TRADE FORWARD
SOUTHERN AFRICA

Roadmap towards European Union (EU) Compliance

for the Export of Farmed Molluscs from South Africa April 2022

Produced by Development Alternatives Incorporated (DAI) and made possible by the Foreign, Commonwealth and Development Office (FCDO) of the United Kingdom

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Trade Forward Southern Africa (TFSA) is a programme under the Foreign, Commonwealth & Development Office (FCDO) of the UK Government, promoting trade in the SACU+M region.

Development Alternatives Incorporated (DAI) is the lead contractor for TFSA, covering the core implementation team and all sub-activities. Imani Development is an implementing partner of DAI for the suite of aquaculture activities and other matters.

This report has been developed from the work in Phase 2 of the TFSA aquaculture pilot. Etienne Hinrichsen (specialist in African aquaculture development and planning), and Ian Goulding (specialist in aquaculture export regulation) provided the required technical expertise.

It is important to note that this report contains information pertaining to the current situation as of April 2022 in South Africa and the EU respectively. Additionally, it should be noted that the guidelines, regulations, legal instruments, and reference materials that have been used to inform this report are subject to amendment and even repeal, from time to time. For this reason, readers and users of this roadmap document should consult the official instruments to check for any such amendments.

CONTENT

FIGURES

ACRONYMS

AAH	Aquatic Animal Health
ASP	Amnesic Shellfish Poisoning
CA	Competent Authority
CCA	Central Competent Authority
CSIR	Council for Scientific and Industrial Research
DALRRD	Department of Agriculture, Land Reform and Rural Development
DFFE	Department of Forestry, Fisheries and the Environment
DG SANTÉ	European Commission's Directorate-General for Health and Food Safety
EU	European Union
HACCP	Hazard Analysis and Critical Control Points
MRL	Maximum Residue Limit
NRCS	National Regulator for Compulsory Specifications
OIE	World Organisation for Animal Health
OVI	Onderstepoort Veterinary Institute
RMP	Residue Monitoring Plan
SABS	South African Bureau of Standards
SASMCP	South African Shellfish Monitoring and Control Program
SPS	Sanitary and Phytosanitary
VMPs	Veterinary Medicinal Products

1 INTRODUCTION

South African operators have expressed a strong interest to export farmed and wild-harvested molluscs (mussels, oysters, and abalone) to the European Union (EU). Until now, the national Competent Authority (CA) has not been able to meet EU food safety and animal health conditions for these products.

Several gaps have been identified in the South African control system for the export of molluscs. Some of the control measures are not well coordinated in law, there is no official monitoring of veterinary residues in aquaculture products, and aquatic animal health control systems equivalent to those in the EU are not in place. This report provides a roadmap towards EU compliance for the export of these products from South Africa to the EU.

2 METHODOLOGY AND SOURCES

EU guidelines and regulatory requirements for sanitary measures applicable to bivalves and gastropod molluscs to be imported into the EU were reviewed and used to inform this report. These included several EU and Food and Agriculture Organization (FAO) guidelines, the Codex Alimentarius, documents of the World Organisation for Animal Health (OIE), as well as EU legal instruments, and the official controls and testing methods for:

a) Bivalve Mollusc Production Food Safety Monitoring and Control Measures

b) General Food Safety Requirements

c) Veterinary Medicines Control Measures

d) Aquatic Animal Health Control Measures

Key measures required by the EU for microbiological and biotoxin controls are summarised in Annex 1. In addition, the reports prepared by the EU Commission following audit missions undertaken by the Directorate-General for Health and Food Safety (DG SANTÉ) officers to assess the controls implemented by the South African Competent Authorities were studied. These reports are listed in Annex 2.

The current situation in South Africa was assessed against the EU requirements, with a view to identifying the main gaps in terms of the control systems for export to the EU.

3 EU SANITARY REQUIREMENTS AND STATUS IN SOUTH AFRICA

3.1 Requirement for Equivalence

Regulation (EC) No 178/20021 requires that conditions applicable to fishery products imported from third countries meet conditions which are at least equivalent to those set out in EU legislation.

> *Article 11: Food and feed imported into the Community; Food and feed imported into the Community for placing on the market within the Community shall comply with the relevant requirements of food law or conditions recognised by the Community to be at least equivalent thereto or, where a specific agreement exists between the Community and the exporting country, with requirements contained therein.*

EU Regulation (EU) 2017/6252, known as the "official controls regulation" sets out the requirements for Governments to implement official controls and related activities (such as certification for international trade) performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products (in other words Sanitary and Phytosanitary (SPS) measures). Article 4 sets out the requirements for controls implemented by food safety Competent Authorities, including those in third countries:

> *Article 4: For each of the areas governed by the rules referred to in Article 1(2), Member States shall designate the Competent Authority or Authorities on which they confer the responsibility to organise or perform official controls and other official activities.*

The initiating event in the steps to be taken towards EU authorisation is therefore the nomination of the Competent Authority for the function of sanitary controls of fishery (including aquaculture) products exported to the EU.

The establishment of an EU equivalent system implies the establishment of:

a) A central Competent Authority, with lawfully mandated regulatory powers.

b) A centrally located corps of qualified inspectors who will undertake official controls in the sector for which they are responsible.

c) A system for addressing non-compliances, resulting in a compliant sector.

1 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
2 EU Regulation (EU) 2017/625 of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products.

Official control of food and feed is defined in Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 as "official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products". Official controls are defined as including the following as appropriate:

a) An examinaton of the controls that operators have put in place and of the results obtained.

b) An inspection of:

   i) Equipment means of transport, premises and other places under their control and their surroundings.

   ii) Animals and goods, including semi-finished goods, raw materials, ingredients, processing aids and other products used for the preparation and production of goods or for feeding or treating animals.

   iii) Cleaning and maintenance products and processes.

   iv) Traceability, labelling, presentation, advertising, and relevant packaging materials including materials intended to come into contact with food.

c) Controls on the hygiene conditions in the operators' premises.

d) An assessment of procedures on good manufacturing practices, good hygiene practices, good farming practices, and of procedures based on the principles of hazard analysis critical control points (HACCP).

e) An examination of documents, traceability records and other records which may be relevant to the assessment of compliance with the rules referred to in Article 1(2), including, where appropriate, documents accompanying food, feed and any substance or material entering or leaving an establishment.

f) Interviews with operators and with their staff.

g) The verification of measurements taken by the operator and other test results.

h) Sampling, analysis, diagnosis, and tests.

i) Audits of operators.

j) Any other activity required to identify cases of non-compliance.

3.2 General Food Safety of Fishery Products

Operators dealing with products of animal origin must comply with Regulations (EC) No 852/2004 of 29 April 2004 on the hygiene of foodstuffs and No 853/2004 of 29 April 2004 laying down specific hygiene rules for food of animal origin. The former sets out basic hygienic requirements relating to location, structure, design, layout, materials, facilities, and personnel hygiene. The Annex to 853/2004 sets out the sanitary conditions applicable to production and placing on the market inter alia of fish and fishery products, and relates to conditions on fishing vessels, freezer vessels and establishments etc.

South Africa has met these conditions and is one of the third countries authorised to supply the EU with certain fishery products. The authorisation is set out in Annex IX of Commission Implementing Regulation (EU) 2021/405 of 24 March 2021, laying down the lists of third countries or regions authorised for import into the EU of certain animals and goods intended for human consumption. However, for South Africa it only applies to products from wild capture fisheries.

3.3 Microbiological and Marine Biotoxin Safety

Additional requirements are set out for live, chilled, frozen, or processed bivalve molluscs, echinoderms, tunicates, and marine gastropods due to the nature of the hazards associated with their feed and feeding methods. These specific requirements are for microbiological classification of harvest areas and their subsequent monitoring for microbiological and marine biotoxin hazards.

The conditions are set out in the Annex to Regulation (EC) No 853/2004 of 29 April 2004, with implementation arrangements set out in the following. These specific measures are summarised in Annex 1 to this report.

a) Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption.

b) Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs.

c) Commission Delegated Regulations (EU) 2019/625 of 4 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption.

However, South Africa has not yet satisfied the EU that it has in place equivalent controls for these products. The list of third countries or regions thereof authorised for the entry into the Union of consignments of live, chilled, frozen, or processed bivalve molluscs, echinoderms, tunicates and marine gastropods, is provided in Annex VIII of Commission Implementing Regulation (EU) 2021/405 of 24 March 2021, laying down the lists of third countries

or regions authorised for the entry into the Union of certain animals and goods intended for human consumption. South Africa is not listed.

3.4 Veterinary Medicine Monitoring and Controls

A requirement for CA's to perform routine monitoring of the residues in products of animal origin is set out in Article 19 of the General Requirement for Residue Monitoring which refers to Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products. Monitoring requirements (sampling rates and specific parameters to be measured) are set out in the Annex to this report and summarised in the box below:

GROUP A - Substances having anabolic effect and unauthorised substances:

1. **Stilbenes, stilbene derivatives, and their salts and esters**
2. Antithyroid agents
3. **Steroids**
4. Resorcylic acid lactones including zeranol
5. Beta-agonists
6. **Compounds included in Annex IV to Council Regulation (EEC) No 2377/90 of 26 June 1990 (no longer in force- see below)**

GROUP B - Veterinary drugs (1) and contaminants:

1. **Antibacterial substances, including sulphonomides, quinolones**
2. Other veterinary drugs:
   - **(a) Anthelmintics**
   - (b) Anticoccidials, including nitroimidazoles
   - (c) Carbamates and pyrethroids
   - (d) Sedatives
   - (e) Non-steroidal anti-inflammatory drugs (NSAIDs)
   - (f) Other pharmacologically active substances
3. **Other substances and environmental contaminants**
   - **(a) Organochlorine compounds including PcBs**
   - (b) Organophosphorus compounds
   - **(c) Chemical elements**
   - **(d) Mycotoxins - Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs**
   - **(e) Dyes**
   - (f) Others

NB: The list is conditioned for each sector by Annex II. The residue or substance group is to be detected by the type of animal, their feeding stuffs, including drinking water, and primary animal product. Parameters in bold are specifically required for aquaculture products.

Countries which have met these conditions for specific products of animal origin are permitted to export those products to the EU. The countries are listed in a Commission Decision of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC.

South Africa has met these conditions for farmed wild game and sheep meat but has not extended the residue monitoring system to aquaculture, and thus is unable to export any aquaculture products to the EU for human consumption.

3.5 Animal Health

EU animal health requirements are set out in Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases. It requires surveillance and eradication measures for listed diseases of relevance to EU animal production, including those of concern in relation to aquatic molluscan health and affected species and vectors. Note that some species are listed species (susceptible targets) e.g., Ostreidae spp. and others identified as vector species e.g., Pectenidae spp.

Key requirements in Part V are set out in Article 166: clinical inspection by an official veterinarian in the exporting third country, Articles 167-169: conditions of despatch and transport and Article 170: from disease free compartments. Articles 172 and 173 provide derogations to the above requirements, including inter alia for live bivalve molluscs or crustacea which are intended for human consumption without further processing, **provided they are packaged for retail sale.**

The countries which have met the specific conditions and where the animal health risk is adequately controlled, are thus permitted to supply the EU with these products. They are listed in Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories, or zones from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429. Annex XXI Aquatic Animals Part 1 shows the list of authorised third countries, territories, zones, or compartments from which the import of live aquatic animals is permitted. South Africa is listed for fish only, not for crustacea or molluscs.

3.6 Certification

The form of certificate required is specified in CIR 2019/2235 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 as regards model animal health certificates, model official certificates and model animal health/official certificates, for entry into the EU and movements within the Union of consignments of certain categories of animals and goods. This applied with effect from 21 April 2021 and sets new model certificates for entry of the following animals and goods intended for human consumption:

a) Products of animal origin and composite products for which such a certificate is required in accordance with Article 13 of Delegated Regulation (EU) 2019/625.

b) Certain live aquatic animals and products of animal origin for which such certificate is required.

The model certificates are shown in the Annex of CIR 2019/2235. Chapter 31 shows the Model Animal Health/Official Certificate for entry into the Union of Live Bivalve Molluscs, Echinoderms, Tunicates, Marine Gastropods and Products of Animal Origin from these animals intended for human consumption (Model MOL-HC). The attestation is important and summarised in the box below.

Attestation under model animal health/official certificate for the entry in the union of live bivalve molluscs, echinoderms, tunicates, marine gastropods, and products of animal origin from these animals intended for human consumption (model mol-hc).

Important points:

1. The declaration commences with "I the undersigned declare…". i.e., it is a personal attestation under a single signature of a single authorised officer of the third country.
2. The model certifies the conditions under which the consignment has been produced and distributed.
3. The declaration relates to food safety, bivalve monitoring programmes, animal health, and veterinary residues. It states that:

II. Health information

II.1 Public health attestation

- The products originate from a country listed as authorised to supply the EU market.
- Originate from an establishment approved for export to the EU.
- Produced in accordance with the requirements set out in Regulation 853/2004 and handled and packaged accordingly.
- Satisfy the health standards set out in 2073/2005.
- Marked and labelled in accordance with 853/2004.
- In case of non- filter feeders, meet the requirements set out in 853/2004 for environmental contaminants.
- Are derived from an area classified as A, B, or C in accordance with Regulation 2019/627 (except for pectenidae, holothurian, echinoderms and marine gastropod molluscs).
- If of aquaculture origin, are subject to residue monitoring plans under Regulation 96/23.
- Comply with maximum residue levels for pesticides.

II.2 Animal health attestation for conditions for live bivalve molluscs:

- Area is not subject to aquatic animal health restrictions.
- Products were not derived as a result of an eradication plan.
- Derived from registered establishments approved by the competent authority with record keeping for three years.
- Produced under regular aquatic animal health controls and visits from an official veterinarian.
- Originate from a disease-free zone indicating its code.
- Have been subject to clinical inspection within 72 hours of consignment and found to be healthy.
- Dispatched directly and not in contact with animals of a lower health status.
- From a compartment declared free of listed diseases such as Mikrocytos mackini, Perkinsus marinus, Marteilia refringens, Bonamia spp, and Ostrid herpes virus 1µvar (OsHV-1 µvar).
- With no undetermined abnormalities evident.
- Subject to transport conditions where there has been no change in water used to carry the animals.
- Not transported in conditions which could change their health status.
- Have not been mixed with other animals with lower health status.
- Labelling of the container is identified with the relevant details.

Note the following exceptions to the above certification requirements:

- Wild molluscs and their products from fishing vessels; or
- If animals cannot survive if returned to water; or
- Packaged for retail sale; or
- Other than live.

3.7 Summary of the Situation in South Africa

3.7.1 Current Status of Controls

To export molluscs to the EU, and depending on the products, a third country may need to comply with each of the areas of controls in relation to general food safety of fish and fishery products, zone controls for microbiological classification and marine biotoxins, aquatic animal health and residues of veterinary medicine products. Each system has its own specific demands in EU legislation. However, it should be noted that the EU requires a single certificate with an attestation signed by a single named authorised officer to certify to all the required and relevant conditions. Compliance with EU requirements should reflect all four required areas of the functional official controls.

Each of the four control areas should be considered separately. At present, South Africa has only met the EU requirements for the first of these areas of general food safety of fishery products, for which the National Regulator for Compulsory Specifications (NRCS) is recognised as the relevant CA. The CA for microbiology/marine biotoxins is the Department of Forestry, Fisheries, and the Environment (DFFE) and as yet, the EU has not accepted the South African Shellfish Monitoring and Control Program (SASMCP) as providing equivalence. The CA for animal health and veterinary residue issues is the Department of Agriculture, Land Reform and Rural Development (DALRRD), although it is not clear whether its mandate in relation to aquatic animals has been confirmed in law. DALRRD has submitted a residue monitoring plan for aquaculture products, but it was not accepted by the Commission. Aquatic animal health control systems remain to be fully developed. There has been no formal submission by South Africa to the EU concerning the aquatic animal health conditions for molluscan shellfish.

3.7.2 Determining the Destinations for the Roadmap

The implication of this analysis for the development of a roadmap is as follows:

a) A roadmap implies a destination, yet in the case of export of South African molluscs to the EU, there are several options for the choice of destination. Not all potential mollusc products considered as having export potential need to be treated equally in terms of compliance with the EU requirements. For example, a sanitary survey and area classification is not required for non-filter feeders such as abalone. Animal health requirements (surveillance and compartments) are not applicable if products are packed for retail sale, or if they are frozen or cooked. Veterinary residue monitoring and control is not applicable if the products are harvested from the wild. The table below illustrates the general scheme of options for South Africa in relation to the export of molluscs for human consumption.

b) The decision on establishing a roadmap for compliance should also consider the relative export potential for the different molluscan shellfish products. It is only economically feasible to develop complex and expensive control systems for products which are going to achieve a significant level of export.

c) It is the prerogative of the CA to seek authorisation for a limited range of products (e.g., abalone only, no live

products, dressed and cooked products only etc.) so that the authorisation may be sought only for those specific products which are subject to the applicable control systems.

Table 1: Control system requirements, and competent authorities for different molluscan shellfish production characteristics.

Feeding	Origin	State	Control system (Certification)			
			Area controls for microbiology & marine biotoxins	Aquatic animal health	Veterinary medicine residues	Food safety & environmental contaminants
			MFMR	MAWF	MAWF	NSI
Filter feeder (oyster & mussel)	Wild	Live	√	√		√
		Processed	√			√
	Aquaculture	Live	√	√	√	√
		Processed	√		√	√
Non-filter feeder (abalone)	Wild	Live	√*	√		√
		Processed	√*			√
	Aquaculture	Live	√*	√	√	√
		Processed	√*		√	√

* Biotoxins only

4 ROADMAP TO COMPLIANCE

4.1 General Food Safety and HACCP Conditions

Official controls for general hygiene and food safety requirements for fishery products are already in place. South Africa has met the requirements for the export of fishery products in general to the EU, including hygiene and Hazard Analysis and Critical Control Points (HACCP) conditions for the approval of establishments. The NRCS is the recognised Competent Authority, and notwithstanding other challenges, no further action is required to develop controls in this area.

4.2 Marine Biotoxins and Microbiological Criteria for Molluscan Shellfish

4.2.1 Overview

Several steps are required for monitoring and control of marine biotoxins and microbiological criteria for marine mollusc production in line with EU requirements. These are illustrated in Figure 1 and the steps described in more detail below.

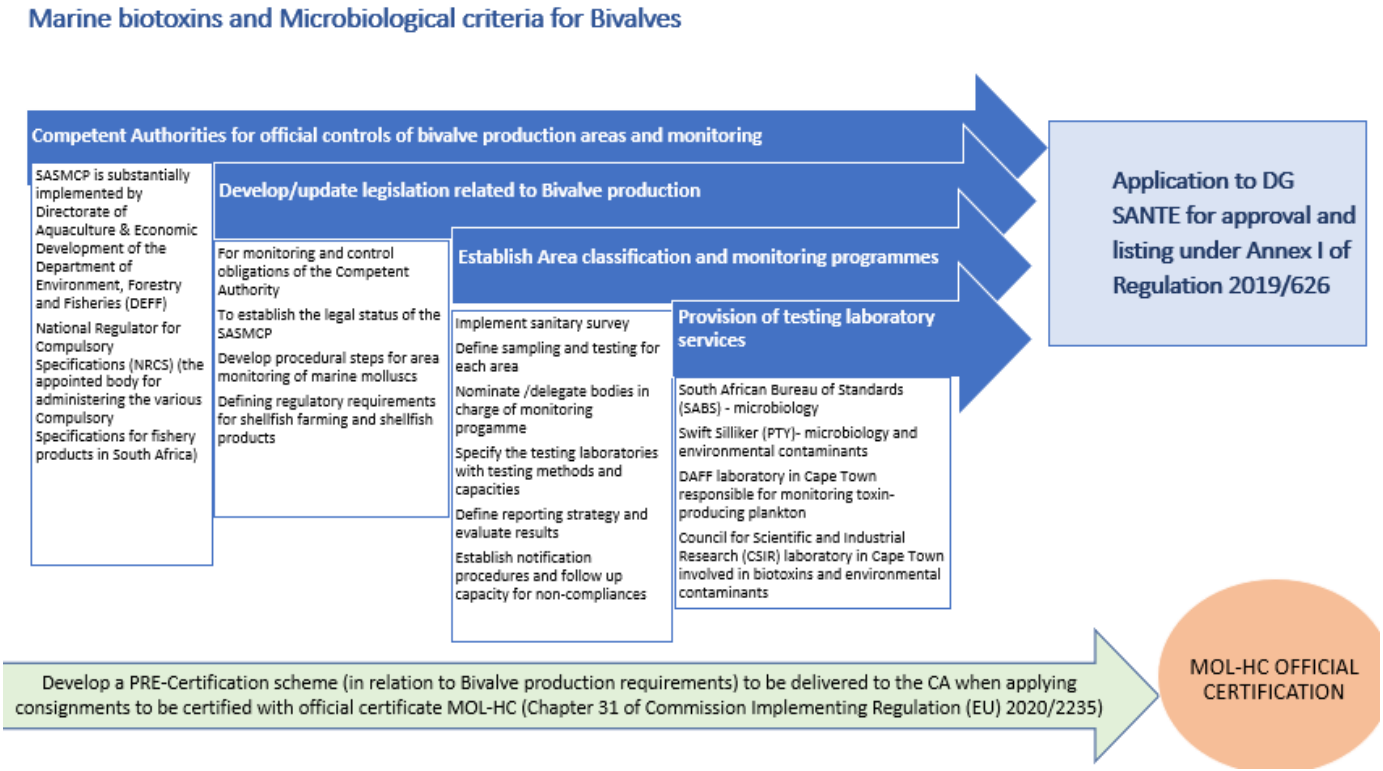

Figure 1: Roadmap for monitoring and control of marine biotoxins and microbiological criteria.

4.2.2 Nominate Competent Authorities for Official Controls of Bivalve Production Areas and Monitoring

In South Africa the SASMCP is substantially implemented by the Fisheries Management Branch under the Directorate of Aquaculture & Economic Development of the Department of Forestry, Fisheries, and the Environment (DFFE). The plan is established under Regulation 73 of the regulations under the Marine Living Resources Act, 1998 (Act No. 18 of 1998) under Government Notice R1111 in Government Gazette 19205 dated 2 September 1998). The plan was developed in cooperation with the NRCS (the appointed body for administering the various Compulsory Specifications for fishery products in South Africa). The legal basis for the establishment of these controls by DFFE is therefore clear.

4.2.3 Develop/update legislation related to bivalve production

Whilst the SASMCP is broadly in line with the requirements of the EU for the classification of areas for production of bivalves, the legal status of the controls is not established. Section 73 of the Marine Living Resources Act, 1998 (Act No. 18 of 1998) states:

Public health

a) No person shall establish a mariculture facility in any area contaminated with toxic substances, faecal matter, human pathogens or marine biotoxins, to the extent that the cultivated fish pose a health risk to consumers.

b) The permit holder shall comply with sanitary standards and tests, including regular testing of water and fish quality, specified in the permit

c) Harvesting from actual and potentially affected growing waters may be restricted during public health emergencies such as marine biotoxin events, oil spills and sewage contamination.

A mission by DG SANTE in 2016 to advise on the conditions of export of abalone to the EU found that "relevant requirements regarding shellfish farming and shellfish products e.g. certificate of acceptability for food premises prior to licensing, limits for contaminants such as heavy metals, radio-active substances (Caesium 134 and 137), polychlorinated biphenyls (PCBs) and pesticides, limits for biotoxins and limits for veterinary drugs, etc. are included in the relevant regulations published under the Foodstuffs Cosmetics and Disinfectants Act, 1972. (Act No. 54 of 1972)". South African legislation does not have the same maximum limits as the EU for some contaminants (e.g., Cadmium, Lead, Dioxins, and Polychlorinated Biphenyls (PCBs) and the marine biotoxin called yessotoxins. These gaps have since been addressed in the plan, but it is not clear whether the regulations published under the Foodstuffs Cosmetics and Disinfectants Act, 1972 were updated in response.

There are no additional regulations in place which govern the activities of the shellfish sector, nor which determine the monitoring and control obligations of the Competent Authority. It should be noted that the current plan applies the requirements to all products (bivalves and gastropod molluscs) whereas the EU requirements are that gastropods, tunicates and holothurians that are not filter feeders, do not have to be subject to site survey and classification of harvest areas, provided that the marine biotoxins are monitored at establishments. Whilst the DG SANTE audit concluded that "a legislative framework governing the production of abalones and fishery products derived thereof is in place, the control system for bivalve molluscs was not evaluated".

This therefore calls into question whether the critical elements of the SASMCP for food safety are enforceable in law in respect of area controls, basis for and powers of closure etc. In these critical respects, the current arrangements may be considered as not equivalent to the EU requirements. One of the first recommended steps in the road map is the adoption into regulations of those elements of the system which correspond to the EU requirements for area monitoring of marine molluscs set out in Annex 1. These should address, at a minimum, sanitary surveys, classification of areas (A, B, C), monitoring requirements, and closure of areas. Since EU legislation was consolidated and revised in 2019, the draft shellfish monitoring, and control plan should be reviewed for consistency.

4.2.4 Establish Area Sanitary Surveys, Classification, and Monitoring

According to the audit report by DG SANTE, permits to cultivate and harvest abalones for direct human consumption or further processing are issued by DFFE, subject to a satisfactory classification of the farm following a sanitary survey. DFFE maintain an updated list of abalone farms for distribution to the NRCS and relevant local health authorities. This list must indicate the current classification and harvesting status (i.e., either open or closed to harvest).

The implementation of the SASMCP insofar as the classification of production areas for bivalve molluscs has not been assessed and will need to be reviewed in line with the new regulations. These should be consistent with the following documents:

a) Community Guide to the Principles of Good Practice for the Microbiological Classification and Monitoring of Bivalve Mollusc Production and Relaying Areas with regard to Regulation 854/2004, European Commission, 2017.

b) Microbiological Monitoring of Bivalve Mollusc Harvesting Areas, Guide to Good Practice: Technical Application - EU Working Group on the Microbiological Monitoring of Bivalve Mollusc, Harvesting Areas, Issue 6: January 2017.

The implementation arrangements should be set out in writing, and should, inter alia:

a) Define the sampling and testing for each area.

b) Nominate /delegate bodies in charge of monitoring programme.

c) Specify the testing laboratories with testing methods and capacities.

d) Define the reporting strategy and evaluate results.

e) Establish notification procedures and follow up requirements for non-compliances.

The 2016 mission by DG SANTE found that the monitoring of abalone farms, including microbiological, phytoplankton, biotoxins and environmental contaminant testing was in place and that "provisions relating to decisions after monitoring, additional monitoring requirements and recording and exchange of information can be considered equivalent to the EU."

4.2.5 Provision of Testing Laboratory Services

Four testing laboratories are nominated for the testing under the SASMCP (for microbiology, toxins producing plankton, biotoxins and environmental contaminants):

a) The South African Bureau of Standards (SABS) for microbiology.

b) Swift Silliker (PTY) for microbiology and environmental contaminants.

c) The DFFE laboratory in Cape Town for monitoring toxin-producing plankton.

d) The Council for Scientific and Industrial Research (CSIR) laboratory in Cape Town involved in biotoxins and environmental contaminants.

The nominated testing laboratories were reviewed by the DG SANTE audit mission in 2016, which found that they were all accredited and participate regularly in proficiency testing with acceptable results. Although no further work is required in terms of the road map, it should be noted that additional private sector laboratories (Amanzi and Seawise) should be checked for proficiency testing and accreditation as requried.

4.2.6 Application to DG SANTE for Approval and Listing under Annex I of Regulation 2019/626

Subject to addressing the above gaps in relation to the development and implementation of regulations addressing the system of area controls, classification and closure and ensuring implementation, South Africa may then formally request the EU for authorisation to supply the relevant farmed and/or wild caught bivalve and gastropod molluscan shellfish products.

4.3 Veterinary Drug Residue Monitoring in Aquaculture Products

4.3.1 Overview

Several steps are required to establish veterinary drug residue monitoring in aquaculture products in line with the EU requirements. These are illustrated in Figure 2 and the steps described in more detail below.

4.3.2 Competent Authorities for Veterinary Medicine Controls used in Aquaculture

The Department of Agriculture, Land Reform and Rural Development (DALRRD) is the central Competent Authority for issuing authorisations for veterinary medicinal products under the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36), albeit that this mandate is directed to the DFFE for fisheries products. The Department of Health is responsible for issuing authorisations under the Medicines and Related Substances Act, 1965 (Act 101). The DALRRD is also responsible for the implementation of the residue monitoring plan via the Chief Directorate of Animal Production and Health.

It is also noted that some powers are drawn under regulations under the Marine Living Resources Act, 1998, which contains provisions in Regulation 72, concerning the use of chemicals or pharmaceutical drugs. This requires that: *"Any person intending to use any chemical, piscicide, pharmaceutical, bio-remediation product, or it derivative, for mariculture shall inform the Minister in advance and shall provide any information in relation to the use of the substance that the Minister may require" and "shall cease or limit the use of any substance referred to on mariculture premises or for the purposes of mariculture, if ordered to do so by written notice by the Minister".*

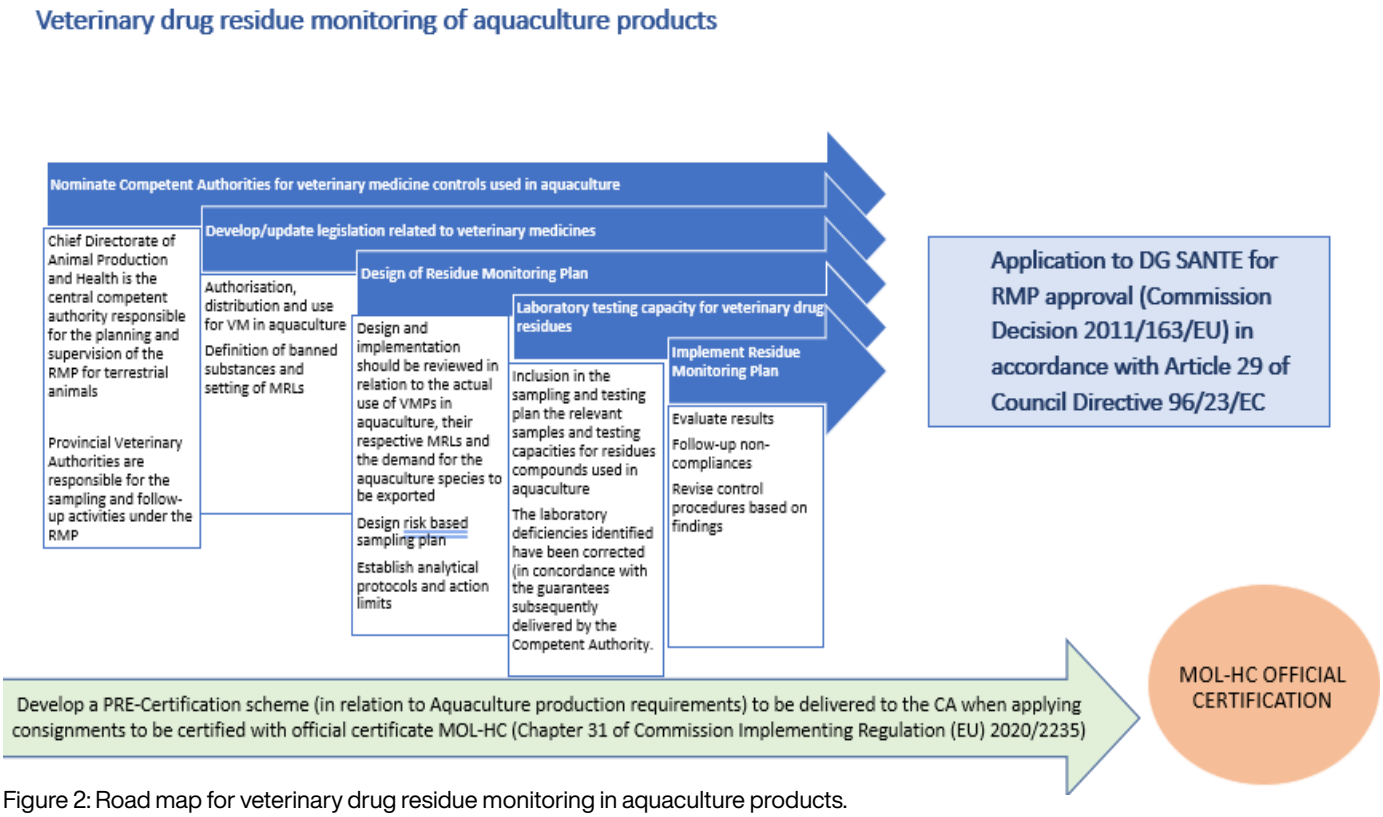

Figure 2: Road map for veterinary drug residue monitoring in aquaculture products.

4.3.3 Develop or Update Legislation Related to Veterinary Medicines

The DALRRD is the CCA for issuing authorisations for veterinary medicinal products under the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36) and the Department of Health is responsible for issuing marketing authorisations under the Medicines and Related Substances Act, 1965 (Act 101). Officials of the nine Provinces are responsible for official controls on the distribution and use of veterinary medicinal products. The DFFE however fulfils these roles for fisheries products.

The system of authorisations for Veterinary Medicinal Products (VMPs) in South Africa is notably different to that applied in the EU. The majority of the specific VMPs for the aquaculture sector (anthelmintics, antibiotics and anti-fungals) are products registered under Act 36, and can be purchased without veterinary prescription over the counter in licensed pharmacies or in retailers and shops. The Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947, also addresses use of growth promoters and hormones.

The DFFE does not maintain a register of veterinary medicinal products. Products on the market, registered under Acts 36 and 101, are listed by the South African Health Products Regulatory Authority, and are shown at https://www.sahpra.org.za/list-of-registered-veterinary-product/. However, authorised species and Maximum Residue Limits (MRLs) are not specified. MRLs are adopted from Codex or other countries. In this respect there may be a need to introduce a specific measure to list those VMPs which may (and may not) be applied in aquaculture species, and to establish MRLs for the approved substances.

4.3.4 Design and Implement a Residue Monitoring Plan

In terms of products exported to the EU the DALRRD has established veterinary residue controls for farmed wild game (crocodile) and ratite (ostrich) meat. The Chief Directorate of Animal Production and Health of the DALRRD is the CCA responsible for the planning and supervision of the Residue Monitoring Plan (RMP), and the nine Provincial Veterinary Authorities are responsible for the sampling and follow-up activities under the RMP. The shellfish farming sector, under guidance from DFFE, has followed the National Residue Control Programme for over 5 years and have recorded no findings in terms of the National Residue Plan. Yet, this has not been audited specifically by the EU.

The South African RMP for veterinary medicines currently focuses on farmed game and ostriches. The existing system of monitoring and controls of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products was audited3 by DG SANTE in 2017, albeit that this audit excluded aquaculture.

The mission found that the planning of residue monitoring complies with the requirements of, and largely adheres to, the guarantees provided by the RMP approved by the EU. Nevertheless, in 2015 and 2016 the RMP was not implemented as planned, either because too few samples were taken (as low as 37% in 2015), information on the

3 Final Report of an audit carried out in South Africa from 14 February 2017 to 27 February 2017 in order to evaluate the control of residues and contaminants in live animals and animal products including controls on Veterinary Medicinal Products, Directorate-General for Heath and Food Safety, Health and Food Audits and Analysis Ref. Ares(2017)2715469 - 30/05/201, DG(SANTE) 2017-6181 – MR.

use of veterinary medicinal products was not taken into consideration in the plan design, or some action levels did not reflect the correct EU MRLs.

In January 2017 an updated version of the RMP for aquaculture was developed and submitted to the European Commission for assessment. There is no information in the audit report regarding the specific inclusion of aquaculture products in the RMP, nor whether the specific combinations of matrices and analysis in the current plan can be considered as related to the existing residue risks. The audit did not report specifically on the aquaculture part of the plan and aquaculture products were not added to the list of authorised products which may be exported under the plan.

Given that the report did note deficiencies in laboratory testing and the omission of testing for some substances indicated in the RMP, its design and implementation should be reviewed in relation to the actual use of VMPs in aquaculture, their respective MRLs, the demand for the aquaculture species to be exported and laboratory testing capacity.

4.3.5 Laboratory Testing Capacity for Veterinary Drug Residues

The DG SANTE audit report on South African controls on VMPs in 2017 identified that although the plan design was broadly satisfactory (with respect to crocodile and ostrich production), the implementation was largely let down by inadequate laboratory testing:

> *"despite the largely adequate planning, sampling and follow-up activities carried out under the national residue monitoring plan, there are important deficiencies in its implementation which, cumulative, seriously question the reliability of the guarantees on the residues status of food of animal origin eligible to be exported to the EU. These deficiencies concern notably the use of analytical methods which are not demonstrably fit for purpose, failures to analyse all samples in a timely fashion, and the lack of testing for some substances indicated in the residue monitoring plan."*

The Rport particularly noted that the effectiveness of the plan was undermined by several delayed turn-around times and the delayed reporting of non-compliances by the Agricultural Research Council-Onderstepoort Veterinary Institute (OVI) under the DALRRD and two sub-contracted laboratories. This prevented effective follow-up actions from taking place in a timely manner.

To ensure that the system is now functional in relation to the needs of aquaculture products, there is a need to ensure that the OVI upgrades it systems to reflect:

a) Inclusion in the sampling and testing plan of the relevant samples and testing capacities for residue compounds used in aquaculture and as set out in Directive 96/23/EEC.

b) The laboratory deficiencies identified have been corrected (in concordance with the guarantees subsequently delivered by the Competent Authority).

4.3.6 Application to DG SANTE for Approval and Listing under Annex I of Regulation 2019/626

Any gaps which are outstanding will need to be addressed, prior to submission of the application to extend the approved RMP under Article 29 of Council Directive 96/23/EC. This will at least need to include a dossier which contains:

a) Completed pre-mission questionnaire.

b) Updated legislation applicable to registration of MRLs for VMPs used in aquaculture.

c) Extended RMP demonstrating inclusion of monitoring of aquaculture animals.

e) RMP implementation report showing results and follow-up to non-compliances.

f) Upgraded laboratory testing capacities addressing deficiencies identified in the 2017 audit.

On the basis of these documents and a satisfactory audit (or provision of guarantees), the Commission may then amend Commission Decision 2011/163/EU to extend authorisation to aquaculture products from South Africa.

It should be noted that some of the tests required under the RMP (concerning environmental contaminants – organochlorine compounds, and heavy metals) are also required under general monitoring of fishery products and the SASMCP and samples are already taken and tested for these purposes. There are opportunities for data on test results on shellfish samples to be shared and used as evidence for more than one set of controls.

4.4 Aquatic Animal Health

4.4.1 Overview

Monitoring and control of aquatic animal health conditions for live bivalve and gastropod mollusc production should be in line with EU requirements for animal health in relation to listed diseases. From an animal health point of view, South Africa (whole territory) is listed by the Commission as authorised to import certain listed species of fish for human consumption only (but not for aquaculture or stocking). However, live molluscs and crustacea are excluded, and will need to be added to the list if such products are to be exported to the EU.

The required measures are illustrated in Figure 3 and the steps described in more detail below. However, these steps do not apply to processed products and are derogated (i.e., not required) when the products are packed ready for retail sale.

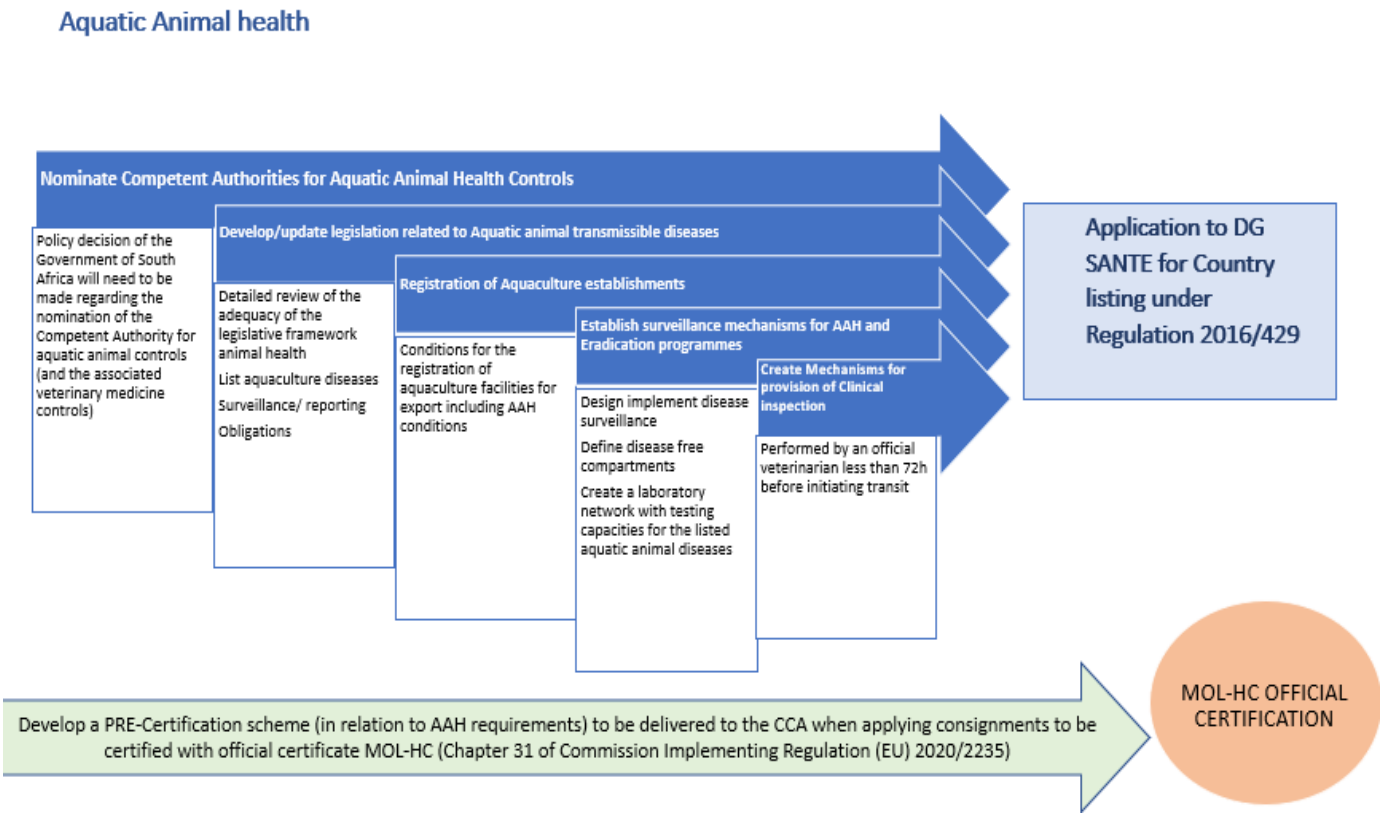

Figure 3: Road map for Aquatic Animal Health.

4.4.2 Competent Authority for Aquatic Animal Health Controls

Animal Health generally falls under the DALRRD, where the Animal Health Unit of the Agricultural Production, Health and Safety Branch is responsible for implementation of the law as set out in the Animal Diseases Act, 1984 (Act No. 35 of 1984).

The aims of the Unit are to:

a) Promote prevention and control of animal diseases.

b) Formulate policy and reduce sanitary risks in the import and export of animals and animal products.

c) Render epidemiological services for early warning and monitoring of animal diseases.

d) Render management support services.

The act defines an “animal” as any mammal, bird, fish, reptile, or amphibian which is a member of the phylum vertebrate, including the carcass of any such animal. Whilst this nominally applies to Aquatic Animal Health conditions, the DALRRD has not focused on the development the controls in the aquaculture sector.

Regulations under the Marine Living Resources Act, 1998 also contains provisions in Regulation 71 relating to powers to define notifiable diseases and which permit the Minister, by notice in the Gazette, to "declare any disease, including a pest or parasite, that kills or causes illness in fish or marine vegetation, or that kills or causes illness in people who eat the infected fish or marine vegetation, to be a notifiable disease".

Ideally the nomination of the Competent Authority for aquatic animal controls should be the same organisation responsible for the associated veterinary medicine controls. This would suggest that the DALRRD should be considered as the nominated CA for AAH.

4.4.3 Develop or Update Legislation Related to Aquatic Animal Transmissible Diseases

Article 155 of the EU Animal Health Regulation 2016/429 states that only third countries and territories which can demonstrate that they meet the animal health standards for entry of the animals and products into the EU should be eligible to export them to the union and be listed for that purpose.

In South Africa the Animal Diseases Act, 1984 (Act No. 35 of 1984) aims to "provide for the control of animal diseases and parasites, for measures to promote animal health and for matters connected therewith". A draft National Aquatic Animal Health Strategic Framework was developed in 2013. It recommended bringing aquatic animals into legislation by developing specific regulations under existing acts to address special requirements for aquatic animal diseases, defining responsibilities for implementation and providing support, especially training, to government officials tasked with implementation. The extent to which these proposals have been implemented remains to be established.

It is not clear whether the EU and the World Organisation for Animal Health (OIE) listed diseases impacting on AAH have been defined as notifiable diseases in South Africa. Whilst Bonamia is listed in the disease database of DALRRD, there are no entries to suggest that there is a monitoring and surveillance programme in place.

If live aquaculture products are to be exported (other than in retail packs), there will be a need for a detailed review of the adequacy of the legislative framework for animal health and the degree of implementation to determine the outstanding gaps for animal health controls.

4.4.4 Registration of Aquaculture Establishments

Out of 56 Veterinary Procedural Notices and 3 Standard Operating procedures governing the registration of export establishments, the import/export division of the Animal Health Unit does not include one set of conditions for the registration of aquaculture facilities for export (whilst those for all other sectors are specified – see https://www.nda.agric.za/vetweb/VPN%20&%20SOP/VPN_SOPs.htm). It is not clear whether any AAH conditions are in place at all for the registration of aquaculture farms and this will have to be developed and reviewed.

In addition to the registration, the CA will need to have in place a regulatory basis declaring as notifiable the AAH diseases of interest to the EU, as well as South Africa. These include several protozoan parasites which infect the haemocytes of oysters and other bivalves, and one virus, as follows:

a) Mikrocytos mackini

b) Perkinsus marinus

c) Bonamia exitiosa

d) Bonamia ostreae

e) Marteilia refringens

f) Ostreid herpes virus 1 µvar (OsHV-1 µVar)

4.4.5 Establish Surveillance Mechanisms for AAH and Eradication Programmes

The legislation should also require disease monitoring and surveillance, with powers to declare zones and their disease status, and to control movement of diseased animals and their products into and out of affected zones. The principles of the control measures should correspond to the EU's Animal Health Regulation 2016/429. This may also require the animal health obligations of aquaculture operators to be defined in more detail (e.g., to report disease/mortalities, to submit to surveillance and diagnostic testing, to observe movement restrictions). A comprehensive review (gap analysis and drafting of suitable amended or additional measures) is required if potentially infective products are to be exported.

As well as having in place suitable measures for the management of listed diseases, this legislation must be implemented. If live or fresh products are to be exported, and unless they are exported already in retail packaging, then only products from disease-free compartments subject to routine surveillance may be certified for the EU.

The detailed arrangements for implementation should correspond to the measures set out in Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 as regards rules for surveillance, eradication programmes, and the disease-free status for certain listed and emerging diseases. ANNEX VI of the regulation provides the specific requirements as regards diseases of aquatic animals.

4.4.6 Develop Laboratory Testing Capacities for the Listed Aquatic Animal Diseases

Article 6 of Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 as regards rules for surveillance, eradication programmes etc. also sets out the diagnostic testing methods to be applied. These must follow the methods set out in EU legislation, or by the OIE.

There is no information concerning the capacity of South African fish pathology laboratories to perform the diagnostic tests required for the listed pathogens, and a thorough review will be required to assess technical capacities and needs, followed by training of staff and development of test methods to the required level of competence.

4.4.7 Create Mechanisms for Provision of Clinical Inspection

The AAH component of the attestation in the official certificate MOL-HC (Chapter 31 of Commission Implementing Regulation (EU) 2020/2235) requires that an animal health check be performed on export of live animals to the EU by an official veterinarian less than 72 hours before despatch. This will require an officer of the DALRRD to visit the establishment, or to perform the check at the port of despatch. Specific arrangements will need to be made to ensure that this is done.

4.4.8 Application to DG SANTE for Country Listing

Any gaps which are outstanding will need to be addressed, prior to resubmission of the application for approval of the animal health controls for aquaculture products under Regulation2016/429. This will at least need to include a dossier which contains:

a) Completed pre-mission questionnaire.

b) Updated legislation applicable to the listing of aquaculture diseases.

c) Design and implementation of a monitoring plan demonstrating monitoring of listed aquaculture animals and their diseases.

d) Laboratory diagnostic capacities.

e) Relevant disease compartments and movement controls.

On the basis of these documents and a satisfactory audit (or provision of guarantees) the Commission may amend Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories or zones from which entry into the union of animals, germinal products and products of animal origin is permitted, thus extending import authorisation for molluscan aquaculture products to South Africa.

4.5 Development of a Pre-certification Scheme

As noted in Section 3, the EU requirements for molluscan shellfish are not homogeneous, and will depend on the feeding mechanism (filter feeding, or otherwise), whether farmed or wild harvested, live, or dead or cooked, and if live, on being packaged for retail sale.

Whatever the nature of the products to be certified for export, this will require coordination between 2 or possibly 3 Competent Authorities. The NRCS will need to certify as to the hygiene and HACCP conditions, the DFFE will need to certify that microbiological classifications and marine biotoxins are monitored in the production areas, and DALRRD will need to demonstrate that residue monitoring and animal health controls are in place, and to undertake the final health check on live animals.

Only one certificate is to be signed by one authorised officer attesting to all the relevant conditions (see certificate MOL-HC in Chapter 31 of Commission Implementing Regulation (EU) 2020/2235 described in 3.6 above). A system of delegated authority and of communication on specific batches will need to be developed to ensure combined decision-making in relation to export certification.

It is recommended that the CAs agree on a Pre-Certification scheme in which one of the CAs should be nominated as the Central CA, who will undertake the attestation on their own behalf (where they are mandated) as well as on behalf of other CAs, on the basis of their recommendations (for example via a system of pre-certification) applied to consignments to be certified with an official certificate. This is represented schematically in the following diagram.

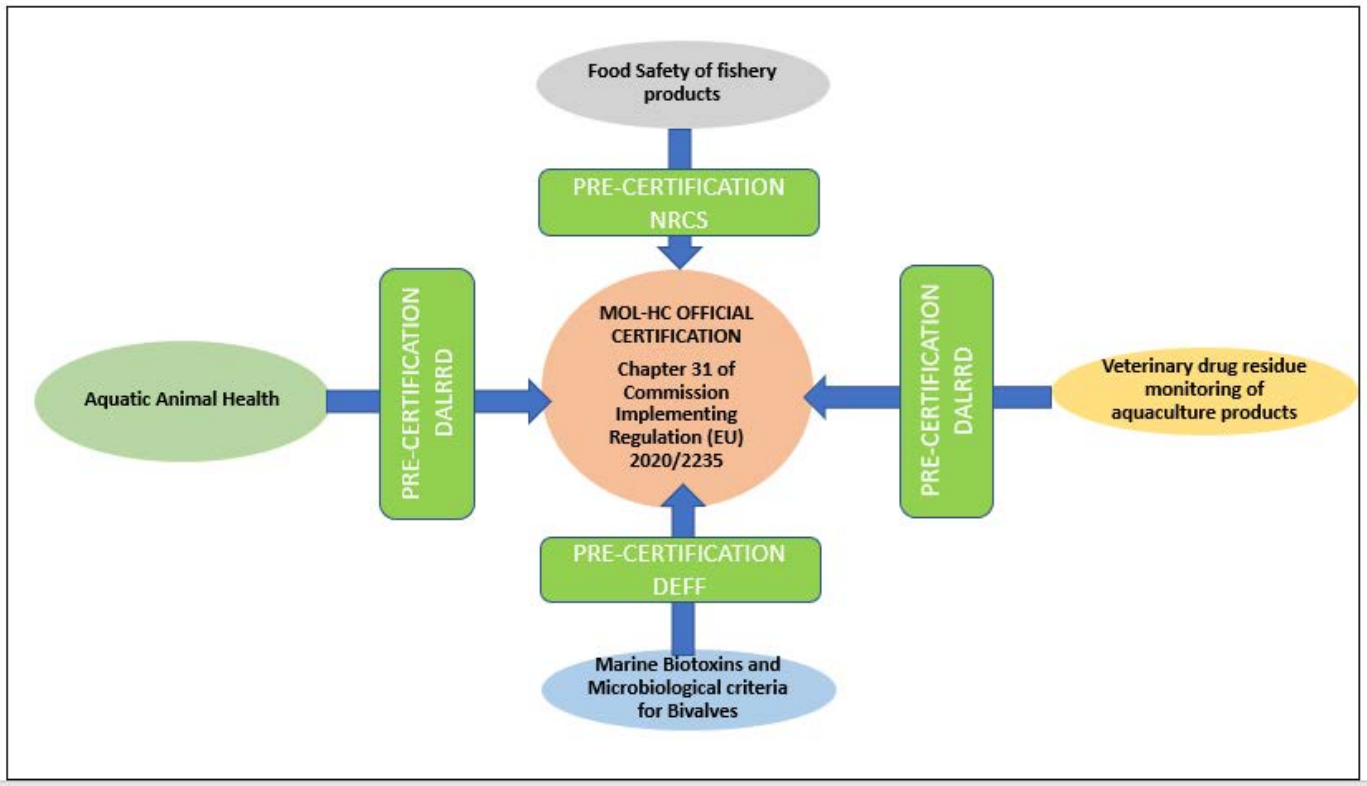

Figure 4: Pre-certification and certification steps for the export of molluscan shellfish.

5 CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusions

South African producers of molluscan shellfish seeking to export their products to the EU face several challenges in meeting sanitary (food safety and animal health) conditions set out in the EU regulations. However, the challenges depend on the nature of the products to be consigned and the specific hazards which may be present. There are several different routes which may be selected depending on the product. The roadmap in each case will involve varying degrees of development of new legislation, building the capacity of CAs responsible for controls, establishing competent testing laboratories and investment by the operators in upgraded facilities and control systems. These substantial investments should be considered in the same way as any other, by firstly establishing the feasibility of the business case, before committing to one path or another.

Several gaps have been identified in the South African control systems for the export of molluscs (depending on the nature of the products to be exported to the EU). Whilst a system is in place to guarantee the food safety of fishery products in general, at present South Africa has not yet met the conditions for:

a) Food safety of filter feeding bivalve and gastropod molluscs.

b) Controls on residues of veterinary medicines in aquaculture products.

c) Aquatic animal health.

Each control system has different requirements for its roadmap towards establishing the conditions which are “at least equivalent” to the EU legislation. In each case, the roadmap should be developed and adopted by a clearly nominated CA, which may be different in each case. General food safety conditions for fishery products are established and fall under the CCA and the NRCS. However, aquatic animal health and veterinary residue controls (under the DALRRD) and monitoring of marine biotoxins and microbiology of production areas (under DFFE) need to be developed.

Whilst the technical steps set out in the SASMCP are broadly in line with EU requirements, the plan cannot be considered “at least equivalent” since the regulatory component of the control measures are not yet reflected in law. There is no official monitoring of veterinary residues in aquaculture products (where the testing laboratory capacity has in the past shown some deficiencies). However, such systems are in place for some other animal products and could be extended to aquaculture. The aquatic animal health measures to ensure control of some important transmissible diseases of shellfish remain to be developed and implemented, including strengthened diagnostic testing capacity, as well as the establishment of compartments based on disease status, and movement controls.

Not all these controls are required for all products. The area based microbiological classification, monitoring of plankton and marine biotoxins is only required in respect of bivalve molluscs. Gastropod molluscs may be monitored for marine biotoxins at establishments. Bivalves and gastropods which are harvested from the wild do not need to be subject to a residue monitoring plan for residues of veterinary medicines. Gastropods, live bivalves packed for retail sale and cooked, or frozen bivalves do not need to come from areas subject to aquatic animal disease surveillance. Live molluscs of all types require a veterinary inspection before certification and despatch. The controls will need to be applied in a flexible way to match the product being exported to ensure that the attestation on the health certificate is true.

Given that potentially three CAs will be involved in ensuring the sanitary compliance of molluscan shellfish exported to the EU, and that the export must be subject to a certificate set by the EU legislation with a single attestation as to compliance with all these requirements, it is clear that there will need to be a high level of coordination and communication between the CAs.

5.2 Recommendations

South African shellfish operators are recommended to:

a) Invest in a market study and business planning exercise to determine the dimensions of the EU demand and the economic feasibility of establishing sanitary controls systems to meet EU requirements.

b) Consider the possibility of requesting the Competent Authorities to establish control systems, in the first place, for specific products which are considered to be the most economically feasible (the easiest and cheapest to establish in relation to the value of the trade flow).

The three CAs involved (NRCS, DFFE and DLRRD) are recommended to:

a) Form a committee for the coordination of risk management and official controls in the shellfish sector.

b) Develop and adopt a prioritised action plan, based on this roadmap, the expressed export priorities of the sector, to extend the current controls for export of fishery products to include, progressively:

   i. classification and monitoring of areas for the production of bivalves.

   ii. residue monitoring for products of aquaculture.

   iii. aquatic animal health controls for live bivalve filter-feeding molluscs.

c) Take the ease of establishing the controls into account when considering the phasing of the action plan. Of the products under consideration, the export of cooked or frozen abalone harvested from the wild would demand the least investment in development of control systems. The system of sampling and testing is

already in place, and only requires the monitoring data to be generated and presented. On the other hand, the export of farmed live, filter-feeding bivalve molluscs (such as oysters) requires a combination of all four control systems and will be the most complex to establish.

d) A further benefit is that these controls will also deliver benefits to South African consumers and to consumers in other countries to which South Africa exports (in terms of safer products). Producers will benefit through reduced risk, lowered impact of disease and improved AAH.

e) In all cases the system requirements should be expressed in new or amended regulations, so that the measures are legally enforceable, and meet the EU requirements for equivalence.

f) Where required (for example where different CAs have different attestations expressed on a single EU health certificate) consideration should be given to a system of pre-certifications to allow each CA to fulfil its mandate whilst delegating final signature of the EU certificate to just the one CA.

Annex 1: Summary of EU Regulations for Shellfish Controls

REGULATION (EC) No 853/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 laying down specific hygiene rules for food of animal origin.
Annex III **Section VII LVBM (page 45)** Applies to live bivalve molluscs. With the exception of the provisions on purification, it also applies to live echinoderms, live tunicates and live marine gastropods. The provisions on the classification of production areas set out in Chapter II, Part A, of that Section do not apply to marine gastropods and to echinoderms which are not filter feeders.
Ch.I General requirements: must distribute from despatch centres, with identification and registration documents.
Ch.II. Sets production and harvest conditions: A. Production areas to be classified (A, B, C only for HC, C may be heat treated). B. Handling and transport conditions. C. Conditions for relaying.
Ch.III Sets additional structural requirements for purification and despatch centres.
Ch.IV Sets additional hygiene & operational requirements for: A. Purification. B. Despatch Centres.
Ch.V. Health standards, specifying maximum limits for different marine biotoxins.
Ch.VI Packaging requirements (packages to be closed).
Ch.VII Identification and marking (information to be expressed on the label).
Ch.VIII Other requirements (temperature control/contact with water).

Ch.IX Pectinidae, Gastropods, Echinoderms and Holothuridae which are not filter feeders: • Ch.II Part B above is applicable. • Ch.V standards for marine biotoxins is applicable. • Ch II. Part A applies to Pectinidae when harvested in area subject to classification. • Must distribute via approved establishment. Ch. III and V apply of it is a despatch centre. • Ch.1 (para 3, 4) applies: registration documents to accompany movement, must specify production area. • Ch.VI applies (packing to be closed). • Ch.VII applies (identification and labelling).
REGULATION (EU) 2017/625 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products.
A18(6) 6. For the purpose of the official controls performed in relation to live bivalve molluscs, the competent authorities shall classify production and relaying areas.
COMMISSION DELEGATED REGULATION (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs.
Article 11 By way of derogation from Article 18(6) of Regulation (EU) 2017/625, official controls on *Pectinidae* and marine gastropods and *Holothuroidea*, which are not filter feeders.
Classification of production and relaying areas is not required provided official controls are carried out at fish auctions, dispatch centres and processing establishments.
Official control to include check on: • Ch.V Annex Section VII LVBM of Annex III 853/2004 (health standards for live bivalve molluscs). • Ch.IX Requirements for Pectinidae and marine gastropods and Holothuroidea which are not filter feeders, that are harvested outside the classified production areas.
COMMISSION DELEGATED REGULATION (EU) 2019/625 of 4 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council, with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption.

Article 8: Requirements for consignments of live bivalve molluscs, echinoderms, tunicates, and marine gastropods: 8.1 Third country production areas for LVBM to be specified and listed by Commission. 8.2 Pectinidae, Gastropods, Echinoderms and Holothuridae which are not filter feeders may enter from unclassified areas.
Article 9: COM to carry out spot checks to ensure validity of guarantees.
COMMISSION IMPLEMENTING REGULATION (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption,
Title 5 LBVM SPECIFIC REQUIREMENTS FOR OFFICIAL CONTROLS CONCERNING LIVE BIVALVE MOLLUSCS FROM CLASSIFIED PRODUCTION AND RELAYING AREAS.
Note not applicable to live marine gastropods and live Holothuroidea that are not filter feeders.
A52: Requirement to fix boundaries of harvest areas, and to classify on basis of E.coli contamination.
A53: Defines requirements for areas classed A.
A54: Defines requirements for areas classed B.
A55: Defines requirements for areas classed C.
A56: Requirement for CA to implement sanitary survey.
A57: Requirements for CA to implement monitoring program. Should specify no. samples, locations of sample points, sample frequency.
A58: CA to apply procedures to ensure validity/representative of a) sanitary survey and b) monitoring.
A59: Monitoring plan should include checks to identify: • Malpractice. • Microbiological quality. • Marine biotoxins and toxin producing phytoplankton. • Chemical hazards (environmental).
A60: Analytical methods to be used (not bio-assay if avoidable).

A61: Specifies sampling plans: • Indicate locations/frequency, to account for variation. • Must monitoring toxic phytoplankton. • Weekly tests for marine biotoxins (except when very low risk). • May use most sensitive as an indicator species.
A62: Areas to be closed (or use relaying/depuration) when conditions not met, or risk indicated.
A63: Sets conditions for re-opening of closed areas.
A64: CA to apply control system to verify compliance of FBO (all stages of production, processing & distribution). Must check marine biotoxins, environmental contaminants and microbiology.
A65: CA to take prompt decisions. Can rely on own checks of operators when laboratory is designated by the CA and agreed sampling/testing protocol in place.
A66: CA to establish list of production areas; communication and notification of changes.

Annex 2: Audit reports of the European Commission

Title	Date	DG SANTÉ Author	Number	Hyperlink
Final Report Of An Audit Carried Out In Namibia From 25 November 2019 To 06 December 2019 In Order To Evaluate The Control Systems In Place Governing The Production Of Fishery Products Intended For Export To The European Union	7 Feb 2020	European Commission, Directorate-General For Health And Food Safety, Health And Food Audits And Analysis	DG(SANTE) 2019-6692 **Ref. Ares(2020)796006 - 07/02/2020**	https://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=4233
Final Report Of An Audit Carried Out In Namibia From 3 To 7 February 2020 In Order To Evaluate The Control Of Residues And Contaminants In Live Animals And Animal Products Including Controls On Veterinary Medicinal Products	15 Jun 2020	European Commission, Directorate-General For Health And Food Safety, Health And Food Audits And Analysis	Ref. Ares(2020)3103002 - 15/06/2020 DG(SANTE) 2020-6996	https://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=4300
Final Report Of An Audit Carried Out In Namibia From 03 To 13 March 2014 In Order To Evaluate The Control Systems In Place Governing The Production Of Live Bivalve Molluscs Intended For Export To The European Union (Pre-Listing)	5 Feb 2015	European Commission, Health, And Consumers Directorate-General, Directorate F - Food And Veterinary Office	DG(SANCO) 2014-7163 - MR FINAL Ref. Ares(2015)474623 - 05/02/2015	https://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3382

Final Report Of An Audit Carried Out In Namibia From 27 February To 07 March 2012 In Order To Evaluate The Control Systems In Place Governing The Production Of Fishery Products Intended For Export To The European Union	27 Feb to 7 March 2012	European Commission, Health, And Consumers Directorate-General, Directorate F - Food And Veterinary Office	Ares(2012)666043 DG(SANCO) 2012-6464 - MR FINAL	https://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=2905

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