TRADE FORWARD
SOUTHERN AFRICA

General Guidelines towards Compliance with European Union (EU) Standards for the Export of Farmed Molluscs from South Africa and Namibia
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Image

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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. 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 guideline document should consult the official instruments to check for any such amendments.

CONTENT

ACRONYMS

AAH	Aquatic Animal Health
AAS	Atomic Absorption Spectrometry
AbHV	Abalone Herpes Virus
ASP	Amnesic Shellfish Poisoning
CA	Competent Authority
CEN	European Committee for Standardisation
DAI	Development Alternatives Incorporated
CEFAS	Centre for Environment, Fisheries and Aquaculture Science
DG SANTÉ	European Commission's Directorate-General for Health and Food Safety
DVS	Directorate of Veterinary Services
EC	European Commission
E.coli	*Escherichia coli*
EU	European Union
EUS	Epizootic Ulcerative Syndrome
FAO	Food and Agriculture Organisation
FBO	Food Business Operator
FCDO	Foreign, Commonwealth and Development Office
HAB	Harmful Algal Bloom
HACCP	Hazard Analysis and Critical Control Points
ISH	In Situ Hybridisation
ISO	International Standards Organisation
MANCP	Multi-Annual National Control Plans
MPN	Most Probable Number
MRL	Maximum Residue Level/Limit
NRCS	National Regulator for Compulsory Standards
NSAID	Non-Steroidal Anti-Inflammatory Drug
NSI	Namibian Standards Institution
OCR	Official Control Regulation
OSHv	Oyster Herpes Virus
OIE	World Organisation for Animal Health
PAH	Polycyclic Aromatic Hydrocarbons
PCB	Polychlorinated biphenyl
PoAO	Products of Animal Origin
PSP	Paralytic Shellfish Poison
RFTM	Ray's Fluid Thioglycolate Medium
RMP	Residue Monitoring Plan
SPS	Sanitary and Phytosanitary
TEM	Transmission Electron Microscopy
UN	United Nations
VMP	Veterinary Medicinal Product
WHO	World Health Organisation
WTO	World Trade Organisation

1 Introduction

South African and Namibian farmers have expressed a strong interest to export molluscs (mussels, oysters, and abalone) to the European Union (EU). This general guideline has been developed to assist industry role players, including farm operators and regulators, in their pursuit towards compliance to the EU standards for the export of these products.

2 Methodology and Sources

In developing this document, relevant guidelines were consulted as these pertain to the management of sanitary and animal health conditions in the production of live bivalve and gastropod molluscs, published by recognised sources.

These are set out in Section 5 and address:

a) General conditions for the import of fishery products into the EU
b) EU Guidelines on bivalve monitoring
c) UK guidelines on shellfish monitoring
d) Codex Codes of Practice and Standards
e) UN / FAO Reference Centre for Bivalve Mollusc Sanitation
f) OIE Aquatic Animal Health Code and Manual of Diagnostic Tests

It should be noted that these guidelines and this document are always subject to the relevant EU legislative instruments (indicated in Sections 6 and 7), which contain provisions concerning the import by the EU of live and prepared bivalve molluscs and gastropod molluscs from third countries, and which address:

a) Food safety
b) Veterinary medicines
c) Aquatic animal health
d) Official controls in relation to the above
e) Monitoring requirements
f) Testing methods (drawing on EU reference laboratories responsible for monitoring and testing methods)

In this document, legal references refer to the consolidated instruments, and not to original measures and amendments. The EU Commission disclaimer on use of consolidated documents therefore applies.

3 Structure of EU Compliance for the Export of Farmed Molluscs

Compliance to the EU Standards rely on the ability of the respective Competent Authorities (the National Regulator for Compulsory Standards (NRCS) in South Africa and the Namibian Standards Institution (NSI) in Namibia) to adequately demonstrate compliance to the European Commission's Directorate-General for Health and Food Safety. This directorate, known as DG SANTE, is responsible for the implementation of the EU laws on food safety and health.

Both South Africa and Namibia have been audited successfully for the export of certain wild-caught fisheries products to the EU but have not yet met the audit requirements for aquaculture products. In a compliance audit DG SANTE will evaluate several food safety control systems and frameworks at national level, all of which depend on the key areas in the following subsections, and which are described in a range of EU regulations.

3.1 The Requirement for Equivalence

Regulation (EC) No 178/2002 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. 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.

Equivalence also implies a food safety related regulatory framework that is comparable to that which is used in the EU.

3.2 General Food Safety Standards

Operators dealing with products of animal origin must comply with Regulations (EC) No 852/2004 on the hygiene of foodstuffs and No 853/2004 laying down specific hygiene rules for food of animal origin. The former sets out basic hygienic requirements related 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 (including aquaculture) products, and relates to conditions on fishing vessels, freezer vessels and establishments etc.

As indicated above, these general food safety standards have been met by both South Africa and Namibia for fisheries products, but not as yet for aquaculture products. An audit by DG SANTE will

necessarily consider the control systems implemented by the respective Competent Authorities, and although on-farm and downstream value chain facilities may be inspected directly, DG SANTE will primarily be concerned with the control systems implemented by the Competent Authorities, including their systems for inspection, findings, and corrective actions. For the Component Authorities to be able to report favourably on general food safety standards, it is important that operators implement internationally recognised food safety measures.

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, such as, but not limited to, those caused by Harmful Algal Blooms (HABs).

The conditions related to microbiological and marine biotoxin safety are set out in the Annex to Regulation (EC) No 853/2004. The monitoring of microbiological and marine biotoxins, the declaration of suitable farming areas, and the closure of areas is a task that falls to the Competent Authority.

3.4 Veterinary Medicine Monitoring and Controls

Competent Authorities are required to perform routine monitoring of the residues in products of animal origin as set out in Article 19 of the General Requirement for Residue Monitoring which refers to Council Directive 96/23/EC. This contains the measures to monitor certain substances and residues thereof in live animals and animal products.

3.5 Animal Health

EU animal health requirements are set out in Regulation (EU) 2016/429. It deals with 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.

3.6 Certification

The form of the certificate that the Competent Authority needs to issue is specified in CIR 2019/2235 Chapter 31, which shows the Model Animal Health/Official Certificate for entry into the EU of Live Bivalve Molluscs, Echinoderms, Tunicates, Marine Gastropods and Products of Animal Origin from these animals intended for human consumption (Model MOL-HC).

4 Responsibility of the Farmer or Operator

As much as the control systems, certification and much of the monitoring is the responsibility of the Competent Authority, it is incumbent on the mollusc farmers and operators to implement a range of best practices that aim to facilitate the work of the Competent Authority, and which ensures the production of farmed products that are safe for human consumption. A column depicting specific responsibilities of food business operators, including farmers) has been included in Section 6 that covers the EU legislative frameworks. The following general practices should form the core of a set of best practices at farm and operator level.

a) Farmers and operators must ensure that they comply with all the approvals, permits and licences for the holding, farming, processing, and sale of farmed molluscs in their respective countries, and must ensure that the conditions associated with these are met.
b) Farmers and operators must work closely with the respective Competent Authorities and ensure that these authorities have access to information that may be required to illustrate that adequate food safety control systems are in place.
c) Farmers and operators must implement internationally recognised food safety measures such as a Hazard Analysis and Critical Control Point (HACCP) system throughout the production cycle to ensure that any biological, chemical, and physical hazards from raw material production and farming, procurement, and handling, to manufacturing, distribution and consumption of the farmed product can be detected, documented, and that products can be recalled.
d) Farmers and operators must check that a suitable microbiological and marine biotoxin monitoring programme is implemented in the farming environment (task of the Competent Authority) and that instructions based on results from this monitoring programme are adhered to.
e) Farmers and operators may only use recognised veterinary medicines as prescribed by registered veterinarians, and must adhere to prescriptions of handling, dosage, storage, and disposal. A veterinary medicine monitoring and control programme must be in place.
f) Farmers and operators must implement an approved biosecurity plan to address all animal health matters in the production cycle.

5 Guidance on Implementation of Bivalve Controls

As indicated above, the responsibility to demonstrate national compliance lies with the Competent Authority. However, several key practices must be implemented by farmers and operators at

production and project level to enable the Competent Authority to do so. Several guidelines have been produced by the EU, but also by the likes of the United Kingdom, Food and Agriculture Organisation (FAO) of the United Nations (UN), the World Organisation for Animal Health (OIE) and others. These guidelines deal mainly with the responsibilities of the Competent Authorities, with due consideration that these responsibilities depend on farmers and operators that pursue compliance to the control systems. These guidelines are indicated in the subsections that follow, while the legal frameworks are summarised in Section 6 and the official testing methods in Section 7.

5.1 EU Guidelines on Import Conditions for Fishery Products

For an overview of import conditions for fishery products and bivalve molluscs the European Commission's Directorate General for Health and Food Safety (DG SANTE) has published generic guidelines. These provide a general review of the rules which non-EU countries should follow to ensure that their export of such products fulfil the same required standards as products from the EU Member States - not only with respect to hygiene and consumer safety but, where relevant, also to their animal health status. The title and link to this general guideline is tabled below:

Title	Link
EU Import Conditions for Seafood and Other Fishery Products, European Commission's Directorate-General for Health & Food Safety.	https://food.ec.europa.eu/system/files/2018-06/ia_trade_import-cond-fish_en.pdf

5.2 EU Guidelines on Microbiological Monitoring of Shellfish

Given that many of the farmed mollusc species are filter feeders, these organisms are directly affected by marine biotoxins, which poses a potential food safety risk. For this reason, specific guidelines have been developed around microbiological and marine biotoxin monitoring. The title and link to these guidelines is tabled below:

Title	Link
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.	food.ec.europa.eu/system/files/2018-12/biosafety_fh_guidance_community_guide_bivalve_mollusc_monitoring_en.pdf

(*NB. 854/2004 repealed and measures included in the OCR 2017/625*).	
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.	**www.cefas.co.uk/media/jyzhl1si/good-practice-guide-issue-6.pdf**

5.3 UK Guidelines on Food Safety of Bivalve Molluscs

Although the UK is no longer an EU member, the UK guidelines around food safety in bivalve molluscs serves as an extensive and useful source of information, with due recognition that compliance with the EU system will ultimately depend on compliance with the EU regulatory frameworks. The UK are leaders in molluscan sanitary measures and making use of the UK guidelines is useful insofar as creating a food safety control system that meets EU equivalence. The title and link to some relevant UK guidelines is tabled below:

Title	**Link**
Sanitary Surveys of Proposed Shellfish Harvest Zones.	**www.cefas.co.uk/data-and-publications/sanitary-surveys/england-and-wales/**
Shellfish Classification System and Conditions.	**www.food.gov.uk/business-guidance/shellfish-classification**
Biotoxin and Phytoplankton Monitoring.	**www.food.gov.uk/business-guidance/biotoxin-and-phytoplankton-monitoring**
Chemical Contaminant Monitoring.	**www.food.gov.uk/business-guidance/chemical-contaminant-monitoring**
Sampling and Collection Protocols for Shellfish Monitoring.	**www.cefas.co.uk/services/programme-management/shellfish-partnership/**

5.4 Global Reference Centre for Bivalve Mollusc Sanitation

The UK's Centre for Centre for Environment, Fisheries and Aquaculture Science (CEFAS) is designated as the Reference Centre for Bivalve Mollusc Sanitation by the Food and Agriculture Organisation (FAO or the United Nations (UN). This reference centre has published several guidance documents on the

development and operation of shellfish sanitation programmes, which can be accessed through their website at **www.cefas.co.uk/icoe/seafood-safety/services/international-guidance/.**

The World Health Organisation (WHO), together with the Food and Agriculture Organisation (FAO or the United Nations (UN), produced the following important reference work related to international food safety standards for molluscs.

Title	Link
Technical Guidance for the Development of the Growing Area Aspects of Bivalve Mollusc Sanitation Programmes, Food Safety and Quality Series, 2018.	www.fao.org/3/CA1213EN/ca1213en.pdf

5.5 Codex Alimentarius Commission

Globally, the Codex standards, guidelines and codes of practice are directed at the regulatory systems. Although universally recognised and applied, they are voluntary in nature and need to be translated into national legislation or regulations to be enforceable. However, in accordance with the World Trade Organisation's (WTO) sanitary and phytosanitary agreements the Codex standards provide the reference standards to be applied for resolution of technical trade barrier disputes between Member States concerning food safety conditions. The key documents of relevance are:

a) Sections 7 (bivalves) and Section 8 (scallops) of CXC 52-2003 Code of Practice for Fish and Fishery Products.
b) CXS 292-2008 Standard for Live and Raw Bivalve Molluscs.
c) CXG 73-2010 Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood.

These documents can be found at **www.fao.org/fao-who-codexalimentarius/codex-texts/en/.**

5.6 Aquatic Animal Health for Bivalve Molluscs

The UK'S Fish Health Inspectorate (**www.gov.uk/government/groups/fish-health-inspectorate**) provides several guidelines related to meeting the animal health requirements for a control system with EU equivalence. Other important reference works around animal health matters related to molluscs are listed by title and reference below:

Title	Link
Overview Report on a Series of Fact-Finding Missions carried out in 2018 on the Implementation of the Rules on Bivalve Mollusc Aquaculture DG(SANTE) 2018-6568	http://ec.europa.eu/food/audits-analysis/overview_reports/act_getPDF.cfm?PDF_ID=1286
Summary of EU legislation on mollusc diseases controls (*several documents*).	www.eurl-mollusc.eu/Legislation

5.7 Conditions of the World Animal Health Organisation (OIE)

The OIE is the intergovernmental organisation responsible for improving animal health worldwide, and provides several guidelines related to meeting the animal health requirements in control systems for bivalves.

The OIE Aquatic Animal Health Code (2021) provides the international standards and guidelines for management of animal health conditions. Countries may apply these measures to international trade without fear that they may be challenged as unreasonable barriers to trade. The Code is available at www.oie.int/en/what-we-do/standards/codes-and-manuals/aquatic-code-online-access/. Of special relevance to molluscs are the chapters on Zoning and Compartmentalisation, Trade Measures, and Diseases of Molluscs.

The OIE Manual of Diagnostic Tests for Aquatic Animals (2022) deals specifically with testing methodologies for molluscs in Chapter 2.4, and can be accessed through this link: www.oie.int/en/what-we-do/standards/codes-and-manuals/aquatic-manual-online-access/.

6 EU Legal Instruments

6.1 Official Controls

The Regulation (EU) 2017/625 (the Official Control Regulation) sets out the common conditions for the application of official controls to ensure that operators are complying with food and feed safety, veterinary medicine and animal health and welfare controls, as well as other related issues (organic certification etc). Regulation (EU) 2017/625 extends the scope to official controls for the verification of compliance with Article 118(1) on antimicrobials.

The tables that follow summarise the remaining official controls, with the respective subsections thereafter listing the legal instruments pertaining to each of the key areas of the control system. The requirements that pertain to the Competent Authorities are separated from those that pertain to the aquaculture farmer or operator.

Applicable Legislation	Matters Relevant to the Competent Authority	Matters Relevant to the Food Business Operator (FBO)
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	**Article 120:** Sets out issues to be addressed by the Commission in considering equivalence. 1. Commission experts may perform controls in third countries in order to: a. verify the compliance or equivalence of third-country legislation and systems, including official certification and the issuance of official certificates, b. verify the capacity of the third country control system to ensure that consignments of animals and goods exported to the Union comply with relevant requirements established by the rules referred to in Article 1(2) or with requirements recognised to be at least equivalent thereto; c. collect information and data to elucidate the causes of recurring or emerging problems in relation to exports of animals and goods from a third country. 2. The controls provided for in paragraph 1 shall have particular regard to:	**Article 15:** Obligations of operators to provide access to Competent Authority staff to: a) the equipment, means of transport, premises and other places under their control and their surroundings; b) their computerised information management systems; c) the animals and goods under their control; d) their documents and any other relevant information.

	a. the legislation of the third country; b. the organisation of the third country's Competent Authorities, their powers and independence, the supervision to which they are subject and the authority they have to enforce the applicable legislation effectively; c. the training of staff of the Competent Authority of the third country in the performance of official controls; d. the resources including analytical, testing and diagnostic facilities available to Competent Authorities; e. the existence and operation of documented control procedures and control systems based on priorities; f. where applicable, the situation regarding animal health, animal welfare, zoonoses and plant health, and procedures for notifying the Commission and relevant international bodies of outbreaks of animal diseases and pests of plants; g. the extent and operation of controls performed by the Competent Authority of the third country	

	on animals, plants and their products arriving from other third countries; and h. the assurances which the third country can give regarding compliance with, or equivalence to, the requirements laid down in the rules referred to in Article 1(2). 3. In order to facilitate the efficiency and effectiveness of the controls provided for in paragraph 1, the Commission may, prior to performing such controls, request that the third country concerned provide: a. the necessary information referred to in Article 125(1); and b. where appropriate and necessary, the written records on the controls its Competent Authorities perform. **CHAPTER I: Nomination of Competent Authority** **Article 12:** Documented control procedures. **Article 13:** Written records of official controls. **Article 18:** Specific rules on official controls and for action taken by the Competent Authorities in relation to the	

	production of products of animal origin intended for human consumption. **Article 19:** Specific rules on official controls and for action taken by the Competent Authorities in relation to the residues of relevant substances in food and feed. **Article 28** Delegation by the Competent Authorities of certain official control tasks. **Article 32:** Obligations of the delegated bodies and natural persons. **Article 34:** Methods used for sampling, analyses, tests, and diagnoses. **Article 37:** Designation of official laboratories. **Article 39:** Audits of official laboratories. **CHAPTER VII: Official Certification** **Article 100:** Designation of national reference laboratories. **Article 101:** Responsibilities and tasks of national reference laboratories. **Article 109:** Multi-annual national control plans (MANCP) and a single body for the MANCP. **Article 113:** Annual reports by the Member States. **Article 115:** Contingency plans for food and feed.	

	Article 137: General obligations of the Competent Authorities as regards enforcement action. **Article 138:** Actions in the event of established non-compliance. **ANNEX II: Training of Staff of the Competent Authorities**	

6.2 Bivalve Mollusc Production Food Safety Monitoring and Control Measures

Applicable Legislation	Matters Relevant to the Competent Authority	Matters Relevant to the Food Business Operator (FBO)
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	Requirement for monitoring of classified production and relaying areas, which requires monitoring of phytoplankton and chemical contaminants, as well as microbiological quality (could be other indicators).	

Commission Implementing Regulation (EU) 2019/627 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625	**Chapter I:** Specific requirements for audits by the Competent Authorities in establishments handling products of animal origin (list of issues to be audited in establishments). **Title V: Specific requirements for official controls concerning live bivalve molluscs from classified production and relaying areas.** **Article 51:** Tile excludes live marine gastropods and live *Holothuroidea* that are not filter feeders. **Article 52:** Classification of production and relaying areas for live bivalve molluscs as Class A, Class B and Class C. **Articles 53, 54 and 56**: Conditions for Class A, Class B and Class C respectively based on concentration of *E.Coli.* *NB. These articles apply to live bivalve molluscs. It also applies to live echinoderms, live tunicates and live marine gastropods. This does not apply to live marine gastropods and live Holothuroidea that are not filter feeders.* **Article 56:** Sanitary survey requirements. **Article 57:** Monitoring programme to be established.	**Article 60:** Recognised methods for the detection of marine biotoxins in live bivalve molluscs. Food business operators shall use these methods where appropriate. *Analytical methods are laid down in Annex V* **Article 65:** Decision by the Competent Authorities. In considering classification, reclassification, opening or closure of production areas Competent Authorities may take into account the results of checks carried out by food business operators only if the laboratory carrying out the analysis is designated by the Competent Authorities, and the sampling and analysis are performed in accordance with a protocol agreed upon jointly by the Competent Authorities and food business operators or organisation concerned.

	Article 59: Monitoring of classified production and relaying areas to check: a) that there is no malpractice with regard to the origin, provenance and destination of live bivalve molluscs; b) the microbiological quality of live bivalve molluscs in relation to the classified production and relaying areas; c) for the presence of toxin-producing plankton in production and relaying waters and marine biotoxins in live bivalve molluscs; d) for the presence of chemical contaminants in live bivalve molluscs. **Article 60:** Recognised methods for the detection of marine biotoxins in live bivalve molluscs. *Analytical methods are laid down in Annex V* **Article 61:** Sampling plans are set out. Weekly sampling for marine biotoxins (unless evidence to the contrary). **CHAPTER III: Management of classified production and relaying areas after monitoring.** **Article 62:** Decisions following monitoring - ability to cause cessation of harvest, conditions in which harvest may	

	proceed (appropriate restrictive measures such as purification, relaying, or processing). **Article 63:** Re-opening of production areas – conditions (for toxins at least two consecutive analytical results separated by at least 48 hours are below the regulatory limit). **Article 64:** Control system: a) The Competent Authorities shall set up a control system to ensure that products of animal origin harmful to human health are not placed on the market. **Article 65:** Decision by the Competent Authorities: a) The Competent Authorities shall act promptly on decisions about opening/closure. b) In considering classification, reclassification, opening or closure of production areas Competent Authorities may consider the results of checks carried out by food business operators only if the laboratory carrying out the analysis is designated by the Competent Authorities, and the sampling and analysis are performed in accordance with a protocol agreed upon jointly by the Competent Authorities and food business operators or organisation concerned.	

	Article 66: Recording and exchange of information: The Competent Authorities shall establish and keep up to date a list of classified production and relaying areas and the list is to be communicated to all operators. **TITLE VI: Specific requirements and uniform minimum frequency of official controls with respect to fishery products.** **Article 67:** Official controls on production and placing on the market; requires checks on establishment hygiene. **Article 70:** Official controls of fishery products shall include at least the practical arrangements laid down in Annex VI as regards: a) organoleptic examinations; b) freshness indicators; c) histamine; d) residues and contaminants; e) microbiological checks; f) parasites; g) poisonous fishery products.	

	ANNEX VI: Practical arrangements for official controls on fishery products in accordance with Article 70. **Article 71:** Decisions after controls - conditions for considering fishery products unfit for consumption.	
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	**Article 4:** Requirement for establishments to be approved by the Competent Authority. **Article 6:** Products of animal origin from outside the Union must be from a permitted third country, an approved establishment in that country and in the case of bivalve molluscs, a the production area that appears on a list drawn up in accordance with Regulation 2017/625. Part A of Chapter II of Section VII of Annex III to Regulation (EC) No 853/2004, states that live bivalve molluscs are to be harvested from production areas classified by the Competent Authorities and from which they authorise the harvesting. The place where official controls are to be performed on the production of these *Pectinidae*, marine gastropods and *Holothuroidea*, which are not filter feeders, should also be established.	**Article 5:** Health and identification marking. Food business operators shall not place on the market a product of animal origin handled in an establishment unless a health marking attached. **ANNEX III: Specific requirements** **SECTION VII: Live Bivalve Molluscs** **CHAPTER I: General requirements for the placing on the market of live bivalve molluscs** (includes requirement for a registration document for each batch). **CHAPTER II: Hygiene requirements for the production and harvesting of live bivalve molluscs** a) Requirements for production areas: Bivalve molluscs to be harvested only from authorised production areas). Limits consumption for Class B and C products. b) Requirements for harvesting and handling following harvesting. Conditions for transport and handling.

	Annex III to Section VII, Chapter V: Health standards for live bivalve molluscs Such products must not contain marine biotoxins in total quantities (measured in the whole body or any part edible separately) that exceed the following limits: a) For paralytic shellfish poison (PSP), 800 micrograms of saxitoxin equivalent per kilogram; b) For amnesic shellfish poison (ASP), 20 milligrams of domoic acid per kilogram; c) For okadaic acid, dinophysistoxins and pectenotoxins together, 160 micrograms of okadaic acid equivalents per kilogram; d) For yessotoxins, 1 milligram of yessotoxin equivalent per kilogram. e) For azaspiracids, 160 micrograms of azaspiracid equivalents per kilogram. **Note Chapter IX:** Specific requirements for *Pectinidae*, marine gastropods and echinoderms which are not filter feeders harvested outside classified production areas.	c) Requirements for relaying live bivalve molluscs. Conditions for and relaying. **CHAPTER III: Structural requirements for dispatch and purification centres** **CHAPTER IV: Hygiene requirements for purification and dispatch centres** a) Requirements for purification centres. b) Requirements for dispatch centres. **CHAPTER V: Health standards for live bivalve molluscs** Contains limits for marine biotoxins. **CHAPTER VI: Wrapping and packaging of live bivalve molluscs** **CHAPTER VII: Identification marking and labelling** **CHAPTER VIII: Other requirements** **CHAPTER IX: Specific requirements for *Pectinidae*, marine gastropods and echinoderms which are not filter feeders harvested outside classified production areas** **SECTION VIII: Fishery products** Applicable to fishery products and to processed (not live) bivalve molluscs, echinoderms, tunicates and marine gastropods

		CHAPTER II: Requirements during and after landing **CHAPTER III: Requirements for establishments, including vessels, handling fishery products** **CHAPTER IV: Requirements for certain processed fishery products** a) Requirements for cooking of crustaceans and molluscs **CHAPTER V: Health standards for fishery products** **Annex III to Section VII, Chapter V: Health standards for live bivalve molluscs** Such products must not contain marine biotoxins in total quantities (measured in the whole body or any part edible separately) that exceed the following limits: a) For paralytic shellfish poison (PSP), 800 micrograms of saxitoxin equivalent per kilogram; b) For amnesic shellfish poison (ASP), 20 milligrams of domoic acid per kilogram; c) For okadaic acid, dinophysistoxins and pectenotoxins together, 160 micrograms of okadaic acid equivalents per kilogram; d) For yessotoxins, 1 milligram of yessotoxin equivalent per kilogram.

		e) For azaspiracids, 160 micrograms of azaspiracid equivalents per kilogram. **Note Chapter IX:** Specific requirements for *Pectinidae*, marine gastropods and echinoderms which are not filter feeders harvested outside classified production areas. **CHAPTER VI: Wrapping and packaging of fishery products** **CHAPTER VII: Storage of fishery products** **CHAPTER VIII: Transport of fishery products**
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 in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council	**Article 11:** Official controls on *Pectinidae* and marine gastropods and *Holothuroidea*, which are not filter feeders, that are harvested from production areas which are not classified in accordance with Article 18(6) of Regulation (EU) 2017/625 (exemption from area monitoring) By way of derogation from Article 18(6) of Regulation (EU) 2017/625, the classification of production and relaying areas is not required in relation to the harvesting of *Pectinidae*, marine gastropods and *Holothuroidea*, which are not filter feeders, when the Competent Authorities carry out official controls on such animals in fish auctions, dispatch centres and processing.	

	ANNEX II: Specific minimum requirements for the official veterinarian, the official auxiliary and the staff designated by the Competent Authorities.	
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 (from listed areas, except *Pectenidae* and non-filter feeding gastropods). **Article 9:** Listing of production areas (guarantees to the Commission). **Article 10:** Special requirements for fishery products (requirement for listing of approved establishment, a factory or freezer vessel or stored in a cold-store or a reefer vessel). **Article 13:** Official certificates to be submitted on entry to the EU.	
Commission Implementing Regulation (EU) 2021/405 of 24 March 2021 laying down the lists of third countries or regions thereof authorised for the entry	**Article 12:** 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. **Annex VIII**: List of countries authorised	

into the Union of certain animals and goods intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council		

6.3 General Food Safety Requirements

Applicable Legislation	Matters Relevant to the Competent Authority	Matters Relevant to the Food Business Operator (FBO)
Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs	**Article 6:** Official controls, registration, and approval. Obligation to register Food Business Operators (FBOs)	**Article 4:** General and specific hygiene requirements. Food business operators carrying out primary production shall comply with the general hygiene requirements laid down in Annex I. **Annex I:** General requirements for primary producers: 2. Food business operators carrying out any stage of production, processing, and distribution of food after primary production shall comply with the general hygiene requirements laid down in general hygiene requirements for all food business operators, which includes: a) General requirements for food premises.

		b) Specific requirements in rooms where foodstuffs are prepared, treated, or processed. c) Requirements for movable and/or temporary premises. d) Transport. e) Equipment requirements. f) Food waste. g) Water supply. h) Personal hygiene. i) Provisions applicable to foodstuff. j) Heat treatment. k) Training. **Article 5:** Hazard analysis and critical control points: Food business operators (except primary producers) shall put in place, implement, and maintain a permanent procedure or procedures based on the HACCP principles. *NB. Additional requirements set for Products of Animal Origin (PoAO) in 853/2004.*
Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general	**SECTION 4 General requirements of food law** **Article 14:** Food safety requirement: General requirement for food to be safe. **Article 15:** Feed safety requirements: General requirements for feed to be safe.	**Article 17:** Responsibilities Food and feed business operators at all stages of production, processing, and distribution, to ensure food and feed safe and to verify compliance. **Article 18:** Traceability

principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety		a) The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing, and distribution. b) Operators shall have in place systems and procedures for traceability. c) Operators to make information available to the Competent Authorities on demand. **Article 19:** Responsibilities for food business operators to withdraw non-compliant food and inform the Competent Authorities thereof. **Article 20:** Responsibilities for feed business operators to withdraw feed and inform the Competent Authorities thereof.
Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption	**Article 4: General obligations** Competent authorities should verify that water intended for human consumption shall be wholesome and clean if all the following requirements are met: a) that water is free from any micro-organisms and parasites and from any substances which, in	**Article 4: General obligations** Water intended for human consumption shall be wholesome and clean if all the following requirements are met: a) that water is free from any micro-organisms and parasites and from any substances which, in numbers or concentrations, constitute a potential danger to human health.

	numbers or concentrations, constitute a potential danger to human health. b) that water meets the minimum requirements set out in Parts A, B and D of Annex I. **Parts A, B and D of Annex I:** Sets water quality parameters and indicator parameters. **ANNEX I: Minimum requirements for parametric values used to assess the quality of water intended for human consumption.** Microbiological parameters: Chemical and indicator parameters for which performance characteristics are specified - sets performance limits. See also **ANNEX III**: Specifications for the analysis of parameters.	b) that water meets the minimum requirements set out in Parts A, B and D of Annex I. **Parts A, B and D of Annex I:** Sets water quality parameters and indicator parameters. **ANNEX I: Minimum requirements for parametric values used to assess the quality of water intended for human consumption.** Microbiological parameters: Chemical and indicator parameters for which performance characteristics are specified - sets performance limits. See also **ANNEX III**: Specifications for the analysis of parameters.
Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs	**Article 1:** The Competent Authority shall verify compliance to this Regulation without prejudice to its right to undertake further sampling and analyses for the purpose of detecting and measuring other micro-organisms, their toxins or metabolites, either as a verification of processes, for food suspected of being unsafe, or in the context of a risk analysis.	**Article 3:** Food business operators shall ensure that foodstuffs comply with the relevant microbiological criteria set out in Annex I. As necessary, the food business operators responsible for the manufacture of the product shall conduct studies in accordance with Annex II in order to investigate compliance

	Annex I: Chapter 1. Food safety criteria Chapter 2. Process hygiene criteria Section 2.4. Fishery products	with the criteria throughout the shelf-life. In particular, this applies to ready-to-eat foods that are able to support the growth of Listeria monocytogenes and that may pose a Listeria monocytogenes risk for public health. **Article 4:** Requires food business operators to perform testing against criteria **Article 7:** Unsatisfactory results **Annex I:** Chapter 1. Food safety criteria Chapter 2. Process hygiene criteria Section 2.4. Fishery products
	Chapter 1, Annex 1, *E.coli* 1.2.5 Live bivalve molluscs and live echinoderms, tunicates and marine gastropods. 2.4.1 Shelled and shucked products of cooked crustaceans and molluscan shellfish. Each sample unit comprises a minimum number of individual animals according to EN/ISO 6887-3. *Listeria monocytogenes*	**Chapter 1, Annex 1,** *E.coli* 1.2.5 Live bivalve molluscs and live echinoderms, tunicates and marine gastropods. 2.4.1 Shelled and shucked products of cooked crustaceans and molluscan shellfish. Each sample unit comprises a minimum number of individual animals according to EN/ISO 6887-3. *Listeria monocytogenes*

	1.2 Ready-to-eat foods able to support the growth of L. monocytogenes, other than those intended for infants and for special medical purposes. Sampling before the food has left the immediate control of the food business operator, who has produced it. *Salmonella* 1.16: Cooked crustaceans and molluscan shellfish 1.17: Live bivalve molluscs and live echinoderms, tunicates, and gastropods. *Coagulase +ve Staph.aureus* 2.4.1 Shelled and shucked products of cooked crustaceans and molluscan shellfish.	1.2 Ready-to-eat foods able to support the growth of L. monocytogenes, other than those intended for infants and for special medical purposes. Sampling before the food has left the immediate control of the food business operator, who has produced it. *Salmonella* 1.16: Cooked crustaceans and molluscan shellfish 1.17: Live bivalve molluscs and live echinoderms, tunicates, and gastropods. *Coagulase +ve Staph.aureus* 2.4.1 Shelled and shucked products of cooked crustaceans and molluscan shellfish. **Annex II:** Specification for studies by operators to investigate compliance with the criteria throughout the shelf-life. (especially Listeria monocytogenes).
Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting	**Article 1:** General rules: The foodstuffs listed in the Annex shall not be placed on the market where they contain a contaminant listed in the Annex at a level exceeding the maximum level set out in the Annex.	**Article 1:** General rules: The foodstuffs listed in the Annex shall not be placed on the market where they contain a contaminant listed in the Annex at a level exceeding the maximum level set out in the Annex.

maximum levels for certain contaminants in foodstuffs	Annex addresses lead, cadmium, mercury, inorganic tin in bivalve molluscs and fishery products etc.	Annex addresses lead, cadmium, mercury, inorganic tin in bivalve molluscs and fishery products etc.
Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed	**Article 3** and Annex limits for various contaminants in animal feeds. Includes heavy metals, PCBs and Dioxins.	**Article 3** and Annex limits for various contaminants in animal feeds. Includes heavy metals, PCBs and Dioxins.

6.4 Veterinary Medicine Control Measures

Applicable Legislation	Matters Relevant to the Competent Authority	Matters Relevant to the Food Business Operator (FBO)
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	**Article 19:** General requirement for residue monitoring. Under Directive 96/23 Annex 1 Monitoring is required for: ***Highlighted parameters are required for aquaculture products.*** 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: Residue or substance group to be detected by type of animal, their feeding stuffs, including drinking water, and primary animal product.** NB 96/23 repealed but Under Article 150 of 2017/625 Transitional measures related to the repeal of Directive 96/23/EC: *Competent authorities shall continue to perform the official controls necessary to detect the presence of the substances and groups of residues listed in Annex I to Directive 96/23/EC, in accordance with Annexes II, III and IV to that Directive, instead of the corresponding provisions of this Regulation, until 14 December 2022 or an earlier date to be determined in the delegated act adopted in accordance with paragraph 3 of this Article.*	
Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on	Entered into application on 28 January 2022, replacing the legal framework for veterinary medicinal products (VMPs) established by Directive 2001/82/EC and Regulation (EC) No 726/2004.	**Article 108:** Record-keeping by owners and keepers of food-producing animals.

veterinary medicinal products	**Article 118:** List of substances not authorised for use in food animals due to reserved use for human medicine. **CHAPTER II: Marketing authorisations – general provisions and rules on applications** Section 1 **Article 5:** Marketing authorisations a) A veterinary medicinal product shall be placed on the market only when a Competent Authority or the Commission, as applicable, has granted a marketing authorisation for that product in accordance with Article 44, 47, 49, 52, 53 or 54. **Article 118:** Animals or products of animal origin imported into the Union a) Article 107(2) shall apply, *mutatis mutandis*, to operators in third countries and those operators shall not use the designated antimicrobials referred to in Article 37(5). b) The Commission shall adopt detailed rules	
Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use	**Article 2:** Requires prohibition of administering of hormonal or thyrostatic action and of ß-agonist substances to farm or aquaculture animals.	

in stock farming of certain substances having a hormonal or thyrostatic action and of ß-agonists	**Article 5:** However, with regard to aquaculture animals, young fish may be treated for the first three months for the purpose of sex inversion with veterinary medicinal products that have an androgenous action. **Article 11:** Third countries whose legislation authorises the placing on the market and administration of stilbenes, stilbene derivatives, their salts and esters, or of thyrostatic substances for administering to all species of animals the meat and products of which are intended for human consumption, may not appear on any of the lists of countries provided for under Community legislation from which Member States are authorised to import farm or aquaculture animals or meat or products obtained from such animals. Member States shall also prohibit the importation from third countries on any of the lists referred to in paragraph 1 of: (a) farm or aquaculture animals (i) to which products or substances referred to in Annex II, List A, have been administered by any means whatsoever. (ii) to which substances referred to in Annex II, List B, and Annex III have been administered, unless those substances were administered in compliance with the provisions and requirements laid down in Articles 4, 5 and 7 and the	

	withdrawal periods allowed in international recommendations have been observed. **ANNEX II:** List of prohibited substances. **ANNEX III:** List of provisionally prohibited substance.	
Commission Regulation (EU) 2019/1871 of 7 November 2019 on reference points for action for non-allowed pharmacologically active substances present in food of animal origin	"*For the purpose of official controls of food of animal origin, the Commission may establish reference values ('reference points for action') for residues of pharmacologically active substances in food of animal origin, for which no maximum residue limit has been laid down*." **Article 8:** Application of new reference points for action set out in the Annex shall apply from 28 November 2022. Until that date the minimum required performance limits for chloramphenicol, nitrofuran metabolites and the sum of malachite green and leucomalachite green, are set out in Annex II to COMMISSION DECISION 2002/657/EC of 14 August 2002. Implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results and shall apply as reference points for action for food	

	of animal origin imported from third countries and for food of animal origin produced in the Union. **ANNEX**: Reference points for action (RPA) for chloramphenicol, malachite green/leucomalachite green, nitrofurans and their metabolites.	
Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin	**TITLE II: Maximum residue limits** **CHAPTER I:** Risk assessment and risk management Maximum residue levels (MRLs) to be set to consider risk assessment. **Article 16:** Administration of substances to food-producing animals. Only pharmacologically active substances which are classified in accordance with Article 14(2)(a), (b) or (c) may be administered to food-producing animals i.e., have an MRL (*may be provisional*) or there are no requirements for an MRL. **TITLE III: Reference points for action** **Article 18:** Commission may establish reference points for action for residues from pharmacologically active substances which are not subject to a classification.	

	Article 24: Action in case of confirmed presence of a prohibited or non-authorised substance. Where the results of analytical tests are below the reference points for action, the Competent Authority shall carry out the investigations provided for by Directive 96/23/EC to determine whether there has been illegal administration of a prohibited or non-authorised pharmacologically active substance and, where relevant, shall apply the penalty provided for.	
Commission Implementing Regulation (EU) 2018/470 of 21 March 2018 on detailed rules on the maximum residue limit to be considered for control purposes for foodstuffs derived from animals which have been treated in the EU under Article 11 of Directive 2001/82/EC	**Article 1:** This Regulation lays down the maximum residue limit to be considered for control purposes for foodstuffs derived from animals. **Article 2**: Food-producing animal species should be placed into groups and related to each other according to the different anatomical and metabolic relationships between them. 1. For the purposes of this Regulation, food-producing animals shall be grouped as follows: (a) ruminants; (b) monogastric mammals; (c) poultry and ratites; (d) fin fish; (e) bees; (f) crustaceans; (g) molluscs. 3. (c) the edible parts of crustaceans and molluscs shall be equated to the target tissue 'muscle' in other animal species.	

	Refers to Commission Regulation (EU) No 37/2010 of 22 December 2009 for the MRLs.	
Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin	**Article 1**: Pharmacologically active substances and their classification regarding maximum residue limits are set out in the Annex. Table 1 List of permitted substances and their MRLs. Note none approved substances for molluscs. Table 2: List of non-permitted substances.	
Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products	**Article 11:** Lays down rules regarding the treatment of food-producing animals affected by a condition for which no veterinary medicinal product is authorised in a Member State. In particular, paragraph 2 of that Article, read together with Article 29 of Regulation (EC) No 470/2009, provides that such animals may be treated with medicinal products containing pharmacologically active substances only if those substances are included in Table 1 of the Annex to Regulation (EU) No 37/2010.	
2011/163/EU Commission Decision of 16 March 2011 on the approval of plans	**Annex 3:** List of authorised countries (aquaculture)	

submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC		

6.5 Aquatic Animal Health Control Measures

Applicable Legislation	Matters Relevant to the Competent Authority	Matters Relevant to the Food Business Operator (FBO)
Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')	The main EU Animal Health Law that sets general rules for surveillance, eradication, and disease-free compartments. The listed diseases in listed populations to be included in the programme are set out in Implementing **Regulation (EU) 2018/1882 (see below)**. **Chapter 1 of Part II** lays down the rules for surveillance of the diseases. **Chapter 3 of Part II** lays down the rules for eradication programmes for the diseases of aquatic animals in relation to: a) the disease control strategy, the territory, the animal populations, the targets, and the period of application.	**Article 10:** Responsibilities of operators for animal health and biosecurity measures. **Article 11:** Requirement for operators to have knowledge of animal health. General responsibility to respect measures adopted under the regulation.

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<td>b) the obligations of operators and Competent Authorities.
c) the disease control measures in the event of suspicion and of confirmation.

Chapter 4 of Part II lays down the rules for disease-free status regarding certain diseases of terrestrial and aquatic animals in relation to the criteria for the approval, maintenance suspension, and the withdrawal or restoration of disease-free status.</td>
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<td rowspan="2">Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases</td>
<td>Article 1: Definitions of category A - E disease, including those of concern (listed diseases) in relation to aquatic animal health and affected species and vectors. Note that some species are listed species (susceptible targets) e.g., Ostreidae spp. and others are identified as vector species e.g., Pectenidae spp.</td>
<td>Requirement of operators to comply with TITLE II: Aquatic animals and products of animal origin from aquatic animals, addressing aquatic animal health controls, registration, approval, movements, disease prevention, certification, obligation to notify and not to spread listed diseases.</td>
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<tr><th rowspan="2">Name of listed disease</th><th rowspan="2">Category</th><th colspan="2">Listed species</th></tr>
<tr><th>Species and group of species</th><th>Vector species</th></tr>
<tr><td>Infection with Mikrocytos mackini</td><td>A+D+E</td><td>Pacific oyster (Crassostrea gigas)</td><td></td></tr>
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			Eastern oyster (*Crassostrea virginica*) Olympia flat oyster (*Ostrea conchaphila*) European flat oyster (*Ostrea edulis*)	
	Infection with *Perkinsus marinus*	A+D+E	Pacific oyster (*Crassostrea gigas*) Eastern oyster (*Crassostrea virginica*)	European lobster (*Homarus gammarus*) Marine crabs *(Brachyura spp*.) Yabi crayfish (*Cherax destructor*) Giant river prawn (*Macrobrachium rosenbergii*) Spiny lobsters (*Palinurus spp*.) Swimming crab (*Portunus puber*) Indopacific swamp crab (*Scylla serrata*) Indian white prawn (*Penaeus indicus*) Kuruma prawn (*Penaeus japonicus*) Caramote prawn (*Penaeus kerathurus*) Blue shrimp (*Penaeus stylirostris*) Whiteleg shrimp (*Penaeus vannamei*)
	Infection with *Bonamia exitiosa*	C+D+E	Australian mud oyster (*Ostrea angasi*) Chilean flat oyster (*Ostrea chilensis*) European flat oyster (*Ostrea edulis*)	Portuguese oyster (*Crassostrea angulata*) Pacific cupped oyster (*Crassostrea gigas*) Eastern oyster (*Crassostrea virgin)*
	Infection with *Bonamia ostreae*	C+D+E	Australian mud oyster (*Ostrea angasi*) Chilean flat oyster (*Ostrea chilensis*)	Common edible cockle (*Cerastoderma edule*) Wedge shell (*Donax trunculus*) Sand gaper (*Mya arenaria*)

			Olympia flat oyster (*Ostrea conchaphila*) Asian oyster (*Ostrea denselammellosa*) European flat oyster (*Ostrea edulis*) Argentinian oyster (*Ostrea puelchana*)	Northern quahog (*Mercenaria mercenaria*) Japanese hard clam (*Meretrix lusoria*) Grooved carpet shell (*Ruditapes decussatus*) Japanese carpet shell (*Ruditapes philippinarum*) European aurora venus clam (*Venerupis aurea*) Pullet carpet shell (*Venerupis pullastra)* Warty venus *(Venus verrucosa*) Great Atlantic scallop (*Pecten maximus*)
	Infection with *Marteilia refringens*	C+D+E	Australian mud oyster (*Ostrea angasi*) Chilean flat oyster (*Ostrea chilensis*) European flat oyster (*Ostrea edulis*) Argentinian oyster (*Ostrea puelchana*)	Common edible cockle (*Cerastoderma edule*) Wedge shell (*Donax trunculus*) Sand gaper (*Mya arenaria*) Northern quahog (*Mercenaria mercenaria*) Japanese hard clam (*Meretrix lusoria*) Grooved carpet shell (*Ruditapes decussatus*) Japanese carpet shell (*Ruditapes philippinarum*) European aurora venus clam (*Venerupis aurea*) Pullet carpet shell *(Venerupis pullastra*) Warty venus (*Venus verrucosa*)

Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products, and products of animal origin	Sets the rules for entry to the EU of animals and animal products. **Part I:** Sets general rules. **Part V:** Requirements for health of aquatic animals for entry into the Union, as well as the movement and handling after the entry, and derogations from those requirements for the following species of aquatic animals at all life stages as well as their products of animal origin, other than wild aquatic animals and products of animal origin from those wild aquatic animals landed from fishing vessels for direct human consumption. Sets out four categories: (a) fish of listed species belonging to the superclass *Agnatha* and to the classes *Chondrichthyes, Sarcopterygii* and *Actinopterygii;* (b) aquatic molluscs of listed species belonging to the phylum *Mollusca*; (c) aquatic crustaceans of listed species belonging to the subphylum *Crustacea;* (d) aquatic animals of species listed in Annex XXIX which are susceptible to the aquatic diseases for which certain Member States have national measures to limit the impact of diseases (other than listed diseases under Regulation (EU)	

	2016/429). This list includes Pacific oyster (*Crassostrea gigas*) susceptible to Ostreid herpes virus 1 µvar (OsHV-1 µVar). **Key Requirements in Part V are for:** **Article 166:** Clinical inspection by an official veterinarian in the exporting third country. **Articles 167-169**: Conditions of despatch and transport. **Article 170**: Products from disease free compartments. **Article 172 and 173**: Derogations to the above (includes live bivalve molluscs or crustacea which are intended for human consumption without further processing, provided that they are packaged for retail sale, and animals supplied for research in Competent Authority approved bio-secure premises). **Article 175**: Additional animal health requirements to limit the impact of non-listed diseases in Annex XXIX i.e. Pacific oyster (*Crassostrea gigas*) and Ostreid herpes virus 1 µvar (OsHV-1 µVar). *NB. OSHv1 is not listed as notifiable by the EU nor the OIE Aquatic Animal Health Code. It is a notifiable disease under legislation of some EU Member States.*	

	Diagnostic tests are reference in the OIE Manual of Diagnostic Tests for Aquatic Animals.	
Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging disease	The regulation sets additional rules on surveillance, eradication programmes and disease-free status for certain listed and emerging diseases of terrestrial, aquatic and other animals as provided for in Regulation (EU) 2016/429. **Article 3:** Design of surveillance. **Article 4:** Targeted animal population. **Article 6:** Diagnostic methods (as set out in EU or OIE methods). **Article 10:** Criteria for and contents of Union surveillance programmes. **Article 11:** Information to be included in the submission of and reporting on Union surveillance programmes. **Article 16:** Disease control strategy based on the disease-free status at establishment level. **Articles 21-23:** Actions in cases of suspected diseased. **Article 24-31:** Disease control from infected establishments. **Chapter 3 of Part II** lays down the rules for eradication programmes for the diseases of aquatic animals referred to	**Article 18:** Obligations of operators with respect to eradication programmes. **Article 52:** Operators shall comply with the requirements set out in points (b) to (f) of paragraph 1 so that the eradication programme can be implemented until such time as it has been successfully completed or is withdrawn. b) the compliance with conditions for the introduction of animals from listed species into the establishment; c) obligation to notify the Competent Authority of any suspicion or detection of the disease d) the fulfilment of disease control measures to be applied if the disease is suspected or confirmed; e) the vaccination regimes that may apply to animals from listed species kept in the establishment; f) any additional measures considered necessary by the Competent Authority

	in points (b) and (c) Article 9(1) of Regulation (EU) 2016/429 in relation to: a) the disease control strategy, the territory, the animal populations, the targets and the period of application; b) the obligations of operators and Competent Authorities; c) the disease control measures in the event of suspicion and of confirmation. **Article 46:** Disease control strategy for the eradication of category B and C diseases of aquatic animals. **Article 50:** Minimum requirements for an eradication programme. **Article 51:** Animal population to be included in eradication programmes for category B and C diseases. **Chapter 4 of Part II** lays down the rules and criteria for allocation of disease-free status with regard to certain diseases of terrestrial and aquatic animals referred to in Article 9(1) of Regulation (EU) 2016/429 in relation to:	

	a) the criteria for the approval of the disease-free status of Member States and zones; b) the criteria for the approval of the disease-free status for compartments keeping aquaculture animals (Section 2 deals with aquaculture animals in Articles 73 to 80); c) the criteria for the maintenance of the disease-free status; d) the suspension, the withdrawal, and the restoration of disease-free status. **Article 81:** Specific criteria on surveillance and biosecurity measures for the maintenance of disease-free status. The disease specific requirements as regards surveillance and biosecurity measures are provided in: a) **Section 4 of Chapter 3 of Part II of Annex VI** for status free from infection with *Marteilia refringens*; b) **Section 4 of Chapter 4 of Part II of Annex VI** for status free from infection with *Bonamia exitiosa*; c) **Section 4 of Chapter 5 of Part II of Annex VI** for status free from infection with *Bonamia ostreae*;	

	ANNEX VI: Specific requirements as regards diseases of aquatic animals **PART I: Risk-based surveillance** **CHAPTER 1** Minimum requirements for risk-based surveillance in certain approved aquaculture establishments. **CHAPTER 2** Risk ranking to be applied in certain approved aquaculture establishments. **CHAPTER 3** Frequency of risk-based animal health visits. **PART II: Disease - Specific requirements for disease-free status of aquatic animals** **CHAPTER 3** Eradication, disease-free status, and diagnostic methods for infection with *Marteilia refringens* **CHAPTER 4** Eradication, disease-free status, and diagnostic methods for infection with *Bonamia exitiosa* **CHAPTER 5** Eradication, disease-free status, and diagnostic methods for infection with *Bonamia ostreae*	
Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories,	**Article 3:** Lists of third countries, territories or zones or compartments thereof from which the entry into the Union of animals, germinal products and products of animal origin shall be permitted.	

or zones thereof 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 of the European Parliament and the Council	Competent Authorities which establish compliance with the animal health requirements under Regulation (EU) 2016/429 and Commission Delegated Regulation (EU) 2020/692 as regards the surveillance, eradication, disease free zones and monitoring activities may be authorised for the entry into the Union of consignments of certain species and categories of animals, germinal products, and products of animal origin from third countries or territories or zones. Those countries which have achieved this are listed in the Annex. **ANNEX XXI: Aquatic animals** **PART 1:** List of third countries, territories, zones or compartments thereof, authorised for the entry into the Union of consignments **of live aquatic animals** of listed species. *Sets out import conditions for live a) fish b) molluscs and c) crustacea from each country.*	
Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations	Sets the model animal health/official certificates. **Article 4:** Certificates for entry into the Union of animals, products of animal origin, composite products, sprouts for human consumption and seeds intended for the production of sprouts for human consumption shall be duly completed	**Article 4:** Operators responsible for consignments shall provide the Competent Authority the information on the description of such consignments.

(EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, and official certification regarding such certificates	and signed by the official veterinarian or certifying officer authorised by the Competent Authority of a third country. The Competent Authority shall ensure that the certificates which include an animal health attestation are signed by the official veterinarian. **Article 5** Requirements for certificates for consignments of animals and goods intended for human consumption. **Article 15:** Model animal health/official certificate and official certificate for the entry into the Union of live bivalve molluscs, echinoderms, tunicates, marine gastropods, products of animal origin from those animals and certain processed bivalve molluscs intended for human consumption drawn up in accordance with the model MOL-HC set out in Chapter 31 of Annex III.	

7 Official Testing Methods

This section sets out the official testing methods as specified in the EU regulations, or, in the absence of a regulatory reference, other official sources such as the relevant EU reference laboratory, the ISO method or in some cases the OIE.

7.1 EU Reference Laboratories

The relevant EU reference laboratories are as follows. They have substantial technical resources available on testing methods, validation etc.

Laboratory	Reference parameters
AECOSAN: Agencia Española de Consumo, Seguridad Alimentaria y Nutrición www.aesan.gob.es/en/CRLMB/web/home.html	Marine biotoxins
ANSES: Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail https://eurl-veterinaryresidues.anses.fr/	Veterinary residues
IFREMER: L'Institut français de recherche pour l'exploitation de la mer www.eurl-mollusc.eu/	Mollusc diseases
DTU Danmarks Tekniske Universitet www.eurl-mn.eu/	Metals and nitrogenous compounds

7.2 Classification and Area Controls for Live Bivalve Molluscs – Biotoxins & Phytoplankton

Test Method Legal Reference	Test Parameter	Official Test Method
Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for community action in the field of water policy	Phytoplankton	**Annex V, Section 1.3.6** - EU Standard EN 15204:2006. Enumeration of phytoplankton species of interest using inverted microscopy (Utermöhl technique).
Commission Implementing Regulation (EU) 2019/627 of 15	Saxitoxin (PSP)	**Annex V** The paralytic shellfish poisoning (PSP) toxin content of the whole body or any part

March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls		edible separately of bivalve molluscs shall be determined using AOAC official method OMA 2005.06, as published in AOAC International Journal 88(6), 1714-1732 (Lawrence method), the mouse bioassay or any other internationally recognised validated method.
	Domoic Acid (ASP)	**Annex V** The amnesic shellfish poisoning (ASP) toxin content of the entire body or any part edible separately of bivalve molluscs shall be determined using the high-performance liquid chromatography with ultraviolet detection (HPLC/UV) method or any other internationally recognised validated method.
	a) Okadaic acid group toxins (DSP): OA, DTX1 and DTX2, including their esters (DTX3) b) Pectenotoxins group toxins: PTX1 and PTX2 c) Yessotoxins group toxins: YTX, 45 OH YTX, homo YTX and 45 OH homo YTX d) Azaspiracids group toxins: AZA 1, AZA 2 and AZA 3	**Annex V** The reference method for the detection of marine toxins as referred to in points (c), (d) and (e) in Chapter V (2) of Section VII of Annex III to Regulation (EC) No 853/2004 shall be the EU reference laboratory liquid chromatography-mass spectrometry/mass spectrometry (EURL LC-MS/MS) method.
	E.coli	**Annex IV** The reference method for analysis of *E. coli* in live bivalve molluscs shall be the

		detection and 'most probable number' (MPN) technique specified in ISO 16649-3. Alternative methods may be used if they are validated against this reference method in accordance with the criteria in ISO 16140.
Directive 2000/60/EC	Marine phytoplankton	Annex V Section 1.3.6 EU Standard EN 15972:2011 Water quality - Guidance on quantitative and qualitative investigations of marine phytoplankton.

7.3 Environmental Contaminants

Test Method Legal Reference	Test Parameter	Official Test Method
Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the control of the levels of trace elements and processing contaminants in foodstuffs	Metals: Pb, Cd, Hg, As	**Article 1:** Methods of sampling and analysis for the control of the levels of lead, cadmium, mercury, inorganic tin, inorganic arsenic, polycyclic aromatic hydrocarbons (PAH) and others to be conducted in accordance with Annex1. Where no specific methods for the determination of contaminants in foodstuffs are prescribed at EU level, laboratories may select any validated method of analysis for the respective matrix provided that the selected method meets the specific performance criteria set out in Tables 5, 6 and 7. **Annex Part C, Table 5:** Performance criteria for methods of analysis for lead, cadmium, mercury, inorganic tin, and inorganic arsenic EURL-

		MN validated methods available form: www.eurl-mn.eu/library/list-of-methods **EN 14084:2003**: Foodstuffs - Determination of trace elements - Determination of lead, cadmium, zinc, copper, and iron by atomic absorption spectrometry (AAS) after microwave digestion. **EN 17266:2019:** Foodstuffs - Determination elements and their chemical species - Determination of organomercury in seafood by elemental mercury analysis. **EN 16801:2016:** Foodstuffs - Determination of elements and their chemical species - Determination of methylmercury in foodstuffs of marine origin by isotope dilution GC-ICP-MS.
Commission Regulation (EU) 2017/644 of 5 April 2017 laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EU) No 589/2014	Polychlorinated biphenyls (PCBs)	**Annex 5 and 6** Screening - Bioanalytical and GC/MS methods. Confirmatory methods- GC-HRMS. For confirming compliance or non-compliance with the maximum level, also GC-MS/MS can be used. See also: www.crl-freiburg.eu/dioxin/methods.html

7.4 Other Applicable Food Safety Requirements

Test Method Legal Reference	Test Parameter	Official Test Method
Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs	*Listeria monocytogenes*	**Chapter 1, Annex 1**
	Salmonella	**Chapter 1, Annex 1** **EN ISO 6579-1** Horizontal method for the detection, enumeration, and serotyping of *Salmonella.*
	E.coli	(MPN) technique specified in **ISO 16649-3**
	Coagulase-positive staphylococci	**EN/ISO 6888-1 or 2**
	Listeria monocytogenes	**EN/ISO 11290-1**
	Additives: e.g., sulphur dioxide, - sulphites, polyphosphates	Various methods available HLPC after extraction or Monier Williams.

7.5 Chemical and Microbiological Standards for Potable Water

Test Method Legal Reference	Test Parameter	Official Test Method
Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption	Potable water *E.coli* *Enterococci* Colony count *Clostridium perfringens*	The methods of analysis for microbiological parameters are: a) *E. coli* and coliform bacteria (**EN ISO 9308-1 or EN ISO 9308-2**); b) Intestinal enterococci (**EN ISO 7899-2**); c) Colony count or heterotrophic plate counts at 22 °C (**EN ISO 6222**); d) *Clostridium perfringens* including spores (**EN ISO 14189**).
	Chemical parameters listed in Table 1 Part A of the Annex.	Minimum performance characteristic 'Uncertainty of measurement' set out on Table 1 Part B.

7.6 Residue Monitoring for Aquaculture Products

Test Method Legal Reference	Test Parameter	Official Test Method
Commission Decision 2002/657/EC of 14 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results	**Group A:** (1) Stilbenes, stilbene derivatives, and their salts and esters (3) Steroids (6) Compounds included in Annex IV to Council Regulation (EEC) No 2377/90 of 26 June 1990 (*no longer in force*) **Group B:** Veterinary drugs and contaminants: (1) Antibacterial substances, including sulphonomides, quinolones (a) Anthelmintics (3) Other substances and environmental contaminants (a) Organochlorine compounds including PcBs (c) Chemical elements (d) Mycotoxins (e) Dyes	Sets performance criteria for testing of veterinary drugs and other residues required under 2017/625 (previously under Directive 93/23). Includes list of suitable confirmatory methods for organic residues or contaminants (Table 1 Annex). 1.Methods used for sampling and for laboratory analyses, tests and diagnoses during official controls and other official activities shall comply with EU rules establishing those methods or the performance criteria for those methods. 2. In the absence of EU rules as referred to in paragraph 1, and in the context of official controls and other official activities, official laboratories shall use one of the following methods according to the suitability for their specific analytical, testing, and diagnostic needs: a) available methods complying with relevant internationally recognised rules or protocols including those that the European Committee for Standardisation (CEN) has accepted; or relevant methods developed or recommended by the EU reference laboratories and validated in accordance with

		internationally accepted scientific protocols; b) in the absence of the suitable rules or protocols, as referred to in point (a), methods which comply with relevant rules established at national level, or, if no such rules exist, relevant methods developed or recommended by national reference laboratories and validated in accordance with internationally accepted scientific protocols; or relevant methods developed and validated with inter- or intra-laboratory validation studies in accordance with internationally accepted scientific protocols. Note that additional guidelines are published at: https://ec.europa.eu/food/safety/chemical_safety/vet_med_residues_en
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	Mycotoxins	Sets performance criteria for analysis

7.7 Aquatic Animal Health Hazzard

Test Method Legal Reference	Test Parameter	Official Test Method
Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging disease www.eurl-mollusc.eu/Diagnostic-manual www.eurl-mollusc.eu/SOPs Commission Implementing Decision 2015/155 of 11 September 2015 lay down rules for the application of Directive 2006/88/EC as regards	*Marteilia refringens*	Histopathology Cytology In situ hybridization *M. refringens* - Probe M2A / M3AS, Le Roux et al. 2001 (ITS1) Conventional PCR *M. refringens,* Le Roux et al. 2001, Primers M2A & M3AS also named Pr4 & Pr5 (ITS1- 412bp). Type discrimination possible by RFLP. Taqman real-time PCR *M. refringens / Bonamia sp.,* Canier et al. 2020 (18S) Taqman real-time PCR *M. refringens* type M / type O, EURL unpublished (ITS1) Histopathology and PCR for surveillance Tissue imprints and PCR for presumptive diagnostic. PCR and sequencing for confirmatory diagnostic.

requirements for surveillance and diagnostic methods (*B. ostreae and M. refringens*).		
	Bonamia ostreae and *Bonamia exitiosa*	Histopathology Cytology In Situ Hybridization *Bonamia sp* - Probe BO / BOAS. Conventional PCR *Bonamia sp.,* Cochennec et al. 2000, primers BO/BOAS (18S - 304bp). Species discrimination possible by RFLP. SYBR Green PCR *B. ostreae / B. exitiosa*, Ramilo et al. 2013, primers BOSTRE-F/R BEXIT F/R (ITS -18S). Taqman real-time PCR *M. refringens / Bonamia sp.*, Canier et al. 2020 (18S). Taqman real-time PCR *B.ostreae/ B.exitiosa*, EURL. Tissue imprints, histopathology, and PCR for surveillance. Tissue imprints and PCR for presumptive diagnostic. PCR & sequencing and transmission electron microscopy for confirmatory diagnostic.
	Perkinsus marinus	Histopathology

		Ray's Fluid Thioglycolate Medium (RFTM) culture. In situ hybrization *P. marinus,* Probe PmarLSU-181DIG, Moss et al. 2006 (LSU). SYBR Green *PCR P. Marinus,* Audemard et al. 2004, Primers PmarITS-70F & PmarITS600R (ITS-509bp). RFTM culture of tissue for surveillance. PCR technique for presumptive diagnostic ISH for confirmatory diagnostic.
	Mikrocytos mackini	Histopathology In situ hybrization *M. mackini*, Probe MACKINI-1 F&R, Meyer et al. 2005 (18S) Conventional PCR *M. mackin*i, Carnegie et al. 2003, Primers MIKROCYTOS-F&R (18S-546 bp) Taqman Real Time PCR *M. mackini,* Polinski et al., 2015 (ITS2) Histopathology and tissue imprints in some cases for surveillance. Histopathology, imprints, PCR and ISH for presumptive diagnostic. PCR, ISH, sequencing, and transmission electron microscopy for confirmatory diagnostic.
EU RL Diagnostic methods for shellfish	Abalone herpes-like virus AbHV (OIE - exotic)	Direct detection methods developed, to date, for detection and identification of

diseases: www.eurl-mollusc.eu/Main-activities/Tutorials See also OIE Manual of Diagnostic Tests for Aquatic Animals Chapter 2.4.1. Infection with Abalone Herpes Virus- www.oie.int/en/what-we-do/standards/codes-and-manuals/aquatic-manual-online-access/?id=169&L=1&htmfile=chapitre_abalone_herpesvirus.htm		AbHV include microscopic methods (examination of tissue sections for typical lesions and electron microscopy for detection of herpes virus particles), conventional and real-time PCR, and in situ hybridisation (ISH).
Reference Methods for OSHv1 www.eurl-mollusc.eu/Main-activities/Tutorials/Herpes-virus-OsHV-1	Oyster Herpes virus type 1 (OSHv1)	PCR (nested; simple; competitive) Histology (only for screening) DNA sequencing (confirmatory) ISH - in situ hybridization (confirmatory) TEM - Transmission electron microscopy (confirmatory) In case of suspicion in larvae: all dead and moribund larvae should be collected for DNA extraction and PCR according to Renault et al. 2000. In case of suspicion in juveniles: tests should preferably be performed on moribund individuals. 30 individuals should be analysed in pools of five animals. DNA

		extraction and PCR are performed according to Renault et al. 2000. In case of suspicion in adults: OsHV-1 has never been associated with mortality of adults. However, adults might be asymptomatic carriers. In situ hybridization can be used to test the presence of OsHV-1 in connective tissues of adults.

8 Conclusion

These general guidelines to compliance insofar as the export of molluscs (mussels, oysters, and abalone) to the EU is concerned, provides extensive background that is linked to existing reference materials and to the legislative framework implemented by the EU. In this regard, it provides a comprehensive reference work that should aid the South African and Namibian aquaculture sectors.