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## Manual for the Inspection and Official Control of Caribbean Fishery Products



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Manual for the Inspection and Official Control of Caribbean Fishery Products

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**Cover Photo:** The capture and packing of the Queen conch (*Lobatus gigas*) plays an important role in the regional fishery sector, but requires effective control of the associated food safety risks



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## GLOSSARY OF TERMS

<b>Approval</b>	Official recognition that the health conditions in a vessel, or establishment meet regulatory requirements.
<b>Audit</b>	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.
<b>Competent Authority</b>	The central authority of a Member State (within the EU), or central national authority in any country, with authority to carry out sanitary checks and certify compliance.
<b>Corrective Action Plan</b>	A documented plan of corrective actions required, including time frames, persons responsible for implementing the plan and the processor's verification that the corrective action is working.
<b>Corrective Action</b>	The procedure that is to be followed whenever a deviation from a critical limit in a HACCP plan occurs or whenever the results of official controls indicate that there is non-compliance with the regulation.
<b>Critical non-compliance</b>	A failure of a fishery business operator's HACCP, GMP or SSOP system that may result, or has already resulted, in the production of an unsafe or fraudulent product.
<b>HACCP</b>	Hazard analysis critical control point system; a product safety management system which identifies critical process variables affecting the level of and presence of hazards to human health in the final product, and which defines critical monitoring indicators and methods to ensure that process variables remain within defined safe limits.
<b>Hazard</b>	A biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse effect on human or animal health
<b>High-risk products</b>	Products that, if not properly prepared or processed, may pose a serious risk to human health and safety.
<b>Hygiene</b>	The measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use;
<b>Inspection</b>	The official examination of establishments, of animals and food, and the processing thereof, of food 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;
<b>Inspector</b>	An official agent authorized by the Competent Authority to perform the duties of inspection in order to ensure food safety.
<b>Monitoring</b>	A planned observation, or measurement of a parameter, at a specified point or time, which is then compared to a target (i.e. a standard, an operational limit, a critical limit).
<b>Non-compliance</b>	A deviation from regulatory requirement.
<b>Official control</b>	Any form of control that the competent authority performs for the verification of compliance with regulatory requirements for food safety

<b>Official inspector</b>	An inspector qualified, in accordance with the extant legal framework, to act in such a capacity and appointed by the competent authority;
<b>Registration</b>	A recognition of the declared existence of an establishment, or other kind of facilities as fishing boats, transport means, certified by the issue of a registration number code.
<b>Risk</b>	A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.
<b>Risk analysis</b>	A process consisting of three components: risk assessment, risk management and risk communication.
<b>Risk assessment</b>	A scientifically based process consisting of hazard identification, hazard characterization, exposure assessment and risk characterization.
<b>Risk management</b>	The process of weighing policy alternatives in the light of results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures.
<b>Standard Sanitation Operation Procedures (SSOP)</b>	A detailed set of instructions, which describes how to carry out a task, related with the Hygiene and sanitation.
<b>Validation</b>	Supportive evidence or documentation to confirm that the values of the critical limits for each Critical Control Point (CCP) are sufficient to prevent, eliminate or reduce to an acceptable level, food safety hazards in the final product.

## LIST OF ABBREVIATIONS

ASP	Amnesic shellfish poisoning
DSP	Diarrheic shellfish poisoning
EU	European Union
FDA	Food and Drug Administration (of the USA)
HACCP	Hazard Analysis and Critical Control Point
MRL	Maximum Residue Level
NSP	Neurotoxic shellfish poisoning
PSP	Paralytic Shellfish Poisoning
RASFF	Rapid Alert System for Food and Feed
WHO	World Health Organization



# FOREWORD

The fishery sector is of great importance for CARIFORUM States, as it provides employment for an estimated 121,000 persons, and contributes significantly to food security and export earnings. The marine capture sector is mostly characterized by a small-scale multi-gear fishery, but several countries have also developed distant water fleets of industrial vessels. Aquaculture is also becoming more important, with some large-scale investments in shrimp and tilapia production as well as numerous experimental and small-scale operations. The fishery sector of CARICOM countries also engages in significant international trade with combined exports worth US\$390 million in 2015, with imports over US\$180 million (which supply not only domestic markets, but also help to sustain our tourism sector). All this business, and the resulting benefits to the people of our region, depend wholly on the fishery products we produce and market being safe for human consumption. However, ensuring such safety against the background of a diversified and globally integrated fishery sector presents significant challenges, requiring not only considerable resources, but also a high level of expertise and knowledge.

The Caribbean Regional Fisheries Mechanism was formed in 2002 with the objective to promote and facilitate the responsible utilization of the Region's fisheries and other aquatic resources for the economic and social benefits of the current and future population of the region. In line with this aim, we are therefore pleased to present this Manual, which is one of a series, which provides valuable, up-to-date, regionally relevant and practical advice on ensuring the food safety of Caribbean fishery products. The Manuals are intended for use by both fishery sector operators, as well as those involved in protecting our consumers, through the implementation and enforcement of sanitary regulations. We are sure that these documents will help to provide a solid technical basis for the ensuring the continued and sustainable growth of our seafood sector.



# 1 INTRODUCTION

## 1.1 Background

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This manual was developed within the framework of the EU funded 10th EDF Sanitary and Phytosanitary (SPS) Project, under the terms of a contract “Capacity Building of regulatory and industry stakeholders in Aquaculture and Fisheries Health and Food Safety to meet the SPS requirements of international trade”, implemented by Megapesca Lda, Portugal.

The primary objective of the project is to:

*Build capacities of CARIFORUM States in health and food safety requirements of fisheries and aquaculture (inland, marine) products, and as such ensure safe food standards for fisheries products in the region, while meeting the requirements of the region's trading partners worldwide.*

The expected result is that capacities will be built at the national and regional levels for health and food safety requirements of fisheries and aquaculture (inland, marine) products. This will also ensure safe food standards for fisheries products in the region, while meeting the requirements of the region's trading partners worldwide.

The strengthening of sanitary conditions throughout the region is expected to lead to improved health and well-being of national populations, and increased international trade in fishery products.

## 1.2 About this manual

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This operational manual is one of eight manuals aimed at providing structured guidelines to ensuring the safety of fish and fishery products for human consumption, in terms of best practices and official controls. It provides guidance for the inspection and official control of the food safety conditions of fishery products produced within the Caribbean region.

This manual therefore focuses only on food safety aspects in the official control of fishery products. It concentrates exclusively on the hazards to human health which may arise in fishery products, and the organisation of a system of official controls, consisting of legislation, and an inspection and enforcement system), which can be used to minimise the probability of injury to health.

It aims to provide up to date advice on the design and implementation of controls, both for inspectors and their technical managers from Competent Authorities nominated by Governments, to perform food safety inspections in the fishery sector. It responds to a need to establish common inspection and control practices within the region, that meet minimum levels of technical competence.

The manual reflects the most recent approaches set out in international requirements for official control of food safety, and apply them to the fishery sector. The guidelines it contains therefore set out approaches in line with the 2004 “food hygiene package” of EU legislation, which brings into full effect all the food safety policies proposed in the 2000 White Paper on Food Safety. They are also in line with the US Food Safety Modernisation Act of 2011. The approach therefore reflects controls that focus on prevention rather than punishment, place the responsibility for food safety on the food business operator, apply a risk-based approach, and address the entire food supply chain (from “farm to fork”).

This document is based on previous work undertaken in 2005 and 2010 by the EDF funded project Strengthening Fishery Product Health Conditions in ACP and OCT Countries<sup>1</sup>.

### 1.3 How to use the document

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The manual is applicable on two levels. Firstly, it will aid management decision making in the design of official control systems, defined as the control activities undertaken by the competent authority to ensure that business operators comply with food law, including enforcement steps. Secondly, on the level of the individual inspector, the manual sets out the steps to be followed in setting up, undertaking, reporting and following up inspections at different stages of the fish supply chain. This considers both technical and organisational points of view, to ensure that inspections are conducted in a fair, unbiased and professional manner.

The manual promotes a risk-based approach to food safety inspections that addresses not only basic hygienic requirements, but also establishes that process variables are under effective control by the fishery business operators (i.e. based on the principles of Hazard Analysis and Critical Control Point). For this reason, the manual should be read in conjunction with the CRFM Guide to Food Safety Hazards in Caribbean Fishery Products, which sets out the specific scientific control measures for some of the major hazards encountered in the region's fishery products.

This manual sets out the principles of control, and describes how to set up and organise a Competent Authority for the official sanitary control of fishery products. It shows some of the technical steps which inspectors need to address in the organisation of their work, to ensure an effective, efficient and thorough coverage of the technical requirements when they are making inspections. It also describes how to go about key tasks such as monitoring, managing and conducting the inspection process, and dealing with alerts and crises. The Annex also presents a HACCP system inspection checklist and record keeping forms which can be adapted and applied as required by inspectors operating in the field.

## 2 RISK MANAGEMENT PRINCIPLES AND RESPONSIBILITIES

### 2.1 Principles of risk management

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Fish inspection is a food safety risk management activity. The joint FAO/WHO Expert Committee defined the structure of risk analysis and the general principles for food safety risk management in 1997<sup>2</sup>.

Risk analysis integrates three activities within the framework of a consumer protection strategy; risk assessment, risk management and formal risk communication. The general principles of food safety risk analysis are:

- Protection of human health should be the primary consideration.
- Risk management should follow a structured approach.

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<sup>1</sup> Manual/Handbook for the Execution of Sanitary Inspection of Fish as Raw Material and Fish-Products as Food for Human Consumption, Mission Ref: CA073GEN, May 2010, published by Strengthening Fishery Products Health Conditions in ACP/OCT Countries (Project No. 8ACPTPS137)

<sup>2</sup> FAO Food and Nutrition Paper N° 65 – Report of a Joint FAO/WHO Consultation, Rome, Italy, 1997, 27 pages



- Determination of risk assessment policy should be included as a specific component of risk management.
- Risk assessment should have scientific integrity, and be functionally separate from risk management and risk communication.
- Risk management decisions should take into account uncertainty in risk assessment.
- Risk management should be a continuing process, using newly generated data to review the management decisions.
- Risk management decisions and practices should be transparent.

Whilst a comprehensive treatment of fishery product hazards is considered in the CRFM Guide to Food Safety Hazards in Caribbean Fishery Products, it is clear that such information should be included in the training of inspectors who are to control these hazards. This is required to be able to provide advice, to be able to assess the effectiveness of control systems applied to reduce or eliminate hazards, and to ensure effective risk management. With respect to risk management, risk may be defined as<sup>3</sup>:

*“a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard”*

Therefore, risk can be viewed as a function of the severity of hazard and the probability that it might arise. Table I indicates how hazards might be classified. Classification of hazards according to risk is a key part of the inspector’s work, and can only be undertaken with a detailed knowledge of the hazards and associated health risks associated with the particular species and products for which the inspector is responsible. Allocation of priorities within each category requires detailed information on the severity and frequency of the hazard.

This knowledge can only be derived from either epidemiological evidence (that is from information regarding the extent and nature of the actual public health problems caused by the hazard), or from sampling and testing of the food products entering the market. Such monitoring programmes are an important part of the control system, providing the inspectors with risk related information on which to base the design of their inspection programmes. This type of assessment should therefore provide the basis for decisions such as frequency of inspections, sample rates, checklist priorities, focus of HACCP plan audits etc., none of which can be undertaken effectively without a full appreciation of the nature of the hazards and their associated risks.

**TABLE I: EFFECT OF RISK AND SEVERITY ON FOOD SAFETY PRIORITIES**

Probability of hazard occurring	Severity of hazard	
	Mild	Severe
<b>HIGH</b>	Medium priority	High priority hazards to receive the main focus of the control system
<b>LOW</b>	Low priority hazards	Medium priority

## 2.2 Responsibilities for food safety

In modern systems for control of food safety within a free market economy, the responsibility for the safety of food is generally considered to be that of the food business operator. This is often

<sup>3</sup> 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.

expressed in law. A scientifically valid risk assessment by the operator is therefore required to indicate the risks and the measures required to eliminate or reduce them to an acceptable level.

Furthermore, Government may also take some general level of responsibility in respect of food chain management, to ensure that food safety risks are managed effectively and food business operators comply with regulations. Here the Competent Authority will be responsible for ensuring that adequate resources are available, in terms of staffing and the financial means in the budget allocations.

It should be noted that not all hazards can be eliminated, and that certain food safety risks may be considered acceptable in the light of circumstances. One example is the almost unavoidable presence of *Listeria monocytogenes* in many ready to eat foods. Risk management is about recognising the most important threats, and locating resources to optimise the food safety benefits.

Risk management may often and intentionally ignore some risks considered to be insignificant. Alternatively, when a risk is associated with an economically insignificant activity, the risks may be better managed by banning the economic activity, rather than seeking to make it safe through regulatory controls. For example, when the cost of control cannot be justified by the value generated by the activity. Finding the balance between the resources available and the risks to be controlled, is one of the most difficult conceptual problems faced by the manager of food inspection systems.

## 2.3 Role of the inspector

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The role of the modern inspector should be aligned with the requirements of the WTO Sanitary and Phytosanitary Agreement. Thus, the job of the inspector is to:

- assess the food safety conditions;
- interpret the legal requirements;
- compare them with the actual food safety conditions; and
- take action to prevent injury or death when conditions do not meet the required standards.

The role of the fish inspector is **not** to:

- promote the local industry;
- assist exports; or
- ensure that the quality is appropriate to the commercial requirements of the market.

Therefore, fish inspectors should be concerned **exclusively** with those matters that affect the safety of the product. Inspectors should consider that the sale of low quality fishery products is acceptable, and even desirable, in terms of resource utilisation, providing that the consumer is not misled and that the product is safe to eat.

However, as noted, food can never be 100% safe. It is a biological material and, in the case of most fishery products, is hunted from a wild environment that is not subject to human controls. Sources of supply, processing technology, and distribution systems are in a constant state of dynamic flux. Inspection and control is a costly activity, and it is neither possible nor desirable to control everything all the time.

The task of the inspector is therefore one of risk management, to ensure that the limited resources available are applied in an efficient and effective manner so that that the risk of a food safety hazard causing harm to the consumer is minimised. Therefore, the core knowledge required by any inspector is of fishery product hazards, how they arise and how they can be controlled.

### 3 FOOD SAFETY HAZARDS AND CONTROLS

There are many types of health hazards associated with fishery products. Humans harvest and consume several thousands of different species of fishery products from several of the major phyla of animals;

- *mollusca* (including bivalve, gastropod and cephalopod molluscs)
- *arthropoda* (including crustacea)
- *invertebrate chordata* such as the tunicates (sea cucumbers) and echinoderms (sea urchins)
- *vertebrate chordata* including Teleostei (the true fishes) and Chondrichthyes (cartilaginous fishes) and mammals.

Each species has its own specific biochemistry and environment. The fish inspector should have a good scientific understanding of how these factors, along with post-harvest variables in handling and processing, can affect food safety.

Hazards in fishery products are typically classified according to their nature, chemical, biological and physical. Some of the hazards, particularly those originating from the source of production, are highly specific to the species of fishery products (species-related hazards). Others are more generic in their nature (for example in relation to post-harvest contamination), and may be encountered in other foodstuffs (process related hazards).

A more detailed treatment of the most serious and frequent food safety hazards associated with Caribbean fishery products is given in the CRFM Guide to Food Safety Hazards in Caribbean Fishery Products. A further and more comprehensive source of information regarding global hazards in fishery products and their controls is provided by the US FDA Fish and Fisheries Products Hazards and Controls Guide<sup>4</sup>. This document describes all the hazards associated with the production, processing, and distribution of fishery products likely to be imported into the USA. It also provides detailed guidance on the design and implementation of HACCP plans to ensure control of the hazards.

Inspectors should have an intimate knowledge of the information contained in these documents. Without this knowledge and the ability to apply it in the fish production and distribution chain, inspectors will not be able to address their basic duties.

## 4 ORGANISATION OF FOOD SAFETY CONTROLS FOR FISHERY PRODUCTS

### 4.1 Regulatory Framework

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Official controls for food safety require a sound regulatory basis to ensure that food business operators can be compelled to apply requirements for food safety using the various enforcement measures available, or failing that, be closed down.

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<sup>4</sup> Available from the Center for Food Safety & Applied Nutrition, US FDA  
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/ucm2018426.htm>

#### 4.1.1 Scope of regulations for food safety of fishery products

In all cases, the source of the technical requirements, specifications, and standards for food safety should be expressed in the legislation. Inspectors should be aware of the content and official interpretation of the legal instruments applicable within their jurisdiction. Typically, a modern regulatory framework would aim to:

Define the responsibilities of food business operators:

- Set out definitions of terms
- Define the unambiguous responsibilities of food business operators at stage of the supply chain from catch to export (and including imports) in terms of product safety, design, operation of facilities, and implementation of control systems
- Set out requirements for raw material, vessels, landing sites aquaculture units, fresh, frozen, cooked, and processed fish
- Require the implementation of controls based on HACCP principles
- Ensure the safety of water used (potability, composition, limit use of seawater)
- Set out the compositional requirements in relation to the food safety hazards
- Set out the requirements for traceability systems

Define the system of official controls:

- Nominate the competent authority responsible for enforcement
- Require the registration of all food business establishments; licensing or approval of high risk establishments
- Provide for nomination of testing laboratories and operational conditions (ISO 17025)
- Define the powers and responsibilities of nominated officers to implement controls (entry, seizure)
- Define enforcement tools and procedures for their application (notices, prosecutions)
- Provide powers for the removal of unsafe food from the market (seizure, recall and withdrawal, destruction of unfit products)
- Define the different kinds of sanctions applicable to non-compliance, including cessation of business activity

Specific recommendations for legislation to cover all of these areas have been developed by the CRFM, and can be adapted to local conditions and adopted as required by Member States<sup>5</sup>.

Note also that food safety conditions are not static but in a constant state of change, with emerging hazards, different patterns of trade, introduction of new process technologies, and new scientific knowledge regarding existing food safety hazards. These factors modify the risk profiles, and the regulations should be kept up to date to reflect these changes.

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<sup>5</sup> CRFM Technical & Advisory Document – Number 2015 / 07, Final Technical Report – Technical support to develop model legislation, protocols, guidelines for health and food safety related to fisheries and aquaculture in CARIFORUM States, prepared by: Christopher Hedley and George Grant, Ocean Governance Consulting, prepared under the 10th EDF funded Sanitary and Phytosanitary, (SPS) Measures Project.

#### 4.1.2 Regulatory system for exports of fishery products

In some cases, export market requirements require specific provisions to be expressed within the legal framework of the exporting country. This is the case with the European Union, whose laws require that the conditions of import be “at least equivalent” to those set out in EU legislation.

Countries supplying this market should have regulations in place which are at least equivalent to the structural and technical criteria set out in EU legislation. There is an important policy decision to be made in terms of the legislative approach. This is whether to apply the technical requirements to:

- a) all production of fishery products (including from domestic consumption),
- b) all fishery product exports (to all regions), or
- c) only to those exported to certain regions (such as the EU, or countries with HACCP requirements)

The factors which determine this provision are the actual health conditions, the developmental, technical, and capital status of the domestic fishery sector, and the level of consumption of domestic fishery product.

Although it is a common situation, it is clearly desirable to avoid promoting a two or three tier system, with lower sanitary conditions permitted for the domestic market. Domestic consumers have the same rights to safe food as anyone else, and unsafe food also undermines the tourist trade. However, if the domestic controls are less developed, policy in this area should permit such derogations, but aim to upgrade health conditions so that the most important requirements are applied for the benefit of the consumers within the territory, as well as those in export markets.

## 4.2 Organisation of the Competent Authority

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### 4.2.1 Nomination

The legislation should nominate the Competent Authority responsible for the implementation of fish health controls for export fishery products. In general, the nomination will be for a unitary authority. Whilst responsibilities shared between one or more organisations are legally acceptable, experience in many countries has shown that the inter-ministry implementation arrangements are insufficiently flexible to respond quickly and effectively to the needs of the industry.

Some examples of organisations which are Competent Authorities for the purpose of the fish hygiene controls are:

- Food Standards Agency
- National Standards Organisation
- Veterinary Department
- Fisheries Department
- Public Health Department

The location of food safety official control functions within organisations responsible for development of the fishery sector (such as a Fisheries department), creates a direct conflict of interest. Control policy should seek to eliminate such conflicts as far as possible, by centralising food safety functions. The tendency is for nomination of a single central authority with responsibility for food safety, which has power to delegate certain functions, such as food safety inspection of fishing vessels and landing sites, to the Fisheries Department.

Inspectors should be aware of the legal status of the Competent Authority for whom they work. The allocation or delegation of powers between the parent ministry and the Competent Authority

should be understood. At all times, the inspector acting in the name of the Competent Authority should be aware of the limits of the powers being exercised. He or she should always endeavour to work within these limits, and to avoid placing the Competent Authority in a situation where it could be considered to be acting *ultra vires* (outside its powers).

#### 4.2.2 Organisation structure and functions of the Competent Authority

The internal organisation of the Competent Authority should reflect the nature, technical level and geographical location of the tasks to be accomplished. The key needs to be addressed are:

- Need for rapid decision making in respect of procedures for certification and suspension of approval, so that non-compliant products can be prevented from reaching the market. This means that powers should be delegated to a sufficiently low level in the organisation for effective on-the-spot decision making.
- Constitutional devolution of responsibilities between central and regional/provincial governments. In some cases inspection and control at local level may be the responsibility of local competent authorities, requiring that attention is paid to effective coordination between these bodies and a central competent authority.
- Sufficient number of technically competent inspectors. It cannot be over emphasised that the most effective means of control is the regular presence of a technically competent inspector at the point of production/processing (whether vessel, market, factory).
- Sufficient resources to allow the inspectors to function effectively, including transport, communication facilities, field equipment, access to testing laboratories, and operational budget to ensure that these means can be employed effectively
- Sufficient administrative and information system support, to ensure that there is a comprehensive record of relevant information available to inspectors regarding the establishments and products they are responsible for

The Competent Authority must have flexibility to be able to deploy inspectors at times and in locations outside the normal government service employment conditions. Fishery sector activities take place at remote locations and outside normal working hours, and the Competent Authority organisation must accommodate the industry practices. A key issue to be addressed in the organisation of the Competent Authority is the local presence of the inspector.

The specific job descriptions should reflect the requirements of the individual situation of the Competent Authority. In all cases the structure should reflect the needs of the work. Key CA functions include risk management, inspection, and ensuring that the laboratory testing services used by the CA (whether in-house or outsourced) are effective and efficient.

#### 4.2.3 Inspection staff training and competences

Technical staff of the Competent Authority must have adequate educational level and technical training to ensure that they can carry out their tasks with an appropriate level of technical competence. Food safety inspection is a multidisciplinary activity, that will combine elements of the following disciplines, and inspectors should be able to work within a multidisciplinary framework. Qualifications should be in one of the following fields:

- Veterinary science
- Public health
- Food microbiology

- Food science and technology
- Food engineering

In the case of the EU, the following list of subjects defines the minimum requirement for the technical training of Competent Authority inspection staff, as required in Annex II of Regulation 882/2004.

**SUBJECT MATTER FOR THE TRAINING OF STAFF PERFORMING  
OFFICIAL CONTROLS**

1. Different control techniques, such as auditing, sampling and inspection
2. Control procedures
3. Feed and food law
4. The different stages of production, processing and distribution, and the possible risks for human health and, where appropriate, for the health of animals and plants and for the environment
5. Assessment of non-compliance with feed and food law
6. Hazards in animal feed and food production
7. The evaluation of the application of HACCP procedures
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
9. Official certification systems
10. Contingency arrangements for emergencies, including communication between Member States and the Commission
11. Legal proceedings and implications of official controls
12. Examination of 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

In all cases, inspectors should also have a detailed knowledge of the content of their national legislation. Particular attention should be paid to:

- Legal status of the inspector as a representative of the Competent Authority
- Procedures laid out for approval of establishments and vessels in the first instance, renewal of approval and withdrawal of approval
- Procedures laid out for health certification of products
- Powers of inspectors (entry, seizure of unfit products, sampling)
- Responsibilities of inspectors (commercial confidentiality)
- Technical food safety conditions to be complied with in relation to fishery products
- Definitions to be applied in the course of controls for health conditions
- Effective communication and reporting systems

The specific approach to all of these matters will vary from country to country, but all inspectors should be aware of the limits of the power and the extent of their responsibilities. In addition, for fish inspection staff, it is recommended that additional training is provided in the areas of:

- Fish biology, taxonomy, identification and composition
- Fish deterioration mechanisms and freshness evaluation
- Bio-toxicology of fishes
- Aquaculture and fishing technologies
- Commonly used fish processing technologies

- Specific hazards related to fish in general and certain species and preparations

For HACCP inspection, the inspector must be aware of the technical requirements of the regulation in respect of HACCP. This is set out in CRFM Guidelines on Developing and Implementing HACCP Plans for Fish and Fishery Products (published under the CARIFORUM Regional Framework for Good Fisheries Hygiene and Production Standards).

#### 4.2.4 Equipment for inspectors

Inspectors should be properly equipped to perform their jobs. This includes transportation, protective clothing, and equipment to record observations, as well as various tools and instruments to make measurements regarding important variables which impact on food safety. A typical inspection equipment kit may therefore contain:

- Protective clothing (coat, rubber boots, hat)
- Notebook
- Voice recorder
- Camera
- Insulated sample box
- Sterile sample bottles and bags
- Digital thermometer
- Flashlight
- Knife
- Portable electric drill
- pH and chlorine colorimetric test kit
- Test kits for qualitative assessment of ciguatera/histamine/sulphites
- Magnifying glass

### 4.3 Financial management of the Competent Authority

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#### 4.3.1 Expenditure

Financial and budgetary issues should be considered, because it is expensive to operate a Competent Authority function to the level required by the EU (and other international) regulations. The main recurrent expenses to be budgeted for are:

<b>Budget item</b>	<b>Examples of costs</b>
Inspection staff	Salaries
Field costs	Transport, accommodation
Database and information	Data input, generation of reports
Laboratory tests	Test fees (including transport of samples)
Laboratory reference functions	Fees to reference laboratories for proficiency testing, training etc.
Administration and management	Secretarial staff, management and personnel, accounting
Communication and networks	International telephone, email, internet, international travel, conferences,
Office costs	Rent, utilities, services, office consumables



#### 4.3.2 Income

The Competent Authority may generate income by charging for some of the services undertaken. Typically, charges are made for annual approval and certification. The income may be used to contribute towards the operational costs of the Competent Authority. However, experience has shown that it is very difficult for the Competent Authority to cover all the operational costs with such charges. An element of state budgetary support is generally required.

Furthermore, income received is often paid (as it should be) directly into the Treasury or Ministry of Finance. Unless it receives an appropriate budget, this may mean that the Competent Authority does not have an effective operational income.

In some cases, the Competent Authority operates a laboratory, and charges for mandatory testing undertaken as the basis for certification. Test fees are then used to subsidise the inspection function. Whilst this approach may meet the financial needs of the CA, there is a risk that the laboratory, as the source of finance, becomes the focus of a control system based on end product certification. This is ineffective, and contrary to the European legislation and the “*at least equivalence*” requirement. The Competent Authority management should be aware of the potential for such conflicts of interest arising when the Competent Authority has chosen to operate an internal laboratory. Especially for small countries with limited resources, the use of external, regional laboratories, provides a better and more reliable service.

#### 4.4 Internal quality assurance system

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The Competent Authority should possess and implement a written system of quality assurance with respect to its own activities. At a minimum, this should govern the following aspects of the work:

- System integrity (independence, transparency, confidentiality etc.)
- Evaluation of compliance with the legal requirements
- Qualifications, training and performance of staff
- Calibration of any instruments used in inspections
- Communication and recording of information relating to compliance
- Calibration of inspection standards

Specific consideration should be given to the means by which the Competent Authority will achieve a uniformity of inspection standards, over time, and by different inspectors. An internal QA Manual should therefore be developed to provide specific measures by which inspection decisions can be calibrated and standardised across the Competent Authority (and preferably with Competent Authorities responsible for the safety of other non-fishery foodstuffs). To achieve these conditions, it is strongly recommended that the Competent Authority allocates a specific budget for quality assurance monitoring and development activities.

As evidence of its achievements in this respect, the Competent Authority may wish to consider seeking third party certification according to international performance standards. Typically, the following have been applied within Competent Authorities responsible for inspection of fishery products:

- ISO 9000: 2015 Standard on Quality Management (see: [http://www.iso.org/iso/home/store/catalogue\\_ics/catalogue\\_detail\\_ics.htm?csnumber=45481](http://www.iso.org/iso/home/store/catalogue_ics/catalogue_detail_ics.htm?csnumber=45481))
- ISO/IEC 17020:2012 General criteria for the operation of various types of bodies performing inspection (see [http://www.iso.org/iso/home/store/catalogue\\_ics/catalogue\\_detail\\_ics.htm?csnumber=52994](http://www.iso.org/iso/home/store/catalogue_ics/catalogue_detail_ics.htm?csnumber=52994))

## 4.5 Anti-corruption measures

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### 4.5.1 Corruption and conflicts of interest

Fishery product export businesses need to have a high turnover to ensure profitability. The amounts of money involved in fixed and working capital investment are substantial, and the potential rewards (and losses) are large. Corruption is present in all countries and industries, and the inspector should be aware that the fish export trade is no different from any other. There is a need for the Competent Authority managers and inspectors to be aware of the different ways in which corrupt practices and conflicts of interest may occur, and to be informed of how they might be avoided.

Especially in countries with weaker governance systems, and small island states where everyone is known or related in some way, inspectors and senior managers in the Competent Authority may come under pressure from peers and superiors not to take strong action against non-compliances. Such non-professional influences may arise from perceived obligations to family, social, ethnic or business groups.

### 4.5.2 Anti-corruption measures

The best counter to corruption is to provide Competent Authority staff and inspectors with adequate pay and conditions, and to ensure that the body of inspectors has a sense of professional *esprit de corps*. If corruption and/or conflicts of interest are considered to be a potential problem, the code of conduct for inspectors should include sections relating to these matters.

On their recruitment, inspectors should receive a specific counselling session on corruption. They should then be required to sign a copy of a civil service code of practice, to the effect that they have read and understood the anti-corruption conditions such as, no gifts to be accepted, prohibition of external employment, and declaration of interests of family members. Steps may also be taken to protect inspectors' recommendations from reversal by superiors due to political pressure (for example, requiring signatures to overturn recommendations based on negative findings).

## 5 ORGANISATION OF LABORATORY TESTING

### 5.1 Organisation of sampling and testing

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The inspector should determine the need for sampling and testing according to the information required to assess safety, or otherwise, of a product or process. The inspector should take the samples, identifiable only by a code, and deliver them to the laboratory. The laboratory should deliver test results only to the inspector, showing in a test certificate the value of the parameter tested. The certificate should not indicate compliance or otherwise with a standard. Such judgments regarding compliance and non-compliance should usually be made by the inspector based on the circumstance of the sampling. Where a testing laboratory passes a judgment on compliance of a sample, this activity should be treated separately to the request for analysis.

Note that there is no requirement for the Competent Authority to operate a testing laboratory. It is acceptable for a Competent Authority to purchase testing services from any laboratory technically competent to provide them. In fact, this is often the best and most cost effective approach in many of the smaller Caribbean countries, since operating a testing laboratory for small volumes of tests is never economically sustainable.

Evidence of technical competence is provided by accreditation to ISO/IEC 17025:2005 "General requirements for the competence of testing and calibration laboratories". The testing services may

be provided by any such laboratory, whether private or public sector. Due to the high cost of providing these services, there is a strong rationale in the Caribbean to develop and use regional testing facilities.

Laboratory functions should be organisationally independent from the Competent Authority. If the Competent Authority does operate a testing laboratory, there should be a clear separation of laboratory functions and control functions. Tasks of laboratory staff should be limited to laboratory testing functions; they should not perform as inspectors, and should never take samples, since this compromises their impartiality as analysts, and is in direct contravention of the accreditation standard. Analytical staff should not be aware of the provenance of the samples which they analyse.

## 5.2 Sampling objectives

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Fishery business operators are required to carry out analyses for internal verification of parameters related with the control of critical aspects of their process, and to check the performance of the hygiene control programmes. These are known as “own checks” conducted by the fishery business operator.

The official inspection of food business operators should at times require the taking of samples for official confirmation of compliance of products with the requirements, and to verify the results provided by the producers as part of their programme of “own checks”.

Monitoring programmes are used to help the Competent Authority assess whether the control system is working effectively to prevent contaminated products being placed on the market. Sampling and testing for monitoring programmes is not a means of controlling composition; non-compliant results indicate a failure of the control system which should be adjusted accordingly.

## 5.3 Testing laboratories

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### 5.3.1 Nomination of Accredited Testing Laboratories

The Competent Authority must designate the official laboratories which may undertake the analysis of samples for official controls. These laboratories must be assessed and accredited in accordance with EN ISO/IEC 17025:2005 Standard on “General requirements for the competence of testing and calibration laboratories”.

Accreditation of a laboratory goes some way to assuring that the test results will be valid and reliable i.e. correct and reproducible. The Competent Authority cannot accredit the laboratory, only nominate accredited laboratories as official testing laboratories. Accreditation is an independent process undertaken by an established accreditation agency. The agency must be clearly established, and must comply with the general criteria for accreditation bodies laid down in ISO/IEC 17040:2005\_“Conformity assessment -- General requirements for peer assessment of conformity assessment bodies and accreditation bodies”. Evidence of this is membership of International Laboratory Accreditation Association (ILAC) <http://www.ilac.org/>.

It is recognised that lack of technical and financial resources limit the ability of many laboratories to achieve accredited status. In the best of cases, establishing systems in line with ISO/IEC 17025:2005 can take several years. Nevertheless, these difficulties should never be an excuse to avoid implementation of feasible quality assurance procedures, many of which, such as calibration and record keeping, can be undertaken through a diligent approach to good laboratory practices and quality assurance methodologies.

Note that it is often desirable that several laboratories are designated as official laboratories by the Competent Authority (to cover different needs and regions). A laboratory may be designated in respect of only some of the tests it undertakes. For example, a laboratory may be designated

for certain microbiological tests, but not for heavy metal testing. Often the Competent Authority will negotiate standard test fees as part of an annual contract with the designated laboratories (or a protocol in the case of state owned laboratories).

The availability of accredited laboratory services is an essential tool which should be available to the Competent Authority for official controls. CRFM and IICA have produced two comprehensive manuals providing guidance for the setting-up, organisation and operation of compliant testing laboratories for these purposes:

- **Fishery products laboratory testing manual;** practical guidelines to managers of testing laboratories and analysts
- **Laboratory quality assurance manual;** setting out the key requirements for ensuring the validity and reliability of laboratory testing, based on the principles of ISO Standard 17025

### 5.3.2 Technical specifications of testing laboratories

The testing capacity of the laboratory will depend on the nature of the hazards encountered within the territory of the third country, the types of controls and the official control and testing requirements. Some of the typical requirements are suggested below.

Note that it is not a requirement that there is capacity for all tests within the national territory of the Competent Authority. Some tests with relatively low demand may require high capital expenditure and high operating costs. In such cases, it is cheaper for the Competent Authority to arrange for the samples to be transported for the test to be undertaken at a laboratory in another country. The Competent Authority must be able to demonstrate that it has made the arrangements for all the tests it requires for official control.

### 5.3.3 Requirements for laboratory accreditation

The detailed requirements are set out in the accreditation standard ISO/IEC 17025:2005. The requirements relate to assuring the quality of the results of the laboratory test, and therefore set out a series of Good Laboratory Practices. For details the Competent Authority should refer to the above standard, which is available at:

[http://www.iso.org/iso/iso\\_catalogue/catalogue\\_tc/catalogue\\_detail.htm?csnumber=39883](http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=39883).

The standards cover such issues as:

- Calibration and metrology of instruments
- Use of official methodologies (ISO, EU regulatory standards or validated methods)
- Staff qualifications
- Documented quality assurance procedures and record keeping
- Participation in proficiency testing and inter-laboratory calibration exercises<sup>6</sup>
- Sample integrity and confidentiality
- Transparent complaints procedure
- Internal and external audit procedures

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<sup>6</sup> For example, as operated by the UK Health Protection Agency <http://www.hpa.org.uk/> (formerly Public Health Laboratory Service)

The Competent Authority should have at least one staff member with sufficient skills and qualifications to manage the technical aspects of the relationship between the Competent Authority and the laboratories.

#### 5.3.4 Standard analytical methodologies

There is no single source of standard testing methodologies used for official controls for fishery products. Harmonised methodologies should be applied where there is an official method specified in the legislation. Where this is not the case, but there is an appropriate ISO or EN standard method, then this should be used. Otherwise the choice of method is not standardised. Some laboratories may choose to use national standards, others to adopt methods from other organisations (e.g. AOAC).

### 5.4 Reference laboratories

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The purpose of the reference laboratory is to co-ordinate the quality of testing services provided by laboratories. It is always itself a testing laboratory. A laboratory will be nominated as a reference laboratory for a single test or group of parameters. Typical tasks it performs are:

- Organising regional comparative tests of standardised samples (proficiency testing) and participating in international inter-calibration tests
- Validating existing methods for local substrates or developing new methods
- Providing information, training and advising on testing methods and validation
- Be a national centre of expertise on analysis of the parameters

As can be seen, the role of reference laboratory is one of great responsibility, and is costly to sustain. The nomination of a laboratory as a reference laboratory should be accompanied by the allocation of an appropriate budget to allow it to function in these tasks. Also, it should be noted that the level of expertise required cannot be developed in the short term. The reference laboratory and the Competent Authority will need to work together closely over a period of years to develop the level of analytical expertise required.

The key European Reference laboratories for testing of parameters related to fishery product safety are listed in the Annex to Regulation 882/2004 (which is updated periodically in this respect).

In regions, such as the Caribbean, there is a strong argument for organising reference laboratories on a regional basis (as is undertaken in the EU).

## 6 OFFICIAL CONTROLS

In European law, the core activity of ensuring compliance with regulatory requirements is termed official control. Official control of food and feed is defined in the Council Regulation (EC) No 882/2004 of 29 April 2004, on official controls to verify compliance with feed and food law, animal health and animal welfare rules as including:

- (a) examination of any control systems
- (b) inspection of:
  - (i) primary producers
  - (ii) raw materials, ingredients, processing aids and other products used for the preparation and production of feed and food;

- (iii) semi -finished products;
  - (iv) materials and articles intended to come into contact with food;
  - (v) cleaning and maintenance products and processes, and pesticides;
  - (vi) labelling, presentation and advertising;
- 
- (c) checks on the hygiene conditions
  - (d) assessment of (GMP), good hygiene practices (GHP), good farming practices and HACCP; examination of records
  - (f) interviews with feed and food business operators and staff;
  - (g) the reading of values recorded by measuring instruments;
  - (h) controls carried out with the competent authority own instruments to verify measurements taken by feed and food business operators;
  - (i) any other activity required to ensure that the objectives of this Regulation are met.

The specific requirements for fishery products are set out in Annexes II and III to the Regulation. It should be noted that the official controls for fishery products consist of a wide range of activities. In US legislation, specific control duties are mandated to control bodies such as the FDA and the US Department of Agriculture, and importers are held responsible for checking on the safety of their supply chains, which may include some reliance on government controls. The key feature of any official control system is that it must cover the whole food chain. All possible sources of hazards must be addressed by the system, and all possible means of information used by the inspector to ensure that the controls are in place. Whilst the responsibility for safe food is that of the producer, the objective of the official control process is to ensure that the food is safe for the consumer.

In terms of the supply system, inspection is exercised at different places, on vessels, at landing, in aquaculture farms, during transportation, processing, storage, and exportation. The main control tool is the approval of vessels, farms and establishments. However, the activities of the inspectors from the Competent Authority must be programmed to cover the entire chain, placing emphasis and priority on those points which are known to present the most risk.

The activities should be set out in an annual inspection plan that guides the routine activities of the CA. Variances from this plan should also be foreseen by the preparation of appropriate emergency or crisis management plans, setting out foreseeable circumstances requiring actions additional to the annual plan, and describing those actions, responsibilities and procedures.

## 6.1 Annual inspection plan

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The Competent Authorities should put in place a surveillance, verification, and auditing plan and system to monitor the performance of the establishments. Under EU regulations, the third countries' Competent Authorities are required to perform a complete audit of each approved establishment/vessel at least once a year. The inspection plan should list all the inspection points, which will include:

- Fishing vessels
- Freezer vessels
- Factory vessels
- Landing sites
- Distributors/wholesalers
- Processing establishments
- Aquaculture producers
- Transport vehicles (including vessels and aircraft)

The plan should also define the different types of inspections that may be applied to each. Generally, there are four types of inspection. Each will have different team compositions and undertake different activities.

Examples are shown below:

Type of inspection	Activity/Purpose
Preliminary approval	Initial inspection of establishments/facilities to confirm degree of compliance with condition and identify works to be undertaken. Often conducted by an informal team, possibly before commissioning of an establishment
Formal approval	Formal approval inspection, to establish whether approval should be granted or not. Conducted by a team, in depth inspection during operation of the establishment covering all issues in detail
Interim routine	Interim detailed inspection conducted to check compliance, follow up on approval conditions, or on progress with works requested.
Spot check	Ad hoc inspection of short duration to observe whether there is any obvious defect/malpractice. Also used as follow up to check compliance with specific previous instructions.

The plan should attempt to assess the risk of different hazards associated with the various inspection points. This information can be used to establish the approximate numbers and types of inspections in each category of inspection points (vessels/establishments/vehicles), to be undertaken during the period. This can be broken down geographically, and by subsector if required. This then sets the target for the inspection department. This information can be further broken down to provide work plans to individual inspectors or groups of inspectors.

The annual plan should be published by the Competent Authority.

## 6.2 Risk – based approach to inspection

The advantage of a risk based approach to inspection is that it improves efficiency in the allocation of resources, allowing them to be focused where they can have a major effect on food safety and public health. A typical approach is to classify the establishments according to high, low and medium risk<sup>7</sup>. This should be undertaken by the Competent Authority, based on scientific knowledge of the hazards in the situation in which they are located.

A typical example might be as shown in Table 2. Note that risk classification of an establishment should be related to the highest risk activity undertaken, and needs to take into account the hazards and risks in the territory covered by the Competent Authority. At the level of the establishment, the assessment of risk should also take into account the compliance record of the individual establishments.

<sup>7</sup> For example, see: “Code of practice on the risk categorisation of businesses to determine the priorities for inspection”, Code of practice no.1/2000, Food Safety Authority of Ireland. <http://lenus.ie/hse/bitstream/10147/44820/1/6377.pdf>

**TABLE 2: RISK CATEGORISATION OF ESTABLISHMENTS**

<b>Risk category</b>	<b>Extent of risk</b>	<b>Fishery product examples</b>
High risk:	Significant potential to put at risk vulnerable groups (elderly, infants, immuno-suppressed) or large numbers of consumers.	Production of ready to eat foods, bivalve shellfish, cooked shrimp, smoked fish, canned fish, frozen fish implicated with histamine production
Medium risk:	Reduced potential to put vulnerable groups at risk, where the distribution may be limited or where the product is to be cooked before consumption;	Frozen fish fillets (non-histamine producers) from aquaculture or freshwater sources
Low risk:	Only a minimal potential to harm consumers	Frozen fish fillets and cephalopods (non-histamine producers) from marine sources

The risk categorisation would then be used to establish a number of operational parameters applied by the inspector:

- Requirements for the design and layout of the establishment
- Frequency of formal approval
- Frequency of interim and spot check inspections
- Level of checks made for certification

### 6.3 Approval system for vessels and establishments

For exports to the EU, factory and freezer vessels, processing establishments, and cold stores should be specifically approved and listed. The technical conditions for approval should correspond to Annex III of Regulation 853/2004.

The approval process should be clearly defined in the procedures of the Competent Authority. The approval process will formally start with an application form, setting out the basic information required for the approval conditions:

- the name and address of the establishment
- sources and species of raw material
- processes to be undertaken
- products to be produced
- specific markets of destination
- number of employees
- production and storage capacities

The Competent Authority should specify which documents should be submitted with an application. Typically, they will include:

- Plans of the establishment at a minimum scale of 1/200 setting out:
  - the establishment facilities and their respective utilisation
  - the flow of products fit for human consumption, and that of products not fit for human consumption
  - the equipment lay-out and its respective utilisation
  - the sanitary facilities (shower rooms, changing rooms and toilets)
  - the plant wash basins and taps
  - the air, smoke and moisture exhaust systems



- the waste water disposal system
  - Water reticulation plan (water outlets or taps serially numbered on the map and in the plant)
  - List of suppliers
  - Specification of process conditions
  - HACCP and quality documentation and record
  - Technical staff CVs
  - The system for handling, storage, and disposal of by-products
  - The pest control system
  - The traceability system
  - Any other formal information (company deeds, land title, lease etc.)

For new establishments, the operator should discuss the design and layout with the Competent Authority at the design stage. Otherwise, there is a risk that costly alterations may be required to a newly constructed establishment before it can be approved. The Competent Authority may consider awarding a provisional approval for new establishments that are in the phase of construction, based on a review of the documents submitted. Final and full approval may be awarded only on the basis of a full inspection of the establishment once it is in operation. This is because the approval should take into account the implementation of the hygiene requirements, including the HACCP system.

The final full audit for approval should then be performed by a team composed of staff from the Competent Authority. This should include the inspector who is routinely responsible for the establishment, plus additional technical specialists as required.

Documentation requirements for factory and freezer vessels are equivalent to those for the shore based establishments (layout plans, water reticulation plan etc.). In addition, they should also submit the GMP documentation, and a control plan in line with HACCP principles, duly documented and followed. Inspection of fishing boats, or freezer or processing vessels (whether nationally flagged or from other third country jurisdictions which request an inspection or certificate of compliance from the Competent Authority) should be arranged by mutual consent when the vessels are in port. Factory and freezer vessels are also required to present a HACCP-based control plan, and will need to comply with the other documentary requirements.

In terms of meeting EU requirements, fishing vessels which are not factory or freezer vessels **do not** need to be subject to individual approval, but they should be subject to regular inspections. However, many Competent Authorities require fishing vessels to have specific sanitary approval, or include these provisions as part of the fishing licence conditions. Similarly, vehicles transporting fishery product, and the ice plants providing ice to the processing establishments or fishing vessels, may also be registered with the Competent Authority, and approved as being in compliance with the specific requirements.

The Competent Authority should always issue an approval document when an establishment or vessel is approved. The approval document should specify details of the establishment and the conditions of the approval as follows:

- Name of establishment
- Location
- Approval number
- Date and period of approval
- Species (or groups of species) and sources of raw material
- Processes to be applied
- Markets (or groups of markets)

The approval should apply to these circumstances only. Should the establishment wish to undertake any activities which are not within the terms of the approval, then a request for a variation of approval conditions should be made to the Competent Authority. This procedure is necessary to prevent an establishment from trying to market high risk products (e.g. cooked shrimp) when it has received approval only for low risk products (e.g. frozen raw shrimp).

The approval period should be finite and subject to periodic conditional renewal. One year is frequently chosen for the validity period. However, this is arbitrary, and a more effective approach would be to choose validity periods based on relative risk. Higher risk establishments or establishments with a record of compliance difficulties, would be subject to more frequent renewal and interim inspections. Low risk establishments, and establishments with good compliance records and well implemented HACCP systems, could be subject to approval periods with longer validity. Since approval renewal will be associated with a cost incurred by the enterprise, this approach would create a financial incentive for compliance.

## 6.4 Inspection frequency

To verify compliance, the Competent Authority performs document checks, pre-approval inspections and verifications *in-situ*, and a final full audit for eventual approval.

The allocation of categories of sanitary compliance is desirable, since it provides an incentive for compliant establishments to improve their standards. It also allows for a quantifiable assessment of the overall standards of the sector, allowing the Competent Authority to monitor development over time, and in response to specific actions or campaigns. The category assigned can determine the frequency of the follow-up inspections, as shown in the following Table 3.

**TABLE 3: CLASSIFICATION AND INSPECTION FREQUENCY**

<b>CATEGORY</b>	<b>STATUS</b>	<b>FOLLOW-UP INSPECTION FREQUENCY</b>
A	Very Good	Every three months
B	Good	Once to twice a month
C	Acceptable	Every week (depends on risk)
D	Deficient	Continuous inspection to up-grade, once the critical deficiencies are corrected

For new vessels/premises the inspections could be more frequent. The frequency of inspection should also take into account previous instructions issued regarding any structural deficiency found during a previous inspection.

## 6.5 Non-compliance procedures

To ensure that official controls are implemented, there is a need for a procedure to be followed when non-compliances are identified. The outcome of the procedure should be that either corrective actions are undertaken by the non-compliant fishery business operator, or that sanctions are applied. The CA should ensure that the following elements are in place:

- Clear written procedures which indicate how the CA will deal with non-compliances detected during inspections, including how the non-compliance is to be notified to the fishery business operator and, crucially, procedures for follow-up inspections; all inspectors should be trained in the procedures.

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- Classification of non-compliances according to the severity of the health risk; severe non-compliances should be treated more urgently and with stronger sanctions than less severe ones;
  - When non-compliance is detected, preparation of a non-compliance summary record sheet for each establishment, recording the following information in relation to each non-compliance:
    1. Non-compliance Number.
    2. Date of inspection
    3. Details of non-compliance
    4. Severity of non-compliance
    5. Date of informal notification for correction
    6. Deadline for correction
    7. Date of follow-up
    8. Finding of follow-up
    9. Date of formal notification for correction
    10. Deadline for correction
    11. Date of follow-up
    12. Finding of follow up
    13. Decision on sanction
    14. Sanction

Record keeping on non-compliances and follow up actions is very important. It should be possible to see at a glance the record of a particular operator in terms of non-compliances identified, corrective actions, and outstanding non-compliances. Over time such a record provides a powerful tool, for example in risk assessment in relation to establishments, or in terms of benchmarking the sector and strata within it. The data may also form part of an annual report, showing how non-compliances are addressed.

## 6.6 Sanctions for non-compliance

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The control system must have a clear system of sanctions to be imposed in cases of non-compliance. To be meaningful, the structure and procedures must be set out in the legislation, and have the force of law. Sanctions may take a number of forms, depending on the severity and extent of the non-compliance, and the apparent response of the business operator to correct it.

Sanctions may therefore include (with increasing severity): refusal to issue a health certificate; suspension of approval (national or international trade); withdrawal of approval (effectively closure of the establishment); fine or imprisonment. Suspension and withdrawal of approval are discussed in more detail below.

Inspectors should be informed of the sanctions procedures to be followed under different circumstances. Frequently, the implementation of sanctions may involve agencies other than the Competent Authority, for example, legal divisions of the host ministry, public prosecutors, and the police. The respective duties and procedures should be defined clearly in the legislation and operating rules of the Competent Authority. Note that an appeals procedure should also be defined.

## 6.7 Suspension or withdrawal of approval

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The approval system must make provision for the suspension and/or withdrawal of approval. These should be legal options defined in the legislation, along with the procedures to be followed. Usually they are last resort actions taken when critical non-compliances are not addressed by the establishment.

*Suspension of approval* means that the establishments ceases to be regarded as listed on the list of approved establishments for a period of time. The limits to the time should be defined in the suspension, either in terms of time or until certain conditions are fulfilled. This means that products may not be marketed, except as specified in conditions attached to the suspension (for example local markets only, certain products or processes only). Once the Competent Authority agrees that the conditions are met, the suspension is regarded as lifted.

*Withdrawal of approval* means that the establishment is permanently and unconditionally removed from the list of approved establishments. After withdrawal, should the establishment wish to become approved again, it will need to commence the approval process once more from the beginning.

## 6.8 Export Certification requirements

### 6.8.1 Nomenclature

WTO Members adopt the Harmonised System of classification for international trade, as determined by the World Customs Union. For certification, whether for tariff or sanitary purposes, the correct codes should be applied. The key definitions relating to fishery products are shown in Table 4, but these codes are extended to 6 figures for a more precise definition (and states have a right to extend them to 8 figures for their own purposes e.g. tariff classes).

**TABLE 4: DEFINITION OF FISHERY PRODUCTS IN TERMS OF HARMONISED SYSTEM TARIFF CODES**

HS code		Description of goods
(a)	0301	Live Fish
	0302	Fish, fresh or chilled, excluding fish fillets other fish meat of heading No 0304«
	0303	Fish, frozen excluding fish fillets and other fish meat of heading No 0304
	0304	Fish fillets and other fish meat (whether or not minced), fresh, chilled or frozen
(b)	0305	Fish, dried, salted or in brine; smoked fish, whether or not cooked before or during the smoking process; flours, meals and pellets of fish, fit for human consumption
(c)	0306	Crustaceans, whether in shell or not, live, fresh, chilled, frozen, dried, salted or in brine; crustaceans, in shell, cooked by steaming or by boiling in water, whether or not chilled, frozen, dried, salted or in brine; meals and pellets of fish, fit for human consumption
	0307	Molluscs, whether in shell or not, live, fresh, chilled, frozen, dried, salted or in brine; aquatic invertebrates other than crustaceans and molluscs, live, fresh, chilled, frozen, dried, salted or in brine; meals and pellets of aquatic invertebrates other than crustaceans, fit for human consumption
(e)	1604	Prepared or preserved fish; caviar and caviar substitutes prepared from fish eggs
(f)	1605	Crustaceans, molluscs and other aquatic invertebrates, prepared or preserved

## 6.8.2 Content of export certificates

Different countries have different requirements regarding the form, content and issuing procedures of the health certificates required for import of a shipment of fishery products. Generally, inspectors are authorised to certify the food safety status of any fishery products. Sometimes an inspector is required to certify that products have been produced in accordance with the importing countries legal requirements. Therefore, a good knowledge of the legislation in the export market may also be required. Inspectors must take reasonable professional steps to ensure that the certification statement is true.

The EU requirements will be described here, since it specifically relates to fishery products imported from a third country. The model health certificates are shown in the Appendix to Annex VI of Commission Regulation (EC) No 2074/2005 of 5 December 2005. Certificates should be drawn up 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, a Member State may consent to the use of an official Community language other than its own.

The terms of the certification are important. The EU certificate requires the signing officer to make a “public health attestation”:

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 VIII, 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

Certification process integrity is important; certificates should be printed forms with consecutive numbering. Certificates and stamps should be kept securely, and records kept of distribution of blank certificates to inspectors. All the information should be provided on a single sheet, and multiple language certificates are acceptable. Copies are generated by having multi-part carbon copy forms. Photocopies are not acceptable. For optimal security, CA's should consider issuing electronic certificates, and placing them on their website for online validation against the certificate number.

### 6.8.3 Export Certification procedures

It is not a specific requirement of EU legislation that the export consignment be sampled and tested before certification, although this may be done if considered necessary. Some countries require a specific certification in terms of certain parameters, in which case sampling and testing may be necessary. Sometimes the time taken to deliver test results can delay or even prevent trade. Therefore, in the case of fresh fish exports only organoleptic or rapid testing should be undertaken.

Sometimes, given the time delays encountered in generating test results, this is often not a practical option (especially for fresh fish).

The certification process should be undertaken by the inspector, who must establish the links between the sample, test result, certificate and fishery products to be exported. The inspector must undertake at least an integrity check, to ensure that any product descriptions and batch numbers indicated on the export documentation match the batch numbers in the export consignment.

HACCP records for the batches being consigned may be consulted, as a means of checking that the production was carried out under controlled conditions. Temperatures of the consignment should be checked where they are critical to the safety of the products (e.g. frozen and chilled products), along with the hygiene of any containers or transport facilities being used.

The inspector should also take steps to ensure that the consignment is not tampered with between the moment of certification and the despatch. If the certification takes place outside a customs controlled area (for example the stuffing of a container at the establishment or cold store), then the consignment should be sealed with an official tamper-proof seal by the inspector after certification.

## 6.9 Annual reports

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The Competent Authority must keep records of all interventions. Using these records as the basis, it should prepare and publish an annual report. This should set out the degree to which the annual plan has been accomplished, in terms of the numbers and types of inspections undertaken, and variances should be explained. The report should also set out the health conditions encountered and how the risks were managed, which should include:

- Results of inspections (categorisation of the establishments, vessels, landing sites etc. and number of non-compliances noted)
- Outcome of non-compliance; actions undertaken, and results of those actions, indicating how the food safety condition was affected
- Numbers and types of certificates issued
- Rejections, rapid alerts, and problems encountered with products reaching export or domestic markets
- Results of any monitoring programmes
- Other information regarding the management of the competent authority (staff deployed, financial income and budgetary expenditure)

## 7 MONITORING PROGRAMMES FOR FISHERY PRODUCTS

This section provides an overview of the arrangements required for the monitoring of the chemical and microbiological safety of fishery products.

### 7.1 Objectives of monitoring

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Monitoring is defined in the Regulation 882/2004 as conducting “*a planned sequence of observations or measurements with a view to obtaining an over view of the state of compliance with feed or food law, animal health and animal welfare rules*”. Article 8 of the Regulation requires that the Competent Authority has in place procedures to:

- Verify the effectiveness of official controls
- Ensure that corrective action is taken when needed

Monitoring is therefore a sampling and testing exercise, undertaken with a view to assessing the status of the health conditions in relation to compliance with the legislation. It provides a means of checking on the effectiveness of the control systems, and as such represents a key component of the internal quality assurance procedures of the Competent Authority. Monitoring is intended to provide the Competent Authority with a clear understanding of the nature and extent of potential food safety problems that might arise in the sector for which they are responsible.

It is **not** intended to be an enforcement exercise. As such it is complementary to, but not part of, the system of official controls. It is a means of providing information to permit a more effective and efficient management of the competent authority resources.

### 7.2 Monitoring plans

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Monitoring programmes should always follow a written plan. The plan should provide a risk based justification for the design of the programme. The plan should be defined in terms of:

- substrates to be sampled
- numbers of samples
- parameters to be tested
- screening protocols
- testing methods
- limits to be applied

After completion of the annual programme, the agency implementing the plan should prepare a monitoring report, setting out the results in terms of compliance levels identified. The design of the monitoring programme, and revising official controls based on its results, should be the exclusive responsibility of the Competent Authority. However, the implementation of the monitoring programme may be contracted to a third party (for sampling, analysis and report preparation). The Competent Authority should ensure that the annual budget provides sufficient resources for the design and implementation of the plan, and for its publication. The Plan and

report should be in the public domain. Examples of the UK RMP and annual reports for residues of veterinary medicines and environmental contaminants are available at:

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/480967/882136-v2-VRC\\_Annual\\_Report\\_2014\\_-\\_AGREED.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/480967/882136-v2-VRC_Annual_Report_2014_-_AGREED.pdf)

### 7.3 Monitoring requirements for fishery products

The EU's requirements for monitoring of fishery products are set out in Annex III of Regulation 854/2004. For exports to the US, the responsibility is placed on the importer to ensure that US regulatory requirements are met. In general, monitoring should cover the parameters set out for official controls as follows:

- |  |
|--|
| <ul style="list-style-type: none"><li>A. Organoleptic Examinations</li><li>B. Freshness Indicators</li><li>C. Histamine</li><li>D. Residues and Contaminants:<ul style="list-style-type: none"><li>• Heavy Metals</li><li>• PCBs</li><li>• Dioxin and Dioxin-Like PCBs</li></ul></li><li>E. Microbiological Checks</li><li>F. Parasites</li><li>G. Poisonous Fishery Products<ul style="list-style-type: none"><li>• Poisonous Fish</li><li>• Fishery Products Containing Biotoxins e.g. ciguatera or shellfish toxins</li></ul></li></ul> |
|--|

However, monitoring should also reflect specific known hazards within the region, for example the historical use in the Caribbean region of certain persistent organic pollutants (such as chlordecone, used in the banana industry) has raised concerns regarding entry in the food chain via run-off into water courses and fish. Such concerns should be reflected in the design of the monitoring programme.

In addition to the general monitoring requirements, there are two specific monitoring requirements set out in the EU law for monitoring of fishery products. These are:

- monitoring relating to the production of bivalve molluscs and
- residue monitoring relating to products of animal origin derived from aquaculture

### 7.4 Monitoring programme for bivalve molluscs

The monitoring requirements for bivalve molluscs, echinoderms, tunicates and gastropods (including conch) are additional and aimed at ensuring their microbiological safety, and that the levels of marine biotoxins are within acceptable limits. In the case of the EU's controls, which are probably the most specific, these are set out in Annex II of Regulation 854/2004.

The features of the monitoring programme are a periodic sampling (every two weeks) of the following substrates from those areas specifically designated and approved for harvest (Table 5).

More information regarding the sampling, testing and action limits for these hazards is set out in the CRFM Guidelines "Guide to Food Safety Hazards in Caribbean Fishery Products" CRFM Special Publication. No. I I.



Written procedures should be in place for rapid closure of the fishery when toxic limits are exceeded, and for public notification and enforcement actions, as well as the criteria for re-opening (specifying the number and period of samples below the limit).

**TABLE 5: SAMPLING REQUIREMENTS FOR MARINE BIOTOXINS**

Substrate	Sampling location	Indicators	Control measures
Live bivalve molluscs (filter feeders)	Production area	<i>E.coli</i> Pathogens ( <i>Salmonella</i> spp, <i>Vibrio</i> spp)	Classification of area for use: A- Consumption live B- Consumption after depuration or cooking C- Consumption only after depuration D- No harvest permitted
		PSP (saxitoxin) DSP okadaic acid/yessotoxin) NSP (brevetoxins) ASP (domoic acid) Ciguatera	Closure of harvest area
Water	Production area	Species of toxin producing phytoplankton	Closure of harvest area
Pectinidae echinoderms, tunicates and gastropods (not filter feeders)	Markets, processing establishments	PSP (saxitoxin) DSP okadaic acid/yessotoxin) NSP (brevetoxins) ASP (domoic acid) Ciguatera	Closure of harvest area

## 7.5 Monitoring requirements for aquaculture products

Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products defines measures to monitor certain substances and residues in live animals and animal products. The Commission publishes guidelines regarding the design, implementation and follow up of monitoring programmes for veterinary medicines in the EU Member States. These are available at:

[http://ec.europa.eu/food/safety/chemical\\_safety/vet\\_med\\_residues/index\\_en.htm](http://ec.europa.eu/food/safety/chemical_safety/vet_med_residues/index_en.htm)

The Directive requires monitoring programmes to be put in place for “aquaculture animals”. That is, it applies only to farmed fish (not fish from capture fisheries). The residue monitoring programme is designed to check that the controls which prevent contamination of aquaculture animals are functioning. The Directive describes two main groups of compounds which must be monitored, shown in Table 6. Clearly not all parameters need to be addressed in all situations. The sampling schedule should be risk based, and relate to the possible practices encountered in the industry.

Inspectors should be aware of the problem areas, and take them into account in the design of the plan. One example might be use of unauthorised substances in the treatment of shrimp diseases. Another might be pesticide run off in freshwater bodies used for aquaculture.

Although compounds in the right-hand column below are not required to be monitored, it should be remembered that these tables have been prepared from a European point of view. There may be some circumstances in third countries which justify a different approach. One example is the European ban on use of anabolic steroids, and their inclusion in Group A compounds. Methyl-testosterone is commonly used as part of the production process for mono-sex tilapia, and should be permitted for this purpose by the veterinary drug control regime. The residue monitoring programme should therefore take this into account.

**TABLE 6: GROUP A AND B SUBSTANCES CONSIDERED IN RESIDUE MONITORING OF FARMED FISH**

<b>Group according to Council Directive 96/23/EC</b>	<b>Requirement for monitoring in aquaculture animals</b>	<b>Not generally required for aquaculture animals</b>
GROUP A - Substances having anabolic effect and unauthorized substances	<p>Stilbenes, stilbene derivatives, and their salts and esters</p> <p>Steroids</p> <p>Compounds included in Annex IV (i.e. banned substances)</p>	<p>Antithyroid agents</p> <p>Resorcylic acid lactones including zeranol</p> <p>Beta-agonists</p>
GROUP B - Veterinary drugs and contaminants, including unlicensed substances which could be used for veterinary purposes	<p>Antibacterial substances, including sulphonamides, quinolones</p> <p>Other veterinary drugs</p> <ul style="list-style-type: none"> <li>- Anthelmintics</li> </ul> <p>Other substances and environmental contaminants</p> <ul style="list-style-type: none"> <li>- Organophosphorus compounds</li> <li>- Chemical elements</li> <li>- Mycotoxins</li> <li>- Dyes</li> <li>- Organochlorine compounds including PCBs</li> </ul>	<ul style="list-style-type: none"> <li>- Anticoccidials, including nitromidazoles</li> <li>- Carbamates and pyrethroids</li> <li>- Sedatives</li> <li>- Non-steroidal anti-inflammatory drugs (NSAIDs)</li> <li>- Other pharmacologically active substances</li> <li>- Others</li> </ul>

Sample requirements are set out in Chapter 3 of the Annex to Directive 96/23, as shown in the following box. Additional requirements for survey design and sampling procedures are set out in Commission Decision 98/179/EC of 23 February 1998 "laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products".

A key aspect of the sampling approach is that for banned substances (Group A), samples are taken during production. Any detectable amount indicates a compliance failure of the sample. For contaminants and permitted substances subject to MRLs (Group B), the presence during production at levels above the MRL cannot constitute a compliance failure, since the production process is not complete. For example, the samples may have been taken during the withdrawal period of a permitted veterinary medicine. For Group B compounds therefore samples must be taken at market level. Finally, it should be noted that the number of samples specified by Directive 96/23 (as set out in the box below) is considered to be a minimum. Sampling rates may be increased and/or skewed to address known or potential food safety problem areas.

**AQUACULTURE PRODUCTS – SAMPLING REQUIREMENTS FOR RESIDUE MONITORING  
ACCORDING TO COUNCIL DIRECTIVE 96/23/EC**

**1. Finfish farming products**

A sample is one or more fish, according to the size of the fish in question and of the requirements of the analytical method.

The minimum number of samples to be collected each year must be at least 1 per 100 tonnes of annual production.

The following breakdown must be respected:

Group A: one third of the total samples: all the samples must be taken at farm level, on fish at all stages of farming, including fish which is ready to be placed on the market for consumption.

Group B: two thirds of the total samples: the sampling should be carried out:

- (a) preferably at the farm, on fish ready to be placed on the market for consumption;
- (b) either at the processing plant or, at wholesale level, on fresh fish, on condition that tracing-back to the farm of origin can be done, in the event of positive results,

In all cases, samples taken at farm level should be taken from a minimum of 10 % of registered sites of production.

**2. Other aquaculture products (non-fish such as molluscs)**

If there is reason to believe that veterinary medicine or chemicals are being applied to other aquaculture products, or when environmental contamination is suspected, then these species must be included in the sampling plan in proportion to their production.

Note that for sea-farming, in which sampling conditions may be especially difficult, samples may be taken from feed in place of samples from fish.

Table 7 describes a typical sample schedule for farmed finfish (such as tilapia) as set out in the Annex to the Directive.

**TABLE 7: TYPICAL MONITORING PARAMETERS FOR FARMED FISH**

Group	Group of substances	Compounds to be analysed	Substrate	MRL/ Action level	No. of samples
A1	Stilbenes	Diethylstilboestrol	Muscle	Not set	50
A6	Annex Table II Commission Regulation (EU) No 37/2010	Chloramphenicol	Muscle	Not set	50
A6	Dyes	Malachite green	Liver		
B1	Antimicrobial substances	Any active agent	Liver	Not set	100
B1	Annex Table I Commission Regulation (EU) No 37/2010	Tetracyclines	Muscle	100µ g/kg	100
B1		Sulphonamides	Muscle	100µ g/kg	100
B1		Quinolones	Muscle	Various	100
B3	Organochlorine compounds	PCBs	Muscle	Not set	100
B3	Chemical elements	Heavy Metals	Muscle	Various	100
B3	Mycotoxins	Aflatoxin B1, B2/G1/G2/M	Feed	Not set	100

## 8 GENERAL GUIDELINES FOR GOOD INSPECTION TECHNIQUES

### 8.1 The inspector

The inspector is an official representative of the Competent Authority, and must exhibit a professional image when dealing with fishery business operators. This includes respect for operators' policies, and maintaining a good level of personal cleanliness and tidiness. They should be well equipped and trained. All information discussed and obtained from a specific company (such as sources of supply and customers) must remain confidential. However, this does not preclude government inspection reports being made available for specific official purposes.

### 8.2 The Inspection sequence

Successful inspections follow a planned sequence of steps, covering:

**Preparation of the inspection:** nomination of inspector or inspection team; definition of the objective, familiarisation with the fishery business operator's file; preparation of checklists, transport and equipment.

**Inspection Preliminaries:** identify person in charge, present identification, explain the reason for the inspection and agree on time frame, inform regarding treatment of results, invite an establishment representative to accompany the inspection team.

**Minimize cross contamination risks:** wear protective clothing, observe the hygiene rules of the establishment, inspection flow from clean to least clean (e.g. start at packaging and end in raw receiving or establishment exterior), utilize hand washing/sanitizing facilities.

**Implementation:** assess establishment working schedule (inspection to be done when operating), bearing in mind need to identify critical control point, review areas of major problems revealed during the last inspection(s).

### 8.3 Inspection procedures

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General procedures to be followed include:

- a) All team members to write up their own worksheet and ratings.
- b) Infractions pointed out to the representative as the inspection is conducted. These infractions are documented, even if they are taken care of immediately (when the correction is also noted).
- c) Ask questions of the operator's representative rather than the workers. Do not make observations or give instructions to the workers.
- d) Set a good example (e.g. when a wash basin is present in the inspection area, wash your hands).
- e) Observe a major clean-up (before start-up or after shut-down);
- f) In storage, mixing, and blending areas, take note of all ingredients, additives, and processing aids, so that they can be verified for compliance with existing regulations.
- g) In the labelling area(s), obtain a sample label of the products for later review
- h) Locate cleaning chemical storage area, note the cleaning compounds so they can be reviewed against the establishment sanitation program, and against a list of approved materials and substances.
- i) Take samples as required, have a clear objective of the reason, notify establishment management of exactly what samples are required, and the purpose of sampling.

### 8.4 Types of inspection

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The inspection may be focused on a particular aspect of the fishery business operation, or general. The following different type of checks can be performed by the inspector.

#### 8.4.1 Documentary Check

The inspection will include a check on the documents submitted as part of an application for approval, as follows:

1. General description of the company, facilities, products and process
2. The company quality policy
3. The description of operations followed, based in the Good Manufacturing Practices principles and Standard Sanitation Operating Procedures (SSOPs)

4. The documented hygiene and sanitation control procedures under the form of specific plans for all regulatory requirements.
5. The HACCP plan
6. HACCP records
7. The description of the product traceability system
8. The documented and formalized withdrawal recall procedures

#### 8.4.2 In-depth inspection

Full inspections can take place only when the fishery business is in operation. It includes an in depth full verification of physical settings, operating conditions, and control strategies concerning the entire production process. They are usually arranged by appointment. The inspection team should:

- Inspect the facility during a full day's operation
- Evaluate the application of all generic good manufacturing practices and specific hygiene control criteria.
- Observe and record deficiencies
- Obtain product samples or other evidence (such as formal statements, photographs) as required (to confirm non-compliances)

#### 8.4.3 Partial inspection

A partial inspection addresses just one or more elements of the operation. For example, to follow up on non-compliances noted during a previous in-depth inspection, within an established deadline date. Another example would be as part of a general campaign by the Competent Authority to address specific aspects of food safety (for example, hand washing or appropriate use of cleaning chemicals).

#### 8.4.4 Periodic programmed inspections:

Interim inspections may be planned, the frequency and depth according to the application of a risk management strategy. Full or partial audits will be applied according to the risk categorisation.

#### 8.4.5 Random Spot checks:

Depending on the Competent Authority's logistical capacity, additional non-programmed inspections could be performed. These are usually unannounced. A particular change in the risk environment may indicate the need for additional checks at certain periods, or in certain areas or types of process, raw material or other reasons.

## 8.5 Inspection outcomes and reporting

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### 8.5.1 Consolidation of inspection results

When the inspection is finished, the team of inspectors should meet privately to compare notes and arrive at a consensus on the inspection results. All deviations found during the inspection that require corrective action are then identified in writing (the Inspection Report).

As well as showing specific findings, the Report should summarise the overall standard of the establishment or vessel. The conditions of the system will be assessed, and the company awarded a category, generally ranging from “Very Good” to “Deficient”.

The non-compliances noted will provide a basis for prioritizing corrective action, re-inspection and compliance activities. The report will also determine the need for, and frequency of, routine follow-up inspections.

#### 8.5.2 Final Management Meeting

The Inspection Report allows the operator to know the inspection findings, and the reason why certain items are unsatisfactory and require correction or improvement. Therefore, after the inspection, the inspection team should meet with appropriate member(s) of the establishments’ management team to present the Inspection Report, highlight unsatisfactory conditions, and to discuss and decide on a time period or a date for the correction of these conditions.

Corrective action should always include an element ensuring that that the problem will not recur. Urgency of corrective actions must always be measured by the degree of existing hazard related to health and safety issues.

An action plan identifying each critical and major deviation should be required from establishment management. Each deviation should be clearly identified with an agreed correction date. This action plan is to be reviewed with and signed by a responsible party from management who shall retain a copy of this document.

#### 8.5.3 Inspection Report Forms

The Inspection Reports forms should contain at least:

- The establishment identification and contacts
- Date
- Inspectors participating
- Objective of the inspection (scope and purpose)
- The results of the inspection
- An overall assessment of compliance (and seriousness of non-compliances observed)
- Corrective actions to be taken and deadline
- Signature of the inspector
- Name and signature of the responsible representative of the business operator

The form must be signed and dated by the representative of the Competent Authority, and the manager of the establishment, or the captain of the vessel. A copy of the finalised report form should be presented to the management of the establishment or captain of the vessel, at the final management meeting. One copy should be entered in the company file organised by the inspection office.

All the corrective actions requested, and deadlines, should also be recorded on a (internal to the CA) non-compliance record for that establishment. The records should be available at any time to permit a proper follow up of deficiencies found during the inspection.

#### 8.5.4 Formal Report and Covering Letter

As soon as possible, a printed copy of the Inspection report should be formally delivered to the management. The report must be accompanied by a covering letter, requesting a written action plan by the agreed date, and indicating the consequences of not meeting the request.

#### 8.5.5 The Company's Written Corrective Action Plan

The written action plan subsequently submitted by the company should be formally evaluated. It should address all the deficiencies reported in the inspection report i.e. long term and short term. An incomplete action plan is not acceptable and should be returned to the company for correction. If an acceptable action plan is not submitted within the appropriate time frame, the inspector should contact the company as a reminder. Non-response may be grounds for the suspension of certification by the Competent Authority. Further action should be taken if the management remains uncooperative.

#### 8.5.6 Non-Compliance

When non-compliance is detected during an inspection, the inspection team should follow the established non-compliance procedure determined by the Competent Authority. In particular, the following steps should be taken:

- All incidences of non-compliance must be recorded in the inspection report.
- Additional actions may need to be taken if non-compliance is detected, depending on the seriousness.
- The response of the Competent Authority should take into account the severity of the findings and/or level of responsibility taken by the establishment.
- The impact of the deficiencies must be evaluated to determine if product safety has been compromised, and what actions, if any, the establishment has taken to determine that the product is safe.
- If the establishment has not demonstrated to the inspector that a batch of product is under control or safe, it should be detained, or other action taken that may be deemed necessary to control the batch (and any others subjected to the same conditions) until it is further evaluated.
- Laboratory analysis of affected lots may be requested to determine the product's safety. The cost of such investigation could be covered by the establishment.
- Establishments which are found not to have notified the Competent Authority when defective conditions are evident, should be subject to sanctions.
- The Competent Authority may authorise the continuation of production under certain circumstances (e.g. permanent inspection, limited production or marketing).
- The Competent Authority and the Company should consider whether withdrawal or recall is necessary.
- If potentially contaminated product has been distributed, and a recall is to be initiated, the inspector should immediately contact the officer responsible for the rapid alert system in place at national level, with the relevant details.

#### 8.5.7 Persistent non-compliance

Special actions may be required where there is repetitive inaction by the establishment management, either to formulate an action plan or to carry out corrective actions.

Once it is determined that discussion and monitoring have been ineffective in achieving compliance, a meeting should be arranged with the appropriate person to explain the deficiencies, and why they must be corrected. The meeting should end with a mutually agreed action plan being developed, with commitment for its implementation.



If subsequent directed inspections do not indicate satisfactory corrective action, and it is felt that compliance will not be forthcoming, steps to cancel or suspend approval may be initiated, following the established non-compliance procedures.

## 9 CHECKLISTS AND RECORD KEEPING SYSTEMS

### 9.1 Types of checklist used

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Checklists provide a useful guide to inspectors by acting as aide memoires during inspections. They can cover sanitary requirements, HACCP, and traceability systems. Different forms can be developed for vessels, establishments and aquaculture farms, or for different subsectors. Checklists which present categories of risks (e.g. ranging from minor to critical, in relation the potential severity of their consequences) are preferred to those to which answers given are “Yes” or “No” only. Note that checklists should be modified to suit the circumstances and should be periodically reviewed by their users.

#### 9.1.1 Checklist for Hygiene Conditions

Hygiene checklists should address the basic points of location, design and layout, construction, facilities, personnel, hygiene conditions etc. Examples of checklists are provided in the Annexes to the relevant CRFM Manuals concerning fishing vessels and fish landing and processing establishments. Many of the variables do not change between inspections (e.g. location or layout) and need not be assessed each time. In the case of an inspection focused on specific aspects, or following up of previous inspections, the check list can be shortened as necessary.

#### 9.1.2 Verification of HACCP systems

No HACCP plan can give good results unless a well-structured prerequisite plans is implemented, taking care of essential hygiene regulatory requirements. HACCP verification should therefore take place only when the establishment has satisfactorily demonstrated that the basic hygiene requirements have been complied with. Examples of checklists for HACCP Plan verification and HACCP implementation are given in Annex I.

#### 9.1.3 Checklist for traceability systems

The traceability system should be assessed, to ensure that all elements are in place. This will include checks on supplier and customer records, proper batch coding and separation of batches during processing and storage. The existence of withdrawal and recall plans should be checked as well, together with evidence that their feasibility has been tested. More information and an appropriate checklist is provided in the CRFM Manual for Implementation of Traceability Systems for Caribbean Fishery Products.

### 9.2 Keeping Records of inspections and results

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Inspection reports and checklists have to be registered into a secure system of documentation control. Records may be held in paper files or computerised formats.

Computerised data bases provide a powerful tool for keeping a record of all official interventions. They provide the additional benefit of:

- Requiring a structured approach, for example in ensuring that there is a proper follow-up of corrective actions
- Allowing analysis of trends (same establishment over time, comparison of sectors)
- Easy collation of results for annual reporting (e.g. no. of non-compliances identified and corrected)
- Reducing inspector discretion in decision making (thus protecting from external influences)

## 10 ALERTS AND CRISIS MANAGEMENT

### 10.1 Need for an alert system

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Modern food distribution systems are so extensive and rapid that the appearance of food hazards in one area often requires control measures to be implemented elsewhere. Alert systems allow for effective communication between authorities responsible for food safety. Examples are the EU's Rapid Alert System for Food and Feed (RASFF), and the US FDA system of import alerts. Both provide means of notifying inspectors and operators regarding the risk of non-compliant products being placed on the market. Information from both is publicly available, and should be regularly reviewed by Competent Authority risk managers. National Competent Authorities should develop national networks to ensure that relevant information received at the international level is communicated domestically.

### 10.2 Types of alert

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The EU system is described on the RASFF home page at: [http://ec.europa.eu/food/safety/rasff/index\\_en.htm](http://ec.europa.eu/food/safety/rasff/index_en.htm)

There are two kinds of RASFF notifications: market notifications and border rejections. A member of the network sends a market notification when a risk is found in a food or feed product placed on the market. A border rejection is sent when a product was refused entry into the Community. There are two types of market notifications: alert and information notifications.

- **Alert notifications** are sent when the food or feed presenting the risk is on the market and when immediate action is required.
- **Information notifications** concern a food or feed for which a risk has been identified, but for which the other members of the network do not have to take immediate action, because the product has not reached their market.

The Commission manages a RASFF database, on which all details of the alert and information notices are entered as they are received by the Commission. Some of the data from this searchable database are available to the public via the internet through the RASFF portal. Annual reports are published, and available on the RASFF home page.

**TABLE 8: EXAMPLE OF AN RASFF ALERT NOTIFICATION**

**Notification details - 2014.0705** ✕

arsenic (2.828 mg/kg - ppm) and mercury (1.327 mg/kg - ppm) in frozen shark steak (*Carcharinus spp*) from Suriname

Reference:	<input type="text" value="2014.0705"/>	Notification type:	<input type="text" value="food - alert - official control on the market"/>
Notification date:	<input type="text" value="21/05/2014"/>	Action taken:	<input type="text" value="withdrawal from the market"/>
Last update:	<input type="text" value="09/10/2014"/>	Distribution status:	<input type="text" value="distribution to other member countries"/>
Notification from:	<input type="text" value="Netherlands (NL)"/>	Product:	<input type="text" value="frozen shark steak (Carcharinus spp)"/>
Classification:	<input type="text" value="alert"/>	Product category:	<input type="text" value="fish and fish products"/>
Risk decision:	<input type="text" value="serious"/>	Published in RASFF Consumers' Portal:	<input type="text" value="has never been published"/>

Follow-up :

Reference	Follow-up from	Date	Follow-up type	Info
inf01	Norway	23/05/2014	outcome of investigations and measures taken	
inf02	Commission Services	09/10/2014	lifting of reinforced border checks	

**Hazards**

Substance / Hazard	Category	Analytical result	Units	Sampling date
arsenic	heavy metals	2.828	mg/kg - ppm	31/03/2014
mercury	heavy metals	1.327	mg/kg - ppm	31/03/2014

Countries/organisations concerned (D = distribution, O = origin)

Source: EU RASFF [http://ec.europa.eu/food/safety/rasff/index\\_en.htm](http://ec.europa.eu/food/safety/rasff/index_en.htm)

### 10.3 How to respond to alerts

The receipt of data from any alert from an export partner should be integrated within the national food safety system. This should be prepared concurrently with the crisis management plans, setting out, for example, the procedures to be followed for recall or withdrawal of products from the market. The key requirement is to define responsibilities for named individuals/posts and ensure an effective communication system between them. This will often involve several organisations such as Veterinary Directorate, Agricultural Inspectorate, Phytosanitary Department, Public Health Department, Local Government departments. There should be a system for release of selected relevant information to the public and industry via website, press release, contacts with industry, and consumer associations. The procedures should be written in a manual, and periodically tested and refined in mock exercises.

### 10.4 Follow up and crisis management

The entire reason for the existence of traceability system becomes evident when a food safety problem is identified, and there is a need to withdraw or recall products from the market. When products produced by enterprises within the responsibility of the Competent Authority are found to be unsafe, then the Competent Authority must work with the business operator concerned, to ensure that the potential risks to consumer health are eliminated, or reduced.

Rapid alerts should always be followed up. The steps to be taken should be specified by the Competent Authority in a crisis management plan.

- The traceability system of export businesses operators should be used to identify the source of the hazard and the reason for it arising.
- Control systems of the business operators concerned should be re-appraised with a view to preventing or minimising re-occurrence of the hazard.
- The competent authority and the business operator should consider the need to initiate withdrawal or recall procedures.
- Report to the Commission on the findings and steps taken

The Crisis management plan should detail the procedures to be followed in each of the above steps, and indicate the specific responsibilities of the various staff and organisations concerned.

The Competent Authority should ensure that information from the alert is used to guide the prioritisation of food safety risks associated with the fishery product exports.

The Crisis Management Plan should also provide information to the CA in the export destination when it detects a potential food safety hazard in products which may have been exported to that country.

## 10.5 Product withdrawal and recall

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Withdrawal from the market requires the food business operator to:

- cease marketing the product or batch concerned when any affected products or batches of product are held in stock
- inform distributors of the problem, so that any affected products or batches of product held in stock are not marketed

Recall from the market requires the food business operator to:

- undertake the above actions as for a product withdrawal
- ensure that any products which may have reached the consumer, but have not been consumed, are not consumed, and are returned to the seller
- provide information to consumers regarding actions to take should the product have been consumed

In both cases there is a need for the food business operator to work under the guidance of, and in collaboration with, the Competent Authority.

A sound food safety law should require food business operators to withdraw food products from the market if they “believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements” (as set out in EU Regulation 178/2002). The responsibility is placed on the operators of the business. In addition, there should be a duty to implement a recall from consumers of product which might already be in their possession. The CA should have powers to mandate withdrawal and recall if this is not undertaken by the business operator.

The recall and withdrawal procedures in the fish export business may involve an international dimension. The need for close collaboration with Competent Authorities in the EU or other

countries should be reflected in the written procedures. Special consideration is also required when raw materials are derived from other third countries e.g. landings from foreign fishing vessels



## Annex 1: Model Inspection form for HACCP system and implementation

### Checklist for the Initial assessment of a HACCP plan

HACCP System for the Quality Assurance - Document			
a) Facilities and Process Description	Yes	No	Comment
Company/section general description providing sufficient information?			
Commitment for quality clearly expressed, including HACCP?			
Management layout and description of responsibilities given?			
HACCP Team:			
HACCP team assembled?			
Coordinator designated?			
Adequate qualification and experience available in the team?			
External resources employed to increase technical capacity?			
Project schedule and objectives (if applicable)?			
Personnel informed about the objectives and the company quality commitment?			
Products:			
Products description clear and complete?			
Origin and specifications of raw material given?			
Composition, packaging, distribution, validity, storage condition?			
Lot identification code providing suitable traceability			
End User Identified:			
Sensitive consumers identified?			
Instructions given for the distribution, storage and utilisation?			

Processing Specification:			
Detailed flow diagram for each product or type of similar products?			
CCPs indicated on diagram?			
Flow diagram confirmed?			
Chart showing the plant layout / products, materials and personnel flow?			
<ul style="list-style-type: none"> <li>• Process description</li> <li>• Reflect standard procedures (SSOPs),</li> <li>• Clearly documented?</li> </ul>			

b) Pre-requisite Programmes	Yes	No	Comment
PP1. Proper general condition of facilities and interferences with surrounding areas under control?			
PP2. Layout preclude cross contamination and dangerous air currents?			
PP3. Adequate Pest Control?			
PP4. Personnel health monitoring:			
Systematic initial medical check?			
Systematic periodic monitoring?			
Daily (at least random) verifications?			
PP5. Personnel hygiene control?			
PP6. Personnel continuous training/sensitised to hygiene concerns?			
PP7. Facilities cleaning and sanitation:			
Properly designed and programmed: feasibility?			
Adequate hygiene control of toilets and other facilities for the personnel?			
PP8. Water quality control:			
Water available as necessary, distribution diagram?			



Automatic treatment system adapted and operational?			
Monitoring of residual chlorine content if added?			
Surveillance of contamination indicators in place. Sampling plan adequate and systematically followed?			
PP9. Preventive maintenance of equipment and tools?			
PP10. Raw materials specifications:			
Regarding fish freshness/quality?			
Regarding the reception conditions/specifications?			
Regarding the condition of transport and storage?			
Regarding the origin verification and coding to keep the trace?			
PP11. Other ingredients and packaging materials specifications:			
For the ingredients?			
For the packaging materials?			
PP12. Codification and labelling system making able to keep the traceability up and down?			
PP13. Operations and systems for the disposal of solid and liquid waste?			

c) Application of HACCP Principles P (principle as in CODEX HACCP application guidelines)	Yes	No	Comment
P1. Hazard analysis:			
All reasonable hazards have been considered at each step?			
Their incidence/probability was evaluated and the relevant risks addressed (risk assessment)			
Preventative measures identified to control each relevant risk.			
P2. Determination of critical control points (CCP):			
The Critical Control Points were identified?			

Adapted preventative control measures were identified for each CCP?			
P3. Adoption of Critical Limits for each critical parameter:			
All critical limits established?			
Are the specified limits valid taking into account published or experimental evidence?			
P4. Adoption of a monitoring procedure for each critical parameter:			
The system mention what to check, where, when, how, who?			
Monitoring continuous or frequent?			
Systematic recording and verification established? (forms?)			
P5. Corrective measures established for each critical parameter:			
Realistic and effective corrective measures adopted for each Control Point			
Destination of non-suitable products established?			
P6. Verification procedures in place:			
Are the procedures providing real tools for verification?			
Specific forms are adopted, including signatures?			
P7. Documentation system:			
Are all the records available, including those concerning control actions?			
Data available from monitoring procedures?			
Information on corrective actions taken/rejection/destination?			
Data on the verification actions available?			
Calibration of instruments?			
P8. Internal audits plan for the system verification adopted?			
P9. System established for the withdrawal/recall of defective products?			

## Checklist for HACCP implementation

ELEMENTS OBSERVED/ASSESSED	DEFECTS				
	Mi	Ma	Se	Cr	Comments
<b>1 MODIFICATIONS</b>					
1.1 Modifications non communicated or approved					
1.2 Modifications of critical parameters non-approved					
1.3 Trained technician non available					
<b>2 RECORDS</b>					
2.1 Records not up to date					
2.2 Falsified or non-trustable records					
2.3 Documents falsified					
2.4 Records non available					
<b>3 OWN-CONTROL PLAN MANAGEMENT</b>					
3.1 Preventative measures not followed					
3.2 Monitoring procedures not followed					
3.3 Corrective measures concerning critical aspects regarding consumer health, not taken/registered					
Total deviations					