. Taxes and duties

32.1 A foreign supplier shall be entirely responsible for all taxes, stamp duties, license fees, and other such levies imposed outside the purchaser's country.

32.2 A local supplier shall be entirely responsible for all taxes, duties, license fees, etc., incurred until delivery of the contracted goods to the purchaser.

32.3 No contract shall be concluded with any bidder whose tax matters are not in order. Prior to the award of a bid the Department must be in possession of a tax clearance certificate, submitted by the bidder. This certificate must be an original issued by the South African Revenue Services.

33. National Industrial Participation (NIP) Programme

33.1 The NIP Programme administered by the Department of Trade and Industry shall be applicable to all contracts that are subject to the NIP obligation.

34 Prohibition of Restrictive practices

34.1 In terms of section 4 (1) (b) (iii) of the Competition Act No. 89 of 1998, as amended, an agreement between, or concerted practice by, firms, or a decision by an association of firms, is prohibited if it is between parties in a horizontal relationship and if a bidder (s) is / are or a contractor(s) was / were involved in collusive bidding (or bid rigging).

34.2 If a bidder(s) or contractor(s), based on reasonable grounds or evidence obtained by the purchaser, has / have engaged in the restrictive practice referred to above, the purchaser may refer the matter to the Competition Commission for investigation and possible imposition of administrative penalties as contemplated in the Competition Act No. 89 of 1998.

34.3 If a bidder(s) or contractor(s), has / have been found guilty by the Competition Commission of the restrictive practice referred to above, the purchaser may, in addition and without prejudice to any other remedy provided for, invalidate the bid(s) for such item(s) offered, and / or terminate the contract in whole or part, and / or restrict the bidder(s) or contractor(s) from conducting business with the public sector for a period not exceeding ten (10) years and / or claim damages from the bidder(s) or contractor(s) concerned.

MARINE LIVING RESOURCES FUND

Foretrust Building ,Martin Hammerschlag Way ,Foreshore, Cape Town, 8001 or Private Bag X2 ,ROGGEBAAI,8012(FASCMILE NO.021-4023228)

MLRF ENTITY MAINTENANCE AND CREDIT ORDER INSTRUCTION

(Please complete or mark with a "X" in black ink where applicable. A bank stamp is required to verify your banking details. In case of a cheque account a cancelled cheque must be included. Please return form by post or by hand delivery or by facsimile.)

TAKE-ON	NEW	UPDATE	ENTITY TYPE	BUSINESS	DEPARTMENT	EMPLOYEE	OTHER

FROM: CREDITOR / ENTITY (DETAILS)

TITLE
SURNAME
FIRST NAME/S
BUSINESS NAME
TRADING NAME
BUSINESS REG No.
VAT REGISTERED Y N
VAT REGISTRATION NO.
ID NO.
DEPARTMENT NAME
PERSAL NO.*

* For employees only

CONTACT DETAILS

STREET / PHYSICAL ADDRESS
POSTAL CODE

POSTAL ADDRESS
POSTAL CODE

BUSINESS TELEPHONE No. DIALLING CODE
BUSINESS FACSIMILE No. DIALLING CODE
NAME OF CONTACT PERSON
E-MAIL ADDRESS
CELLULAR TELEPHONE No.

DETAILS OF FINANCIAL INSTITUTION FOR ELECTRONIC BANKING TRANSFERS:

BANK NAME:
BRANCH NAME & CITY/TOWN
BRANCH NUMBER/CODE
ACCOUNT NUMBER
ACCOUNT TYPE CURRENT SAVINGS TRANSMISSION

BANK DATE STAMP (COMPULSORY)

I / We hereby request, instruct and authorise you to pay any amounts which may accrue to me / us to the credit of my / our account with the abovementioned bank.

I / we understand that the credit transfers hereby authorised will be processed electronically through a system known as the "ACB ELECTRONIC FUNDS TRANSFER SERVICE", and I/we also understand that no additional advice of payment will be provided by my/our bank. Details of each payment will be printed on my/our bank statement or any accompanying voucher.

I / We understand that a payment advice will be supplied by the Marine Living Resource Fund in the normal way, and that it will indicate the date on which funds will be available in my / our account.

This authority may be cancelled / changed by giving prior written notice, by way of registered post or facsimile.

SIGNATURE OF AUTHORISED PERSON
POSITION HELD
PRINT NAME OF AUTHORISED PERSON
DATE (DD/MM/YYYY):

forestry, fisheries
& the environment

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

TERMS OF REFERENCE

MLRF189/22- THE APPOINTMENT OF A SERVICE PROVIDER TO UNDERTAKE SAMPLING OF MARINE FISH FARMS LOCATED IN THE NORTHERN CAPE, WESTERN CAPE AND EASTERN CAPE FOR A PERIOD OF THIRTY-SIX (36) MONTHS.

Contents

1. PURPOSE

The Marine Living Resources Fund (MLRF), as the managing and regulatory authority for aquaculture activities, has the obligation to appoint a suitably qualified and experienced service provider to undertake official sampling of marine fish farms located in the Northern Cape, Western Cape and Eastern Cape for a period of thirty-six (36) months. This is in fulfilment of the requirements of the South African Shellfish Monitoring and Control Programme (SASM&CP), South African Aquacultured Marine Fish Monitoring and Control Programme (SAAMFM&CP) and the National Residue Control Programme (NRCP) developed to regulate marine fish farms in South Africa.

2. INTRODUCTION AND BACKGROUND

2.1. The Marine Living Resources Fund (MLRF) is a Schedule 3a Public Entity established in terms of the Public Finance Management Act, 1999 (Act No 1 of 1999), in its commitment to the principles enshrined in the constitution of the Republic of South Africa, 1996, adheres to the provisions of the Broad Based Black Economic Empowerment Act, 2003 (Act No. 53 of 2003) (B-BBEE), the Preferential Procurement Policy Framework Act, 2000 (Act No. 5 of 2000) ("PPPF") and the Preferential Procurement Regulations, 2017.

2.2. The National Aquaculture Policy Framework for South Africa of 2013 aims at creating an enabling environment that will promote growth and sustainability of the marine aquaculture sector in South Africa, as well as to enhance the industry's contribution to economic growth. The Directorate: Sustainable Aquaculture Management (D: SAM) within the Branch Fisheries Management is mandated to support the strategic objectives of the policy through the development and implementation of relevant enabling legislation, policies and programmes as well as be responsive and compliant to international obligations and agreed standards.

2.3. The Food Safety Office (FSO) of the Aquatic Animal Health and Environmental Interactions (AAHEI) sub-directorate within D: SAM is responsible for the development and implementation of food safety programmes stipulated in the permit conditions of permits issued in terms of section 13 of the Marine Living Resources Act (MLRA), 1998 (Act No. 18 of 1998). The food safety programmes include the South African Shellfish Monitoring and Control Programme (SASM&CP), South African Aquacultured Marine Fish Monitoring and Control Programme (SAMFM&CP) and the National Residue Control Programme (NRCP). The objectives of these programmes include providing guarantees to domestic and international markets and consumers confirming that harvested South African cultured fish are safe for human consumption.

2.4. The risks to food safety for human consumption of cultured fish include environmental and veterinary medicine residues and the accumulation of biotoxins and pathogenic microbiological organisms. The aquaculture industry is monitored and controlled in terms of the MLRA which includes the marine shellfish and finfish aquaculture farms regulated by the Department.

2.5. The marine fish cultured in South Africa include shellfish and finfish. The shellfish species cultured include abalone *(Haliotis midae)*, oyster (*Crassostrea gigas*), Mediterranean Mussel (*Mytilus galloprovincialis*) and Black Mussel (*Choromytilus meridionalis*). The finfish species include Kob (*Argyrosomus japonicus*), Cape Yellowtail (*Seriola lalandi*) and Rainbow Trout (*Onchorhynchus mykiss*).

2.6. The marine fish farms are located along the South African coast from Port Nolloth in the Northern Cape to Haga Haga in the Eastern Cape. The majority of the abalone farms are located in the Walker Bay and Buffeljags region on the south-west coast and to a lesser extent along the West Coast and Northern Cape coast and one farm is located near East London. Oyster and mussel farms are predominantly located in Saldanha Bay and one oyster farm is situated in Algoa Bay. There is one finfish farm located in Saldanha Bay and one finfish farm in the East London Industrial Development Zone.

2.7. The MLRF seeks to appoint an independent service provider to undertake sampling of marine fish farms located in the Northern Cape, Western Cape and Eastern Cape for a period of thirty-six (36) months. This is in fulfilment of the requirements of the SASM&CP, SAAMFM&CP and the NRCP developed to regulate marine fish farms in South Africa.

3. OBJECTIVES OF THE APPOINTMENT

The objective is to appoint an independent service provider to undertake official sampling of marine fish farms located in the Northern Cape, Western Cape and Eastern Cape for a period of thirty-six (36) months on behalf of the MLRF. This is in fulfilment of the requirements of the SASM&CP, SAAMFM&CP and the NRCP developed to regulate marine fish farms in South Africa.

4. SCOPE AND EXTENT OF WORK

4.1. The service provider is required to conduct the following duties:

4.1.1. Sample marine fish farms on a routine basis and submit samples to accredited laboratories in accordance with:

- South African Shellfish Monitoring and Control Programme (2021) (Annexure 1) with specific reference to sections 9, 10.2, 11.2, 12.2, 15, 20.1 and 22 and the associated Biotoxin Action Plan and Microbiological Action Plan for the respective production areas. The relevant sections in the revised South African Shellfish Monitoring and Control Programme shall be applicable if the programme is revised during the contractual period;
- Biotoxin and microbiological sampling programme (Annexure 2); the revised programme shall be applicable if the programme is revised during the contractual period;
- South African Aquacultured Marine Fish Monitoring and Control Programme (2020) (Annexure 3) with specific reference to section 11, 16, 18, 19 and 20. The relevant sections in the revised programme shall be applicable if the programme is revised during the contractual period;
- National Residue Control Programme (Annexure 4 – **This annexure should be requested from MLRFTENDERS@DFFE.GOV.ZA and it will be provided to the bidder/s upon signing a confidentiality form**); the revised programme shall be applicable if the programme is revised during the contractual period; and
- Standard Operating Procedure: Sampling and Transport of Aquacultured Marine Fish (Annexure 5).

4.1.2. Sampling of marine fish farms in the event of contingency measures being implemented in accordance with Standard Operating Procedure: Contingency Measures and the South African Shellfish Monitoring and Control Programme (Annexure 1) with specific reference to sections 10.3, 11.3 and 12.3. The proposal must cater for 30 contingency events per year, being cognisant that each contingency event may include multiple farms, particularly in Saldanha Bay.

4.1.3. Sampling of additional farms when required, for example new farms being established during the contract period. There are potentially 6 additional bivalve farms in Saldanha Bay, four (4) additional abalone ranching operations in the Northern Cape and one (1) urchin farm in the Western Cape. These farms can only be included in the sampling programmes if and when they are officially being sampled. The MLRF, however, can only be invoiced for the sampling of new farms that are sampled during the contract period.

4.1.4. Resampling of a farm will be required should a sample not arrive at a laboratory or not be fit for testing on arrival at a laboratory. The proposal must cater for 30 resampling events per year. The MLRF, however, can only be invoiced for farms that are resampled during the contract period.

4.1.5. .4.1.5 The MLRF can only be invoiced for the sampling of farms that are operational and being monitored in terms of the above-mentioned food safety programmes. Should a farm no longer be officially monitored, the MLRF cannot be invoiced for the sampling of the farm.

4.1.6. Attend virtual monthly progress meetings.

4.1.7. Draft monthly progress sampling reports, starting from date of appointment and submit these to the MLRF Project Manager.

4.1.8. Drafting of the Annual Sampling Report summarising the activities achieved over the year and submit to the MLRF Project Manager.

4.1.9. Perform secretariat duties of the monthly progress meetings by arranging meetings, printing documents (i.e., agendas and meeting minutes), archiving and filing all documents and drafting meeting minutes and monthly progress reports, for approval by the MLRF Project Manager.

4.1.10. Virtual meeting platforms will be used for most monthly progress meetings, but the service provider must cost for two physical meetings in Cape Town per annum. Progress meeting minutes to be drafted by the service provider and approved by the MLRF Project Manager.

4.1.11. Facilitation of a hand over meeting and all relevant documents to the next service provider to allow for continuation of the work. This will not be a comprehensive and costly task, it will simply include handover of historical data and supporting documentation derived during the contract period.

5 EXPECTED DELIVERABLES / OUTCOMES

The expected outcomes and deliverables are as follows:

5.1 Routine sampling of marine fish farms regulated by the MLRF in accordance with Section 4.1.1 above.

5.2 Sampling of marine fish farms in the event of contingency measures being implemented in accordance with Section 4.1.2 above.

5.3 Resampling of a farm should a sample not arrive at a laboratory or not be fit for testing on arrival at a laboratory.

5.4 Submission of the samples to SANAS accredited laboratories indicated in the above sampling programmes. Email copies of the sample requisition forms and Residue Sampling Reports where applicable to SAMSanitation@dffe.gov.za and cc the MLRF Project Manager within 24 hours of sampling.

5.5 Provide logistical arrangements and secretariat functions of the monthly progress meetings including the drafting of minutes for meetings held in terms of this contract. Finalised minutes shall be submitted to the MLRF Project Manager within one week of the meeting.

5.6 Attend the monthly progress meetings.

5.7 Compile required monthly and annual reports and submit to the MLRF Project Manager as per the agreed time schedule.

5.8 Facilitate the hand over meeting and documentation to the next appointed service provider at completion of the contract.

6 PERIOD / DURATION OF APPOINTMENT

The appointment/s will run during the period/s indicated per survey and will commence as agreed in the Service Level Agreement (SLA) signed between the Department/MLRF and the service provider.

7 COSTING / COMPREHENSIVE BUDGET

7.1 A comprehensive budget costing must be submitted as an all-inclusive price in a separate envelope indicating unit prices per resource (inclusive of VAT, including) by way of a Bill of Quantity to provide the services indicated in the Scope, Section 4. The costing including as a minimum: staff time, transport costs, courier costs, sampling frequency per area and sampling materials (SBD 3.3 for detailed costing).

7.2 Refer to annexure 6 for the detailed pricing schedule.

8 EVALUATION METHOD

8.1 The evaluation for this bid will be carried out in three (3) phases:

- Phase 1: Pre-compliance or Initial Screening
- Phase 2: Mandatory requirements
- Phase 3: Price and B-BBEE.

8.2 **PHASE 1: Pre-compliance or Initial Screening**

8.2.1 During this phase, bid documents will be reviewed to determine compliance with Supply Chain Management (SCM) returnable, tax matters and whether the Central Supplier Database (CSD) report has been submitted with the bid documents at the closing date and time of the bid. Bids which do not satisfy the compliance criteria will not be evaluated further.

8.2.2 The bid proposal will be screened for compliance with administrative requirements as indicated below:

Item No.	Administrative Requirements	Check/Compliance	Non-submission may result in disqualification?
1	SCM - SBD 1 - Invitation to Bid	Completed and signed	*YES
2	SCM - SBD 2 - Tax Clearance Certificate Requirements	CSD registration number/SARS PIN and CSD summary report	**NO
3	SCM - SBD 3.3 – Pricing Schedule	Completed and signed	*YES
4	SCM - SBD 4 - Declaration of Interest	Completed and signed	*YES
5	SCM - SBD 6.1 - Preference Points Claim Form in terms of the Preferential Procurement Regulations 2017	Completed and signed, supported by B-BBEE Certificate if applicable or Affidavit if applicable	**NO
6	In case of bids where Consortia / Joint Ventures, Consortia agreement signed by both parties must be submitted with bid proposal	JV agreement completed and signed, if applicable	*YES
7	Comprehensive Curriculum Vitae (CV) – Project Manager and supervisors	Detailed CV of the supervisors and Project Manager, supported by copies of qualification(s).	*YES
8	Proof training of samplers for the taking of fish samples for the testing of contaminants indicated in the Scope, Point 4.1.1.	Provided	*YES

Item No.	Administrative Requirements	Check/Compliance	Non-submission may result in disqualification?
9	Certified copies of the IDs of the owners including shareholders of the company	Provided	*YES

YES – MLRF reserves the right to reject proposals that are not submitted in the prescribed format or where information presented is illegible and/or incomplete and will not be further evaluated for Phase 2.
****NO** – MLRF reserves the right to request such information during the evaluation process of the proposal and such information must be presented within short notice.

8.3 PHASE 2: MANDATORY REQUIREMENTS

8.3.1 Only bid proposals that meet pre-compliance requirements will be evaluated on mandatory requirements. The service provider must complete the section below by answering **YES or NO**. If, yes, please attach proof.

	Requirement	Comply: Yes or No	Evidence attached:
Mandatory Requirements:	At the time of submitting the bid all the samplers are trained for food safety sampling (microbiological, veterinary medicine and environmental residues) by a certified service provider(s) and the service provider has allocated budget to ensure that future samplers (new and additional) are trained.		Provide proof of suitable training on microbiological, veterinary medicine and environmental residues.
	The service provider South African National Accreditation System (SANAS) certified for ISO 17020 compliance, with specific competence in food safety sampling for aquaculture products.		Provide valid company SANAS ISO 17020 certificate.
	Signed letter that there is no conflict of interest in relation to the producers of marine aquaculture products including financial or ownership interests by the company's directors, trustees, shareholders, members or staff members of the service provider.		Provide a signed letter.
	A detailed project plan/ proposal with **ALL** of the following requirements: • Sampling schedule in line with Point 4.1 of the Scope including allowance for contingency measures and resampling • Contingency measures • Number of re-sampling budgeted for • Clearly identified deliverables including progress reports • Timeframes • Available staff and logistical resources to undertake the sampling as per the sampling schedule and the delivery of samples to the relevant laboratories.		Provide a detailed plain with the above components.

	The service provider demonstrate at least two (2) years' experience in food safety sampling of aquaculture/livestock farms which includes collection of samples, chain of evidence, sample handling, sample traceability, record keeping, document management and transporting of samples in terms of food safety requirements. With at least one (1) of the two (2) years' experience in sampling in aquaculture farms.		Signed referral letters that are issued in the name of the service provider.

NOTE: Failure to meet all the mandatory requirements will lead to the service provider being disqualified.

8.4 **PHASE 3: Preference Point System 80/20**

8.4.1 The third phase is to perform an evaluation of Price and BBBEE on the bidders that successfully meet Phase 2 (mandatory requirements).

8.4.2 Calculation of points for price - The PPPFA prescribes that the lowest acceptable bid will score 80 points for price. The bidder that quoted higher prices will score lower points for price on a pro-rata basis.

8.5 **Calculating of points for B-BBEE status level of contribution**

8.5.1 Points will be awarded to a bidder for attaining the B-BBEE status level of contribution by submitting original and valid B-BBEE Status Level Verification Certificate issued by SANAS Accredited Verification Agency or certified copies thereof; or B-BBEE Certificate issued by CIPC, or Sworn Affidavit commissioned by Commissioner of Oaths together with their bids, to substantiate their B-BBEE rating claims. SBD 6.1 must also be duly completed, signed, and submitted alongside the bid to claim preference points. Failure to do so will result in B-BBEE preference points being forfeited.

Phase 3: The following table must be used to calculate the B-BBEE scores (80/20)	
PRICE	
B-BBEE Status Level Contributor	**Number of points (80/20)**
1	
2	
3	
4	
5	
6	
7	
8	
Non –compliant contributor	

9 BID SUBMISSION REQUIREMENTS

9.1. The bidders should ensure that the following submission requirements, which will be needed for evaluation purposes are included in their bid proposal and are as follows:

9.1.1. The bidders must draft a table of contents which will indicate where each document is in the proposal.

9.1.2. The proposal shall consist of two parts, namely the technical bid and the pricing bid (master and copies).

9.1.3. Copies of the accredited training certificates for the samplers, the relevant tertiary qualifications or equivalent from supervisory staff and project managers. The bidders are expected to ensure that nominated Team Members with foreign qualifications submit South African Qualifications Authority (SAQA) Certificates with the bid submission for evaluation. **Failure to do so will result in the disqualification of the bidder/s.**

9.1.4. The information in the Profile / CV of the proposed Key Staff Members should include relevant experience and qualifications in the chosen area of expertise demonstrating the required competency.

9.1.5. Project reference specifying the role played by the service provider in the listed projects or assignments, project value and the duration of the project (start and end date).

9.1.6. A detailed Project Plan with clear indication of who will be responsible for the management of the assignment as well as its execution. The allocation of team members on the assignments should be based on the experience in delivering the scope of work as listed.

9.1.7. Master bid document and five (5) Copies of the master bid documents

9.1.8. Standard bidding documents (SBD1, 2, 3.3, 4 and 6.1).

9.1.9. Tax clearance certificate requirements and Central Supplier Database (CSD) summary report for major bidder, joint ventures and sub-contractors. SARS Pin number and Central Supplier Database (CSD) number or report.

9.1.10. Suppliers/Service Providers are requested to submit the original and valid B-BBEE Status Level Verification Certificate or certified copies thereof issued by verification agencies accredited by SANAS only or an original or certified copy of DTI sworn affidavit in terms of Codes of good practice indicating that service provider is an EME/ QSE

9.1.11. Certified copies of identity documents of directors and shareholders of the company.

9.1.12. Entity registration Certificate (CK1).

9.1.13. Letter of Authority to sign documents on behalf of the company.

10 SPECIAL CONDITIONS OF CONTRACT

10.1 On appointment, the performance measures for the delivery of the agreed services will be closely monitored by the MLRF.

10.2 The MLRF will not be held responsible for any costs incurred by the service providers in the preparation, presentation, and submission of the proposal.

10.3 The Project Manager allocated to the service by the MLRF shall do the ongoing management of the Service Level Agreement (SLA).

10.4 The Service Provider/s will be required to submit soft copies of the monthly reports to the Project Manager, within four (4) working days after the end of each month for the duration of the project. Failure to submit these reports on time may result in penalties.

10.5 The Service Provider/s must guarantee the presence of the Team Leader in charge of the project throughout the duration of the contract. Prior to the appointment of a replacement, the Project Manager from the MLRF must approve such appointment. If the Team Leader has to leave the project, a period of at least one month is required in which the senior manager must work parallel with the next person (senior manager with similar expertise and equal years of experience) appointed to be able to transfer skills and knowledge.

10.6 All the conditions specified in the General Conditions of Contract (GCC) will apply and where the conditions in the special conditions of contract contradict the conditions in the general conditions of contract the special conditions of contract will prevail.

10.7 The proposals should be submitted with all required information as per the requirements stipulated in these Terms of Reference.

10.8 Travelling costs and time spent or incurred between home and office of the service provider and MLRF office will not be for the account of MLRF.

10.9 Bidders failing to meet all the mandatory requirements will automatically be disqualified.

10.10 Bidders are requested to submit the original and valid B-BBEE Status Level Verification Certificate issued by SANAS Accredited Verification Agency or certified copies thereof.

10.11 A trust, consortium or joint venture will qualify for points for their B-BBEE status level as a legal entity, provided that the entity submits their B-BBEE status level certificate.

10.12 A trust, consortium or joint venture will qualify for points for their B-BBEE status level as an unincorporated entity, provided that the entity submits their consolidated B-BBEE scorecard as if they were a group structure and that such a consolidated B-BBEE scorecard is prepared for every separate proposal.

10.13 If the application is made by a Joint Venture or Partnership, the accreditation credentials in the name of joined entity should be submitted. Both members in the joint venture must meet the requirement of the proposal.

10.14 Poor or non-performance by the bidder will result in cancellation of the bid and the SLA.

10.15 The MLRF has the right to exclude a bidder and or terminate the contract if the bidder or its sub-contractors are party to an interest group or entity involved in legal proceedings opposing the MLRF.

10.16 Suitably trained samplers must be provided throughout the duration of the project.

11 SUB-CONTRACTING CONDITIONS/ REQUIREMENTS

11.1 In a case whereby sub-contracting is not set as a pre-qualification criterion, however the bidder is intending to sub-contract portion of the work, such bidder awarded a contract may only enter into sub-contracting arrangements with the approval of the MLRF.

11.2 In relation to a designated sector, a contractor will not be allowed to subcontract in such a manner that the local production and content of the overall value of the contract is reduced to below the stipulated minimum threshold.

11.3 A bidder will not be awarded the points claimed for B-BBEE status level of contribution or contract if it is indicated in the bid documents that such a bidder intends subcontracting more that 25% of the contract value to any other enterprise that does not qualify for at least the same number of points that the bidder qualifies for, unless the intended sub-contractor is an EME that has the capability and ability to execute the sub-contract.

11.4 The contractor is not allowed to sub-contract more than 25% of the contract value to another enterprise that does not have equal or higher B-BBEE status level, unless the intended sub-contractor is an EME that has the capability and ability to execute the sub-contract.

12 PAYMENT TERMS

12.1 The MLRF undertakes to pay out in full or as per deliverables within 30 (thirty) days all valid claims for work done to its satisfaction upon presentation of a substantiated claim and the required reports stipulated in special conditions. No payment will be made where there is outstanding information/work not submitted by the Service Provider/s until that outstanding information is submitted.

13 COMPULSORY BRIEFING SESSION

13.1 The MLRF will arrange a virtual information session via Microsoft Teams (see below details) for all interested parties, and the attendance of the session is compulsory. The tender documents will be explained during this session. The virtual session will take place as follows:

- 30 September 2022 (Friday) at 10h00

13.2 The link for the sessions can be requested via email:

Name	Email address
Lwandisa Hoza	MLRFTENDERS@DFFE.GOV.ZA
Talitha Bikani	

**Suppliers should use "MRLF189/22: Briefing Session" as the subject of the email of requesting link for the briefing session.*

14 ENQUIRIES

14.1 Should you require any further information in this regard, contact:

Name	Email address
Lwandisa Hoza	MLRFTENDERS@DFFE.GOV.ZA
Talitha Bikani	

**Suppliers should use "MRLF189/22: Enquiries" as the subject of the email when enquiring.*

ANNEXURE 1

SOUTH AFRICAM SHELLFISH MONITORING AND CONTROL PROGRAMME

environment, forestry
& fisheries

Department:
Environment, Forestry and Fisheries
REPUBLIC OF SOUTH AFRICA

SOUTH AFRICAN SHELLFISH MONITORING AND CONTROL PROGRAMME

Branch: Fisheries Management

Chief Directorate: Aquaculture & Economic Development

Directorate: Sustainable Aquaculture Management

Issue 8: January 2021

TITLE

South African Shellfish Monitoring and Control Programme

COMMENCEMENT

This programme comes into force on 1 January 2020.

REVOCATION

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

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

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

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DEPUTY DIRECTOR-GENERAL

FISHERIES MANAGEMENT

DATE:

Contents

Tables

Appendices

1. BACKGROUND

Food safety laws throughout the world give special consideration to shellfish for a number of reasons. Some of them are filter feeding shellfish that accumulate hazardous levels of biotoxins and other toxins and pathogenic micro-organisms (viruses, protozoa, bacteria and helminths) in their flesh causing them to become naturally contaminated. Gastropods also accumulate biotoxins, particularly Paralytic Shellfish Toxins (PST) and to a lesser extent Lipophilic Shellfish Toxins as well as numerous other residues. In many cases no thermal process is applied to shellfish prior to sale to eliminate pathogens and therefore, further microbiological multiplication is likely to occur. The presence of marine biotoxins is also not eliminated by cooking. Raw shellfish receive the second highest hazard rating for all foods by the International Commission on Microbial Specification for Foods.

2. PURPOSE

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

3. SCOPE AND AUTHORIZATION

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

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

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

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

5) The manual includes the monitoring activities required for audit of production areas and establishments in the interests of public health. These activities will be managed and controlled by the Department of Environment, Forestry and Fisheries (DEFF) under the Marine Living Resources Act, 1998 (Act No. 18 of 1998) and the relevant municipal health authorities under the National Health Act, 2003 (Act No. 61 of 2003) and the Municipal Structures Act, 1998 (Act No. 117 of 1998); in cooperation with the National Regulator for Compulsory Specifications (NRCS) (the appointed body for administering the various Compulsory Specifications for fishery products in South Africa).

6) The functions of this programme are to:

    a) Establish the production area classification system.

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

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

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

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

4. DOCUMENT CONTROL

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

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

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

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

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

3) A detailed record of all amendments shall be maintained.

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

5. DEFINITIONS

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

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

"Approved areas (Class A)" means the classification by the Department of a production area where shellfish may be harvested for sale for direct human consumption at any time outside of temporary closures. An approved area must meet the microbiological requirements set out in paragraph 8.3. An approved area may be temporarily closed to harvesting, e.g. when a flood, storm or marine biotoxin event occurs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Harvester" means a person or entity with a marine aquaculture right to harvest shellfish by any means from a production area.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Process water" means seawater in depuration tanks during the time that the shellfish are being depurated, or the water used in a tank system where shellfish are cultivated, or the water in wet storage tanks during the time the shellfish are being wet stored.

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

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

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

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

"Restricted area (Class B)" means a production area classified by the Department as an area from which shellfish may be harvested only by special permit. A restricted area must comply with the microbiological requirements set out in Section 8.4. Shellfish from restricted areas may be processed (e.g. canning, cooking and freezing as per Section 8.4, paragraph 4) or subjected to an approved depuration process such as relaying or depuration.

"Sanitary Survey" means the evaluation, in accordance with the requirements of Section 8.2 of this manual, by a party approved by the Department, of all actual and potential pollution sources and environmental factors that may affect shellfish production water quality.

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

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

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

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

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

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

6. ABBREVIATIONS

"ADP" means approved depuration process

"AST" means Amnesic Shellfish Toxins

"AZA" means azaspiracid

"BMP" means better management practice

"CITES" means Convention on International Trade in Endangered Species

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

"DTX" means Dinophysis toxins

"E. coli" means *Escherichia coli*

"EC" means European Commission

"FPE" means Fish Processing Establishment

"FSO" means Food Safety Office

"GPS" means global positioning system*

"IATA" means International Air Transport Association

"ILAC" means International Laboratory Accreditation Cooperation

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

"LST" means Lipophilic Shellfish Toxins

"MCP" means Monitoring and Control Programme

"MPN" means Most Probable Number

"MRL" means maximum residue limit

"NRCP" means National Residue Control Programme

"NRCS" means National Regulator for Compulsory Specifications

"NRP" means National Residue Plan

"OA" means okadaic acid

"PST" means Paralytic Shellfish Toxins

"PTX" means Pectenotoxins

"SANAS" means South African National Accreditation System

"SANS" means South African National Standard

"SOP" means Standard Operating Procedure

"WWTW" means waste water treatment works

"YTX" means yessotoxin

7. RULES

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

2) The Department is the Regulatory Authority authorising the undertaking of aquaculture activities, i.e. farming, harvesting and transporting of shellfish for wholesale trading in terms of the Marine Living Resources Act, 1998 (Act No. 18 of 1998) and associated Regulations. Authorisations are administered through the granting and issuing of a Marine Aquaculture (mariculture) Rights and permits respectively. Associated activities such as relaying, depuration and wet storage require special authorisation from NRCS and the Department in conjunction with the relevant local health authorities.

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

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

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

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

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

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

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

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

- Monitoring data and notices.
- Enforcement action reports.
- All data, criteria and protocols relating to the operation of a restricted area such as relaying reports, depuration reports, harvesting permits and harvesting control records.
- Correspondence with farmers.

10) The officially approved inspector servicing an establishment where shellfish are landed for relaying, wet storage, depuration, preparation, processing and final packaging or repacking must also keep a file containing copies of the relevant records, documents and reports described in Section 7, paragraph 7.

11) Industry shall keep complete, accurate and legible shellfish transaction records for at least 5 years in a permanently bound ledger book (or other approved method). The records shall be readily accessible and available for inspection by any authorised person and shall be retrievable within 24 hours. This pertains to each authorised marine farmer including relayer, depuration plant, wet storage facility and establishment packing and/or processing shellfish. Such records shall include:

- All information necessary to trace all purchases and sales of shellfish back to their production area.
- Dates of harvesting of shellfish and of their arrival at the licensed premises for the intended process, including dates of shucking, packing and dispatch.
- Results of laboratory analyses instigated by industry.
- Permanent records of relaying and depuration activities where applicable.

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

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

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

8. CLASSIFICATION OF SHELLFISH PRODUCTION AREAS

8.1. Overview of classification system

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

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

3) Microbiological classification of production areas is based on analyses of shellfish flesh. Where the culture species is not available in a new production area an alternative species may be used as

advised by the Department. In the case of bivalves, it may be necessary to place bags containing the culture species in the production area to provide flesh for testing.

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

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

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

8.2. Sanitary Surveys

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

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

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

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

8.3. Approved areas

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

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

   a) The *E. coli* Most Probable Number (MPN) in the shellfish may not exceed 230 *E. coli* per 100 g of flesh and intravalvular liquid in 80% of the samples. No sample may exceed 700 *E. coli* per 100 g of flesh and intravalvular liquid.

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

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

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

8.4. Restricted areas

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

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

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

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

4) The permitted treatment methods are:

   a) sterilisation in hermetically sealed containers; and

   b) heat treatments involving:

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

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

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

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

8.5. Prohibited zone

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

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

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

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

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

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

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

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

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

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

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

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

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

   c) the characteristics of the receiving water, including:

      i) bathymetry;

      ii) current velocity;

      iii) net transport velocity;

      iv) water depth and volume;

      v) direction of flow;

      vi) water stratification;

      vii) tidal characteristics;

      viii) dilution rate; and

      ix) likely dispersion;

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

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

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

8.6. Conditional areas

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

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

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

8.7. Review of classification

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

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

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

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

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

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

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

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

b) a field review of all existing pollution sources;

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

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

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

a) retain or change the existing classification; and

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

8.8. Extension of production areas

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

   a) further sample stations;

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

   c) additional tests for potentially harmful substances.

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

9. MONITORING OF SHELLFISH PRODUCTION AREAS AFTER CLASSIFICATION

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

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

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

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

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

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

10. MICROBIOLOGICAL MONITORING

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

2) Microbiological monitoring is mandatory during harvesting periods (See Appendix 6). Farm managers must inform the Department of extended periods of no harvest and dates when harvesting is to be resumed. Failure to comply will result in temporary closure until testing is reinstated.

10.1. Microbiological management plan

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

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

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

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

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

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

   e) the routine monitoring programme for shellfish;

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

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

10.2. Sampling and analysis of samples

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

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

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

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

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

6) A minimum of 12 samples must be collected from each station over a 12 month period in approved and restricted areas. These results will be evaluated by adding the samples to the pre-existing bacteriological results that accurately reflect the current situation. The annual evaluation shall address at least the last 20 samples for Approved and Restricted areas and at least the last 30 samples for Conditional areas. The period evaluated should not be less than the last 12 months.

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

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

10.3. Contingency measures

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

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

3) When an epidemiologically confirmed shellfish-borne illness is reported involving two or more persons and implicating a shellfish production area, the Health authority responsible for the particular area, in association with the Department and the NRCS, shall undertake appropriate actions as outlined in an official contingency standard operating procedure.

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

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

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

11. MONITORING OF ENVIRONMENTAL AND VETERINARY DRUG RESIDUES

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

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

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

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

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

11.1. National Residue Plan and National Residue Control Programme

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

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

   a) Compound or marker residue

   b) Matrix to be analysed

   c) Screening method where relevant

   d) Confirmatory method

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

   f) Confirmatory method LOD

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

   h) Laboratory to be used

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

   a) Farm name and farm code

   b) Sampling date

   c) Sample reference number

   d) Test method

e) Sample condition i.e. frozen or chilled

f) Matric to be tested

g) Laboratory to be used

h) Age cohort to be sampled

i) Sample Size (Flesh mass)

11.2. Sampling and analysis of samples

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

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

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

4) Non-compliance at any sampling point will require retesting as outlined in Appendix 6. If the retest fails, sampling should be expanded to trace the source of contamination. Production areas face long-term or permanent closure if the situation cannot be restored.

11.3. Contingency measures

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

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

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

12. BIOTOXIN MONITORING

1) Biotoxin monitoring is mandatory during harvesting periods (See Appendix 7). Farm managers must inform the Department of extended periods of no harvest and dates when harvesting is to be resumed. Failure to comply will result in temporary closure until testing is reinstated.

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

12.1. Biotoxin management plan

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

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

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

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

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

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

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

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

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

   h) Contingency measures should the regulatory levels be exceeded.

12.2. Sampling and analysis of samples

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Table 2: Maximum allowable time between routine biotoxin sampling events

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

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

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

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

12.3. Contingency measures

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

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

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

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

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

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

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

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

13. PHYTOPLANKTON MONITORING

13.1. Sampling and analysis of samples

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

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

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

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

14. REQUIREMENTS FOR HARVESTING AND TRANSPORT OF LIVE SHELLFISH

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

14.1. Harvesting requirements

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

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

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

3) Where necessary, shellfish shall be washed using clean seawater or potable water under pressure to remove mud, bottom sediments or attached biota as soon as practicable after harvesting. Wash water may not be recycled.

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

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

14.2. Transport and Vessels

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

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

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

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

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

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

14.3. Temperature control

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

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

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

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

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

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

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

   a) equipped with automatic temperature controls; and

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

14.4. Documentation and records

1) A movement document issued by the Department shall accompany each batch of live shellfish during transport from the production area up to, and including, arrival of the batch at a dispatch centre or processing establishment (see Appendix 8). The movement document must be completed in full and contain the following information:

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

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

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

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

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

6) The harvester must keep a copy on file of all movement documents issued recording all the information contained in the document for a period of not less than 5 years.

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

15. SAMPLING AND TRANSPORT OF SAMPLES

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

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

16. REQUIREMENTS FOR RELAYING SHELLFISH

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

16.1. Conditions

1) Relaying refers to the transfer of shellfish with limited levels of pollution to approved areas where the ambient environment provides the medium for biological depuration. Relaying may be applied to reduce microbial and biotoxin contamination to acceptable levels. Relaying is not recommended for the reduction of other toxic or hazardous substances unless studies are conducted that verify depletion of the contaminant(s) of concern to acceptable levels.

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

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

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

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

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

16.2. Source of shellfish

1) No shellfish that exceed the contaminant levels for restricted areas (Section 8.4) may be relayed. Shellfish must not be contaminated with biotoxins to the extent that safe levels cannot be achieved at the end of the relaying period.

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

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

16.3. Relaying areas

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

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

16.4. Operating procedures

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

   - Source and species of shellfish.
   - Contaminant levels of source shellfish and after depuration.
   - Methods of transport to the relaying site.
   - Relevant information regarding the use of a conditionally approved area for relaying.
   - Information on the water quality and quality of shellfish indigenous to the relaying area.
   - Method of holding shellfish at the relaying site and maintaining identity of individual source lots.

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

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

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

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

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

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

16.5. Records

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

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

2) The Department shall maintain records of the following:

- The sanitary survey reports and monitoring data for the relaying area.
- Approved procedures for operation of the relaying area.
- Results of product sampling and environmental monitoring by the relayer.
- Movement documents.

17. DEPURATION

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

17.1. Conditions

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

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

3) The premises and hygienic standards must comply with the Regulations Governing the General Hygiene Requirements for Food Premises and the Transport of Food, Regulation 638 published under the Foodstuffs , Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972). Certification of depuration plants shall require Approval of plant design, construction and operation including remodelling.

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

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

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

17.2. Process verification

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

- Shellfish species and source.
- Maximum pre-depuration level of faecal contamination to ensure that end point criteria are consistently achieved during normal operations (not to exceed limits given in Section 8.4).
- Design construction and operation of the plant with regard to flow rates, loading rates, tank dimensions and spacing of shellfish.

- Water quality variables such as temperature, salinity, dissolved oxygen and turbidity. Any seasonal effect must be addressed.
- Depuration times.
- End point criteria.
- Process monitoring.
- Plant sanitation.

17.3. Source of shellfish

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

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

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

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

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

17.4. Structural requirements

1) The construction of floors, walls, ceilings (where provided) and installation of lighting, plumbing and sewage disposal systems must comply with the provisions of the Regulation 638 published under the Foodstuffs , Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972).

2) Vermin control shall be implemented in accordance with Regulation 638 published under the Foodstuffs , Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972). Effective barriers shall be provided to prevent the entry of vermin, animals and birds into the area and above the storage tanks.

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

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

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

17.5. Process water quality and operation

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

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

   a) Treated water on entry to a depuration unit shall contain no detectable *E. coli*. Water must be sampled as described in the latest version of SANS 241 and analysed according to SANS 5221. Water treatment must not leave residues that will interfere with the depuration process or product quality.

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

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

3) Operational procedures shall promote water quality uniformity within depuration units. Consideration must be given to flow rates, tank loading rates and shellfish spacing as established in the process verification study.

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

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

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

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

17.6. Cleaning and Sanitizing of facilities, utensils and equipment

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

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

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

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

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

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

17.7. Quality assurance

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

2) Shellfish from single process batches may not be released to market unless laboratory results confirm that the end product meets the microbiological standards for approved areas (Section 8.3).

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

4) In the event of a process batch failing to meet the release criteria, the operator shall notify the Department and an investigation shall be conducted into the cause for failure. The following actions may be required through consultation with the local Health authority or the NRCS as relevant:

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

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

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

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

17.8. Records

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

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

18. WET STORAGE

Wet storage refers to the holding of live shellfish in near-shore waters or onshore tanks for temporary storage or conditioning purposes prior to processing/packaging for sale.

18.1. Conditions

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

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

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

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

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

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

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

   a) Should a production area supplying the wet storage be closed due to the biotoxin concentration in the shellfish exceeding the regulatory limit, the last batch to enter the wet storage shall be tested for the implicated biotoxin. Should the test result for the last batch be below the regulatory limit, the last batch and any prior batches contained in the wet storage may be placed on the market.

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

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

   a) Should the production area from which the wet storage plant draws its water be closed for biotoxins, the wet storage facility shall also be closed.

   b) Should there not be a biotoxin monitoring programme for the source waters of the wet storage plant, the shellfish shall be tested as stipulated in Appendix 3.

18.2. Source of shellfish

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

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

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

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

18.3. Structural and design requirements

1) As for depuration.

18.4. Water quality

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

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

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

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

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

6) Re-circulating systems or systems using water of a quality inferior to the approved water criteria must be treated. Treated water entering wet storage tanks shall have no detectable levels *E. coli*, as for depuration (Section 17.5) The following conditions apply:

   a) The operator of the facility shall conduct a study on the effectiveness of the disinfection process as assurance that the system will consistently supply water free of *E. coli* under normal operation. Samples of treated water entering the storage system shall be taken at a minimum frequency of 3/day over a period of 5 days. Additional samples shall be taken daily of untreated source water. Any positive sample for *E. coli* in treated water shall require corrective procedures and re-evaluation of treatment effectiveness.

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

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

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

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

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

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

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

b) Should any production areas in the vicinity be closed for biotoxins, the incoming filtered water shall be analysed once a week for phytoplankton until all production areas are re-opened.

18.5. Records

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

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

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

19. REQUIREMENTS FOR DISPATCH CENTRES

19.1. Receiving and storage

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

2) The premises and hygienic standards must comply with the Regulation 638 published under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972) and must be inspected at least once annually and approved by an NRCS inspector and/or relevant local health authority as is applicable. Dispatch centres must be issued with a permit as for a processing establishment in terms of the Marine Living Resources Act, 1998 (Act No. 18 of 1998).

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

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

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

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

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

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

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

19.2. Marking of consignments and records

1) All packages in a consignment of live shellfish shall bear a label so that the original dispatch centre may be identified at all times during transport and distribution until retail sale. The label shall contain the labelling requirements specified in the relevant regulations published under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972), Legal Metrology Act, 2014 (Act No 9 of 2014), Compulsory Specifications in terms of the National Regulator for Compulsory Specifications Act, 2008 (No. 5 of 2008) and importing country regulations where relevant.

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

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

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

19.3. Transport from a dispatch centre

1) The transport of live shellfish intended for human consumption must comply with the relevant provisions of Regulation 638 published under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972). Consignments of live shellfish intended for human consumption must be transported wrapped in sealed packages until offered for sale to the retailer, restaurant or end consumer.

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

3) Live shellfish must be transported and distributed using closed vehicles or containers which maintain the product at a temperature that does not adversely affect quality and viability. Live bivalves intended for the market in a live, chilled state must be brought to a temperature of 7°C or less before leaving the centre. Abalone, echinoderms and crustaceans shall be maintained at

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

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

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

19.4. Export

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

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

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

20. FEED MANAGEMENT AND MONITORING

20.1. Feed testing

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

20.2. Farm manager responsibility

1) Feed that is compounded industrially or at the aquaculture facility shall contain only such additives, growth promoting substances, flesh colouring agents; anti-oxidizing agents, caking agents, veterinary drugs or any other feed ingredient that are permitted for shellfish by the Department and/or relevant legislation. Substances prohibited in terms of relevant legislation shall not be used.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20.3. Feed producer responsibility

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

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

3) Labelling shall comply with relevant legislation.

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

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

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

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

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

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

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

21. DRUG MANAGEMENT

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

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

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

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

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

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

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

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

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

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

11) The Drug Procurement Register shall contain at least the following information:

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

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

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

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

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

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

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

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

22. SAMPLES AND SAMPLE TAKING

22.1. Sampling requirements

1) The responsibility of the FSO includes:

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

   b) compiling sampling plans relevant to this manual; and

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

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

   a) training, certifying and listing samplers;

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

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

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

   a) Sample size

   b) Sampling method

   c) Sampling equipment

   d) Tissue to be sampled

   e) Temperature control

22.2. Training of samplers

1) Samplers must be:

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

   b) certified by the competent authority.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

k) the significance of following correct procedures;

l) the classification and status of growing areas;

m) marine biotoxin management;

n) the patchiness of harmful algae blooms;

o) the significance of toxigenic phytoplankton monitoring;

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

q) the significance of timing in MCP strategy sampling;

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

s) the significance of routine sampling;

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

u) the organisation and management of sampling runs; and

v) occupational health and safety requirements.

22.3. Responsibilities of samplers

1) Every sampler must:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ii) before dispatching the sample to the laboratory; and

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

22.4. Sample submission forms

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

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

a) the name and contact details of the sampler;

b) the date and time the sample was taken;

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

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

e) the type of tests to be carried out.

22.5. Labels of samples

1) Samplers must ensure that each sample is labelled.

2) The label must:

a) clearly identify the sample to which it relates;

b) include a unique sample number;

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

d) the sample type; and

e) the date and time of sampling.

23. LABORATORY RESPONSIBILITY

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

2) Only validated test method shall be used.

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

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

5) The laboratory shall not accept official samples where:

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

23.1. Receipt of samples

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

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

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

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

   d) the sample packaging is intact;

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

   f) that the sample was received:

      i) within 24 hours after sample collection; or

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

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

      i) sampling occurred on the same day; and

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

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

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

   b) record the details of the defect;

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

   d) analyse as a priority any replacement sample.

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

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

23.2. Tracking systems

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

23.3. Sample temperature and storage

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

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

23.4. Method performance

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

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

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

   b) the laboratory considers this may affect the results.

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

   a) notify the FSO within 24 hours;

   b) investigate the response; and

   c) if possible, identify the unknown compound.

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

5) The FSO may direct a laboratory to:

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

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

24. REFERENCES

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

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

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

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

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

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

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

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

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25. SOUTH AFRICAN LEGISLATION

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

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

Appendix 1: Sanitary survey

1) Establishing sampling stations

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

   b) Water abstracted for onshore cultivation must comply with the requirements for an approved area (Section 8.3). If water is to be treated to conform to these requirements the microbiological quality of source water, prior to disinfection, and recirculated water shall meet, at a minimum, the restricted production area standards (Section 8.4). Water that does not meet the criteria for an Approved area may not be used for marine aquaculture.

   c) The production area survey in open waters shall take into account the proposed positioning of cultivation structures and potential pollution sources. Where a possible point source of pollution is indicated, a sampling station should be positioned on the boundary of the production area nearest to this point taking the predominant circulation patterns into account. The positioning of other non-pollution point microbiological sampling stations shall also be dictated by the local hydrodynamics. All sampling points must be fixed and indicated on a chart of the production area. Samples should be collected as close as possible to the nominal positions.

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

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

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

2) Frequency of Sampling Required for Classification

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

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

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

   d) If at any stage during the sampling regime the test results fall outside specifications, weekly sampling shall either be initiated until such time as the problem is identified. More frequent

sampling may also be required when environmental conditions indicate a high potential for faecal contamination.

e) The samples are to be taken by the Department sanctioned personnel (Section 7, paragraph 6) at a fixed frequency (determined by the Department) under sufficiently broad environmental conditions to identify possible adverse scenarios. It is expected that the collection of this information will cover a period of at least 12 months for full classification of an area. All data collected during this period will be used for classification purposes.

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

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

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

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

3) Sampling and analytical protocols for microbiological parameters

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

b) The five-tube, three-dilution MPN method of Donovan et al. (1998) is required for enumeration of *E. coli* (Appendix 4). Alternative methods for *E. coli*, including other MPN methods, should be validated against the reference method following an internationally accepted protocol (e.g. ISO 16140).

Appendix 2: Sanitary survey report

The following provides an outline of the many factors to be considered in performing and reporting on the sanitary survey as required in Section 8.2. These guidelines act as a checklist and provide a model for the structure of the report.

1) Summary

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

2) Background information

   a) Motivation for the study.

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

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

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

   e) History of production area classification:

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

3) Pollution source (shore line) survey

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

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

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

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

4) Hydrographic and meteorological characteristics

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

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

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

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

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

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

   g) River discharges – volumes and seasonality.

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

5) Water quality studies

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

   b) Map showing sampling stations.

   c) Description of sample collection and analytical procedures.

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

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

   f) Assessment of risk imposed by biotoxin producing phytoplankton.

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

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

6) Recommended classification.

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

7) Recommendations.

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

   b) Monitoring actions for biotoxins.

c) Monitoring actions for drugs and residues.

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

8) Enforcement action reports

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

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

9) Management plans

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

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

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

i) Wastewater treatment facility - performance standards based on:

- Peak effluent flow.
- Bacteriological, chemical and physical quality of the effluent.
- Bypasses.
- Design, construction and maintenance to minimise mechanical failure or overloading.
- Monitoring of wastewater treatment efficacy and feedback system in the case of inadequate treatment.

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

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

d) Implementation of conditional area closures.

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

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

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

e) Criteria for reopening a conditional area after a pollution event. The Department shall establish the following control elements to define re-opening criteria:

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

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

Appendix 3: Analysis methods and regulatory limits for biotoxins

BIOTOXIN	TEST METHODS	STANDARDS
Paralytic Shellfish Toxins (PST)		
Saxitoxin	^Lawrence method (AOAC Official Method 2005.06) (Commission Regulation (EC) No 1664/2006).	≤ 0.8 mg saxitoxin hydrochloride equivalent per kg edible flesh# (Regulation (EC) No 853/2004).
Lipophilic Shellfish Toxins (LST)		
Okadaic acid group toxins: OA, DTX 1, DTX 2 & DTX 3 and Pectenotoxins group toxins: PTX 1 & PTX 2	^Liquid Chromatography Mass Spectrometry (EU-RL* LC-MS/MS method) (Commission Regulation (EC) No 15/2011)	≤ 0.16 mg okadaic acid equivalent per kg edible flesh# (Commission Regulation (EC) No 853/2004).
Yessotoxins group toxins: YTX, 45 OH YTX, homo YTX, and 45 OH homo YTX	^Liquid Chromatography Mass Spectrometry (EU-RL LC-MS/MS method) (Commission Regulation (EC) No 15/2011)	≤ 8 mg yessotoxin equivalent per kg edible flesh# (Codex).
Azaspiracids group toxins: AZA1, AZA2 and AZA3.	^Liquid Chromatography Mass Spectrometry (EU-RL LC-MS/MS method) (Commission Regulation (EC) No 15/2011)	≤ 0.16 mg azaspiracid equivalent per kg edible flesh# (Commission Regulation (EC) No 853/2004).
Amnesic Shellfish Toxins (AST)		
Domoic acid	^High Performance Liquid Chromatography with UV detection after methanolic extraction and SAX-cleanup (Quilliam *et al.* 1995) (Commission Regulation (EC) No 2074/2005). Liquid Chromatography Mass Spectrometry (LC-MS/MS method)	≤ 20 mg domoic acid equivalent per kg edible flesh# (Commission Regulation (EC) No 853/2004).

*European Union Reference Laboratory

^ Reference Method

Includes intravalvular fluid with regard to bivalves

Appendix 4: Analysis methods and regulatory limits for microbiological contaminants

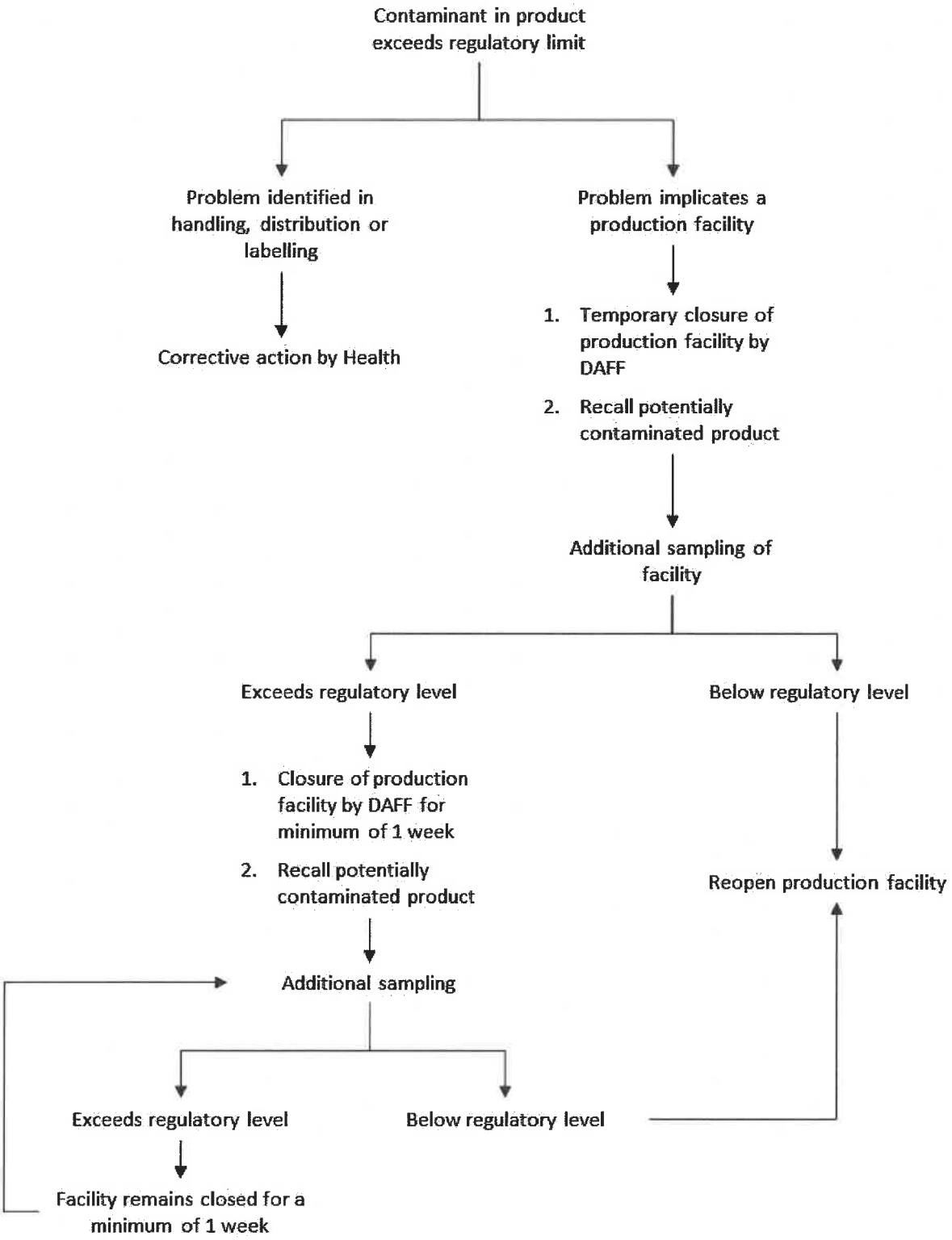
MICROBIAL AGENTS	**TEST METHOD**	**STANDARDS**
Escherichia coli	SANS 16649-3:2008/ISO/TS 16649-3:2005 (Donovan *et al.* 1998)	≤230.100g^{-1} edible flesh (Class A) <4 600.100g^{-1} g edible flesh (Class B)
Salmonella	SANS 6579:2003/ISO 6579:2002	Absence in 25 g
Vibrio cholerae & *V. parahaemolyticus*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

Appendix 5: Thresholds that trigger intensive biotoxin testing

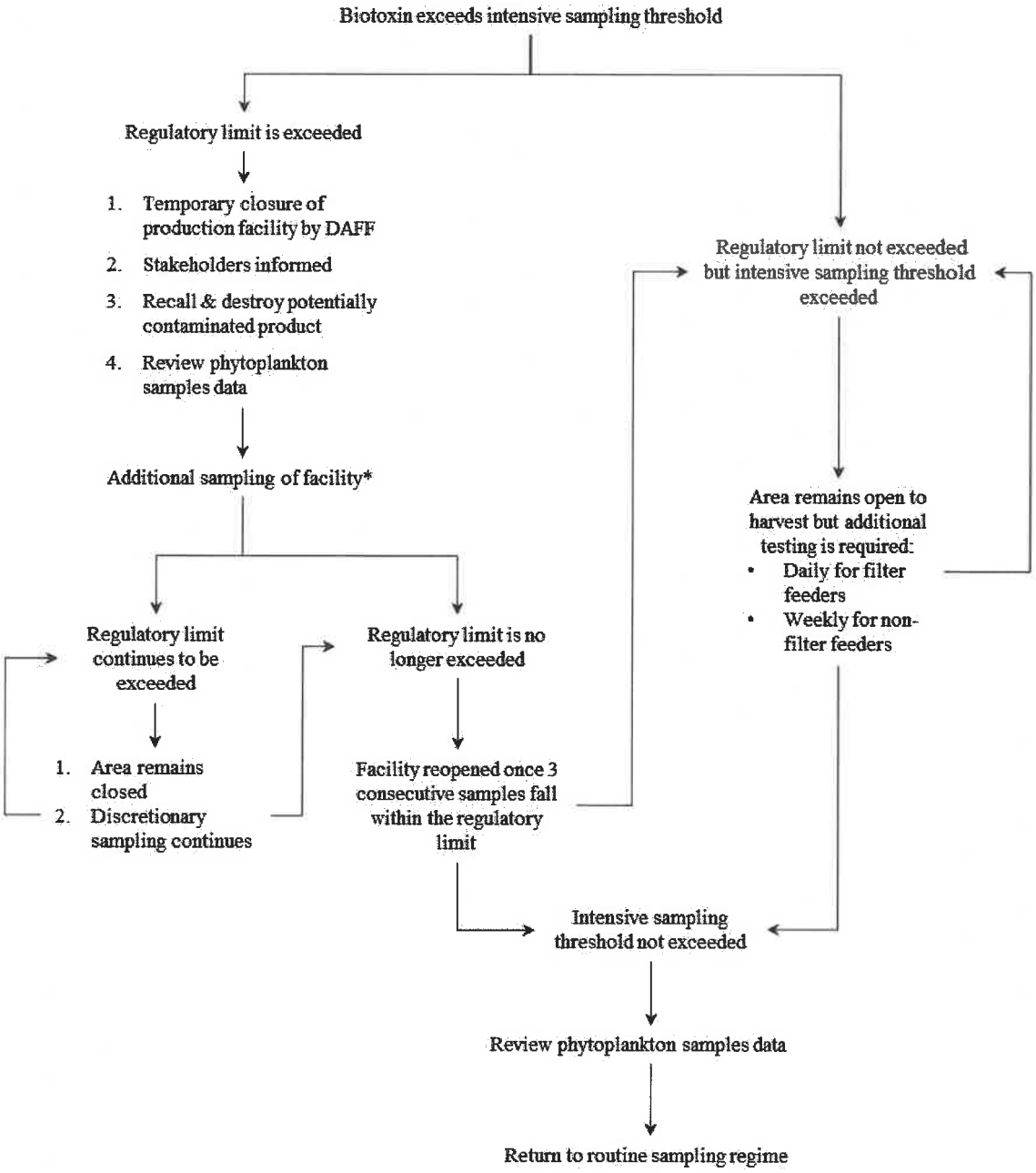
The following biotoxin concentration thresholds shall trigger daily testing for the implicated toxin in filter feeders and weekly testing in abalone, echinoderms or crustaceans if the production area is not temporarily closed for harvesting:

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

Appendix 6: Microbiological and hazardous substance contingency measures



Appendix 7: Biotoxin contingency measures



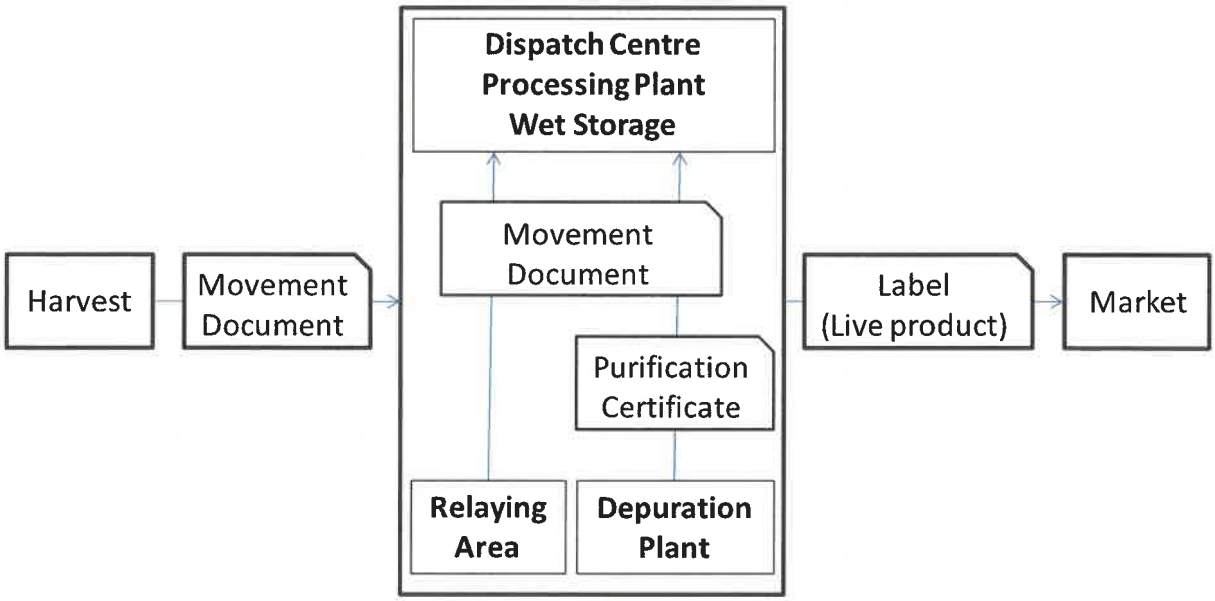
*Frequency of sampling is at farm managers discretion, but no more than one sample may be submitted per day. Multiple samples on the same day will be considered one sample.

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

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

2) A label is required for all batches of live shellfish dispatched from the FPE. This label allows the dispatch centre of origin to be identified.

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



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

Appendix 9: Phytoplankton species that are toxic to humans

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

Dinophyceae

Alexandrium catenella

Alexandrium minutum

Dinophysis acuta

Dinophysis acuminata

Dinophysis fortii

Dinophysis hastata

Dinophysis tripos

Dinophysis rotundata#

Protoceratium reticulatum

Gonyaulax spinifera

Lingulodinium polyedrum

Karenia cristata

Bacillariophyceae

Pseudo-nitzschia spp

Appendix 10: Prohibited substances

The following substances are prohibited during the growing of shellfish:

- Stilbenes
- Steroids
- Chloramphenicol
- Nitrofurans
- Nitroimidazoles

Appendix 11: Controlled substances

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

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

ANNEXURE 2

FOOD SAFETY SAMPLING PROGRAMME

Food Safety Sampling Plan 2022

Farm Code	Species	Organization name and Address	Biotoxin sampling	Microbiological sampling
		Northern Cape region		
FW 07	Abalone	Diamond Coast Aquaculture, Kleinzee	Week 1: PST, LST & AST (BSSA1) Week 3: PST (BSSA1)	N/A
FW 10	Abalone ranching	Port Nolloth Sea Farms, Kleinzee	Week 1: PST & LST, AST (BSSA2) Week 3 PST (BSSA2)	Week 1: *E coli* monthly for 12 months to attain full classification status.
FW 06	Abalone ranching	Diamond Coast Abalone	Week 1: PST & LST, AST (BSSA3) Week 3 PST (BSSA3)	Week 1: *E coli* monthly for 12 months to attain full classification status.
		West Coast region		
FW 09	Abalone	Doringbaai Abalone, Doringbaai	Week 1: PST, LST & AST Week 3: PST (BSSB2)	N/A
FW 01	Abalone	West Coast Abalone, St Helena Bay	Week 1: PST, LST & AST (BSSB1) Week 3: PST	N/A
FW 03	Abalone	Jacobsbaai Sea Products, Jacobsbaai	Week 1: PST, LST & AST (BSSB2) Week 3: PST (BSSB2)	N/A
-	Oysters Mussels	Small Bay Farms, Saldanha Bay	2/week 1,2,3,4: PST (SSS1) Week1: AST (SSS1) Week 1,2,3,4: LST (SSS1)	Week 1, 2, 3, 4 : (MSS1, MSS2 and MSS3)
-	Oysters Mussels	Big Bay Farms, Saldanha Bay	2/week: 1,2,3,4: PST (SSS4) Week1: AST (SSS4) Week: 1,2,3,4: LST (SSS4)	Week 1: (MSS4) Week 1: Sample *E coli* from the new bivalve production facilities in Big Bay
-	Mussels	Outer Bay North Farms, Saldanha Bay	2/week 1,2,3,4: PST (SSS2) Week1: AST (SSS2) Week 1,2,3,4: LST (SSS2)	Week 1: (MSS5) Week 1: Sample *E coli* from the new bivalve production facilities in Outer Bay North
		South West Coast region		
See Table 1	Abalone	Gansbaai Abalone Farms	Week 1: PST, LST & AST (BSSC6, BSSC7 and BSSC8) (see: Table 1)	N/A
See Table 1	Abalone	Buffeljags, Abalone Farms	Week 1: PST, LST & AST (BSSC9 and BSSC10) (see: Table 1)	N/A
See Table 1	Abalone	Hermanus Abalone Farms	Week 1: PST, LST & AST (BSSC1, BSSC2, BSSC3 BSSC5 and BSSC5) (see: Table 1)	N/A

Farm Code	Species	Organization name and Address	Biotoxin sampling	Microbiological sampling
FE 13	Abalone	Relmar Holdings (Tuna Marine), Hermanus	Week 1: PST, LST & AST	N/A
		South and East Coast region		
FE 16	Oysters	Zwembezi Farms, Port Elizabeth	Week 1: PST, LST & AST (ASSS1) Week 2: LST (ASSS1)	*Weekly E coli*: Wet storage *Weekly E coli:* Week 1: (AMSS 1) Post rainfall event only (AMSS 1)
FE 17	Abalone	Ulwandle Fishing, Port Elizabeth	Week 1: PST, LST & AST	N/A
-	Oysters	Siyazama Aquaculture, Hamburg	None at this stage	*E coli* weekly for 3 months and every two weeks for 9 months for classification purposes.
FE 11	Abalone	Wild Coast abalone, East London	Week 1: PST, LST & AST (BSSD1)	N/A

Heavy metals and residues are tested in accordance with the National Residue Programme

Abbreviations used: AST= Amnesic shellfish toxins, LST=Lipophilic shellfish toxins, PST=Paralytic shellfish toxins, MSS=Microbiological Sampling Station, SSS=Sentinel Sampling Station, E= test only for *Escherichia coli* MPN count according to ISO 16649-3.

Table 1: Official biotoxin sampling stations for abalone farms

Station	Represented Farms	Coordinates	Farm Code
BSSC1	Abagold Sea View and Amaza	34°26'4.65"S, 19°13'19.12"E	E 10
BSSC2	Abagold Sulamanzi	34°26'1.48"S, 19°13'8.07"E	E 10
BSSC3	Abagold Bergsig	34°25'56.02"S, 19°13'21.28"E	E 10
BSSC4	Aqunion Whale Rock	34°26'7.34"S, 19°13'16.25"E	FE 06
BSSC5	HIK Hermanus	34°26'2.69"S, 19°13'14.29"E	FE 04
BSSC6	I & J	34° 37.667'S, 19° 17.871'E	FE 08
BSSC7	Aqunion Romanbaai	34°36'5.47"S, 19°20'22.52"E	02 E
BSSC8	Premier Fishing	34° 35.421'S, 19° 20.326'E	FE 05
BSSC9	Buffeljags Abalone Farm	34° 45.261'S, 19° 36.765'E	FE 14
BSSC10	HIK Buffeljags	34°44'36.98"S, 19°36'5.20"E	FE 07

Table 2: New bivalve production facilities in Saldanha Bay (collect *E coli* Samples only)

Big Bay (Cluster 3)			**Farm Codes**
Simunye Mussels (A)	Mussels	33° 2'16.81"S, 18° 1'4.07"E	FW35
Simunye Mussels (B)	Mussels	33° 2'25.68"S, 18° 0'56.07"E	FW35
Atlantic Mussels	Mussels	33° 2'43.66"S, 18° 0'33.74"E	FW36
Ulwazi Kukutya	Mussels	33° 2'28.91"S, 18° 0'40.22"E	FW37
Wada Projects	Mussels	33° 2'0.56"S, 18° 1'2.53"E	FW38
Blue Lagoon Products	Oysters	33° 2'9.38"S, 18° 1'32.20"E	FW43
Well Done Works (A)	Mussels	33° 2'21.79"S, 18° 1'18.71"E	FW39
Well Done Works (B)	Mussels	33° 2'28.22"S, 18° 1'21.26"E	FW39
CEX Enterprises	Mussels	33° 2'5.29"S, 18° 1'17.43"E	FW44
K2019005713 (K13)	Mussels	33° 2'3.19"S, 18° 1'10.21"E	FW52
K2019005725 (K25)	Mussels	33° 1'58.65"S, 18° 0'55.45"E	FW45
Lagoon Aqua Farm	Mussels	33° 2'6.94"S, 18° 1'24.81"E	FW46
Madima General Agriculture Trading	Mussels	33° 2'21.63"S, 18° 0'39.46"E	FW47
Mika	Mussels	33° 2'34.97"S, 18° 0'49.59"E	FW48
MMM Agri Consult	Mussels	33° 2'14.67"S, 18° 0'51.77"E	FW49
Molapong	Mussels	33° 2'26.25"S, 18° 0'15.99"E	FW50
Pluto Mussels and Trading	Mussels	33° 2'15.17"S, 18° 0'36.44"E	FW51
Outer Bay North (Cluster 4)			
Xesibe A	Mussels	33° 2'17.33"S, 17°56'52.28"E	FW42
Xesibe B	Mussels	33° 2'28.97"S, 17°56'39.71"E	FW42

ANNEXURE 3

SOUTH AFRICAN CULTURED MARINE FISH MONITORING AND CONTROL PROGRAMME

forestry, fisheries
& the environment

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

SOUTH AFRICAN CULTURED MARINE FINFISH

MONITORING AND CONTROL PROGRAMME

Branch: Fisheries Management

Chief Directorate: Aquaculture & Economic Development

Directorate: Sustainable Aquaculture Management

Version IV: May 2022

TITLE

South African Cultured Marine Fish Monitoring and Control Programme

COMMENCEMENT

This programme comes into force on 1 May 2022.

REVOCATION

This programme version revokes and replaces South African Cultured Marine Fish Monitoring and Control Programme, Version III.

This South African Cultured Marine Finfish Monitoring and Control Programme is published as a measure to facilitate compliance with regulation 73 of the Regulations in terms of the Marine Living Resources Act (Government Notice R1111 in *Government Gazette* 19205 dated 2 September 1998).

DIRECTOR SUSTAINABLE AQUACULTURE MANAGEMENT

DATE: 2022/4/21

Contents

Tables

Appendices

1. BACKGROUND

Food safety laws throughout the world give special consideration to finfish for several reasons, one of which is the fact that they accumulate environmental residues from the aquatic environment in which they are cultured, or through their feed, which may contain hazardous residues. Finfish 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.

2. PURPOSE

The purpose of this the Programme is to identify, monitor, evaluate and manage the risks associated with the commercial grow-out, harvesting, sorting and transporting of finfish for human consumption. In this way the necessary safeguards are put in place and assurances may be provided to local and international markets and foreign governments regarding the safety of the cultured finfish for human consumption.

3. SCOPE AND AUTHORISATION

The Programme addresses, amongst others:

1) The public health concerns of finfish harvested from marine aquaculture production areas which is intended for direct human consumption or for further processing prior to consumption. It should be noted that hatcheries and nurseries are not subject to these public health requirements provided that the product is not harvested and/ or processed for human consumption within 6 months from the date when the finfish reaches minimum market size; the limited processing activities carried out post-harvest, such as packing, gilling and gutting, in facilities that are situated on the production site and applies to finfish as defined in this programme' and all activities related to the commercial farming of finfish prior to market, including production, harvesting, packaging, dispatch, transporting, labelling and storage.

2) The placing on the market of fresh and frozen and the canning of finfish is controlled by the relevant Compulsory Specifications published under the National Regulator for Compulsory Specifications (NRCS) Act, 2008 (Act No. 5 of 2008) and is therefore not included in this programme.

3) The monitoring activities required for audit of production areas and establishments in the interests of public health are covered in the Programme. These activities are 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 NRCS, the statutory body responsible for administering the various Compulsory Specifications for fishery products in South Africa.

4) The functions of this programme are to set standards and monitoring requirements to ensure that finfish intended for human consumption, or for further processing prior to consumption, meet safety thresholds with respect to hazardous substances and environmental and veterinary drug residues. It addresses the requirements for the certification and/ or issue of permits for the production, harvesting, feed and drug management, transport and handling of finfish.

4. DOCUMENT CONTROL

The Programme has been prepared by the Department in association with the division Food and Associated Industries within the NRCS and the finfish farming industry. The programme may be reviewed

and amended as pertinent new information becomes available. Any review process will include consultation with representatives from the Department, NRCS, industry, and the Department of Health, including provincial and/or municipal health authorities where applicable. Table 1 below shows all previous iterations of the Programme.

Table 1: Publications of the South African Finfish Monitoring and Control Programme

Version	Date of issue
I	01 September 2013
II	01 January 2015
III	01 January 2016

Suggestions for amendments which would improve the Programme should be forwarded to the co-ordinator, supported by the rationale for the 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

A detailed record of all amendments is kept by the Department and the latest version is available on the Department's website http://www.dffe.gov.za. A copy can also be requested from JFoord@dffe.gov.za.

5. DEFINITIONS

"Acceptable" means acceptable to the Department responsible for the approval and licensing of finfish production and harvesting waters and to the competent authority responsible for inspecting and certifying such product for export (where applicable).

"Accredited laboratory" for the purposes of the Programme means any laboratory as contemplated in the Accreditation for Conformity, Assessment, Calibration and Good Laboratory Practice Act 2006 (Act No. 19 of 2006).

"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.

"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).

"Central file" means the file system maintained by the persons responsible for management of this programme in the Department.

"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 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 finfish.

"Closed area" means a production area where the harvesting of finfish 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.

"Degree day" is 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

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

"Facility number" means the official approval number for a production area issued by the Department.

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

"Finfish" means the fish in the class Osteichthyes.

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

"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 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 finfish by any means from a production area.

"Health Authority" means 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).

"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, 1998 (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.

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

"Point source" 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.

"Processing" means the physical or chemical treatment of finfish that substantially alters the initial product in a manner that adds value 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. Packing and repacking are also regarded as processing for the purpose of this document.

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

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

"the Programme" means the South African Cultured Marine Finfish Monitoring and Control 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 the form used to document each purchase or sale of finfish at the wholesale level.

6. ABBREVIATIONS

"BMP" means Better Management Practice

"CoA" means Certificate of Acceptability

"EC" European Commission

"FPE" means Fish Processing Establishment

"FSO" means Food Safety Office

"HACCP" means Hazard Analysis and Critical Control Point

"ILAC" means International Laboratory Accreditation Cooperation

"MLRA" means Marine Living Resources Act, 1998 (Act No. 18 of 1998)

"MRL" means Maximum Residue Limit

"NRCP" means National Residue Control Programme

"NRCS Act" means National Regulator Compulsory Specifications Act, 2008 (Act No. 5 of 2008)

"NRCS" means National Regulator for Compulsory Specifications

"NRP" means National Residue Plan

"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

7. RULES

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

2) The Department is the regulatory authority authorising the undertaking of aquaculture activities, i.e. farming, harvesting and transporting of finfish for wholesale trading in terms of the MLRA and associated regulations. Authorisations are administered through the granting and issuing of Marine Aquaculture (mariculture) Rights and permits respectively.

3) The NRCS is recognised internationally as the competent authority that provides 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 specifications as well as through market surveillance to ensure compliance with the requirements of the compulsory specifications and technical regulations published under the NRCS Act.

4) Establishments packing or processing finfish 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 CoA issued by the local municipality or 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 at least 3 months prior to expiry. Each establishment must be issued with a CoA by the local municipality or approved by the NRCS annually (or for the time permissible by a conditional approval obtained from the NRCS).

5) The Programme addresses all activities related to the commercial farming of finfish prior to placing it on the market, including the production, harvesting, packaging, dispatch, transporting, labelling and storage of finfish. The processing of finfish is controlled by the relevant compulsory specifications published under the NRCS Act.

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

7) Where inter-governmental guarantees are sought (health certificate), the NRCS will be provided with access to records kept by the Department.

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

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

   - Copies of permits and other approvals;
   - official laboratory test reports (certificates);
   - monitoring data and notices;
   - enforcement action reports (e.g. contingency notifications, warnings etc.); and
   - correspondence with harvesters and producers.

10) The officially approved inspector servicing an establishment where finfish are processed must also keep a file containing amongst others, inspection reports and sample requisition forms.

11) Industry shall keep complete, accurate and legible finfish 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 and establishment packing and/or processing finfish. Such records shall include:

- All information necessary to trace all purchases and sales of finfish back to their production area;
- dates of harvesting of finfish and of their arrival at the licensed premises for the intended process, including dates of packing and dispatch; and
- results of laboratory analyses instigated by industry.

12) Producers that export are required, in addition, to comply with the importing country's requirements.

8. SITE SELECTION

1) The siting, design 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 taken into account 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 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. MONITORING OF FINFISH PRODUCTION AREAS

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

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

3) The Department must maintain an updated list of farms indicating each farm's 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 finfish are intended for export, the official limits applicable to the importing country shall be adhered to.

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

10. MICROBIOLOGICAL MONITORING

1) Microbiological monitoring will be undertaken in the end-of-line products by the NRCS.

2) The regulatory limits for microbiological contamination and the recognised test methods are included in the relevant regulations published under the Foodstuffs Act and as per the relevant compulsory specifications administered by the NRCS for the relevant packaged products.

11. MONITORING OF ENVIRONMENTAL AND VETERINARY DRUG RESIDUES

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

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

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

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

11.1. National Residue Plan and National Residue Control Programme

1) Residues monitored shall include, though not be limited to those substances listed in Appendix 1 and where relevant Appendix 2.

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

   a) Compound or marker residue;

   b) matrix to be analysed;

   c) screening method where relevant;

   d) confirmatory method;

   e) screening method level of detection (LOD) where relevant;

   f) confirmatory method LOD;

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

   h) accredited laboratory to be used.

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

   a) Farm name and farm code;

   b) sampling date;

   c) sample reference number;

   d) compound to be tested;

   e) test method;

   f) sample condition i.e. frozen or chilled;

   g) matrix to be tested;

   h) laboratory to be used;

   i) age cohort to be sampled; and

   j) sample size (flesh mass)

11.2. Sampling and analysis of samples

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

2) Sampling for specific contaminants is recommended when there is concern due to a paucity of data or there is a known risk.

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

11.3. Contingency measures

1) Non-compliance at any sampling point will require retesting as outlined in an official standard operating procedure. If the retest fails, sampling must be expanded to trace the source of contamination. Production areas face long-term or permanent closure if the corrective action is not effective.

2) In the case where non-compliant environmental contaminants or veterinary drug residue test results are confirmed the procedures outlined in an official contingency standard operating procedure drafted by the Department shall be followed.

3) Where an event occurs (such as the spillage of a toxic substance for example) the Department is required temporarily to close the affected finfish production area immediately, if in the opinion of the Department the event may pose a food safety risk.

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

12. REQUIREMENTS FOR HARVESTING AND TRANSPORT OF HARVESTED FINFISH

This section deals with the requirements for harvesting and transport of harvested finfish to a fish processing establishment (FPE).

12.1. Harvesting and slaughtering requirements

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

2) Harvesting techniques shall be undertaken efficiently and in a humane manner, must not cause excessive trauma to the finfish and no incisions shall be made into the finfish.

3) 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.

4) 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.

5) Once removed from the ice slurry the fish 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 continuously drained out of the bins, without contaminating bottom bins if the bins are stacked on top of each other.

6) All equipment and holding facilities shall be easy to clean and to disinfect and shall be cleaned and disinfected regularly and as appropriate.

7) Containers for storage of finfish must be clean and made from impervious, easily cleanable materials.

12.2. 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 finfish.

4) Where the vessel or vehicle deck is not channelled, graded or adequately drained, the finfish 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 approved by the official inspector.

6) Human waste (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 finfish for processing shall comply with the requirements stipulated in a standard operating procedure for vehicles and vessels that will form part of this programme. The vehicles and/ or vessels shall be constructed, operated, cleaned and maintained so as to prevent contamination, deterioration or decomposition of the finfish transported.

13. TIME AND TEMPERATURE CONTROL

1) All finfish harvested for human consumption must be temperature controlled from the time of harvesting.
2) Chilling shall commence as soon as possible after harvesting.
3) Finfish shall be kept chilled, processed and distributed with care and minimum delay.
4) Sufficient and adequate icing or chilled or refrigerated water systems where appropriate, shall be employed to ensure that finfish are kept chilled at a temperature below 5 °C and as close as possible to 0 °C once slaughtered.
5) Finfish shall be stored in shallow layers and surrounded by finely divided melting ice to maximize cooling capacity.
6) Chilled or refrigerated water systems and/ or cold storage systems should be designed and maintained to provide adequate cooling and/ or freezing capacities during peak loads.
7) Finfish shall not be stored in refrigerated water systems to a density that impairs its working efficiency.
8) 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.
9) A documented control program shall be implemented to guarantee that temperature monitoring is in place and that the requirements stipulated above are complied with.

14. HANDLING OF FINFISH

1) Poor handling practices can lead to damage of finfish that can accelerate the rate of decomposition and increase unnecessary post-harvest losses.
2) Finfish must be handled and conveyed with care particularly during transfer and sorting in order to avoid physical damage such as puncture and mutilation.
3) Finfish shall not be trampled or stood upon.
4) Where boxes are used for storage of finfish, they should not be overfilled or stacked too deep.
5) While finfish are on deck, exposure to the adverse effects of the elements should be kept to a minimum in order to prevent unnecessary dehydration.
6) In refrigerated water storage areas, the density of the fish shall be controlled to prevent damage.

15. TRACEABILITY SYSTEM

1) A traceability system 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 required. The requirement relies on the 'one-step back-one-step forward' approach.
2) The Department shall compile a standard operating procedure that shall form part of this programme, 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 relevant standard operating procedure referred to in paragraph 15, sub-paragraph 2) in order to ensure traceability of the product from farm to final sale as is applicable.

4) Production facilities and/ or FPEs shall ensure effective procedures are in place to implement the complete product tracing and rapid recall of any lot of non-compliant fishery product from the market.

16. SAMPLING AND TRANSPORT OF SAMPLES

1) The Department shall compile a standard operating procedure that shall form part of this programme, which details the procedures and requirements for sampling and transport of samples for food safety testing

2) The sampling and transport of samples shall be implemented in terms of the relevant standard operating procedure indicated in paragraph 20.1, sub-paragraph 3).

17. REQUIREMENTS FOR FISH PROCESSING ESTABLISHMENTS

17.1. Receiving, sorting and storage

1) The premises and hygiene standards must comply with the Regulation 638 and must be inspected at least once annually and approved by an NRCS inspector and/ or relevant local health authority as is applicable. A FPE may not conduct fish processing activities in the absence of a permit to operate as a processing establishment in terms of the Marine Living Resources Act, 1998 (Act No. 18 of 1998).

2) Finfish 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.

3) Finfish must have been harvested and transported according to the requirements of this Programme (Section 12).

4) Finfish shall be processed within 24 hours of harvesting.

5) In any sorting or dry storage area, finfish must comply with the temperature control requirements stipulated in Section 13.

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

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

8) Finfish 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 finfish in a particular consignment and all associated production sites shall be managed together during the implementation of contingency measures.

9) The food business operators shall have a system in place enabling them 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 food business operator to whom the fish was supplied must be included. The requirement relies on the 'one-step back'-'one-step forward' approach.

17.2. Packaging material

1) Subject to the relevant requirements of the Regulations promulgated under the Foodstuffs, 1972, 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. The fish product shall be packed in a dustproof and liquid-proof container.

17.3. Marking of consignments and records

1) All packages and containers in a consignment of finfish products 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 Act, the Legal Metrology Act, 2014 (Act No 9 of 2014), Compulsory Specifications in terms of the NRCS 2008 (and the importing country's 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 sent and received for a period of not less than 5 years to enable products to be traced and recalled if necessary.

4) If finfish 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.

17.4. Transport from a fish processing establishment

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

3) Finfish products must be transported and distributed using closed vehicles or containers which maintain the product at a temperature that does not adversely affect quality and viability. Chilled finfish products intended for the market must be brought to a temperature of melting ice, with a deviation of not more than 2°C, before leaving the FPE. This temperature shall be maintained during transport and storage.

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

5) Ice used for temperature control must have been made from Potable Water or Clean Seawater.

17.5. 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 recognised by the Department in accordance with the requirements of the country of destination. As required, finally prepared and packaged finfish will be monitored on the basis of a random testing and surveillance programme, in addition to the sampling of product prior to dispatch.

18. FEED MANAGEMENT AND MONITORING

18.1. Feed testing

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

18.2. Farm manager responsibility

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

2) Each batch procured shall be recorded on a 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

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

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

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

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

7) The storeroom shall be dry, well ventilated and kept clean.

8) The storeroom must be vermin proof.

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

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

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

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

13) Feeds medicated after procurement shall be clearly labelled as medicated on the package. The label shall indicate what medication was used.

14) Medicated feed shall be stored separately from the non-medicated feed.

15) Feed that is produced by a farm shall meet the requirements stipulated in Section 18.3.

18.3. Feed producer responsibility

1) Feed that is compounded industrially or at the aquaculture facility shall contain only such additives, growth promoting substances, flesh colouring agents; anti-oxidizing agents, caking agents, veterinary drugs or any other feed ingredient that are permitted for finfish by the Department and/ or relevant legislation. Substances prohibited in terms of relevant legislation shall not be used.

2) Feed producers which supply feed to the aquaculture industry are required to be registered with the Department of Agriculture, Land Reform and Rural Development. 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.

3) The feed importer or local distributor shall ensure that a CoA accompanies the registration forms and that the product is safe for fish consumption.

4) 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.

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

6) 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.

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

8) Labelling shall comply with relevant legislation.

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

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

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

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

13) Medicated feed shall be stored separately from the non-medicated feed.

19. DRUG MANAGEMENT

1) Veterinary drugs or medicated feeds should be used according to manufacturer instructions, with particular attention to withdrawal periods.

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

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

5) Veterinary drugs listed in Appendix 1 shall not be used and shall be monitored for in the finfish.

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

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

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

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

10) A post-harvest control shall reject all finfish 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 Drug Procurement Register shall contain at least the following information:

- Date purchased
- Supplier's name and contact details
- Name of drug
- Quantity purchased
- Batch number
- Expiry date
- Withdrawal period

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

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

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

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

16) Withdrawal times shall be observed before finfish is harvested for human consumption.

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

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

- Date of movement
- Name and facility number of the production facility receiving the finfish and /or origin of the finfish
- Quantity (mass) of finfish transferred.
- Note any chemical or drug treatment of the finfish at least 200 Degree Days prior to movement.

20. SAMPLES AND SAMPLE TAKING

20.1. Sampling requirements

1) The responsibility of the FSO includes:

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

   b) compiling sampling plans relevant to this manual;

2) The responsibility of the duly authorised sampling service provider includes:

   a) sampling of the aquaculture facilities;

   b) training and competency verification;

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

   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 a standard operating procedures drafted by the Department. The SOP shall include:

   a) Sample size

b) Sampling method

c) Sampling equipment

d) Tissue to be sampled

e) Temperature control

f) Sample Identification

20.2. Training of samplers

1) Samplers must be:

a) trained and audited by or under the supervision of the service provider duly authorised by the Department; and

b) certified by the NRCS or 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; and

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 all of the following where relevant:

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

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

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

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

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

f) the significance of the number of finfish to be collected including the variation in contaminants between individual finfish;

g) the correct method for taking finfish samples for residue analyses;

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

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

j) the significance of following correct procedures;

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

l) the organisation and management of sampling runs; and

m) occupational health and safety requirements.

20.3. Responsibilities of samplers

1) Every sampler must:

   a) follow the procedures outlined in a standard operating procedure on sampling and transport of samples;

   b) ensure that the equipment used during sampling 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 drug 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) complete the sample submission form in writing and sign it:

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

      ii) before dispatching the sample to the laboratory;

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

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

20.4. Sample submission forms

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

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

   a) address of the Department;

   b) the name and contact details of the sampler;

c) the date and time the sample was taken;

d) sample batch code;

e) official code number of the sample;

f) animal species;

g) sample matrix;

h) the sample station code, name;

i) substances or substance groups for examination; and

j) particular remarks.

20.5. Labels of samples

1) Samplers must ensure that each sample is labelled. 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.

21. 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 standard operating procedure published in terms of this programme.

22. LABORATORY RESPONSIBILITY

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

2) Only validated test method shall be used and that is either accredited to ISO 17025, or in the process of being accredited to ISO 17025.

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

4) 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.

5) The laboratory shall not accept official samples where:

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

- The sampling report is incorrect or incomplete

22.1. Receipt of samples

1) When a laboratory receives a sample, it must check the following:
   a) that the sample is clearly marked or identified to allow it to be traced back to the sample submission form;
   b) that the information on the sample submission form is consistent with the sample;
   c) the sample provided is suitable for the particular test required;
   d) the sample packaging is intact;
   e) there are no visible signs of contamination of the sample;
   f) that the sample was received:
      i) within 24 hours after sample collection and is chilled (<10°C); or
      ii) if delivery was delayed, within 48 hours after sample collection, but only if the sample is frozen and is determined to be still suitable for analysis by the laboratory.
   g) the sample temperature for microbiological samples is less than 10°C, unless:
      i) sampling occurred on the same day; and
      ii) the sample has not had adequate time if placed in a chilled container to reach a temperature cooler than 10°C.
2) If any of the requirements of this clause are not met, or if the laboratory considers the sample may not be suitable for testing, the laboratory must:
   a) decide whether to analyse the sample or seek direction from the FSO;
   b) record the details of the defect;
   c) notify the FSO within 1 working day of sample receipt; and
   d) analyse as a priority any replacement sample.
3) The 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) 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
5) The laboratory must keep records of all notifications given to FSO under this clause.
6) The FSO must keep records of action taken as a result of reported laboratory non-compliances.

22.2. Tracking systems

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

22.3. Sample temperature and storage

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

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

22.4. Method performance

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

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

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

   b) the laboratory considers this may affect the results.

3) The FSO may direct a laboratory to:

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

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

22.5. Reporting of test results

1) Obtain permission from the production facility to share the official test results with the Department and submit the test results to the Department on the same day the results are finalised.

2) The test certificates shall include at least the following information:

   a) Sample description that includes the facility identification

   b) Sample batch number

   c) Sample date

   d) Date Received

   e) Test method used and whether or not it is accredited

   f) Contaminant tested for and the contaminant level

23. REFERENCES

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

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

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

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

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

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

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

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SANS 241: 2015 Drinking Water.

SANS 5221: 2012 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.

Appendix 1: Prohibited substances

The following substances are prohibited during the growing of finfish:

- Stilbenes
- Steroids
- Chloramphenicol
- Nitrofurans
- Nitroimidazoles

Appendix 2: Controlled substances

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

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

Appendix 3: South African Legislation

The following South African legislation is applicable to the South African Finfish Monitoring and Control 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)Medicines & Related Substances Control Act, 1965 (Act No. 101 of 1965)
6. Municipal Structures Act, 1998 (Act No.117 of 1998)
7. National Health Act, 2003 (Act No. 61 of 2003)
8. 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
9. South African water quality guidelines viz. SANS 241
10. Veterinary and Para-veterinary Professions Act, 1982 (Act No. 19 of 1982)

ANNEXURE 4

NRCP SAMPLING SCHEDULES 2022

This annexure should be requested from MLRFTENDERS@DFFE.GOV.ZA and it will be provided to the bidder/s upon signing a confidentiality form.

ANNEXURE 5

SOP SAMPLING & TRANSPORT OF AQUACULTURED MARINE FISH

NRCS. BU	FOOD AND ASSOCIATED INDUSTRIES			Copy No:
DOCUMENT:	PROCEDURE			Page 1 of 8
SUBJECT:	SAMPLING AND TRANSPORT OF AQUACULTURED MARINE FISH			Document no: 574 Proc. 051
				Rev (Amdt) No: 00
Compiler:	Technical Coordinator FAI	Signature:		Effective date: 2018-03-01
Approving officer:	General Manager	Signature:		

1.SCOPE

This document covers the procedures for the sampling, control, handling and transport of shellfish and finfish that is aqua-cultured at official monitored and controlled production areas that are approved and classified by DAFF. Sampling of shellfish and finfish takes place at various production areas that are located over a wide area in South Africa, covering but not limited to the East Coast and the West Coast.

2.BACKGROUND

Shellfish such as mussels, oysters, etc. and finfish are deemed by the international trading countries as specialized products that command a high price in the market.
The South African aquaculture industry has established international markets, especially in the East for the export of shellfish predominantly in the aqua-cultured state.
The Industry with Government identified the development and promotion of the aquaculture industry as a key component of the Ocean Economy to be tapped into, in order to promote this industry.
NRCS with DAFF established the South African Molluscan Shellfish Monitoring and Control Program and the South African Aqua-cultured Marine Fish Monitoring and Control Program.
A memorandum of understanding was also established between DAFF and NRCS, where NRCS are responsible to administer and implement the sampling programme for marine aquaculture farms in terms of the two above-specified sanitation programs.

3.DEFINITIONS

3.1- Representative Sample- Is a sample that is drawn on a random basis, that is unaltered from sampling until testing and that has been taken at the correct sampling point in the production area.
3.2- Aqua-cultured Marine Finfish- Is finfish that has been aqua-cultured for human consumption.
3.3- Aqua-cultured Shellfish- Is marine Molluscan shellfish and crustaceans that have been aqua-cultured for human consumption.

4.GENERAL PRINCIPLES

- Sampling shall be strictly executed according to this procedure
- Sampling shall be executed at the harvesting area and not at the pack-house or at shore, to ensure trace-ability of the samples at all times
- Sampling shall strictly be undertaken by the sampling officer
- Samples shall under no circumstances leave the control of the sampling officer unless couriered by a third party to the laboratory
- Samples shall only to be taken at the unique coordinates and sign that will be clearly posted at each sampling point, when applicable
- No samples shall be taken in the absence of such marked and identified sampling points, when applicable
- In the event where the sampling cannot be executed at the required frequency, due to unforeseen circumstances (bad weather, breakdown of transport vessel), then this to be immediately reported to the manager responsible for the particular area. Sampling to be executed the very next day if unforeseen circumstances do not persist
- The temperature of samples with a transport time of less than 4 hours to be less than the temperature at the point of sampling, when reaching the laboratory
- samples should be cleaned of dirt, sediment and other organisms
- samples shall be cleaned in the sea water at the sampling site

- samples shall be drained before being placed in the sampling bag
- the labels to be affixed to the sampling bags directly after sampling
- Damaged and diseased specimens shall not be sampled
- Sampling shall be done under optimum hygienic conditions
- Bio-security procedures at production sites to be respected and followed
- Full trace-ability shall be effected to all samples at the sampling point
- Sampling officers to report unusual observations, such as boating activity, dredging activities, animals in the water, plankton blooms, etc.)
- Samples for chemical testing shall not be in spawning cycle state and condition
- All necessary equipment shall at all times be available and coordinated by the sampler
- All samples to be secured and sealed by the sampler to ensure that it is tamper proof
- For veterinary residues and contaminants testing the residue sampling report to be completed
- For micro testing the BF 97 to be completed
- For bio-toxin testing the BF 42A to be completed
- All samples to be accompanied by a sample submission form obtainable at the respective laboratories
- The sampling form shall be clearly and neatly completed for all samples
- samples shall be identified with the following information on the labels:
    - collectors name
    - source or production area identifier
    - position of sampling
    - the time and date of sampling
    - intended analysis

5.TESTING VETERINARY RESIDUES & CONTAMINANTS

- The production facility, veterinary drug residues and environmental contaminants to be tested for in finfish and abalone are listed in the South African Finfish Residue Plan and the South African Abalone Residue Plan respectively.
- The sample size and sampling frequency for finfish and abalone is outlined in the Finfish Residue Sampling Schedule and Abalone Residue Sampling Schedule respectively.
- Samples collected for analysis for veterinary medicinal products and environmental contaminants (excluding dyes) shall comprise of stock close to the market size.
- Samples to be tested for unauthorized substances (including dyes) shall be taken at farm level at all stages of farming including fish ready to be placed on the market for consumption.
- The samples shall be placed into a waterproof bag that is tied off and then placed into a tamperproof bag that is to be securely sealed to prevent tampering of the sample. S
- The samples bag shall be clearly labeled as outlined below.
- Where a tamperproof bag is used, the seal number shall be accurately recorded on the Residue Sampling Report (Appendix 2) and the Laboratory Sample Submission Form (Appendix 3).
- The samples shall be chilled for same day delivery, otherwise frozen.
- The laboratory shall log whether or not the sample arrived in a tamper proof bag and that it was not tampered with.

- Should the sample arrive in tamper proof bag, the laboratory shall cut the bag open along the dotted line at the bottom of the tamper proof bag as evidence that the seal at the top of the bag was not tampered with.
- A sub-sample and, the tamper proof bag, shall be kept by the laboratory until requested to be disposed of by the South African Molluscan Shellfish Monitoring and Control Programme office. This is in the event of a retest being required for legal processes.

6.TESTING MICROBIOLOGICAL CONTAMINANTS

- The following microbiological contaminants are tested for in bivalves
  - E. coli
  - Salmonella
  - Vibrio cholera
  - Vibrio parahaemolyticus
- Abalone samples from the production area shall be tested for *E. coli* should the end-of-line product exceed the regulatory requirements as per the SAMSM&CP.
- The sample size and sampling frequency for shellfish is outlined in the Microbiological and Biotoxin Sampling Schedule.
- Samples collected for analysis for microbiological contaminants shall comprise of stock close to the market size.
- The stated Representative Monitoring Point (RMP) location should be used to identify the position of sampling for bivalves.
- The samples shall be placed into a sterile waterproof bag that is tied off and then placed into a second clear bag.
- The samples shall be clearly labelled as outlined below.
- The label shall be placed into a water proof sleeve and placed into the second bag referred to above.
- Samples should be transported in cooler boxes between 2°C and 10°C.
- In the event of overnight storage, micro samples to be stored at 3±2°C.
- The samples shall arrive at the laboratory within 24 hours of sampling.

SPECIES	Sample size (Min 100 g flesh)
Abalone	5
Lobster	5
Mussels	30
Oysters	20

7.TESTING BIOTOXINS

- The following biotoxins shall be tested for in shellfish (abalone, bivalves and crustaceans) that utilize natural seawater for production:
  - Paralytic Shellfish Poisoning toxins
  - Diarrhetic Shellfish Poisoning toxins
  - Amnesic Shellfish Poisoning toxins

- The sample size and sampling frequency for the shellfish is outlined in the Microbiological and Biotoxin Sampling Schedule.
- sampling should be done by the method used for commercial harvesting
- the temperature of the water to be measured and recorded on the BF 97 and BF 42A as applicable
- The stated Representative Monitoring Point (RMP) location should be used to identify the position of sampling for bivalves.
- Samples collected for analysis for biotoxins shall comprise of stock close to the market size.
- The samples shall be placed into a waterproof bag that is tied off and then placed into a second clear bag.
- The samples shall be clearly labelled as outlined below.
- The label shall be placed into a water proof sleeve and placed into the second bag referred to above.
- The samples shall be chilled for same day delivery, otherwise frozen.

SPECIES	Sample size (Min 100 g flesh)
Abalone	5
Lobster	5
Mussels	30
Oysters	20

8.TESTING RADIONUCLIDES

- Samples shall be taken for the testing Radionuclides (Cesium 134 and 137).
- The samples shall be taken once every three years.
- The samples shall be placed into a waterproof bag that is tied off and then placed into a second clear bag.
- The samples shall be clearly labelled as outlined below.
- The label shall be placed into a water proof sleeve and placed into the second bag referred to above.
- The samples shall be chilled for same day delivery, otherwise frozen.
- The sample size will consist of a minimum of 1 kg of flesh weight.

9.EQUIPMENT REQUIREMENTS FOR SAMPLING

The availability and the use of proper equipment for the protection and preservation of the samples are essential during the sampling process. As is highlighted in section 4 above, the sampler is responsible that equipment is available at all times to sample the required number of samples during a sample run per day and that the equipment to be arranged from the laboratory or the regional office timeously, in order to prevent any deviation from the sampling procedure.

The following equipment to be available:

- Micro bags for microbiological samples
- Chemical bags for residue and biotoxin samples
- Tamper proof bags
- Cleaning buckets and brush
- Cooler box
- Ice packs
- Insulating foam when necessary

- Self- adhesive labels
- Thermometer
- Disinfectant

10.PREPARATION AND PACKAGING OF SAMPLES

- Samples , especially shellfish to be rinsed with fresh potable water or clean sea water from the immediate sampling area
- Shellfish not to be totally re-immerse in water to prevent the possible introduction of contamination at the sampling point
- Ice packs and foam packaging to be used when the transport time is more than 4 hours to the laboratory as per the following configuration:

TOP 2 LAYERS OF FOAM
TOP LAYER OF 3 ICE PACKS
TOP LAYER OF FOAM
SAMPLES
BOTTOM LAYER OF FOAM
BOTTOM LAYER OF 3 ICE PACKS

- When the transport time is less than 4 hours, then other suitable insulating material may be used such as bubble wrap, newspaper, etc.)
- Samples intended for micro testing must not be frozen
- The time and temperature to be recorded on the sample submission form

11. THE TRANSPORT OF SAMPLES

- The above stipulated storage and transport temperature to be validated at the testing laboratory on arrival
- Cooler box with effective insulating capabilities are to be used for the transport of samples.
- When samples are couriered to the laboratory, the sampling officer should liaise with the laboratory regarding the sample delivery and the requirement to measure the sample surface temperature and to record this and the condition of the samples

- The sampling officer to ensure that the surface temperature of the sample is measured and that this and the condition of the samples are recorded at the laboratory

12. HEALTH AND SAFETY AND BIOSECURITY MEASURES

- Sampling officers shall comply with the Health and Safety policies of the NRCS.
- Sampling officers shall at all times respect, familiarize and implement the bio-security measures that are prevalent at the sampling points/ farms.
- Sampling officers shall treat all disposable items as clinical waste.
- Sampling officers shall ensure that hands are disinfected between each sampling station to prevent the spread of disease or contaminate the next sample in the series.

13.REFERENCES

South African Molluscan Shellfish Monitoring and Control Programme
South African Aqua-cultured Marine Fish Monitoring and Control Programme

ATTACHMENTS

APPENDIX 1: SA FINFISH RESIDUE SAMPLING SCHEDULE
APPENDIX 2: ABALONE RESIDUE SAMPLING SHEDULE
APPENDIX 3: BIVALVES SAMPLING SHEDULE
APPENDIX 4: LOBSTER SAMPLING SHEDULE
APPENDIX 5: BIOTOXIN AND MICROBIOLOGICAL SAMPLING SCHEDULE
APPENDIX 6: RESIDUE SAMPLING REPORT
APPENDIX 7: LABORATORY SAMPLE SUBMISSION FORM

- AMENDMENT REGISTER

Amendment History		
Amendment No.	Date Approved	Nature of Amendment
00	2018-03-01	First issue – (Amendment 2: 2018/02/08)

RETURN OF SAMPLES

NRCS national regulator for compulsory specifications

Sample of:	From:	Date dispatched:	Sample/Carton No:	Inspector: .....
Live Cultivated Abalone ☐	Hermanus: ☐			Date: .....
Live Cultivated Oysters ☐	West Coast: ☐			
	Northern Cape: ☐			

Distribution **Laboratory:** ASPIRATA ☐ OTHER ☐

	Sample mass (g)	Biotoxin			Time Sampled	Remarks
		PSP	DSP	ASP		
						Please test for: PSP ☐ DSP ☐ ASP ☐
Farm Number/Name:						**NOTE: A Report of the results must be forwarded to:**
Number of Animals:						COMPANY NAME:
Representative samples of Cultivated Live Abalone from different tanks ☐						DAFF ☐
Representative samples of Cultivated Live Oysters from different tanks ☐						NRCS ☐
			Batches sampled:	Size class	Batch code	
Harvesting date:						
Consignment date:						
Test date:						
Witnessed by:			Received by:			
Date:			Date:			
Time:			Time:			

Comments:

REQUISITION FORM: OTHER MÉRIEUX NUTRISCIENCES SERVICES

Report to:

Account to:

Swift Silliker (Pty) Ltd t/a Mérieux NutriSciences
7 Warrington Road / Claremont
Cape Town / South Africa / 7708
Tel: +27 (21) 683 8436 / 08613 SWIFT
Fax: +27 (21) 683 8422 / Email: za-info@mxns.com
www.merieuxnutrisciences.com

Date: _____

Order No.: _____

Time Rec: _____

Tel. No.: _____

Fax No.: _____

PRODUCT TYPE	DESCRIPTION	TEST CODE	TEST METHOD	LABORATORY	ADDITIONAL COMMENTS
Select one		Select one		Select one	
Select one		Select one		Select one	
Select one		Select one		Select one	
Select one		Select one		Select one	
Select one		Select one		Select one	
Select one		Select one		Select one	
Select one		Select one		Select one	
Select one		Select one		Select one	
Select one		Select one		Select one	
Select one		Select one		Select one	

Customer: _____ Processed by: _____

Signature: _____

ANNEXURE 6

OFFICIAL PRICING SCHEDULE A, B & C

Pricing Schedule A

Deliverables/Activities						
Independent sampling location (province/geographic cluster)	Type of sample	Transport costs (per km)	Disbursment	Staff cost	Quantity (Sampling frequency)	Total Cost
e.g Saldanha Bay, WC						
Sub-total						R0,00

Pricing Schedule B

Deliverables/Activities				
Other Costs	**Period**	**Rate/unit**	**Quantity**	**Total Cost**
Sub-total				**R0,00**

Total cost	
Pricing Schedule A	0
Pricing Schedule B	0
Total cost	0