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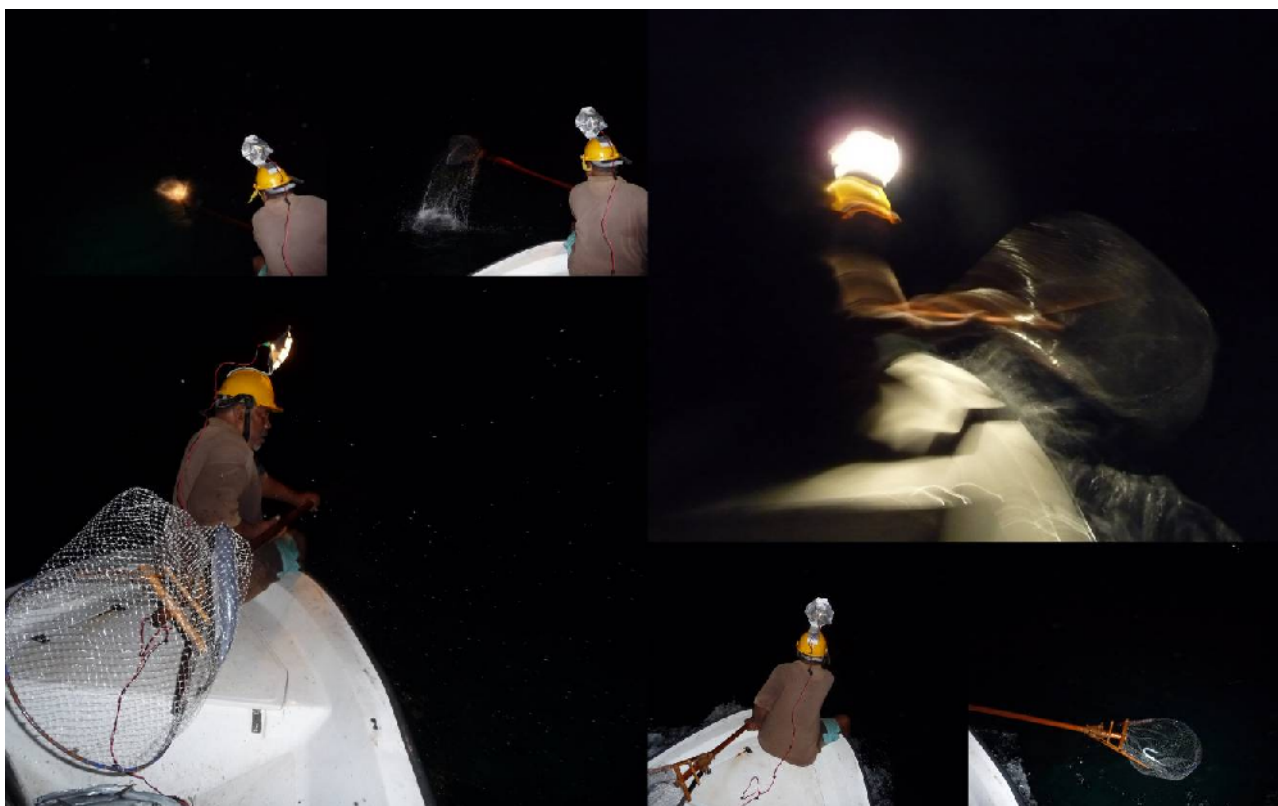


Programme Implemented  
by Secretariat of ACP  
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**FINAL REPORT**  
**Drafting of food safety legislation for Kiribati fishery products**  
**Ref: CA093KIR**

October 2010



**Strengthening Fishery Products Health Conditions in ACP/OCT Countries**



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## **Drafting of food safety legislation for Kiribati fishery products** **11-20 October 2010** **CA093KIR**

**October 2010**

**Richard Chivers**

**Cardno Emerging Markets (UK) Ltd in association with  
MacAlister Elliott and Partners Ltd and Megapesca Lda**

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reflect the views of the European Commission**

The picture on the cover shows fisherman lamping for garfish and flyingfish, Christmas Island, Kiribati

Module I  
Strengthening National Health Control Capacity for Fishery Products  
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**Strengthening Fishery Products Health Conditions in ACP/OCT Countries 8ACPTPS137**



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## Contents

<b>ABBREVIATIONS</b> .....	<b>II</b>
<b>LAYMAN’S SUMMARY</b> .....	<b>III</b>
<b>EXECUTIVE SUMMARY</b> .....	<b>III</b>
<b>RÉSUMÉ POUR NON-EXPERTS</b> .....	<b>IV</b>
<b>RÉSUMÉ OPÉRATIONNEL</b> .....	<b>IV</b>
<b>1 INTRODUCTION</b> .....	<b>1</b>
<b>2 CONTEXT OF THE ASSIGNMENT</b> .....	<b>1</b>
2.1 WORK ENVIRONMENT.....	1
2.2 IN RELATION TO OTHER TA AND DEVELOPMENT INITIATIVES .....	1
<b>3 METHODOLOGY</b> .....	<b>1</b>
<b>4 PERFORMANCE IN RELATION TO TERMS OF REFERENCE</b> .....	<b>1</b>
4.1 GENERAL RESPONSE TO TERMS OF REFERENCE.....	<b>ERREUR ! SIGNET NON DEFINI.</b>
<b>5 DISCUSSION</b> .....	<b>ERREUR ! SIGNET NON DEFINI.</b>
5.1 DRAFT FPR .....	<b>ERREUR ! SIGNET NON DEFINI.</b>
5.2 ILLEGAL, UNREPORTED AND UNREGULATED FISHING LAW .....	1
<b>6 CONCLUSIONS AND RECOMMENDATIONS</b> .....	<b>2</b>
6.1 RECOMMENDATION (5.1).....	2
6.2 RECOMMENDATION (5.2).....	2
<b>7 ANNEXES</b> .....	<b>3</b>
<b>ANNEXES</b> .....	<b>4</b>
ANNEX 1: TERMS OF REFERENCE.....	4
ANNEX 2: DRAFT FISHERY PRODUCT REGULATIONS .....	7
ANNEX 3: MFMRD ATTORNEY GENERAL LIAISON CONTACT .....	99
ANNEX 4: TERMS OF REFERENCE FOR FUTURE ACTIVITIES.....	100
ANNEX 5: BIBLIOGRAPHY .....	102

## ABBREVIATIONS

ACP	African, Caribbean and Pacific States (Lomé Convention IV)
CA	Competent Authority
EC	European Commission
EU	European Union
FP	Fisheries Products
FVO	Food and Veterinary Office
HACCP	Hazard Analysis and Critical Control Points
HC	Health Certificate
ISO	International Organisation for Standardisation
PCBs	Polychlorinated biphenyls
PMU	Project Management Unit
SANCO	DG Health and Consumer Protection
SFP	Strengthening Fishery Products
SPS	Sanitary and Phytosanitary
ToR	Terms of Reference

## **LAYMAN'S SUMMARY**

Kiribati has no fishery products regulations (FPR) in place but hopes to benefit from a new joint venture that will redevelop a factory on South Tarawa and potentially a larger one on Christmas Island. An early mission (CA085KIR) identified the need for FPR and began the process of drafting them. The current mission completed the draft regulations to provide Kiribati with legislation which is equivalent to that of the European Union (EU).

## **EXECUTIVE SUMMARY**

Kiribati does not have a nominated Competent Authority (CA) and has no fishery products regulations (FPR) in place on which to base guarantees of food safety for exports from the country. Kiribati has never been visited by a DG Health and Consumer Protection (SANCO) mission and at present has very few products that it could realistically hope to export to the European Union (EU). This situation is about to change however. A Chinese-led joint venture with the Government of Kiribati intends to redevelop the existing Government-owned factories in South Tarawa and Christmas Island with a view to extending exports of frozen and fresh fish (mainly tuna) to the USA and the EU. In order to achieve the aim of exporting to the EU Kiribati will need to establish a CA and it was to make an initial assessment of the needs that the previous Strengthening Fishery Products (SFP) mission (CA085KIR) was launched.

One of the needs the mission identified was for fishery products legislation to allow a CA to operate. As the new factory will begin operating in April 2011 and the legislation will take at least one year to implement, an early start was deemed necessary by the Programme Management Unit (PMU) and this mission was launched at the very end of the SFP programme in order to start the ball rolling and to pass future work on to other donor projects such as the DEVFISH 2 programme.

The work was carried out from the consultant's home base in the UK over a period of nine days in October 2010. Draft FPR were drawn up and recommended for presentation to the Attorney General of the Kiribati Government to use as a foundation for EU-equivalent legislation.

## **RÉSUMÉ POUR NON-EXPERTS**

Kiribati n'a pas de réglementations des produits de la pêche (FPR) mais espère bénéficier d'un nouveau partenariat commercial qui développera une usine à Tarawa-Sud et une autre potentiellement plus importante dans l'île de Noël. La mission antérieure (CA085KIR) a identifié le besoin de FPR et a commencé à procéder à leur élaboration. La mission actuelle a complété le projet de réglementations visant à fournir à Kiribati une législation équivalente à celle de l'Union Européenne (UE).

## **RÉSUMÉ OPÉRATIONNEL**

Kiribati n'a pas d'autorité compétente nommée (AC) et n'a pas de FPR sur lesquelles elle pourrait baser des garanties de sécurité alimentaire en vue des exportations au départ du pays. Kiribati n'a jamais été visitée par une mission DG SANCO (Direction Generale de la Sante et de la Protection du Consommateur) et elle a actuellement très peu de produits pouvant donner de façon réaliste l'espoir de pouvoir exporter vers l'Union Européenne (UE). Cependant, cette situation est sur le point de changer. Un partenariat commercial mené par les Chinois avec le Gouvernement de Kiribati a l'intention de redévelopper les usines existantes appartenant au Gouvernement à Tarawa-Sud et à l'île de Noël, visant à élargir les exportations de poisson surgelé et frais (principalement le thon) vers les États-Unis et l'UE. Pour atteindre l'objectif d'exportation vers l'UE, Kiribati aura besoin de l'AC, et c'est pour réaliser une évaluation initiale des besoins que la mission du programme Strengthening Fishery Products (SFP) antérieure (CA085KIR) a été lancée.

L'un des besoins identifié était que la législation relative aux produits de la pêche permette à l'AC d'opérer. Étant donné que la nouvelle usine sera mise en service en avril 2011 et que la législation aura besoin d'un an au moins pour la mise en œuvre, un démarrage précoce a été considéré comme nécessaire par l'Unité de gestion du programme (UGP), et cette mission a été lancée tout à fait à la fin du programme SFP, pour faire rouler la balle et répercuter le travail futur sur les autres projets des donateurs tels que le programme DEVFISH 2.

En octobre 2010, le travail a été accompli depuis le domicile du consultant au Royaume-Uni pendant une période de neuf jours. Les élaborations des FPR ont été tracées et recommandées en vue de leur présentation au Ministre de la justice du Gouvernement de Kiribati afin qu'il utilise un fondement de législation équivalent à celui de l'UE.

## **1 INTRODUCTION**

Kiribati wished to begin the process of developing a Competent Authority (CA) which would allow the country to take advantage of the export potential presented by a new factory development. There was, however, no national legislation in place to provide a legal foundation for an inspection service of equivalent standard to that of the European Union (EU). The Strengthening Fishery Products (SFP) programme launched the current mission to complete draft legislation that had been begun by a previous mission, CA085KIR. The latter had focused on the entire need for establishing a CA but had also begun the process of building up the regulatory basis. This mission completed the process of drawing up draft fishery product food safety regulations for presentation to the Attorney General.

An expert from Macalister Elliott and Partners (a partner in the consortium, Cardno Emerging Markets (UK) Ltd in association with MacAlister Elliott and Partners Ltd and Megapesca Lda) undertook the work in October 2010.

## **2 CONTEXT OF THE ASSIGNMENT**

### **2.1 Work environment**

The work was undertaken from the consultant's home base over a nine-day period in October 2010. No further contact was made with the Kiribati authorities as the consultant had already spoken with them on the subject during the mission CA085KIR and had received a positive reply to the suggestion that a donor draw up the regulations.

### **2.2 In relation to other Technical Assistance and development initiatives**

SFP mission CA085KIR, a needs assessment mission carried out in August 2010, had identified the steps needed to create of CA and the drafting of legislation.

The DEVFISH 2 project is just starting work and may be in a position to assist with the legislation should the Kiribati authorities need further guidance.

## **3 METHODOLOGY**

The work was undertaken as a desk study.

## **4 PERFORMANCE IN RELATION TO TERMS OF REFERENCE**

### **4.1 General response to Terms of Reference**

Draft FPR were produced as a single document that was comprehensive in its coverage of the EU regulations. The regulations were fully referenced throughout to present the legal specialist (the Attorney General) with as few problems as possible.

### **4.2 Nomination of the Competent Authority**

The Government of Kiribati will need to bring the CA into existence as a legal entity through headline, in this case, it will most probably be by an amendment to the recently passed Fisheries Act 2009. The following paragraph provides an example of suitable wording.

'The Competent Authority for all official controls of fish and fishery products, will be the Ministry of Fisheries and Marine Resource Development.'

## **5 DISCUSSION**

### **5.1 Draft FPR**

The draft regulations covered the Government's requirements for establishing a CA that could provide the guarantees demanded by the EU.

The consultant retained references to the EU legislation throughout because:

- a) The EU fishery products legislation is tried and tested.
- b) It is probably the most comprehensive and demanding in international trade of fish.
- c) The specific aim of this CA093KIR intervention was to develop EU equivalent legislation.
- d) Given these caveats, the EU regulations present themselves as an international standard to which the Kiribati laws can address themselves.

The consultant decided to take the approach that all relevant legislation should be contained within the main text, reserving the detailed instructions for a series of annexes. The intent was to present the FPR in a single comprehensive body incorporating all aspects of legislation needed for equivalence to the EU legislation. This vertical approach was deemed suitable to initiate Kiribati food safety legislation which is currently insufficiently developed to accept a horizontal delivery covering all food groups.

By starting with a single piece of legislation future amendments need only be made to one regulation, rather than a series of separate regulations that refer back to the root.

The staff of the Kiribati Ministry of Fisheries Marine Resources Department indicated that the legislation would take approximately one year to become law. This time scale is not excessive but ideally should not take longer, even though Kiribati faces the challenge of passing the Food and Veterinary Office (FVO) inspection before it is free to provide the guarantees needed.

Kiribati intends to seek assistance from the Fijian CA whose staff would carry out the inspections of their behalf, while the Kiribati CA provides the certificates. Prior to doing so however the Kiribati authorities have to create a body with the necessary powers, which brings the need for these regulations into sharp focus.

## **5.2 Illegal, Unreported and Unregulated Fishing Law**

Illegal, Unreported and Unregulated (IUU) laws are now required in most developing countries with large Exclusive Economic Zones (EEZ). Kiribati will need support in the production of this legislation, which works in partnership with the FPR.

## **6 CONCLUSIONS AND RECOMMENDATIONS**

The FPR were presented in a form that was easy to understand and fully referenced so that a reader who is not conversant with the EU legislation would be able to access the root legislation on which the FPR were based. A degree of legal understanding is required for implementation and presentation in Kiribati's own style but the consultant felt that this would not be an impediment as the laws he reviewed during his earlier visit to Tarawa indicated that the Government was fully conversant with the legislative process and would have no difficulty in drawing up the final version.

### **6.1 Recommendation (5.1)**

It is recommended that the FPR be presented to the Kiribati Attorney General through his liaison officer within the MFMRD.

### **6.2 Recommendation (5.2)**

It is also recommended that IUU legislation be drawn up by another donor body. In this respect the Forum Fisheries Agency (FFA) has been employed to operate the DEVFISH 2 scheme and this requirement may be one that the Agency could take further.

## **7 ANNEXES**

Annex 1: Original Terms of Reference

Annex 2: Draft Fishery Products Regulations



Annex 3: MFMRD Contacts

Annex 4: Terms of Reference for Future Activities

Annex 5: Bibliography

## ANNEXES

## ANNEX 1: TERMS OF REFERENCE

 SFP ACP/OCT Programme 8ACPTPS137 	
Assignment name and number	<b>CA093KIR: Drafting of food safety legislation for Kiribati fishery products</b>
Coordinator	Coordinator, Module 1.
Technical Supervisor	Expert on sanitary conditions of Fishery products – SFP PMU
Background to assignment	<p>Kiribati has significant tuna and other fishery resources, which are mostly exploited by foreign fishing vessels operating under access agreements. To date, benefits to the country from this fishery have been primarily in the form of government revenues from licensing. Kiribati Government policy aims to enhance these benefits through the creation of fishery-related direct and indirect employment, which in turn requires the establishment of onshore fish processing operations.</p> <p>After several failed attempts to develop such operations in the past, there is now the prospect of a joint venture operation between the existing government-owned fishing company Central Pacific Producers Ltd, and partner companies from Fiji and China. CCPL has operational bases in Tarawa and Kiritimati (Christmas Island), both of which will be used for the production of export fishery products. The marketing strategy of the proposed joint venture is to export fresh and frozen value-added tuna products (loins, steaks and fillets) to the EU as well as other international markets (Japan, China and the USA). Fresh product will be sent by air to Honolulu and frozen product will be exported by ship via the facilities of the partner companies in Fiji. Access to the EU market will be a key to maximising export revenues from this and other fish processing ventures in Kiribati.</p> <p>Kiribati does not currently have fishery product food safety legislation equivalent to EU requirements, nor has it nominated an agency which can carry out the functions of a fishery product food safety Competent Authority (CA). In order to access the EU and other overseas markets, Kiribati will need to establish the legislative and operational basis for a CA that is capable of exercising food safety controls over fishery product exports to meet the requirements of these markets. Apart from the proposed joint venture, large volumes of Kiribati-caught tuna are exported to canneries and other processing facilities worldwide, many of which in turn export product to the EU. If Kiribati is to continue supplying these markets, approved arrangements must be put in place to guarantee the safety of its fishery products.</p> <p>SFP Module 1 mission CA085KIR to Kiribati undertook an initial needs assessment and provided a road map for the Kiribati Government and its development partners in regard to the development of a fishery product food safety CA in Kiribati. The findings of that mission included a recommendation that food safety regulations for Kiribati fishery products, which commenced under the mission, be completed.</p> <p>All parties understand that the establishment of a CA in Kiribati may be a multi-</p>

	<p>year enterprise, and that a single short TA mission by the SFP will only be able to provide initial assistance. Nevertheless, it is essential for Kiribati to start the process of CA establishment sooner rather than later, and it is timely to take advantage of the technical assistance available through the SFP before the programme closes later in 2010. Preparation of appropriate legislative instruments is the first step in this process. It is anticipated that the initial work undertaken by the SFP will provide a foundation on which the Kiribati Government, and other programmes such as the EU-funded DEVFISH2 project, can build further.</p>
Issues to be addressed	<p>The present mission will complete work initiated under earlier mission CA085KIR, and will provide the Government of Kiribati with draft regulations which will facilitate the process of establishing a system of official controls over fishery product food safety.</p>
Activities of the Consultant	<p>Using materials and other information gathered during earlier mission CA085KIR, the expert will undertake the following tasks:</p> <ol style="list-style-type: none"> <li>1. Complete drafting of the Kiribati Fishery Products Regulations for consideration by the Kiribati Attorney-General's Office and eventual adoption by the Government of Kiribati.</li> </ol> <p>The work will be undertaken from the expert's home base.</p>
Expected outputs	<p>The main outputs of the mission will be draft Regulations which:</p> <ol style="list-style-type: none"> <li>1. establish and empower the operation of an official fishery product food safety control system in Kiribati;</li> <li>2. provide equivalence with EU legislation on fishery product food safety.</li> </ol> <p>The expert is required to produce a report detailing his activities, findings, outputs and recommendations for any follow-up actions needed by the Kiribati Government.</p> <p>The report is to be produced using MS Word for word processing, as well as other MS Office software where necessary. The report must be made available in hard copy and electronic form, both in Word/ MS Office as appropriate, and in pdf format, with all elements combined in a single file. More information on the report format is contained in the next section.</p>
Report format	<p>The Consultant will be provided with a standard document template in MSWord which must be used as the basis for the mission report. The report will be prepared in English, according to the following structure:</p> <ul style="list-style-type: none"> <li>- Title pages in model format as per other Programme Reports</li> <li>- Table of contents, to three levels, formal format</li> <li>- List of annexes</li> <li>- Tables of tables, figures and pictures all formal format</li> <li>- Abbreviations and acronyms</li> <li>- A 'Layman's Summary' of 4-5 lines, as per EC visibility requirements</li> <li>- Executive Summary (maximum 2 pages), in English and French</li> <li>- Introduction</li> <li>- Main body of report divided into different sections as appropriate, normally Context, Methodology, Performance in relation to TOR, and</li> </ul>

	<p>Discussion (up to 20 pages)</p> <ul style="list-style-type: none"> <li>- Conclusions and recommendations (each recommendation must be preceded by a conclusion, that refers to a discussion in the main body of the report)</li> <li>- Annex 1 Terms of reference</li> <li>- Annex 2 Schedule and people met (with contacts)</li> <li>- Any other annex (es) as appropriate.</li> </ul> <p>Format as per PMU indications.</p>										
Report to be reviewed by	SFP Programme Manager										
Duration/ indicative schedule of work activities	<p>The following schedule of inputs is indicative only, and subject to amendment by the consultant in response to operational considerations (especially changes in flight schedules).</p> <table border="1"> <thead> <tr> <th>Activity</th> <th>Working days</th> </tr> </thead> <tbody> <tr> <td>Drafting of Kiribati Fishery Product Regulations</td> <td>6</td> </tr> <tr> <td>Report preparation</td> <td>1</td> </tr> <tr> <td>Debriefing in Brussels</td> <td>2</td> </tr> <tr> <td>Total</td> <td>9</td> </tr> </tbody> </table> <p>Total working days will equal 9 calendar days.</p>	Activity	Working days	Drafting of Kiribati Fishery Product Regulations	6	Report preparation	1	Debriefing in Brussels	2	Total	9
Activity	Working days										
Drafting of Kiribati Fishery Product Regulations	6										
Report preparation	1										
Debriefing in Brussels	2										
Total	9										
Start date	October 2010 (estimated)										
Experience and qualification	<p>Experts of category II (at least 10 years of experience)</p> <p>Qualifications and skills:</p> <ul style="list-style-type: none"> <li>- A University degree in veterinary, food technology or related sciences</li> <li>- Knowledge of English is essential.</li> <li>- The applicant must be of EU or ACP member states nationality.</li> </ul> <p>General professional experience:</p> <ul style="list-style-type: none"> <li>- Comprehensive knowledge of EU regulations relevant to control of fish and fishery products sanitary status.</li> <li>- Demonstrated long-term background in fish and fish products surveillance</li> </ul> <p>Specific professional experience:</p> <ul style="list-style-type: none"> <li>- Long term background in the application of EU legislation and procedures for inspection and certification in third countries; the drafting of manuals of procedures for the inspection and certification, and the design and setting up of self-control systems, based on HACCP methodology, by the food industry as well as their audit by official inspection bodies.</li> </ul>										
Locations and travel	Expert Module 1 based in Wellington, Somerset, United Kingdom. No travel required.										

## **ANNEX 2: DRAFT FISHERY PRODUCT REGULATIONS**

### **DRAFT FISH PRODUCTS REGULATIONS**

#### **Laws of Kiribati**

#### **Fisheries Act 2010**

#### **Subsidiary Legislation Fishery Products Regulations**

#### Arrangement of Regulations

#### **General**

Part 1 Preliminary (General description and intent)

Part 2 Definitions

Part 3 General principles and requirements of food law

Part 4 Official controls performed to ensure the verification of compliance

Part 5 General provisions on the hygiene of foodstuffs

Part 6 Specific hygiene rules for food of fish origin

Part 7 Specific rules for the organisation of official controls on products of fish origin

Part 8 Product Testing

#### **Annexes**

ANNEX 1: General Hygiene Conditions

ANNEX 2: Requirements of the Food Business Operator

ANNEX 3: Concerning the activities of the Competent Authority

ANNEX 4: Official Controls on fishery products

ANNEX 5: Food Safety Criteria: Microbiological Limits, Testing and Sampling

ANNEX 6: Freshness rating

ANNEX 7: Sampling and analysis of contaminants

ANNEX 8: Model Health Certificate

ANNEX 9: References

## LAWS OF KIRIBATI

### Fisheries Act 2010

#### Subsidiary Legislation

In exercise of the powers conferred on him by the ..... Act of ....., the Minister of ..... hereby makes the following Regulations.

<b>PART 1</b>	<b>Preliminary</b>
These Regulations may be cited as the Fishery Products Regulations 2010 and shall come into force on such date as the Minister may appoint by notice published in the Gazette.	
These regulations are subject throughout to the provision that Kiribati's exports of fishery products will comply with the food safety and marketing requirements of the importing state.	
<b>PART 2</b>	<b>Definitions</b>
General terms	<p>In these Regulations unless the context otherwise requires:</p> <p>“food” (or “foodstuff”) means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans;</p> <p>“food law” means the laws, regulations and administrative provisions governing food in general, food quality and safety in particular. It covers any stage of production, processing and distribution of food, and also of feed produced for or fed to, food-producing animals;</p> <p>“feed law” means the laws, regulations and administrative provisions governing food in general and feed safety in particular. It covers all stages of production, processing and distribution of feed and use of feed;</p> <p>“equivalence” means the capability of different systems or measures to meet the same objectives;</p> <p>“equivalent” means, in respect of different systems or measures, capable of meeting the same objectives;</p> <p>‘marketing’ shall mean the first offer for sale and/or the first sale, on Kiribati territory, for human consumption;</p> <p>“placing on the market” means the holding or displaying of fishery products for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves, excluding retail sales;</p> <p>‘presentation’ shall mean the form in which the fish is marketed, such as whole, gutted, headless, etc.</p> <p>“primary production” covers the farming, fishing and collection of live fishery products with a view to their being placed on the market;</p> <p>“associated operations” (to primary production) cover any of the following operations, if carried out on board fishing vessels: slaughter, bleeding, heading, gutting, removing fins, refrigeration and wrapping: they also include:</p> <p>the transport and storage of fishery products the nature of which has not been substantially altered, including live fishery products, within fish farms on land and,</p>

	<p>the transport of fishery products the nature of which has not been substantially altered, including live fishery products, from the place of production to the first establishment of destination;</p> <p>“stages of production, processing and distribution” means any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed for animal production.</p> <p>“means of transport” means those parts set aside for goods in automobile vehicles and aircraft, the holds of vessels, and containers for transport by land, sea or air;</p> <p>“retail” means the handling and/or processing of fishery products and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets;</p> <p>“objectionable industry” means any industry neighbouring the fish preparation/processing plant that could cause contamination of the product either directly or indirectly. Includes a coal loading facility, cemetery, rubbish tip or sewerage treatment plant;</p> <p>“final consumer” means the ultimate consumer of a fishery product who will not use the food as part of any food business operation or activity;</p> <p>“importation” means the release for free circulation of feed or food or the intention to release feed or food for free circulation into the territory of fishery products from other countries;</p> <p>“consignment” means the quantity of fishery products bound for one or more customers in the country of destination and conveyed by one means of transport only;</p> <p>“lot” means a quantity of fishery products of a given species which have been subjected to the same treatment on sea and may have come from the same fishing grounds and the same vessel;</p> <p>“batch” means the quantity of fishery product obtained under practically identical circumstances, during a period of time from an identifiable processing line and indicated by a specific code;</p> <p>“fishing grounds” shall be interpreted as the customary name given by the fishing industry to the place from which fishery products have been taken;</p> <p>“ingredient” means any substance used in the processing of fish that ends up in the final product;</p> <p>“salt” means food grade sodium chloride;</p> <p>“shall” denotes a mandatory requirement;</p> <p>“should” denotes a recommended requirement;</p>
Definitions in relation to fish business	<p>“fish business” means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of fishery products;</p> <p>“fish business operator or management” means the natural or legal persons responsible for ensuring that the requirements of food law are met within the fish</p>

	<p>business under their control;</p> <p>“establishment” (plant or factory) means any unit of a fish business;</p>
Definitions in relation to water	<p>“potable water” means water that is fit and intended for human consumption and is compliant with the standards laid down in Part XI;</p> <p>“clean water” means clean seawater and fresh water of a similar quality;</p> <p>“clean seawater” means natural, artificial or purified seawater or brackish water that does not contain micro-organisms, harmful substances or toxic marine plankton in quantities capable of directly or indirectly affecting the health quality of food;</p>
Definitions in relation to feed business	<p>“feed” (or “feeding-stuff”) means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to fish;</p> <p>“feed business” means any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any producer producing, processing or storing feed for feeding to animals on their own holding;</p> <p>“feed business operator” means the natural or legal persons responsible for ensuring that the requirements of food law are met within the feed business under their control;</p>
Definitions in relation to constructions and equipment	<p>“domestic distribution system” means the pipe work fittings and appliances which are installed between the taps that are normally used for human consumption and the distribution network but only if they are not the responsibility of the water supplier;</p> <p>“gully trap” means a water sealed trap, designed to hold a liquid seal that prevents the passage of gas and air but will not affect the flow of a liquid. It is installed in the drainage of premises, through which the premise drainage is connected to the external drain, installed to cut off an open drainage system from the outside air and to avoid the entrance of pests;</p> <p>“bell siphon trap” means a water sealed trap, designed to hold a liquid seal that prevents the passage of gas and air but will not affect the flow of a liquid, installed to drain a floor, whereby the grid part is constructed at floor level and the liquid seal is under the floor level and connected to the external drain;</p> <p>“siphon air trap” means a fitting or device, bent in the shape of a horizontal S-tube, installed under a sink and that is designed to hold a liquid seal that will prevent the passage of gas, but will not affect the flow of a liquid;</p>
Definitions in relation to vessels	<p>“freezer vessel” means any vessel on board which freezing of fishery products is carried out, where appropriate after preparatory work such as bleeding, heading, gutting and removal of fins and, where necessary, followed by wrapping or packaging;</p> <p>“factory vessel” means any vessel on board which fishery products undergo one or more of the following operations, followed by wrapping or packaging :filleting, slicing, skinning, shelling, shucking, mincing or processing;</p>
Definitions in relation to products	<p>“fishery products” means all sea water or fresh water animals (except for live bivalve molluscs, live echinoderms, live tunicates, and live marine gastropods, and all mammals, reptiles and frogs) whether wild or farmed and including all edible forms, and products of such animals;</p> <p>‘Products of animal origin’ means</p>

	<ul style="list-style-type: none"> <li>i. food of animal origin</li> <li>ii. live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods intended for human consumption and</li> <li>iii. other animals destined to be prepared with a view to being supplied live to the final consumer</li> </ul> <p>“bivalve molluscs” means filter-feeding lamellibranch molluscs;</p> <p>“aquaculture products” means all fishery products born and raised in controlled conditions until placed on the market as a foodstuff. However, seawater or fresh water fish or crustaceans caught in their natural environment when juvenile and kept until they reached the desired commercial size for human consumption are also considered to be aquaculture products. Fish and crustaceans of commercial size caught in their natural environment and kept alive to be sold at a later date are not considered to be aquaculture products if they are merely kept alive without any attempt being made to increase their weight or size;</p> <p>“fish product” means any derivative of fish;</p> <p>“presentation” means the form in which fish is marketed, such as whole, gutted and headless;</p> <p>“High risk product” means a product that has a higher likelihood to be contaminated during a part of the production process such as, for cooked product;</p> <p>‘Processed fishery products’ means processed products resulting from the processing of fishery products or from the further processing of such processed products;</p>
Definitions in relation to bivalves	<p>“production area” means any sea, estuarine or lagoon area, containing either natural beds of bivalve molluscs or sites used for the cultivation of bivalve molluscs, and from which live bivalve molluscs are taken;</p> <p>“gatherer” means any natural or legal person who collects live bivalve molluscs by any means from a harvesting area for the purpose of handling and placing on the market;</p> <p>“conditioning” means the storage of live bivalve molluscs coming from class A production areas, purification centres or dispatch centres in tanks or any other installation containing clean seawater, or in natural sites, to remove sand, mud or slime, to preserve or to improve organoleptic qualities and to ensure that they are in a good state of vitality before wrapping or packaging;</p> <p>‘Marine biotoxins’ means poisonous substances accumulated by bivalve molluscs, in particular as a result of feeding on plankton containing toxins;</p> <p>“relaying” means the transfer of live bivalve molluscs to sea, lagoon or estuarine areas for the time necessary to reduce contamination to make them fit for human consumption. This does not include the specific operation of transferring bivalve molluscs to areas more suitable for further growth or fattening;</p> <p>“relaying area” means any sea, estuarine or lagoon area with boundaries clearly marked and indicated by buoys, posts or any other fixed means, and used exclusively for the natural purification of live bivalve molluscs;</p> <p>“purification centre” means an establishment with tanks fed by clean seawater in which live bivalve molluscs are placed for the time necessary to reduce contamination to make them fit for human consumption;</p> <p>“dispatch centre” means any off-shore establishment for the reception, conditioning,</p>

	washing, cleaning, grading, wrapping and packaging of live bivalve molluscs fit for human consumption;
Definitions in relation to preparing and processing of fishery products	<p>“fresh fishery products” means unprocessed fishery products, whether whole or prepared, including products packaged under vacuum or in a modified atmosphere, that have not undergone any treatment to ensure preservation other than chilling;</p> <p>“unprocessed products” means fishery products that have not undergone processing, and includes products that have been divided, parted, severed, sliced, boned, minced, skinned, cut, cleaned, trimmed, chilled, frozen, deep-frozen or thawed;</p> <p>“prepared fishery products” means unprocessed fishery products that have undergone an operation affecting their anatomical wholeness, such as gutting, heading, slicing, filleting, chopping;</p> <p>“mechanically separated fishery product” means any product obtained by removing flesh from fishery products using mechanical means resulting in the loss or modification of the flesh structure;</p> <p>“processing” means any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes;</p> <p>“preserve” means the process whereby products are packed in hermetically sealed containers and subjected to heat treatment to the extent that any micro-organisms that might proliferate are destroyed or inactivated, irrespective of the temperature at which the product is to be stored;</p> <p>“hermetically sealed container” means a container that is designed and intended to be secure against the entry of hazards;</p>
Definitions in relation to smoking	<p>“primary tar fraction” shall refer to the purified fraction of the water-insoluble high-density tar phase of condensed smoke and shall fall within the definition of “smoke flavourings”;</p> <p>“primary smoke condensate” shall refer to the purified water-based part of condensed smoke and shall fall within the definition of “smoke flavourings”;</p> <p>“primary products” shall refer to primary smoke condensates and primary tar fractions;</p> <p>“derived smoke flavourings” shall refer to flavourings produced as a result of the further processing of primary products and which are used or intended to be used in or on foods in order to impart smoke flavour to those foods;</p> <p>“smoke flavouring” means a smoke extract used in traditional foodstuff smoking processes;</p> <p>“flavouring” means flavouring substances, flavouring preparations, process flavourings, smoke flavourings or mixtures thereof;</p>
Definitions in relation to food additives	<p>“sweeteners” means food additives which are used to impart a sweet taste to foodstuffs and/or table-top sweeteners;</p> <p>“colours” means food additives which add or restore colour in a food;</p>
Definitions in relation to chilling	<p>“chilling” means the process of cooling fishery products to a temperature approaching that of melting ice;</p> <p>“chiller” means a chamber or room used for reducing the temperature of fish;</p> <p>“chill storage room” means a chamber or room for the storage of chilled fish;</p>

	<p>“refrigerated seawater” means clean seawater cooled by a suitable method;</p> <p>“refrigerated brine” means brine cooled by a suitable refrigeration system;</p> <p>“brine” means a mixture of potable water or clean seawater and food grade salt;</p>
Definitions in relation to freezing	<p>“freezing of fish” : the term freezing is applied to the continuous and quick process of reducing the thermal core temperature of fish or fishery products from an ambient temperature to <math>-18^{\circ}</math> C or lower ;</p> <p>“freezer” means a room used for the purpose of reducing fish temperature to <math>-18^{\circ}</math> C or lower;</p> <p>“frozen products” means products which have undergone a freezing process to reach a core temperature of <math>-18^{\circ}</math> C or lower after temperature stabilisation;</p> <p>“cold storage room” means a chamber or room used for the storage of frozen fishery products (<math>-18^{\circ}</math> C or lower);</p> <p>“ice room” means a chamber or room used only for the manufacture and/or storage of ice;</p>
Definitions in relation to wrapping and packaging	<p>“wrapping” means the placing of fishery product in a wrapper or container in direct contact with the foodstuff concerned, and the wrapper or container itself;</p> <p>“container” means the principal covering in which fish are packed;</p> <p>“packaging” means the placing of one or more wrapped fishery products in a second container, and the latter container itself;</p>
Definitions in relation to quality assurance	<p>“code of best practices” are those practices to be implemented under the responsibility of the fish business operator that ensure quality of the fishery products on a structural and operational level, not directly related to food safety (in the areas of plant construction, maintenance, use of processing water, raw material acceptance, cleaning and disinfecting, hygiene, pest control, manufacturing, storage, transport, by-products and waste disposal) and are the prerequisite measures and conditions necessary to control hazards by the safety assurance system (HACCP);</p> <p>“CP” means control point, a processing step where the company may wish to address a quality concern not related to food safety;</p>
Definitions in relation to safety assurance	<p>“HACCP (Hazard Analysis Critical Control Points)” describes the safety assurance system related to food safety;</p> <p>“hazard” means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect;</p> <p>“marine biotoxins” means poisonous substances accumulated by bivalve molluscs, in particular as a result of feeding on plankton containing toxins;</p> <p>“CCP (Critical Control Point)” means a factor, practice, procedure, process or location that can be controlled in order to prevent, reduce or eliminate a hazard;</p> <p>“critical limit” means a standard or criterion which separates acceptability from unacceptability;</p> <p>“corrective action” means action taken when the results of monitoring at the CCP indicate a loss of control;</p> <p>“verification”(relating to HACCP) means the application of methods, procedures and tests, in addition to those used in monitoring, to determine compliance with the HACCP plan and/or whether the HACCP plan needs modification;</p>

	<p>“verification”(relating to inspection) means checking, by examination and the consideration of objective evidence, whether specified requirements have been fulfilled;</p> <p>“risk” means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;</p> <p>“risk analysis” means a process consisting of three interconnected components: risk assessment, risk management and risk communication;</p> <p>“risk assessment” means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk;</p> <p>“risk management” means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options;</p> <p>“risk communication” means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions;</p>
Definitions in relation to parasites	<p>“candling” means, in respect of flat fish or fish fillets, holding up fish to a light in a darkened room to detect parasites;</p> <p>“visual inspection” means a non-destructive examination of fish or fishery products without optical means of magnifying and under good light conditions for human vision, including if necessary, candling;</p> <p>“visible parasite” means a parasite or group of parasites which has a dimension, colour or texture which is clearly distinguishable from fish tissues; and can be seen without optical means of magnifying and under good light conditions for human vision;</p>
Definitions in relation to inspection and control	<p>“Competent Authority” means the central authority of a country competent to ensure compliance with the requirements of these Regulations, competent to carry-out veterinary checks and to organise official controls (or any other authority to which that central authority has delegated that competence);</p> <p>“control body” means an independent third party to which the Competent Authority has delegated certain control tasks;</p> <p>“control plan” means a description established by the Competent Authority containing general information on the structure and organisation of its official control systems;</p> <p>“Inspectorate” means the veterinary unit (fish inspection unit), responsible for the organisation and the inspection of the quality control and safety assurance systems;</p> <p>“approved” means approved by the Head of the Competent Authority in writing;</p> <p>“auto-control”(own checks) means the quality and safety assurance systems implemented by the management of the establishment;</p> <p>“documentary check” means the examination of commercial documents and where appropriate, of documents required under feed or food law that are accompanying the consignment;</p> <p>“identity check” means a visual inspection to ensure that certificates or other</p>

documents accompanying the consignment tally with the labelling and content of the consignment;

“physical check” means a check on the feed or food itself, which may include checks on the means of transport, on the packaging, labelling and temperature, the sampling for analysis and laboratory testing and any other check necessary to verify compliance with feed or food law;

“verification” (relating to inspection) means checking, by examination and the consideration of objective evidence, whether specified requirements have been fulfilled;

“traceability” means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution;

“fail safe control system” means a system to ensure control and monitoring against a standard and by implementing corrective actions if any deviation of the standard is identified;

“inspection” means the examination of establishments, of animals and food, and the processing thereof, of fish businesses, and their management and production systems, including documents, finished product testing and feeding practices, and of the origin and destination of production inputs and outputs, in order to verify compliance with the legal requirements in all cases;

“non compliance” means failure to meet the requirements of these Regulations;

“audit” means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives;

“monitoring” means conducting a planned sequence of observations or measurements with a view to obtaining an overview of the state of compliance with feed or food law;

“surveillance” means a careful observation of one or more feed or food businesses, feed or food business operators or their activities;

“official control” means any form of control that the Competent Authority performs for the verification of compliance with food law;

“official fish inspector” means a Public Health Officer (mentioned as Health Inspector in the Public Health Law,) qualified in accordance with these Regulations, to act in such a capacity and appointed by the Competent Authority;

“approved fish inspector” means a fish inspector designated by the Competent Authority to carry out specific official controls on holdings on its behalf;

“official auxiliary” means a person qualified, in accordance with these regulations, to act in such a capacity, appointed by the Competent Authority and working under the authority and responsibility of an authorized official;

“official certification” means the procedure by which the Competent Authority or control bodies, authorised to act in such a capacity, provide written, electronic or equivalent assurance concerning compliance;

“official detention” means the procedure by which the Competent Authority ensures that feed or food is not moved or tampered with pending a decision on its destination; it includes storage by feed and food business operators in accordance

	with instructions from the Competent Authority;	
	“sampling for analysis” means taking feed or food or any other substance (including from the environment) relevant to the production, processing and distribution of feed or food or to the health of animals, in order to verify through analysis compliance with feed or food law or animal health rules;	
	“sound” means free from disease, mould, decay or deterioration and fit for human consumption;	
	“health mark” means a mark indicating that, when it was applied, official controls had been carried out in accordance with these Regulations;	
Definitions in relation to laboratories	“official analysis” means analysis carried out by an official laboratory;	
	“official laboratory” means the laboratory which is approved by the Competent Authority and is by that able to carry out official analyses.	
<b>PART 3</b>	<b>Laying down the general principles and requirements of food law, and procedures in matters of food safety<sup>1</sup></b>	
Scope	1	a) This Regulation provides the basis for the assurance of a high level of protection of human health and consumers’ interest in relation to food including traditional products.
		b) This Regulation shall apply to all stages of fish product processing and distribution and to feed for aquaculture. It shall not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption.
Risk analysis	2	Measures adopted by the Government of Kiribati concerning food and feed should generally be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.
	3	Where food law is aimed at the reduction, elimination or avoidance of a risk to health, the three interconnected components of risk analysis - risk assessment, risk management, and risk communication - provide a systematic methodology for the determination of effective, proportionate and targeted measures or other actions to protect health.
	4	In order for there to be confidence in the scientific basis for food law, risk assessments should be undertaken in an independent, objective and transparent manner, on the basis of the available scientific information and data.
Precautionary Principle	5	a) The precautionary principle has been invoked to ensure health protection.  In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure a high level of health protection, pending further scientific information for a more comprehensive risk assessment, will be taken.
		b) Measures adopted shall be proportionate and no more restrictive of trade than is required to achieve a high level of health protection, regard being

<sup>1</sup> Source: EU Regulation 178/2002 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

			had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.
Traceability one up one down	6	a)	It is necessary to establish a comprehensive system of traceability within the fish products businesses so that targeted and accurate withdrawals can be undertaken or information given to consumers or control officials.
		b)	It is necessary to ensure that a fish business including an importer can identify at least the business from which the food has been supplied, to ensure that on investigation, traceability can be assured at all stages.
Food safety requirements	7		Fish products shall not be placed on the market if they are unsafe.
	8		Food shall be deemed to be unsafe if it is considered to be:
		a)	injurious to health;
		b)	unfit for human consumption.
	9		In determining whether any food is unsafe, regard shall be had:
		a)	to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and
		b)	to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.
	10	a)	In determining whether any food is injurious to health, regard shall be had: <ul style="list-style-type: none"> <li>(i) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;</li> <li>(ii) to the probable cumulative toxic effects;</li> <li>(iii) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.</li> </ul>
		b)	In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.
	11		Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.
Feed safety	12		Feed shall not be placed on the market or fed to any food-producing

		animal if it is unsafe.
	13	Feed shall be deemed to be unsafe for its intended use if it is considered to: - have an adverse effect on human or animal health; - make the food derived from food-producing animals unsafe for human consumption.
	14	Where a feed which has been identified as not satisfying the feed safety requirement is part of a batch, lot or consignment of feed of the same class or description, it shall be presumed that all of the feed in that batch, lot or consignment is so affected, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment fails to satisfy the feed safety requirement.
Business Operator's Responsibilities	15	Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.
Traceability food/feed operator's responsibility	16	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.
	17	Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed.  To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the Competent Authorities on demand.
	18	Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the Competent Authorities on demand.
	19	Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the Competent Authorities on demand.
	20	If a fish business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, they shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the Competent Authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumer of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.

	21		A food business operator shall immediately inform the Competent Authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health. Operators shall inform the Competent Authorities of the action taken to prevent risks
	22		Food business operators shall collaborate with the Competent Authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.
Rapid Alert	23		The Competent Authority shall devise a rapid alert system for the notification of a direct or indirect risk to human health deriving from fish products. The system must provide for contacts in countries to which the product has been sent.
Crisis Management	24		The Competent Authority shall draw up a general plan for crisis management in the field of the safety of food and feed, specifying.
		a)	The types of situation involving direct or indirect risks to human health deriving from fish products which are not likely to be prevented, eliminated or reduced to an acceptable level by provisions in place;
		b)	Practical procedures necessary to manage a crisis, including the principles of transparency to be applied and a communication strategy.
<b>PART 4</b>	<b>Official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules<sup>2</sup></b>		
Scope	25		This Regulation lays down general rules for the performance of official controls to verify compliance with rules aiming, in particular, at preventing, eliminating or reducing to acceptable levels risks to humans and animals, either directly or through the environment.
General obligation of the Competent Authority	26		Official controls shall be carried out regularly, on a risk basis and with appropriate frequency, so as to achieve the objectives of this Regulation taking account of:
		a)	identified risks associated with animals, feed or food, feed or food businesses, the use of feed or food or any process, material, substance, activity or operation that may influence feed or food safety, animal health or animal welfare;
		b)	feed or food business operators' past record as regards compliance with feed or food law or with animal health and animal welfare rules;
		c)	the reliability of any own checks that have already been carried out.
	27		Official controls shall be carried out without prior warning, except in cases such as audits where prior notification of the feed or food business operator is necessary. Official controls may also be carried out on an ad hoc basis.
	28		Official controls shall be carried out at any of the stages of production, processing and distribution of feed or food and of animals and animal products. They shall include controls on feed and food businesses, on the use of feed and food, on the storage of feed and food, on any process, material, substance, activity or operation including transport

<sup>2</sup> EU Regulation 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

			applied to feed or food and on live animals, required to achieve the objectives of this Regulation.
Overall responsibilities of the Competent Authority	29		Responsibilities of the Competent Authority shall be in accordance with the tasks, duties and responsibilities given in the Fisheries Act 2010/Food Safety Act 2006, and with the responsibilities concerning health control laid down in this Regulation.
Designation of Competent Authority	30	a)	<p>The government of Kiribati shall designate the Competent Authority responsible for the purposes and official controls set out in these Regulations.</p> <p>The Competent Authority shall ensure:</p> <ul style="list-style-type: none"> <li>i. the effectiveness and appropriateness of official controls on feed and food at all stages of production, processing and distribution, and the use of feed;</li> <li>ii. that staff carrying out official controls are free from any conflict of interest;</li> <li>iii. that they have, or have access to, an adequate laboratory capacity for testing and a sufficient number of suitably qualified and experienced staff so that official controls and control duties can be carried out efficiently and effectively;</li> <li>iv. that they have appropriate and properly maintained facilities and equipment to ensure that staff can perform official controls efficiently and effectively;</li> <li>v. that they have the legal powers to carry out official controls and to take the measures provided for in these Regulations;</li> <li>vi. that they have contingency plans in place, and are prepared to operate such plans in the event of an emergency;</li> <li>vii. that the feed and food business operators are obliged to undergo any inspection carried out in accordance with these Regulations and to assist the staff of the Competent Authority in the accomplishment of their tasks.</li> </ul>
		b)	When, within the Competent Authority, more than one unit is competent to carry out official controls (e.g. at regional level), efficient and effective co-ordination and co-operation shall be ensured between the different units;
		c)	Competent Authorities shall ensure the impartiality, quality and consistency of official controls at all levels. The criteria listed in paragraphs i) – vii) of clause 30 a) above must be fully respected by every authority on which the competence to carry out official controls is conferred;
		d)	Competent Authorities shall carry out internal audits or may have external audits carried out, and shall take appropriate measures in the light of their results, to ensure that they are achieving the objectives of these regulations. These audits shall be subject to independent scrutiny and shall be carried out in a transparent manner.
Delegation of tasks by the Competent	31	a)	The Competent Authority may delegate specific tasks related to official controls to one or more control bodies in accordance with paragraphs

Authority		<p>(a) to (f) of this clause.</p> <p>A list of tasks that may or may not be delegated may be established. However, activities in relation to enforcement procedures as actions in case of non-compliance and sanctions shall not be the subject of such a delegation.</p> <p>The Competent Authority may delegate specific tasks to a particular control body only if:</p> <ul style="list-style-type: none"> <li>a) there is an accurate description of the tasks that the control body may carry out and of the condition under which it may be carried out;</li> <li>b) there is proof that the control body: <ul style="list-style-type: none"> <li>i. has the expertise, equipment and infrastructure required to carry out the tasks delegated to it;</li> <li>ii. has a sufficient number of suitably qualified and experienced staff; and</li> <li>iii. is impartial and free from any conflict of interest as regards to the exercise of the tasks delegated to it.</li> </ul> </li> <li>c. the control body works and is accredited in accordance with Standard EN 45004 “General criteria for the operation of various types of bodies performing inspection and/or another standard if more relevant to the delegated tasks in question”;</li> <li>d. laboratories operate in accordance with International standards ISO 17025 and Good Laboratory Practices;</li> <li>e. the control body communicates the results of the controls carried out to the Competent Authority on a regular basis and whenever the Competent Authority so requests. If the results of the controls indicate non-compliance or point to the likelihood of non-compliance, the control body shall immediately inform the Competent Authority;</li> <li>f. there is efficient and effective co-ordination between the delegating Competent Authority and the control body.</li> </ul>
		<p>b) Competent Authorities delegating specific tasks to control bodies shall organise audits or inspections of control bodies as necessary. If, as a result of an audit or an inspection, it appears that such bodies are failing to carry out properly the tasks delegated to them, the delegating Competent Authority may withdraw the delegation. It shall withdraw it without delay if the control body fails to take appropriate and timely remedial action.</p>
Staff performing Official Controls	32	<p>The Competent Authority shall ensure that its staff performing official controls:</p>
		<p>a) receive, for the area of competence appropriate training enabling them to undertake their duties competently and to carry out official controls in a consistent manner.</p> <p>This training to include:</p> <ol style="list-style-type: none"> <li>1. Different control techniques, such as auditing, sampling and</li> </ol>

			<p>inspection</p> <ol style="list-style-type: none"> <li>2. Control procedures</li> <li>3. Feed and food law</li> <li>4. The different stages of production, processing and distribution, and the possible risks to human health, and where appropriate to the health of animals and plants and to the environment</li> <li>5. Assessment of non-compliance with feed and food law</li> <li>6. Hazards in animal feed and food production</li> <li>7. The evaluation of the application of HACCP procedures</li> <li>8. Management systems, such as quality assurance programmes, that feed and food businesses operate and their assessment in so far as these are relevant for feed or food law requirements</li> <li>9. Official certification systems</li> <li>10. Contingency arrangements for emergencies, including communication between Member States and the Commission</li> <li>11. Legal proceedings and implications of official controls</li> <li>12. Examination of written, documentary material and other records, including those related to proficiency testing, accreditation and risk assessment, which may be relevant to the assessment of compliance with feed or food law; this may include financial and commercial aspects</li> <li>13. Any other area, including animal health and animal welfare, necessary to ensure that official controls are carried out in accordance with this Regulation</li> </ol>
		b)	Keep up to date in their areas of competence and receive regular additional training as necessary;
		c)	Have aptitude for multidisciplinary cooperation.
Transparency and confidentiality	33	a)	The Competent Authority shall ensure that they carry out their activities with a high level of transparency. To this purpose, relevant information held by them shall be made available to the public as soon as possible.
		b)	In general, the public shall have access to information on the control activities of the Competent Authorities and their effectiveness;
			The Competent Authority shall take steps to ensure that members of their staff are required not to disclose information acquired when undertaking their official control duties which by its nature is covered by professional secrecy in duly justified cases.
		c)	<p>Information covered by professional secrecy in particular:</p> <ol style="list-style-type: none"> <li>i. the confidentiality of preliminary investigation procedures or of current legal proceedings;</li> <li>ii. personal data;</li> <li>iii. information protected by national legislation concerning in particular professional secrecy, the confidentiality of</li> </ol>

			deliberations, international relations and national defence, shall not be disclosed.
Control and verification procedures	34	a)	<p>The Competent Authority shall carry out official controls in accordance with documented procedures.</p> <p>These procedures shall contain information and instructions for staff performing official controls including on these areas:</p> <ol style="list-style-type: none"> <li>i. The organisation of the Competent Authority and the relationship between central Competent Authorities and authorities to which they have delegated tasks to carry out official controls</li> <li>ii. The relationship between Competent Authorities and control bodies to which they have delegated tasks related to official controls</li> <li>iii. A statement on the objectives to be achieved</li> <li>iv. Tasks, responsibilities and duties of staff</li> <li>v. Sampling procedures, control methods and techniques, interpretation of results and consequent decisions</li> <li>vi. Monitoring and surveillance programmes</li> <li>vii. Action to be taken following official controls</li> <li>viii. Cooperation with other services or departments that may have relevant responsibilities</li> <li>ix. Verification of the appropriateness of methods of sampling, methods of analysis and detection tests</li> <li>x. Any other activity or information required for the effective functioning of the official controls.</li> </ol>
		b)	The government shall ensure that it has legal procedures in place to guarantee that staff of the Competent Authorities have access to premises and documentation kept by fish business operators.
		c)	<p>The Competent Authority shall have procedures in place:</p> <ol style="list-style-type: none"> <li>i. to verify the effectiveness of official controls that they carry out and;</li> <li>ii. to ensure that corrective action is taken when needed and that relevant documentation is updated as appropriate.</li> </ol>
		d)	<p>These documented procedures shall constitute the Quality Manual and may include Good Manufacturing Practice Guidelines or similar codes of practice as appropriate and include in particular recommendations concerning official controls on;</p> <ol style="list-style-type: none"> <li>i. the implementation of HACCP principles;</li> <li>ii. management systems that feed or food business operators operate with a view to meeting the requirements of feed or food law;</li> <li>iii. the microbiological, physical and chemical safety of feed and food.</li> </ol>

Reports	35	a)	The Competent Authority shall draw up reports on the official controls that it has carried out.
		b)	These reports shall include a description of the purpose of the official controls, the control methods applied, the results of the official controls and, where appropriate, action that the business operator concerned is to take.
		c)	The Competent Authority shall provide the business operator concerned with a copy of the report referred to in paragraph 2, at least in case of non-compliance.
Control activities methods and techniques	36	a)	Tasks related to official controls shall, in general, be carried out using appropriate control methods and techniques such as monitoring, surveillance, verification, audit, inspection, sampling and analysis.
		b)	<p>Official controls on feed and food shall include the following activities:</p> <ul style="list-style-type: none"> <li>i. examination of any control systems that feed and food business operators have put in place and the results obtained;</li> <li>ii. inspection of: <ul style="list-style-type: none"> <li>a) primary producers' installations, feed and food businesses, including their surroundings, premises, offices, equipment, installations and machinery, transport, as well as of feed and food;</li> <li>b) raw materials, ingredients, processing aids and other products used for the preparation and production of feed and food;</li> <li>c) semi-finished products;</li> <li>d) materials and articles intended to come into contact with food;</li> <li>e) cleaning and maintenance products and processes, as well as pesticides;</li> <li>f) labelling, presentation and advertising.</li> </ul> </li> <li>iii. checks on hygiene conditions in feed and food businesses;</li> <li>iv. assessment of procedures on good manufacturing practices (GMP), good hygiene practices (GHP), good farming practices and HACCP, taking into account the use of guides established in accordance with these regulations;</li> <li>v. examination of written material and other records which may be relevant to the assessment of compliance with feed or food law;</li> <li>vi. interviews with feed and food business operators and with their staff;</li> <li>vii. the reading of values recorded by feed or food business measuring instruments;</li> <li>viii. controls carried out with the Competent Authority's own instruments to verify measurements taken by feed and food business operators.</li> </ul>
Methods of sampling and analysis	37	a)	Sampling and analysis methods used in the context of official controls shall comply with relevant national rules or,

			<ul style="list-style-type: none"> <li>i. if no such rules exist, with internationally recognised rules or protocols, for example those that the European Committee for Standardisation (CEN) has accepted or those agreed in national legislation or;</li> <li>ii. in the absence of the above, with other methods fit for the intended purpose or developed in accordance with scientific protocols.</li> </ul>
		b)	Where Clause 37 a) above does not apply, validation of methods of analysis may take place within a single laboratory according to an internationally accepted protocol.
		c)	Wherever possible, methods of analysis shall be characterised by the appropriate criteria set out in the relevant Annex.
		d)	<p>The following implementing measures may be taken if deemed necessary:</p> <ul style="list-style-type: none"> <li>i. methods of sampling and analysis, including the confirmatory or reference methods to be used in the event of a dispute;</li> <li>ii. performance criteria, analysis parameters, measurement uncertainty and procedures for the validation of the methods referred to in (i) and;</li> <li>iii. rules on the interpretation of results.</li> </ul>
		e)	The Competent Authorities shall establish adequate procedures in order to guarantee the right of feed and food business operators whose products are subject to sampling and analysis to apply for a supplementary expert opinion, without prejudice to the obligation of Competent Authorities to take prompt action in case of emergency.
		f)	In particular, they shall ensure that feed and food business operators can obtain sufficient numbers of samples for a supplementary expert opinion, unless impossible in case of highly perishable products or very low quantity of available substrate.
		g)	Samples must be handled and labelled in such a way as to guarantee both their legal and analytical validity.
Official laboratories	38	a)	The Competent Authority shall designate laboratories that may carry out the analysis of samples taken during official controls.
		b)	<p>However, Competent Authorities may only designate laboratories that operate and are assessed and accredited in accordance with the following European standards:</p> <ul style="list-style-type: none"> <li>i. EN ISO/IEC 17025 on ‘General requirements for the competence of testing and calibration laboratories’;</li> <li>ii. EN ISO/IEC 17011 on ‘General requirements for accreditation bodies accrediting conformity assessment bodies’.</li> </ul> <p>Taking into account criteria for different testing methods laid down in feed and food law.</p>
		c)	The accreditation and assessment of testing laboratories referred to in Clause 38 b) may relate to individual tests or groups of tests.
Crisis management contingency plans	39	a)	The Competent Authority shall draw up operational contingency plans

			setting out measures to be implemented without delay when feed or food is found to pose a serious risk to humans or animals either directly or through the environment.
		b)	These contingency plans shall specify: <ul style="list-style-type: none"> <li>i. the administrative authorities to be engaged;</li> <li>ii. their powers and responsibilities; and</li> <li>iii. channels and procedures for sharing information between the relevant parties.</li> </ul>
		c)	The Competent Authority shall review these contingency plans as appropriate, particularly in the light of changes in the organisation of the Competent Authority and of experience including experience gained from simulation exercises.
Official controls feed of non- animal origin	40	a)	The Competent Authority shall carry out regular official controls on aquaculture feed of non-animal origin. It shall organise these controls on the basis of the potential risks. The controls shall cover all aspects of feed and food law.
		b)	These controls shall be carried out at an appropriate place, including the point of entry of the goods, the point of release for free circulation, warehouses, the premises of the importing feed and food business operator, or other points along the feed chain.
Types of checks on feed of non-animal origin	41	a)	The official controls shall include at least a systematic documentary check, a random identity check and, as appropriate, a physical check
		b)	Physical checks shall be carried out at a frequency depending on: <ul style="list-style-type: none"> <li>i. the risks associated with different types of feed;</li> <li>ii. the history of compliance with the requirements for the product concerned of the exporting country and establishment of origin and of the feed business operators importing and exporting the product;</li> <li>iii. the controls that the feed business operator importing the product has carried out;</li> <li>iv. the guarantees that the Competent Authority of the third country of origin has given.</li> </ul>
		c)	The Competent Authority shall ensure that physical checks are carried out under appropriate conditions and at a place with access to appropriate control facilities allowing investigations to be conducted properly, a number of samples adapted to the risk management to be taken, and the feed and food to be handled hygienically. Samples must be handled in such a way as to guarantee both their legal and analytical validity. The Competent Authority shall ensure that the equipment and methodology are adequate for measuring the limit values laid down under national legislation.
		d)	The Competent Authority shall, for the organisation of the official controls referred to: <ul style="list-style-type: none"> <li>i. designate particular points of entry in their territory which have access to the appropriate control facilities for different types of</li> </ul>

			<p>feed and food and;</p> <p>ii. require feed and food business operators responsible for consignments to give prior notification of their arrival and nature.</p>
Action in case of suspicion	42		In case of suspicion of non-compliance or if there is doubt as to the identity or the actual destination of the consignment, or as to the correspondence between the consignment and the certified guarantees, the Competent Authority shall carry out official controls in order to confirm or to eliminate the suspicion or doubt. The Competent Authority shall place the consignment concerned under official detention until it obtains the results of such official controls.
Action following official controls on imports		a)	<p>The Competent Authority shall place under official detention feed or food from third countries that does not comply with feed or food law and, having heard from the feed or food business operators responsible for the consignment, it shall take the following measures in respect of such feed or food:</p> <p>i. order that such feed or food be destroyed, subjected to a special treatment, other appropriate measures such as the use of feed or food for purposes other than those for which they were originally intended may also be taken;</p> <p>ii. if the feed or food has already been placed on the market, monitor it or, if necessary, order its recall or withdrawal before taking one of the measures referred to above;</p> <p>iii. verify that feed and food does not give rise to any adverse effects on human or animal health, either directly or through the environment, during or pending the implementation of any of the measures referred to in subparagraphs i) and ii).</p>
		b)	<p>If however:</p> <p>i. the official controls indicate that a consignment is injurious to human or animal health or unsafe, the Competent Authority shall place the consignment in question under official detention pending its destruction or any other appropriate measure necessary to protect human and animal health;</p> <p>ii. feed of non-animal origin for which an increased level of controls has been laid down is not presented for official controls, or is not presented in accordance with any specific requirements, the Competent Authority shall order that it be recalled and placed under official detention without delay and that it be then either destroyed or re-dispatched.</p>
		c)	When it does not permit the introduction of feed or food, the Competent Authority shall notify customs services, together with information as regards the final destination of the consignment.
		d)	Decisions on consignments shall be subject to the right of appeal.
Costs	43		The feed or food business operator responsible for the consignment or its representative shall be liable for the reasonable costs incurred by Competent Authorities for the activities referred to above.
Financing official controls	44		The Competent Authority shall ensure that adequate financial resources

			are available to provide the necessary staff and other resources for official controls by whatever means considered appropriate, including through general taxation or by establishing fees or charges.
Expenses arising from additional official controls	45		<p>When the detection of non-compliance leads to official controls that exceed the Competent Authority's normal control activities, the Competent Authority shall charge the operators responsible for the non-compliance, or may charge the operator owning or keeping the goods at the time when the additional official controls are carried out, for the expenses arising from the additional official controls.</p> <p>Normal control activities are the routine control activities required by this regulation. Activities that exceed normal control activities include the taking and analysis of samples as well as other controls that are required to check the extent of a problem, to verify whether corrective action has been taken, or to detect and/or substantiate non-compliance.</p>
Official certification	46		<p>Requirements for official controls shall include:</p> <ol style="list-style-type: none"> <li>i. the circumstances in which official certification is required;</li> <li>ii. model certificates;</li> <li>iii. qualifications of the certifying staff;</li> <li>iv. the principles to be respected to ensure reliable certification, including electronic certification;</li> <li>v. the procedures to be followed in case of withdrawal of certificates and for replacement certificates;</li> <li>vi. consignments that are split into smaller consignments or that are mixed with other consignments;</li> <li>vii. documents that must follow goods after official controls have been carried out.</li> </ol>
	47		<p>Where official certification is required, it shall be ensured that:</p> <ol style="list-style-type: none"> <li>i. a link exists between the certificate and the consignment;</li> <li>ii. the information in the certificate is accurate and authentic.</li> </ol>
	48		A single model certificate shall, where appropriate, combine requirements concerning the official certification of food and other requirements for official certification.
Registration/approval of feed and food business establishments	49	a)	<ol style="list-style-type: none"> <li>i. Competent Authorities shall establish procedures for feed and food business operators to follow when applying for the registration of their establishments in accordance with this Regulation or with future regulations on feed hygiene;</li> <li>ii. They shall draw up and keep updated a list of feed and food business operators which have been registered. Where such a list already exists for other purposes, it may also be used for the purposes of this Regulation.</li> </ol>
		b)	<ol style="list-style-type: none"> <li>i. Competent Authorities shall establish procedures for feed and food business operators to follow when applying for the approval of their establishments in accordance with this Regulation.</li> <li>ii. Upon receipt of an application for approval from a feed or food</li> </ol>

			<p>business operator, the Competent Authority shall make an on-site visit.</p> <p>iii. It shall approve an establishment for the activities concerned only if the feed or food business operator has demonstrated that it complies with the relevant requirements of feed or food law.</p> <p>iv. The Competent Authority may grant conditional approval if it appears that the establishment meets all the infrastructure and equipment requirements. It shall grant full approval only if it appears from a new official control of the establishment, carried out within three months of granting conditional approval, that the establishment meets the other relevant requirements of feed or food law. If clear progress has been made but the establishment still does not meet all of the relevant requirements, the Competent Authority may prolong conditional approval. However, conditional approval shall not exceed a total of six months.</p> <p>v. The Competent Authority shall keep the approval of establishments under review when carrying out official controls. If the Competent Authority identifies serious deficiencies or has to stop production at an establishment repeatedly and the feed or food business operator is not able to provide adequate guarantees regarding future production, the Competent Authority shall initiate procedures to withdraw the establishment's approval. However, the Competent Authority may opt only to suspend an establishment's approval if the feed or food business operator can guarantee that it will resolve deficiencies within a reasonable time;</p> <p>vi. The Competent Authorities shall maintain up-to-date lists of approved establishments.</p>
Multi-annual national control plans	50		To ensure the continuity and integration of official controls the Competent Authority shall draw up a single integrated multi-annual national control plan. The plan shall be regularly updated in the light of developments.
Principles for the preparation of multi-annual national control plans	51	a)	<p>Each multi-annual national control plan shall contain general information on the structure and organisation of the systems of feed and food control, and of animal health and animal welfare control in Kiribati, in particular on:</p> <p>i. the strategic objectives of the plan and on how the prioritisation of controls and allocation of resources reflect these objectives;</p> <p>ii. the risk categorisation of the activities concerned;</p> <p>iii. the designation of Competent Authorities and their tasks at central, regional and local level, and on resources available to these authorities;</p> <p>iv. the general organisation and management of official controls at national, regional and local level, including official controls in individual establishments;</p> <p>v. control systems applied to different sectors and coordination</p>

			<p>between the different services of Competent Authorities responsible for official controls in these sectors;</p> <ul style="list-style-type: none"> <li>vi. where appropriate, the delegation of tasks to control bodies;</li> <li>vii. methods to ensure compliance with the operational criteria;</li> <li>viii. the training of staff performing official controls;</li> <li>ix. the documented procedures;</li> <li>x. the organisation and operation of contingency plans for animal or food-borne disease emergencies, feed and food contamination incidents and other human health risks;</li> <li>xi. the organisation of cooperation and mutual assistance.</li> </ul>
		b)	<p>Multi-annual national control plans may be adjusted during their implementation. Amendments may be made in the light of, or in order to take account of, factors including:</p> <ul style="list-style-type: none"> <li>i. new legislation;</li> <li>ii. the emergence of new diseases or other health risks;</li> <li>iii. significant changes to the structure, management or operation of the competent national authorities;</li> <li>iv. any amendment of the guidelines, codes of practices or standards used as reference documents;</li> <li>v. scientific findings;</li> <li>vi. the outcome of audits performed by a third country.</li> </ul>
Guidelines for multi-annual plans	52		<p>These guidelines shall in particular:</p> <ul style="list-style-type: none"> <li>i. promote a consistent, comprehensive and integrated approach to official controls of feed and food, animal health and animal welfare legislation, and embrace all sectors and all stages of the feed and food chain, including import and introduction;</li> <li>ii. identify risk-based priorities and criteria for the risk categorisation of the activities concerned and the most effective control procedures;</li> <li>iii. identify other priorities and the most effective control procedures;</li> <li>iv. identify the stages of production, processing and distribution of feed and food, including the use of feed, which will provide the most reliable and indicative information about compliance with feed and food law;</li> <li>v. encourage the adoption of best practices at all levels of the control system;</li> <li>vi. encourage the development of effective controls on traceability systems;</li> <li>vii. provide advice on the development of systems to record the performance and results of control actions;</li> <li>viii. reflect relevant international bodies' standards and recommendations regarding the organisation and operation of</li> </ul>

			<p>official services;</p> <p>ix. lay down criteria for the conduct of the audits;</p> <p>x. lay down the structure of, and information to be included in the annual reports;</p> <p>xi. indicate the main performance indicators to be applied in assessing multi-annual national control plans.</p>
Action in case of non-compliance	53	a)	When the Competent Authority identifies non-compliance, it shall take action to ensure that the operator remedies the situation. When deciding which action to take, the Competent Authority shall take account of the nature of the non-compliance and of that operator's past record with regard to non-compliance.
		b)	Such action shall include, where appropriate, the following measures: <ul style="list-style-type: none"> <li>i. the imposition of sanitation procedures or any other action deemed necessary to ensure the safety of feed or food or compliance with feed or food law, animal health or animal welfare rules;</li> <li>ii. the restriction or prohibition of the placing on the market, import or export of feed, food or animals;</li> <li>iii. monitoring and, if necessary, ordering the recall, withdrawal and/or destruction of feed or food;</li> <li>iv. the authorisation to use feed or food for purposes other than those for which they were originally intended;</li> <li>v. the suspension of operation or closure of all or part of the business concerned for an appropriate period of time;</li> <li>vi. the suspension or withdrawal of the establishment's approval;</li> <li>vii. the measures on consignments from third countries;</li> <li>viii. any other measure the Competent Authority deems appropriate.</li> </ul>
		c)	The Competent Authority shall provide the operator concerned, or a representative, with: <ul style="list-style-type: none"> <li>i. written notification of its decision concerning the action to be taken in accordance with clause 53 a), together with the reasons for the decision and;</li> <li>ii. information on rights of appeal against such decisions and on the applicable procedure and time limits.</li> </ul>
		d)	All expenditure incurred pursuant to this Article shall be borne by the responsible feed and food business operator.
Sanctions	54		The Kiribati government shall lay down the rules on sanctions applicable to infringements of feed and food law relating to the protection of animal health and welfare and shall take all measures necessary to ensure that these are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

<b>PART 5</b>		<b>General provisions on the hygiene of foodstuffs<sup>3</sup></b>	
Scope	55	a)	<p>This Regulation lays down general rules for food business operators on the hygiene of foodstuffs, taking particular account of the following principles:</p> <ul style="list-style-type: none"> <li>i. primary responsibility for food safety rests with the food business operator;</li> <li>ii. it is necessary to ensure food safety throughout the food chain, starting with primary production;</li> <li>iii. it is important, for food that cannot be stored safely at ambient temperatures, particularly frozen food, to maintain the cold chain;</li> <li>iv. general implementation of procedures based on the HACCP principles, together with the application of good hygiene practice, should reinforce food business operators' responsibility;</li> <li>v. guides to good practice are a valuable instrument to aid food business operators at all levels of the food chain with compliance with food hygiene rules and with the application of the HACCP principles;</li> <li>vi. it is necessary to establish microbiological criteria and temperature control requirements based on a scientific risk assessment.</li> </ul> <p>This Regulation shall apply to all stages of production, processing and distribution of food and to exports, and without prejudice to more specific requirements relating to food hygiene.</p>
		b)	<p>This Regulation shall not apply to:</p> <ul style="list-style-type: none"> <li>i) primary production for domestic use;</li> <li>ii) the domestic preparation, handling or storage of food for private domestic consumption;</li> <li>iii) the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer.</li> </ul>
Food Business Operators' Obligations	56		Food business operators shall ensure that all stages of production, processing and distribution of food under their control satisfy the relevant hygiene requirements laid down in this Regulation.
General and specific hygiene requirements	57	a)	Food business operators carrying out primary production and those associated operations listed in Annex 1 shall comply with the general hygiene provisions laid down in part A of Annex 1 and any specific requirements provided for in this Regulation.
		b)	Food business operators carrying out any stage of production, processing and distribution of food after those stages to which paragraph a) applies shall comply with the general hygiene requirements laid down in Annex 1 and any specific requirements

<sup>3</sup> Source: EU Regulation 852/2004 on the hygiene of foodstuffs

			provided for in this Regulation.
		c)	<p>Food business operators shall, as appropriate, adopt the following specific hygiene measures:</p> <ul style="list-style-type: none"> <li>i. compliance with microbiological criteria for foodstuffs;</li> <li>ii. procedures necessary to meet targets set to achieve the objectives of this Regulation;</li> <li>iii. compliance with temperature control requirements for foodstuffs;</li> <li>iv. maintenance of the cold chain;</li> <li>v. sampling and analysis.</li> </ul>
		d)	The criteria, requirements and targets referred to in paragraph c), and associated sampling and analysis methods shall be laid down by the Competent Authority.
		e)	When this Regulation, and its implementing measures do not specify sampling or analysis methods, food business operators may use appropriate methods laid down by internationally recognised standards or national legislation or, in the absence of such methods, methods that offer equivalent results to those obtained using the reference method, if they are scientifically validated in accordance with internationally recognised rules or protocols.
		f)	Food business operators may use the guides and codes of practice as an aid to compliance with their obligations under this Regulation.
Hazard Analysis Critical Control Point	58	a)	Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.
		b)	<p>The HACCP principles referred to in paragraph 58 a) consist of the following:</p> <ul style="list-style-type: none"> <li>i. identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;</li> <li>ii. identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;</li> <li>iii. establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;</li> <li>iv. establishing and implementing effective monitoring procedures at critical control points;</li> <li>v. establishing corrective actions when monitoring indicates that a critical control point is not under control;</li> <li>vi. establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (i) to (v) are working effectively; and</li> <li>vii. establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs</li> </ul>

			(i) to (vi). When any modification is made in the product, process, or any step, food business operators shall review the procedure and make the necessary changes to it.
		c)	Paragraph 58 a) shall apply only to food business operators carrying out any stage of production, processing and distribution of food following primary production and those associated operations listed in Annex 1.
		d)	Food business operators shall: <ul style="list-style-type: none"> <li>i. provide the Competent Authority with evidence of their compliance with paragraph 1 in the manner that the Competent Authority requires, taking account of the nature and size of the food business;</li> <li>ii. ensure that any documents describing the procedures developed in accordance with this Article are up-to-date at all times;</li> <li>iii. retain any other documents and records for an appropriate period.</li> </ul>
Official controls, registration and approval	59	a)	Food business operators shall cooperate with the Competent Authorities in accordance with national law.
		b)	In particular, each food business operator shall notify the appropriate Competent Authority, in the manner that the latter requires, of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the registration of each such establishment.  Food business operators shall also ensure that the Competent Authority continually receives updated information on establishments, including by notifying any significant change in activities and any closure of an existing establishment.
		c)	However, food business operators shall ensure that establishments are approved by the Competent Authority, following at least one on-site visit, when approval is required by this regulation or any other national law.
Guides to good practice	60		Food business operators will use recognised national and international guides to best practice e.g. Codex Alimentarius and World Health Organization publications.
<b>PART 6</b>	<b>Specific hygiene rules for food of fish origin<sup>4</sup></b>		
Scope	61		This Regulation lays down specific rules on the hygiene of food of fish origin for food business operators. They shall apply to unprocessed and processed products of fish origin.
General Provisions	62		Unless expressly indicated to the contrary, this Regulation shall not apply to retail.
	63		This Regulation shall apply without prejudice to:

<sup>4</sup> Source: EU Regulation 853/2004 laying down specific hygiene rules for food of animal origin

		a)	animal welfare requirements;
		b)	requirements concerning the identification of animals and the traceability of products of animal origin.
General obligations of food business operators	64	a)	Food business operators shall comply with the relevant provisions of Annex 2.
		b)	Food business operators shall not use any substance other than potable water or, when this Regulation permits its use, clean water — to remove surface contamination from products of animal origin, unless use of the substance has been approved. Food business operators shall also comply with any conditions for use that may be adopted under the same procedure. The use of an approved substance shall not affect the food business operator's duty to comply with the requirements of this Regulation.
Registration and approval of establishments	65	a)	Food business operators shall place products of fisheries origin on the market only if they have been prepared and handled exclusively in establishments: <ul style="list-style-type: none"> <li>i) that meet the relevant requirements of this Regulation, those of Annexes 1 and 2 of this Regulation and other relevant requirements of food law;</li> <li>and</li> <li>ii) that the Competent Authority has registered or, where required, approved.</li> </ul>
		b)	Establishments handling those products of animal origin for which Annexes 1 and 2 to this Regulation lays down requirements shall not operate unless the Competent Authority has approved them in accordance with these Regulations, with the exception of establishments carrying out only: <ul style="list-style-type: none"> <li>i) primary production;</li> <li>ii) transport operations;</li> <li>iii) the storage of products not requiring temperature-controlled storage conditions.</li> </ul>
	66		An establishment subject to approval in accordance with these regulations shall not operate unless the Competent Authority has, in accordance with this Regulation laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption: <ul style="list-style-type: none"> <li>i) granted the establishment approval to operate following an on-site visit;</li> <li>or</li> <li>ii) provided the establishment with conditional approval.</li> </ul>
	67		Food business operators shall cooperate with the Competent Authorities in accordance with their responsibilities under this Regulation. In particular, food business operators shall ensure that an establishment ceases to operate if the Competent Authority withdraws its approval or, in the case of conditional approval, fails to prolong it

			or to grant full approval.
	68		<p>This Article shall not prevent an establishment from placing food on the market between the date of application of this Regulation and the first subsequent inspection by the Competent Authority, if the establishment:</p> <p>(a) is subject to approval in accordance with these regulations and placed products of animal origin on the market in accordance with national legislation immediately prior to the application of this Regulation;</p> <p>or</p> <p>(b) is of a type in respect of which there was no requirement for approval prior to the application of this Regulation.</p>
Health and identification mark	69	a)	<p>Food business operators shall not place on the market a product of animal origin handled in an establishment subject to approval in accordance with this Regulation unless it has either:</p> <p>i) a health mark applied in accordance with this Regulation;</p> <p>or</p> <p>ii) when the Regulation does not provide for the application of a health mark, an identification mark will be applied in accordance with Annex II of this Regulation.</p>
		b)	<p>Food business operators may apply an identification mark to a product of animal origin only if the product has been manufactured in accordance with this Regulation in an establishment meeting its requirements.</p>
Products of animals origin from outside the country	70		<p>Food business operators importing products of animal origin from third countries shall ensure that importation takes place only if:</p> <p>(a) in the case of live bivalve molluscs, echinoderms, tunicates and marine gastropods, the production area appears on a list drawn up in accordance with this Regulation, when applicable;</p> <p>(b) the product satisfies:</p> <p>(i) the requirements of this Regulation, including the requirements on health and identification marking;</p> <p>and</p> <p>(ii) any import conditions laid down in accordance with Kiribati legislation governing import controls for products of animal origin;</p> <p>and</p> <p>(c) the requirements concerning certificates and documents are satisfied, when applicable.</p>
Documents	71	a)	<p>When required in accordance with Annex 2, food business operators shall ensure that certificates or other documents accompany consignments of products of animal origin.</p>
		b)	<p>In accordance with these regulations:</p>

			<p>i) model documents may be established;</p> <p>and</p> <p>ii) provision may be made for the use of electronic documents.</p>
Specific decisions	72		<p>Implementing measures may be laid down:</p> <ol style="list-style-type: none"> <li>i. to lay down other treatments that may be applied in a processing establishment to live bivalve molluscs from class B or C production areas that have not been submitted to purification or relaying;</li> <li>ii. to specify recognised testing methods for marine biotoxins (refer to Annex 2);</li> <li>iii. to lay down additional health standards for live bivalve molluscs in cooperation with the relevant laboratory, including: <ol style="list-style-type: none"> <li>(a) limit values and analysis methods for other marine biotoxins;</li> <li>(b) virus testing procedures and virological standards;</li> </ol> <p>and</p> <ol style="list-style-type: none"> <li>(c) sampling plans and the methods and analytical tolerances to be applied to check compliance with the health standards;</li> </ol> </li> <li>iv. to lay down health standards or checks, where there is scientific evidence indicating that they are necessary to protect public health;</li> <li>v. to extend Annex 3 to live bivalve molluscs other than Pectinidae;</li> <li>vi. to specify criteria for determining when epidemiological data indicate that a fishing ground does not present a health hazard with regard to the presence of parasites and, consequently, for determining when the Competent Authority may authorise food business operators not to freeze fishery products in accordance with Annex 2;</li> <li>vii. to lay down freshness criteria and limits with regard to histamine and total volatile nitrogen for fisheries products.</li> </ol>
<b>PART 7</b>	<b>Specific rules for the organisation of official controls on products of fish origin intended for human consumption<sup>5</sup></b>		
Scope	73		This part lays down specific rules for the organisation of official controls on products of animal origin.
Approval of establishments	74		The Competent Authorities shall approve establishments when, and in the manner, specified in these regulations.
	75		In the case of factory and freezer vessels flying the flag of Member States, the maximum periods of three and six months applying to the conditional approval of other establishments may be extended, if necessary. However, conditional approval shall not exceed a total of

<sup>5</sup> Source: EU Regulation 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

			12 months. Inspections of such vessels shall take place as specified in Annex 3.
	76		The Competent Authority shall give each approved establishment, including those with conditional approval, an approval number, to which codes may be added to indicate the types of products of animal origin manufactured. For wholesale markets, secondary numbers indicating units or groups of units selling or manufacturing products of animal origin may be added to the approval number.
	77		In the case of wholesale markets, the Competent Authority may withdraw or suspend approval in respect of certain units or groups of units.
	78		The above paragraphs shall apply both:  (a) to establishments that begin placing products of animal origin on the market on or after the date of application of this Regulation;  and  (b) to establishments already placing products of animal origin on the market but in respect of which there was previously no requirement for approval. In the latter case, the Competent Authority's on-site visit takes place as soon as possible.
General principles for official controls in respect of all products of animal origin falling within the scope of this Regulation	79		Food business operators offer all assistance needed to ensure that official controls carried out by the Competent Authority can be performed effectively.  They shall in particular:  - give access to all buildings, premises, installations or other infrastructures;  - make available any documentation and record required under the present Regulation or considered necessary by the Competent Authority for judging the situation.
	80		The Competent Authority shall carry out official controls to verify food business operators' compliance with the requirements of this Regulation.
	81		The official controls shall include:  (a) audits of good hygiene practices and hazard analysis and critical control point (HACCP)-based procedures;  (b) the official controls;  and  (c) any particular auditing tasks specified in the Annexes.
	82		Audits of good hygiene practices shall verify that food business operators apply procedures continuously and properly concerning at least:  (a) checks on food-chain information;  (b) the design and maintenance of premises and equipment;  (c) pre-operational, operational and post-operational hygiene;

		<p>(d) personal hygiene;</p> <p>(e) training in hygiene and in work procedures;</p> <p>(f) pest control;</p> <p>(g) water quality;</p> <p>(h) temperature control;</p> <p>and</p> <p>(i) controls on food entering and leaving the establishment and any accompanying documentation.</p>
	83	<p>Audits of HACCP-based procedures shall verify that food business operators apply such procedures continuously and properly, having particular regard to ensuring that the procedures provide the guarantees specified in these regulations. They shall, in particular, determine whether the procedures guarantee, to the extent possible, that products of fish origin:</p> <p>(a) comply with microbiological criteria laid down under these regulations;</p> <p>(b) comply with these regulations on residues, contaminants and prohibited substances;</p> <p>and</p> <p>(c) do not contain physical hazards, such as foreign bodies.</p> <p>When, in accordance with these regulations, a food business operator uses procedures set out in guides to the application of HACCP principles rather than establishing its own specific procedures, the audit shall cover the correct use of these guides.</p>
	84	<p>Verification of compliance with the requirements of this regulation concerning the application of identification marks shall take place in all establishments approved in accordance with this regulation, in addition to verification of compliance with other traceability requirements.</p>
	85	<p>When carrying out auditing tasks, the Competent Authority shall take special care:</p> <p>(a) to determine whether staff and staff activities in the establishment at all stages of the production process comply with the relevant requirements of this Regulation. To support the audit, the Competent Authority may carry out performance tests, in order to ascertain that staff performance meets specified parameters;</p> <p>(b) to verify the food business operator's relevant records;</p> <p>(c) to take samples for laboratory analysis whenever necessary;</p> <p>and</p> <p>(d) to document elements taken into account and the findings of the audit.</p>
	86	<p>The nature and intensity of auditing tasks in respect of individual establishments shall depend upon the assessed risk. To this end, the</p>

			Competent Authority shall regularly assess: (a) public and, where appropriate, animal health risks; (b) the type and throughput of the processes carried out; and (c) the food business operator's past record as regards compliance with food law.
Live bivalve molluscs	87		The Competent Authority shall ensure that the production and placing on the market of live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods undergo official controls as described in Annex 3.
Fishery products	88		The Competent Authority shall ensure that official controls with respect to fishery products take place in accordance with Annex 3.
Documents	89		A document meeting the requirements set out in Annex 8 shall accompany consignments of products of animal origin when they are exported.
	90		The document referred to in paragraph 89 shall certify that the products satisfy: (a) the requirements laid down in these regulations or provisions that are equivalent to those requirements; and (b) any specific import conditions established in accordance with these Regulations.
Special provisions	91		The procedures laid down in these regulations do not apply to fresh fishery products landed in Kiribati directly from a fishing vessel flying the flag of a third country.  Official controls with respect to such fishery products shall take place in accordance with these regulations and specifically in accordance with its Annexes 2 and 3.
	92	a)	Fishery products that may reach the EU market and which are imported into Kiribati from a factory or freezer vessel flying the flag of a third country shall come from vessels that appear on a list drawn up and updated in accordance with EU Decision 2006/766.
		b)	However, by way of exemption, a vessel may also be included on such lists:  (i) on the basis of a joint communication from the Competent Authority of the third country the flag of which the vessel is flying and from the Competent Authority of another third country to which the former Competent Authority has delegated responsibility for the inspection of the vessel concerned, on condition that:  — that third country appears on the list of third countries, allowed to export to the EU, found in EC Decision 2006/766 establishing the lists of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates,

			<p>marine gastropods and fishery products are permitted;</p> <ul style="list-style-type: none"> <li>— all fishery products from the vessel concerned that are destined for placing on the market in the European Community are landed directly in that third country;</li> <li>— the Competent Authority of that third country has inspected the vessel and has declared that it complies with European Community requirements;</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>— the Competent Authority of that third country has declared that it will regularly inspect the vessel to ensure that it continues to comply with European Community requirements.</li> </ul>
<b>PART 8</b>	<b>Product Testing</b>		
<b>A</b>	<b>Microbiological contaminants<sup>6</sup></b>		
General requirements	93		Food business operators shall ensure that foodstuffs comply with the relevant microbiological criteria set out in Annex 1.
	94		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 with the criteria throughout the shelf-life. In particular, this applies to ready-to-eat foods that are able to support the growth of <i>Listeria monocytogenes</i> and that may pose a <i>Listeria monocytogenes</i> risk to public health.
	95		Guidelines for conducting these studies may be included in the guides to good practice referred to in Annex 1.
	96		Food business operators shall decide the appropriate sampling frequencies, except where Annex 1 provides for specific sampling frequencies.
Rules for testing and sampling	97		The analytical methods and the sampling plans and methods in Annex 1 shall be applied as reference methods.
	98		When testing against food safety criteria set out in Chapter 1 of Annex 1 provides unsatisfactory results, the product or batch of foodstuffs shall be withdrawn or recalled in accordance with Article 19 of Regulation (EC) No 178/2002 together with other corrective actions defined in their HACCP-based procedures and other actions necessary to protect the health of consumers.
	99		Food business operators shall analyse trends in the test results. When they observe a trend towards unsatisfactory results, they shall take appropriate actions.
<b>B</b>	<b>Contaminants<sup>7</sup></b>		
General	100		The edible part of foodstuffs listed in Annex 7 shall not be placed on the market where they contain a contaminant listed in the Annex at a level

<sup>6</sup> Source: EU Regulation 2073/2005 on microbiological criteria for foodstuffs

<sup>7</sup> Source: EU Regulation 1881/2006 setting maximum levels for certain contaminants in foodstuffs

			exceeding the maximum level set out in the Annex.
Sampling and analysis	101		Sampling and analysis for these official controls shall follow the systems described in Commission Regulation (EC) No 1883/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs or any amendment of the regulation and Commission Regulation No 333/2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs.
<b>C</b>	<b>Freshness Rating<sup>8</sup></b>		
Freshness categories	102		The freshness category of each lot shall be determined on the basis of the freshness of the product and a number of additional requirements.
	103		Freshness shall be defined by reference to the special ratings for different types of products.  Each lot must contain products of the same degree of freshness. A small lot need not, however, be of uniform freshness; if it is not, the lot shall be placed in the lowest freshness category represented therein.
	104		Pelagic species may be graded in the different categories of freshness and size on the basis of a system of sampling. This system must ensure that the freshness and size of the products contained in the lot are as uniform as possible.
Products from third countries	105		The freshness category of fish intended for export from third countries to the EU must be determined by a means that is equivalent in meaning and clearly understood by EU inspection services. An example of the EU style of presentation is provided for comparison purposes in Annex 6.
	106		Products exported to the EU must have the following information is clearly and legibly marked: <ul style="list-style-type: none"> <li>- country of origin, printed in Roman letters at least 20 mm high,</li> <li>- production method</li> <li>- catch area (FAO area)</li> <li>- scientific name of product and its trade name,</li> <li>- presentation,</li> <li>- freshness and size categories,</li> <li>- net weight in kilograms of products in the package,</li> <li>- date of grading and date of dispatch,</li> <li>- name and address of consignor</li> <li>- in the case of freshwater or aquaculture fish the country of origin</li> </ul>
	107		Products landed at an EU Community port direct from the fishing grounds from vessels flying the flag of Kiribati, and intended for marketing, shall be subject to the same provisions as those applicable to

<sup>8</sup> Source: EU Regulation 2406/96 laying down common marketing standards for certain fishery products

			EU Community catches, without prejudice to IUU Regulation No 1005/2008.
<b>D</b>	<b>Monitoring, testing, sampling and analysis of aquaculture substances and residues<sup>91011</sup></b>		
Monitoring residues	108		The Competent Authority shall monitor the substances and groups of residues listed in EU Directive 96/23 “on measures to monitor certain substances and residues thereof in live animals and animal products ...”
Maximum residue limits	109		The Competent Authority shall provide guarantees that veterinary medical products in foodstuffs of aquaculture origin do not breach the maximum limits listed in EU Regulation 2377/90 laying down an EU Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin.
Analytical methods	110		The Competent Authority shall ensure that analytical methods and the interpretation of their results comply with those described in EU Commission Decision 2002/657 ‘Implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results’.
<b>E</b>	<b>Water<sup>12</sup></b>		
Water quality requirement	111		The Competent Authority is to provide guarantees on the potability of water by following the testing, sampling frequencies and methods described in EU Directive 98/83/EC on the quality of water intended for human consumption.

<sup>9</sup> Sources: EU Decision 2002/657 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results

<sup>10</sup> Source: EU Council Directive 96/23 on measures to monitor certain substances and residues thereof in live animals and animal products

<sup>11</sup> Source: EU Regulation 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin

<sup>12</sup> Source: in EU Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption

## **ANNEX 1: General Hygiene Conditions**

### **SECTION I**

#### **PART A: GENERAL HYGIENE PROVISIONS FOR PRIMARY PRODUCTION AND ASSOCIATED OPERATIONS**

##### **I. Scope**

1. This Annex applies to primary production and to the following associated operations:
  - a) the transport, storage and handling of primary products at the place of production, provided that this does not substantially alter their nature;and
  - b) in the case of fishery products, transport operations to deliver primary products, the nature of which has not been substantially altered, from the place of production to an establishment.

##### **II. Hygiene provisions**

2. As far as possible, food business operators are to ensure that primary products are protected against contamination, having regard to any processing that primary products will subsequently undergo.
3. Notwithstanding the general duty laid down in paragraph 2, food business operators are to comply with appropriate national legislative provisions relating to the control of hazards in primary production and associated operations, including:
  - a) measures to control contamination arising from the air, soil, water, feed, fertilisers, veterinary medicinal products, plant protection products and biocides and the storage, handling and disposal of waste;and
  - b) measures relating to animal health and welfare and plant health that have implications for human health, including programmes for the monitoring and control of zoonoses and zoonotic agents.
4. Food business operators rearing, harvesting or hunting animals or producing primary products of animal origin are to take adequate measures, as appropriate:
  - a) to keep any facilities used in connection with primary production and associated operations, including facilities used to store and handle feed, clean and, where necessary after cleaning, to disinfect them in an appropriate manner;
  - b) to keep clean and, where necessary after cleaning, to disinfect, in an appropriate manner, equipment, containers, crates, vehicles and vessels;
  - c) to use potable water, or clean water, whenever necessary to prevent contamination;
  - d) to ensure that staff handling foodstuffs are in good health and undergo training on health risks;
  - e) as far as possible to prevent animals and pests from causing contamination;
  - f) to store and handle waste and hazardous substances so as to prevent contamination;
  - g) to prevent the introduction and spread of contagious diseases transmissible to humans through food, including by taking precautionary measures when introducing new animals and reporting suspected outbreaks of such diseases to the Competent Authority;

- h) to take account of the results of any relevant analyses carried out on samples taken from animals or other samples that have importance to human health;

and

- i) to use feed additives and veterinary medicinal products correctly, as required by the relevant legislation.

5. Food business operators producing or harvesting plant products are to take adequate measures, as appropriate:

- (a) to keep clean and, where necessary after cleaning, to disinfect, in an appropriate manner, facilities, equipment, containers, crates, vehicles and vessels;
- (b) to ensure, where necessary, hygienic production, transport and storage conditions for, and the cleanliness of, plant products;
- (c) to use potable water, or clean water, whenever necessary to prevent contamination;
- (d) to ensure that staff handling foodstuffs are in good health and undergo training on health risks;
- (e) as far as possible to prevent animals and pests from causing contamination;
- (f) to store and handle wastes and hazardous substances so as to prevent contamination;
- (g) to take account of the results of any relevant analyses carried out on samples taken from plants or other samples that have importance to human health;

and

- (h) to use plant protection products and biocides correctly, as required by the relevant legislation.

6. Food business operators are to take appropriate remedial action when informed of problems identified during official controls.

### **III. Record-keeping**

7. Food business operators are to keep and retain records relating to measures put in place to control hazards in an appropriate manner and for an appropriate period, commensurate with the nature and size of the food business. Food business operators are to make relevant information contained in these records available to the Competent Authority and to receiving food business operators on request.

8. Food business operators rearing animals or producing primary products of animal origin are, in particular, to keep records on:

- (a) the nature and origin of feed fed to the animals;
- (b) veterinary medicinal products or other treatments administered to the animals, dates of administration and withdrawal periods;
- (c) the occurrence of diseases that may affect the safety of products of animal origin;
- (d) the results of any analyses carried out on samples taken from animals or other samples taken for diagnostic purposes, that have importance for human health;

and

- (e) any relevant reports on checks carried out on animals or products of animal origin.

9. The food business operators may be assisted by other persons, such as veterinarians, agronomists and farm technicians, with the keeping of records.

**PART B: RECOMMENDATIONS FOR GUIDES TO GOOD HYGIENE PRACTICE**

1. National guides should contain guidance on good hygiene practice for the control of hazards in primary production and associated operations.
2. Guides to good hygiene practice should include appropriate information on hazards that may arise in primary production and associated operations as well as on actions to be implemented to control hazards.

Examples of such hazards and measures may include:

- (a) the control of contamination such as marine toxins and heavy metals;
- (b) the use of water, organic waste and fertilisers;
- (c) the correct and appropriate use of veterinary medicinal products and feed additives and their traceability;
- (d) the preparation, storage, use and traceability of feed;
- (e) the proper disposal of dead fish, waste and litter;
- (f) protective measures to prevent the introduction of contagious diseases transmissible to humans through food, and any obligation to notify the Competent Authority;
- (g) procedures, practices and methods to ensure that food is produced, handled, packed, stored and transported under appropriate hygienic conditions, including effective cleaning and pest-control;
- (h) measures relating to the observation of cleanliness during the slaughter and production of fish;
- (i) measures relating to record-keeping.

## **Section II**

### **GENERAL HYGIENE REQUIREMENTS FOR ALL FOOD BUSINESS OPERATORS (EXCEPT WHEN SECTION I APPLIES)**

#### **INTRODUCTION**

Chapters IV to XI apply to all stages of production, processing and distribution of food and the remaining Chapters apply as follows:

- Chapter I applies to all food premises;
- Chapter II applies to all rooms where food is prepared, treated or processed, except dining areas;
- Chapter III applies to all transportation.

#### **CHAPTER I**

##### **General requirements for food premises**

1. Food premises are to be kept clean and maintained in good repair and condition.
2. The layout, design, construction, siting and size of food premises are to:
  - (a) permit adequate maintenance, cleaning and/or disinfection, avoid or minimise air-borne contamination, and provide adequate working space to allow for the hygienic performance of all operations;
  - (b) be such as to protect against the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces;
  - (c) permit good food hygiene practices, including protection against contamination and, in particular, pest control;

and

- (d) where necessary, provide suitable temperature-controlled handling and storage conditions of sufficient capacity for maintaining foodstuffs at appropriate temperatures and designed to allow those temperatures to be monitored and, where necessary, recorded.
3. An adequate number of flush lavatories are to be available and connected to an effective drainage system. Lavatories are not to open directly into rooms in which food is handled.
4. An adequate number of washbasins are to be available, suitably located and designated for cleaning hands. Washbasins for cleaning hands are to be provided with running water, materials for cleaning hands and for hygienic drying. Where necessary, the facilities for washing food are to be separate from the hand-washing facility.
5. There is to be suitable and sufficient means of natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area is to be avoided. Ventilation systems are to be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.
6. Sanitary conveniences are to have adequate natural or mechanical ventilation.
7. Food premises are to have adequate natural and/or artificial lighting.
8. Drainage facilities are to be adequate for the purpose intended. They are to be designed and constructed to avoid the risk of contamination. Where drainage channels are fully or partially open, they are to be so designed as to ensure that waste does not flow from a contaminated area towards or into a clean area, in particular an area where foods likely to present a high risk to the final consumer are handled.
9. Where necessary, adequate changing facilities for personnel are to be provided.

10. Cleaning agents and disinfectants are not to be stored in areas where food is handled.

## **CHAPTER II**

### **Specific requirements in rooms where foodstuffs are prepared, treated or processed**

1. In rooms where food is prepared, treated or processed, the design and layout are to permit good food hygiene practices, including protection against contamination between and during operations. In particular:
  - (a) floor surfaces are to be maintained in a sound condition and should be easy to clean and, where necessary, to disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials unless food business operators can satisfy the Competent Authority that other materials used are appropriate. Where appropriate, floors are to allow adequate surface drainage;
  - (b) wall surfaces are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials and require a smooth surface up to a height appropriate for the operations unless food business operators can satisfy the Competent Authority that other materials used are appropriate;
  - (c) ceilings (or, where there are no ceilings, the interior surface of the roof) and overhead fixtures are to be constructed and finished so as to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable mould and the shedding of particles;
  - (d) windows and other openings are to be constructed to prevent the accumulation of dirt. Those which can be opened to the outside environment are, where necessary, to be fitted with insect-proof screens which can be easily removed for cleaning. Where open windows would result in contamination, windows are to remain closed and fixed during production;
  - (e) doors are to be easy to clean and, where necessary, to disinfect. This will require the use of smooth and non-absorbent surfaces unless food business operators can satisfy the Competent Authority that other materials used are appropriate;

and

- (f) surfaces (including surfaces of equipment) in areas where foods are handled and in particular those in contact with food are to be maintained in a sound condition and should be easy to clean and where necessary, to disinfect. This will require the use of smooth, washable, corrosion-resistant and non-toxic materials, unless food business operators can satisfy the Competent Authority that other materials used are appropriate.
2. Adequate facilities are to be provided, where necessary, for the cleaning, disinfecting and storage of working utensils and equipment. These facilities are to be constructed of corrosion-resistant materials, should be easy to clean and should have an adequate supply of hot and cold water.
  3. Adequate provision is to be made, where necessary, for washing food. Every sink or other such facility provided for the washing of food is to have an adequate supply of hot and/or cold potable water consistent with the requirements of Chapter VII and should be kept clean and, where necessary, disinfected.

## **CHAPTER III**

### **Transport**

1. Conveyances and/or containers used for transporting foodstuffs are to be kept clean and maintained in good repair and condition to protect foodstuffs from contamination and are, where necessary, to be designed and constructed to permit adequate cleaning and/or disinfection.

2. Receptacles in vehicles and/or containers are not to be used for transporting anything other than foodstuffs where this may result in contamination.
3. Where conveyances and/or containers are used for transporting anything in addition to foodstuffs or for transporting different foodstuffs at the same time, there is, where necessary, to be effective separation of products.
4. Bulk foodstuffs in liquid, granulate or powder form are to be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs. Such containers are to be marked in a clearly visible and indelible fashion, to show that they are used for the transport of foodstuffs, or are to be marked 'for foodstuffs only'.
5. Where conveyances and/or containers have been used for transporting anything other than foodstuffs or for transporting different foodstuffs, there is to be effective cleaning between loads to avoid the risk of contamination.
6. Foodstuffs in conveyances and/or containers are to be so placed and protected as to minimise the risk of contamination.
7. Where necessary, conveyances and/or containers used for transporting foodstuffs are to be capable of maintaining foodstuffs at appropriate temperatures and of allowing these temperatures to be monitored.

## **CHAPTER IV**

### **Equipment requirements**

1. All articles, fittings and equipment with which food comes into contact are to:
  - (a) be effectively cleaned and, where necessary, disinfected. Cleaning and disinfection are to take place at a frequency sufficient to avoid any risk of contamination;
  - (b) be so constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination;
  - (c) with the exception of non-returnable containers and packaging, be so constructed, be of such materials and be kept in such good order, repair and condition as to enable them to be kept clean and, where necessary, to be disinfected;and
  - (d) be installed in such a manner as to allow adequate cleaning of the equipment and the surrounding area.
2. Where necessary, equipment is to be fitted with any appropriate control device to guarantee fulfilment of this Regulation's objectives.
3. Where chemical additives have to be used to prevent corrosion of equipment and containers, they are to be used in accordance with good practice.

## CHAPTER V

### Food waste

1. Food waste, non-edible by-products and other refuse are to be removed from rooms where food is present as quickly as possible, so as to avoid their accumulation.
2. Food waste, non-edible by-products and other refuse are to be deposited in closable containers, unless food business operators can demonstrate to the Competent Authority that other types of containers or evacuation systems used are appropriate. These containers are to be of an appropriate construction, kept in sound condition, and should be easy to clean and, where necessary, to disinfect.
3. Adequate provision is to be made for the storage and disposal of food waste, non-edible by-products and other refuse. Refuse stores are to be designed and managed in such a way as to enable them to be kept clean and, where necessary, free of animals and pests.
4. All waste is to be eliminated in a hygienic and environmentally friendly way in accordance with national legislation applicable to that effect, and is not to constitute a direct or indirect source of contamination.

## CHAPTER VI

### Water supply

1. (a) There is to be an adequate supply of potable water, which is to be used whenever necessary to ensure that foodstuffs are not contaminated;

(b) Clean water may be used with whole fishery products.

Clean seawater may be used with live bivalve molluscs, echinoderms, tunicates and marine gastropods; clean water may also be used for external washing.

When clean water is used, adequate facilities and procedures are to be available for its supply to ensure that such use is not a source of contamination for the foodstuff.

2. Where non-potable water is used, for example for fire control, steam production, refrigeration and other similar purposes, it is to circulate in a separate duly identified system. Non-potable water is not to connect with, or allow reflux into, potable water systems.
3. Recycled water used in processing or as an ingredient is not to present a risk of contamination. It is to be of the same standard as potable water, unless the Competent Authority is satisfied that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form.
4. Ice which comes into contact with food or which may contaminate food is to be made from potable water or, when used to chill whole fishery products, clean water. It is to be made, handled and stored under conditions that protect it from contamination.
5. Steam used directly in contact with food is not to contain any substance that presents a hazard to health or is likely to contaminate the food.
6. Where heat treatment is applied to foodstuffs in hermetically sealed containers it is to be ensured that water used to cool the containers after heat treatment is not a source of contamination for the foodstuff.

## **CHAPTER VII**

### **Personal hygiene**

1. Each person working in a food-handling area is to maintain a high degree of personal cleanliness and is to wear suitable, clean and, where necessary, protective clothing.
2. No person suffering from, or being a carrier of a disease likely to be transmitted through food or afflicted, for example, with infected wounds, skin infections, sores or diarrhoea is to be permitted to handle food or enter any food-handling area in any capacity if there is any likelihood of direct or indirect contamination. Any person so affected and employed in a food business and who is likely to come into contact with food is to report immediately the illness or symptoms, and if possible their causes, to the food business operator.

## **CHAPTER VIII**

### **Provisions applicable to foodstuffs**

1. A food business operator is not to accept raw materials or ingredients, other than live animals, or any other material used in processing products, if they are known to be, or might reasonably be expected to be, contaminated with parasites, pathogenic microorganisms or toxic, decomposed or foreign substances to such an extent that, even after the food business operator had hygienically applied normal sorting and/or preparatory or processing procedures, the final product would be unfit for human consumption.
2. Raw materials and all ingredients stored in a food business are to be kept in appropriate conditions designed to prevent harmful deterioration and to protect them from contamination.
3. At all stages of production, processing and distribution, food is to be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.
4. Adequate procedures are to be in place to control pests. Adequate procedures are also to be in place to prevent domestic animals from having access to places where food is prepared, handled or stored (or, where the Competent Authority so permits in special cases, to prevent such access from resulting in contamination).
5. Raw materials, ingredients, intermediate products and finished products likely to support the reproduction of pathogenic micro-organisms or the formation of toxins are not to be kept at temperatures that might result in a risk to health. The cold chain is not to be interrupted. However, limited periods outside temperature control are permitted, to accommodate the practicalities of handling during preparation, transport, storage, display and service of food, provided that it does not result in a risk to health. Food businesses manufacturing, handling and wrapping processed foodstuffs are to have suitable rooms large enough for the separate storage of raw materials from processed material and sufficient separate refrigerated storage.
6. Where foodstuffs are to be held or served at chilled temperatures they are to be cooled as quickly as possible following the heat-processing stage, or final preparation stage if no heat process is applied, to a temperature which does not result in a risk to health.
7. The thawing of foodstuffs is to be undertaken in such a way as to minimise the risk of growth of pathogenic microorganisms or the formation of toxins in the foods. During thawing, foods are to be subjected to temperatures that would not result in a risk to health. Where run-off liquid from the thawing process may present a risk to health it is to be adequately drained. Following thawing, food is to be handled in such a manner as to minimise the risk of growth of pathogenic microorganisms or the formation of toxins.
8. Hazardous and/or inedible substances, including animal feed, are to be adequately labelled and stored in separate and secure containers.

## **CHAPTER IX**

### **Provisions applicable to the wrapping and packaging of foodstuffs**

1. Materials used for wrapping and packaging are not to be a source of contamination.
2. Wrapping materials are to be stored in such a manner that they are not exposed to a risk of contamination.
3. Wrapping and packaging operations are to be carried out so as to avoid contamination of the products. Where appropriate and in particular in the case of cans and glass jars, the integrity of the container's construction and its cleanliness is to be assured.
4. Wrapping and packaging material re-used for foodstuffs is to be easy to clean and, where necessary, to disinfect.

## **CHAPTER X**

### **Heat treatment**

The following requirements apply only to food placed on the market in hermetically sealed containers:

1. any heat treatment process used to process an unprocessed product or to process further a processed product is:
  - (a) to raise all parts of the product treated to a given temperature for a given period of time;and
  - (b) to prevent the product from becoming contaminated during the process.
2. to ensure that the process employed achieves the desired objectives, food business operators are to check regularly the main relevant parameters (particularly temperature, pressure, sealing and microbiology), including by the use of automatic devices;
3. the process used should conform to an internationally recognised standard (for example, pasteurisation, ultra high temperature or sterilisation).

## **CHAPTER XI**

### **Training**

Food business operators are to ensure:

1. that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity;
  2. that those responsible for the development and maintenance of the procedure for the operation of relevant guides have received adequate training in the application of the HACCP principles;
- and
3. compliance with any requirements of national law concerning training programmes for persons working in certain food sectors.

## **ANNEX 2: Requirements of the Food Business Operator**

### **REQUIREMENTS CONCERNING SEVERAL PRODUCTS OF ANIMAL ORIGIN**

#### **SECTION I: IDENTIFICATION MARKING**

When required in accordance with these regulations food business operators must ensure that products of animal origin have an identification mark applied in compliance with the following provisions.

##### **A. APPLICATION OF THE IDENTIFICATION MARK**

1. The identification mark must be applied before the product leaves the establishment.
2. However, a new mark need not be applied to a product unless its packaging and/or wrapping is removed or it is further processed in another establishment, in which case the new mark must indicate the approval number of the establishment where these operations take place.
3. Food business operators must, in accordance these regulations, have in place systems and procedures to identify food business operators from whom they have received and to whom they have delivered products of animal origin.

##### **B. FORM OF THE IDENTIFICATION MARK**

4. The mark must be legible and indelible, and the characters easily decipherable. It must be clearly displayed for the Competent Authorities.
5. The mark must indicate the name of the country in which the establishment is located, which may be written out in full or shown as a two-letter code in accordance with the relevant ISO standard.

Food business operators may continue to use stocks and equipment that they ordered before the entry into force of this Regulation until they are exhausted or require replacement.

6. The mark must indicate the approval number of the establishment. If an establishment manufactures both food to which this Regulation applies and food to which it does not, the food business operator may apply the same identification mark to both types of food.

##### **C. METHOD OF MARKING**

7. The mark may, depending on the presentation of different products of animal origin, be applied directly to the product, the wrapping or the packaging, or be printed on a label affixed to the product, the wrapping or the packaging. The mark may also be an irremovable tag made of a resistant material
8. For products of animal origin that are placed in transport containers or large packages and are intended for further handling, processing, wrapping or packaging in another establishment, the mark may be applied to the external surface of the container or packaging.
9. When products of animal origin are placed in a package destined for direct supply to the final consumer, it is sufficient to apply the mark to the exterior of that package only.

## **SECTION I: LIVE BIVALVE MOLLUSCS**

1. This Section applies to live bivalve molluscs. With the exception of the provisions on purification, it also applies to live echinoderms, tunicates and marine gastropods.
2. The requirements of this Section supplement those laid down in the General Hygiene requirements of this regulation: in the case of operations that take place before live bivalve molluscs arrive at a dispatch or purification centre, they supplement the requirements of this regulation.

### **Chapter I: General Requirements for the Placing on the Market of Live Bivalve Molluscs**

1. Live bivalve molluscs may not be placed on the market for retail sale otherwise than via a dispatch centre, where an identification mark must be applied in accordance with these regulations.
2. Food business operators may accept batches of live bivalve molluscs only if the documentary requirements set out in points 3 to 7 have been complied with.
3. Whenever a food business operator moves a batch of live bivalve molluscs between establishments, up to and including the arrival of the batch at a dispatch centre or processing establishment, a registration document must accompany the batch.
4. The registration document must be in at least one official language of the importing state in which the receiving establishment is located and contain at least the information specified below.
  - (a) In the case of a batch of live bivalve molluscs sent from a production area, the registration document must contain at least the following information:
    - i. the gatherer's identity and address;
    - ii. the date of harvesting;
    - iii. the location of the production area described in as precise detail as is practicable or by a code number;
    - iv. the health status of the production area;
    - v. the shellfish species and quantity;
    - and
    - vi. the destination of the batch.
  - (b) In the case of a batch of live bivalve molluscs sent from a relaying area, the registration document must contain at least the information referred to in (a) and the following information:
    - i. the location of the relaying area;
    - and
    - ii. the duration of relaying.
  - (c) In the case of a batch of live bivalve molluscs sent from a purification centre, the registration document must contain at least the information referred to in (a) and the following information:
    - i. the address of the purification centre;
    - ii. the duration of purification;
    - and
    - iii. the dates on which the batch entered and left the purification centre.

5. Food business operators sending batches of live bivalve molluscs must complete the relevant sections of the registration document so that they are easy to read and cannot be altered. Food business operators receiving batches must date stamp the document on receipt of the batch or record the date of receipt in another manner.
6. Food business operators must keep a copy of the registration document relating to each batch sent and received for at least twelve months after its dispatch or receipt (or such longer period as the Competent Authority may specify).
7. However, if:
  - (a) the staff gathering live bivalve molluscs also operate the dispatch centre, purification centre, relaying area or processing establishment receiving the live bivalve molluscs;
  - and
  - (b) a single Competent Authority supervises all the establishments concerned, registration documents are not necessary if that Competent Authority so permits.

## **Chapter II: Hygiene Requirements for the Production and Harvesting of Live Bivalve Molluscs**

### **A. REQUIREMENTS FOR PRODUCTION AREAS**

1. Gatherers may only harvest live bivalve molluscs from production areas with fixed locations and boundaries that the Competent Authority has classified — where appropriate, in cooperation with food business operators — as being of class A, B or C in accordance with the descriptions in this regulation.
2. Food business operators may place live bivalve molluscs collected from class A production areas on the market for direct human consumption only if they meet the requirements of this regulation.
3. Food business operators may place live bivalve molluscs collected from class B production areas on the market for human consumption only after treatment in a purification centre or after relaying.
4. Food business operators may place live bivalve molluscs collected from class C production areas on the market for human consumption only after relaying over a long period in accordance with this regulation.
5. After purification or relaying, live bivalve molluscs from class B or C production areas must meet all of the requirements of this regulation. However, live bivalve molluscs from such areas that have not been submitted for purification or relaying may be sent to a processing establishment, where they must undergo treatment to eliminate pathogenic micro-organisms (where appropriate, after removal of sand, mud or slime in the same or another establishment). The permitted treatment methods are:
  - (a) sterilisation in hermetically sealed containers;
  - and
  - (b) heat treatments involving:
    - i. immersion in boiling water for the period required to raise the internal temperature of the mollusc flesh to not less than 90 °C and maintenance of this minimum temperature for a period of not less than 90 seconds;
    - ii. cooking for three to five minutes in an enclosed space where the temperature is between 120 and 160 °C and the pressure is between 2 and 5 kg/cm<sup>2</sup>, followed by shelling and freezing of the flesh to a core temperature of – 20 °C;

and

- iii. steaming under pressure in an enclosed space satisfying the requirements relating to cooking time and the internal temperature of the mollusc flesh mentioned under (i). A validated methodology must be used. Procedures based on the HACCP principles must be in place to verify the uniform distribution of heat.
6. Food business operators must not produce live bivalve molluscs in, or harvest them from, areas that the Competent Authority has not classified, or which are unsuitable for health reasons. Food business operators must take account of any relevant information concerning areas' suitability for production and harvesting, including information obtained from own-checks and the Competent Authority. They must use this information, particularly information on environmental and weather conditions, to determine the appropriate treatment to apply to harvested batches.

## **B. REQUIREMENTS FOR HARVESTING AND HANDLING FOLLOWING HARVESTING**

Food business operators harvesting live bivalve molluscs, or handling them immediately after harvesting, must ensure compliance with the following requirements.

1. Harvesting techniques and further handling must not cause additional contamination or excessive damage to the shells or tissues of the live bivalve molluscs or result in changes significantly affecting their suitability for treatment by purification, processing or relaying. Food business operators must in particular:
  - (a) adequately protect live bivalve molluscs from crushing, abrasion or vibration;
  - (b) not expose live bivalve molluscs to extreme temperatures;
  - (c) not re-immerses live bivalve molluscs in water that could cause additional contamination;and
  - (d) if carrying out conditioning in natural sites, use only areas that the Competent Authority has classified as being of class A.
2. Means of transport must permit adequate drainage, be equipped to ensure the best survival conditions possible and provide efficient protection against contamination.

## **C. REQUIREMENTS FOR RELAYING LIVE BIVALVE MOLLUSCS**

Food business operators relaying live bivalve molluscs must ensure compliance with the following requirements.

1. Food business operators may use only those areas that the Competent Authority has approved for relaying live bivalve molluscs. Buoys, poles or other fixed means must clearly identify the boundaries of the sites. There must be a minimum distance between relaying areas, and also between relaying areas and production areas, so as to minimise any risk of the spread of contamination.
2. Conditions for relaying must ensure optimal conditions for purification. In particular, food business operators must:
  - (a) use techniques for handling live bivalve molluscs intended for relaying that permit the resumption of filter-feeding activity after immersion in natural waters;
  - (b) not relay live bivalve molluscs at a density that prevents purification;
  - (c) immerse live bivalve molluscs in seawater at the relaying area for an appropriate period, fixed depending on the water temperature, which period must be of at least two months'

duration unless the Competent Authority agrees to a shorter period on the basis of the food business operator's risk analysis;

and

- (d) ensure sufficient separation of sites within a relaying area to prevent mixing of batches; the 'all in, all out' system must be used, so that a new batch cannot be brought in before the whole of the previous batch has been removed.
3. Food business operators managing relaying areas must keep permanent records of the source of live bivalve molluscs, relaying periods, relaying areas used and the subsequent destination of the batch after relaying, for inspection by the Competent Authority.

### **Chapter III: Structural Requirements For Dispatch And Purification Centres**

1. The location of premises on land must not be subject to flooding by ordinary high tides or run-off from surrounding areas.
2. Tanks and water storage containers must meet the following requirements:
  - (a) Internal surfaces must be smooth, durable, impermeable and easy to clean.
  - (b) They must be constructed so as to allow complete draining of water.
  - (c) Any water intake must be situated in a position that avoids contamination of the water supply.
3. In addition, in purification centres, purification tanks must be suitable for the volume and type of products to be purified.

### **Chapter IV: Hygiene Requirements for Purification and Dispatch Centres A. Requirements for Purification Centres**

Food business operators purifying live bivalve molluscs must ensure compliance with the following requirements.

1. Before purification commences, live bivalve molluscs must be washed free of mud and accumulated debris using clean water.
2. Operation of the purification system must allow live bivalve molluscs rapidly to resume and to maintain filter feeding activity, to eliminate sewage contamination, not to become re-contaminated and to be able to remain alive in a suitable condition after purification for wrapping, storage and transport before being placed on the market.
3. The quantity of live bivalve molluscs to be purified must not exceed the capacity of the purification centre. The live bivalve molluscs must be continuously purified for a period sufficient to achieve compliance with allow the health standard of these regulations and microbiological criteria adopted in accordance with this regulation.
4. Should a purification tank contain several batches of live bivalve molluscs, they must be of the same species and the length of the treatment must be based on the time required by the batch needing the longest period of purification.
5. Containers used to hold live bivalve molluscs in purification systems must have a construction that allows clean seawater to flow through. The depth of layers of live bivalve molluscs must not impede the opening of shells during purification.
6. No crustaceans, fish or other marine species may be kept in a purification tank in which live bivalve molluscs are undergoing purification.
7. Every package containing purified live bivalve molluscs sent to a dispatch centre must be provided with a label certifying that all molluscs have been purified.

## **B. REQUIREMENTS FOR DISPATCH CENTRES**

Food business operators operating dispatch centres must ensure compliance with the following requirements.

1. Handling of live bivalve molluscs, particularly conditioning, calibration, wrapping and packing, must not cause contamination of the product or affect the viability of the molluscs.
2. Before dispatch, the shells of live bivalve molluscs must be washed thoroughly with clean water.
3. Live bivalve molluscs must come from:
  - (a) a class A production area;
  - (b) a relaying area;
  - (c) a purification centre;or
  - (d) another dispatch centre.
4. The requirements laid down in points 1 and 2 also apply to dispatch centres situated on board vessels. Molluscs handled in such centres must come from a class A production area or a relaying area.

### **Chapter V: Health Standards for Live Bivalve Molluscs**

In addition to ensuring compliance with microbiological criteria adopted in accordance with this regulation, food business operators must ensure that live bivalve molluscs placed on the market for human consumption meet the standards laid down in this Chapter.

1. They must have organoleptic characteristics associated with freshness and viability, including shells free of dirt, an adequate response to percussion and normal amounts of intravalvular liquid.
2. They 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 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;and
  - (e) for azaspiracids, 160 micrograms of azaspiracid equivalents per kilogram.

### **Chapter VI: Wrapping and Packaging of Live Bivalve Molluscs**

1. Oysters must be wrapped or packaged with the concave shell downwards.
2. Individual consumer-size packages of live bivalve molluscs must be closed and remain closed after leaving the dispatch centre and until presented for sale to the final consumer.

### **Chapter VII: Identification Marking and Labelling**

1. The label, including the identification mark, must be waterproof.
2. In addition to the general requirements for identification marks contained in Annex II, Section I, the following information must be present on the label:
  - (a) the species of bivalve mollusc (common name and scientific name);

and

(b) the date of packaging, comprising at least the day and the month.

By way of derogation from the labelling regulations, the date of minimum durability may be replaced by the entry ‘these animals must be alive when sold’.

3. The retailer must keep the label attached to the packaging of live bivalve molluscs that are not in individual consumer- size packages for at least 60 days after splitting up the contents.

### **Chapter VIII: Other Requirements**

1. Food business operators storing and transporting live bivalve molluscs must ensure that they are kept at a temperature that does not adversely affect food safety or their viability.
2. Live bivalve molluscs must not be re-immersed in, or sprayed with, water after they have been packaged for retail sale and left the dispatch centre.

### **Chapter IX: Specific Requirements for Pectinidae Harvested Outside Classified Production Areas**

Food business operators harvesting pectinidae outside classified production areas or handling such pectinidae must comply with the following requirements.

1. Pectinidae may not be placed on the market unless they are harvested and handled in accordance with Chapter II, Part B, and meet the standards laid down in Chapter V, as proved by a system of own-checks.
2. In addition, where data from official monitoring programmes enable the Competent Authority to classify fishing grounds

— where appropriate, in cooperation with food business operators — the provisions of Chapter II, Part A, apply by analogy to pectinidae.

3. Pectinidae may not be placed on the market for human consumption otherwise than via a fish auction, a dispatch centre or a processing establishment. When they handle pectinidae, food business operators operating such establishments must inform the Competent Authority and, as regards dispatch centres, comply with the relevant requirements of Chapters III and IV.
4. Food business operators handling pectinidae must comply:
  - (a) with the documentary requirements of Chapter I, points 3 to 7, where applicable. In this case, the registration document must clearly indicate the location of the area where the pectinidae were harvested;

or

(b) as regards packaged pectinidae, and wrapped pectinidae if the wrapping provides protection equivalent to that of packaging, with the requirements of Chapter VII concerning identification marking and labelling.

### **SECTION VIII: FISHERY PRODUCTS**

1. This Section does not apply to bivalve molluscs, echinoderms, tunicates and marine gastropods when placed on the market live. With the exception of Chapters I and II, it applies to such animals when not placed on the market live, in which case they must have been obtained in accordance with Section VII.
2. Chapter III, Parts A, C and D, Chapter IV and Chapter V apply to retail.
3. The requirements of this Section supplement those laid down in the general food hygiene clauses of this regulation:

- (a) In the case of establishments, including vessels, engaged in primary production and associated operations they supplement the requirements of this Regulation.
  - (b) In the case of other establishments, including vessels, they supplement the requirements of this Regulation.
4. In relation to fishery products:
- (a) primary production covers the farming, fishing and collection of live fishery products with a view to their being placed on the market;
- and
- (b) associated operations cover any of the following operations, if carried out on board fishing vessels: slaughter, bleeding, heading, gutting, removing fins, refrigeration and wrapping; they also include:
    - i. the transport and storage of fishery products the nature of which has not been substantially altered, including live fishery products, within fish farms on land;
- and
- ii. the transport of fishery products the nature of which has not been substantially altered, including live fishery products, from the place of production to the first establishment of destination.

### **Chapter I: Requirements for Vessels**

Food business operators must ensure that:

1. vessels used to harvest fishery products from their natural environment, or to handle or process them after harvesting, comply with the structural and equipment requirements laid down in Part I;
- and
2. operations carried out on board vessels take place in accordance with the rules laid down in Part II.

## **I. Structural and equipment requirements**

### **A. Requirements for all vessels**

1. Vessels must be designed and constructed so as not to cause contamination of the products with bilge-water, sewage, smoke, fuel, oil, grease or other objectionable substances.
2. Surfaces with which fishery products come into contact must be of suitable corrosion-resistant material that is smooth and easy to clean. Surface coatings must be durable and non-toxic.
3. Equipment and material used for working on fishery products must be made of corrosion-resistant material that is easy to clean and disinfect.
4. When vessels have a water intake for water used with fishery products, it must be situated in a position that avoids contamination of the water supply.

### **B. Requirements for vessels designed and equipped to preserve fresh fishery products for more than 24 hours**

1. Vessels designed and equipped to preserve fishery products for more than 24 hours must be equipped with holds, tanks or containers for the storage of fishery products at the temperatures laid down in Chapter VII.
2. Holds must be separated from the engine compartments and from the crew quarters by partitions which are sufficient to prevent any contamination of the stored fishery products. Holds and containers used for the storage of fishery products must ensure their preservation under satisfactory conditions of hygiene and, where necessary, ensure that melt water does not remain in contact with the products.
3. In vessels equipped for chilling fishery products in cooled clean seawater, tanks must incorporate devices for achieving a uniform temperature throughout the tanks. Such devices must achieve a chilling rate that ensures that the mix of fish and clean seawater reaches not more than 3 °C six hours after loading and not more than 0 °C after 16 hours and allow the monitoring and, where necessary, recording of temperatures.

### **C. Requirements for freezer vessels**

Freezer vessels must:

1. have freezing equipment with sufficient capacity to lower the temperature rapidly so as to achieve a core temperature of not more than -18 °C;
2. have refrigeration equipment with sufficient capacity to maintain fishery products in the storage holds at not more than -18 °C. Storage holds must be equipped with a temperature-recording device in a place where it can be easily read. The temperature sensor of the reader must be situated in the area where the temperature in the hold is the highest;

and

3. meet the requirements for vessels designed and equipped to preserve fishery products for more than 24 hours laid down in part B, point 2.

### **D. Requirements for factory vessels**

1. Factory vessels must have at least:
  - (a) a receiving area reserved for taking fishery products on board, designed to allow each successive catch to be separated. This area must be easy to clean and designed so as to protect the products from the sun or the elements and from any source of contamination;
  - (b) a hygienic system for conveying fishery products from the receiving area to the work area;

- (c) work areas that are large enough for the hygienic preparation and processing of fishery products, easy to clean and disinfect and designed and arranged in such a way as to prevent any contamination of the products;
- (d) storage areas for the finished products that are large enough and designed so that they are easy to clean.

If a waste-processing unit operates on board, a separate hold must be designated for the storage of such waste;

- (e) a place for storing packaging materials that is separate from the product preparation and processing areas;
- (f) special equipment for disposing waste or fishery products that are unfit for human consumption directly into the sea or, where circumstances so require, into a watertight tank reserved for that purpose. If waste is stored and processed on board with a view to its sanitation, separate areas must be allocated for that purpose;
- (g) a water intake situated in a position that avoids contamination of the water supply;

and

- (h) hand-washing equipment for use by the staff engaged in handling exposed fishery products with taps designed to prevent the spread of contamination.

2. However, factory vessels on board which crustaceans and molluscs are cooked, chilled and wrapped, need not meet the requirements of point 1 if no other form of handling or processing takes place on board such vessels.
3. Factory vessels that freeze fishery products must have equipment meeting the requirements for freezer vessels laid down in part C, points 1 and 2.

## **II. Hygiene requirements**

1. When in use, the parts of vessels or containers set aside for the storage of fishery products must be kept clean and maintained in good repair and condition. In particular, they must not be contaminated by fuel or bilge water.
2. As soon as possible after they are taken on board, fishery products must be protected from contamination and from the effects of the sun or any other source of heat. When they are washed, the water used must be either potable water or, where appropriate, clean water.
3. Fishery products must be handled and stored so as to prevent bruising. Handlers may use spiked instruments to move large fish or fish which might injure them, provided that the flesh of the products suffers no damage.
4. Fishery products other than those kept alive must undergo chilling as soon as possible after loading. However, when chilling is not possible, fishery products must be landed as soon as possible.
5. Ice used to chill fishery products must be made from potable water or clean water.
6. Where fish are headed and/or gutted on board, such operations must be carried out hygienically as soon as possible after capture, and the products must be washed immediately and thoroughly with potable water or clean water. In that event, the viscera and parts that may constitute a danger to public health must be removed as soon as possible and kept apart from products intended for human consumption. Livers and roes intended for human consumption must be preserved under ice, at a temperature approaching that of melting ice, or be frozen.
7. Where freezing in brine of whole fish intended for canning is practised, a temperature of not more than  $-9\text{ }^{\circ}\text{C}$  must be achieved for the product. The brine must not be a source of contamination for the fish.

## Chapter II: Requirements During and After Landing

1. Food business operators responsible for the unloading and landing of fishery products must:
  - (a) ensure that unloading and landing equipment that comes into contact with fishery products is constructed of material that is easy to clean and disinfect and maintained in a good state of repair and cleanliness;and
  - (b) avoid contamination of fishery products during unloading and landing, in particular by:
    - i. carrying out unloading and landing operations rapidly;
    - ii. placing fishery products without delay in a protected environment at the temperature specified in Chapter VII;and
    - iii. not using equipment and practices that cause unnecessary damage to the edible parts of the fishery products.
2. Food business operators responsible for auction and wholesale markets or parts thereof where fishery products are displayed for sale must ensure compliance with the following requirements.
  - (a)
    - i. There must be lockable facilities for the refrigerated storage of detained fishery products and separate lock- able facilities for the storage of fishery products declared unfit for human consumption.
    - ii. If the Competent Authority so requires, there must be an adequately equipped lockable facility or, where needed, room for the exclusive use of the Competent Authority.
  - (b) At the time of display or storage of fishery products:
    - i. the premises must not be used for other purposes;
    - ii. vehicles emitting exhaust fumes likely to impair the quality of fishery products must not have access to the premises;
    - iii. persons having access to the premises must not introduce other animals;and
    - iv. the premises must be well lit to facilitate official controls.
3. When chilling was not possible on board the vessel, fresh fishery products, other than those kept alive, must undergo chilling as soon as possible after landing and be stored at a temperature approaching that of melting ice.
4. Food business operators must cooperate with relevant Competent Authorities so as to permit them to carry out official controls in accordance with the rules on official controls detailed in this regulation, in particular as regards any notification procedures for the landing of fishery products that the Competent Authority of the Member State the flag of which the vessel is flying.

### **Chapter III: Requirements for Establishments, Including Vessels, Handling Fishery Products**

Food business operators must ensure compliance with the following requirements, where relevant, in establishments handling fishery products.

#### **A. REQUIREMENTS FOR FRESH FISHERY PRODUCTS**

1. Where chilled, unpackaged products are not distributed, dispatched, prepared or processed immediately after reaching an establishment on land, they must be stored under ice in appropriate facilities. Re-icing must be carried out as often as necessary. Packaged fresh fishery products must be chilled to a temperature approaching that of melting ice.
2. Operations such as heading and gutting must be carried out hygienically. Where gutting is possible from a technical and commercial viewpoint, it must be carried out as quickly as possible after the products have been caught or landed. The products must be washed thoroughly with potable water or, on board vessels, clean water immediately after these operations.
3. Operations such as filleting and cutting must be carried out so as to avoid contamination or spoilage of fillets and slices. Fillets and slices must not remain on the worktables beyond the time necessary for their preparation. Fillets and slices must be wrapped and, where necessary, packaged and must be chilled as quickly as possible after their preparation.
4. Containers used for the dispatch or storage of unpackaged prepared fresh fishery products stored under ice must ensure that melt water does not remain in contact with the products.
5. Whole and gutted fresh fishery products may be transported and stored in cooled water on board vessels. They may also continue to be transported in cooled water after landing, and be transported from aquaculture establishments, until they arrive at the first establishment on land carrying out any activity other than transport or sorting.

#### **B. REQUIREMENTS FOR FROZEN PRODUCTS**

Establishments on land that freeze fishery products must have equipment that satisfies the requirements laid down for freezer vessels in Section VIII, Chapter I, Part I. C, points 1 and 2.

The means of transport, warehousing, and storage of quick-frozen foodstuffs shall be fitted with suitable recording instruments to monitor, at frequent and regular intervals, the air temperature to which the quick-frozen foodstuffs are subjected.

The temperature, as provided for in paragraph 1, shall comply with EN 12830, EN 13485, and EN 13486 standards. Food operators shall keep all relevant documents permitting verification that the instruments referred to above conform to the relevant EN standard.

Temperature recording shall be dated and stored by the food operator for a period of a least one year, or for a longer period taking into account the nature and the shelf life of the quick-frozen foodstuffs.

#### **C. REQUIREMENTS FOR MECHANICALLY SEPARATED FISHERY PRODUCTS**

Food business operators manufacturing mechanically separated fishery products must ensure compliance with the following requirements.

1. The raw materials used must satisfy the following requirements.
  - (a) Only whole fish and bones after filleting may be used to produce mechanically separated fishery products;
  - (b) All raw materials must be free from guts.
2. The manufacturing process must satisfy the following requirements:
  - (a) Mechanical separation must take place without undue delay after filleting.

- (b) If whole fish are used, they must be gutted and washed beforehand.
- (c) After production, mechanically separated fishery products must be frozen as quickly as possible or incorporated in a product intended for freezing or a stabilising treatment.

#### **D. REQUIREMENTS CONCERNING PARASITES**

1. The following fishery products must be frozen at a temperature of not more than – 20 °C in all parts of the product for not less than 24 hours; this treatment must be applied to the raw product or the finished product:
  - (a) fishery products to be consumed raw or almost raw;
  - (b) fishery products from the following species, if they are to undergo a cold smoking process in which the internal temperature of the fishery product is not more than 60 °C:
    - i. herring; mackerel; sprat and any other pelagic fish that are known to harbour pathogenic nematodesand
  - (c) marinated and/or salted fishery products, if the processing is insufficient to destroy nematode larvae.
2. Food business operators need not carry out the treatment required under point 1 if:
  - (a) epidemiological data are available indicating that the fishing grounds of origin do not present a health hazard with regard to the presence of parasites;and
- (b) the Competent Authority so authorises.
3. A document from the manufacturer, stating the type of process they have undergone, must accompany fishery products referred to in point 1 when placed on the market, except when supplied to the final consumer.

#### **Chapter IV: Requirements For Processed Fishery Products**

Food business operators cooking crustaceans and molluscs must ensure compliance with the following requirements.

1. Rapid cooling must follow cooking. Water used for this purpose must be potable water or, on board vessels, clean water. If no other method of preservation is used, cooling must continue until a temperature approaching that of melting ice is reached.
2. Shelling or shucking must be carried out hygienically, avoiding contamination of the product. Where such operations are done by hand, workers must pay particular attention to washing their hands.
3. After shelling or shucking, cooked products must be frozen immediately, or be chilled as soon as possible to the temperature laid down in Chapter VII.

#### **Chapter V: Health Standards For Fishery Products**

In addition to ensuring compliance with microbiological criteria adopted in accordance with the general food hygiene clauses of this regulation, food business operators must ensure, depending on the nature of the product or the species that fishery products placed on the market for human consumption meet the standards laid down in this Chapter.

##### **A. ORGANOLEPTIC PROPERTIES OF FISHERY PRODUCTS**

Food business operators must carry out an organoleptic examination of fishery products. In particular, this examination must ensure that fishery products comply with any freshness criteria.

**B. HISTAMINE**

Food business operators must ensure that the limits with regard to histamine are not exceeded.

**C. TOTAL VOLATILE NITROGEN**

Unprocessed fishery products must not be placed on the market if chemical tests reveal that the limits with regard to

TVB-N or TMA-N have been exceeded.

**D. PARASITES**

Food business operators must ensure that fishery products have been subjected to a visual examination for the purpose of detecting visible parasites before being placed on the market. They must not place fishery products that are obviously contaminated with parasites on the market for human consumption.

Visual inspection shall be performed on a representative number of samples. The persons in charge of establishments on land and qualified persons on board factory vessels shall determine the scale and frequency of the inspections

In the case of manual evisceration, in a continuous manner by a handler qualified in inspection at the time of evisceration and washing;

In the case of mechanical evisceration, by sampling carried out on a representative number of samples being not less than 10 fish per batch.

**E. TOXINS HARMFUL TO HUMAN HEALTH**

1. Fishery products derived from poisonous fish of the following families must not be placed on the market: Tetraodontidae, Molidae, Diodontidae and Canthigasteridae.
2. Fishery products containing biotoxins such as ciguatoxin or muscle-paralysing toxins must not be placed on the market. However, fishery products derived from bivalve molluscs, echinoderms, tunicates and marine gastropods may be placed on the market if they have been produced in accordance with Section VII and comply with the standards laid down in Chapter V, point 2, of that section.

**Chapter VI: Wrapping and Packaging of Fishery Products**

1. Receptacles in which fresh fishery products are kept under ice must be water-resistant and ensure that melt-water does not remain in contact with the products.
2. Frozen blocks prepared on board vessels must be adequately wrapped before landing.
3. When fishery products are wrapped on board fishing vessels, food business operators must ensure that wrapping material:
  - (a) is not a source of contamination;
  - (b) is stored in such a manner that it is not exposed to a risk of contamination;
  - (c) intended for re-use is easy to clean and, where necessary, to disinfect.

**Chapter VII: Storage of Fishery Products**

Food business operators storing fishery products must ensure compliance with the following requirements.

1. Fresh fishery products, thawed unprocessed fishery products, and cooked and chilled products from crustaceans and molluscs, must be maintained at a temperature approaching that of melting ice.

2. Frozen fishery products must be kept at a temperature of not more than  $-18^{\circ}\text{C}$  in all parts of the product; however, whole frozen fish in brine intended for the manufacture of canned food may be kept at a temperature of not more than  $-9^{\circ}\text{C}$ .
3. Fishery products kept alive must be kept at a temperature and in a manner that does not adversely affect food safety or their viability.

### **Chapter VIII: Transport of Fishery Products**

Food business operators transporting fishery products must ensure compliance with the following requirements.

1. During transport, fishery products must be maintained at the required temperature. In particular:
  - (a) fresh fishery products, thawed unprocessed fishery products, and cooked and chilled products from crustaceans and molluscs, must be maintained at a temperature approaching that of melting ice;
  - (b) frozen fishery products, with the exception of frozen fish in brine intended for the manufacture of canned food, must be maintained during transport at an even temperature of not more than  $-18^{\circ}\text{C}$  in all parts of the product, possibly with short upward fluctuations of not more than  $3^{\circ}\text{C}$ .
2. Food business operators need not comply with point 1(b) when frozen fishery products are transported from a cold store to an approved establishment to be thawed on arrival for the purposes of preparation and/or processing, if the journey is short and the Competent Authority so permits.
3. If fishery products are kept under ice, melt water must not remain in contact with the products.
4. Fishery products to be placed on the market live must be transported in such a way as not adversely to affect food safety or their viability.

## **ANNEX 3: Concerning the activities of the Competent Authority**

### **LIVE BIVALVE MOLLUSCS**

#### **CHAPTER I: SCOPE**

This Annex applies to live bivalve molluscs and, by analogy, to live echinoderms, live tunicates and live marine gastropods.

#### **CHAPTER II: OFFICIAL CONTROLS CONCERNING LIVE BIVALVE MOLLUSCS FROM CLASSIFIED PRODUCTION AREAS**

##### **A. CLASSIFICATION OF PRODUCTION AND RELAYING AREAS**

1. The Competent Authority must fix the location and boundaries of production and relaying areas that it classifies. It may, where appropriate, do so in cooperation with the food business operator.
2. The Competent Authority must classify production areas from which it authorises the harvesting of live bivalve molluscs as being of one of three categories according to the level of faecal contamination. It may, where appropriate, do so in cooperation with the food business operator.
3. The Competent Authority may classify as being of Class A areas from which live bivalve molluscs may be collected for direct human consumption. Live bivalve molluscs taken from these areas must meet the health standards for live bivalve molluscs laid down in Annex III, Section VII, Chapter V, of Regulation (EC) No 853/2004.
4. The Competent Authority may classify as being of Class B areas from which live bivalve molluscs may be collected and only placed on the market for human consumption after treatment in a purification centre or after relaying so as to meet the health standards referred to in paragraph 3. Live bivalve molluscs from these areas must not exceed, in 90 % of the samples, 4 600 E. coli per 100 g of flesh and intravalvular liquid. In the remaining 10 % of samples, live bivalve molluscs must not exceed 46 000E. coli per 100 g of flesh and intravalvular liquid.
5. The reference method for this analysis is the five-tube, three dilutions Most Probable Number (MPN) test specified in ISO 16649-3. Alternative methods may be used if they are validated against this reference method in accordance with the criteria in EN/ISO 16140
6. The Competent Authority may classify as being of Class C areas from which live bivalve molluscs may be collected and only placed on the market after relaying over a long period so as to meet the health standards referred to in paragraph 3. Live bivalve molluscs from these areas must not exceed 46 000E. coli per 100 g of flesh and intravalvular liquid. The reference method for this analysis is the five-tube, three dilutions MPN test specified in ISO 16649-3. Alternative methods may be used if they are validated against this reference method in accordance with the criteria in EN/ISO 16140.
7. If the Competent Authority decides in principle to classify a production or relaying area, it must:
  - (a) make an inventory of the sources of pollution of human or animal origin likely to be a source of contamination for the production area;
  - (b) examine the quantities of organic pollutants which are released during the different periods of the year, according to the seasonal variations of both human and animal populations in the catchment area, rainfall readings, waste-water treatment, etc.;
  - (c) determine the characteristics of the circulation of pollutants by virtue of current patterns, bathymetry and the tidal cycle in the production area;

and

- (d) establish a sampling programme of bivalve molluscs in the production area which is based on the examination of established data, and with a number of samples, a geographical

distribution of the sampling points and a sampling frequency which must ensure that the results of the analysis are as representative as possible for the area considered.

## **B. MONITORING OF CLASSIFIED RELAYING AND PRODUCTION AREAS**

1. Classified relaying and production areas must be periodically monitored 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 production and relaying areas;
  - (c) for the presence of toxin-producing plankton in production and relaying waters and biotoxins in live bivalve molluscs;

and

- (d) for the presence of chemical contaminants in live bivalve molluscs.
2. To implement paragraph 1(b), (c) and (d), sampling plans must be drawn up providing for such checks to take place at regular intervals, or on a case-by-case basis if harvesting periods are irregular. The geographical distribution of the sampling points and the sampling frequency must ensure that the results of the analysis are as representative as possible for the area considered.
3. Sampling plans to check the microbiological quality of live bivalve molluscs must take particular account of:
  - (a) the likely variation in faecal contamination, and
  - (b) the parameters referred to in paragraph 6 of Part A.
4. Sampling plans to check for the presence of toxin-producing plankton in production and relaying waters and for biotoxins in live bivalve molluscs must take particular account of possible variations in the presence of plankton containing marine biotoxins. Sampling must comprise:
  - (a) periodic sampling to detect changes in the composition of plankton containing toxins and their geographical distribution. Results suggesting an accumulation of toxins in mollusc flesh must be followed by intensive sampling;
  - (b) periodic toxicity tests using those molluscs from the affected area most susceptible to contamination.
5. The sampling frequency for toxin analysis in the molluscs is, as a general rule, to be weekly during the periods at which harvesting is allowed. This frequency may be reduced in specific areas, or for specific types of molluscs, if a risk assessment on toxins or phytoplankton occurrence suggests a very low risk of toxic episodes. It is to be increased where such an assessment suggests that weekly sampling would not be sufficient. The risk assessment is to be periodically reviewed in order to assess the risk of toxins occurring in the live bivalve molluscs from these areas.
6. When knowledge of toxin accumulation rates is available for a group of species growing in the same area, a species with the highest rate may be used as an indicator species. This will allow the exploitation of all species in the group if toxin levels in the indicator species are below the regulatory limits. When toxin levels in the indicator species are above the regulatory limits, harvesting of the other species is only to be allowed if further analysis on the other species shows toxin levels below the limits.
7. With regard to the monitoring of plankton, the samples are to be representative of the water column and to provide information on the presence of toxic species as well as on population trends. If any changes in toxic populations that may lead to toxin accumulation are detected, the

sampling frequency of molluscs is to be increased or precautionary closures of the areas are to be established until results of toxin analysis are obtained.

8. Sampling plans to check for the presence of chemical contaminants must enable the detection of any overshooting of the levels laid down in Commission Regulation (EC) No 466/2001 (1).

### **C. DECISIONS AFTER MONITORING**

1. Where the results of sampling show that the health standards for molluscs are exceeded, or that there may be otherwise a risk to human health, the Competent Authority must close the production area concerned, preventing the harvesting of live bivalve molluscs. However, the Competent Authority may reclassify a production area as being of Class B or C if it meets the relevant criteria set out in Part A and presents no other risk to human health.
2. The Competent Authority may re-open a closed production area only if the health standards for molluscs once again comply with these regulations. If the competent authority closes a production because of the presence of plankton or excessive levels of toxins in molluscs, at least two consecutive results below the regulatory limit separated at least 48 hours are necessary to re-open it. The Competent Authority may take account of information on phytoplankton trends when taking this decision. When there are robust data on the dynamic of the toxicity for a given area, and provided that recent data on decreasing trends of toxicity are available, the competent authority may decide to re-open the area with results below the regulatory limit obtained from one single sampling.

### **D. ADDITIONAL MONITORING REQUIREMENTS**

1. The Competent Authority is to monitor classified production areas from which it has forbidden the harvesting of bivalve molluscs or subjected harvesting to special conditions, to ensure that products harmful to human health are not placed on the market.
2. In addition to the monitoring of relaying and production zones referred to in paragraph 1 of Part B, a control system must be set up comprising laboratory tests to verify food business operators' compliance with the requirements for the end product at all stages of production, processing and distribution. This control system is, in particular, to verify that the levels of marine biotoxins and contaminants do not exceed safety limits and that the microbiological quality of the molluscs does not constitute a hazard to human health.

### **E. RECORDING AND EXCHANGE OF INFORMATION**

The Competent Authority must:

- (a) establish and keep up to date a list of approved production and relaying areas, with details of their location and boundaries, as well as the class in which the area is classified, from which live bivalve molluscs may be taken in accordance with the requirements of this Annex. This list must be communicated to interested parties affected by this Annex, such as producers, gatherers and operators of purification centres and dispatch centres;
- (b) immediately inform the interested parties affected by this Annex, such as producers, gatherers and operators of purification centres and dispatch centres, about any change of the location, boundaries or class of a production area, or its closure, be it temporary or final;

and

- (c) act promptly where the controls prescribed in this Annex indicate that a production area must be closed or reclassified or can be re-opened.

### **F. FOOD BUSINESS OPERATORS' OWN CHECKS**

To decide on the classification, opening or closure of production areas, the Competent Authority may take into account the results of controls that food business operators or organisations representing food business operators have carried out. In that event, the Competent Authority must

have designated the laboratory carrying out the analysis and, if necessary, sampling and analysis must have taken place in accordance with a protocol that the Competent Authority and the food business operators or organisation concerned have agreed.

### **CHAPTER III: OFFICIAL CONTROLS CONCERNING PECTINIDAE HARVESTED OUTSIDE CLASSIFIED PRODUCTION AREAS**

Official controls on pectinidae harvested outside classified production areas are to be carried out in fish auctions, dispatch centres and processing establishments. Such official controls are to verify compliance with the health standards for live bivalve molluscs.

## **ANNEX 4: Official Controls on fishery products**

### **CHAPTER I: OFFICIAL CONTROLS OF PRODUCTION AND PLACING ON THE MARKET**

1. Official controls on the production and placing on the market of fishery products are to include, in particular:
  - (a) a regular check on the hygiene conditions of landing and first sale;
  - (b) inspections at regular intervals of vessels and establishments on land, including fish auctions and wholesale markets, to check, in particular:
    - i. where appropriate, whether the conditions for approval are still fulfilled,
    - ii. whether the fishery products are handled correctly,
    - iii. for compliance with hygiene and temperature requirements, and
    - iv. the cleanliness of establishments, including vessels, and their facilities and equipment, and staff hygiene;and
  - (c) checks on storage and transport conditions.
2. However, subject to paragraph 3, official controls of vessels:
  - (a) may be carried out when vessels call at a port in Kiribati;
  - (b) concern all vessels landing fishery products at ports in Kiribati, irrespective of flag;and
  - (c) may, if necessary, when the Competent Authority of the state the flag of which the vessel is flying carries out the official control, be carried out while the vessel is at sea or when it is in a port in Kiribati or in a third country.
3.
  - (a) In the case of an inspection of a factory or freezer vessel flying the flag of a third country carried out with a view to the approval of the vessel, the Competent Authority of the third country, the flag of which the vessel is flying is to carry out inspections in such a manner as to comply with the requirements these regulations. If necessary, that Competent Authority may inspect the vessel while it is at sea or when it is in a port in a third country.
  - (b) When the Competent Authority of the state the flag of which the vessel is flying has granted the vessel conditional approval, that competent authority may authorise a Competent Authority of:
    - i. another state, or
    - ii. a third country that appears on a list of third countries (as drawn up in EU Decision 2006/766) from which imports of fishery products are permitted, to carry out a follow-up inspection with a view to granting full approval or prolonging conditional approval in accordance with these regulations. If necessary, that Competent Authority may inspect the vessel while it is at sea or when it is in a port in another Member State or in a third country.
4. When the Competent Authority of Kiribati authorises the Competent Authority of a third country to carry out inspections on its behalf in accordance, the two Competent Authorities are to agree on the conditions governing such inspections. These conditions are to ensure, in particular, that the competent authority of Kiribati receives reports on the results of inspections

and on any suspected non-compliance without delay, so as to enable it to take the necessary measures.

## **CHAPTER II: OFFICIAL CONTROLS OF FISHERY PRODUCTS**

Official controls of fishery products are to include at least the following elements.

### **A. ORGANOLEPTIC EXAMINATIONS**

Random organoleptic checks must be carried out at all stages of production, processing and distribution. One aim of these checks is to verify compliance with the freshness criteria established in accordance with these regulations. In particular, this includes verifying, at all stages of production, processing and distribution, that fishery products at least exceed the baselines of freshness criteria established in accordance with Community legislation.

### **B. FRESHNESS INDICATORS**

When the organoleptic examination reveals any doubt as to the freshness of the fishery products, samples may be taken and subjected to laboratory tests to determine the levels of total volatile basic nitrogen (TVB-N) and trimethylamine nitrogen (TMA-N).

The Competent Authority is to use the criteria laid down under Community legislation.

When the organoleptic examination gives cause to suspect the presence of other conditions which may affect human health, appropriate samples are to be taken for verification purposes.

### **C. HISTAMINE**

Random testing for histamine is to be carried out to verify compliance with the permitted levels laid down under these regulations.

### **D. RESIDUES AND CONTAMINANTS**

Monitoring arrangements are to be set up to control the levels of residues and contaminants in accordance with these regulations.

### **E. MICROBIOLOGICAL CHECKS**

Where necessary, microbiological checks are to be performed in accordance with the relevant rules and criteria laid down under these regulations.

### **F. PARASITES**

Random testing is to take place to verify compliance with these regulations on parasites.

### **G. POISONOUS FISHERY PRODUCTS**

Checks are to take place to ensure that:

1. fishery products derived from poisonous fish of the following families are not placed on the market: Tetraodontidae, Molidae, Diodontidae and Canthigasteridae;
2. fresh, prepared, frozen and processed fishery products belonging to the family Gempylidae, in particular *Ruvettus pretiosus* and *Lepidocybium flavobrunneum*, may only be placed on the market in wrapped/package form and must be appropriately labelled to provide information to the consumer on preparation/cooking methods and on the risk related to the presence of substances with adverse gastrointestinal effects. The scientific names of the fishery products and the common names must appear on the label;
3. fishery products containing biotoxins such as ciguatera or other toxins dangerous to human health are not placed on the market. However, fishery products derived from bivalve molluscs, echinoderms, tunicates and marine gastropods may be placed on the market if they have been produced in accordance with these regulations and comply with the standards laid down.

## **I TOTAL VOLATILE BASIC NITROGEN (TVB-N) LIMIT VALUES FOR CERTAIN CATEGORIES OF FISHERY PRODUCTS AND ANALYSIS METHODS TO BE USED**

Unprocessed fishery products shall be regarded as unfit for human consumption where organoleptic assessment has raised doubts as to their freshness, and chemical checks reveal that TVB-N limits referenced against the species are exceeded:

60mg of nitrogen/100g of whole fishery products used directly for the preparation of fish oil for human consumption.

The reference method to be used for checking the TVB-N limits involves distilling an extract deproteinised by perchloric acid as set out in EU Regulation 2074/2005 or any related legislation.

## **J TESTING METHODS FOR DETECTING MARINE BIOTOXINS (Ref 2074)**

### **Testing Methods for Detecting Marine Biotoxins**

The following analytical methods shall be used by the Competent Authorities to check compliance with the limits for marine biotoxins.

#### **Paralytic Shellfish Poison (PSP) Detection Method**

The paralytic shellfish poison (PSP) content of edible parts of molluscs (the whole body or any part edible separately) must be detected using the high performance liquid chromatography (HPLC) method or any other internationally recognised method.

However, for screening purposes, the 2006.02 ASP ELISA method as published in the AOAC Journal of June 2006 may also be used to detect the total content of ASP of edible parts of molluscs.

If the results are challenged, the reference method shall be the HPLC method.

#### **Lipophilic Toxin Detection Methods**

Biological methods

A series of mouse bioassay procedures, differing in the test portion (hepatopancreas or whole body) and in the solvents used for extraction and purification, may be used for detecting the marine toxins: paralytic shellfish poison; amnesic shellfish poison; okadaic acid (plus dinophysistoxins and pectenotoxins); yessotoxins; azaspiracids.

A single mouse bioassay involving acetone extraction may be used to detect okadaic acid, dinophysistoxins, pectenotoxins and yessotoxins. This assay may be supplemented, if necessary, with liquid/liquid partition steps with ethyl acetate/water or dichloromethane/water to remove potential interferences. Azaspiracid detection at regulatory levels by means of this procedure shall involve the use of the whole body as the test portion.

## **CHAPTER III: DECISIONS AFTER CONTROLS**

Fishery products are to be declared unfit for human consumption if:

1. organoleptic, chemical, physical or microbiological checks or checks for parasites have shown that they are not in compliance with these regulations;
2. they contain in their edible parts contaminants or residues in excess of the limits laid down in these regulations or at levels where the calculated dietary intake would exceed the acceptable daily or weekly intake for humans;
3. they derive from:
  - i. poisonous fish,
  - ii. fishery products not complying with the requirement of part G, point 2, of Chapter II concerning biotoxins,

or

- iii. bivalve molluscs, echinoderms, tunicates or marine gastropods containing marine biotoxins in total quantities exceeding the limits referred to in this Regulation;

or

- 4. the Competent Authority considers that they may constitute a risk to public or animal health or are for any other reason not suitable for human consumption.

## **REQUIREMENTS FOR CERTIFICATES ACCOMPANYING IMPORTS**

1. The representative of the Competent Authority issuing a certificate to accompany a consignment of products of animal origin destined for the European Community must sign the certificate and ensure that it bears an official stamp. This requirement applies to each sheet of the certificate if it consists of more than one. In the case of factory vessels, the Competent Authority may authorise the captain or another ship's officer to sign the certificate.
2. For exports to the European Community certificates must be drawn up at least in the official language or languages of the Member State of destination and those of the Member State in which the border inspection takes place, or be accompanied by a certified translation into that language or languages. However, an EU Member State may consent to the use of an official Community language other than its own.
3. The original version of the certificate must accompany consignments on entry into the European Community.
4. Certificates must consist of:
  - (a) a single sheet of paper;or
  - (b) two or more pages that are part of an integrated and indivisible sheet of paper;or
  - (c) a sequence of pages numbered so as to indicate that it is a particular page in a finite sequence (for example, 'page 2 of four pages').
5. Certificates must bear a unique identifying number. Where the certificate consists of a sequence of pages, each page must indicate this number.
6. The certificate must be issued before the consignment to which it relates leaves the control of the Competent Authority.

## ANNEX 5: Food Safety Criteria: Microbiological Limits, Testing and Sampling

Food category	Microorganisms, their toxins, metabolites	Sampling plan <sup>1</sup>		Limits <sup>2</sup>		Analytical reference method <sup>3</sup>	Stage where criterion applies
		n	c	M	M		
1. Ready to eat foods able to support <i>Listeria monocytogenes</i>	<i>Listeria monocytogenes</i>	5	0	100cfu/g <sup>3</sup>		EN/ISO 11290-2 <sup>6</sup>	Products placed on the market during their shelf-life
		5	0	Absence in 25g <sup>7</sup>		EN/ISO 11290-1	Products placed on the market during their shelf-life
2. Cooked crustaceans and molluscan shellfish	<i>Salmonella</i>	5	0	Absence in 25g		EN/ISO 6579	Products placed on the market during their shelf-life
3. Live bivalve shellfish and live echinoderms, tunicates and gastropods	<i>Salmonella</i>	5	0	Absence in 25g		EN/ISO 6579	Products placed on the market during their shelf-life
4. Live bivalve molluscs and live echinoderms, tunicates and gastropods	<i>E. coli</i> <sup>8</sup>	1 <sup>9</sup>	0	230 MPN/100 g of flesh and intra-valvular liquid		ISO TS 16649-3	Products placed on the market during their shelf-life
5. Fishery products from fish species associated with a high amount of histidine <sup>10</sup>	Histamine	9	2	100 mg/kg	200 mg/kg	HPLC	Products placed on the market during their shelf-life
6. Fishery products which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histidine	Histamine	9	2	200 mg/kg	400 mg/kg	HPLC	Products placed on the market during their shelf-life

1. n = number of units comprising the sample; c = number of sample units giving values between m and M.

2. For points 1 - 4 m = M.

3. The most recent edition of the standard shall be used.

4. Regular testing against the criterion is not required in normal circumstances for the following ready-to-eat foods:-

those which have received heat treatment or other processing effective to eliminate *L. monocytogenes*, when recontamination is not possible after this treatment (for example, products heat treated in their final package) – including live bivalve molluscs.

5. This criterion shall apply if the manufacturer is able to demonstrate, to the satisfaction of the Competent Authority, that the product will not exceed the limit 100 cfu/g throughout the shelf-life.

6. 1ml of inoculum is plated on a Petri dish of 140 mm diameter or on three Petri dishes of 90 mm diameter.
7. This criterion shall apply to products before they have left the immediate control of the producing food business operator, when he is not able to demonstrate, to the satisfaction of the Competent Authority, that the product will not exceed the limit of 100 cfu/g throughout the shelf-life.
8. *E. coli* is used here as an indicator of faecal contamination.
9. A pooled sample comprising a minimum of 10 individual animals.
10. Particularly fish species of the families: *Scombridae*, *Clupeidae*, *Engraulidae*, *Coryfenidae*, *Pomatomidae*, *Scombresosidae*.

### Interpretation of the results

The limits given refer to each sample unit tested, excluding live bivalve molluscs and live echinoderms, tunicates and gastropods in relation to testing *E. coli*, where the limit refers to a pooled sample.

The test results demonstrate the microbiological quality of the batch tested

*L. monocytogenes* in ready-to-eat foods able to support the growth of *L. monocytogenes* before the food has left the immediate control of the producing food business operator when he is not able to demonstrate that the product will not exceed the limit of 100 cfu/g throughout the shelf-life.

- satisfactory, if all the values observed indicate the absence of the bacterium,
- unsatisfactory, if the presence of the bacterium is detected in any of the sample units.

*L. monocytogenes* in other ready-to-eat foods and *E. coli* in live bivalve molluscs:

- satisfactory, if all the values observed are ≤ the limit,
- unsatisfactory, if any of the values are > the limit.

*Salmonella* in different food categories:

- satisfactory, if all the values observed indicate the absence of the bacterium,
- unsatisfactory, if the presence of the bacterium is detected in any of the sample units

Histamine in fishery products from fish species associated with a high amount of histidine:

- satisfactory, if the following requirements are fulfilled:
  1. the mean value observed is  $\leq m$ .
  2. a maximum of  $c/n$  values observed are between  $m$  and  $M$
  3. no values observed exceed the limit of  $M$
- unsatisfactory, if the mean value observed exceeds  $m$  or more than  $c/n$  values are between  $m$  and  $M$  or one or more of the values observed are  $>M$ .

Food category	Microorganism	Sampling plan		Limits		Analytical reference method	Stage where criterion applies	Action in case of unsatisfactory Results
		n	c	m	M			
Shelled and shucked products of cooked crustaceans and molluscan shellfish	<i>E. coli</i>	5	2	1/g	10/g	ISO TS 16649-3	End of the manufacturing process	Improvements in production hygiene
	Coagulase-positive staphylococci	5	2	100 cfu/g	1000 cfu/g	EN/ISO 6888-1 or 2	End of the manufacturing process	Improvements in production hygiene

### Interpretation of the test results:

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

*E. coli* in shelled and shucked products of cooked crustaceans and molluscan shellfish:

- satisfactory, if all the values observed are  $\leq m$ ,
- acceptable, if a maximum of  $c/n$  values are between  $m$  and  $M$ , and the rest of the values observed are  $\leq m$ ,
- unsatisfactory, if one or more of the values observed are  $> M$  or more than  $c/n$  values are between  $m$  and  $M$ .

Coagulase-positive staphylococci in shelled and cooked crustaceans and molluscan shellfish:

- satisfactory, if all the values observed are  $\leq m$ ,
- acceptable, if a maximum of  $c/n$  values are between  $m$  and  $M$ , and the rest of the values observed are  $\leq m$ ,
- unsatisfactory, if one or more of the values observed are  $> M$  or more than  $c/n$  values are between  $m$  and  $M$ .

## **ANNEX 6: Freshness rating**

The ratings established in this Annex apply to the following products or groups of products, by reference to appraisal criteria specific to each of them.

### **A. Whitefish (adapted for easier comparison)**

White fleshed fish including round bodied and flat bodied fish such as: cod, grouper, snapper, redfish, Ray's bream, anglerfish, bogue, picarel, conger, gurnard, mullet, sole, dab, scabbard fish.

### **B. Bluefish**

Albacore or longfinned tuna, bluefin tuna, bigeye tuna, blue whiting, herring, sardines, mackerel, horse mackerel, anchovy, sprat.

### **C. Selachii (adapted for easier comparison)**

Sharks, skates and rays.

### **D. Cephalopods**

Cuttlefish.

### **E. Crustaceans**

1. Shrimps

## A. WHITEFISH

	Criteria			
	Freshness category			Not admitted (1)
	Extra	A	B	
Skin	Bright, iridescent pigment (except for redfish) or opalescent; no discolouration	Pigmentation bright but not lustrous	Pigmentation in the process of becoming discoloured and dull	Dull pigmentation (2)
Skin mucus	Aqueous, transparent	Slightly cloudy	Milky	Yellowish grey, opaque mucus
Eye	Convex (bulging); black, bright pupil; transparent cornea	Convex and slightly sunken; black dull pupil; slightly opalescent cornea	Flat; opalescent cornea; opaque pupil	Concave in the centre; grey pupil; milky cornea (2)
Gills	Bright colour; no mucus	Less coloured	Brown/grey becoming discoloured; thick, opaque mucus	Yellowish; milky mucus (2)
Peritoneum (in gutted fish)	Smooth; bright; difficult to detach from flesh	Slightly dull; can be detached from flesh	Speckled; comes away easily from flesh	Does not stick (2)
Smell of gills and abdominal cavity	Seaweedy	No smell of seaweed; neutral smell	Fermented; slightly sour	Sour (2)
Flesh	Firm and elastic; smooth surface(3)	Less elastic	Slightly soft (flaccid), less elastic; waxy (velvety) and dull surface	Soft (flaccid) (2); scales easily detached from skin, surface rather wrinkled

(1) This column will apply only until a Commission Decision is taken establishing criteria for fish which is unfit for human consumption, pursuant to Council Directive 91/493/EEC.

(2) Or in a more advanced state of decay.

(3) Fresh fish prior to the onset of rigor mortis will not be firm and elastic but will still be graded in category Extra.

**B. BLUEFISH**

	<b>Criteria</b>			
	<b>Freshness category</b>			<b>Not admitted (1)</b>
	<b>Extra</b>	<b>A</b>	<b>B</b>	
Skin (2)	Bright pigmentation, bright, shining iridescent colours; clear distinction between dorsal and central surfaces	Loss of lustre and shine; duller colours; less Difference between dorsal and ventral surfaces	Dull, lustreless, insipid colours; skin creased when fish curved	Very dull pigmentation; skin coming away from flesh (3)
Skin mucus	Aqueous, transparent	Slightly cloudy	Milky	Yellowish grey opaque mucus (3)
Consistency of flesh (2)	Very firm, rigid	Fairly rigid, firm	Slightly soft	Soft (flaccid) (3)
Gill covers	Silvery	Silvery, slightly red or brown	Brownish and extensive seepage of blood from vessels	Yellowish (3)
Eye	Convex, bulging; blue-black bright pupil, transparent 'eyelid'	Convex and slightly sunken; dark pupil; slightly opalescent cornea	Flat; blurred pupil; blood seepage around the eye	Concave in the centre; grey pupil; milky cornea (3)
Gills (2)	Uniformly dark red to purple. No mucus	Less bright colour, paler at edges. Transparent mucus	Becoming thick discoloured opaque mucus	Yellowish; milky mucus (3)
Smell of gills	Fresh seaweed; pungent; iodine	No smell or seaweed. Neutral smell	Slightly sulphureous (4) fatty smell, rancid bacon cuttings or rotten fruit	Rotten sour (3)

(1) This column will apply only until a Commission Decision is taken establishing criteria for fish which is unfit for human consumption, pursuant to Council Directive 91/493/EEC.

(2) For herring and mackerel preserved in cool seawater (either chilled by ice (CSW) or refrigerated by mechanical means (RSW)) complying with the requirements laid down in Directive 92/48/EEC (OJ No L 187, 7. 7. 1992, p. 41) Annex II, point 8, the following freshness categories apply: — criterion A applies for Extra and A categories.

(3) Or in a more advanced state of decay.

(4) Iced fish goes rancid before stale, CSW/RSW fish goes stale before rancid.

**C. SELACHII** (sharks, skates and rays)

	<b>Criteria</b>			
	<b>Freshness category</b>			<b>Not admitted (1)</b>
	<b>Extra</b>	<b>A</b>	<b>B</b>	
Eye	Convex, very bright and iridescent; small pupils	Convex and slightly sunken; loss of brightness and iridescence, oval pupils	Flat, dull	Concave yellowish (2)
Appearance	In rigor mortis or partially in rigor; small quantity of clear mucus present on skin	Beyond rigor stage; no mucus on skin and especially in mouth and gill openings	Some mucus in mouth and on gill openings; slightly flattened jaw	Large quantities of mucus in mouth and on gill openings (2)
Smell	Seaweed smell	No smell or very slight stale but not an ammonia smell	Slight ammonia; sour	Pungent ammonia smell (3)

**Specific or additional criteria for skates and rays**

	<b>Criteria</b>			
	<b>Freshness category</b>			<b>Not admitted (1)</b>
	<b>Extra</b>	<b>A</b>	<b>B</b>	
Skin	Bright, iridescent and shiny pigmentation, aqueous mucus	Bright pigmentation, aqueous mucus	Pigmentation in the process of becoming discoloured and dull, opaque mucus	Discolouration, skin creased, thick mucus
Texture of the flesh	Firm and elastic	Firm	Soft	Flaccid
Aspect	Edge of the fins translucent and curved	Stiff fins	Soft	Drooping
Belly	White and shiny with a mauvish edge around the fins	White and shiny with red patches limited to around the fins	White and dull, with numerous red or yellow patches	Yellow to greenish bellies red patches in the flesh itself

(1) This column will apply only until a Commission Decision is taken establishing criteria for fish which is unfit for human consumption.

(2) Or in a more advanced state of decay.

**D. CEPHALOPODS**

	<b>Criteria</b>		
	<b>Freshness category</b>		
	<b>Extra</b>	<b>A</b>	<b>B</b>
Skin	Bright pigmentation, skin sticks to flesh	Dull pigmentation; skin sticks to flesh	Discoloured; easily detached from flesh
Flesh	Very firm; pearly white	Firm; chalky white	Slightly soft; pinky white or slightly yellowing
Tentacles	Resistant to removal	Resistant to removal	More easily removed
Smell	Fresh; seaweed	Slightly or no smell	Ink smell

**E. CRUSTACEANS**

	<b>Criteria</b>	
	<b>Freshness category</b>	
	<b>Extra</b>	<b>A</b>
Minimum requirements	<ul style="list-style-type: none"> <li>— Surface of shell: moist and shiny</li> <li>— Shrimps must fall out separately when transferred from one container to another</li> <li>— Flesh must be free from any foreign odour</li> <li>— Shrimps must be free from sand, mucus and other foreign bodies</li> </ul>	The same as for Extra category
Appearance of: 1. shrimp with shell	Clear reddish-pink in colour with small white flecks; pectoral part of shell predominantly light in colour	— Ranging in colour from slightly washed-out reddish-pink to bluish-red with white flecks; pectoral part of shell should be light coloured tending towards grey
2. deep-water prawn	Uniformly pin	— Pink with possibility of star of blackening of head
Condition of flesh during and after shelling	<ul style="list-style-type: none"> <li>— Shells easily with only technically unavoidable losses of flesh</li> <li>— Firm but not tough</li> </ul>	<ul style="list-style-type: none"> <li>— Shells less easily with small losses of flesh</li> <li>— Less firm, slightly tough</li> </ul>
Fragments	Occasional fragments of shrimp allowed	Small quantity of fragments of shrimp allowed
Smell	Fresh seaweed, slightly sweet smell	Acidulous; no smell of seaweed

## ANNEX 7: Sampling and analysis of contaminants

### Metals

Foodstuffs		Maximum levels (mg/kg wet weight)
	<b>Lead</b>	
1	Muscle meat of fish (1, 2)	0.30
2	Crustaceans, excluding brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans ( <i>Nephropidae</i> and <i>Palinuridae</i> ) (3)	0.50
3	Bivalve molluscs (3)	1.5
4	Cephalopods (without viscera) (3)	1.0

Foodstuffs		Maximum levels (mg/kg wet weight)
	<b>Cadmium</b>	
5	Muscle meat of fish (1) (2), excluding species listed in points 7, 8, 9	0.050
6	Muscle meat of the following fish (1) (2): bonito ( <i>Sarda sarda</i> ) common two-banded seabream ( <i>Diplodus vulgaris</i> ) eel ( <i>Anguilla anguilla</i> ) grey mullet ( <i>Mugil labrosus labrosus</i> ) horse mackerel or scad ( <i>Trachurus species</i> ) louvar or luvar ( <i>Luvarus imperialis</i> ) mackerel ( <i>Scomber species</i> ) sardine ( <i>Sardina pilchardus</i> ) sardinops ( <i>Sardinops species</i> ) tuna ( <i>Thunnus species</i> , <i>Euthynnus species</i> , <i>Katsuwonus pelamis</i> ) wedge sole ( <i>Dicologlossa cuneata</i> )	0.10
7	Muscle meat of the following fish (1) (2): bullet tuna ( <i>Auxis species</i> )	0.20
8	Muscle meat of the following fish (1) (2): anchovy ( <i>Engraulis species</i> ) swordfish ( <i>Xiphias gladius</i> )	0.30
9	Crustaceans, excluding brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans ( <i>Nephropidae</i> and <i>Palinuridae</i> ) (3)	0.50
10	Bivalve molluscs (3)	1.0
11	Cephalopods (without viscera) (3)	1.0

Foodstuffs		Maximum levels (mg/kg wet weight)
	<b>Mercury</b>	
12	Fishery products (3) and muscle meat of fish (1) (2), excluding species listed in point 13. The maximum level applies to crustaceans, excluding the brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans ( <i>Nephropidae</i> and <i>Palinuridae</i> )	0.50

Foodstuffs		Maximum levels (mg/kg wet weight)
	<b>Mercury</b>	
13	Muscle meat of the following fish (1) (2): anglerfish ( <i>Lophius species</i> ) Atlantic catfish ( <i>Anarhichas lupus</i> ) bonito ( <i>Sarda sarda</i> ) eel ( <i>Anguilla species</i> ) emperor, orange roughy, rosy soldierfish ( <i>Hoplostethus species</i> ) grenadier ( <i>Coryphaenoides rupestris</i> ) halibut ( <i>Hippoglossus hippoglossus</i> ) kingklip ( <i>Genypterus capensis</i> ) marlin ( <i>Makaira species</i> ) megrim ( <i>Lepidorhombus species</i> ) mullet ( <i>Mullus species</i> ) pink cusk eel ( <i>Genypterus blacodes</i> ) pike ( <i>Esox lucius</i> ) plain bonito ( <i>Orcynopsis unicolor</i> ) poor cod ( <i>Tricopterus minutes</i> ) Portuguese dogfish ( <i>Centroscymnus coelolepis</i> ) rays ( <i>Raja species</i> ) redfish ( <i>Sebastes marinus, S. mentella, S. viviparus</i> ) sail fish ( <i>Istiophorus platypterus</i> ) scabbard fish ( <i>Lepidopus caudatus, Aphanopus carbo</i> ) seabream, pandora ( <i>Pagellus species</i> ) shark (all species) snake mackerel or butterfish ( <i>Lepidocybium flavobrunneum, Ruvettus pretiosus, Gempylus serpens</i> ) sturgeon ( <i>Acipenser species</i> ) swordfish ( <i>Xiphias gladius</i> ) tuna ( <i>Thunnus species, Euthynnus species, Katsuwonus pelamis</i> )	1.0

### Tin (inorganic)

Foodstuffs		Maximum levels (mg/kg wet weight)
14	Canned foods other than beverages	200

### Dioxins and PCBs <sup>(4)</sup>

Foodstuffs		Maximum Levels	
		Sum of dioxins (WHOPCDD/ F-TEQ) (5)	Sum of dioxins and dioxin-like PCBs (WHOPCDD/ F-PCB-TEQ) (5)
15	Muscle meat of fish and fishery products and products thereof, excluding eel (2) (7). The maximum level applies to crustaceans, excluding the brown meat of crab and excluding	4,0 pg/g wet weight	8,0 pg/g wet weight

	head and thorax meat of lobster and similar large crustaceans ( <i>Nephropidae</i> and <i>Palinuridae</i> )		
16	Muscle meat of eel ( <i>Anguilla anguilla</i> ) and products thereof	4,0 pg/g wet weight	12,0 pg/g wet weight
17	Marine oils (fish body oil, fish liver oil and oils of other marine organisms intended for human consumption)	2,0 pg/g fat	10,0 pg/g fat
18	Fish liver and derived products thereof with the exception of marine oils referred to in point 5.10	-	2,0 pg/g wet weight (5) (10)

### Polycyclic aromatic hydrocarbons

Foodstuffs		Maximum levels (µg/kg wet weight)
	<b>Benzo(a)pyrene (8)</b>	
19	Oils and fats (excluding cocoa butter) intended for direct human consumption or use as an ingredient in foods	2.0
20	Muscle meat of smoked fish and smoked fishery products (2) (9), excluding bivalve molluscs. The maximum level applies to smoked crustaceans, excluding the brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans ( <i>Nephropidae</i> and <i>Palinuridae</i> )	5.0
21	Muscle meat of fish (1) (2), other than smoked fish	2.0
22	Crustaceans, cephalopods, other than smoked (3). The maximum level applies to crustaceans, excluding the brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans ( <i>Nephropidae</i> and <i>Palinuridae</i> )	5.0
23	Bivalve molluscs (3)	10,0

- (1) Fish listed in this category as defined in category (a), with the exclusion of fish liver falling under code CN 0302 70 00, of the list in the Article 1 of Council Regulation (EC) No 104/2000 (OJ L 17, 21.1.2000, p.22) as last amended by the Act.
- (2) Where fish are intended to be eaten whole, the maximum level shall apply to the whole fish.
- (3) Foodstuffs falling within category (c) and (f) of the list in the Article 1 of Regulation (EC) No 104/2000, as appropriate (species as listed in the relevant entry). In case of dried, diluted, processed and /or compound foodstuffs Article 2 (1) and 2 (2) apply.
- (4) Dioxins (sum of polychlorinated dibenzo-para-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs), expressed as World Health Organisation (WHO) toxic equivalent using the WHO- toxic equivalency factors (WHO-TEFS) and sum of dioxins and dioxin-like PCBs (sum of PCDDs, PCDFs and polychlorinated biphenyls (PCBs), expressed as WHO toxic equivalent using the WHO-TEFs).

Congener	TEF value	Congener	TEF value
Dibenzo-p-dioxins (PCDDs)		Dioxin-like PCBs: Non-ortho PCBs + Mono-ortho PCBs	
		<i>Non-ortho PCBs</i>	
2,3,7,8 – TCDD	1	PCB 77	0.0001
1,2,3,7,8 – PeCDD	1	PCB 81	0.0001
1,2,3,4,7,8 – HxCDD	0.1	PCB	0.1
1,2,3,6,7,8 – HxCDD	0.1	PCB	0.01
1,2,3,7,8, 9 – HxCDD	0.1		
1,2,3,4, 6,7,8 – HpCDD	0.01		
OCDD	0.0001		
Dibenzofurans (PCDFs)		<i>Mono-ortho PCBs</i>	
2,3,7,8 – TCDD	0.1	PCB 105	0.0001
1,2,3,7,8 – PeCDF	0.05	PCB 114	0.0005
2,3,4,7,8 – PeCDF	0.5	PCB 118	0.0001
1,2,3,4,7,8 – HxCDF	0.1	PCB 123	0.0001
1,2,3,6,7,8 – HxCDF	0.1	PCB 156	0.0005
1,2,3,7,8, 9 – HxCDF	0.1	PCB 157	0.0005
2,3,4,6,7,8 – HxCDF	0.1	PCB 167	0.00001
1,2,3,4,6,7,8 – HpCDF	0.01	PCB 189	0.0001
1,2,3,4,7,8,9 – HpCDF	0.01		
OCDF	0.0001		
Abbreviations: T = tetra; Pe = penta; Hx = hexa; Hp = hepta; O = octa; CDD = chlorodibenzodioxin; CDF = chlorodibenzofuran; CB = chlorobiphenyl			

- (5) Upperbound concentrations: Upperbound concentrations are calculated on the assumption that all the values of the different congeners below the limit of quantification are equal to the limit of quantification
- (6) The maximum level is not applicable for foods containing <1% fat.
- (7) Foodstuffs listed in this category as defined in categories (a), (b), (c), (e), and (f) of the list in Article 1 of Regulation (EC) No 104/2000, with the exclusion of fish liver.
- (8) Benzo (a) pyrene, for which maximum levels are listed, is used as a marker for the occurrence and effect of carcinogenic polycyclic aromatic hydrocarbons.
- (9) Foodstuffs listed in this category as defined in categories (b), (c), and (f) of the list in Article 1 of Regulation (EC) No 104/2000
- (10) In the case of canned fish liver, the maximum level applies to the whole edible content of the can.

## **ANNEX 8: Model Health Certificates**

(Source EU Reg 2074/2005)

**MODEL HEALTH CERTIFICATE FOR IMPORTS OF FISHERY PRODUCTS INTENDED FOR HUMAN CONSUMPTION**

COUNTRY		Veterinary certificate to EU		
Part I: Details of dispatched consignment	I.1. Consignor Name  Address Postal code Tel. No		I.2. Certificate reference number	I.2.a.
			I.3. Central Competent Authority	
			I.4. Local Competent Authority	
	I.5. Consignee Name  Address Postal code Tel. No		I.6.	
	I.7. Country of origin	ISC code	I.8. Region of origin	Code
			I.9. Country of destination	ISO code
			I.10.	
	I.11. Place of origin Name Address		I.12.	
			I.13. Date of departure	
	I.13. Place of loading		I.14. Date of departure	
I.15. Means of transport Aeroplanes <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> Identification: Documentary references:		I.16. Entry BIP in EU		
		I.17.		
I.18. Description of commodity		I.19. Commodity code (HS code)		
		I.20. Quantity		
I.21. Temperature of product Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>		I.22. Number of packages		
I.23. Identification of container/seal number:		I.24. Type of packaging		
I.25. Commodities certified for Human consumption <input type="checkbox"/>				
I.26.		I.27. For import or admission into EU <input type="checkbox"/>		
I.28. Identification of the commodities Species (Scientific name) Nature of commodity Treatment type Approval number of establishments Manufacturing plant Number of packages Net weight				

COUNTRY		Fishery products
Part II: Certification	II. Health attestation	II.a. Certificate reference number II.b.
	II.1 (1) <b>Public health attestation</b>	
	I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 and certify that the fishery products described above were produced in accordance with those requirements, in particular that they:	
	— come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004;	
	— have been caught and handled on board vessels, landed, handled and where appropriate prepared, processed, frozen and thawed hygienically in compliance with the requirements laid down in Section VIII, Chapters I to IV of Annex III to Regulation (EC) No 853/2004;	
	— satisfy the health standards laid down in Section VII, Chapter V of Annex III to Regulation (EC) No 853/2004 and the criteria laid down in Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs;	
	— have been packaged, stored and transported in compliance with Section VIII, Chapters VI to VIII of Annex III to Regulation (EC) No 853/2004;	
	— have been marked in accordance with Section I of Annex II to Regulation (EC) No 853/2004;	
	— the guarantees covering live animals and products thereof, if from aquaculture origin, provided by the residue plans submitted in accordance with Directive 96/23/EC, and in particular Article 29 thereof, are fulfilled; and	
	— have satisfactorily undergone the official controls laid down in Annex III to Regulation (EC) No 854/2004.	
II.2 (2)(4) <b>Animal health attestation for fish and crustaceans of aquaculture origin</b>		
II.2.1 (3)(4) <b>[Requirements for susceptible species to Epizootic ulcerative syndrome (EUS), Epizootic haematopoietic necrosis (EHN), Taura syndrome and Yellowhead disease</b>		
I, the undersigned official inspector, hereby certify that the aquaculture animals or products thereof referred to in Part I of this certificate:		
(6) originate from a country/territory, zone or compartment declared free from (4)[EUS] (4)[EHN] (4)[Taura syndrome] (4)[Yellowhead disease] in accordance with Chapter VII of Directive 2006/88/EC or the relevant CIE Standard by the competent authority of my country,		
(i) where the relevant diseases are notifiable to the competent authority and reports of suspicion of infection of the relevant disease must be immediately investigated by the official services,		
(ii) all introduction of species susceptible to the relevant diseases come from an area declared free of the disease, and		
(iii) species susceptible to the relevant diseases are not vaccinated against the relevant diseases]		
II.2.2 (3)(4) <b>[Requirements for species susceptible to Viral haemorrhagic septicaemia (VHS), Infectious haematopoietic necrosis (IHN), Infectious salmon anaemia (ISA), Koi herpes virus (KHV) and White spot disease intended for a Member State, zone or compartment declared disease free or subject to a surveillance or eradication programme for the relevant disease</b>		
I, the undersigned official inspector, hereby certify that the aquaculture animals or products thereof referred to in Part I of this certificate:		
(6) originate from a country/territory, zone or compartment declared free from (4)[VHS] (4)[IHN] (4)[ISA] (4)[KHV] (4)[White spot disease] in accordance with Chapter VII of Directive 2006/88/EC or the relevant CIE Standard by the competent authority of my country,		
(i) where the relevant diseases are notifiable to the competent authority and reports of suspicion of infection of the relevant disease must be immediately investigated by the competent authority,		
(ii) all introduction of species susceptible to the relevant diseases come from an area declared free of the disease, and		
(iii) species susceptible to the relevant diseases are not vaccinated against the relevant diseases]		
II.2.3 <b>Transport and labelling requirements</b>		
I, the undersigned official inspector, hereby certify that:		
II.2.3.1	the aquaculture animals referred to above are placed under conditions, including with a water quality, that do not alter their health status;	
II.2.3.2	the transport container or well boat prior to loading is clean and disinfected or previously unused; and	
II.2.3.3	the consignment is identified by a legible label on the exterior of the container, or when transported by well boat, in the ship's manifest, with the relevant information referred to in boxes I.7 to I.11 of Part I of this certificate, and the following statement:	
“(4)[Fish](4)[Crustaceans] intended for human consumption in the Community”.		

COUNTRY		Fishery products						
II. Health attestation	II.a. Certificate reference number	II.b.						
<p><b>Notes</b></p> <p><b>Part I:</b></p> <ul style="list-style-type: none"> <li>— Box reference I.8: Region of origin: For frozen or processed bivalve molluscs, indicate the production area.</li> <li>— Box reference I.11: Place of origin: name and address of the dispatch establishment.</li> <li>— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). Separate information is to be provided in the event of unloading and reloading.</li> <li>— Box reference I.19: use the appropriate HS codes: 03.01, 03.02, 03.03, 03.04, 03.05, 03.06, 03.07, 05.11.91, 15.04, 15.18.00, 16.03, 16.04, 16.05.</li> <li>— Box reference I.23: Identification of container/Seal number: Where there is a serial number of the seal it has to be indicated.</li> <li>— Box reference I.28: Nature of commodity: Specify whether aquaculture or wild origin. Treatment type: Specify whether live, chilled, frozen or processed. Manufacturing plant: includes factory vessel, freezer vessel, cold store, processing plant.</li> </ul> <p><b>Part II:</b></p> <ul style="list-style-type: none"> <li>(1) Part II.1 of this certificate does not apply to countries with special public health certification requirements laid down in equivalence agreements or other Community legislation.</li> <li>(2) Part II.2 of this certificate does not apply to:                     <ul style="list-style-type: none"> <li>(a) non-viable crustaceans, which means crustaceans no longer able to survive as living animals if returned to the environment from which they were obtained,</li> <li>(b) fish which are slaughtered and eviscerated before dispatch,</li> <li>(c) aquaculture animals and products thereof, which are placed on the market for human consumption without further processing, provided that they are packed in retail-sale packages which comply with the provisions for such packages in Regulation (EC) No 853/2004,</li> <li>(d) crustaceans destined for processing establishments authorised in accordance with Article 4(2) of Directive 2006/88/EC, or for dispatch centres, purification centres or similar businesses which are equipped with an effluent treatment system inactivating the pathogens in question, or where the effluent is subject to other types of treatment reducing the risk of transmitting diseases to the natural waters to an acceptable level,</li> <li>(e) crustaceans which are intended for further processing before human consumption without temporary storage at the place of processing and packed and labeled for that purpose in accordance with Regulation (EC) No 853/2004.</li> </ul> </li> <li>(3) Parts II.2.1 and II.2.2 of this certificate only apply to species susceptible to one or more of the diseases referred to in the title. Susceptible species are listed in Annex IV to Directive 2006/88/EC.</li> <li>(4) Keep as appropriate.</li> <li>(5) For consignments of species susceptible to EUS, EHN, TaJra syndrome and/or Yellowhead disease this statement must be kept for the consignment to be authorised into any part of the Community.</li> <li>(6) To be authorised into a Member State, zone or compartment (boxes I.9 and I.10 of Part I of the certificate) declared free from VHS, IHN, ISA, KHV or Whitespot disease or with a surveillance or eradication programme established in accordance with Article 44(1) or (2) of Directive 2006/88/EC, one of these statements must be kept if the consignment contain species susceptible to the disease(s) for which disease freedom or programme(s) apply(ies). Data on the disease status of each farm and mollusc farming area in the Community are accessible at <a href="http://ec.europa.eu/food/animal/liveanimals/aquaculture/index_en.htm">http://ec.europa.eu/food/animal/liveanimals/aquaculture/index_en.htm</a></li> </ul> <p>— The colour of the stamp and signature must be different to that of the other particulars in the certificate.</p>								
<p>Official inspector</p> <table border="0"> <tr> <td>Name (in capital letters):</td> <td>Qualification and title:</td> </tr> <tr> <td>Date:</td> <td>Signature:*</td> </tr> <tr> <td>Stamp:</td> <td></td> </tr> </table>			Name (in capital letters):	Qualification and title:	Date:	Signature:*	Stamp:	
Name (in capital letters):	Qualification and title:							
Date:	Signature:*							
Stamp:								

**MODEL HEALTH CERTIFICATE FOR IMPORTS OF LIVE BIVALVE MOLLUSCS ECHINODERMS, TUNICATES AND MARINE GASTROPODS INTENDED FOR HUMAN CONSUMPTION**

**COUNTRY**

**Veterinary certificate to EU**

Part I: Details of dispatched consignment	I.1. Consignor Name		I.2. Certificate reference number		I.2.a.		
	Address		I.3. Central Competent Authority				
	Postal code		I.4. Local Competent Authority				
	Tel. No						
	I.5. Consignee Name		I.6.				
	Address						
	Postal code						
	Tel. No						
	I.7. Country of origin		ISO code	I.8. Region of origin		Code	I.9. Country of destination
							I.10.
I.11. Place of origin Name		Approval number		I.12.			
Address							
I.13. Place of loading		I.14. Date of departure					
I.15. Means of transport Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/>		I.16. Entry BIP in EU					
Identification:		I.17.					
Documentary references:							
I.18. Description of commodity		I.19. Commodity code (HS code)		03 07			
				I.20. Quantity			
I.21.		I.22. Number of packages					
I.23. Identification of container/Seal number		I.24. Type of packaging					
I.25. Commodities certified for Human consumption <input type="checkbox"/>							
I.26.		I.27. For import or admission into EU		<input type="checkbox"/>			
I.28. Identification of the commodities		Species (Scientific name)		Approval number of establishments Manufacturing plant	Number of packages	Net weight	

**COUNTRY** **Live bivalve molluscs, echinoderms, tunicates and marine gastropods**

	II. Health attestation	II.a. Certificate reference number	II.b.
<b>Part II: Certification</b>	<p><b>II.1 (1)Public health attestation for live bivalve molluscs, echinoderms, tunicates and marine gastropods</b></p> <p>I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 and certify that the (4)[live bivalve molluscs] (4)[live echinoderms] (4)[live tunicates] (4)[live marine gastropods] described above were produced in accordance with those requirements, in particular that they:</p> <ul style="list-style-type: none"> <li>— come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004;</li> <li>— have been harvested, where necessary relayed and transported in accordance with Section VII, Chapters I and II of Annex III to Regulation (EC) No 853/2004;</li> <li>— were handled, where necessary purified, and packaged in compliance with Section VII, Chapters III and IV of Annex III to Regulation (EC) No 853/2004;</li> <li>— satisfy the health standards laid down in Section VII, Chapter V of Annex III to Regulation (EC) No 853/2004 and the criteria laid down in Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs;</li> <li>— have been packaged, stored and transported in compliance with Section VII, Chapters VI and VIII of Annex III to Regulation (EC) No 853/2004;</li> <li>— have been marked and labelled in accordance with Section I of Annex II and Section VII, Chapter VII of Annex III to Regulation (EC) No 853/2004;</li> <li>— in the case of <i>pectinidae</i> harvested outside classified production areas, comply with the specific requirements laid down in Section VII, Chapter IX of Annex III to Regulation (EC) No 853/2004, and</li> <li>— have satisfactorily undergone the official controls laid down in Annex II to Regulation (EC) No 854/2004.</li> </ul>		
	<p><b>II.2 (2)(4)Animal health attestation for live bivalve molluscs of aquaculture origin</b></p>		
	<p><b>II.2.1 (3)(4)[Requirements for species susceptible to <i>Bonamia exitiosa</i>, <i>Perkinsus marinus</i> and <i>Microcytos mackini</i></b></p> <p>I, the undersigned official inspector, hereby certify that the live bivalve molluscs referred to in Part I of this certificate:</p> <p>(5)originate from a country/territory, zone or compartment declared free from (4)[<i>Bonamia exitiosa</i>] (4)[<i>Perkinsus marinus</i>] (4)[<i>Microcytos mackini</i>] in accordance with Chapter VII of Directive 2006/88/EC or the relevant OIE Standard by the competent authority of my country,</p> <ul style="list-style-type: none"> <li>— where the relevant diseases are notifiable to the competent authority and reports of suspicion of infection of the relevant disease must be immediately investigated by the official services, and</li> <li>— all introduction of species susceptible to the relevant diseases come from an area declared free of the disease.]</li> </ul>		
	<p><b>II.2.2 (3)(4)[Requirements for species susceptible to <i>Marteilia refringens</i> and <i>Bonamia ostreae</i> intended for a Member State, zone or compartment declared disease free or subject to a surveillance or eradication programme for the relevant disease</b></p> <p>I, the undersigned official inspector, hereby certify that the live bivalve molluscs referred to above:</p> <p>(5)originate from a country/territory, zone or compartment declared free from (4)[<i>Marteilia refringens</i>] (4)[<i>Bonamia ostreae</i>] in accordance with Chapter VII of Directive 2006/88/EC or the relevant OIE Standard by the competent authority of my country,</p> <ul style="list-style-type: none"> <li>(i) where the relevant diseases are notifiable to the competent authority and reports of suspicion of infection of the relevant disease must be immediately investigated by the official services, and</li> <li>(ii) all introduction of species susceptible to the relevant diseases come from an area declared free of the disease.]</li> </ul>		
	<p><b>II.2.3 Transport and labelling requirements</b></p> <p>I, the undersigned official inspector, hereby certify that:</p>		
	<p><b>II.2.3.1</b> the live bivalve molluscs referred to above are placed under conditions, including with a water quality, that do not alter their health status,</p>		
	<p><b>II.2.3.2</b> the transport container or well boat prior to loading is clean and disinfected or previously unused; and</p>		
	<p><b>II.2.3.3</b> the consignment is identified by a legible label on the exterior of the micro container, or when transported by well boat, in the ship's manifest, with the relevant information referred to in boxes I.7 to I.11 of Part I of this certificate, and the following statement:</p> <p>"Live bivalve molluscs intended for human consumption in the Community".</p>		

**COUNTRY** **Live bivalve molluscs, echinoderms, tunicates and marine gastropods**

II. Health attestation	II.a. Certificate reference number	II.b.						
<p><b>Notes</b></p> <p><b>Part I:</b></p> <ul style="list-style-type: none"> <li>— Box reference I.8: Region of origin: indicate the production area.</li> <li>— Box reference I.11: Place of origin: name and address of the dispatch establishment.</li> <li>— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). Separate information is to be provided in the event of unloading and reloading.</li> <li>— Box reference I.23: Identification of container/Seal number: Where there is a serial number of the seal it has to be indicated.</li> <li>— Box reference I.28: Manufacturing plant: includes dispatch centre, purification centre.</li> </ul> <p><b>Part II:</b></p> <ul style="list-style-type: none"> <li>(1) Part II.1 does not apply to countries with special public health certification requirements laid down in Equivalence Agreements or other Community legislation.</li> <li>(2) Part II.2 does not apply to:             <ul style="list-style-type: none"> <li>(a) non-viable molluscs, which means molluscs no longer able to survive as living animals if returned to the environment from which they were obtained.</li> <li>(b) live bivalve molluscs placed on the market for human consumption without further processing, provided that they are packed in retail-sale packages which comply with the provisions for such packages in Regulation (EC) No 853/2004.</li> <li>(c) live bivalve molluscs destined for processing establishments authorised in accordance with Article 4(2) of Directive 2006/88/EC, or for dispatch centres, purification centres or similar businesses which are equipped with an effluent treatment system inactivating the pathogens in question, or where the effluent is subject to other types of treatment reducing the risk of transmitting diseases to the natural waters to an acceptable level.</li> <li>(d) live bivalve molluscs which are intended for further processing before human consumption without temporary storage at the place of processing and packed and labelled for that purpose in accordance with Regulation (EC) No 853/2004.</li> </ul> </li> <li>(3) Parts II.2.1 and II.2.2 only apply to species susceptible to one or more of the diseases referred to in the title. Susceptible species are listed in Annex IV to Directive 2006/88/EC.</li> <li>(4) Keep as appropriate.</li> <li>(5) For consignments of species susceptible to <i>Bonamia exitiosa</i>, <i>Perkinsus marinus</i> and <i>Microcytos mackini</i> this statement must be kept for the consignment to be authorised into any part of the Community.</li> <li>(6) To be authorised into a Member State, zone or compartment (boxes I.9 and I.10 of Part I of the certificate) declared free from <i>Marteilia refringens</i> or <i>Bonamia ostreae</i> or with a surveillance or eradication programme established in accordance with Article 44 (1) or (2) of Directive 2006/88/EC, one of these statements must be kept if the consignment contains species susceptible to the disease(s) for which disease freedom or programme(s) apply(ies). Data on the disease status of each farm and mollusc farming areas in the Community are accessible at <a href="http://ec.europa.eu/food/animal/liveanimals/aquaculture/index_en.htm">http://ec.europa.eu/food/animal/liveanimals/aquaculture/index_en.htm</a></li> </ul> <p>— The colour of the stamp and signature must be different to that of the other particulars in the certificate.</p>								
<p><b>Official inspector</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Name (in capital letters):</td> <td style="width: 50%;">Qualification and title:</td> </tr> <tr> <td>Date:</td> <td>Signature:</td> </tr> <tr> <td>Stamp:</td> <td></td> </tr> </table>			Name (in capital letters):	Qualification and title:	Date:	Signature:	Stamp:	
Name (in capital letters):	Qualification and title:							
Date:	Signature:							
Stamp:								

## ANNEX 9: References

Legislation reviewed in these Regulations:

1. COMMISSION DECISION of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results
2. COUNCIL DIRECTIVE 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC
3. COUNCIL DIRECTIVE 98/83/EC of 3 November 1998 on the quality of water intended for human consumption
4. COMMISSION REGULATION (EC) No 37/2005 of 12 January 2005 on the monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption
5. 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
6. COMMISSION REGULATION (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs
7. REGULATION (EC) No 852/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on the hygiene of foodstuffs
8. REGULATION (EC) No 853/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004
9. laying down specific hygiene rules for food of animal origin
10. REGULATION (EC) No 854/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004
11. laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
12. REGULATION (EC) No 882/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004
13. on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
14. COMMISSION REGULATION (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
15. COMMISSION REGULATION (EC) No 1883/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs
16. COMMISSION REGULATION (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs
17. COUNCIL REGULATION(EC) No 2406/96 of 26 November 1996 laying down common marketing standards for certain fishery products

18. COMMISSION REGULATION (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004

**ANNEX 3: MFMRD ATTORNEY GENERAL LIAISON CONTACT**

Name	Designation	Contact
Mr. Ribanataake Awira	Permanent Secretary, Ministry of Fisheries and Marine Resources Development, Tarawa, Kiribati	<a href="mailto:riba@mfmrd.gov.ki">(riba@mfmrd.gov.ki)</a>
Ms Ruria Iteraera Fisheries Legal Counsel	Attorney General Liaison	<a href="mailto:ruriai@mfmrd.gov.ki">ruriai@mfmrd.gov.ki</a>

**ANNEX 4: TERMS OF REFERENCE FOR FUTURE ACTIVITIES**

Issues to be addressed	<p>Illegal Unreported and Unregulated Fishing law is regarded as an essential element of maritime law in most parts of the developing world but at present Kiribati has nothing specific in place, although the 2010 Act for the conservation, management and development of Kiribati fisheries and control of foreign fishing and for connected purposes mentions fines for unlicensed fishing vessels.</p> <p>If the Government of Kiribati wishes to put IUU legislation in place it will require assistance with the development process.</p>																									
Activities of the Consultant	<p>Using materials and other information gathered during earlier missions CA085KIR and CA093KIR, the expert will undertake the following tasks:</p> <p>Drafting IUU legislation for consideration by the Kiribati Attorney-General's Office and eventual adoption by the Government of Kiribati.</p> <p>Undertake the work from the expert's home base, followed by a week for introductory work with the Ministry of Fisheries and Marine Resource Development (MFMRD) staff</p>																									
Expected outputs	<p>The main outputs of the mission will be draft Regulations which:</p> <p>Establish and empower the operation of IUU fisheries legislation for control of access to the Kiribati Exclusive Economic Zone (EEZ);</p>																									
Duration/indicative schedule of work activities	<p>The following schedule of inputs is indicative only, and subject to amendment by the consultant in response to operational considerations.</p> <table border="1" data-bbox="392 1137 1377 1787"> <thead> <tr> <th>Activity</th> <th>Working days</th> </tr> </thead> <tbody> <tr> <td>Brief by donor organisation</td> <td>1</td> </tr> <tr> <td>Prepare draft legislation</td> <td>10</td> </tr> <tr> <td>Travel Kiribati</td> <td>3</td> </tr> <tr> <td>Brief EC Delegation Fiji</td> <td>1</td> </tr> <tr> <td>Brief MFMRD</td> <td>5</td> </tr> <tr> <td>Debriefing MFMRD</td> <td>1</td> </tr> <tr> <td>Debriefing EC Delegation Fiji</td> <td>1</td> </tr> <tr> <td>Travel from Kiribati</td> <td>3</td> </tr> <tr> <td>Writing report</td> <td>1</td> </tr> <tr> <td>Debrief donor organisation</td> <td>1</td> </tr> <tr> <td><b>Total</b></td> <td><b>27</b></td> </tr> </tbody> </table> <p>Total working days will equal XX calendar days.</p>		Activity	Working days	Brief by donor organisation	1	Prepare draft legislation	10	Travel Kiribati	3	Brief EC Delegation Fiji	1	Brief MFMRD	5	Debriefing MFMRD	1	Debriefing EC Delegation Fiji	1	Travel from Kiribati	3	Writing report	1	Debrief donor organisation	1	<b>Total</b>	<b>27</b>
Activity	Working days																									
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Brief MFMRD	5																									
Debriefing MFMRD	1																									
Debriefing EC Delegation Fiji	1																									
Travel from Kiribati	3																									
Writing report	1																									
Debrief donor organisation	1																									
<b>Total</b>	<b>27</b>																									
Start date	XXX (estimated)																									
Completion dates for reports	Draft report to management unit	10 working days after return to home base																								
	YYY comments	Within 2 weeks of reception																								

	Final report	10 working days after reception of PMU comments (including comments of authorities if appropriate)	
Experience and qualification	<p>Expert of category II (at least 10 years of experience)</p> <p>Qualifications and skills:</p> <ul style="list-style-type: none"> <li>- A University degree in veterinary, food technology or related sciences</li> <li>- Knowledge of English is essential.</li> <li>- The applicant must be of EU or ACP member state nationality.</li> </ul> <p>General professional experience:</p> <ul style="list-style-type: none"> <li>- Comprehensive knowledge of European Union (EU) regulations relevant to the control of fish and fishery products' sanitary status.</li> <li>- Demonstrated long-term background in fish and fish product surveillance</li> </ul> <p>Specific professional experience:</p> <ul style="list-style-type: none"> <li>- Long-term background in the application of EU legislation and procedures for inspection and certification in third countries; the drafting of manuals of procedures for the inspection and certification, and the design and setting up of self-control systems, based on HACCP methodology, by the food industry as well as their audit by official inspection bodies.</li> </ul>		
Locations and travel	<p>Based in XXXXXXXXX:</p> <ul style="list-style-type: none"> <li>- Mission 1 journey from XXXX to XXX;</li> <li>- Debrief 1 journey from XXXX to XXX;</li> <li>- up to XX nights' per diem in XX;</li> <li>- up to 1 night's per diem in XX;</li> </ul>		

## ANNEX 5: BIBLIOGRAPHY

1. COMMISSION DECISION of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results
2. COUNCIL DIRECTIVE 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC
3. COUNCIL DIRECTIVE 98/83/EC of 3 November 1998 on the quality of water intended for human consumption
4. COMMISSION REGULATION (EC) No 37/2005 of 12 January 2005 on the monitoring of temperatures in the means of transport, warehousing and storage of quick frozen foodstuffs intended for human consumption
5. 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
6. COMMISSION REGULATION (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs
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19. COMMISSION REGULATION (EC) No 2065/2001 of 22 October 2001 laying down detailed rules for the application of Council Regulation (EC) No 104/2000 as regards informing consumers about fishery and aquaculture products