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**DIRECTORATE FOR FOOD, AGRICULTURE AND FISHERIES
FISHERIES COMMITTEE**

WORKSHOP ON SEAFOOD INSPECTION

Held on 21-23 January 1998

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FOREWORD

The Workshop on Seafood Inspection was convened in Paris on 21-23 January 1998 under the auspices of the OECD Committee for Fisheries. This document contains the papers that were submitted to the workshop proceedings. Accordingly, the papers are accurate reflections of the seafood inspection issues and institutions at the end of 1997. The document begins with a short introductory note that provides a brief description of the origin and context of the workshop. The note also outlines the response of the Committee for Fisheries to the workshop's main recommendations.

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INTRODUCTION

The Workshop on Seafood Inspection was convened in Paris on 21-23 January 1998 under the auspices of the Committee for Fisheries. The results of the workshop were reported to, and discussed by, the Committee at its 81st Session on 18-20 March 1998. The purpose of this note is provide a brief description of the origin and context of the workshop. This note also provides the response of the Committee for Fisheries to the workshop's main recommendations.

Background

In recent years, concern has been expressed by members of the Committee for Fisheries that no international organisation, with the exception of Codex Alimentarius of the Food and Agriculture Organization of the United Nations (FAO), has given consideration to seafood inspection procedures and systems which are vital in assuring access to wholesome seafood. Moreover, differences in seafood inspection regimes often have caused trade disruptions resulting in financial losses for seafood exporters and higher prices for consumers.

Most OECD member countries have in recent years begun to implement a food inspection known as Hazard Analysis and Critical Control Point ("HACCP"). The HACCP principles aim at giving greater assurance of product safety without relying on finished product inspection of domestically-produced and imported seafood. Several OECD member countries have or will have, in varying degrees, mandatory programmes of HACCP in the near future.

In a global context, HACCP could ostensibly emerge as the common system for seafood inspection. In light of this trend, there is a growing need to determine a degree of equivalency. At this point however, the major problem to a successful determination of equivalence of different systems is the varying degree in the HACCP system's application.

Equivalency is defined as the capability of different inspection and certification systems to meet the same objectives. In determining equivalency, one must recognise that inspection and certification systems should be organised for the risk involved, taking into consideration that seafood items produced in different countries may present different hazards, and that control methodologies can be different but achieve equivalent results. As an example, sampling and strict application of sound seafood processing practices, with limited end product testing for verification purposes, may produce a result equivalent to extensive end product testing for quality in products. Equivalence controls should result in reduced frequency and intensity of controls by the importing country.

Cognisant of the changing environment and practices involving seafood inspection and the efforts by competent authorities to address equivalency, the Committee saw significant value in providing a forum for the discussions on these matters. Following a proposal by Iceland, at the 78th Session on 1-4 October 1996, the Committee for Fisheries agreed to hold a Workshop on Seafood Inspection.

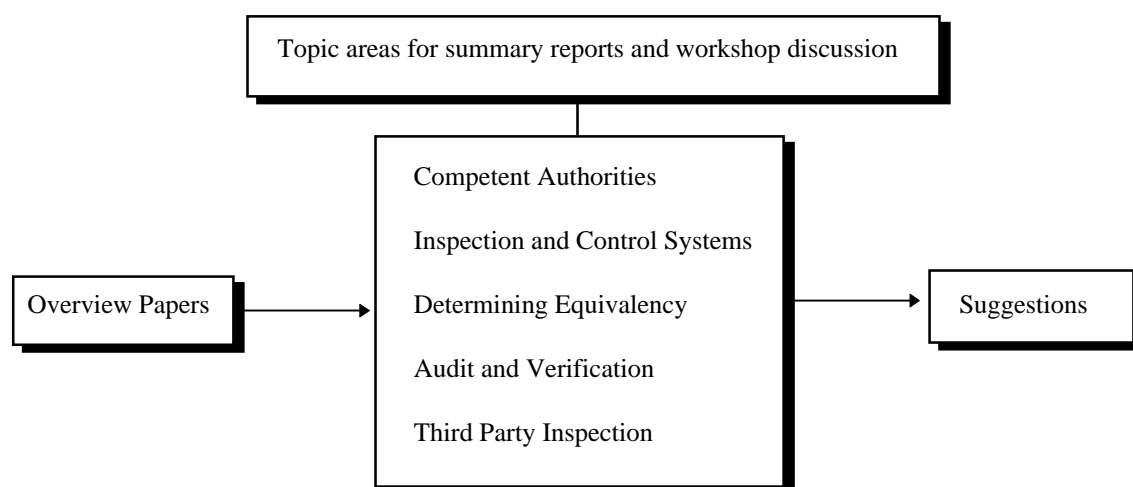
A steering group was established, comprised of representatives from Iceland (co-ordinator), Canada, Japan, Ireland, Mexico and the United States. Participation in this group was open to all Member countries.

The Workshop Process

The workshop was divided into five discussion sessions. These discussion sessions were chaired by “facilitators”. Discussion in each of the sessions was based upon presentations of summary reports prepared and distributed before the workshop. These reports drew from information contained in the country overview papers which were submitted by participating countries. Although in total 19 overview papers were submitted, there was not sufficient time to include all the papers in the summary reports. A large amount of information was submitted and summarised in the process of preparing for the workshop.

The discussions in the workshop were managed in such a way to work towards some specific suggestions. By the end of the workshop the group reached consensus on a number of issues raised. In addition a large number of observations were noted. The workshop process for synthesising the information from Member countries is illustrated in figure 1.

Figure 1. Workshop Process



Participants

There was a good level of representation from Member countries. There was senior level representation from the relevant agencies in key seafood importing and exporting countries. This considerably enhanced both the quality and significance of the dialogue. In addition, representatives from Lithuania, the Republic of Estonia and the Russian Federation prepared overview papers and contributed to the discussions. Reports were received from 16 Member countries and 3 observing countries.

Experts from the FAO and the European Free Trade Association Surveillance Authority also attended and actively contributed to the discussions.

General Impressions

The workshop was welcomed by participants as an extremely valuable opportunity for an exchange of views on seafood inspection matters. Participants noted that the OECD provided a useful forum since it is not a formal negotiating context, nor is it a forum where disputes are heard. This relatively informal setting allowed the participants, who would normally meet in more structured contexts, to exchange views with considerably more freedom. While differences obviously remain, opportunities exist for improved understanding of the legislation and regulatory controls used by countries in seafood safety matters.

The FAO participants were especially enthusiastic about the workshop. There may have been some initial fears that this would duplicate the work of the FAO Codex Alimentarius Committees. However, these fears were dispelled and the FAO participants appreciated the quality of the workshop discussions. At the end of the workshop, the view was expressed that workshops of this kind complement the more formal work of the Codex Committees.

Workshop Suggestions

The participants at the workshop reached a degree of consensus on a number of issues. The participants also agreed that further discussions and joint work are needed in the field of seafood inspection. Several suggestions and observations were made, some of which actually relate more to improved understandings and clarifications rather than to specific actions. However, there were three distinct suggestions that the participants felt were important that for the OECD to pursue. These suggestions from the workshop were discussed by the Committee for Fisheries at its 81st Session on 18-20 March 1998. The Committee's response to each of these suggestions is shown below.

Suggestion 1: The Secretariat Internet website include a specific section on identifying the competent seafood inspection authorities in Member countries. This will serve as a valuable point of reference.

Committee response: The Committee recommended the establishment in the Secretariat website of a section relating to seafood safety. Member countries are to submit information to the Secretariat using the matrix in Annex I. For those Member countries who have an Internet site for their relevant seafood inspection authority, the site address can be submitted to the Secretariat instead.

Suggestion 2: A forum be held to discuss the criteria for seafood inspectors involved in conducting audits of other countries' inspection and control systems. Auditing and verifying seafood plants requires well trained and qualified personnel. As auditing and verification methods change, so too should the skill and qualifications profile of the people performing these important tasks.

Committee response: The possibility of a further workshop on guidelines for seafood inspectors would be considered in the context of the future discussions on the post-1999 Programme of Work.

Suggestion 3: The Committee for Fisheries work with other Committees in the OECD to co-ordinate with Codex Alimentarius in facilitating, perhaps through workshops, a better understanding by Member countries of the WTO Agreements on Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT).

Committee response: The value of improving the understanding of WTO Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) Agreements was noted. Future Committee discussions

could, in the context of the post-1999 Programme of Work, explore how the Committee could contribute to an improved understanding of these matters.

Committee Appreciation

The Committee for Fisheries wishes to express its appreciation for the work of the Steering Group for organising the workshop. In particular, the Committee appreciates the work of the co-ordinator of the Group: Mr. Gylfi Petursson from the Icelandic Ministry of Fisheries.

**ANNEX I: INFORMATION MATRIX: COMPETENT AUTHORITY AND ORGANISATION
STRUCTURE OF FISH AND FISHERY PRODUCT INSPECTION SYSTEM**

Legislation and Regulation		Export	Import
		Name: Contact: Address: Telephone: Fax: E-mail:	Name: Contact: Address: Telephone: Fax: E-mail:
Operation	Product Inspection	Name: Contact: Address: Telephone: Fax: E-mail:	Name: Contact: Address: Telephone: Fax: E-mail:
	Listing of Approved export plants/facilities	Name: Contact: Address: Telephone: Fax: E-mail:	
	Issue of Certificates	Name: Contact: Address: Telephone: Fax: E-mail:	

Definitions:

Name: Name of the Official/Recognised Inspection Authority

Contact: Person designated by the Official/Recognised Inspection Authority.

ANNEX II: FAO TECHNICAL ASSISTANCE**Comments by Mr. Gregory Orriss, Chief, Food Quality and Standard Services, Food and Agriculture Organization, Rome**

There are a number of important factors driving the process of strengthening food quality and safety measures in OECD countries. Consumer protection and the facilitation of the international trade in food are two of these important factors.

The WTO Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) Agreements have also resulted in new obligations and rights for member countries. These Agreements have established the ground rules for establishing and applying food quality and safety measures and reference the Codex Alimentarius standards, guidelines and recommendations as the benchmark in this area.

The increased rigour behind the Member countries food safety and quality measures will result in improved consumer protection and trade opportunities for OECD Member countries. It will also present significant challenges to developing countries wishing to export food to the OECD countries.

Growing interdependence among the world's food markets presents increased opportunities for food trade. However, while the Uruguay Round Agreements result in reduced tariffs, quotas, and other readily identifiable barriers to trade, the regulatory changes taking place in a number of OECD countries have the potential to result in new trade barriers based on differing sanitary and technical requirements especially since some of the changes in requirements are being pursued independently. The development of sanitary measures and requirements that differ from the Codex standards, guidelines and recommendations could have a negative impact on trade into these markets and may be inconsistent with the provisions of the SPS and TBT Agreements. It is therefore important that efforts to harmonise sanitary requirements with international standards be reinforced and that efforts to achieve consensus in the adoption of international standards be pursued.

Most developing countries, especially the least developed, presently have neither the capacity nor the resources to face the challenges and take advantage of the opportunities flowing from the WTO SPS and TBT Agreements while also preparing themselves for the next round of multilateral trade negotiations. Therefore, there is a need to provide technical assistance to assist these countries.

Article 9 of the SPS Agreement, *Technical Assistance* directs contracting parties to facilitate the provision of technical assistance to other contracting parties, especially developing country contracting parties, either bilaterally or through the appropriate international organisations to allow such countries to adjust to and comply with, sanitary or phytosanitary measures necessary to achieve the appropriate level of sanitary or phytosanitary protection in their export markets.

Article 11 of the TBT Agreement, *Technical Assistance to Other Members* includes that contracting parties, if requested, are to advise other contracting parties, especially the developing country Members, on the preparation of technical regulations. It also provides that technical assistance be

provided regarding the establishment of national standardising bodies, and participation in the international standardising bodies.

Consumer protection and successful trading globally will be greatly enhanced where standards and legislation are harmonised based on Codex standards, guidelines and recommendations and where effective food control systems are in place. There is however much work to be done, particularly in developing countries, in establishing or harmonising food legislation with international requirements and strengthening food control administrative and technical capacities to ensure adherence to the legislation.

FAO is prepared to provide the necessary technical assistance and seeks to collaborate closely with other national or international organisations in this regard. The type of technical assistance provided varies according to the needs of the country and the availability of resources. Short seminars and workshops, funded from FAO's Regular Programme and often supported by contributions from the private sector, have been used to address specific technical issues and to inform government officials, industry and consumers about the relevance of Codex and its relationship to the WTO SPS and TBT Agreements. Longer term development projects such as revision of national legislation, strengthening food control administration and technical capacities and the up-grading of physical facilities are funded through FAO's Technical Co-operation Programme or by external donors.

FAO's Food Quality and Standards Service has a strong comparative advantage in providing technical assistance and advice to developing countries and countries with transitional economies as a result of: its responsibility for the Secretariats of the Codex Alimentarius Commission and the Joint FAO/WHO Expert Committee on Food Additives; its close relationship with the World Trade Organisation's Committee on Sanitary and Phytosanitary Measures and Committee on Technical Barriers to Trade; and the strong technical competence and experience of the professional staff. The Food Quality and Standards Service also benefits from the expertise of other technical divisions in FAO in providing assistance and advice that is based on scientific evidence and that is current and appropriate to the international environment.

The SPS and TBT Agreements advise contracting parties to play a full part, within the limits of facilitating the active participation of developing country contracting parties in the relevant international organisations. FAO will continue to provide technical assistance to contracting parties in this regard.

SUMMARY PAPERS

COMPETENT AUTHORITY DESCRIPTION AND ORGANIC STRUCTURE

by José Luis Flores Luna, Ministere de la sante, Mexico

Introduction

OECD countries have legislation that define the competent authorities who have the responsibility to emit regulations and to define the competent official organisations to manage inspection systems to control and to inspect requirements of production, processes and fish and fishery products commercialisation, import controls and official certification systems.

Resources have been invested in order to establish the rules that must be accomplished by the products as well as the means to obtain such products. Codex guidelines have served as a reference to harmonise such rules. In addition, it has advanced on the conditions that the competent official institutions require in the design, operation and implementation of inspection and certification systems of foods. These conditions must be met in order to provide to the consumers with fish and fishery products that are safe, wholesome, properly labelled, and are not fraudulent.

Organisation and operation of the official inspection systems implemented in each country has its own unique characteristics. They are influenced by the consumers to whom the products are provided and the areas or premises to be controlled and inspected, the country development, and the government available resources to accomplish the functions and responsibilities, and with many other factors of different nature.

The experience on the development of an audit system of official inspection systems, like that presented by the European Community in its purpose on creating a single market without borders, is a valuable background. It is possible to learn from the conditions that need to be fulfilled when promoting a global food market, while at the same time protecting consumers.

This document's purpose is to give a general overview of the competent authorities in the OECD countries, and their organic structures, in a systematic way in order to identify and highlight similarities and differences. In addition, this document focuses on the characteristics of the competent authorities and their organisations in order to identify some critical issues that would then promote their understanding and improvement.

Definitions

For the purpose of this paper, some terms are taken or are interpreted from the definitions contained in the Principles for Food Import and Export Inspection and Export Certification Systems (CAC/GR20-1995).

Official inspection systems and official certification systems: systems administered by a government agency having jurisdiction empowered to perform a regulatory or enforcement function or both. For the purpose of this paper, this definition is divided into **competent central authority** and **competent authority**.

Competent central authority: the government organisation empowered by the country legislation to establish food commerce requirements. Such requirements embrace those intended for the public health, consumer protection and the suitable conditions for a fair competition.

Competent authority: the competent official organisation empowered to execute various functions. In addition, it manages the official systems of inspection or certification at the regional or local level.

Officially recognised authority: the officially authorised organisation, or recognised by a competent official organisation, that manages the inspection and certification systems.

Subsidiary principle: the principle that establishes the responsibility among the EU Member States and the European Commission. In the subsidiary principle, the Community legislation neither establishes neither the harmonised requirements, nor the functioning of the national official inspection systems. For these reasons, each Member State must be consulted by the European Commission, in order to make the respective reports about the national structures. The European Commission assesses the capacity of the competent National authorities and the performance of their inspection systems.

Legislation to protect the consumer and to promote the fair competence

Each OECD country has established legislation to protect the health of consumers and to promote fair competence. Fishery products, production, process, and commercialisation must formulate requirements that establish responsibilities for the product and the means used by companies to obtain products that conform with the requirements. Countries have developed their legislation years before Codex Alimentarius was created. Of course, countries now tend to use the guidelines given by the Codex in order to establish their own regulations.

In a single market (e.g. the EU), harmonisation of the existing national regulations in order to eliminate controls at internal borders was facilitated by the adoption of four guidelines that provide a legal framework for the harmonisation of the fishery inspection systems. This framework must comprise a certain flexibility so it can be adapted into national legislation.

While the adoption of guidelines for common markets is desirable, the natural differences in development levels, as well as the differences in official inspection systems, makes this a difficult task. Even the EU Member States, who have dedicated themselves to the harmonisation process, have not met the relevant Council guidelines on putting into full operation control and inspection systems of fish and fishery products.

Company responsibility

The product requirements are safety, wholesomeness, proper labelling and essential quality. Countries have established different requirements in response to consumer needs. The competent central

authorities have consider to have the scientific bases to sustain these requirements and whether there is the infrastructure to support the inspection system.

The means used to obtain the product in the food chain must conform to requirements. Such obligations cover the environment where the product is cultured or harvested, the fishery boats, the landing ports, the process establishments, the warehouses and transportation. Good sanitation practices, good catch or “aquaculture” or manufacture practices are required, as well as self-controls that the enterprises are responsible for.

Even though the HACCP (Hazard Analysis and Critical Control Point) system has around for some years, it has in a relatively short time an accepted approach in international commerce. Central competent authorities sometimes sustain it as voluntary scheme that is required by the importing country. Sometimes it complements the existing requirement framework of good manufacturing practices, or self-controls based on the HACCP principles. In some other countries it is a mandatory requirement for the processor. In these cases, risk analysis is a valuable tool when decisions are made.

Competent Authorities’ Responsibility and Functions

There are fundamental differences, even among OECD countries, on how governments are structured. There are federal countries or centralist ones. Countries with vocation of food exporters; others that are large consumers and importers. There are raw seafood exporters and some that export value added products.

In some countries the central competent authority is the responsibility of the Health Ministry (Germany, Spain, Italy, Japan, Mexico, and USA). In others the responsibility lies with the Agriculture Ministry (Canada, France, New Zealand, Great Britain, Denmark, and Greece). In other countries it is the responsibility of the Ministry of Fisheries (Korea, Ireland, and Iceland).

Some governments establish co-existing systems that make a distinction among the local consumer and the foreigner consumers. Countries have legislation that empowers the Health Ministry as the competent authority for the commercial products on the local market and they have another legal framework for inspection and certification for food for export. Frequently, the system for certification of exports is designed to promote improved flexibility and opportunity to assign special resources, and to adapt to importing country requirements. Large consumers influence the competent authority and systems in other countries (e.g. shellfish sanitation systems in Korea, Mexico and New Zealand).

In spite of differences, there are conditions and components that governments should strive for (See Annex I).

Conditions:

The central competent authority needs to be vested by basic law and the competent authorities (regional or local) empowered by legislation. Conditions, components and functions should be developed by a transparent process. A risk analysis framework should be set up to conduct risk assessment and manage the available resource to cope with risk situations to assign priorities based on sound science (and also perceptions of risk and political sensibility). The risk analysis will assist in defining the objectives of the system.

Components:

An inspection system requires infrastructure including: legal framework, control programme and procedures, criteria and decision making, facilities, equipment, transport and communications, laboratories and personnel (trained and independent).

Certification systems should be provided with the same components as the inspection system. If not, there should be scope for sharing resources with the inspection system.

Audit and verification methods are an integral in ensuring that inspection and certification systems achieve their objectives.

If third party test laboratories, inspection units or certification bodies are officially recognised by competent authorities, an official accreditation system should be developed to assess technical and management capabilities and independence of judgement.

Inspection Systems and Infrastructure

Consumer characteristics and technology have an important influence on requirements and the inspection and certification systems. Examples include: EC directives on self-checks based on HACCP principles; the FDA's HACCP regulation in seafood processing companies. Both regulations are intended to assure that products are safe. Inspection and certifications systems from foreign countries wishing to export to the EU or to the USA need to integrate verification and audit techniques to assure that companies have an effective HACCP system in place.

There are also requirements and special inspection systems in some countries to control labelling characteristics and essential product quality. For example, Japan where the Ministry of Agriculture Forestry and Fisheries manage the Japanese agricultural standards, there are essential standards for specific items which are to be graded.

Self-checks or HACCP regulations assume that companies in the food chain have achieved a degree of technological development that allows them to design and implement a quality assurance management type system. This is not always the case. The same is true with regard to the state of competent authority infrastructure and personnel capabilities.

Inspection and certification systems are designed, implemented and operated taking into account the number of areas and premises that need to be inspected or verified, their characteristics, and their geographic distribution. Use of electronic systems for data management and communication can improve the efficiency of risk analysis and thus make the most use of scarce resources.

Diminishing budgets, downsizing, and increased demands from exporters, importers and consumers, increase the need for assistance from other government authorities, regional or local competent authorities, private third party test laboratories and certification bodies. Access to assistance is essential for developing the legal framework and formal mechanisms necessary to evaluate competence and independence. Confidence from consumers, industry and government can be achieved only if the competent authority establishes a system to control the delegated system. Timing of internal development of the system together with importing country's acceptance is vital.

Responsibilities and Functions of the Supranational Institutions

The document provided by the European Commission has interesting information on the responsibility and functions of this supranational institution. The removal of controls at the internal borders of the European Union, in addition to the harmonisation requirements existing regulations, created the necessity that the European Community has the right to supervise the application of its guidelines for the EU Member States.

Such right is exercised primarily by the control of the transposition of the Community guidelines into the national legislation of Member States. Second, the right is exercised by on-site verifications of the application of the guidelines. The EU Member States must provide all the assistance to Commission experts. The supranational audit system for assessment and verification of existing systems is still being developed and it is based on the subsidiary principle. These experiences establish patterns which could be of use in the formation of other free trade markets.

Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS)

Globalisation of trade, evidenced by reduced tariffs scheduled under the WTO/GATT Agreements, is a driving force to develop mechanisms for new rules in food trade so as to ease access to global markets and protect consumers. The Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) has been working to develop guidelines on components, conditions and functions that systems require in order to achieve good performance in the protection of consumers. These guidelines will ease the development of equivalence agreements or the acceptance of such systems by the importing countries, and as a result, to promote the international commerce in safe, wholesome and properly labelled foods.

Future work should follow in the same direction. It should consider that organisational structures of competent authorities have characteristics of their own. Government design and implementation of its organic structure is influenced by multiple factors. However, CCFICS provides a model to assist competent authorities redesign and improve their systems.

Country Profiles

A summary of documents from Germany, Canada, Korea, USA, Iceland, Japan, Mexico and New Zealand are shown in Annexes II and III.

Critical Areas

- Product requirements: safety, wholesomeness, proper labelling, economic fraud, and essential quality characteristics.
- Self-controls based on HACCP principles versus the HACCP unrestricted application.
- Application of risk assessment to assign priorities in the design, implementation and operation of inspection systems. Future work must address conditions and practical applications.

- Impact of changes on: competence redistribution; reinforcement of inspection systems; standardisation; widening scope and increasing demand; development of audit and verification systems; on competent authority and organisational structure.
- Considerations about the needs that OECD members have in relation to CCFICS work.

ANNEX I

Design, operation, assessment and accreditation of food import and export inspection and certification systems (Alinorm 97/30, Appendix II)		
<p>Risk Analysis</p> <p>Quality assurance</p> <p>Equivalence</p> <p>Equivalence agreements</p> <p>Define the principal objective</p> <p>Transparency</p>	<p>Infrastructure of the system of inspection and certification</p> <p>Legal framework</p> <p>Control program and procedures</p> <p>Criteria and decision making</p> <p>Facilities, equipment, transport and communications</p> <p>Laboratories</p> <p>Personnel</p>	<p>Official accreditation</p> <p>System of certification</p> <p>Assessment and verification of existing systems</p> <p>Procedures for conducting an assessment and verification by an importing country of inspection and certification systems of an exporting country</p>

ANNEX II

a) Competent Official/Delegated Inspection Authority

Member States	Central Authority		Delegate authority	Private Third Parties
	Foreign trade	Local market		
Canada	Fish Inspection Directorate from the Ministry of Agriculture and Agri-Foods			Agreement is now being negotiated with SCC for third party laboratories
Germany	Federal Health Ministry		Ministries of Laender/ District government/ Vet. Office of county	Authorised Plant Laboratories for own checks. Accredited Private Laboratories on behalf of the company for own checks system
Iceland	Directorate of Fisheries under the Ministry of Fisheries		Accreditation Department of the Icelandic Metrology and Accreditation Service – Swedish accreditation body	Testing laboratory Inspection Body
Japan	Veterinary Sanitary Division from Environmental Health Bureau of the Ministry of Health and Welfare / Ministry of Agriculture, Forestry and Fisheries (MAFF)		Governors of any prefecture, some majors of cities and special ward in Tokyo Inspection bodies from MAFF, Prefectures government	No third parties for seafood safety Third party bodies called “registration and ranking bodies”
New Zealand	Ministry of Agriculture Regulatory Authority & Quality Management	Ministry of Health	Domestic Local Council Crown Health Enterprise	
Mexico	General Directorate of Sanitary Quality of Goods and Services & General Directorate of Environmental Health under Ministry of Health		State Public Health Services	Testing laboratory Inspection Units Certification Bodies (in development)
Korea	National Fisheries Product Inspection Service from the Ministry of Maritime Affairs and Fisheries	Korean FDA & National Quarantine Station from the Ministry of Health and Welfare	Local Food and Drug Offices	
USA	Food and Drug Administration under Department of Health and Human Services NMFS under Dept. of Commerce. Voluntary Inspection/ Certification Services for Domestic and Export		State Health Agencies State governments NFPA	Testing laboratories for import entries

b) Laboratories, staff number and training

Member States	Laboratories	Staff Number	Training
Canada	7 regional labs	397	New staff: BS and a 2-year development program. Training in GMP, HACCP and audit techniques, product evaluation, sensory workshop
Germany	National Reference Laboratory of Medicine Laender Laboratories Authorised Plant Laboratories for own checks. Accredited Private Laboratories on behalf of the company for own checks system		Veterinary Staff: University study of veterinary medicine with final examination. Approbation by government body. Every veterinary surgeon is under the obligation for continuous education by approbation order and veterinary chamber statutes Food inspectors: Completed schooling in a main school plus job training or at least 2 years of working experience. Participation in a re-training course at least every 3 years.
Iceland	Private test laboratories accredited by the Accreditation Department of Metrology and Accreditation Services		Assessment of inspection bodies, testing bodies and certification bodies is divided into two parts: the quality system and the technical assessment in conformity with EN 45000 standard and Icelandic regulations, and which fulfil the provisions of impartiality. This system came into effect beginning 1998.
Japan	The MHW has 3 laboratories Centre for quality control and consumer service inspects and analyses the quality of the products		Qualifications of food sanitation inspectors are graduate studies in medicine, dentistry, veterinary science, animal husbandry, the science of fisheries or agricultural chemistry in universities or colleges. Completion of prescribed courses in training institutes designated by the MHW for two or more years. The qualifications to be a registration and ranking body are: (1) (1) Experience in inspection of products for more than 5 years; (2) High school graduate with experience of inspection of products for more than 3 years; (3) University graduate or similar school and mastered the techniques of production of foods with experience in inspection of products for more than 1 year.
Korea		135 inspectors specialist	

Member States	Laboratories	Staff Number	Training
Mexico	National reference laboratory; 2 Approved state laboratories; 13 accredited and approved private laboratories (all foods)	DGCSBS have 84 officials in inspection/ compliance (all foods)	<p>New inspectors or compliance officials are BS in chemistry, biology, and veterinarian science or food technology. Completion of training course in quality management, regulations, GSP, HACCP and policy and procedures. And at least 3 month on the job training.</p> <p>Accreditation / Approval of inspection bodies and certification bodies is integrated by the quality system and the technical assessment of conformity with NMX standards and with Mexican regulations to fulfil the provisions of independence. No private inspection or certification body approved yet</p>
New Zealand	Approved laboratory services are available to undertake analyses (species verification, mishandled product assessments, residue analysis, water testing and microbiological analysis)		<p>Travelling Meat Inspectors are required to have: Completed specialist training appropriate to areas of responsibility. Including in the training is a section on fish, post mortem changes in seafood, freezing and storage of fish, quality assurance, inspection and audit of premises and certification. Specialist training in areas such as canning, shellfish management and fishing vessel inspection are undertaken where these tasks are required.</p>
USA	17 regulatory laboratories (all foods) 4 laboratories dedicated to seafood safety research	<p>FDA has 394 in seafood related activities.</p> <p>NMFS has a staff of 179 in the Seafood Inspection Program.</p>	<p>FDA newly hired investigators require BS or higher in biological science, chemistry, pharmacy, physical science, food technology, nutrition, medical science, engineering, epidemiology, veterinary medical science, or related scientific fields or a combination of equivalent education and experience. They are required to take FDA courses in Food and Drug Law, Interviewing Techniques, Evidence Development, and Quality Auditing. Laboratory personnel require a bachelor's or higher degree consistent with the field of analyses. They may also take nationally available training such as analytical techniques for seafood or organoleptic analysis of seafood.</p> <p>Hiring qualification for NMFS inspectors are similar to FDA's. The training specialists of Technical Services, and the Quality Team are continually updating their training activities which include inspection procedures for fishery products, low-acid canned foods, sensory analysis, HACCP principles and implementation, auditing practices, European Union requirements, and retail food safety.</p>

ANNEX III

Name of the Country: Canada

1. Description of competent authority (National laws that provide legal authority to central competent authority)

The Fish Inspection Directorate (FID) is responsible for enforcing:

- The Fish Inspection Act (FIA) and the regulation made thereunder (Fish Inspection Act, R.S.C., 1985 c. F-12 as amended by R.S.C., 1985 c.31 (1st supp.) Statutes of Canada, 1992 c.1; Fish Inspection Regulations made under the Fish Inspection Act, C.R.C., 1978 c.802.
- The Food and Drugs Act and Regulations R.S.C. 1985 c. F-27 (Foods , Division 1; Food Additives 16; and Marine and Fresh Water Animal Products, Division 21).
- The Consumer Packaging Act and Regulations, c. 38 1970 -71 -72 c.41, s.1. (Product identity declarations; Net quantity declarations; Dealer's name and address; General exemptions; Non-mandatory information; Packaging).
- Management of the Contaminated Fisheries Regulations Order under the Fisheries Act of Canada P.C./C.P. 1990. 1120.

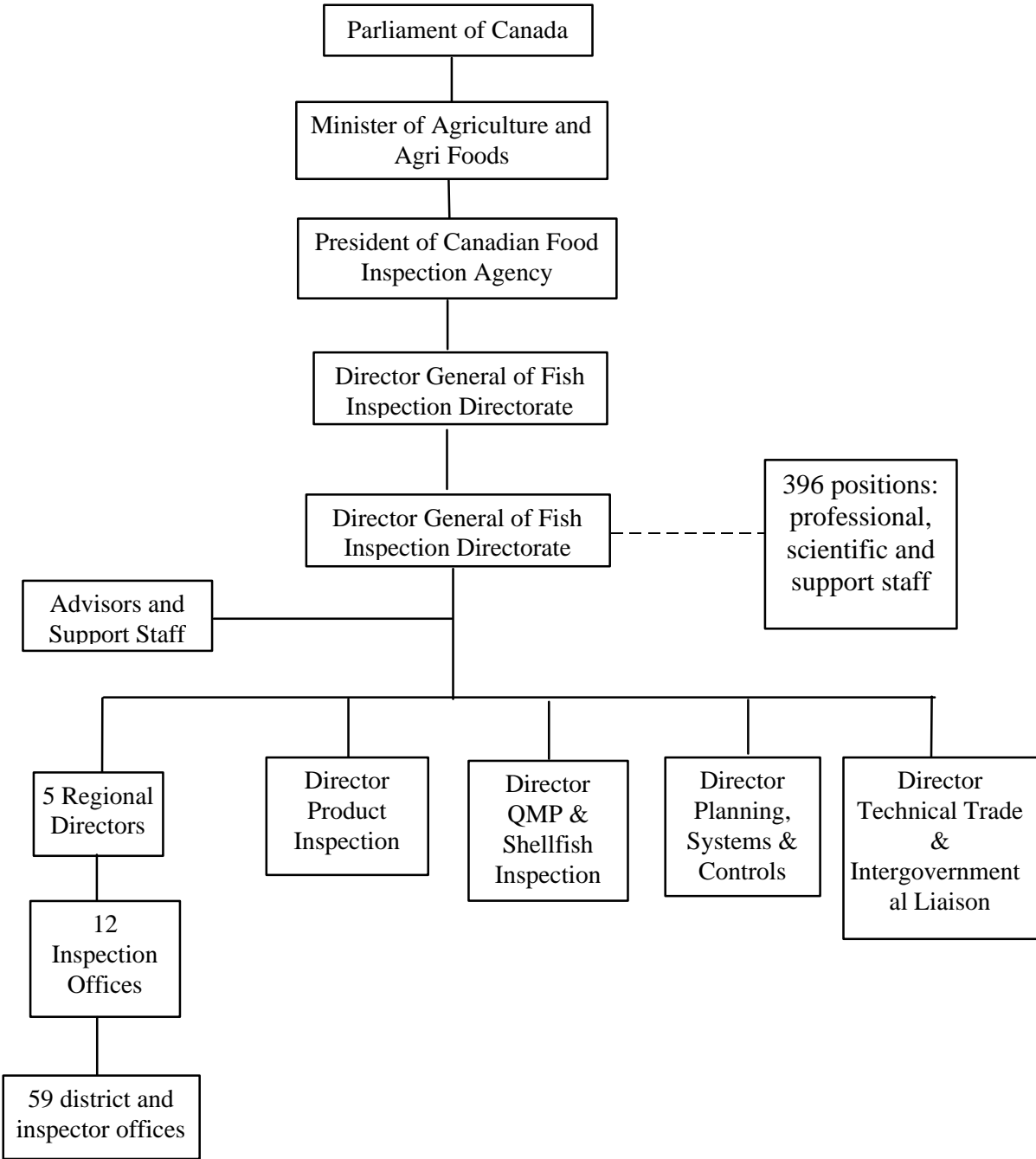
2. Powers of authorities

The FID of the CFIA administers, applies and enforces the FIA over all fish and fish products and marine plants intended for export, inter provincial trade and all fish imported into Canada. It is responsible for the overall administration of the FIA which is designed to ensure that fish and fish products and marine plants are harvested, transported and processed under conditions such that marketed commodities meet national and international standards of wholesomeness, quality, composition, packaging, and labelling.

The FID does not recognise the use of third party inspection systems.

3. *Organisational structure (inspection and compliance)*

Figure 1: **Organisational Structure in Canada**



4. *Laboratory services to support the program*

The laboratories of the Fish Inspection Directorate are well equipped for the inspection and determination of quality and safety: chemical and microbiological. There are 7 regional labs. An agreement is now being negotiated with Standards Council of Canada for the accreditation of Third party private inspection laboratories for use in QMP.

5. *Human resources*

Criteria for the assignment of number of inspectors and compliance officers per number of establishments monitored are by geographic size and various other workload factors (such as number of molluscan shellfish sites, registered facilities, fish import centres, etc.).

Training requirements. Minimum academic training required for all new staff is a Bachelor of Science, with some positions requiring further training. And a two year development program during which time senior inspectors and supervisors provide on the job guidance, training and evaluation of GMP, HACCP and Audit techniques (Facilities evaluation), Product evaluation, Sensory workshops and other training modules.

Table 1: Human Resources of the Fish Inspection Directorate

Region	Newfound land	Martimes	Quebec	Central and Arctic	Pacific	National Head Quarters	Total
Field	57	88	31	35	31	0	242
Laboratory	10	24	12	12	13	0	71
Programme Management	6	9	5	6	7	14	47
Administration Support	5	10	4	7	8	3	37
Total	78	131	52	60	59	17	397

Name of the Country: Germany**1. Description of competent authority**

Germany is bound by European Community law. In principle national legislation transposes Community legislation. Decisions of the European Community are recommendations unless transposed into national law or made officially known by the Federal Health Ministry.

National Legislation:

- Food and Commodity Law (Lebensmittel- und Bedarfsgegenständegesetz)
- Fish Hygiene Order (Fischhygiene-Verordnung)
- Official publication of the EC-Decision on HACCP in fishery product plants

European Community Legislation:

- Directive 91/492/EEC: Live bivalve molluscs
- Directive 91/493/EEC: Fishery products, as modified by Directive 95/71/EC
- Directive 92/48/EEC: Fishing vessels - Freezer vessels
- Decision 93/25/EEC: Heat treatment - bivalve molluscs and gastropods
- Decision 93/51/EEC: Microbiological criteria - crustaceans and shellfish
- Decision 93/140/EEC: Parasites
- Decision 93/351/EEC: Mercury
- Decision 93/383/EEC: Biotoxines - Laboratory
- Decision 94/356/EEC: HACCP
- Decision 95/149/EC: TVBN
- Decision 95/328/EC: Health Certificates - Fishery products
- Decision 96/333/EC: Health Certificate - live bivalve molluscs
- Decisions concerning imports of fishery products from certain countries are numerous and are constantly changing due to inspection results or the disease situation (e.g. Cholera)

2. Powers of authorities

2.1 Central Competent Authority (CCA):

Federal Health Ministry (BMG) in Bonn with responsibilities of Preparing national legislation, especially transposition of EC directives into national legislation; co-ordination of interpretation of food hygiene legislation within Germany; representing the Federal Republic of Germany at the European Community level in Brussels (Foreign Policy). No direct technical or administrative supervision of the Laender in relation to food legislation enforcement

2.2 Competent Authority (CA):

Ministries of the Laender (usually Ministries in charge of Agriculture, Rural Areas, Nutrition, Environment, Social Affairs or Health). Their responsibility is executing food legislation and its enforcement in the respective land; Delegation of responsibilities to subordinate administrative bodies, e.g. responsibility of approving plants, in some Laender; Technical supervision of subordinate administrative bodies. In most Laender, however, no administrative supervision of subordinate bodies

2.3 Regional Competent Authority (RA):

District Governments (not existent in all of the Laender). Their responsibilities are approval of food processing establishments; technical supervision of subordinate county veterinarians. In most Laender no administrative supervision of county veterinarians

2.4 Local Competent Authority (LA):

Veterinary Office of the county. Its responsibilities are Food law enforcement; inspection service (hygiene inspections) and, training of inspection personnel (veterinarians, food inspectors)

2.5 Use of Third Parties' Inspection Bodies:

None in the frame of law enforcement.

Remark: Companies are free to use the services of consultant firms to establish their own controls, which is frequently done, especially regarding the HACCP system or quality management programs.

3. Organisational structure

Germany is a Federal Republic consisting of 16 Laender, which are bound by federal laws and orders, however, independent in the means of carrying out and enforcing those laws. Federalism and the subsidiary principle are unchangeably rooted in the Grundgesetz (constitution). Law enforcement competence of the Federal Government is constitutionally restricted to Foreign Affairs and National Defence.

4. Laboratory services to support the program

4.1 Federal Laboratories

National Reference Laboratory for Marine Biotoxins at the Federal Institute for Consumer Health Protection and Veterinary Medicine

4.2 Laender Laboratories:

Veterinary / Chemical Investigation Offices: Scientifically qualified staff. Responsibilities are Analytical investigation of food and food-related hygiene (microbiological, chemical, physical and sensory investigations); Sampling at the plant in some Laender (in others sampling on the spot is carried out by the OVS; Transposition of national residue testing plans; Food monitoring investigations).

4.3 Private Laboratories

- Authorised Plant Laboratories with responsibilities of own checks of companies
- Accredited Private Laboratories with responsibilities of analysis of samples on behalf of the company within the own checks system

5. Human resources

I. Veterinary staff:

a. Veterinary Offices:

5 years of University study of veterinary medicine including several basic training in food hygiene and ending with a final examination (state examination). Approbation by government body and enlisting in veterinary register (veterinary chamber). Promotion (in former days required, nowadays optional). Additional government training course including another final examination (examination for state veterinary service): Information on changes in legislation and co-ordination of interpretation are forwarded down the veterinary hierarchy to the Veterinary offices in regular intervals and whenever necessary. Every veterinary surgeon is under the obligation for continuous education by approbation order and veterinary chamber statutes and may e.g. prove compliance by joining federal veterinary chamber bodies like Academy for veterinary continuous education (Akademie für tierärztliche Fortbildung - ATF-) which officially recognises the education potential in seminars, meetings, congresses and similar events in all fields of veterinary practice and veterinary service and certifies participation

b. Veterinary investigation centres:

5 years of University study of veterinary medicine including a final examination (state examination). Approbation by government body. Promotion (in former days required, nowadays optional)

II. Non-veterinary staff

a. Veterinary offices

Food inspectors. The general requirements are laid down in the Food Inspectors Order (Lebensmittelkontrolleur-Verordnung). Specification of training courses, final examination and re-training is under the responsibility of the Laender. Successfully completed schooling in a main school plus successfully completed job training or at least 2 years of working experience in a food related job, police administration service or general administration job plus months of successful training in a food hygiene course (including a final examination). Participation in a re-training course at least every 3 years.

b. Veterinary investigation centres

Chemist, biologist, microbiologists. Ordinary study in university with final examination.

Name of the Country: Iceland**1. Description of competent authority:**

Directorate of Fisheries (DOF) under the Ministry of Fisheries is the central competent authority. The Accreditation Department of the Metrology and Accreditation Services performs the accreditation of inspection bodies; testing bodies and certification bodies in accordance with the Weights, Measures and Accreditation Act No 100/1992

2. Powers of authorities**2.1 Central competent authorities**

The Ministry of Fisheries sets all main rules and issues all necessary regulations and It is responsible for the interpretation of Icelandic Regulation being consistent with EC Directive 91/493 and any others that are relevant. It is planned for the DOF to withdraw from direct inspections wherever possible once accredited inspection bodies take over and concentrate instead on monitoring the work of the inspection bodies.

The Directorate of Fisheries will provide the Metrology and Accreditation Service with technical expertise for audits; It will undertake surveillance of inspection bodies and licensed producers; It will measure the effectiveness of the system; It will undertake any aspects of surveillance that cannot be accommodated within the accredited inspection body system; It is responsible for licensing of producers providing that conditions have been fulfilled, cf. Art. 12 Act No 93/1992; And approval of inspection bodies cf. Art. 14 No 93/1992 providing that the set conditions have been fulfilled (e.g. accreditation) and to rescind approval if these conditions cease to be fulfilled; It will issue public documents of certification where demanded.

2.2 The Accreditation Department of Metrology and Accreditation Services

This Department performs accreditation of inspection bodies, testing bodies and certification bodies. Its role is to assess and declare the competence and impartiality of parties. The assessment is divided into two parts: the quality system assessment and the technical assessment in conformity with EN 45000 standard and Icelandic regulations, and which fulfil the provisions of impartiality.

2.3 Private third party bodies

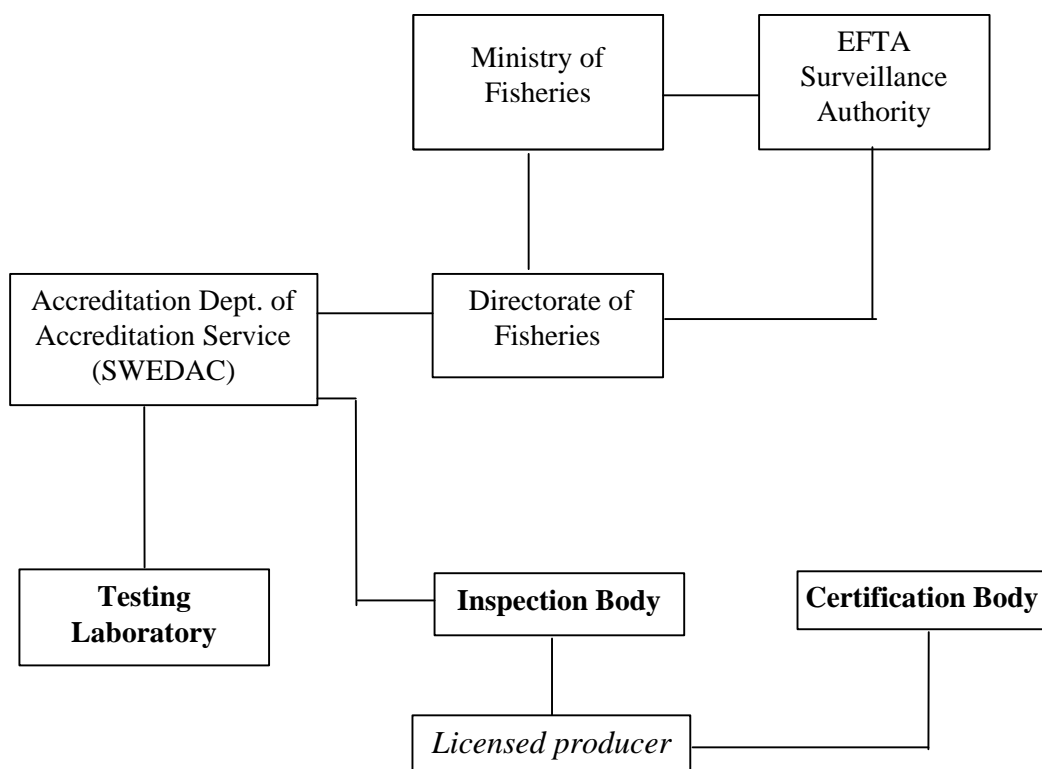
Inspection bodies shall undertake inspection of the conditions for production and the placing on the market of fisheries products, including plant inspection and own checks of processors which are licensed as producers. They shall supply the DOF with regular information on the state of the licensed producer, which do not fulfil the defined competence requirements, and on request.

Test laboratories supply analytical services to producers/processors when testing is conducted by outside parties.

Certification bodies cannot perform a direct role in inspection of producers/processors. Certification bodies may be expected to perform an important role in certification of quality systems to the ISO 9000 and ISO 14000 standards, where part of the certification is conditional upon an own checks mechanism based on the principles of HACCP.

3. **Organisational structure (inspection and compliance)**

Figure 2: **Structure of Seafood Inspection in Iceland**



4. **Private test laboratories**

4.1 Accreditation by the Accreditation Department of Metrology and Accreditation Services with the collaboration of Swedish accreditation body SWEDAC

4.2 Official analytical methods: Council directive No 88/320/ECE, Appendix B, on good laboratory practice. Requirements of testing laboratories, in accordance with EN 45001.

The methods to verify competence and impartiality of parties conducting inspections, testing and certification have been described in ISO Guides, while in Europe CEN has described them in its EN 45000 series of standards. These standards have also been adopted in Iceland (ÍST EN 45000).

Name of the Country: Japan

1. Description of competent authority:

1.1 Central competent authority

1.1.1 Seafood safety and hygiene:

The Ministry of Health and Welfare (MHW) enacts the Food Sanitation Law; The Enforcement Ordinance (Cabinet order); The Enforcement Regulations (ministerial ordinance) and; The Standards and specification of food

1.1.2 Quality of Seafood

The Ministry of Agriculture, Forestry and Fisheries (MAFF) established the quality and labelling standards called Japanese Agricultural Standards (JAS) which are based on the Law Concerning Standardisation and Proper Labelling of Agriculture and Forestry Products.

1.2. Other local / regional authority

1.2.1 Seafood safety and hygiene:

Under article 17 of the Food Sanitation Law, MHW, the governor of any prefecture, the mayor of any city establishing health centres or any special ward in Tokyo shall appoint food sanitation inspectors to execute inspection of establishments or to collect samples or any action required.

1.2.2 Quality of Seafood

Inspection bodies from the MAFF, Prefectures government and private Third parties evaluate quality and labelling. Those products that pass the standards are permitted to attach the JAS mark.

Third party inspection bodies are called “registration and ranking bodies”.

2. Powers of authorities

2.1. Seafood safety and hygiene:

2.1.1 Central competent authorities (CCA)

The Food Sanitation Law provides specific authority for the MHW to establish standards pertaining to: Seafood safety; hygienic and sanitary conditions and practices in a processing facility; the labelling of seafood; license for business; others (method for the breeding of fish and shellfish)

The Veterinary Sanitation Division, Environmental Health Bureau, MHW is the central competent authority responsible of the interpretation and planning of the Food Sanitation law, its Enforcement Ordinances and Enforcement Regulations concerning seafood safety.

MHW is also vested with the authority to direct and supervise.

2.1.2 Local / regional authorities

Inspections of fish and fishery product processing facilities are carried out by each prefecture's designated inspectors, in Japan system, such affairs are to be handled by the CCA and the prefectures are to take charge of the affairs on behalf of CCA.

2.1.3 Private third party bodies

The MHW does not designate a non-government organisation as the responsible authority for seafood or seafood inspection.

2.2 Quality of Seafood

2.2.1 Central competent authorities (CCA)

The Centre for Quality Control and Consumer Service, which is the inspection body of MAFF, surveys and directs to registration and ranking bodies and producers who produce the food attached JAS mark, and monitor the food from a point of view to secure reliability of the system.

2.2.2 Local / regional authorities

Regional agricultural administration offices and Local food agency offices, which belong to MAFF, direct the food which is the object of the quality labelling standards in the quality labelling standards system in co-operation with the Centre for Quality Control and Consumer Service. Prefecture government also directs about labelling, collection of reports, making of inspections, acceptance of the request from consumers and surveillance by the mandate from CCA.

2.2.3 Private third party bodies

The ranking based on JAS is done mainly by registration and ranking bodies.

3. ***Organisational structure (inspection and compliance)***

3.1 *Seafood safety and hygiene:*

Actual inspection of fish and fishery product processing, manufacturing, preparing and holding facilities and sampling of products are to be carried out by each prefecture's food sanitation inspectors. At the end of 1997, there are 845 health centres and 7,367 food sanitation inspectors.

3.2 *Quality of Seafood*

Centre for quality control and consumer services: 8

Regional agricultural administration offices and Local food agency offices: 47

Prefecture governments: 47

Registration and ranking bodies: 5

4. ***Laboratory services to support the program***

4.1 *Seafood safety and hygiene*

The MHW has 3 laboratories: 1) The National Institute of Infection Disease, 2) National Institute of Public Health, 3) National Institute of Health Science. The laboratory should comply with standards established under the Ministerial Ordinance Article 18-6. The standard is based on Good Laboratory Practice in accordance with ISO/IEC Guide 25 (General requirements for the competence of calibration and testing laboratories). The applicable methods of analysis are those stipulated in the standards and criteria (notification of MHW) directives issued by the MHW addressing the metropolitan and prefecture authorities, and in guidelines for the inspection of food sanitation (compiled under the supervision of the MHW).

4.2 *Quality of Seafood*

Centre for quality control and consumer service inspects and analyses the quality of the products which are made in authorised factories

5. *Human resources*

5.1 *Seafood safety and hygiene*

Qualifications of food sanitation inspectors are graduate studies in medicine, dentistry, veterinary science, animal husbandry, the science of fisheries or agricultural chemistry in universities or colleges. Completion of prescribed courses in training institutes designated by the MHW and nutritionists who have engaged in work related to food sanitation for two or more years or more.

Training for beginner's, middle and expert stage: 3 day HACCP training course; 2 day training for inspectors of facilities authorised to process fish to be exported to the US; 3 days training for inspectors of facilities authorised to process fish and fishery products to be exported to the EU; HACCP verification training by the government (2 day on site training) for prefecture food sanitation inspectors. In addition, the National Institute of Public Health the MHW's education, training and research centre, conducts the Food Sanitation Control course for food sanitation inspectors (a month course), which includes HACCP and GLP.

5.2 *Quality of Seafood*

The qualification to be a registration and ranking body are: (1) Experience in inspection of products for more than 5 years; (2) The person who graduates from high school and who has experience of inspection of products for more than 3 years; (3) The person who graduates from university or similar school and mastered the techniques of production of foods and who has experience in inspection of products for more than 1 year.

Name of the Country: Korea

1. Description of competent authority

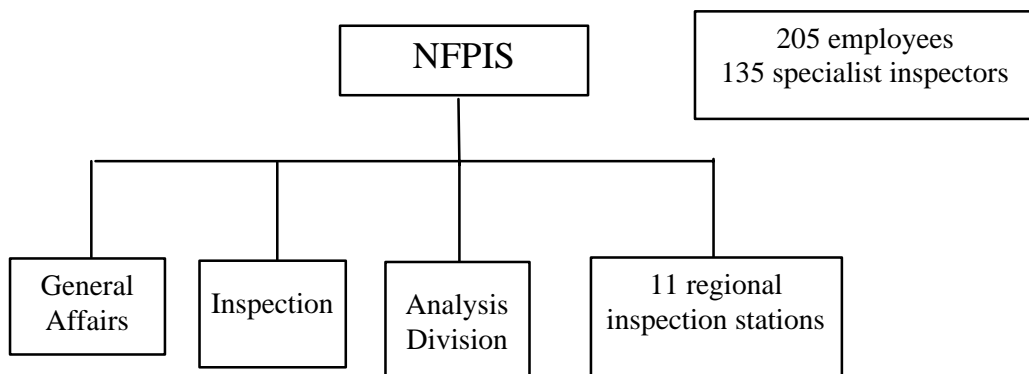
The competent authority is the Korean Food and Drug Administration (KFDA) and the National Quarantine Station (NQS) from Ministry of Health and Welfare (MHW) and local governments in accordance with Food Sanitation Law (FSL), Amendment Dec 1993 and Food Hygiene Inspection Regulation, early 1995, to control consumption of fishery products processed, manufactured and distributed domestically.

KFDA and NQS inspect highly processed products such as canned fish, fish meat paste products and seasoned products.

Under Fisheries Product Inspection Law, National Fishery Product Inspection Station (NFPIS) from the Ministry of Maritime Affairs and Fisheries (MOMAF) is responsible for inspection of imports of raw material and simply processed products (fresh, chilled, frozen, salted, smoked and dried). It is responsible to mandatory inspect 13 items for export; And to certificate EU directives for exports of fishery and aquaculture products (live, fresh, frozen, chilled and canned fish products and Shellfish Sanitation Control through MOU with US public health standard for export of live shellfish to USA through safety inspection in aquaculture areas.

2. Organisational structure (inspection and compliance)

Figure 3: National Fishery Product Inspection Station Organisation Structure



Name of the Country: Mexico

Population: 93,008,000 (1994)

Political Division: 31 States and 1 Federal District

Exports of processed foods and beverages amounts 3% of exports

1. Description of competent authority

1.1 National laws that provide legal authority to central competent authority

Under the Organisational Law of the Federal Public Administration the Ministry of Health (MH) is the government's authority responsible for the sanitary regulation of foods. The General Directorate of Sanitary Quality of Goods and Services (DGCSBS) is the central competent authority responsible (CCA) for inspection and compliance of all food products. And the General Directorate of Environmental Health (DGSA) is the government's authority responsible for the co-ordination of inspection and certification of the quality of water used to grow molluscan shellfish

Ministry of Environment, Natural Resources and Fisheries is the official inspection authority for fishery products grown by methods of aquaculture (except molluscan shellfish).

1.2 Laws that provide legal authority to other local / regional authority

SSA has authority and responsibility over the Sanitary Control of all foods, and delegates this authority to State Public Health Services by means of co-ordination agreements. There are already co-ordination agreements in place for the sanitary control of domestic consumption products.

2. Powers of authorities.

2.1 Central competent authorities

DGCSBS is the government's authority responsible of sanitary control of food processing and storage facilities; establish standards pertaining to food safety, hygienic and sanitary conditions and practices in a processing facility, and the labelling of foods. It is responsible for the enforcement of food standards and co-ordinate activities with other agencies in account to sanitary control, regulation and promotion; as well as certification of processors that export foods including fish and fishery products (except molluscan shellfish). Also It is responsible to define and supervise the policy, procedures and instruments that other sanitary authorities should apply for the sanitary control of the process, import and export of foods.

2.2 Local / regional authorities

State Public Health Services require a co-ordination contract with the Ministry of Health to make inspection and compliance of food processing plants. At present control exist on specific food segments. State Public health authorities give priority to retailers and ready to eat food outlets.

2.3 Private third party organisations

Designation of non-governmental organisations by the government is being considered in the Federal Law on Metrology and Standardisation and the General Law of Health. These private third parties organisations are for verification and certification of conformity of the Mexican official standards mainly for international trade purposes. An Accreditation Body authorised by the Ministry of Commerce and Industrial Promotion (SECOFI) are responsible for evaluation of administrative skills and independence. And the Ministry of Health is responsible for the evaluation of technical skills and approval of inspection units and certification bodies.

3. Organisational structure

3.1 Central Competent Authority.

The organisation of DGCSBS is functional. It is designed in accordance with the structure of the general control program. Those areas of DGCSBS that are involved in inspection and compliance are Directorate of Sanitary Information, Directorate of Sanitary Surveillance, Directorate of Sanitary Compliance and Promotion and Underdirectorate of Sanitary Supervision. DGCSBS has 237 positions. Those involved with inspection, compliance and enforcement are 148.

Table 2: **Staff of DGCSBS**

Area	Heads	Technical officials	Administrative	Total
Surveillance	5	44*	10	59
Compliance	6	27	16	49
Sanitary information	5	6	15	26
Sanitary Standardisation	4	10	9	23
Administrative co-ordination	2	4	46	52
Sanitary Supervision	2	7	5	14
Total	24	98	96	223

* Including 7 technical officials for fish and fishery products.

3.2 Officially Recognised Authority.

There are 32 State Public Health Services. They have responsibility for inspection and compliance of local food processors for domestic consumption and food retailers. Every State Public Health Service has several Sanitary Jurisdiction offices. There are 214 Sanitary Jurisdictions in the country. And there are more than 1800 inspectors for the control of food safety and hygiene programs, therapeutic products programs, control of environmental health and regulation of medical services. Organisational structure resembles DGCSBS, but smaller.

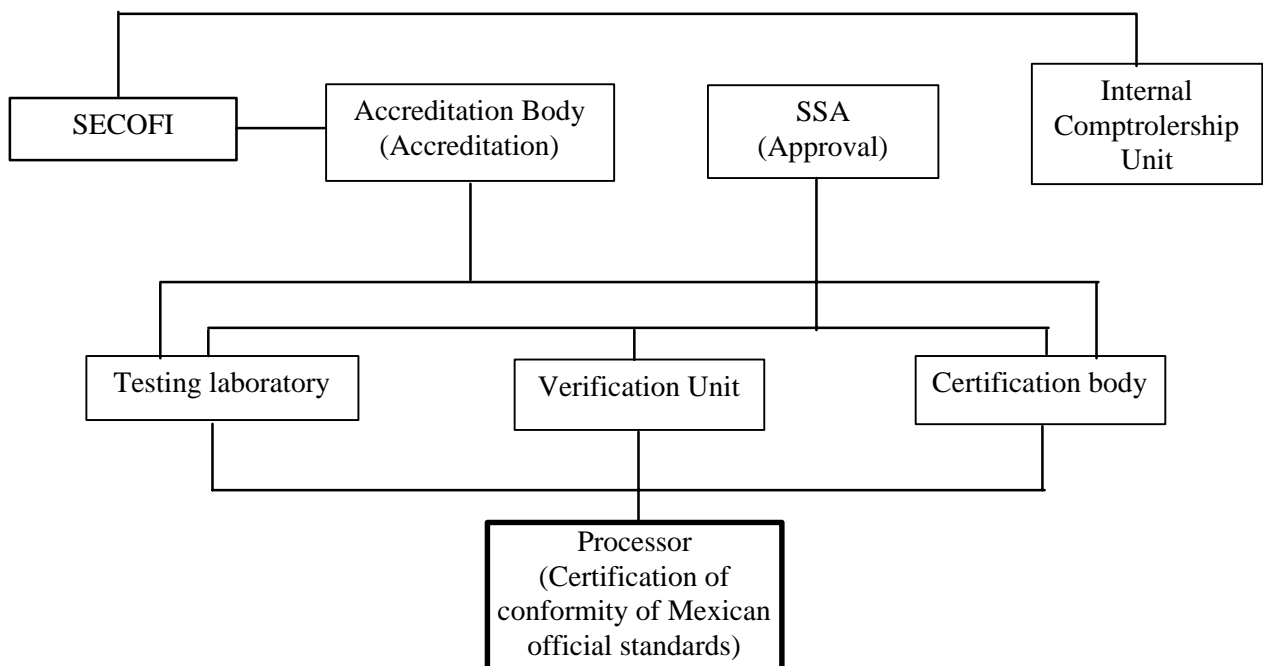
3.3 Third Party Inspection units and Certification bodies.

The evaluation of candidates for verification units started late 1997. Use of Mexican Voluntary Standards (NMX series) translations of ISO 10011 guidelines and ISO 9000 series are the basis for accreditation and assessment. They were used for audit management and evaluation of conformance with requisites of verification units. Technical guidelines developed for the supervision of State Public Health offices were used. At present, no verification unit has been approved.

4. Laboratory services to support the program

Laboratory services that support the inspection system are laboratories operated by the government and also private operated laboratories. At present, there are 16 laboratories that has been accredited by SECOFI and approved by the government central laboratory for all kind of foods: Three operated by government and thirteen private laboratories.

Figure 4: Structure of accreditation and approval of private third parties for certification of conformity



5. *Human resources*

Requisites of DBCSBS for hiring new inspectors or compliance officials are a Bachelors of Science degree in chemistry, biology, and veterinarian science or food technology. All existing inspectors had been trained in good sanitation practices and HACCP.

A Training program in Sanitary Verification has been developed with the collaboration of Mexico Autonomous National University (U.N.A.M.) and the Pan-American Health Organisation: The program includes 160 hours in classroom and at least 3 month on the job training. At present 60 people had been trained, 46 from the DGCSBS and 14 from State Regulatory Agencies.

Also a training course on Good Sanitation and HACCP including on site-inspection training (40 hours) for State Regulatory agencies. All inspectors from DGCSBS have been trained through this mechanism and more than 50 regulatory officials from Public Health State Services have been trained.

Name of the Country: New Zealand

1. *Description of competent authority*

The Ministry of Health has the legal responsibility for food safety in New Zealand after the product is released onto the domestic market. The Ministry of Health is responsible for the safety, composition and labelling of imported foods to be sold in New Zealand market. All the legal requirements relating to these topics are stated in the Food Regulations 1984.

The Ministry of Agriculture is responsible of quarantine requirements for importation of seafood. The Ministry of Agriculture has the legal responsibility for the food safety standards, which relates to the export of live animals, plants, dairy products, meat, farmed venison, and wild game, fish, shellfish or any part derived thereof from New Zealand. The Meat Act 1981 and its regulations provide appropriate regulatory controls of meat, farmed venison, wild game and seafood (products and by-products). The Ministry of Agriculture is the government agency responsible for the safety of bivalve molluscs destined for export

2. *Powers of Ministry of Agriculture*

2.1. *Under the Meat Act 1981 the Director General of the Ministry of Agriculture controls*

- The appointment and powers of Inspectors,
- The requirements for licensing of premises,
- The inspection, production and prerequisites for the sale of meat, farmed venison, wild game, seafood and their products for human consumption prior to their release on the domestic market, and
- The requirements for the export of meat, farmed venison, wild game and seafood
- Primarily, concerns are for the safety and wholesomeness of food, as well as for truth of labelling.
- Delegations of powers are contained in the Ministry of Agriculture and Fisheries Act 1953 and the State Sector Act 1988.

2.2. *The Meat Act 1981 is supported by the Fish Export Processing Regulations 1995.*

These regulations cover:

- Requirements for the construction and standards of plant and equipment in fish premises
- Obligations on the licensee to maintain hygiene and quality

- Requirements that any fish and shellfish accepted at a fish packing house be fit for human consumption
- Requirements for operation of a premises, storage and transportation
- Requirements that companies carry out regular checks on compliance with requirements, results are recorded and corrective actions taken
- The Director General can declare a species type of fish or an area where fish is taken unsafe due to contamination
- Requirement that no fish and shellfish is exported from NZ unless accompanied by an export certificate
- Providing Inspector with power to examine and sample fish and to remove and dispose of unfit fish, and prohibit the use of equipment or premises
- Providing for exemption from licensing for whole fish processing premises and limited processing fishing vessels.

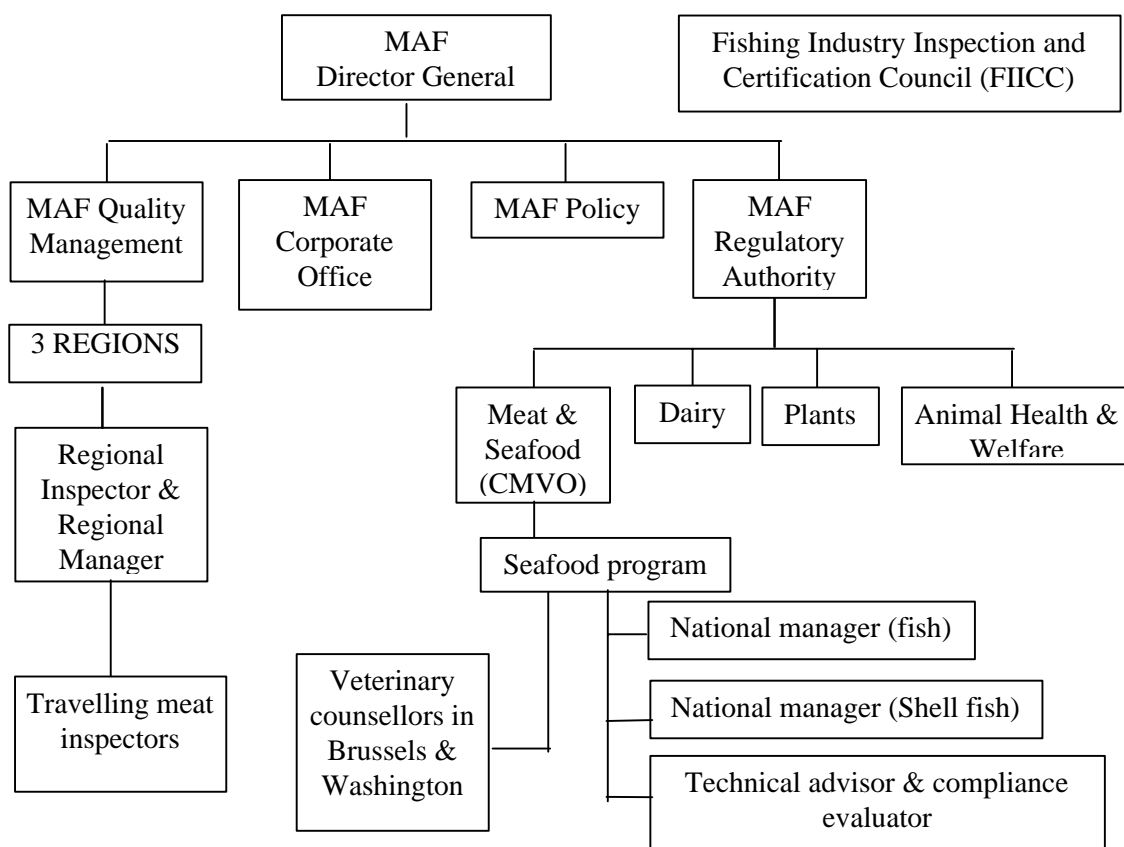
3. *Organisational structure of Ministry of Agriculture*

3.1 The Director General heads the Ministry of Agriculture. He has control over the four sub unit organisations. These are MAF Quality Management, MAF Corporate Office, MAF Policy and MAF Regulatory Authority.

3.1.1 MAF Regulatory Authority is further divided into four generic groups: Meat and Seafood, Dairy, Plants, Animal Health and Welfare. MAF Regulatory Authority (Meat and Seafood) provides policy, specifications and independent audit. MAF Regulatory Authority (Meat and Seafood) is the Controlling Authority for meat, farmed venison, wild game and seafood, and has accountability and responsibility for food safety standards, branding and certification of products and by-products.

3.1.2 MAF Quality Management is the Delivery Organisation and as such provides the “hands on” inspection service. MAF Quality Management has responsibility for inspection product and by-product, ensuring compliance with standards, and providing certification on behalf of MAF Regulatory Authority (Meat and Seafood). MAF Regulatory Authority (Meat and Seafood) audits the performance of MAF Quality Management in these roles.

Figure 5: Ministry of Agriculture Organisation Chart



3.1.3. Classification of shellfish growing areas accordingly with a sanitary survey is undertaken by Authorised Health Officers with the Crown Health Enterprise under the surveillance of MAF.

4. Laboratory services to support the program

Approved laboratory services are available to undertake analyses such as species verification, mishandled product assessments, residue analysis, water testing and microbiological analysis. And each commercial shellfish growing area is sampled weekly and tested for each of the four marine biotoxins, ASP, DSP, NSP and PSP.

5. Human resources

Travelling Meat Inspectors are required to have: Completed specialist training appropriate to areas of responsibility. Including in the training is a section on fish, post mortem changes in seafood, freezing and storage of fish, quality assurance, inspection and audit of premises and certification. Specialist training in areas such as canning, shellfish management and fishing vessel inspection are undertaken where these tasks are required. On-going training is scheduled at a regional level on: thorough knowledge of standards and processing techniques; high levels of communication, problem solving and conflict resolution skills, and commitment to MAF Quality Management operations, goals, and business philosophy.

Name of the Country: United States**1. Description of competent authority***1.1 National laws that provide legal authority to central competent authority*

The majority of US federal regulatory authority and activity for seafood regulation is vested with Food and Drug Administration (FDA) in the Department of Health and Human Service. The Federal Food, Drug and Cosmetic Act of 1938, as amended (21 U.S.C. 301-392), The Fair Packaging and Labelling Act (15 U.S.C. 1451-1461), and The Public Health Service Act, relating to biological products for human use (42 U.S.C.262-263) and control of communicable disease (42 U.S.C.).

1.2 Laws that provide legal authority to other local or regional authority or private third party organisations

Individual US States conduct inspections of fishery related operations with their jurisdictions. Contract and partnership with States are based on similar overlapping laws and regulations to those of the federal government. Many US States have enacted a basic Uniform Food, Drug and Cosmetics Bill, and other States have adopted at least a part of the bill. Most States without the Uniform Bill have laws based on the 1906 Food and Drug Act.

Most larger cities also have their own ordinance and regulations.

The National Marine Fisheries Services (NMFS), under the National Oceanic and Atmospheric Administration of the US Department of Commerce, operates a Seafood Inspection Program under the authority of Agricultural Marketing Act of 1946.

For fishery products, FDA currently reviews third party laboratory analyses submitted for import entries subject to “detention without physical examination”.

2. Powers of authorities*2.1 Central competent authorities*

Section 704 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 374) provides the basic authority for FDA investigators to enter and inspect establishments or vehicles being used to process, to hold or transport seafood. Section 792 of the Act (21 U.S.C. 372) authorises the taking of samples for examination and investigations purposes. Regulations enforced by FDA in association with these laws are promulgated under Title 21 Code of Federal Regulations.

2.2 Recognised competent authority

NMFS operates a voluntary, fee-for-service, Seafood Inspection Program and is a recognised competent authority to conduct inspection, grading and certification of fish and fishery products.

FDA establishes contracts with state health agencies to assist with the inspection of food plants, including seafood plants. Seafood inspection are part of the contracts with 33 of these states.

FDA has also recently been entering into and pursuing state “partnership” to increase the efficiency and avoid the redundancy of state and federal inspections of the same plants by co-ordinating, accepting and relaying on state inspection activities under some circumstances. FDA has approximately 57 food safety related inspection partnerships with States.

The National Shellfish Sanitation Program (NSSP) ensures the proper and safe growing, harvesting, handling and distribution of molluscan shellfish. In this program the opening and closing of harvest waters is monitored and enforced by Individual State governments that posses shellfish harvesting waters. FDA administers and provides oversight of the NSSP including audits and evaluations of the State programs.

The Salmon Control Plan is administer through the National Food Processors Association and provides assurance of the safety and quality of domestically processed canned salmon.

3. *Organisational structure (inspection and compliance)*

3.1 Central competent authorities

Much of the seafood policy development and inspection programming takes place at the Office of Seafood within the Centre for Food Safety and Applied Nutrition (CFSAN). At the field (inspection) level of the FDA, each of the 21 district directors reports to the appropriate 5 regional directors who, in turn, report to the Associate Commission of Regulatory Affairs (ACRA) at headquarters. The Offices of Regional Operational Operations, Enforcement, and Criminal Investigations also reports to the ACRA. The ACRA and the director of CFSAN, report to the Deputy Commissioner for Operations who then reports to the FDA Commissioner. The Commissioner reports to the Secretary of the Department of Health and Human Services.

4. *Laboratory services*

4.1 Government operated

FDA currently maintains seventeen regulatory laboratories across the nation. Each has the ability to conduct seafood related analyses for a vast array of defects including microbial pathogens and parasites, chemical contaminants, decomposition, filth, illegal or undeclared food or colour additives, drugs, pesticides, radionuclids, marine toxins, species substitutions and net weight falsification or other misbranding. FDA has four laboratories dedicated to seafood safety research. Procedures and methodologies for conducting analyses for enforcement purposes are well documented and controlled at FDA.

5. *Human resources*

5.1 *Number of positions*

FDA: Approximately the equivalent of 340 positions are assigned to seafood related activities in the Office of Regulatory Affairs. These positions are equally divided to domestic and import activities. And the equivalent of approximately 54 FDA positions in CFSAN are involved in seafood related regulatory activities.

NMFS: 179 professionals, scientist and support personnel staff the Seafood Inspection Program. Of these, eight are located at headquarters and the remaining 171 are located in the field or support offices through the US, Puerto Rico, and American Samoa.

5.2 *Training*

- Newly hired investigators to FDA are required to have successfully completed a full 4 year course in an accredited college or university leading to a bachelor's or higher degree in one or a combination of biological science, chemistry, pharmacy, physical science, food technology, nutrition, medical science, engineering, epidemiology, veterinary medical science, or related scientific fields. Alternatively they may have a combination of education and experience which consists of at least the 30 semester hours of study in the above sciences plus appropriate experience or additional education.
- Laboratory personnel will generally be required to have a bachelor's or higher degree consistent with the field of analyses the employee is expected to conduct.
- All newly hired investigators are required to take FDA courses in Food and Drug Law, Interviewing Techniques, Evidence Development, and Quality Auditing. They are exposed to other nationally offered courses depending on the types of investigations they will be conducting. Laboratory personnel may also take nationally available training such as Analytical Techniques for Seafood or Organoleptic Analysis of Seafood, or specialised training by the Centres or non-FDA sources as necessary.
- With the advent of the HACCP regulations, FDA has reached approximately 6,000 federal, state, local, and foreign government regulators, as well as industrial participants, through an Alliance training effort co-ordinated between FDA, academia, and industry.
- FDA provides technical assistance to the States through its State Training and information Branch and annually conducts seafood training of state and local regulators as part of its mandatory seafood shellfish programs. This training in inspection analysis of samples traditionally reaches over 100 state and local inspectors and analysts per year.
- Hiring qualification for NMFS inspectors are similar to FDA's. The training specialists of Technical Services, and the Quality Team are continually updating their training activities to reflect changing needs of the inspectors and their related industry functions. Areas of training include inspection procedures for fishery products, low-acid canned foods, sensory analysis, HACCP principles and implementation, auditing practices, European Community

requirements, and retail food safety, These may be presented as formal groups sessions, home study, or individual exercises according to the need.

OUTLINE OF INSPECTION AND CONTROL SYSTEMS

by Yuko Nakamura, Ministry of Health and Welfare, Japan

Introduction

This paper summarises information on seafood inspection and control systems that was provided in ten representative reports (Canada, European Community, Finland, Germany, Iceland, Japan, Korea, Mexico, New Zealand and the United States). Key elements of inspection and control systems are focused on:

1. Items to be inspected.
2. Mandatory/voluntary regulation and inspection
3. Who is responsible for inspection? Government agency or third party? (if third party, how are they accredited?)
4. What systematic inspection system is used? How was it implemented?

Member countries will find more detail in the tables in Annex I to this paper.

Items to be inspected

Inspection is an official examination of a facility to determine its compliance with regulations. The responsible agent inspects seafood processing, handling and storage operations. Inspection covers:

1. Sanitation: plant design and construction, sanitation control procedures, water quality assurance, disinfecting and/or other chemical substances control, pest control;
2. Specifications: biological, chemical, physical standards, manufacturing process standards;
3. Labelling: truth in labelling standards; and
4. Systems: Hazard Analysis and Critical Control Point (HACCP)-based inspection including sanitation standards and processing and product specifications

After facilities implement HACCP systems, HACCP-based inspection criteria should be used.

Inspection covers all fish and fish products. Most member countries have jurisdiction over all fish and fish products, including imports, for domestic consumption. Products for export are also regulated.

For example, in the United States, "Fish" means fresh or saltwater fin fish (finned fish), crustaceans, other forms of aquatic animal life (including, but not limited to alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin, and their roe of such animals), and all molluscs. "Fishery product" means any food product for human in which fish is a characterising ingredient. While, in the EC, "Fishery product" means all saltwater or freshwater animals or parts thereof, including their roe, excluding aquatic mammals, frogs and aquatic animals, covered by other Community acts. Fishery products also covers live bivalve molluscs.

Seafood may also mean fish products for the purpose of regulating their processing, storage, packing, labelling, and transportation. Of particular concern is the cultivation, harvesting and processing of shellfish.

In Japan, all seafood processors are required to meet general standards of sanitation, specifications and labelling. Processors of products for which a specific processing standard has been developed may apply HACCP system and/or request Minister of Health and Welfare's approval. The Japanese regulation, Food Sanitation Law, has established HACCP standards only for surimi (fish paste) products and high-pressure/high temperature canned seafood. Items are designated by Cabinet Order. The Ministry of Health and Welfare (MHW) is now evaluating the applicability of HACCP to other fish product industries.

In Korea, the Korean Food Sanitation Law was revised in December 1995 to add an article authorising the implementation of the HACCP system. According to this law, the HACCP system for fish products was expected to be published this past December.

Canada is strengthening its good manufacturing practices (GMP) with the recent introduction of a quality management program (QMP) which follows HACCP concepts. For example, additional requirements for ready-to-eat, smoked fish and deputation facilities and canneries have already been implemented as part of this QMP.

Mandatory / voluntary regulation and inspection

1. Sanitation standards: mandatory.
2. Specification standards: mandatory.
3. HACCP/ISO9000 etc. standards: mandatory or voluntary

In most countries, HACCP implementation includes the mandatory maintenance of the sanitation standards, and process and product specifications in seafood plants. Truth in labelling standards are also generally mandated. In most countries, an implementation of ISO9000 Quality Management Systems is voluntary; ISO-certified companies have usually integrated the HACCP concept into their overall quality control systems. HACCP adoption in some countries, which import more seafood than they export, is voluntary for the domestic market, but mandatory for exports.

Who is responsible for inspection? Government agency or third party?

Most countries do not accept third parties in their inspection systems. However some are now providing for accreditation of inspection laboratories which will verify interim and/or final analyses and

product specifications. Inspection agencies should use laboratories which have been appropriately accredited in order to ensure reliability of test results.

Only Iceland currently allows the use of a non-government third party as an accredited inspection body.

Japan accepts the draft guideline for the design, operation, assessment and accreditation of food import and export inspection and certification systems which was discussed and developed by the Codex Committee on Import and Export Food Inspection and Certification Systems (CCFICS).

Third party accreditation

Definition

According to the Draft Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (ALINORM 97/30A, Appendix 2), *official accreditation is the procedure by which a government agency having jurisdiction formally recognises the competence of an inspection and/or certification body to provide inspection and certification services*. To be officially accredited, an inspection body must meet objective criteria and comply with the standards set out in this guideline, particularly with regard to the competence, independence and impartiality of personnel.

Iceland requires that inspection agents ensure the competence and impartiality of inspectors; they must function with complete independence and not be linked to the inspectee.

Inspection methods and procedures

For accreditation, working procedures of the inspection bodies shall be clearly documented in order to ensure transparency. The accreditation body should monitor the competence and activities of the inspection bodies. Inspection procedures shall be documented and provided for use of the inspectors.

Relationship to responsible authority

Accredited inspection bodies act on behalf of the inspection authority. In Iceland, the Directorate of Fisheries is responsible for approving inspection bodies.

Declaration of competence (requirement of accreditation)

According to the Codex guideline, *the performance of officially accredited inspection or certification bodies should be regularly assessed by the competent authority. Procedures should be initiated to correct deficiencies and, as appropriate, enable withdrawal of official accreditation*. Accreditation is a privilege; if monitoring (as above) discloses some inadequate performance of the inspection bodies, it results in loss of accreditation unless deficiencies are corrected.

What systematic inspection system is used? How was it implemented?

Inspection agencies attempt to verify specifications of final products at markets (for domestic consumption) or at ports or international airports (for imported foods). Some countries rely only on plant-spot-checks and random sampling of finished products to try to ensure food safety. These measures are neither efficient nor cost effective. Instead, control for manufacturing process which means identification of food safety hazards reasonably likely to occur and preventative measures against significant hazards in processing steps is efficient to ensure food safety.

Concerns with systematic inspection systems:

- I. Risk analysis for seafood inspection:
 - A. categories: high, medium, low;
 - B. plant selection; and
 - C. frequency of inspection.
- II. Implementing HACCP-based inspection systems.

Risk analysis

According to the Codex guideline, *inspection systems should be organised for the risk involved, recognising that the same food produced in different plants may present different hazards*.

Risk categories for seafood inspection

With systematic inspection systems, inspection agencies should identify risk categories for seafood inspection and **conduct** risk analysis.

Frequency

The frequency and intensity of inspections should be reflect degree of risk and the reliability of controls carried out by producers, exporters and importers.

Implementing HACCP-based inspection systems

Most member countries are now shifting to use a systematic seafood inspection which concentrates on a verification of processor's preventative measures during seafood processing. Countries, such as the USA, Canada, Mexico, New Zealand, EU member states, Korea and Japan are using HACCP-based inspection to protect consumers from foodborne hazards.

Because HACCP application in seafood plants has been recognised as valid, more government resources can now be directed to areas which may present food safety hazards. HACCP provides a systematic basis for the identification and control of hazards to ensure the safety of seafood. Plants are

inspected along with procedures describes in an annex of the CCFICS draft guideline for conducting an assessment and verification as follows:

- I. Opening meeting.
- II. Examination:
 - A. Document review;
 - B. On-site verification; and
 - C. Follow-up audit.
- III. Working documents.
- IV. Closing meeting.

Future directions for seafood inspection:

A. *International acceptance of systematic inspection approaches (HACCP-based inspection systems/ISO9000 etc.)*

In the future, systematic seafood inspection approaches will direct international acceptance and conformity.

B. *Conformity of systematic inspection approaches (HACCP based inspection systems/ISO9000 etc.)*

As the submitted reports indicate, some countries which have required or advised use of HACCP principles do not yet consistently follow HACCP-based inspection practices. Most member countries are currently continuing to expand an implementation of HACCP system in seafood processing plants and introduce HACCP-based inspection by regulatory authorities. This process will continue, and is not yet finalised in any country.

C. *Possible expansion of accredited third-party inspection system*

Considering possible expansion of accredited third party inspection systems, it is important to define/distinguish the roles of the regulatory agencies and other third parties. The CCFICS guidelines will assist member countries in the formation of a more standardised accreditation process for third-party inspectors.

ANNEX I: OUTLINE OF INSPECTION AND CONTROL SYSTEMS

Country	Regulation						Inspection		Objective of HACCP/ ISO 9000 etc. Implementation	Imports
	Area	Item	Statutes	Implementation	Safety/ Quality	Mandatory/ Voluntary	Govt. Agency	Third Party		
Japan	Domestic	All fish and fish products Surimi products and canned products Surimi products Boiled octopus Frozen processed fish Oysters for raw consumption	Japanese Food Sanitation Law Comprehensive food safety controlled manufacturing process Standards and Specifications	Sanitation labelling etc. HACCP Processing standards, specifications	S S S	M V M	MHW	None	Deregulation and for international conformity	same as domestic consumption
	Export	All seafood	Equivalency agreements	HACCP and sanitation	S	M	MHW	None		
Korea	Domestic	All seafood	Korean Food Sanitation Law	Sanitation etc. HACCP	S, Q S	M V	MHW	None	For international conformity	Same as domestic consumption
	Export	All seafood All Seafood Shellfish	Fish Products Inspection Law Sanitation agreement (cf. US) Sanitation agreement (cf. EU)	Sanitation HACCP and sanitation HACCP and sanitation	S S S, Q	V M M	MOMAF	None	To comply with requirements	Two types of inspection: (1) NFPIS KFDA; (2) quarantine station.
USA	Domestic	All seafood Low-acid canned foods Acidified foods Raw bivalve molluscs	Seafood HACCP regulation (21CFR123) Current good manufacturing practice (21CFR110) Low-acid canned foods regulation (21CFR113) Acidified foods regulation (21CFR114) National Shellfish Sanitation Program	HACCP GMP (sanitation) Processing standards, specifications Harvesting standards, specifications	S S S	M M M	FDA State Government	None (A competent 3rd party designated by the importer may be responsible) None	Importers implement written verification procedures: (1) product specifications; (2) affirmative steps	
	Export	Controlled as for domestic consumption								
Canada	Domestic	All seafood Ready to Eat Canned Bivalve Molluscs Any others that may present a hazard	Fish Inspection Act Quality Management Program	Sanitation, labelling etc. QMP and HACCP	S, Q S, Q S	M M M	CFIA	None	For international conformity	Same as domestic consumption (quality management program for importers)
	Export	Controlled as for domestic consumption								

Country	Regulation						Inspection		Objective of HACCP/ ISO9000 etc. Implementation	Imports
	Area	Item	Statutes	Implementation	Safety/ Quality	Mandatory / Voluntary	Govt. Agency	Third Party		
Mexico	Domestic	Fish and fish products	Health Law	Sanitation, labelling etc. HACCP	S, Q S	M M	SPHS	Testing laboratory bodies	For international conformity	Same as domestic consumption
	Export	Controlled as for domestic consumption						HS	ISO-IEC Guide 39 (in development)	
New Zealand	Domestic	The Ministry of Health is responsible for the domestic market								
	Export	Fish, shellfish and derived products Bivalve Molluscs	Meat Act 1981: The Fish Export Processing Regulations 1995 Industry Agreed Implementation Standards National Shellfish Sanitation Programme (USFDA)	Sanitation, labelling etc. Standards, Specifications HACCP and Sanitation	S, Q S S	M M M	MAF	None	All companies are advised to follow HACCP standards	The Ministry of Health is responsible for imported fish and shellfish (Food Regulations 1984)
EC	Domestic	All seafood Live bivalve molluscs	Council Directive 91/493/EEC Commission Decision 94/356/EC Council Directive 91/492/EEC	Sanitation, labelling etc. HACCP Sanitation, specifications	S S S	M M M	FVO	None	To conform with EU regulations	Same as domestic consumption Export country's inspection competent authority is responsible for exported seafood.
	Export	N/A	N/A	N/A						
Iceland	Domestic	All seafood covered by 91/493/EEC, 91/492/EEC	Icelandic Regulations No.429/1992 No.684/1995 No.558/1997	Sanitation etc. HACCP.	S S	M M	DOF	Accreditation body (as at 1.1.98, inspection is done by accredited agents) inspection (EN45004)	To comply with 91/493/EEC	N/A
	Export	Controlled as for domestic consumption								
Finland	Domestic	Seafood	The Act of Food Hygiene	GMP, GHP and HACCP	S	M	MAF (NVFRI)	None	To conform with EU	Veterinary Border Inspection
	Export	Controlled as for domestic consumption								
Germany	Domestic	All seafood covered by 91/493/EEC, 91/492/EEC	Fish Hygiene Order	HACCP, sanitation, specification, labelling, etc.	S	M	FHM (BMG)	None	To conform with EU regulation	Same as domestic consumption
	Export	N/A	N/A	N/A						

CRITERIA FOR DETERMINING EQUIVALENCY OF FISH INSPECTION SYSTEMS

by Mary Snyder, Food and Drug Administration, United States of America

My presentation today will summarise the status, within the OECD, of the development of criteria for how a country determines whether another country is equivalent to it with regard to assurances of human food safety. However, few of the papers that were submitted to be used as a basis of the summary papers for this meeting addressed criteria for determining equivalence. Consequently, my remarks will be based on those papers which addressed the topic as well as the draft Codex discussion paper developed by Australia, New Zealand, Canada and the United States. This paper was also referenced by Japan as a possible model for equivalence criteria.

A finding of equivalence has far reaching implications.

- First, where equivalence has been determined to exist, an importing country can receive an assurance of safety beyond that which can normally be provided through border checks of products being offered for import.
- Second, determinations of equivalence promote a free flow of commerce because less border checks are needed where equivalence exists.
- Third, the regulatory system of the importing country can better focus on problem areas where no equivalence determination has been made.

In the United States, the Food and Drug Administration has a long history of entering into agreements with other countries relating to food safety. The primary purpose of many of these agreements has been to solve food safety problems originating in the country of origin by bringing the other country into compliance with US requirements.

An agreement based on equivalence, on the other hand, is intended to recognise an opposite situation: one where confidence exists with the country of origin, even though that country may employ measures that are not in exact compliance with US domestic requirements. It involves a new way of thinking for many of us.

The concept of equivalence has recently become the focus of much international attention. The impetus behind this interest — and in the development of criteria for determining equivalence — derives largely from two factors. The first is the fact that member states of World Trade Organization now have a right to obtain equivalence determinations from their trading partners. The WTO's Sanitary and Phytosanitary (WTO/SPS) Agreement, in effect since January 1995, stipulates that:

Members shall accept the sanitary and phytosanitary measures of other Members as equivalent, even if these measures differ from their own...if the exporting Member

objectively demonstrates to the importing member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection.

It also stipulates that "Members shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures."

Thus, all of the countries represented here today have obligated themselves to at least consider whether equivalence exists with a trading partner when requested to do so.

The second factor is the growing international acceptance of Hazard Analysis Critical Control Point (HACCP) principles as the food safety control system of choice. The seven principles of HACCP provide a common language for all nations that can make equivalence much easier to determine than might otherwise have been the case.

As a result of both factors, including the development of a mandatory HACCP program for seafood in the US that became effective only a month ago, FDA published a rather lengthy draft document in June, 1997 that provides criteria for how the United States will judge equivalence for seafood and certain other food products and the reasoning behind those criteria.

The international community, through Codex Alimentarius, is also developing principles and guidelines for judging equivalence. New Zealand, with assistance from Australia, Canada, and the US, recently completed a draft document that will provide the basis for discussion at the upcoming meeting of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS).

We do not perceive the Codex document as necessarily superseding our own criteria. Rather, we expect that Codex will articulate basic principles and concepts while our document will articulate how the United States will apply those principles and concepts to its own circumstances.

Thus, we assume that there will be room for national criteria in addition to the Codex criteria, although it may turn out that many countries will rely solely on Codex or at least wait until the Codex criteria are completed before deciding whether any amplification for domestic purposes is needed. That appears to be the case with most of the OECD member states, although we note that Canada's submission to this workshop includes criteria that Canada will apply in determining the equivalency of fish inspection and control systems to the Canadian system.

It is simply not possible to summarise the draft Codex document, the Canadian submission, and the US document, in their entirety in my remarks. I would like to address what I believe are some of the more fundamental points.

The development of criteria for determining equivalence is not an easy task. We all know from the SPS agreement that equivalence involves meeting another country's appropriate level of sanitary and phytosanitary protection. But what exactly is a "level of protection," not to mention an appropriate one, and how do we know when that level of protection has been achieved? The SPS agreement does not define the term.

We know from the SPS agreement that a level of protection is achieved through "measures," which are broadly defined as virtually anything that a country does to protect health within its territory, and include "all relevant laws, decrees, regulations, requirements, and procedures."

Does it then follow that "appropriate level of protection" is simply the sum of a country's measures? That is a question that we at FDA have grappled with, both during the development of our own criteria and as part of the consultative process by which New Zealand developed the draft Codex document. And, while the intuitive answer to that question might seem at first glance to be yes, both the FDA draft document and the Codex draft reflect an opposite conclusion. An analogy to help understand how this conclusion was reached is that the height of a mountain is not dependant on the measures used to climb it.

In the draft Codex document, "appropriate level of protection" — the "mountain" in my analogy — is defined as a country's expressed goals in protecting its population from particular foodborne hazards, as reflected in legislation, guidelines and other official documents. These goals may be expressed in quantitative or qualitative terms.

The FDA document is consistent with this approach. The US level of protection is governed by broad, qualitative provisions in national food safety law and regulations issued under it, which state the circumstances in which a product will be deemed to present an unacceptable risk to consumers. These governing provisions express levels of protection in terms of overarching public health standards.

It will inevitably occur from time to time in any country — hopefully temporarily — that a country's measures will not achieve its own expressed goals in protecting its population. Food safety is a dynamic concept and countries must periodically respond to new problems or to breakdowns in protection that allow for the recurrence of old ones. These circumstances may warrant new measures or more vigorous implementation of existing measures. Even so, it stands to reason that a country should still be entitled to reject imports that do not meet its expressed food safety goals even though its own measures are not at the moment fully achieving those goals either. This is one reason why we could not conclude that appropriate level of protection is simply the sum of a country's measures.

But how, then, is equivalence to be measured? National goals often are expressed in terms that are extremely broad, such as "reasonable certainty of no harm," or similarly articulated concepts. Conversely, measures to achieve those goals can be very specific, such a standard of 1 part per million for a particular contaminant in food. As a first step, a way is needed to establish a clear and rational relationship between broadly stated public health goals — i.e., appropriate levels of protection — and the measures that have been designed to achieve them.

It may not be self evident, for example, how or whether a limitation of 1 part per million is intended to achieve, or contributes to the achievement of "reasonable certainty of no harm," or how or whether an alternative measure could achieve the same level of protection.

Consequently, the Codex document contains the concept of a "food safety objective" in order to bridge the gap between appropriate level of protection and measures. The Codex document defines "food safety objective" as the reason or purpose for a sanitary measure. A food safety objective should provide a rationale for how and why a sanitary measure achieves or contributes to the achievement of a country's appropriate level of protection.

For example, a measure could be a requirement for the design of a particular piece of equipment. The food safety objective behind this measure might be ease of cleaning in order to achieve good sanitation. This food safety objective thus explains how equipment design contributes to the achievement of that country's appropriate level of protection.

Another country seeking a determination of equivalence might not have an identical requirement for equipment design but its measures might succeed in achieving the same food safety objective.

I think that this bridge concept is vital and inevitable in the development of equivalence criteria. Without it, equivalence could easily degenerate into a question of whether one country is in compliance with the myriad details of another country's regulatory system.

Not coincidentally, the FDA equivalence criteria effort independently developed a similar bridge concept, which we called an "operating definition." An operating definition explains how a broadly stated public health goal in the US food safety law is to be applied to a particular risk. The US level of protection for a particular risk consists of both the relevant, broadly stated provision of law and its operating definition relative to that risk.

For example, for a food additive, the statutory goal of "reasonable certainty of no harm" is operationally defined as the exposure to that additive that will not produce adverse effects in humans, as obtained through the application of a scientifically based safety factor (100 fold) to the lowest no effect level observed in a toxicological study in animals. The resulting measure is an approved level of the additive that is permissible in a particular food.

Another example involves HACCP. US national food safety law says that food should not be prepared, packed or held under conditions whereby it may become injurious to health. FDA operationally defines this standard for seafood as a prevention-oriented system of food safety controls to ensure that hazards are identified in advance and then controlled through the application of seven internationally recognised principles. The primary measure by which this level of protection is achieved is a regulation, and the details contained within it, that requires seafood processors to establish and operate such a system.

For purposes of equivalence, the details of another country's system of processing controls for seafood may differ from ours so long as the broader purposes of the system, as articulated by the US appropriate level of protection — that is, the statutory goal and its operational definition — are met.

The Codex document categorises the measures that comprise a food safety control system as: (1) Infrastructure, including laws and administrative systems; (2) Program Design and Implementation, including provisions for certification, audit and enforcement; and (c) Specific Requirements, including retorting for canned goods and HACCP for seafood. The Codex document points out that determinations of equivalence require an assessment of the measures in all three categories. Individual measures should not be considered in a vacuum.

The Canadian document is consistent with that approach, and states that Canada will be looking for (1) The existence of a national fish inspection and control system, including a legislative framework, governmental structures, and a good enforcement history; (2) The ability to identify fish processing establishments and to ensure that these processors are operating under a system of preventive controls based on the principles of HACCP; and (3) The ability to perform audit procedures on the inspection control system.

The FDA document is also consistent, although the categories are not identical to those in the Codex draft and Canadian submissions. The FDA document provides a broad inventory of US measures against which equivalence will be judged, including: (1) Infrastructure, which includes laws, the characteristics and capabilities of regulatory agencies; (2) Implementation, which includes how the regulatory infrastructure is actually performing; (3) Measures involving conditions of production, which are the requirements, such as HACCP, of the regulatory authority on how foods are to be processed (i.e.,

processing controls); and (4) Measures relating to outcome, which refers to requirements relating to tolerances and maximum residue levels for contaminants, additives, pesticides, and drug residues.

With regard to the processing controls, the FDA draft states, consistent with the concepts of "food safety objective" and "operating definition," that equivalent measures may differ in terms details so long as they meet the objectives and purposes of the US processing controls. This comparison may be made on a provision-by-provision basis, as necessary.

With regard to outcome oriented measures, such as maximum residue levels (MRLs), the FDA document applies the same principles, but states that as a practical matter, it would be unlikely to achieve the US appropriate level of protection and at the same time exceed the US MRLs. That's because significant problems would have to be worked out in order to determine whether two different MRLs actually offer the same level of protection.

First, the two countries would have to agree on all the assumptions and methodologies that would be used in the risk assessments for each MRL. Second, the exporting country's risk assessment would have to take into account conditions in the importing country relating to food consumption patterns and total exposure to the contaminant.

It remains to be seen whether these kinds of problems can be resolved.

Both the Codex and FDA draft documents agree that it will often not be possible to quantify the level of protection achieved by the application of a particular measure, and that qualitative descriptions of hazard control may have to suffice.

The draft Codex document stresses the need for a rational process for a determination of equivalence and outlines a reasonable series of steps that countries may follow. Some of the more notable points address the responsibility that an importing nation should have to adequately describe the food safety objectives of its sanitary measures and the appropriate level of protection that these measures are designed to achieve and the development by the exporting country of an objective demonstration of how an alternative measure will achieve the level of protection deemed appropriate by the importing country.

We believe that the draft Codex document provides the OECD and the international community with an excellent starting point for discussion on the subject of equivalence. There is much to discuss. We are starting to realise, for example, that there are a number of natural tensions that will have to be reconciled if the international community is to agree on basic principles of equivalence.

The first is the natural tension between importing and exporting nations. An exporting nation is, understandably, concerned about ease of access, and thus about ensuring that equivalence criteria allow it to export without having to fundamentally change its existing system and standards.

An importing nation, on the other hand, is understandably concerned about ensuring that imports meet its existing standards and requirements and the level of protection they are intended to afford.

The other natural tension that will have to be reconciled will be that between the developed and developing nations. Developing nations will understandably be concerned that principles established by the more developed nations will effectively preclude them from being able to enter into equivalence agreements, while developed nations will be reluctant to accept principles that, from their standpoint, risk adversely affecting their food safety standards.

So much remains to be done. However, given the importance of the subject, and the benefits in terms of both food safety and trade that can be derived, we are confident that the international community can appreciate and reconcile the legitimate concerns that must be worked through if equivalence is to mature as a tool of international commerce. After all, that is one of the reasons why we are here today.

AUDIT AND VERIFICATION METHODS

by Bob Mills, Department of Fisheries and Oceans, Canada

Introduction

Audit and verification methods are deemed an integral component to ensuring that inspection or other systematic control programmes which have been put in place function in a relevant manner and achieve the desired effect of controlling food safety hazards and other aspects of non compliant product or processes. The implementation and maintenance of effective audit and verification methods will serve to ensure confidence between buyers and sellers of seafood products, maintain confidence in implementing or maintaining inspection equivalency agreements, and ensuring that individual plant and processing requirements as regulated by a competent authority are being met.

This summary paper is intended to provide an overview of the current status of the audit and verification methods in use by OECD countries as part of their seafood inspection and control methods. The paper focuses on the definition and delineation of audit and verification methods as they apply to food inspection systems, their relevant use and application by industry, government and third party inspection bodies, and identifies some critical issues to guide the discussion of this topic at the workshop.

Definition of Audit and Verification Methods

Quite often the terms “audit” and “verification” are used interchangeably. For the purpose of this paper the term *audit* is taken from the definitions contained in the Principles for Food Import and Export Inspection and Certification as elaborated by the Codex Committee on Food Import and Export Inspection and Certification Systems (Alinorm 95/30A, Appendix II). These principles define audit as a systematic and functionally independent examination to determine whether activities and related results comply with planned objectives.

Verification is a term which has gathered additional meaning because of the world wide acceptance of Hazard Analysis Critical Control Point (HACCP) as the *de facto* system to enhance food safety. FAO and the WHO have fully accepted HACCP with the adoption of the Guidelines for the Application of the HACCP system (Alinorm 97/13A, Appendix II) by the Codex Alimentarius Commission at its Twenty-second Session. These guidelines provide seven principles for the adoption of the HACCP system which includes Principle 6 which states “Establish procedures for verification to confirm that the HACCP system is working effectively”. Verification is defined in the guidelines as “The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.” Another term commonly associated with the development of HACCP plans is that of “validation” which is self assessment process used to ensure that the initial design of the HACCP plan is meeting its objectives.

Influence of the World Trade Organisation (WTO) and Codex on Audit and Verification Methods

The globalisation of trade, coupled with the reduced tariff schedules under the GATT/WTO Agreements, are major driving forces which are contributing to the increased interest in the development of bilateral and multilateral agreements in food trade. In addition, the world-wide adoption of Hazard Analysis Critical Control Point (HACCP) system is not only being used as a systematic approach to improve the safety of foodstuffs but is also considered one of the major building blocks for many such agreements for purposes of judging the equivalence between different inspection and control systems which exists between countries. Currently some of the largest importing countries are now requiring both their domestic and imported fish and fishery products be produced under a HACCP system as a fundamental tool to ensuring food safety. Fish processing establishments who have not adopted HACCP systems or countries who lack the infrastructure and capability to implement HACCP systems might find that market access will be denied unless HACCP or equivalent inspection systems have been implemented.

While the adoption of Codex standards and other reference texts including guidelines and codes of practice by member countries of the WTO will be non-mandatory, failure to become consistent with the provisions of the WTO Sanitary and Phytosanitary (SPS) and the Technical Barriers to Trade (TBT) texts might create circumstances leading to challenges under the WTO provided the injured party can demonstrate that the standards being applied are more trade restrictive than necessary to achieve the desired level of protection. Contracting parties may, on the other hand, introduce higher levels of SPS protection provided these are scientifically justified and are appropriate to achieve the desired level of protection. In this case the role of risk assessment is very important in justifying that the standards or measures being applied are necessary to maintain the level of protection. The Codex Alimentarius Commission has a key role in providing guidance in this area, to facilitate the harmonisation or making equivalent the various international standards, recommendations and guidelines under HACCP-based food control systems.

Much focus is now being given to the development and implementation of HACCP-based systems by individual processing establishments and the mandatory or voluntary application and enforcement of HACCP and integrated quality systems by the competent authorities of individual countries. It is becoming evident in the development of bilateral inspection agreements between countries that a need exists to assess and verify the veracity of information which is being exchanged between producers, importers, exporters and regulatory authorities or other third party inspection bodies or organisations. Audit and verification is considered an important element for the determination of equivalency between trading partners. This process validates the inspection and certification system, providing both parties with confidence that products traded will be in compliance.

International Application of Audit and Verification Methods

At a global level the International Standards Organisation (ISO) have developed guidelines for basic audit principles, criteria, and practices, and provides guidelines for establishing, planning, carrying out and documenting audits of quality systems. These guidelines are contained in ISO 10011. In Europe these standards have been described in the EN 45000 series of standards.

The ISO 10011 guidelines are described in three parts:

- Part 1: Auditing

- Part 2: Qualification criteria for quality systems auditors
- Part 3: Management of audit programmes

This systematic approach to auditing has very broad applications integrating the ISO 9000 series of standards into a total quality management approach to food inspection to ensure that the quality system is meeting its objectives. The ISO auditing system has received wide endorsement by many sections of the industry with its systematic approach being adopted by many companies, competent authorities and third party inspection bodies for assessing quality control systems.

HACCP, on the other hand, is a food safety management system which incorporates verification as one of its seven underlying principles. While its primary objective is to control food safety hazards through the process of identifying critical control points, the principles of HACCP can also be extended into a broader application covering other elements of food control such as decomposition, labelling, etc.

Consideration of the use of ISO 9000 standards and HACCP has also been extensively discussed by the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS). While there was some support within CCFICS to retain the ISO 9000 series of standards noting its link to the HACCP system, the CCFICS decided that HACCP by itself satisfactorily addressed the issue of food safety and that it would be inappropriate to endorse a particular quality assurance system such as the ISO 9000 standards. The Committee agreed to discontinue work on its development as an official Codex document.

CCFICS has also developed Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (Alinorm 97/30, Appendix II) which were adopted by the Codex Alimentarius Commission at its Twenty-second Session. The guidelines are intended to assist countries in the application of requirements for trade, in determining equivalency and in maintaining confidence in the inspection and certification system of an exporting country for purposes of facilitating trade. This document provides guidance for developing a framework of import and export inspection and certification systems on:

- use of risk analysis and HACCP as a fundamental tool;
- voluntary use of quality assurance systems encouraged;
- discusses how equivalence principles can be used in developing equivalency agreements between countries;
- recommends the following areas for inspection and certification infrastructure:
 - legislative framework
 - controls and procedures
 - facilities, equipment, transportation and communication
 - laboratories
 - personnel and training

- accreditation of inspection and certification bodies to provide inspection services on behalf of official inspection agencies;
- encourages self-assessment or third party-audits using internationally-recognised assessment and verification procedures which are contained in an annex.

Guidelines on Procedures for Conducting an Assessment and Verification by An Importing Country of Inspection and Certification Systems of an Exporting Country (CCFICS Alinorm 97/30)

These short guidelines were developed along the principles espoused in the ISO audit standards offering guidance for use by countries in assessing the effectiveness of the inspection and certification systems rather than on specific commodities or establishments, however, the approach described may be applied to specific inspection regimes of a single producer or group of producers.

Described in the document are details on **preparations** for the audit including such aspects as the subject, depth and scope of the audit; its date and location, along with a time table; identity of the auditors and team; language of the audit and the report to be issued; schedule of meetings and visits to establishments; and confidentiality requirements. It recommends that the plan should be reviewed in advance with representatives of the country and where necessary of the organisations being audited.

Other details are described for the **initial opening of the meeting** with representatives of the exporting country where the audit plan is reviewed including resources, documentation and other necessary facilities for conducting the audit. A section describes the **examination** of documentary material and an on-site verification. On-site verification may involve visits to manufacturing facilities including food handling or storage areas to check on compliance with the documentary material. It also discusses briefly the need for follow-up audits to verify correction of deficiencies.

Working documents such as the need for forms to report assessment findings and conclusions should be standardised as much as possible to make the approach more uniform and consistent.

A **closing meeting** is also described where the findings of the audit are presented including, if possible, an action plan for correction of any deficiencies as agreed. The draft **report** is also discussed where the report of the audit findings are presented with supporting evidence for each conclusion, along with the details of the significance discussed during the closing meeting. The final report should also contain the comments from the appropriate authorities of the exporting country.

Overview of OECD Countries' Audit and Verification Methods

Overview submissions were received from a number of OECD representatives including Canada, Japan, New Zealand, Iceland, Mexico, Korea, the European Community, and the United States. Based on a review of the submissions it would appear that with the exception of the methods as elaborated under HACCP for verification of the HACCP system that there are some differences as expected of the fundamental approaches to audit and verification methods for either self-assessment of inspection and control systems or for conducting audits of third party inspection systems or the inspection and control systems of regulatory authorities in exporting countries. In the latter case, audits would be required to facilitate the development of inspection agreements for purposes of equivalency or compliance to requirements under existing agreements. In some cases the audit and verification methods are still under development but will be based on ISO approaches or those defined in guidelines developed by CCFICS.

In the submission by **New Zealand** it was reported that the Ministry of Agriculture (MAF) operates a Compliance Group whose role is to verify that delivery organisations effectively implement and maintain standards and specifications and ensure that corrective action is taken when necessary. In relation to fish and shellfish the Compliance Group undertakes audits of the MAF Quality Management inspectors. All inspectors whether located at premises, central certifying or regional offices are subject to audit. Audits also include verification checks of all premises licensed under the Meat Act 1981. Reviews are also carried out of licensed premises and of any specific activities, disciplines or systems associated with MAF to ensure uniform application of the specifications and to maintain MAF integrity. The Fish Export Processing regulations provide for circulars to be issued which provides a means of implementing and achieving the standards in the industry. One of these standards (IAIS 003.8) details the procedures to be carried out by MAF inspectors and by companies when undertaking inspections and audits.

Japan in its submission stated that the discussion of this item should be based on the Codex Guidelines for the Design, Operation, Assessment, and Accreditation of Food Import and Export Inspection and Certification Systems and the associated annex "Guidelines on Procedures for Conducting an Assessment and Verification by an Importing Country of Inspection and Certification Systems". It was also suggested that consideration should also be given to the "Proposal for development of a Codex guideline for the judgement of equivalency measures associated with food inspection and certification systems" which will be discussed by CCFICS at its next session in February 1998.

In the overview of the Fish Inspection System in **Iceland** it was noted that reforms are being undertaken in Iceland in the form of accreditation of privately owned inspection bodies which are authorised to inspect on behalf of the competent authority (Department of Fisheries) the facilities, hygiene and own checks in fish processing establishments. The accreditation of the inspection bodies approved by the Directorate of Fisheries is conducted by the Accreditation Department of the Icelandic Metrology and Accreditation Service. The inspection bodies is accredited and defined under the EN 45000 with the result that it is independent of all interested parties. Roles and responsibilities have been elaborated in the document including that the Directorate of Fisheries will provide technical expertise for audits as necessary for the accreditation of inspection bodies.

Mexico reported that audit and verification procedures are presently being developed and implemented. It reported that it is undertaking a mandatory program of HACCP and that delegation of authority for inspections is conducted under contract between federal and state government. Mexico also has official recognition of third party inspection as provided for under the Federal law of metrology and standardisation. Audit techniques are adapted from the ISO 10011 Guidelines for auditing quality systems.

Korea was silent on audit and verification methods although it reported in its overview paper that it has revised its Food Sanitation Laws in December 1995 to add an article authorising the implementation of the HACCP system in addition to the current Good Manufacturing Practices. Korea reported that implementation methods are being monitored for fishery products and that specific standards are expected to be published in December 1997.

The Overview of the Fish Inspection Systems in the **United States** outlined the audit and verification methods used by the Food and Drug Administration (FDA). It was reported by FDA that it has traditionally conducted auditing and verification procedures of third party laboratory results either by sampling and analysing the testing of detained imported shipments or by visiting laboratory to verify its results and capabilities. Auditing is also integral to the initiation and maintenance of memoranda of understandings (MOU) with foreign governments to assure the continuation of inspection agreements. The policy is described in FDA's Compliance Policy Guide 100.900 wherein FDA conducts audits in

association with foreign governments on the safety and wholesomeness of molluscan shellfish. FDA also reported that it could rely on various tools to audit and verify equivalency arrangements with foreign governments including:

- communication with foreign governments to ensure compliance of imported goods;
- on-site visits to examine foreign processors and/or activities of the foreign government;
- import product sampling and testing for verification that systems are working.

FDA reported that it is its desire to minimise the amount of verifying necessary to ensure that products are safe, wholesome and truthfully labelled.

FDA verification procedures for processors are described in section 123.8 of 21 CFR part 123 of the US Federal Register. In addition to FDA's mandatory seafood inspection program a voluntary fee-for-service program is administered in the US by National Marine Fisheries Service which has adopted the ISO 10011 standards for auditing of quality systems under its jurisdiction.

In the overview paper on the Fish Inspection System in the **European Community** three levels of responsibility and accountability are described. In the third level of responsibility/accountability it is reported that the EC has the right of inspection over the application of its directives by member states which includes the transposition of EC directives into national legislation and the auditing of enforcement of regulations by member states. It reported a realignment of the organisation of the European Commission such that a new Food and Veterinary Office (FVO) has been established under DG XXIV, with responsibilities for consumer policy and consumer health protection. New inspector positions have been created which, in the past, were primarily responsible for inspecting slaughter houses; however, the responsibilities of the FVO being much broader will require the development of new standardised work methods. The role of FVO is to evaluate the ability of member state inspection service to enforce legislation properly and whether the legislation is being enforced properly. Training courses on audit principles are also being developed for new inspectors. In addition, a procedural manual is now being developed which will include principles for auditing responsible authorities.

The overview further states that performance evaluation of inspection systems will include on-site visits in the company of inspectors from member states to assess actual sanitation and the activities of national inspectors and verification that self-assessment of inspection system and controls are properly carried out.

The Overview of Seafood Inspection Procedures in **Canada** provided a more in-depth description of its audit and verification methods. Described in the section on Establishment of Criteria for Determining Equivalence is the approach on self-assessment procedures and procedures for assessing equivalency using internationally recognised Codex assessment and verification procedures. These are more fully described in part by the section entitled "The Guiding Principles for Regulatory Verification Systems". The principles described apply to all federally registered fish processing establishments, licensed fish importers and to offshore fish processing establishments inspected under bilateral/multilateral fish inspection agreements or arrangements. It states that Regulatory Verifications will focus on assessing the adequacy of a company's written quality management system and verifying that the company applies the system as described and that it is effective in maintaining compliance with the regulatory requirements. Regulatory verifications will consist of a combination of audit and inspection verification activities the frequency of which will be based on risk and degree of regulatory compliance. Audit activities consist of a systems audit which is an audit of the company's documented

quality management system done on the initial submission and on amendments made by the company and a compliance audit which is an audit of the operating quality management system to verify that the industry is implementing the quality management system and that the system is operating effectively. Inspection activities applies to compliance assessment of construction, sanitation and operation requirements. The document elaborates on the use of general audit principles which includes the following details:

- company informed on time, place scope and objectives of the audit;
- encourage company to be part of the audit;
- use of accepted audit procedures including planning, preparing, conducting and analysing the results of an audit and agreeing on corrective actions;
- use of inspection teams (2 or 3 inspectors) where practicable;
- documentation of non-conformities and classifying these as critical, major or minor;
- completion of a compliance verification report;
- corrective action procedures; and
- audit closure.

The principles espoused in this document would also apply to a process of self-assessment and for purposes of verification of equivalency as described.

Some Critical Issues for Consideration by the OECD Workshop

Some critical issues for consideration by workshop participants on audit and verification methods include:

- the role of risk assessment and a country's desired level of protection in focusing how an audit/verification is to be conducted for purposes of making a determination of equivalency on inspection and control systems between trading partners.
- transparency of methods to ensure consistency using internationally approved approaches for audit and verifications.
- training of auditors to ensure auditors/inspectors are competent and professional in their judgements in dealing with officials in establishments and governments.
- confidentiality and the communication of the results of audits and verifications where such results may become assessable under freedom to information requests.
- ensuring national treatment on the use of audit and verification methods and procedures.

THIRD PARTY INSPECTION

by Ágúst Þór Jónsson, Iceland

1. Introduction

Inspection in seafood production is at present mostly done by governmental agencies in the countries of the world. The principles used when developing the existing regulatory and enforcement systems called for all activities to be performed by “competent governmental authorities”. The idea was that only people employed by the governments could be considered as competent and, most of all, impartial in their judgement compliance to stated requirements. These principles have been used in all sectors of societies and have led to the building up of comprehensive governmental institutions that have been considered more or less responsible for the safety and wholesomeness of all products on the market in the countries. These developments have diminished the responsibilities of the producers. The government institutions have also seen it as their role to support producers by providing guidance in how to fulfil the mandatory requirements on the market.

In many cases requirements are implemented by the same institution that issues the guidance. In this way the systems have in many cases led to situation where governmental officials have a conflict of interest. First, they participate in developing the rules and regulations. Then the same officials give guidance to the producers in how to fulfil the requirements put forward in the rules and regulations. Finally, they evaluate the producers’ compliance with the requirements.

The increase in the number of safety, health and environmental mandatory and voluntary requirements means that there is a growing need for conformity assessment to be performed. If conformity assessment is to be done mostly by governmental institutes in the future then there must be a drastic change in enforcement mechanisms. However, this is not in the line with the political and public policy trends in most countries where one of the keys to prosperous future is considered to be the minimisation of government structures and the economic impact of the government administrations. This is one of the reasons for the introduction of third party inspection, certification and testing bodies into the enforcement mechanisms in many countries. The best example of this is the ideology presented in the New Approach to Technical Regulation by the European Union which is now being implemented for the regulation of industrial products on the internal market of the Union. This was initiated back in the middle of the 1980s.

The New Approach includes provisions for a global system for conformity assessment procedures to be used when producers of industrial products prove that their products fulfil the stated requirements. The system is based on the use of certification bodies, test laboratories and inspection bodies that have demonstrated their competence and impartiality (best done through the act of accreditation). In this case no mandatory control is performed before the marketing of the products. On the other hand, the governments are obliged to perform organised and effective market surveillance after the marketing of the products. Experience has shown that that the mandatory control activities are

reduced drastically and the cost of the enforcement of the mandatory requirements is, to a large extent, placed on the producers.

This trend of increasing use of independent competent third party inspection bodies, testing laboratories and certification bodies is bound to have an effect on seafood inspection as well as on other areas of food production. The trend can already be seen in the work done in the FAO/WHO Codex Alimentarius Commission, who are developing the “Codex Guidelines for the Design, Operation, Assessment, and Accreditation of Food Import and Export Inspection and Certification Systems and the associated Annexes Guidelines on Producers for Conducting an Assessment and Verification by an Importing Country of Inspection and Certification Systems”. The ideology used here is in line with what the European Union introduced in the New Approach.

The purpose of this summary paper is to provide an overview of the use of third party inspection in the OECD countries as a part of the national enforcement mechanisms in seafood production. The paper first focuses on the present use of third party inspection in the reporting countries. The paper then explores principles used when using a third party inspection as a part of the governmental legislation enforcement mechanisms.

2. Overview of the Use of Third Party Inspection in the OECD Countries

Reports were received from eight countries and the European Community (representing 15 member states). The use of third party inspection in OECD countries is as follows:

New Zealand — No third party inspection is applied.

Japan — No third party inspection is applied.

Korea — No third party inspection is used. All seafood inspection for export is performed by the designated competent authority the National Fisheries Products Inspection Station (NFPIS)

United States — According to the US country paper, third party inspection is not applied. It is however possible that a competent third party designated by an importer may be responsible for the affirmative steps of inspection. The following is stated in the country report:

“FDA does not generally approve or accredit inspection bodies or laboratories to assure the acceptability of the products it regulates. However, the use of reliable third-party information to assist FDA in making regulatory decisions is becoming more attractive in light of pressures on the availability of federal funds and resources coupled with improving communications and capabilities of external interests”.

Canada — The Fish Inspection Directorate does not recognise the use of third party inspection systems. However, an agreement is being negotiated with the Standards Council of Canada for the accreditation of inspection laboratories for use in Quality management Programme for importers.

Mexico — The relevant competent authorities in general do health and safety inspections but accredited inspection bodies (according to the International Standards Organisation (ISO) Guide 39) are used for inspection of product labelling.

Iceland — All on-site inspections are done by accredited inspection bodies (According to EN 45 004). The inspection bodies report to the competent authority on a daily bases, which in turn is responsible for all enforcement activities. The competent authority does on-site inspections as a part of the follow-up activities and ad hoc inspections when needed.

Finland — No third party inspection is applied.

Germany — No third party inspection is applied.

European Community — The European Community does not recognise the use of third party inspection to take over the responsibilities of the Competent Authorities as their role is defined in the relevant directives. The way the member states organise their practical inspection activities is however not decided within the harmonised European legislation. It is up to the member states to take a decision on how the enforcement is organised.

Based on the information received, the major conclusion is that third party inspection is not widely used. But there are indications third party inspection will in near future be implemented into national systems.

3. Definitions

When discussing the issue of developing a world-wide system for equivalence for seafood inspection it is important that the major terminology used is understood the same. One of the major reasons for non-equivalence is the barrier of communication due to linguistic misunderstanding. This is the reason why the International Standards Organisation (ISO) established vocabulary standards in the area of standardisation and conformity assessment in order to ensure that communication in this important field is done with common understandings. The country reports show that many of the terms used are understood in a different way. A good example of this is the use of the term “third party inspection”.

Before discussing the use of third party inspection as a part of the future enforcement mechanisms within the seafood area it is necessary to clarify how the most important terms are understood in this paper. The source of the definition is identified in each case. (The proposed definitions can also be seen as the first proposal for accepted definitions)

Accreditation (En 45 020):

Formal recognition that a body (test laboratory, certification body or an inspection body) is competent to carry out specific tasks (tests, certification or inspection).

Accreditation is not branch-orientated and is used to declare competence. Accreditation is always done by an independent body, which is operated under the responsibility of the government. The technique of assessing the competence of a body on a regular basis done by highly qualified experts in the relevant field. These experts work according to internationally recognised procedures. This technique can therefore be one of the tools to be used to develop transparency with the aim of establishing equivalency in seafood inspection.

Certification (EN 45 012)

Action by a third party, demonstrating that adequate confidence is provided that a duly identified product, process or service is in conformity with a specific standard or other normative documents.

The act of certification can therefore be described as a comparison of the identified state of art (e.g. through testing or inspection) to documented requirements.

Testing (EN 45 001)

Technical operation that consists of the determination of one or more characteristics of a given product, process or service, according to a specified procedure.

Testing includes both calibration and laboratory testing. Testing is a technical process where identified procedures are used to identify particular characteristics.

Inspection (EN 45 004)

Examination of a product design, product, service, process or plant and determination of their conformity with specific requirements, or — on the bases of professional judgement — general requirements.

When performing inspection the emphasis is on the role of the inspector and the way he or she executes his or her professional judgement. Systems to establish equivalence in the act of inspection is therefore aimed at developing a sufficiently well identified environment for the inspectors so they can arrive at a similar conclusion given the same information. The environment includes, for example, legal frameworks, identified requirements, working procedures etc.

Third party (EN 45.020)

Person or body that is recognised as being independent of the parties involved as concerns the issue in question.

Parties involved are usually supplier (first party) and purchaser (second party) interests. (When seafood inspection is concerned, the involved parties are all those that have an interest in the result or the of the inspections performed. e.g. fishermen, establishments, sales organisations etc.)

Audit (Alinorm 95/30A)

A systematic and functionally independent examination to determine whether activities and related results comply with planned activities.

An audit is therefore a systematic procedure to be applied when performing an inspection, certification or accreditation.

Verification

Confirmation, by examination of evidence, that a product, process or service fulfils specific requirements.

Verification is a conformation whether identified requirements have been fulfilled or not. The element of professional judgement is not involved to the same extent as in inspection, as verification is done by an examination. The definition of the term verification is given in Alinorm 97/13A, Appendix II. There it says that compliance to a HACCP (Hazard Analysis and Critical Control Point) plan can be considered as a derived definition fully in line with the overall definition.

3. The Use of Third Party Inspection in Mandatory Control

Mandatory control is established within the countries to secure that legal requirements for ensuring the safety and health of humans and animals and the environment are followed. The structures developed are based on the legal enforcement mechanisms established through the constitutional framework. Seafood inspection is a part of such structures and is to be seen as:

all activities needed on behalf of governmental authorities to assess compliance to mandatory requirements within the seafood area and to implement all needed corrective actions.

Closely related are voluntary conformity assessment procedures that are used in relations between sellers and buyers. These conformity assessment procedures are in many cases based on the same mechanisms as the mandatory control. It is important to distinguish between the two. In this paper mandatory control of seafood is mainly discussed.

Seafood inspection can be divided into two major parts: the *authoritative* part and the *inspection* part. The authoritative part includes the identification of the essential requirements on safety, health and environment (through the legislative systems), the management of needed corrective actions when enforcing the requirements, and the overall responsibility for the area. The inspection part covers the actual on-site assessment of the economic operators in the industry with respect to the implemented requirements.

At present it is difficult to envisage that the authoritative part of seafood inspection is given to private entities in the OECD countries unless a new ideology is applied and significant changes occur in government administrations of the countries. For the purpose of this paper it is therefore anticipated that third party inspection is only used as a support to the relevant competent authorities and is only a service provided to the authorities by private inspection bodies.

The use of independent private inspection bodies places new requirements on the authorities. The scope of the inspection, together with the inspection methods and procedures to be used, have to be developed in much more detailed way than has been done until now. Inspection bodies require guidance on how to perform the inspections and how to evaluate non-compliance. A system for the monitoring and assessing the operations of the inspection bodies needs to be established.

The third party inspection bodies operate as a prolonged arm of the responsible competent authorities and report to them. The authorities on the other hand take all decisions and are responsible for all corrective actions taken as a result of the reports of the inspection bodies. If an establishment is found not to fulfil the requirements, and the nature of the non-compliance calls for the closing down of the

establishment, this is done by the authorities — not by the inspection body. The inspection body has no authority.

The use of independent inspection bodies is not new. A well-defined system for their operation is described in regional (e.g. European Standards) and international standards (ISO standards and guides). A world-wide system for the evaluation of their performances exists and is being used in other areas such as the industrial area and inspection of products in use. In these cases, the evaluation is done by accreditation bodies that operate according to international standards and guidelines. The world-wide network of accreditation bodies is used to ensure that certification bodies, testing laboratories and inspection bodies operate according to the same methods and procedures, often put forward in standards, to develop equivalence between the different countries. This system is now under rapid expansion due to the new World Trade Organisation (WTO) Technical Barriers to Trade (TBT) Agreement where reference is given to the process of establishing trust between countries when bringing down technical barriers to trade through the use of identified conformity assessment procedures. The system is an evident choice when establishing equivalence within the seafood area. The relevant standards which would be used are shown in Table 1.

The system described in the standards listed above defines the environment and operation of third party inspection bodies, certification bodies and testing laboratories. The standards call for full transparency of their operations by the use of quality systems and that the level of competence is kept at all times in line with the requirements of the relevant authorities (qualifications of the staff, procedures used, method of inspection, training of staff etc.). When developing the required quality systems, the standards ISO 9000 and ISO 10011 can be used as references for developing methods and procedures with respect to auditing etc. The system can therefore cover both the structures and operations of the inspection bodies in a way that is internationally recognised. An assessment of their work would take place at least once each year by the accreditation bodies and whenever needed.

The competent authorities can rely on independent inspection bodies if these bodies have demonstrated their competence through accreditation and thus prove they fulfil all the necessary requirements. However, additional monitoring on the performances of the inspection bodies is needed (e.g. through statistics etc.).

When using a system as described here above the roles of the different players in the inspection system can be as follows:

Table 1: **Seafood Inspection Standards for Establishing Equivalence**

Name	EN Standard	ISO Reference
General criteria for the operation of testing laboratories.	EN 45 001	ISO/IEC Guides 25 (1990), 43 (1984), 58 (1993)
General criteria for the assessment of testing laboratories.	EN 45 002	ISO/IEC Guide 58 (1993)
General criteria for laboratory accreditation bodies	EN 45 003	ISO/IEC Guide 58 (1993)
General criteria for the operation various types of bodies performing inspection	EN 45 004	ISO/IEC Guide 38
General requirements for assessment and accreditation of certification/registration bodies.	EN 45 010	ISO/CASCO 226 (it will be published as ISO/IEC guide 61)
General criteria for certification bodies operating product certification	EN 45 011	ISO/IEC Guide 28 (1982), 40 (1983) – ISO/CASCO 228 will replace ISO Guide 40
General criteria for certification bodies operating product certification	EN 45 011	ISO/CASCO 228
General criteria for certification bodies operating quality system certification.	EN 45 012	ISO/IEC Guides 40 (1983), 48 (1986)
General requirements for bodies operating assessment and certification/registration of quality system.	EN 45 012	ISO/CASCO 227 (it will be published as ISO/IEC Guide 62)
General criteria for certification bodies operating certification of personnel	EN 45013	
General criteria for suppliers declaration of conformity	EN 45014	ISO/IEC Guide 2 (1991)

The roles of the Competent Authorities

- I. Preparing bills for the Parliament.
- II. Issuing regulations.
- III. Policy-making for the organisation, application and extent of the inspection activities.
- IV. Developing inspection methods and procedures and giving guidance in interpreting the requirements in the legislation (often put forward in an inspection manual).

- V. Taking action in individual cases when necessary, based on the reports from the inspection bodies, such as withdrawal of licenses.
- VI. Following-up on the performances of the inspection bodies, e.g. through:
 - A. results from submitted inspection reports/certificates;
 - B. statistics;
 - C. the results of the assessment of the accreditation bodies; and
 - D. complains and appeals.
- VII. Dealing with appeals concerning the performances of individual inspection bodies

The roles of the Inspection body:

1. Performing on-site inspections in accordance with the rules issued by the competent authority.
2. Reporting to the competent authority.
3. Performing follow-up actions when requested by the competent authority.

The roles of the Accreditation Body:

1. Accrediting the inspection body according to the relevant standards and guidelines and the relevant normative documents issued by the competent authority.
2. Making periodical assessments of the inspection body.
3. Report to the competent authority when non-conformities are found in the operations of the inspection bodies.
4. Participating in the follow-up activities of the competent authority

The system here described to be used for third party inspection can also be used for building of trust between countries where inspection activities are done by the competent authorities themselves. The performances of the inspection activities of the competent authorities can also be assessed by accreditation bodies with the aim of demonstrating their competence.

In some of the OECD member countries the use of independent laboratories within the seafood area is recognised. When this is done there is a requirement for an assessment to be performed regarding their competence. In some cases the competent authorities do this themselves but in other cases this is done by accreditation bodies. The use of third party bodies in line with what is described above, as a part of a national seafood inspection system, is therefore already known to some OECD countries.

4. The development of equivalence

The development of equivalence in seafood inspection is an issue that has been under discussion for a long time. Under the WTO Agreement on the Sanitary and Phytosanitary (SPS) measures, article 4 states that contracting parties shall enter into consultations with the aim of achieving bilateral and multilateral agreements on the equivalence of specific measures (e.g. related to conformity assessment). The agreement also describes measures for notification of technical regulations and standards and for the dissemination of information on mandatory conformity assessment procedures. It is important to follow these systems when developing systems for equivalence in the seafood area.

The development of equivalence can be seen as a two phased approach. First, it is necessary for all countries to have ready access to the mandatory requirements on the different markets and the conditions for import. This can be achieved through the WTO notification system. Second, it is necessary to develop mutual understanding on the effect of the national inspection systems and to develop mutual guidelines for the operation of inspection services. For this the international systems for standardisation (ISO), the internationally developed co-operation between national accreditation bodies and the international metrology system can be used as the bases for the work.

5. Themes for discussion at the Workshop of Seafood Inspection

The topics discussed within the workshop on seafood inspection should include the:

1. use of existing international systems as the bases for the development of equivalence in seafood inspection (International Standards Organisation, International Associations of Accreditation Bodies, The World Trade Organisation etc.);
2. recognition of third party inspection bodies; and
3. development of a common terminology to be used.

ISSUE PAPERS

FISH INSPECTION AND HACCP: AN OVERVIEW

by Krissana Sophonphong¹ and Carlos A. Lima dos Santos²

Abstract

The development of fish inspection has undergone dramatic changes over the past decade. Main events that influenced fish inspection activities in the last few years are reviewed and their impact on the safety and quality of fish and fishery products analysed. Particular attention is given to the increasing application of the HACCP (Hazard Analysis Critical Control Point)-concept in the fish industry, the advent of Canadian Quality Management Programme (QMP), the harmonisation of EC fish inspection procedures, the implementation of the US mandatory HACCP seafood regulation and to the strengthening of fish inspection systems in developing countries. FAO activities in the sector are briefly described. Consideration is also given to future challenges and trends in fish inspection.

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Introduction

Fish inspection has been affected during the last 5-10 years by developments that provoked radical changes in traditional working procedures and methods of carrying on these activities. The advent of the HACCP-concept, the harmonisation of the EC fish inspection regulations and the implementation of the US mandatory seafood regulations are the main driving forces for the changes in the way government and industry apply fish inspection everywhere. Acceleration is foreseen for the near future, since actually many players are still unable to understand the need for such changes and/or to put them into practice.

Fish inspection was discussed at international level on three main occasions:

1. First International Conference on Fish Inspection and Quality Control, Halifax , Nova Scotia, Canada, 1969;
2. International Conference on Quality Assurance in the Fish Industry, Lyngby, Denmark 1991; and
3. Second International Conference on Fish Inspection and Quality Control, Arlington, Virginia, USA.

A considerable amount of information on national fish inspection systems was obtained during these events, as well as the few reviews that analyse the subject matter at global level (FAO, 1971; Huss, Jacobsen & Liston, 1992; Martin, Collette & Slavin, 1997).

Recent information on fish inspection and HACCP may also be obtained from the proceedings of smaller international, regional and national meetings held in: Shetland, United Kingdom (UNIDO, 1992); Montevideo, Uruguay, 1996 (INFOPECA, 1996); Pascagoula, Mississippi, USA, 1996 (FAO/DANIDA/NMFS, 1996); Toronto, Canada, 1996 (DFO, 1996) and 1997 (NFCC, 1997); and ASEAN-Canada (1996).

This paper presents an overview of fish inspection and HACCP at global level, paying particular attention to the main changes — and the reasons for these changes — observed at this level during the last 5-10 years. An attempt is made to foresee what the near future will offer in the form of challenges and trends for the government and industry.

Why and How Things Started?

Food Control is as old as human civilisation, being a form of supervision exercised by some authority over production and supply of goods in groups of human civilisation. There are two broad political motives for food control: (1) control of available food in order to rule the population, and (2) whoever is in possession of food supplies is in a position to yield power.

For example, inspection and quality control of fish and fishery products has a long tradition in Europe. It originates from medieval times when it covered a number of trade aspects related to the transport and sale of fish and fishery products. The type, weight and quality of products were severely controlled in the different harbours and markets. For instance, in France a barrel of salted pickled herring could be closed only after visual approval of an inspector who would then apply the official village seal on the barrel's tap. (Thomazi, 1947).

Fish Inspection at the Occasion of the Halifax 1969 Conference

At the occasion of the First International Conference on Fish Inspection and Quality Control held in Halifax, Nova Scotia, Canada, 1969, attended by 153 participants.

The Conference covered seven topics: the need for fish inspection; Fish Inspection programs; Inspection of fishery products; Industrial and commercial aspects of quality control; Methods of quality assessment; Hygienic and safety aspects of quality control; Training in fish inspection and quality control; and International Co-operation in the promotion of quality control.

Among the main items discussed by the participants were: the definition of fish inspection and quality control; the role of government and industry concerning each one of these activities; if inspection should be mandatory or voluntary; if research and inspection activities should be carried on by the same institution; and the benefits of in-plant inspection against end-product inspection.

From 84 papers presented, 23 were related to methods of sampling and quality assessment of fishery products, and other nine to the development and application of standards for fish and fishery products. This reflected the traditional reliance on the retrospective method of end-product testing for controlling microbial food safety and quality.

The topic of fish inspection programmes was discussed in 23 papers covering global issues and national efforts in 12 industrialised countries (Belgium, Canada, Denmark, France, Germany, Iceland, Ireland, Japan, Poland, Sweden, United Kingdom, USA) and one developing country (India). This reflected how fish inspection and quality control was poorly understood and applied by most developing countries at the time of the Conference.

During the meeting, participants learned about the introduction in the United States Congress of a law calling for mandatory inspection of the US fishing industry, and equivalent inspection of fishery processing facilities in foreign countries that wished to export seafood products to USA (Allen, 1971).

Twenty-Seven Years After : Washington 1996 Conference

Over 450 industry and government representatives from 66 countries attended the Second Conference on Fish Inspection and Quality Control held in Washington, DC. The meeting included 11 sessions covering: International trade considerations; Emerging inspection systems; Special hazards and their control; Essential quality and product integrity; Special quality control considerations in handling and processing; Inspection and quality assurance monitoring operations; Automated computer systems; Country discussions of progress in implementing HACCP-based seafood inspection programs; and Training of regulatory and Industry Personnel. The Conference emphasised equivalency and harmonisation in the implementation of HACCP-based programmes.

The Conference demonstrated that HACCP-based programmes are in the process of being implemented in the fish industry on a global scale. From 98 papers presented 42 dealt with the HACCP-concept. The papers covered HACCP regional and global issues and national efforts in 12 industrialised countries (Australia, Canada, Denmark, European Union, Iceland, Ireland, Japan, New Zealand, Norway, Poland, Russia, USA) and nine developing countries (Brazil, Chile, Indonesia, Korea, Mexico, Morocco, Oman, China, Thailand).

Participants learned that in December 1995 the USFDA (United States Food and Drug Administration) published a regulation that requires HACCP systems for seafood processed in the USA and for seafood imported into the USA. 18 December 1997 was established as the date of implementation of the regulation.

The HACCP Concept

Traditionally, the means of preventing food-borne illness have been by inspection and surveillance of final products, concentrating efforts on the retrospective method of end-product testing. This was a strategy adopted from chemical food hygiene where it was fit for that purpose. This has clearly been a tactical error, as even the most careful and thorough inspection program and final product testing scheme will never lead to proper management of risks (Huss, 1992; Huss, 1994; Mossel, Struijk & Jansen, 1997). According to Mossel, it is almost inconceivable that the inspection and testing approach has endured for more than 80 years (Mossel, Struijk & Jansen, 1997).

In contrast with the traditional food control approach, a study leading to the control of all factors related to every stage of the food chain comprises what is known as the Hazard Analysis Critical Control Point (HACCP) approach (Huss, 1992; Huss, 1994). The HACCP system, which is science based and systematic, identifies specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing. HACCP can be applied through the food chain from primary production to final consumption and its implementation should be guided by scientific evidence of risks to human health. In addition, the application of HACCP systems can aid inspection by regulatory authorities and promote international trade by increasing confidence in food trade (CAC, 1997).

To Garrett and Hudak-Roos (1992), it must be understood that:

“HACCP is a non-traditional inspection system. It is a system that does not require continuous inspection, and as such, separates the nice from the necessary, or the essential from the non-essential. This separation allows proper focusing of limited resources. Under HACCP the inspectional frequency should be much less than that currently employed under traditional inspectional approach — called Good Manufacturing Practices (GMPs) — or relying on end-product examination when the product is produced under unknown hygienic operations such as would be the case with imports.”

HACCP was considered a superior method of fish inspection by the participants of the International Conference on Quality Assurance in the Fish Industry held in Lyngby, Denmark 1991. Participants also agreed that the HACCP concept should be applied in the fish industry to cover food safety, plant/food hygiene and economic fraud issues (FAO, 1992). During the Second International Conference on Fish Inspection and Quality Control held in Washington, USA, participants noted that HACCP-based programmes are in the process of being implemented on a global scale. Governments and industry were urged to continue their efforts and to give a high priority to full implementation of HACCP-based systems (Martin, Collette & Slavin, 1997).

Canada Jumps Ahead and Shows the Way!

The Quality Management Programme (QMP) was implemented in February 1992 and was the first mandatory food inspection programme in the world to be based on HACCP principles. QMP was

developed jointly by both industry and government to meet national and international challenges. It represented the first step ahead in the evolution of National Fish Inspection Programmes towards HACCP. QMP, a HACCP-based system, does not only address the issues of public health and safety, but something more: it is designed to ensure compliance with Canadian regulations, addressing issues related to unacceptable quality and economic fraud. QMP involves comprehensive in-plant quality management by each fish processing establishment, accompanied by verification of regulatory compliance by the Government Fish Inspection Service (White and Noseworthy, 1992).

Since 1989, the FAO has been spreading the Canadian QMP approach around the developing world. Carried out by the FAO Fish Utilization and Marketing Service, this activity was mainly through two global projects:

1. UNDP/FAO Training Programme in Quality Assurance of Fishery Products (INT/90/026); and
2. DANIDA/FAO Regional Workshops on Fish Technology and Quality Control (GCP/INT/391/DEN).

During the last five years QMP was introduced in ASEAN member countries (Brunei, Indonesia, Malaysia, Philippines, Singapore, Thailand and Vietnam) through the ASEAN-CANADA Project.

European Union — Harmonisation Reached!

The harmonisation of national legislation of EU Member States into a single Directive is a unique step in the field of upgrading inspection and quality control of fishery products at the international level. According to Bélvèze (1992), the inspection of imported products — the main practical objective of the EC Directive — is to assure the safety of these products and to avoid the systematic detention, heavy sampling and laboratory checks at the point of entry in the Community. A clear shift to the preventive systematic approach provided by the HACCP concept is the main technical characteristic of the Directive, under the overall umbrella of its key word — EQUIVALENCE.

The adoption of the HACCP concept and its enforcement in the EU Member States and in those countries wishing to export to the Community is a major step towards assuring the safety and better quality of fish as food at a global level

Concerning the trade aspects, the introduction of the HACCP concept forces better communication and understanding between the private sector (producer, exporter, importer), the regulatory agencies, the scientific community and the general public. The HACCP concept brings benefits to all these parties. It should also facilitate international trade of fish and fishery products from developing countries.

Since the moment of its issue (1991), EC Directives were transmitted to participants of all training activities in fish inspection and quality control promoted and/or implemented by FAO/FIUI at global, regional and national level.

USA — Finally Mandatory Fish Inspection!

During the late 1980s the National Marine Fisheries Service (NMFS) — upon a specific request of the US Congress — designed, in consultation with the Food and Drug Administration (FDA) and the Department of Agriculture (USDA), a new mandatory seafood inspection programme based upon the HACCP concept (Garrett & Hudak-Roos, 1991). As a result, the Model Seafood Surveillance Project (MSSP) was completed in 1989 and the Administration directed FDA and NMFS to begin a Joint Voluntary HACCP Program. The Program was based upon the co-operative activities of the two agencies specified in a Memorandum of Understanding (Cano, 1997).

In 1992, the NMFS published in the Federal Register its Voluntary HACCP Program. The scope of this program includes safety, wholesomeness, quality and economic integrity. During July 1997 there were 85 facilities in the program with another 25 under review. From 1992 to 1996, NMFS trained nearly 3,000 persons on HACCP design and implementation (Cano, 1997). A successful collaboration was established with FIU/FAO with the participation of NMFS inspectors making part of the international HACCP lecturing teams in FAO training courses.

The US FDA mandatory HACCP system came into effect on 18 December 1997. It is designed only for safety — processors are free to apply HACCP to quality and economic fraud — but are not required to do so. The new regulations apply to all domestic seafood processors and to all overseas processors that export seafood to the USA. Importers are required to take an active role in verifying that the products they import were processed under HACCP (Spiller, 1997).

Over 50 per cent of seafood consumed in the USA is imported. Traditionally, FDA's primary strategy for checking imports has been through examination at ports of entry. FDA traditionally has conducted a limited number of inspections of overseas processors. Checking at ports of entry will continue. How FDA targets its checking will change, however, based on whom the US has entered into equivalence-type agreements with and whom they have not. The development of these agreements will be a priority (Spiller, 1997).

Since the initial issue of the draft proposed legislation, FIU/FAO included in all its training programs in the field of fish inspection and quality control USAFDA the new mandatory HACCP regulation and relevant documentation.

The Impact of HACCP on Fish Inspection Activities

An overview of the status of HACCP application in the fish industry was presented at the Washington Conference as a result of an FAO survey (Lima dos Santos, 1997). The report indicated that HACCP has taken on a truly global role in the production and inspection of fish and fishery products. However, the survey indicated that a number of countries, including some industrialised countries, needed to work harder towards making the application of HACCP a reality. The presentation covered the industry as well as the Government sector, emphasising the main benefits, difficulties and problems faced by those apply HACCP, and gave suggestions for future work.

The survey indicated that, concerning the application of HACCP in the fish industry, the situation at the global level was dynamic, volatile and changed almost daily, therefore, the picture described was by no means comprehensive and reflected the best FAO knowledge at the moment the survey was analysed.

According to the survey, some countries have achieved extraordinary progress such as Canada, Australia, Iceland, Thailand, Chile and Morocco. Others were struggling to make progress, such as most of the EU Member States (with a few exceptions, e.g. Ireland).

A first group of countries included those whose *Governments and fish processing industry* have firmly decided to introduce the HACCP-concept. This group could be subdivided in (1) countries that have started earlier (1985-1991), such as Canada, Uruguay, Brazil, Chile, Ecuador, Australia, New Zealand, Thailand, Iceland, and United States, and (2) the new-comers, including Argentina, Peru, Ireland, Cuba, Morocco, Norway, Sri Lanka, and Vietnam. In general, these countries have taken legal procedures for the application of HACCP-based systems. A few have made it compulsory for all fish processing establishments, including Canada, Norway, Brazil, Cuba, Peru, United States and the European Community? However, most countries have made the system mandatory only for exports (particularly to the EC). This is the case of Thailand, India, Vietnam, Morocco, South Africa, Argentina, Ecuador and Uruguay. Others, such as Chile and New Zealand, have left the option voluntary for the industry. Most of the countries in this first group in the last 3-8 years have developed and applied a national programme of awareness and training at various levels, including the preparation of HACCP guidelines, manuals, auditing instructions, etc.

A second group included countries whose Governments have taken *unilateral initiatives* in introducing HACCP, through issuing Government regulations. Co-operation between the Government's regulatory agency and the producing sector and awareness/training programmes had no marked success. This was the case of Mexico, Venezuela, Russia and most EU Member States (e.g. Italy, Germany and France).

A third group included countries where the private sector was taking the lead and *voluntarily* trying to introduce HACCP-based programmes in the production of their exports. Accordingly, companies spread all over the world have designed and are placing into operation HACCP-based programmes. This is the case of companies located in Madagascar, Guatemala, Honduras, Tunisia, Myanmar, Portugal, etc.

The last group was formed of countries whose Governments have decided to apply HACCP but *not yet defined HOW* they should do it. The best example given by the survey was Japan, followed by Russia and China. This group also included undefined "silent" countries such as Bangladesh, Pakistan, South Korea, Iran, Colombia, Panama, East and Central European countries (with the exception of Poland) and most African States.

The FAO survey has identified a number of difficulties and problems faced by industry and inspection services in the implementation of HACCP. The main challenges revealed by the survey were the following:

- “players”(industry & inspection service) not yet convinced;
- fear to change;
- lack of trained personnel;
- lack of political will;
- lack of financial resources;

- lack of communication between inspection authorities;
- implementation time;
- HACCP plan "ownership";
- lack of clear instructions;
- threat of new trade barrier;
- influence of international factors;

On the other hand, the FAO survey revealed the following general benefits and advantages:

- particular benefits to developing countries;
- closer collaboration between Government and Industry;
- overall commitment "to improve safety and quality";
- education and training activities at all levels;
- optimistic approach: "we must, we can do it"; and
- the prize: maintain & increase markets & better prices.

At the occasion of the Washington Conference, the FAO survey was complemented by national information provided by a number of countries not included in the investigation, i.e. Japan, Mexico, Russia, Korea, Oman and China. Immediately after the Washington Conference, further information on the status of HACCP implementation in developing countries was also provided during the *FAO/DANIDA/NMFS Seminar on HACCP Implementation and Training for Developing Countries Fisheries Industries* held in Pascagoula, Mississippi, USA, July 1996. The new data obtained covered Argentina, Cuba, Guyana, India, Mozambique, Nigeria, Senegal, Uruguay and Vietnam (FAO/DANIDA/NMFS, 1996).

Since the Washington Conference the implementation of the HACCP-concept by fish inspection services and fish industry is being intensified world-wide. In the particular case of some developing countries, the rate of change is outstanding, such as in Bahamas and Cuba in the Caribbean, Mexico, Ecuador and Peru in Latin America, Morocco, Mozambique and Senegal in Africa, and Bangladesh, Indonesia and Vietnam in Asia. Papers prepared for this workshop provide up-to-date information on the status of HACCP application in the fish industry of most OECD member countries.

Fish Inspection present and future challenges and trends

What facets of the past and present fish inspection approach can be used in meeting future challenges? What new challenges will be presented for government inspection programmes? These and other relevant issues were recently discussed during the *National Conference on Past, Present and Future*

Inspection organised by the Canadian Fish Inspection in September 1996 in Mississauga, Ontario (DFO, 1996).

Facing present and future challenges to fish inspection, the following issues might be considered:

- importance of aquatic resources as a source of food, employment and income;
- public health aspects of fish as food;
- depletion of fish stocks;
- increasing importance of aquaculture;
- world trade of fish and fishery products;
- present trend of reduction of government resources;
- present trend of transfer responsibilities to private sector;
- past and present objectives of fish inspection;
- implications of world-wide application of HACCP-concept.

Taking into account the above issues, answers should be given to the following questions:

- There are limits for some of these factors, for instance, how much should we try to reduce government efforts in fish inspection?
- What have been achieved by fish inspection up to today? With what efforts? At what costs?
- What should be done at national and international level to implement the HACCP-concept at industry and government level?
- Equivalence of fish inspection systems: how will this concept affect fish inspection and the daily work of fish inspectors?
- HACCP implies in covering the whole production and distribution chain: what should be done at national and international level concerning fish inspection at fish farms, fishing vessels, fish landing places, retail stores, catering, sport fishing, consumers, etc.,?
- What are the responsibilities that could be transferred from government to private sector: Routine laboratory analysis? Training? Plant inspection? Product inspection? Verification/auditing of HACCP programmes?
- What could not be transferred to private sector: accreditation of private labs and/or Inspection/Quality Control private firms? International affairs?
- Should rapid testing methods for food quality/safety assessment be used more often?

- After HACCP, what will come? Should governments continue dictating to industry how they should perform quality and safety controls? Should government assist the fish industry or be assisted by the fish industry? Should government restrict its role in fish inspection only to enforcement?

Fish inspectors around the world will need to face these and other challenges at national level and through international co-operation. The issue of international co-operation of fish inspection services was dealt by OECD in the early 1960's and the points raised at that occasion by Mr. Paul Fr. Jensen, former Director, Inspection Service for Fish Products under the then Danish Ministry of Fisheries, are still valid today (Jensen, 1963). According to Jensen, two types of co-operation should be considered, i.e.:

- co-operation in the daily work, generally on a bilateral basis, for the purpose of strengthening food safety/quality and facilitating the interstate trade of fish and fishery products; and
- co-operation for the purpose of solving general problems on a really international basis.

To achieve these goals the main conditions needed for international co-operation would be the following:

- mutual knowledge;
- mutual confidence;
- mutual understanding;
- harmonisation of regulations; and
- uniform levels of training.

In fact, problems faced today by fish inspectors at international level were recently analysed by Sophonphong & Lima dos Santos (1997), with special attention to developing countries. In their paper, these authors called attention to the following issues:

- lack of communication;
- lack of understanding/confidence;
- end-product sampling and analysis approach;
- certificates and their problems;
- qualification and training of fish inspectors; and
- HACCP implementation.

Higher priority in our field of activity — fish inspection — should be accorded to daily problems related to assuring safety and quality of fish and fishery products and facilitating trade. Having people able to deal efficiently with these problems should be our main target. The identification of training needs is essential. Large challenges lie, in the specific field of fish as food, in the understanding

of HACCP and its application, HACCP verification/auditing procedures, and the understanding and application of risk analysis.

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FISH INSPECTION EQUIVALENCE AGREEMENTS: OVERVIEW AND CURRENT DEVELOPMENTS - DEVELOPING COUNTRIES PERSPECTIVE³

by Krissana Sophonphong⁴ and Carlos A. Lima dos Santos⁵

Abstract

In the international market of fish and fishery products, one of the most serious difficulties faced by exporters from developing countries consists in the different standards and regimes being imposed by importing countries to ensure products meet their domestic requirements. Even after the ratification of the Sanitary and Phytosanitary Agreement (SPS) under the World Trade Organisation (WTO), differences are expected to continue between various national standards and inspection systems maintaining or creating new non-tariff trade barriers. Moving towards the “equivalence” approach is now considered the best way to remove such a burden and liberalise the international seafood trade without sacrificing food quality or safety. “Equivalence” is the capability of different inspection and certification systems to meet the same objectives, according to the Codex Alimentarius Commission.

This paper offers an update description of developing countries’ efforts to apply the “equivalence” approach in the field of inspection and quality control of internationally traded fish and fishery products. Problems and difficulties to pursue this kind of agreements are also identified.

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Introduction

Developing countries are responsible for more than 50 per cent of fish and fishery products involved in international trade. Almost all developing countries export some fishery products and for most of them the revenue from these exports is a major source of foreign currency. The European Union (EU), Japan and the USA, account for about 80 per cent of world fish and fishery product imports. They dominate the market both in terms of prices and quality requirements. Sanitary and hygienic regulations imposed by main importing countries have come to play an increasingly important role during recent years due to negative public perceptions which have grown in their domestic markets (Ahmed, 1991).

Developing countries have often complained that they are being penalised by the complexity of health and quality regulations applied by major importing countries. In the past it has been suggested that these regulations have been used as non-tariff barriers. There is no doubt that the way in which the regulations are implemented, and the lack of consistent criteria, has certainly inhibited seafood trade (Lima dos Santos *et al.*, 1993; Emberley, 1997).

The differences between the legislation, standards, organisation and function of inspection services, and “modus operandi “ of such services are among the most important practical difficulties faced by developing countries to comply with the requirements imposed by importing countries to ensure that products meet their domestic standards. Certificate requirements of different countries cause inconvenience to both exporter and responsible government regulatory agency. There are a number of different forms and languages which often result in confusion.

Application of the Hazard Analysis Critical Control Point (HACCP) concept is an alternative choice to such traditional barriers, which is now embraced everywhere by public and private sectors. The world-wide application of HACCP principles is expected to become the vehicle which will stimulate international harmonisation of the fish inspection system.

Following this direction, global efforts are being pursued towards the establishment of country bilateral and multilateral agreements with the intended effect of removing seafood trade barriers. The goal is to maintain and/or gain better access to key international seafood markets, that means - basically - exporting countries are seeking recognition from importing countries concerning their capability to produce and sell safe and quality products.

This paper addresses guidelines recommended by internationally recognised agencies and requirements set down by importing countries to achieve “*equivalence*” recognition of inspection and certification system. Problems and difficulties encountered, especially by the developing countries, to pursue this kind of agreements are also identified.

What is “Equivalence”? The International Approach

According to the SPS Agreement, “*equivalence*” is achieved when an exporting country assures an importing country “the appropriate level of sanitary or phytosanitary protection”, even though the measures adopted are not the same as those of the importing country. That means we are not dealing with the equivalence of specific standards of food products and their components (e.g. food hygiene, additives and contaminants, labelling and quality requirements) but with that of the inspection system .

According to the Codex Alimentarius Commission (CAC), “*Equivalence* is the capability of different inspection and certification systems to meet the same objectives” (Codex Alimentarius Commission, 1997). Accordingly, emphasis is given on the capability of different inspection and certification systems to achieve the same objectives, regardless of details related to the methods applied by both systems.

The “Proposed Draft Guidelines for the Design, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems” recently prepared by the Codex Alimentarius Commission (1997) recommend necessary steps to be taken for determination of equivalence between two or more interested trading countries. The matters of consideration should include the national legislative framework, effectiveness and adequacy of enforcement and control programmes and availability of facilities, equipment, transportation and communications. The document also encourages the use of the HACCP approach and emphasises the importance of government and industry staff training on the subject. As indicated before, the general assumption is that HACCP principles will play a fundamental role in every equivalence agreement. Prerequisite requirements for sanitation, end-product sampling and testing by exporting countries would play a minor but necessary part to fulfil the objective of the agreement. Importing countries are expected to avoid systematic physical checks on imports which will lead us back to the traditional way of inspection.

A key point reiterated by the Codex Alimentarius Commission in their proposed draft guidelines is the need to abide by risk assessment principles. Risk assessment is the scientific evaluation of the likelihood and severity of known or potential adverse health effects resulting from human exposure to foodborne hazards (FAO/WHO, 1995). For the determination of equivalence between inspection systems, different countries may present different hazards and risk assessment. Control methods can be different but able to achieve equivalent results. Inspection services should draw up control programs based on precise objectives and appropriate risk analysis. In the absence of detailed scientific research, control programs should be based on requirements developed from current knowledge and practice. Every effort should be made to apply risk analysis based on internationally-accepted methodology.

With the world moving towards HACCP principles and equivalence agreement, where control from harvesting to consumption is emphasised, end-product analysis for certification purposes should be kept to a minimum. Time, cost and effort should instead be shifted to prevent the occurrence of possible health hazards in the production chain.

Equivalence and the European Union (EU)

The harmonisation of the national laws of European Union countries into a single Directive was a unique step in the field of upgrading inspection and quality control of fishery products at international level. A shift to the preventive systematic approach provided by the HACCP concept is the main technical characteristic of the new inspection and quality control procedures included in the Council Directive 91/493/ EC of 22 July 1992 under the overall umbrella of its key word -“*equivalence*” (Lima dos Santos *et al.*, 1993). Though the primary objective of the legislation is to harmonise practices within the European Community, it is a principle of the Directive that its provisions should apply to imports from “third countries” (countries that do not belong to the Community) and that there should be a common import system applied by all member states of the Community. Therefore, exporters to the EC should comply with the content of Article 10 of the Directive:

"Provisions applied to imports of fishery products from third countries shall be equivalent to those governing the placing on the market of Community products."

The EC version of “Equivalence” is rather different from that of the Codex Alimentarius Commission and USED (US Food and Drug Administration). To achieve an equivalent status, the exporting country must demonstrate that its “National Competent Authority” (NCA) has the capability to enforce EC legislative regulations to ensure safe and wholesome products being produced and placed in commerce.

There is no MOU (“Memorandum of Understanding”) kind of agreement in the EC perspective. The “equivalence”, alias “harmonisation”, according to EC terminology, takes place in a form of specific Decisions made by the Commission of the European Communities approving individual countries to export to the EU. The NCA of an exporting country is required to submit a list of approved establishments that comply with concerned Directives for subsequent approval by the EC.

The EC has introduced a system called “Own Health Checks”, as appeared in the Directive 94/356/EC issued on May 20, 1994. The system is based on HACCP principles. There is no direct enforcement applied by the EC on how a plant implements the system. The responsibility lies upon the NCA to ensure that an approved establishment has a HACCP plan in place and effectively implements it. The competent authority has to ensure appropriate training of inspection staff authorised to perform official checks on the own-checks system.

One may state that EC is applying a true “equivalence” scheme, on its own way, by approving processors of third countries under the supervision of exporting countries’ NCAs. Exporting countries’ NCAs take full responsibility for regular sanitary plant inspection, verification of HACCP-plans, and end-product sampling and analysis.

A health certificate is to be issued and signed by the authority to accompany each shipment. The certification is still an important tool for reassuring EC that their standards and requirements are constantly met. This creates a doubt if this “equivalence”/“harmonisation” approach is in line with the objectives of WTO and SPS agreement to liberalise free trade globally.

The EC may be standing on the verge of utilising trade barriers in many occasions. The EC allows higher residue level of food additives, such as benzoic acid, in temperate water shrimp products than in tropical ones. Some EU Member States practically issue import alert lists for products from specific countries or companies, without the support of EC Decision. Furthermore, the EC reserves the right, according to Article 11(6) of the Directive 91/493/EEC, to approve an individual establishment in a third country if the NCA of the exporting country is identified as unable to satisfy EC import requirements. Generally, considerable efforts are made by the NCA of an exporting country, both in terms of finance and human resources, to comply with EC Directives and maintain its industry’s status in the EU market. The pressure from EC is constant on third countries forcing to make NCAs strictly achieve compliance. The scale of efforts, tension and losses faced nation-wide by the governments and private sectors of exporting countries cannot compare with that of a single company (in many occasions having a foreign owner, based in an EC country). Therefore, the EC alternative of offering special approval for private individuals is by all means unacceptable.

A common and serious complaint made by a number of countries exporting fish and fishery products to the EU consists in inadequate qualification of the EC inspectors being sent to perform official inspection missions in these countries. European inspectors are not trained in the technology, hygiene, inspection and quality control of fish and fishery products. They are not trained in the development and application of the HACCP concept in the fish industry, and they do not have practical experience in the inspection of fishing vessels, fish farms, fish handling places and fish processing products. Generally, they are Veterinarians experienced in technology and inspection of food of animal origin - not fish and fishery

products. Here is a first issue to harmonise and make “equivalence” a reality, i.e. the technical and practical training qualification of fish inspectors at importing and exporting country level.

Equivalence and the USA

Seafood processors of an exporting country are given two choices to enable them to export their products to the US market after the D-day (18 December 1997): the day the Mandatory Seafood HACCP Regulation will enter in force:

- Through the first option, the foreign processor must submit its HACCP-plan to the US fish importer for approval. The US importer is responsible for verifying the effectiveness and proper application of the plan. Hence, the importer can only pursue trade with a foreign processor who has in place an efficient HACCP plan.
- Secondly, if there is an existence of a Memorandum of Understanding (MOU) between the governments of the US and the exporting country, all establishments approved by the latter will gain access to the US market without the complicated steps for the approval of the HACCP plan by the US importer.

To establish a “Memorandum of Understanding” (MOU) with the USA, based on the “equivalence” between the fish inspection systems, foreign countries are provided with a do-it-yourself document prepared by the USED to use for preliminary checking of its own inspection system. The process is known as a “side by side comparison”, where health protection systems of both USA and the requesting party are compared.

Seafood exporters would prefer very much to see their governments having established equivalence agreement with the US. However, despite rigorous approach and efforts attempted by governments of several exporting countries, USED has yet to develop an agreement with any country - negotiations with USED for reaching a MOU are still proceeding at a snail’s pace. According to USED, it is most likely that no MOU will be signed until the end of 1997 (FDA, 1997(a)). The signature of a MOU with Canada may be the only possible exception, since the negotiation between the two countries are said to be in an advanced stage.

Guidelines developed by USED for the establishment of an equivalence agreement between fish inspection systems are clear and precise. Different from the compliance-based MOUs signed in the past with a number of countries (e.g. New Zealand), USED is now prepared to accept unidentical measures which can achieve the same level of health protection. Nevertheless, there are still some important hidden details to take into account. For example, the differences of Maximum Residue Levels (MRL’s) for food contaminants or drugs between the US legal standards and those of other countries. The latter must be able to demonstrate that products exported to the US will not contain contaminants in excess of the US MRL. In the same line, US labelling requirements are likely to remain unchanged since there is still no conclusion on how determination of equivalence on this issue should be made to be in line with the SPS agreements.

The US automatic detention scheme is a significant burden for USED to decide on in the development of bilateral agreements. With a number of fishery establishments appearing on the import alert list, USED expresses its concern to settle the existing problems first. Major causes of seafood detention are still decomposition in canned tuna and canned shrimp, and detection of *Salmonella arizona* and filth in frozen raw shrimp. These defects should be carefully revised in the light of risk analysis.

Processors appeared in the list may not be aware of their status at all. Once a shipment from a listed plant arrives at a US port, the importer seeks random sampling and analysis by a private laboratory and obtains a certificate to proceed with custom clearance. The process can go on and on, but the alert list remains unchanged. To be withdrawn from the list is too costly and time consuming. Importers would prefer to deal with sample analysis on a shipment by shipment basis. The USED should also solve this problem by investigating whether the violation still exists. The USED may have to apply risk assessment for each specific cause of rejection/detention as well. Close communication and co-operation between USED and the exporting country's NCA will help resolve this shortcoming.

The USED does not fully rely on end-product testing because the results of the sampling may or may not be representative of the risk and quality of the whole lot. Many factors are involved such as product uniformity and sampling size. Hence, the USED does not require a certificate to accompany an imported shipment. This has long been the USED approach for imports, which is in line with the HACCP approach where raw material and processing controls are emphasised. Nevertheless, it is expected that the USED will continue to sample and analyse lots of seafood imports even after the HACCP regulation has taken effect - a reflection of an existing thick umbilical cord with traditional inspection procedures.

After December 18, 1997, the trend is that less inspection will be conducted in exporting countries by USED inspectors. This kind of control may be considered a threat to a projected offshore establishment. Though stated in USED Federal Register (FDA, 1997(b)) that an official inspection visit to a foreign processor will be done after official consultation with the concerned NCA of the visiting country, USED has in the past, on several occasions, made direct visiting arrangement with foreign processors/exporters without local authority's knowledge (e.g. inspections conducted by the USED programme on Low Acid Canned Food). Joint inspection and regular exchange of information should be considered as the correct approach when the USED considers a necessary inspection of an establishment in a foreign country.

It is possible, but rather difficult, for most individual US importers to regularly inspect and verify HACCP-plans of foreign seafood establishment. This shortcoming creates job opportunities for HACCP consultancy firms. Many foreign processors are misled, purposely or not, that by obtaining consultancy assistance from firms claiming to have a special approval from USED and/or relevant US private associations, the processor will be guaranteed a ticket to enter the US market. Of course, a tailored HACCP plan for each plant will be established and applied. There is no technical harm in using competent consultancy assistance but the truth is that such consultancy can cost a fortune and does not assure free access to the US market. On the other hand, this procedure has serious negatives since it may jeopardise national efforts, particularly in the case of a number of developing countries. Several governments are doing their utmost to train and provide technical guidance to the industry on the design and application of HACCP principles. A significant number of seafood processing plants world-wide have operational HACCP plans and are ready for the new regulation. At the same time they are uncertain whether they can demonstrate the effectiveness of the plans to the US importer and gain approval. Many are considering paying a huge consultancy fees to persons/firms who know their plants less than they do, just to secure their place in the US market. A certificate and/or statement from the exporting country's NCA that the exported seafood product being sent to the US is processed under an efficient HACCP plan should be adequate. The establishment of MOU of "equivalence" between fish inspection systems between the US and the government of its trade partners is a must.

Equivalence and Japan

Japan is the world largest seafood importing country. The Ministry of Health and Welfare (MHW) is entrusted to control imports of all food products including seafood in accordance with the Food Sanitation Law. Though, for many countries, random sampling and finished product testings are no longer considered a reliable measure to ensure full control of health hazards, Japan still depends heavily on the traditional fish inspection system. Food imports are subjected to regulatory inspection by food sanitation inspectors at the port of entry. Health certificates are not required by Japanese laws, however, they obviously facilitate custom clearance (Yamagata, 1992). A foreign laboratory performing analytical tests on the products must be recognised by the Japanese authority. The MHW may accept documents and test results from more than one recognised government agency in an exporting country.

In order to simplify import procedures, products with good compliance history will qualify for reduced inspection scheme. The MHW has introduced the advanced confirmation or pre-certification system. Prior to importing, food products and its manufacture may be registered with Japan through a recognised local authority. However, it is necessary that the food product obtains clearance compliance with Japanese food sanitation regulations. Import notifications for the registered products are promptly accepted (Toyofuku, 1997). This system covers only processed seafood such as surimi and surimi-based products. Monitoring programmes using sampling and laboratory analyses are conducted continuously particularly on high risk fishery products such as puffer fish and shellfish. The use of HACCP-based systems is encouraged in seafood production but the system is voluntary.

As a major importer, Japan does not seem ready to adopt a global trend in equivalence agreement based on inspection system. Japan appears to rely on close collaboration with recognised foreign governments to resolve seafood safety problems on a case by case basis. Whenever a violation to the laws is identified, the MHW will require the exporting authority to immediately and closely investigate the cause and exercise necessary steps to eliminate the problem. This approach apparently has provided satisfactory and reasonable assurance to the Japanese authority .

The Japanese government so far has had no MOU with the government of an exporting country. However, being an exporter of fishery products as well, the Japan Canned Food Inspection Association (JCFIA) which is a private agency, signed a MOU with the Canadian Department of Fisheries and Oceans in February 1997 regarding imports of canned tuna into Canada. The substance of the MOU is identical to those previously established between Canada and Thailand and the Philippines.

Equivalence and Canada

Canada has been actively and efficiently implementing a number of “Memoranda of Understanding”(MOUs) with the governments of trade partner countries. In the case of imports, the substance of the agreements is to ensure that specific fishery products processed in qualified fish processing plants and imported into Canada meet Canadian requirements. The Canadian requirements are based on its Quality Management Program (QMP), an HACCP-based mandatory system. Canada does not require a health certificate to accompany a shipment. The frequency of import inspections depends on the performance history of the exporting company. Preferred Status or reduced inspection rate is given to a foreign firm covered by a respective MOU. So far, among those countries having successfully established MOU with Canada are Australia, Ecuador, Iceland, Indonesia, Japan, and Philippines.

Equivalence is not a novelty to the Canadian perspective. In April 1996, the Canadian DFO signed an Equivalence Agreement with New Zealand on control measures for the safety and quality of fish

and fishery products. A Mutual Recognition Agreement (MRA) on the equivalence of fish and fishery products inspection control system, which may be claimed the first recognition of unidentical systems in the world, was signed in April 1997 with Thailand. The MRA was drafted in accordance with the guideline recommended by the *Codex Committee on Food Import and Export Inspection and Certification Systems*. It is foreseen that Canada will continue to pursue this kind of agreement with other trading partners equipped with a National Competent Authority (Government Inspection Agency) and qualified processing plants. The approach has proved efficient and dramatically encouraged trade flow.

Current Developments involving Developing Countries

Among developing countries, those from Asia and Latin America are working harder in the pursuit of equivalence recognition for their national fish inspection programmes. In most cases, the objective is to obtain a special treatment for their seafood products in the major importing countries, in particular the EU and the USA. However, Brazil and Argentina are also worried with protecting their national markets. The efforts of developing countries are aimed at the establishment of bilateral or multilateral agreements.

Bilateral agreements

The agreement on the equivalence of fish and fishery products inspection and quality control system signed between the governments of Canada and Thailand on April 9, 1997, deserves particular attention. The Mutual Recognition Agreement (MRA) was the result of a long-term MOU between the Canadian Department of Fisheries and Oceans (DFO) and the Thai Department of Fisheries (DOF). This MOU was initiated in the early 1980's specifically for inspection and quality control of canned tuna. It was then converted to an umbrella or basic MOU in 1992 adding another product, i.e. frozen raw shrimp, and in 1996 incorporating cooked and value added shrimp products to the annexes.

The above MOUs significantly contributed to the success of the Thai export of seafood products to Canada. Thailand has enjoyed a satisfactory market share for canned tuna and frozen shrimp in Canada of 65 per cent and 21 per cent during the first half of 1997, respectively. Nevertheless, the number of establishments under the previous MOUs were limited. When the Thai Government had confidence in its inspection system and in the performance of the fishery industry, the country has approached the Canadian Government for negotiation of the MRA. After a lengthy period of paper review and plant visits, the MRA was finally established. The agreement covers fish and fishery products with the exception of live molluscan shellfish. More qualified processing plants are included providing better opportunities to access the market. Privileges for minimised sampling are given as an incentive. Substance of the MRA is that both parties are committed to maintain close collaboration in notification and consultation if a problem regarding public health and consumer protection arises. A specific time frame is laid down for reporting of any serious and immediate concerns.

With regard to the audit procedures for assessment and verification of the effectiveness of the system, the MRA abides by the "Guidelines on Procedures for Conduction and Assessment and Verification by an Importing Country of Inspection and Certification Systems of and Exporting Country" as developed by the *Codex Committee on Food Import and Export Inspection and Certification Systems* and adopted by Codex Alimentarius Commission (1997).

Canada also has a similar two-way agreement with the New Zealand Government. The "Equivalency" arrangement, signed in April 1996, recognises mutual control measures for the safety and

quality of fish and fishery products. The essence of the arrangement is to facilitate bilateral trade in fish and fishery products that are safe and wholesome for consumers.

Indonesia, the Philippines and, more recently, Ecuador also succeeded in signing a MOU with Canada which gives their products (frozen shrimp for all and additional canned tuna for the Philippines) a special treatment by the Canadian Food Inspection Agency.

Due to dramatic changes in Brazil's international trade policies, for a few years now Brazil has been importing larger amounts of seafood than it exports. Therefore, its traditional Federal Food Inspection Service (DIPOA) has been pursuing the establishment of MOUs not only with Inspection Services of countries that import seafood from Brazil but also with that which *export seafood products to Brazil*. These MOUs aim at achieving mutual recognition of inspection systems.

According to the Brazilian approach, it is the foreign government of the exporting country that is responsible for the evaluation of their fish processing/exporting plants and authorise those which may export to Brazil. The Brazilian Inspection Service monitors the effectiveness of the enforcing government's control programme in accordance with the established MOU. Under presently established MOUs, the enforcing Official Inspection Service of the exporting country should provide the Brazilian authority with periodic lists of processors that meet the requirements of the mutual recognition agreement (Costa Jr., 1997).

Actually, MOUs have been established by Brazil with Argentina and Peru, while negotiations for establishing MOUs with Norway and Ecuador are well advanced. Preliminary correspondence was initiated with Canada in 1996 aiming at establishing a MOU. Chile and Uruguay are the next target countries for Brazil concerning the establishment of such agreements, due to the volume of imports from these two countries.

Multilateral agreements

The Organisation for Economic Co-operation and Development (OECD) was established in France in 1960 and comprises, to date, 29 member countries from Europe, North America, Asia and Australia: all of them are developed countries except for Mexico and the Republic of Korea. OECD has policies to promote co-operation among members to sustain expansion of economy and trade. Realising the significance of determining equivalence of fish inspection systems among member countries, the OECD Committee for Fisheries will organise a **Workshop on Seafood Inspection** early in 1998. Member countries are expected to share information on their existing fish inspection systems. Similarities and dissimilarities will be identified, summarised and presented during the workshop. Representatives from FAO and the Codex Committee on Food Import and Export and Export Inspection and Certification Systems are invited to participate and provide input to the workshop.

The above OECD initiative aiming at determining equivalence in seafood inspection procedures reflects a strong determination and transparency strategy to achieve seafood safety as well as fair market access to seafood. This is a positive effort of industrialised countries towards harmonisation of fish inspection systems, provided that the benefits will not only benefit upon themselves. The outcome of the workshop must be practical and realistic for developing countries as major trading partners.

Member countries of MERCOSUR - Argentina, Brazil, Chile, and Uruguay - actively work on the establishment of a subregional agreement aiming at harmonizing their fish inspection systems. In this direction, MERCOSUR countries established a Seafood Safety Committee during July 1997.

MERCOSUR countries are also trying to establish a common front of discussion with the European Union. Common problems and difficulties concerning the application of EC Directives and Decisions, the different criteria applied during the official visits of EC Inspectors, the different hygiene criteria applied by EC with reference to fishing vessels from EU Member States and those from Third Countries are among the relevant issues discussed. Attention is also given to problems and difficulties which might occur from December 18, 1997, in consequence of the enforcement of the USED Final Rule for seafood imports to USA.

NAFTA (North American Free Trade Agreement) - though established with the major objective of promoting free trade among USA, Canada and Mexico by streamlining border-crossing process and eliminating tariffs - signatories have been working on the harmonization of standards, testing and certification procedures. The provisions of the agreement also emphasize removal of trade barriers by allowing free flow of goods which meet "rules-of-origin" requirements. That means goods are not subject to repeated inspection at subsequent ports of entry. The policy, in turn, benefits fishery exporting countries especially those having an equivalence agreement or MOU with any of the NAFTA members. However, this free movement will be markedly affected when the HACCP mandatory will be in force in the US.

Founded on the basis of common economic interests, APEC (Asia-Pacific Economic Cooperation) is promoting equivalence agreement on foods and food products among 18 member countries. APEC Mutual Recognition Arrangement on Conformity Assessment of Foods and Food Products or APEC Food MRA is a voluntary mechanism designed to facilitate trade by minimizing food inspection controls at the point of entry into importing economies (countries) on the basis of assurances provided through pre-export conformity assessment using official and officially recognized inspection and certification systems, and by establishing a mechanism for resolving issues which may otherwise disrupt trade. The agreement could be established between two economies at first stage. APEC encourages multilateral agreements to form from the nucleus which will promote more trade flows. HACCP is recommended to be included as an integral component of the exporting party's inspection program. The agreement shall be established in accordance with SPS and TBT (Technical Barriers to Trade) Agreements and with principles detailed in standards, guidelines, and recommendations developed by Codex, in particular those developed by the Codex Committee on Food Import and Export Inspection and Certification Systems.

The Common Market for Eastern and Southern Africa (COMESA) is a regional, intergovernmental body comprising 20 member countries in Africa. This international collaboration aims at promoting economic cooperation among member states and trade within and outside the region. COMESA has been cooperating closely with FAO on improving regional fish inspection and quality assurance system. A recent proposed project to receive technical assistance from FAO identifies the needs for implementation of a national HACCP-based quality assurance system for fish and fishery products to ensure compliance with the new requirements for fish imports to EU and USA, as well as to improve the safety and quality of seafood sold on the national markets of the COMESA region.

Effects of Equivalence Agreements

Positive Effects

Achieving an agreement with main seafood importing countries based on the "equivalence" of fish inspection systems is the highest goal for fish exporting countries. However, the process is long,

complicated and tedious. The main reason is that there is no compromise in food safety. Some countries may find that there is so much to improve and change throughout quality and legislative systems. However, most exporting countries are reacting positively to these new challenges. There have been increasing demands world-wide for technical assistance extended by international aid organisations such as FAO. The “Equivalence” approach may be considered not appropriate for some exporting countries with a lack of basic infrastructure, facilities, qualified personnel of both government and private sectors, effective legislative structure and basic Good Manufacturing Practices (GMP).

To exporting countries, the main advantages of “Equivalence” agreements on fish inspection systems are the following:

- to reduce or eliminate the risk of placing health hazardous fishery products on the market;
- to reduce the rate of shipment rejection and economy losses;
- to maintain and/or increase access to international markets;
- to reduce financial and personnel resources actually spent in end-product testing and certification;
- to facilitate import administrative measures and speed up custom clearance;
- to shift regulatory agency efforts to main fish illness problem areas, strengthening the role of the agency in the field of prevention and control of foodborne diseases and seafood quality assurance; and
- to liberalise trade and remove trade barriers caused by the imposition of too stringent or non-scientific based standards and unnecessary hygiene regulations.

Not only the exporting party will benefit from equivalence approach, but also the importing party will enjoy the positive aspects of such agreement, as follows :

- to ensure that importing standards and requirements are constantly met, and safe and wholesome products are being domestically marketed;
- to reduce financial and human resources actually spent in the regular imports inspection both at local and overseas levels;
- to ensure that seafood safety problems are quickly identified and dealt with through close liaison with National Competent Authorities of foreign countries, as a substance of the agreement; and
- to increase opportunities to access the other party’s market as well.

Negative effects

The obligation of the establishment of “Equivalence” agreements could also create adverse effects to exporting countries that are not ready for the new approach. Fishery products from those countries could be less competitive. Specific restrictions may be imposed against their imports resulting

in additional costs and possible delays in the importing process. For example, when the inspection and quality control systems are not deemed equivalent, extensive end product sampling and testing are still mandatory. Importers may prefer to import from countries having easier access and given privileges to enter their market.

The exporting countries, as suggested by Goulding and Stroud (1997), will need to urgently improve necessary infrastructure, increase knowledge and awareness of food hygiene, modify existing government legislation to coincide with importing countries requirements, training staff and effectively implement GMP and HACCP. Financial investment is another burden to achieve this improvement. Importing countries, especially developed nations, always when possible, should provide financial and technical support. Co-operation at regional level should be established as well, apart from the assistance which may be provided by international agencies.

Whilst equivalence may not be an immediate goal for several countries, to remain competitive on the global market, priority should be given to improving or establishing an effective fish inspection and quality control as well as regulatory systems. Compliance with basic requirements, such as implementation of HACCP or EC Directives, in order to acquire import permission is a more realistic goal to achieve for the time being.

Conclusion and Recommendations

In achieving global free trade and providing maximum health protection, equivalence agreements based on recommended Codex guidelines should be actively pursued. The ultimate goal cannot be accomplished if communication, understanding and mutual confidence between inspection services of both trading partners are not improved. Importing countries should exercise more positive attitudes towards fish inspection and quality control efforts made by exporting countries. The introduction and mandatory implementation of preventive approach or HACCP concept has obviously made a considerable impact in national inspection services world-wide. It reflects in a number of developing countries that are in the process of promulgating new legislation to mandate HACCP in fish processing establishments and throughout the production chain. While exporting countries are struggling to implement HACCP under intense scrutiny by the buyers, the latter should also ensure that a proper HACCP based system is effectively applied within their own fish industry. It should be noted that, despite strong efforts made by international organisations such as WTO and CODEX to oppose non-tariff trade barriers, the problem is still existing and is far from eliminated.

Importing countries which are well advanced in fish inspection system should contribute to less developed trading partners in terms of technical assistance and financial supports. This would lead to a mutual benefit to all parties concerned. Problems of shortage of qualified staff, adequate training and auxiliary facilities to achieve better performance in the field of inspection and verification should be addressed and tackled by international aid organisations as well as industrialised countries. Exporting and importing countries should organise and implement joint training programmes for their inspectors so as to promote better understanding and communication between inspection agencies. Traditional fish inspection approach of end product testing should be reduced to a minimum to avoid unnecessary economic losses in carrying out laboratory tests and misleading consumers in the level of health protection. Certificate requirements should no longer be considered a major criteria for accepting a shipment. The process only yields additional work and creates false expectation in the quality of the certified lot. Importing countries should apply more realistic and achievable standards and regulations based on scientific justification and risk assessments recommended by recognised international organisations.

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USE OF THIRD PARTY ENTITIES FOR CERTIFICATION OF FOOD SAFETY AND QUALITY SYSTEMS

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Introduction

Over the past several years, the topic of third party certification bodies has increasingly occurred as an option for governments to employ when certifying food safety or quality systems for import, export, and public needs. Increasingly, governments are faced with diminished budgets, downsizing, and increasing food production facilities and exports, making it difficult to meet the certification requirements demanded. Some assistance is found through methods of electronic certification, formal agreements of trade, and other such concepts. However, all still require some method of evaluation to be performed to determine the acceptability of the product to be traded or consumed. End item inspection is becoming a very expensive and labour intensive method of determining product acceptability. Also, at times this method requires product inspection both at the producing country and at the receiving country in an import-export situation. For these and other reasons, governments are moving to a system based upon a quality audit practice, evaluating the process that produces the food, not the finished product. This method has proven to be more effective and cost efficient to the firm, as well as to the government body. Now that quality auditing is becoming the norm, the question of whether to utilise the growing number of private and government independent auditing and registration bodies is upon us.

How to Evaluate the Evaluators

In order to accept the use of a third party auditing organisation, as well as their results, there must be a method to evaluate their performance and their acceptance. Fortunately, such a method does exist and was developed by an organisation that is independent in nature--the International Organization for Standardisation (ISO). This organisation has prepared a series of standards for auditing and auditing functions known as the Guidelines for Auditing Quality Systems ISO 10011. The standards come in three parts: 1) Auditing, 2) Qualification Criteria for Quality Systems Auditors, and 3) Management of Audit Programs. As a set, all three are being adopted by governments as national standards. Together, they provide a strong framework for identifying the needs and methods of an acceptable auditing function. A detailed look at the third part of the standard can provide more information.

Elements of ISO 10011-3: Management of Audit Programs

Organization

The very nature of auditing functions is to be independent of the area being audited and to provide the client with information based upon facts. If these two concepts are violated, then the results

of the audit are suspect and can offer no useful information. This means that even if an audit function receives fees for its endeavours, to provide a report that is suspect would mean that the organisation would soon be out of business, as their integrity as an auditing function would be under suspicion and their reports would be considered unacceptable.

Standards

In order to properly perform an audit of a quality system, the audit must be performed against a written standard. In addition, the audit function management must take steps to ensure that the standards are understood and that the auditors have received proper training in applying the standard. This provides a strong role for the government entities, in that they can provide the necessary training and technical assistance to the audit functions.

Qualification of Staff

Part 2 of the ISO 10011 standard speaks specifically to the qualifications of the auditors. Auditors must have not only formal training but audit experience and workplace experience as well. Even then, it is up to an evaluation panel to determine the acceptability of the auditor's qualifications. This intricate system of auditor qualification may have many facets, including a role for the government entity on the evaluation panel.

Suitability of Team Members

Audit program management is compelled by the standard to determine, through listed criteria, if the members of the chosen audit team are suitable for the assignment. The criteria includes technical expertise and auditing expertise to complete the audit properly.

Monitoring and Maintenance of Auditor Performance

The standard asks that audit program management make certain that the auditors maintain their performance. The standard talks of evaluating auditor performance for the purposes of improvement and to identify unsuitable performance. All evaluation information is to be provided to an evaluation panel. In addition, methods are to be established to compare auditor performance. Such methods should include training, performance comparisons, review of reports, etc., all for the purposes of monitoring that different auditors will arrive at similar conclusions on the same operation. Audit program management is to regularly assess the training needs of auditors.

Operational Factors

Several points on the operation of the audit program are discussed in the standard. The standards indicates that procedures should be established to ensure that adequate resources are available to accomplish audit program objectives. Also, procedures should be established for planning and scheduling the program of audits, to control corrective action follow-up if requested, to safeguard the confidentiality of any audit or auditor information that they may hold, and that report formats should be formalised.

Joint Audits

There may be instances when several auditing organisations co-operate to audit jointly a quality system. Where this is the case, agreement should be researched on the specific responsibilities of each organisation particularly in regard to lead auditor authority, interfaces with the auditee, methods of operation and distribution of audit results before the audit commences.

Audit Program Improvement

Audit program management should establish a method of continuously improving the audit program through feedback and recommendations from all parties concerned.

Code of Ethics

Audit program management should consider the need to include a code of ethics into the operation and management of the audit programs.

Example: The NOAA Seafood Inspection Program

For over forty years, the NOAA Seafood Inspection Program has been offering a voluntary program for any party in the seafood industry who wishes to utilise the service. The majority of the program's participant's are seafood processors who request their products be inspected and certified, ultimately bearing our certification marks. Since 1972, the program has been offering a system of reduced inspection, which relies upon the facility's quality plan to be audited by government personnel, rather than product by product certification. In July 1992, this Integrated Quality Assurance program was joined by the HACCP-based Inspection Program, where the use of quality auditing was further brought to the forefront.

It was noted early in 1992 that more formal procedures were necessary to strengthen our auditing procedures. The use of the ISO 10011 series of auditing standards was felt to best help us meet our goal. All three of the standards are diligently used in the process of determining who will be auditors of quality systems and what is expected of them.

The NOAA Seafood Inspection program maintains an independent audit function in two ways. First, acting as a government agency, the function is inherently third party and independent. The auditor does not derive his income from the auditee but is paid by the government itself. This is true even though the program is a fee-for-service institution. In addition, the program management has formed an independent quality team to further add assurance that the audit function maintains its independence. This is done through performance reviews as well as training functions.

All audits are performed against a written standard, including the audit function itself. Standards typically include the ASQC/ANSI 10011 (technical equivalent to ISO 10011), ASQC/ANSI 9000 (technical equivalent to ISO 9000), the regulations of the FDA Title 21, Part 123, Federal Standard 369, etc.

To become an auditor, the inspector must first pass the formal course, perform the minimum number of audits described in the standard, then take a final test. Lead auditors must undergo the evaluation panel process. Only auditors with sufficient experience and expertise in the product or process

are chosen to perform an audit. This expertise would include any prerequisite training and certification in specific subject areas, such as HACCP. The auditor's performance is evaluated not only by his/her supervisor, but also evaluated every three years by a member of the quality team. This three year evaluation must be performed if the auditor wishes to keep his certification current. Finally, the auditors are bound to the Code of Ethics that are dictated to all US Government employees and this code of ethics is similar in depth and scope to most other known codes.

Procedures have been established to ensure that adequate resources are available to accomplish audit program objectives. Procedures are also established for planning and scheduling the program of audits at all levels, to control corrective action follow-up as necessary, to safeguard the confidentiality of any audit or auditor information, and the formalising of all report formats.

Continuous improvement of the audit function has been considered as well. A quality team has been formed to evaluate the auditor's capabilities and to continue to standardise the methods and formats of reports. This team also is the main body used to assess the performance of auditors on a three year basis, in addition to the performance appraisals of the auditor's superiors. The quality team also serves as the point of appeal for the auditee, when the needs arises. This function assures that the auditee has a point of contact and judgement that is not involved with the original finding.

Pros and Cons of Utilising Third Parties

The debate of utilising third parties is not new. But its level of importance has risen in recent years. Several government agencies have opted to use third parties to assist in whole or in part with the establishment of food safety or quality certification. In some cases, those firms registered under the country's ISO 9000 system have been permitted to use such a system to meet export certification requirements. In other cases, third party government corporations or agencies have performed the certification service, in lieu of the public health authority.

The main concern over the use of independent third parties appears to centre around the authority's perceived lack of control of the system or the suspicion of the data. This suspicion is often touted as a concern over the abilities and integrity of the individual auditors. Even the public has some concerns when the government itself does not "inspect each and every fish, cow, or pig". This concern usually stems from either a lack of understanding of what is necessary for the audit function to operate or from a fear of losing ground in the ever escalating war over resources and personnel. Also, a very real concern is the certification of the certifiers; how do we determine if the independent audit function has the necessary background and diligence to do the job correctly? And should the industry pay for such a service?

A positive factor can be gained by using such services. Again, in some countries, the establishment of a government agency that is fee-for-service is not far removed from the use of a private entity. The independence and competence of each must certainly be determined through a formal mechanism. But this question again has been answered by some as acceptable. For others, rather than look at the difficulties with acceptance by the public health agency, consider the expansion of resources in using these third parties. This would mean that the third parties could maintain those strong players in the industry while the public health authority could focus their dwindling personnel upon the members of the industry with a poor record.

Summary and Conclusions

With all that has been considered to date, it makes perfect reasonable sense to accept the use of third party audit bodies. The crucial point of their acceptance would be to focus on the mechanism used to ascertain the independence of the body, such as that found in ISO 10011. Or the responsible agency could have their own determination method. The real questions lie in how to get the agencies' field personnel to view this move not as a threat but as assistance. Also, what must be considered is the international acceptance of third parties to meet several countries needs. In this way, one independent third party audit function could be considered acceptable to more than one responsible agency, thereby meeting the fiscal and cost efficient needs of the industry and the public.

AQUACULTURE IN NORWAY: QUALITY ASSURANCE

by Bjarne Aalvik, Directorate of Fisheries, Norway

Market Demand for Quality

The aquaculture industry is, world-wide, devoted to more to volume and less concerned with market demand. Clearly, there should be better correlation between the quality of product the market demands and the quality which the industry supplies (i.e. a market-controlled production). Sufficient attention needs to be devoted to this side of the industry.

It is a prerequisite that production be cost-effective, while at the same time complying with the health and environmental requirements which are essential in defining product quality. In addition, the control procedures for aquaculture products start at the very beginning of the production line and are followed all the way to the market.

The control procedures at the slaughtering and processing plants are very important for the end quality of the aquaculture product. However, there are many other steps in the production chain from egg to market which exert great influence on the quality of the final product.

The quality of the aquacultured fish or other aquaculture organisms depends on the raw material brought to the slaughtering plant. Nothing is added and the main task in the slaughtering process and the accompanying control procedures, is to preserve the quality potential already in the fish. Later, transport to the market has to occur in accordance with sound hygienic principles.

To build and sustain the quality of aquaculture organisms through the production line to the market involves a complicated and long process which involves a variety of different measures in order to achieve the main goal: a high quality product on the market. Activities to achieve this goal concentrate on preventive measures. If anything goes wrong in the production chain it might affect the product in a way that makes it difficult to restore the product to its potential quality. There is no simple answer to the question how to construct a perfect preventive quality line throughout the production chain since there are a great variety of aquacultured organisms, (e.g. biological differences, different feeding habits (carnivorous, herbivorous or omnivorous species)), different climatic conditions, organisms reared in fresh-, brackish- or saltwater, etc. At the same time many differences are connected to the availability of sites, structure of the society, level of education and research, experience in aquaculture, infrastructure, management, funding, etc. With such diversity it is not possible to construct and point out the correct quality line in the production from egg to market.

Production and Features in Favour of Aquaculture

Production

Norway is a relative latecomer to the field of aquaculture, having started with rainbow trout (*Oncorhynchus mykiss*) at the beginning of the 1960's. Atlantic salmon (*Salmo salar*) took over as the predominant species around 1977. From negligible production of the two species in 1970, the total production reached a quantity of 320 000 metric tons in 1996, of which the Atlantic salmon represented approximately 90 per cent.

Features in Favour of Aquaculture in Norwegian Sea Water

There are several reasons for the large growth of the aquaculture industry in Norway. As a country it has a number of unique features favouring fish farming in the open sea waters including:

- enough unpolluted freshwater to raise smolt all the year around;
- favourable coastal water temperature (due to the Gulf Stream);
- clean sea water;
- long and protected coastline;
- abundant fish feed of good quality;
- good infrastructure along the coast; and
- leading scientific community.

Management Measures in the Norwegian Aquaculture Industry

Regulation of fish farming Licensing system

The network of governmental regulations, which are promulgated in co-operation with fish farmers, seem to be of growing importance in connection with steadily increasing production and especially with regard to combating infectious diseases and ensuring high quality of the fish products. As such, official regulations play an important role in the quality assurance programme within the aquaculture industry.

One important aspect of the marketing of Norwegian aquaculture products is the public control system with the quality control of raw materials, feed and finished products. This is one of the Directorate of Fisheries' ongoing activities.

The Norwegian aquaculture industry is strictly controlled by a number of laws and regulations administered by four different Ministries (Ministry of Fisheries, Ministry of Environment, Ministry of Agriculture and Ministry of local Government and Labour). The Act of Fish Farming (The Ministry of Fisheries) introduced the licensing system in 1973. The system imposes limitations on size of farms, and

on number of permits issued for fish farming. Today Norway has a total of 800 licences for raising salmon and rainbow trout in salt water. Additionally, close to 500 licences are granted for different marine species, including shellfish. Only a fraction of these 500 licences are in operation.

The licensing system is the main instrument used by the authorities to maintain the fish farming industry as a profitable and viable regional industry. As such, the total number of permits has been limited. The Act of Fish Farming regulates all activities concerning fish farming. The Act regulates the breeding in freshwater as well as brackish water and salt water.

There are several conditions which have to be met before a licence is issued. A licence shall not be granted if the facility:

- will cause risk of spreading diseases among fish and shellfish;
- will cause risk of pollution; or
- has a distinctly unfortunate location in relation to the environment, lawful traffic or other exploitation of the area..

Applications for licences are sent to the Veterinary authority (Act of Fish Diseases), Environmental authority (Act of Pollution) and Local Government and Labour authority (Act of Building and Planning).

The conditions attached to the licence restrict the activities of the operators of the fish farm. However, these measures have been introduced to ensure maximum benefit to the society from the industry, including reducing as far as possible any injurious effects on the environment and conflicts between users.

Qualifications of a Fish Farm Manager

When granting new licences, emphasis is placed on the professional qualifications of the operator of the fish farm. The Norwegian school system offers a special education programme, established in 1985, for students in junior high school who wish to specialise in practical fish farming. It takes 3 years to complete the programme. When level 2 (after 2 years) is completed, the student may qualify as manager of a fish farm. There are also vocational school in aquaculture.

The education programme plays an important role in the quality assurance efforts.

Minimum 2 years of practice as manager of a fish farm is accepted as corresponding to the academic education described above.

Aquaculture Sites

The environmental conditions are extremely important for the siting of aquaculture farms both in sea — brackish — and freshwater. Early salmon farms were located in protected fjords or bays which have poor flushing capabilities, leading to an accumulation of fish faeces and excess feed underneath the pens. Today a premium is placed on water flow to ensure an ever changing water supply through and around the pens.

The distance between each fish farm should be at least 1 km. The distance between a salmon grow-out farm at sea and a broodstock farm should be at least 3 km. There have been discussions suggesting the lengthening of the distances to up to 3 km. between fish farms and 5 km to broodstock farms.

The main goal is to have three sites per licence. Due to lack of sites, this might be difficult to fulfil in all parts of the country. On average, 70 per cent of our fish farms have two or more sites per license. This makes it possible for the ordinary operation of a fish farm, always to have one site free of fish every third year, or at least lay fallow a part of the year. This operation system will substantially reduce the number of infectious particles on the site within a relatively short space time. Most of the pathogenic bacteria and viruses will die out within weeks, although there are exceptions (e.g., the bacteria causing furunculosis, *Aeromonas salmonicida*). Any accumulation of fish faeces and excess feed underneath the pens will also disperse during the period of no operation.

Applications for new aquaculture sites are sent to the regional fishery authority (Act of Fishfarming), Veterinary authority (Act of Fish Diseases), Environmental authority (Act of Pollution) and Local Government and Labour authority (Act of Building and Planning).

Aquaculture Research

Aquaculture research is extremely important for the industry. Norwegian aquaculture research was internationally evaluated in 1991-1992 by peer review. According to the evaluation, certain aspects of the Norwegian research are the best in the world. Also, the evaluation found that research plays an important role in quality assurance efforts.

Another peer review took place in 1996 and the researchers and the other Norwegians involved in aquaculture hope to be similarly acclaimed again.

Central Breeding Stations

Breeding plays an important role in the Norwegian fish farming industry. No fish intended for human consumption or commercial purposes has been genetically modified. Norway has two central breeding stations organised as a joint-stock company. (NORSK LAKSEAVL AS). Today, using ordinary breeding principles, these stations have managed to produce smolt with higher resistance against furunculosis, vibriosis and cold water vibriosis. The programme conducting research in several other fields of importance for quality assurance (e.g., higher colour index in salmon flesh, increase in growth rate, delay in maturity, etc.). It has been calculated that the value of the breeding programme in Norway is equivalent to NKr 100 million a year (US\$15 million).

The Norwegian Fish Farmers Association like to stress that no fish in Norwegian aquaculture meant for human consumption or commercial purposes has been genetically modified, and the Association want sit to stay that way in the future.

Health Certificate: Transportation of Smolts

The Norwegian aquaculture industry wishes to keep the farmed fish free from contagious diseases. Some of the infectious diseases will cause serious losses due to death, lower growth rate and

inferior quality of fish flesh. According to the regulations, it is the responsibility of the Norwegian fish farmer to make sure that no smolt are placed in the sea without having a veterinary health certificate. In other words, it is illegal to sell smolt without a health certificate.

There are specific regulations for the transport of smolts by boats, cars and helicopters in order to avoid infection during the transport. Vehicles for smolt transportation must be approved.

Recording System on Fish Farms

Daily activities in connection with the operation and maintenance of facilities have to be recorded in accordance with rules laid down by the Director of Fisheries. The information is available for inspectors from different governmental control authorities and forms the base for a quality assurance system which, in the near future, will be instituted for each fish farm in Norway.

Veterinary Reports on Diseases

Norway has a monitoring system for specific fish diseases. The data are based on an official monitoring programme run by the veterinary field services and surveys performed by the veterinary diagnostic laboratories. Classification of diseases is carried out according to the specific grading system (A, B and C-diseases) applied by the International Office of Epizootics (OIE).

The diseases are reported, on standard notification forms, to the central Norwegian veterinary authority and official reports are published quarterly.

Compulsory Health Control

Norwegian regulations aim to be compatible with EU regulations. In accordance with the EU-Directive (91/67) every fish farm should be inspected twice a year.

Approval of Slaughter Plants

Only approved industrial plants, which are given an official registration number, are allowed to slaughter and process farmed fish. The requirements comply with standards laid down by European Community Law in regard to production and hygiene in the fishing industry. It is illegal to place fishery products on the market from non-approved plants.

Quality Assurance: "Own-Checks" System

The fish farmers submit information to the Directorate of Fisheries in advance of slaughtering. The information is given on a standard notification form. In slaughterhouses and processing plants the fishery authorities have introduced the so-called "own-checks" system. This refers to all those actions aimed at ensuring and demonstrating that a fishery product will conform to the requirements of EU Council Directive 91/493/EEC.

As part of this internal approach, the establishment may use guides of good manufacturing practice drawn up by appropriate professional organisations and acceptable to the relevant authorities.

The persons responsible for the establishment must ensure that all staff concerned with "own-checks" receive adequate training in order to effectively participate in their implementation. The "own-checks" system is based on Hazard Analysis of Critical Control Point (HACCP).

A critical control point (CCP) is any point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to acceptable levels. All CCPs useful for ensuring compliance with the hygiene requirements of Directive 91/493/EEC must be identified.

CCPs are specific to each establishment depending on the raw materials it uses and on its manufacturing processes, structures and equipment, end products and marketing system.

Tracing of Salmon and Trout

An electronic registration system for plants and fish farms is used to inspect and label boxes of slaughtered farmed fish. The system makes it possible to trace the fish on the market back to the approved plant, and further back to the single farm. In a few years time it might be possible through electronic devices to trace each individual salmon or trout all the way from smolt to market.

Reporting Procedures on Veterinary Drugs

Antibacterial substances and other drugs are only obtainable by veterinary prescription. There are specific reporting procedures for the use of antibiotics and other drugs for the treatment of farmed salmon and trout. The Directorate of Fisheries receives weekly copies of all such prescriptions, sent in on standard forms. The Directorate compiles all information from prescriptions in a database. This database contains updated information on all uses of medicine in every single Norwegian fish farm. Regulations impose laboratory control in advance of slaughter for all fish treated with antibiotics or chemotherapeutics during the previous 12 months.

Good management, effective vaccines and a successful campaign against infectious diseases during the last four to five years has reduced the quantity of antibacterial drugs being used in the Norwegian aquaculture industry from approximately 48.5 tonnes in 1987 to 1.0 tonnes in 1996. In the same period of time, the production of farmed fish increased by approximately 200 000 tons. Preventive health care and close co-operation between fish farmers, scientists and official authorities is needed in order to combat contagious diseases, throughout the production line from broodstock to market.

Control Programme for Antibacterial Drugs

There are established withdrawal periods for all drugs used in treatment of fish. If the farmed fish has been medicated during the last 12 months it is compulsory to perform a laboratory test for any residues. The tests are carried out by the Directorate of Fisheries. There are no accepted residue levels in farmed fish meant for the national or international market.

It is illegal to use growth hormone in the production of farmed fish.

Monitoring on grow-out farms Modelling (MOM)

The main environmental objectives of a sustainable aquaculture industry are to:

- meet environmental requirements of the cultured organisms; and
- keep the environmental quality standards defined by society.

To promote a sustainable aquaculture industry the environmental impact of the individual fish farm must be adjusted to the holding capacity of the site.

A regulatory system for the individual sites is being developed. The system is called MOM, which is an acronym for a Monitoring-On grow-out fish farms-Modelling. It consists of two integrated parts, a monitoring program and a simulation model. The Norwegian authorities are showing great interest in the MOM-system and it will probably be integrated in the public regulations of the aquaculture industry in the near future.

Joint Environmental Objectives

A set of joint environmental objectives for the Norwegian aquaculture industry has been drawn up by the four different ministries (Ministry of Environment and Pollution, Ministry of Fisheries, Ministry of Agriculture and Ministry of Health.)

Both long-term environmental objectives and result objectives (short-term result goals) have been defined in five problem areas. In addition to defining objectives for each problem area, the areas have also been allocated priorities. The priority of the problems is as follows: escapees, diseases, medicines, chemicals and organic matter.

Statistical data are collected within the defined problem areas and these constitute the basis for the annual evaluation of progress towards the environmental objectives.

The Norwegian aquaculture industry was awarded a national environmental prize in 1995.

Co-operation between fish farmers and the authorities

It is very important that the regulations given by the authorities are implemented by the fish farmer and others dealing with aquaculture.

Close co-operation between the fish farmers and all the official authorities concerned with fish farming is needed in order to prevent contagious diseases being a problem for the Norwegian aquaculture industry or the wild stocks of salmon. The salmon farmers are the key operators in preventive health care. In this context, quality assurance system for each fish farm is very important. The farmer is also the key operator dealing with different types of environmental problems.

Finally, different Ministries and Directorates have to co-operate in order to reduce the conflicts between salmon farming and wild stocks.

Dead and diseased farmed fish offals and by-products from slaughterhouses/processing plants.

Both ethical and a resource questions need to be taken into account to deal with dead diseased fish and offals and by-products from the aquaculture industry. In Norway more than 50 000 tonnes are collected each year from these sources. The waste, if not taken care of, might create environmental

problems and a source of infectious micro-organisms that can be transmitted to aquaculture and wild organisms.

The dead diseased farmed fish should be collected from the pens every day in summer and every second day during winter. There are specific rules for handling dead fish. The fish should be ground with formic acid and stored in a tank on the farm and later transported to a factory processing offals and by-products from farmed fish and fish slaughterhouses. Nearly 100 per cent of the dead diseased fish, offals and by-products are processed in these factories. The silage is heated to 85- 90°C and centrifuged. Two main components are produced, protein concentrate and fish oil. The protein concentrate is turned into feed for warm-blooded animals. Fish oil is produced from the offal and is mostly used for technical purposes.

Fish meal and feed for farmed salmonides.

Fish meal is the main constituent in feed for farmed salmonides and as such is an important determinant of the quality of the flesh. The nutritional value (amount and quality of protein, content of minerals and vitamins, etc.) of the feed is of great importance for the growth and health of farmed fish. At the same time close attention should be paid to the content of pollutants (e.g., heavy metals, organic pollutants, radioactive compounds, etc.) in fish meal. Any pollutants in the feed might be concentrated in the flesh or other organs of the farmed fish. Or said in other words: "You are what you eat".

The fish feed industry is closely supervised according to public regulations. The supervision is based on HACCP principles.

Data base for pollutants in fish and other seafood

Pollution is often the subject of public debate and the market reacts immediately on the slightest suspicion that the consumption of food represents possible hazards to human health. To take care of the short and long-term interests of the fishing industry it is important to address pollution issues on the basis of established knowledge. The wild and farmed marine resources should ideally not be polluted as a result of human activity. This implies that pollutants should not be detected above a certain background level representing the unpolluted resource. The description of the normal background level is thus of vital importance.

The laboratories of the Ministry of Fisheries have established a database for pollutants in seafood. This provides a current overview of the concentrations of pollutants in marine food from Norwegian waters, including fish farm locations. Samples were taken from nine randomly chosen locations along the coast. From each site five salmon, weighing 2.5 to 3.0 kg, were sampled and later examined in the laboratories for about 70 parameters. The information provided will be used to document nutritive quality/health and promote fair trade in the export of fish and fishery products.

COUNTRY OVERVIEW PAPERS

AUSTRALIA

HACCP BASED INSPECTION PROGRAMS: A REGULATORY APPROACH TO HACCP - THE AUSTRALIAN PERSPECTIVE⁶

Summary

The Australian Quarantine and Inspection Service (AQIS) has played a significant role over the past ten years encouraging Australian export seafood manufacturers to develop and implement HACCP and ISO 9000 based quality management systems. In line with government policy and international trends on food inspection, AQIS introduced a mandatory HACCP based inspection system to the existing voluntary ISO 9000 based inspection system to ensure that seafood products exported from Australia are safe for human consumption. The introduction of these HACCP and ISO 9000 based inspection systems have caused the industry some concern, but AQIS believes that these systems are the most effective way of assuring the safety of exported seafood products. AQIS, in conjunction with the Australian export seafood industry and other government agencies, is committed to ensuring that the Australian export seafood industry continues to increase their understanding and the implementation of HACCP and ISO 9000 quality management systems.

The future of seafood inspection in Australia depends upon the international acceptance of AQIS's HACCP and ISO 9000 based inspection systems. For this to occur AQIS is committed to participating in international forums to harmonise regulatory HACCP based inspection systems. AQIS believes the future direction of seafood inspection in Australia is towards contestable third party delivered inspection systems.

Introduction

Australia's commercial fisheries production in 1994-95 was valued at A\$1.74 billion, with exports to Japan, Hong Kong, Taiwan, and the United States of America valued at more than A\$1.37 billion.

With approximately 79 percent of Australian seafood products being exported, the Australian Quarantine and Inspection Service (AQIS), as the competent regulatory authority responsible for controlling seafood exports, has played a significant role over the past ten years encouraging Australian export seafood manufacturers to develop and implement Hazard Analysis and Critical Control Point

6. This paper was presented at the International Conference in Fish Inspection and Quality Control: A Global Focus.

(HACCP) and International Organisation for Standardisation (ISO) 9000 based quality management systems.

Background

Implementation of HACCP based Inspection Systems in Australia

Prior to 1993, AQIS relied mainly on traditional end-product inspection, known as Product Monitoring System (PMS), and Good Manufacturing Practices (GMP) to ensure that seafood products were of export quality. AQIS was also responsible for regulating both food safety standards and commercial 'quality' parameters, as well as ensuring that the integrity of seafood products was maintained throughout the export system.

Although in 1986, AQIS introduced another inspection system known as Approved Quality Assurance Arrangement (AQA), which still remains an option for export seafood manufacturers today. The AQA system of inspection is closely aligned with ISO 9000 quality management systems, but with the mandatory integration of HACCP principles. Seafood manufacturers must fully document a quality system that will ensure that it meets AQIS's and overseas country authorities requirements. Considering the limited understanding of HACCP and ISO quality management systems within the Australian seafood industry in the late 1980s, it is not surprising that only manufacturers preparing mainly simple low risk products (live lobsters/crayfish) chose to implement this system.

However, in 1993 in line with government policy on industry self-regulation and international trends concerning food inspection, AQIS introduced new regulatory controls for the export of seafood products. These new requirements were incorporated into the *Export Control (Processed Food) Orders No 9, 1992* to ensure that export seafood products would be wholesome, safe for human consumption, accurately described and comply with the food safety standards imposed by AQIS and any importing country authorities. Although most of the existing regulatory requirements were retained, commercial 'quality' parameters and prescriptive structural and operational hygiene requirement were excluded from the Orders.

The new mandatory HACCP based inspection system, known as Food Processing Accreditation (FPA), was introduced to ensure that export seafood manufacturers focused on the critical aspects of their operations and AQIS's and other overseas countries requirements. FPA signalled a permanent shift away from resource intensive end-product inspection and testing to a system of preventative controls of hazards at all stages of seafood operations.

The FPA system of inspection is a food safety risk and performance based inspection system that utilises HACCP principles and GMP. Seafood products are allocated a low, medium or high food safety risk category, based on the potential health risk associated with the consumption of the food. For each category there are four possible performance ratings under which an export seafood manufacturer can operate. With the exception of vessels, the frequency of an AQIS review of an FPA program will vary according to this rating. Review frequency may be as little as once a year for good performing low risk establishments or as frequent as every fortnight for poor performing high risk establishments.

Therefore, while both inspection systems have the minimum requirements of HACCP and GMP to ensure the safety of seafood products, Australian export seafood manufacturers are able to make a

commercial decisions as to which system they will implement based on their understanding of HACCP and ISO quality management systems and the requirements of overseas markets.

Australia's Experience Implementing HACCP Based Inspection Systems

Mandatory Verses Voluntary Introduction of HACCP Based Inspection Systems

From a regulatory point of view, the mandatory introduction of HACCP based inspection systems in the Australian export seafood industry has allowed AQIS to focus on the critical aspects of seafood operations that have the potential to cause food safety problems, rather than relying on inspecting finished product. A secondary benefit has been the more effective and efficient utilisation of resources resulting from scheduled FPA reviews and AQA audits.

Opponents of the mandatory introduction of HACCP and ISO based inspection systems believe that unless the export seafood industry is voluntarily committed to these systems, have an understanding of the principles of HACCP and quality management systems, and have the technical expertise necessary to develop and support these systems, they will fail. Some consumers groups and food inspection unions in Australia fear that the mandatory introduction of HACCP and ISO based inspection systems has been hastily introduced, and are being used as a low cost substitute for inspection services. AQIS firmly believes that the introduction of HACCP and ISO based inspection systems has proven to be the most effective and efficient method of ensuring the safety of exported seafood products.

AQIS acknowledges the difficulties that some export seafood manufacturers have experienced making the transition to HACCP programs over the past two years, but has assisted the majority of export seafood manufacturers develop and implement FPA programs by:

- the consultative approach taken with the Australian export seafood industry during the development and introduction phase of the new regulatory requirements;
- conducting industry awareness seminars throughout Australia prior to the commencement of the regulatory requirements;
- HACCP and legislative training workshops conducted after the introduction of regulatory requirements; and
- the publication of a self-help handbook on FPA and AQA.

AQIS spent many years promoting HACCP and ISO quality management systems to the export seafood industry to ensure that they fully understood the principles of HACCP and ISO quality management systems. It has also meant that AQIS has had to train and re-educate its inspection staff in AQIS about HACCP and ISO quality management systems.

Resistance from the Export Seafood Industry

The mandatory introduction of HACCP based inspection systems met with some resistance from the Australian export seafood industry, especially amongst smaller manufacturers. Some of the

difficulties that export seafood manufacturers have experienced in trying to implement HACCP based program included:

- a lack of understanding of HACCP and ISO quality management principles (non-English speaking background, lack of education/training etc.);
- a lack of personnel with technical expertise to implement and maintain a HACCP program;
- limited resources (time and money) to develop and implement a HACCP program, especially small operators;
- reliance on AQIS to check product of compliance with product standards;
- a belief that this new inspection system was unnecessary considering that most export seafood manufacturers had success preparing safe and wholesome products under PMS of inspection and GMP.

Although AQIS appreciates the difficulties some export seafood manufacturers have experienced implementing HACCP programs, but believes that these systems are clearly the most effective way of ensuring the safety of seafood products exported from Australia. The Australian export seafood industry also realises that they will need to continue to implement HACCP and ISO quality management systems to ensure international market access in the future.

Confusion about HACCP Requirements

While the primary application of HACCP is to ensure the safety of food by identifying specific hazards and implementing preventative measures for their control, AQIS has also incorporated non-safety elements such as decomposition and fraud or misrepresentation (accurate trade description). Elements of GMP have also been excluded from HACCP documentation, though compliance is still required as part of the FPA system of inspection. Although some overseas countries have expressed their concerns at the inclusion of non-safety elements, it is important that in light of emerging international trade agreements that a more consistent application of HACCP based inspection systems be achieved.

There has also been misconceptions amongst Australian seafood manufacturers about the requirements of HACCP and ISO quality management systems. Seafood manufacturers have insisted that 'quality' parameters which are of commercial importance to them, as well as food safety elements be included. In these circumstances agreement between AQIS and individual seafood manufacturers is usually reached about the regulatory requirements that will be reviewed during normal FPA and AQA inspections.

Quality Initiatives in the Australian Seafood Industry

AQIS's involvement in the development and implementation of HACCP and ISO quality management inspection systems over the past ten years has encouraged the Australian export seafood industry, as well as other sectors of the processed food industry, to implement quality management systems.

Although AQIS will continue to provide assistance to the Australian export seafood industry, other government and industry agencies have also been developing quality initiatives to assist export seafood manufacturers implement quality management systems appropriate to their needs. These include;

- The Food Quality Program of the Department for Industry, Science and Technology (DIST) was established in May 1994 to accelerate the uptake of quality management systems in the Australian food industry. Providing \$6 million dollars (Australian) over three years to encourage the Australian food industry to develop and implement quality management strategies appropriate to their needs.
- SeaQual Australia, established in 1995, has been jointly funded by the Australian Seafood Industry Council, the Department of Primary Industry and Energy and the Fisheries Research and Development Corporation to identify, implement and expand on existing quality management strategies and to encourage governments and industry to develop policies and programs which build on existing systems to create industry-wide quality management strategies.
- The National Seafood Industry Quality Assurance Project has been jointly funded by the AgriFood Council of the Department of Industry, Science and Technology, the Queensland Department of Primary Industries and the Queensland Commercial Fishermen's Organisation to progress quality management systems and strategies in the Queensland seafood industry
- The Australian Prawn Promotion Association (APPA) has commissioned a Code of Practice for on-board processing and the Western Australian Crayfish Association is also developing a code of practice for the preparation of freshwater crayfish

Future Direction of Australia's Regulatory Approach to HACCP

While HACCP principles have generally been widely accepted by regulatory authorities world-wide, the challenges that face AQIS and the Australian export seafood industry will be to ensure that our HACCP and ISO based inspection systems gain international acceptance. AQIS will endeavour that the application of HACCP based inspection systems in Australia remains consistent with other regulatory authorities.

Finally, AQIS believes that the future direction of seafood inspection in Australia will be to investigate the possibility of introducing a system by which regulatory audit functions can be delivered by a contestable third party inspection system for those export seafood manufacturers with a certified ISO 9000 system. This change is dependent upon the Australian export seafood industry's commitment to increasing their understanding and implementation of HACCP and ISO quality management systems.

CANADA

CANADA'S SEAFOOD INSPECTION PROCEDURES

I. Description of Competent Authorities and Organisation Structure

a) *Human Resources*

The total complement of professional, scientific and support staff which are engaged in the implementation of the National Fish Inspection Program by the Fish Inspection Directorate of the Canadian Food Inspection Agency (CFIA) is 397 positions. Annex I summarises the categories of these positions by groups across Canada.

b) *Legislation*

The Fish Inspection Directorate is responsible for enforcing the Fish Inspection Act and Regulations, appropriate sections of the Food and Drugs Act and Regulations, appropriate sections of the Consumer Packaging Act and Regulations, and the Management of the Contaminated Fisheries Regulations.

Fish Inspection Act, R.S.C., 1985 c.F-12 (as amended by R.S.C., 1985 c.31 (1st supp) Statutes of Canada, 1992 c.1)

The Federal Fish Inspection Act, administered, applied and enforced by the Fish Inspection Directorate of the Canadian Food Inspection Agency (CFIA), has jurisdiction over all fish and fish products and marine plants intended for export, interprovincial trade and all fish imported into Canada.

Inspection Directorate of CFIA is responsible for the overall administration of the Fish Inspection Act. The Act is designed to ensure that fish and fish products and marine plants are harvested, transported and processed under conditions such that marketed commodities meet national and international standards of wholesomeness, quality, composition, packaging, and labelling. These are national standards with constitutional and legislative authority derived from the Constitution Act. The Constitution Act provides power to protect the public from health hazards and fraud and to control inter-provincial and international trade

The Fish Inspection Act:

- provides enforcement powers for inspectors;
- prohibits the import, export or possession for export of tainted, decomposed or unwholesome fish;
- seizure, detention and forfeiture of product; provides minimum and maximum fines and imprisonment terms for violations.

The Act defines fish as any fish, including shellfish and crustaceans, and marine animals, and any parts, products or by-products thereof. Processing for the purposes of the Act includes cleaning, filleting, icing, packing, canning, freezing, smoking, salting, cooking, pickling, drying or preparing fish for market in any other manner. The Act is divided into 3 parts: Part I — Fish and Fish Containers; Part II — Marine Plants; and Part III — General.

Fish Inspection Regulations made under the Fish Inspection Act, C.R.C., 1978 c.802.

The Fish Inspection Act is principally enabling legislation. The substance of the Canadian fish product, processing, harvesting and transportation requirements are set forth in the Fish Inspection Regulations.

The Fish Inspection Directorate has developed an extensive series of interpretative policy and procedural manuals which provide fish inspectors, industry and members of the general public with detailed guidance regarding the interpretation, application and enforcement of all fish inspection regulatory requirements.

The Fish Inspection Regulations derives its authority from Section 3 of the Fish Inspection Act.

The regulations establish requirements for:

- Access to and inspection of fish and fish products; minimal acceptable quality and safety levels for all fish and fish products; the registration or licensing of processing establishments; transportation and unloading, handling and holding of fish products; and the certification of vessels (Part I of the regulations);
- Labelling (Part II);
- Marking (Part III);
- Canned Fish (Part IV)
- Fresh and Frozen Fish (Part V);
- Pickled, Spiced and Marinated Fish (Part VI) ;
- Bloaters and Bloater Fish (Part VII) ;
- Salted Fish (Part VIII);
- Construction and Equipment Requirements for Establishments (Schedule I) ;

- Operating Requirements for Establishments (Schedule II);
- Requirements for Vessels Used for Fishing and Transporting Fish for Processing (Schedule III);
- Requirements for Establishments Storing Frozen Fish (Schedule IV);
- Requirements for Vehicles and Equipment Used for Unloading, Handling, Holding and Transporting Fresh Fish for Processing (Schedule V); and
- Requirements Regarding Quality Management Programs (Schedule VI).

The Food and Drugs Act and Regulations R.S.C. 1985 c.f. - 27

Inspectors administer and apply the Food and Drugs Act and Regulations during the inspection of domestically produced or imported fish and fish products.

The main sections of the Act that are applicable to fish and fish products are:

- **The Foods Division** (Division 1) which addresses definitions, common names, packaging dates, language and the definitions of standardised foods.
- **The Food Additives Division** (Division 16) which describes the food additives that are permitted for use in the production of food products and the levels that are permissible in food products.
- **The Marine and Fresh Water Animal Division** (Division 21) which defines marine and fresh water animals, describes the use of these animals in the production of fish products (including prepared fish) and prescribes requirements for the processing of certain types of fish and fish products and species.

Consumer Packaging and Labelling Act and Regulations, c.38 1970-71-72 c.41, s.1.

CFIA inspectors also administer and apply the Consumer Packaging & Labelling Act and Regulations during the inspection of domestically produced or imported fish and fish products. The main features of this Act and Regulations are specific requirements for:

- **Product Identity Declarations** — definitions used in the Act & Regulations, language requirements, design of the principal panel, type and height of lettering to be used, and exemption conditions regarding labelling of products.
- **Net Quantity Declarations** — manner of declaration, language requirements, type and height of lettering, unit of measurement requirements, precision of numbers used, tolerances and exemptions.
- **Dealer's Name and Address** — in addition to the definitions, type and height of lettering to be used, and exemption conditions, this section also deals with imported products.

- **General Exemptions** — bilingual labelling exemptions, test market products and exemptions from detailed labelling requirements.
- **Non-mandatory Information and Packaging** — prohibition of false and misleading information on consumer pre-packaged product, standardisation of package designs, fill levels and the issuance of a temporary one year exemption from the package standardisation requirements.

Management of Contaminated Fisheries Regulations Order under the Fisheries Act of Canada P.C./C.P. 1990.1120

Samples are withdrawn from harvest areas and are analysed in strategically located fish inspection laboratories across Canada for detection of the presence of pathogenic biotoxins, contaminants and/or bacteria of public health significance. Where analytical results exceed standards considered safe for human consumption, harvest areas are closed to fishing under the Management of Contaminated Fisheries Regulations. Those closed areas are then posted and patrolled by Fishery Officers until such time as they are reopened.

c) Organisation

General Organisation

The Fish Inspection Directorate is led by a Director General who reports to the President of the Canadian Food Inspection Agency. The President, in turn, reports to the Parliament of Canada through the Minister of Agriculture and Agri-Foods Canada. The Director General has complete responsibility for the fish and fishery products inspection and control system.

The Inspection Directorate is organised as follows:

- National Headquarters - Ottawa
- Regions
 - Pacific Region, Headquarters - Burnaby, B.C.
 - Central and Arctic Region - Headquarters - Winnipeg, Manitoba
 - Quebec Region, Headquarters - Quebec City, Quebec
 - Maritimes Region, Headquarters - Moncton, New Brunswick
 - Newfoundland Region, Headquarters - St. John's, Newfoundland

National Headquarters structure is comprised of:

a) Director Generals' Office

The Director General is responsible for the overall management of the Fish inspection program. This office includes a Senior Scientific Advisor.

b) Director, QMP and Shellfish

Responsible for developing strategy, policy and procedures related to the inspection of facilities including harvesting vessels, unloading sites, transport vehicles, frozen storage, and processing establishments. The Director takes the lead role in the continued development of the Quality Management Program (QMP) and its full incorporation of Hazard Analysis and Critical Control Point (HACCP) principles. The director is also responsible for identifying national training priorities related to facility inspections, QMP, and HACCP principles and the implementation of programs to ensure national uniformity in the evaluation of facilities.

c) Director of Fish and Fish Products

Responsible for the development of strategies, policies and procedures related to fish and fish products, both domestic and imported. The director is also responsible for identifying national training priorities as related to fish and fish products and for the implementation of programs to ensure national uniformity in the evaluation of fish and fish products.

d) Director of Technical Trade & Intergovernmental Liaison

Responsible for the management and direction of all international and intergovernmental programs. These responsibilities include the development and maintenance of various memoranda of understanding and mutual recognition agreements with the objectives of facilitating trade in fish products between countries, minimising inspection costs and increasing the assurance that products that are traded meet national and international standards.

e) Director of Planing Systems and Control

Responsible for the development of inspection plans both on an annual and long term basis. Also responsible for administrative liaison with other government agencies related to issue of finance and personnel and program integration. Has responsibility for the development of a National training program and the co-ordination of its implementation.

A National Headquarters Organisation Chart is attached as Annex II.

Regions

Depending on geographic size and various other workload factors (such as number of molluscan shellfish sites, registered facilities, fish import centres etc.) each region is comprised of two or more Area Offices and several District/Inspector Offices. Each regional office is staffed with a Director, Chief of Technical Services, Chief of Operations and Chief of Planning, Systems & Control. The Regional Director reports to the Director General at National Headquarters and is responsible for managing the Inspection Program in their respective region. The Area office is headed by a Chief that reports to the

Regional Director and is responsible for managing the Inspection Program in their respective area. There are 12 Area offices.

Table 1: Fish Inspection Directorate Area Inspection Offices

Region	Area Office Location
Newfoundland	Carbonear, Grand Falls
Maritimes	Sydney, Yarmouth, Black's Harbour., Shediac
Laurentian	Longueuil, Gaspe
Central & Arctic	Mississauga, Edmonton
Pacific	Burnaby, Victoria

Depending on the geographic size of the area and workload factors noted above, each Area is broken down into several Districts that are comprised of a District Supervisor and Inspectors. There are 59 district and inspector offices across the country.

A generic Regional Organisation Chart is attached as Annex III.

d) Laboratories

The laboratories and field activities of the Fish Inspection Directorate are well equipped for the inspection and determination of quality and safety. Laboratory personnel operate in modern laboratories well equipped to conduct evaluations of products to determine compliance to chemical and microbiological requirements. All chemical methods have been reviewed and microbiological methods are under review.

Each of the five geographic Regions in Canada has at least one regional laboratory. Each regional laboratory has one or more laboratories that are headed by the Chief of Technical Services. The laboratories are comprised of a Microbiological Section and a Chemistry Section. For some chemical analyses one Regional Laboratory may conduct the analyses for all Regions due to cost of equipment and scientific expertise.

In addition to the regional laboratories, there are two national laboratories responsible for Sensory Science Workshops and Chemical Quality Indicators. These are located in Winnipeg and Halifax respectively. In total, there are seven laboratories.

Table 2: Fish Inspection Directorate Laboratories

Region	Laboratory Location
Newfoundland & Labrador	St. John's
Maritimes	Moncton, Halifax
Laurentian	Longueuil
Central & Arctic	Mississauga, Winnipeg
Pacific	Burnaby

Microbiological Section

The product destined for export is subjected to bacteriological examination (depending on the type of product and Canadian and importing country requirements) for the following: E. Coli; Faecal coliforms; Listeria monocytogenes; Salmonella species; Standard plate count; Staph. Aureus; Sterility; and Vibrio species.

Records are maintained in a filing system under each packers' name. The laboratory supervisor indicates in the test record whether the test is pass or fail based on the standard requirement of the country of destination or Canadian standards, which ever is more stringent.

Chemical Section

The product destined for export is subjected to chemical analysis (depending on the type of product and Canadian and importing country requirements) for the following: Histamine; Food additives; Sodium and potassium; Heavy metals, other than mercury; Mercury; Moisture content; Pesticides and PCBs; Salt content; Marine toxins; Drug residues; pH; Water activity; and Tuna colour.

Records are maintained in a filing system under each packers' name. The laboratory supervisor indicates in the test record whether the test is pass or fail based on the standard requirement of the country of destination or Canadian standards, which ever is more stringent. Lots that fail to meet Canadian requirements but pass importing country standards are labelled "For export to Foreign Country Name Only".

Quality indices laboratory

This laboratory plays an important role in developing standards, setting up workshops and training sessions. The following types of analyses are conducted to assist in the training and accreditation of inspectors for sensory analysis of fish and shellfish: trimethylamine nitrogen; histamine; indole; ethanol; putrescine and cadavarine; and thiobarbituric acid.

e) *Use of Third Parties' Inspection Bodies*

The Fish Inspection Directorate does not recognise the use of Third Party Inspection System. An agreement is now being negotiated with the Standards Council of Canada for the accreditation of inspection laboratories for use in Quality Management Program for Importers (QMPI).

f) *Training*

Training for Inspectors and Laboratory Personnel

The National Training program is administered by the Manager of National Training Programs - Ottawa. The minimum current academic training required for all new staff is a Bachelor of Science, with some positions requiring further academic training.

Extensive external and in house training programs are also provided to staff, related to the full range of laboratory and field inspection activities. Laboratory training is specialised and varies with specific responsibilities. Recent training has focused on audit techniques and HACCP principles. As well, new staff have to complete a two year development program during which time senior inspectors and supervisors provide on the job guidance, training and evaluation. In addition, there are both internal and external courses on processing procedures, internal policies and procedures, fish and fish product inspections, HACCP principles and departmental objectives and mandate.

Inspector training for both new and more senior officers focuses on a variety of areas related to Facility and Product evaluations. Internal training modules have been developed for the following subjects:

- **Facility evaluation:** An Introduction to QMP; QMP Policies and Procedures; QMP Submission Guide; Evaluation of the Submission Guide; Inspection of an In-Plant QMP; The QMP Inspection Method; QMP 1994 Update; Principles and Methods of Pickling; Principles and Methods of Smoking; Principles and Methods of Chilling; Freezing and Cold Storage; and Vessel Inspection - Gear and License Types.
- **Product Evaluation:** Metal Can Integrity - Critical Points of Inspection; Metal Can Integrity - Metal Can Fabrication; Metal Can Integrity - Double Seam Formation; Metal Can Integrity - Double Seam Measure; Metal Can Integrity - Metal Can Defects; Fish Borne Illnesses and their Causative Agents; Fish Spoilage; Initial Inspection Procedures; Reinspection Procedures; Detention and Release Procedures; Seizure Procedures; Species Identification; Fish Morphology - Introductory; Fish Morphology - Advanced Course; Sensory Inspection Training - one week; and Sensory Inspection Training - three weeks.
- **Sensory Workshops:** Canned Tuna Sensory Training; Canned Tuna Sensory Accreditation; Canned Shrimp Sensory Training; Canned Shrimp Sensory Accreditation; Frozen Shrimp Sensory Training; Frozen Shrimp Sensory Accreditation; Groundfish Sensory Training; Groundfish Sensory Accreditation; Scallop Sensory Training; and Scallop Sensory Accreditation.

For most products a specific product standard has been developed and Inspectors must demonstrate a competency to evaluate product in compliance to the standard.

A formal process has been established to verify evaluation ability as well as to evaluate Inspectors who can be used as Experts/Trainers for future workshops. For some of the more important species processed or imported, chemical indices of quality have been developed to assist in the standardisation of inspectors application of product sensory attributes.

Other training Modules include: Canada's System of Justice; Canadian Charter of Rights and Freedoms; Young Offender's Act; Legal Forms; Search Warrants; Notes and Notebooks; Legal Proceedings - Statements and Confessions; Rules of Evidence; Court Briefs; and Court Procedure.

Staff are trained in a variety of areas which assist in the overall delivery of an effective inspection program including supervisory/ management skills, communication skills and budget management techniques and program assessment methods.

II. Description of Inspection and Control Systems

a) *Use of Systematic Inspection Approaches*

These approaches apply equally for fish and fish products for domestic consumption and for export.

Mandatory Quality Management Programme (QMP)

Canada's mandatory national QMP:

- is largely based on HACCP
- is the first major food inspection program to implement a national HACCP based system on a mandatory basis for a specific food commodity;
- has resulted in increased industry accountability and acceptance of responsibility for the products it produces, while fish inspectors have switched from performing "quality control" type of inspection activities designed to inspect product problems (i.e., the traditional approach) to auditing plant QMPs that are designed to prevent defects from occurring in the first place;
- has been recognised internationally in that Canada:
 - receives numerous requests annually from other countries requesting technical training in QMP methodology or assistance in establishing QMP style programs for their fish processing industry;
 - has received recognition from the European Union (EU) that QMP essentially meets EU requirements for fish processing operations and sanitary control; and
- recognises the world-wide trend towards the adoption of HACCP systems.

HACCP Approaches

Canada is building on its QMP's success and has re-engineered the QMP to fully incorporate all seven HACCP principles to:

- require that establishments perform hazard analysis for each process operation they currently conduct at their processing facilities and, based on the hazards identified, determine the appropriate preventative measures or Critical Control Points (CCPs) to control the hazards;
- enhance process controls for fish processing operations, notably for “ready-to-eat”, “smoked fish” and “depuration” facilities where additional requirements may be enacted;
- enact additional requirements designed to ensure that industry performs verification audits to ensure that establishments' QMPs are functioning as designed;
- study the implications of enhancing existing limited requirements for formal training of plant management, supervisory, quality control and worker personnel to require that they have certain minimum training in food safety and handling.

Registered canneries have already implemented major elements of HACCP as part of their QMP and may only be required to provide a HACCP product description and process flow diagram showing the location of all CCPs.

Many of the “ready-to-eat” and “smoked fish” operations have already implemented QMPs to prevent the growth of *Listeria*. The application of HACCP will serve to complement these efforts.

Hazard analysis and the consequent exercise of describing each product, the operation, documenting the process flow, determining the hazards, CCPs and control measures should result in better plant understanding of HACCP, QMP and potential food safety threats confronting producers of food products. In turn, this should strengthen industry commitment and “buy-in” to QMP and its tenets.

Generic HACCP programs have been developed jointly by the Fish Inspection Directorate and representatives from the processing industry. Each processing establishment must develop a HACCP plan appropriate to their processing practice and hygiene and sanitation status

Amendments are now being made to the Fish Inspection Regulations to strengthen the Schedule VI QMP requirements to incorporate hazard analysis requirements, strengthen process control and verification requirements, potentially enhance employee qualification, training requirements and various construction, equipment and operating requirements.

Role of industry

Each operation must institute a QMP that meets the requirements of Schedule VI of the Fish Inspection Regulations. The operation must be maintained in compliance with the Fish Inspection Construction & Equipment Requirements (Schedule I) and Operating Requirements (Schedule II). Each establishment must comply with their written QMP. As part of maintaining compliance with their QMP, the company must establish approved guidelines, institute a system of regular monitoring and record keeping at identified CCPs. Records must also be kept of all corrective actions and verification that the corrective action was completed and adequate.

ISO 9000 is not recognised as a regulatory approach by the Fish Inspection Directorate.

The reference standard used for the application of QMP in Canada can be found in Annex IV.

b) *Mandatory vs Voluntary*

It is mandatory for all seafood sold and produced in Canada to meet the requirements under the Fisheries Inspection Regulations (FIR). Certain size grade quality requirements, also specified in the FIR, are voluntary.

c) *Import Requirements*

The Department of Fisheries and Oceans' (DFO) Import Inspection Program inspects imported products upon entry into Canada and prior to distribution to wholesale or retail outlets. DFO inspects products, using the same requirements as for domestically produced fish products, for compliance with quality, safety, composition and identity standards. The inspection rate is based on the compliance history of the product and producer

Under the current Import Inspection Program:

- All importers of fish and fishery products must be licensed and notify DFO of incoming shipments for inspection purposes;
- All products are inspected upon first importation. If a product fails inspection, the regulations stipulate that the product must be placed on a Import Alert List (IAL) and that future imports of the product from the processing plant in question must be inspected.
- After being placed on the IAL, future imports of that product from the specific processor must pass four consecutive inspections before being returned to a normal inspection frequency.
- Unless otherwise specified in a Memorandum of Understanding (MOU), products not on the IAL are subject to the regular inspection frequency of one inspection for every five shipments, with a minimum of one inspection per year.
- Fees are imposed for certain import inspection activities in accordance with the import cost recovery initiative.

Quality Management Program for Importers (QMPI)

The CFIA is currently implementing a new Import Inspection Program, which is known as the Quality Management Program for Importers (QMPI). This program will create faster market access for products and reduce the costs associated with import inspection.

The QMPI is intended to mirror aspects of the Quality Management Program for Canadian fish processors. Like QMP, QMPI is also a HACCP-based system which requires the importer to take more responsibility for performing regularly required evaluations. Importers are able to participate at one of

three levels of QMPI — Basic, Shared, or Enhanced. All importers must at least meet the requirements of the Basic level QMPI. The Shared and Enhanced levels are entirely voluntary.

The Inspection Directorate audits the records of all importers to ensure their compliance with the requirements of the applicable QMPI program.

IV. Establishment of Criteria for Determining Equivalence

The determination of the equivalency between the fish inspection and control systems between Canada and other countries is based on an analysis of the following criteria.

a) *Existence of a National Fish Inspection and Control System*

Legislative Framework

Both responsible authorities should have the authority, based on adequate legislation, to establish and enforce regulatory requirements. Legislation should provide the necessary authority to carry out controls at all stages of production, processing, importation, storage, transportation, distribution, and export of fish and fishery products.

Governmental Structures

Both responsible authorities should identify the main objectives to be addressed by their fish inspection and control systems.

Where different authorities in the same country have jurisdiction over different parts of the food chain, conflicting requirements should be avoided to prevent legal and commercial problems and obstacles to trade. This system should include, but not be limited to:

- The responsible authority should have in place a management structure that can set priorities, establish policies, decide personnel issues, and monitor that authority's activities.
- The responsible authority should have in place an effective code of ethics for its personnel, addressing both bribery and conflict of interest. There should be adequate training of personnel in the code of ethics, appropriate periodic evaluations, adequate surveillance measures to track effectiveness of ethical controls, and effective means of taking action to prevent or correct problems.

Adequate Resources/Tools

The responsible authority should have in place the necessary legislative framework, controls, procedures, standard setting mechanisms, enforcement options, facilities, equipment, laboratories, transportation, communications, personnel and training to support the objectives of the fish inspection and control program

Appropriate Implementation of Mandate

Appropriate regulations or policies for conducting inspections should formally document inspection working methods and techniques. The inspection program should be based on identified objectives and appropriate risk evaluation. In the absence of sufficient scientific information, inspection programs should be based on the authority's best scientific judgement, taking into account current knowledge and practice. Procedures should be in place to ensure that inspections are carried out using priorities based on risk, to address known or suspected non-compliance situations; and in a co-ordinated manner between different regulatory authorities, if several exist.

Training for Inspectors and Laboratory Personnel

Training for inspectors should include a standard basic level of training in the regulations and policies for conducting inspections, a standard basic level of training in the scientific requirements for conducting an inspection, specialised and/or advanced training programs, and continuing training programs, including basic elements of sensory examinations. Training for laboratory personnel should include training, where appropriate, in regulatory requirements, chemical, microbiological and sensory analytical methods, and maintaining the integrity of evidence.

Inspection and Sampling Plans

System for conducting inspections should be sufficient to assure compliance with laws and regulations. Sampling plans should be established to ensure that the results are reliable in relation to the specific objective. Pre-inspection preparation should assure that the scope and focus of the inspection is defined and that the inspector is familiar with the compliance history of the firm. Inspection techniques should include record review, use and conduct of interviews, inspection notes, and a report of observations to the firm at the close of the inspection. Post inspection activities should include sample analysis using validated analytical methods and the production of a fully documented inspection report.

Certification Systems

When required, certification should provide assurance of the conformity of a product or batch of products and may be based on:

- regular checks by the inspection service;
- analytical results;
- evaluation of quality assurance procedures; and
- any inspections specifically required for the issuance of a certificate.

Responsible authorities should take all necessary steps to ensure the integrity, impartiality and independence of certification systems. Personnel empowered to validate certificates must be appropriately trained and fully aware of the significance of the contents of each certificate which they complete.

Enforcement History

The responsible authority should have a consistent, documented record of taking the necessary legal actions to protect public health and reduce the likelihood of recurrence of deviations from laws and regulations, for product designated for export.

b) *Identification of Fish Processing Establishments*

Both parties should establish a system for identifying and maintaining an inventory of fish processing establishments that is capable of being updated on a regular basis.

The responsible authority should have a system to ensure that seafood processors who are to be included under the Agreement have adopted a system of preventive controls that will prevent the occurrence of food safety hazards or other regulatory infractions in fish and fishery products exported to either party. This system of preventive controls should be based on internationally recognised principles of HACCP.

c) *Ability to Perform Audit Procedures on the Inspection Control System*

Self-assessment or third-party audits should be carried out periodically at various levels of the fish inspection and control system, using internationally-recognised assessment and verification procedures. Self-assessment should be used for such purposes as assuring the adequacy of health and consumer protection and other matters of national interest, improving internal efficiency or to ensure exports meet the requirements of the other party.

A system should be in place for assuring the reliability of laboratories used for sample analysis. Laboratories should demonstrate that they have consistently acceptable performance through programs that include adequate quality assurance controls, the use of validated analytical methods, and other measures necessary to document the reliability of test results.

Verification of equivalency of the Parties shall be conducted by:

- reviewing each other's fish inspection and control systems, including conducting a side-by-side comparison of items identified in section a) above;
- verifying the effectiveness of the fish inspection and control systems in meeting the requirements of the importing Party by conducting a compliance audit of the fish inspection and control system using the procedures identified below in section V under "Guidug Principles Details of Compliance Verification Audits"; and
- reviewing the compliance history of products imported into the other Party.

V. Audit and Verification Methods

Guiding principles are used in the application of audits and verifications of inspection and control systems. The principles are applied domestically and for assessment of inspection and control systems of third countries.

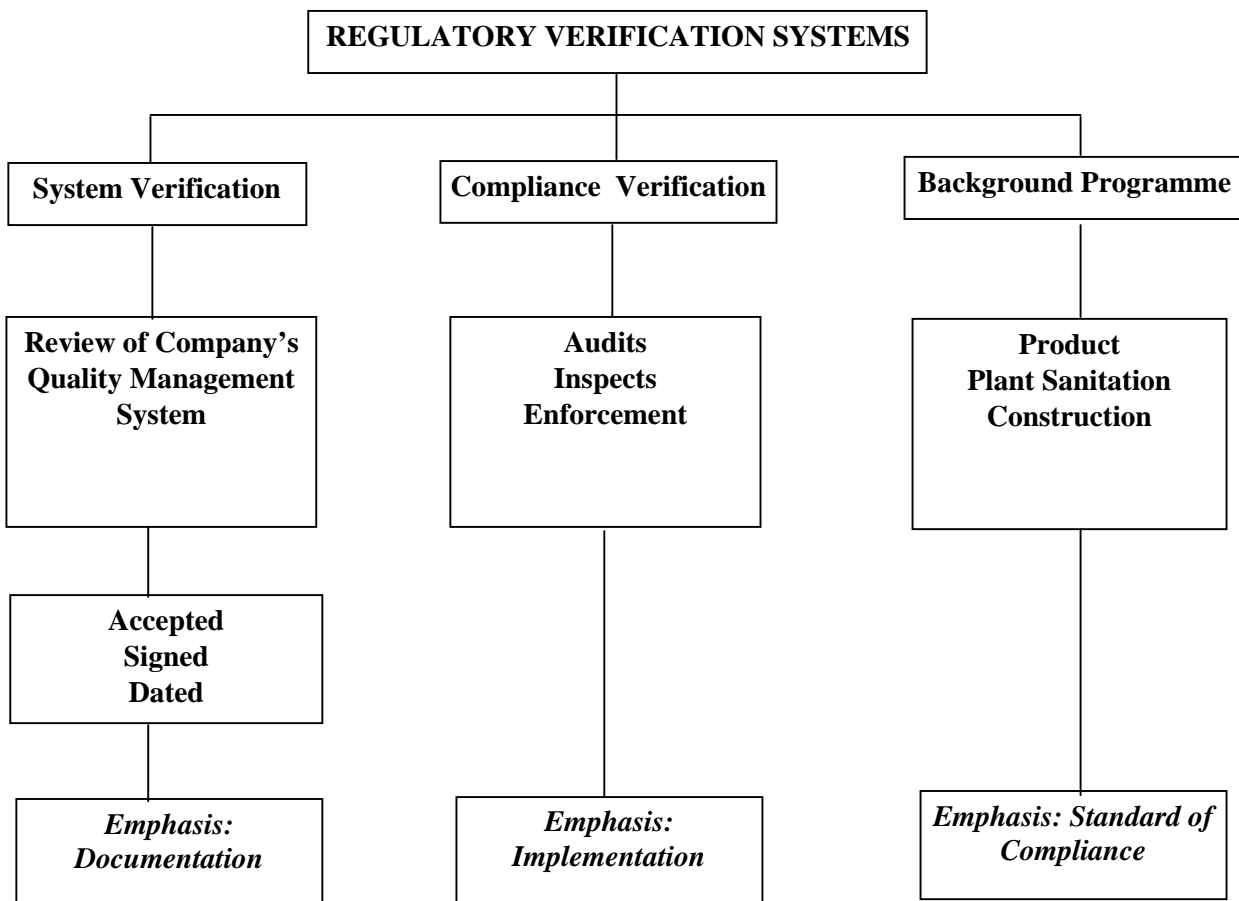
The Guiding Principles for Regulatory Verification Systems

a) Scope

This section outlines the guiding principles to be followed and respected during the development and delivery of “Regulatory Verification Systems” applied to:

- Federally registered domestic fish processing establishments;
- Federally licensed fish importers; and
- Offshore fish processing establishments inspected under bilateral/multilateral fish inspection agreements or arrangements.

b) Diagram of the Regulatory Verification System.



c) Guiding Principles

These guiding principles will be followed in the development of the regulatory verification systems:

Roles and Responsibilities of Government

- I. The Fish Inspection Directorate is responsible for developing, in consultation with industry, regulations, standards, policies and procedures which are the guidelines for industry compliance. The Directorate is also responsible for verifying that industry operates within the compliance guidelines.
- II. The Fish Inspection Directorate will assess industry's compliance through regulatory verifications. The regulatory verifications will focus on assessing the adequacy of a company's written quality management system and verifying that the company applies the system as described and that it is effective in maintaining compliance with the regulatory requirements.
- III. The Fish Inspection Directorate is responsible for taking the appropriate enforcement action when regulations are violated.

Roles and Responsibilities of Industry

- I. Industry (fish processors, fish importers) is responsible for designing and implementing the appropriate quality management system to ensure compliance to the applicable regulations and agreements.
- II. Industry is responsible for ensuring that they have the personnel, on staff or under contract, with the necessary knowledge and skills required to develop, implement and maintain their quality management system and to ensure that their operation is in compliance with all applicable regulations and agreements.
- III. Industry is solely responsible and liable for the fish products they produce, sell and/or import.

Regulatory Verification System

- I. The **Regulatory Verification** of industry's quality management system will consist of a combination of audit and inspection activities. Audit activities will be carried out in accordance with recognised audit principles.
- II. The frequency of the regulatory verifications will be based on risk (health and trade) and the degree of regulatory compliance.
- III. The Regulatory Verification System may include the following audit/inspection activities:
 - A. A **systems verification audit**: an audit of the company's documented quality management system against a standard agreed upon by industry and government and

based upon the applicable regulations and agreements. The system verification audit is done on the initial submission and on amendments made by the company.

- B. A **compliance verification audit**: an audit of the operating quality management system to verify that the industry is implementing the quality management system as designed and that the system is effective in meeting the applicable regulatory and offshore agreement requirements as set out in the standard. The details of compliance verification audits are outlined in section 4.
- C. An **Inspection of**:
 - 1. **Domestic plants** for compliance to construction, sanitation and operational requirements, at least annually and as appropriate during a compliance verification audit.
 - 2. **Basic Importers** for compliance to documentation on consumer complaint and recall systems and process controls for high risk products on an annual basis.
 - 3. **Product** as part of the import product monitoring system or a compliance verification audit.
- D. A **Background Program**: a monitoring program to provide the Fish Inspection Directorate with base data to confirm regulatory compliance levels in areas such as product, facilities, plant sanitation, water.

Details of the Compliance Verification Audits

General audit principles:

- I. In general, the company should be informed in advance of the audit, the time, the place, the scope and the objectives of the audit. An audit schedule should be developed outlining all the areas to be audited. Where the company is misusing this advance notification of the audit, the inspector can conduct an inspection without advance notice.
- II. The company has a right to be part of the audit and should be encouraged to provide a staff member to accompany each audit team member to confirm non-conformities and facilitate interviews with company staff.
- III. Accepted audit procedures should be followed at each stage of the compliance verification including; planning, preparing, conducting an audit, analysing the results, agreeing on the corrective actions and verifying effective completion of each audit.
- IV. Where practical compliance verifications should be performed by teams of Inspector (2 or 3). There are circumstances where a team approach is unnecessary and would not be an effective use of resources. A guideline should be developed to direct the managers in this area.

Types of Compliance Verification Audits

Compliance verifications can be either a full verification, a partial verification or a follow-up verification.

- I. A full compliance verification will entail a complete verification of all aspects of the company's quality management system.
- II. A partial compliance verification will focus on critical areas of a company's quality management system.
- III. A follow-up compliance verification will focus on verifying that the company has completed committed corrective actions.

Company's Quality Control technical knowledge

As part of the compliance verification, Inspectors may assess, as necessary, the qualifications and abilities of the company's Quality Control staff in conducting inspection analysis, such as sensory analysis, can integrity, process controls, plant sanitation.

Non-Conformities

- I. Deficiencies in the company's quality management system will be documented as non-conformities or observations. Each non-conformity will be evaluated based on objective evidence collected by the Inspector.
- II. Non-conformities will be classified as critical, major or minor:
 - A. Critical non-conformities are those deficiencies in the quality management system that may or have resulted in unsafe or fraudulent product. Immediate actions will be taken to correct the critical non-conformities.
 - B. Major non-conformities are those deficiencies that violate the agreed upon reference standard but do not present a health or safety risk.
 - C. Minor non-conformities are those deficiencies where procedures specified in the quality management system were not followed, but there is no violation against regulations.
- III. Observations are deficiencies which, if not dealt with, could lead to a non-conformity.

Compliance Verification Report

After each of the compliance verifications, a verification report will be completed identifying the scope of the verification and the non-conformities that were identified during the audit.

Corrective Actions

- I. The company must take immediate corrective action on critical non - conformities.
- II. For major and minor non-conformities, the company is responsible for initiating and implementing corrective actions needed to correct a nonconformity or to correct the cause of a nonconformity. Corrective actions should be implemented as soon as practicable with the goal of establishing or re-establishing the quality management system mandates.
- III. Corrective actions will be verified by the Fish Inspection Directorate.

Audit Closure

- I. Closure of a regulatory verification audit can only take place after all non -conformities have been corrected. The compliance Verification Report should be updated with the corrective actions implemented by the company and signed off by the inspector.
- II. If the verification cannot be closed, the Fish Inspection Directorate will take the appropriate enforcement action, which could be in the form of a warning letter, suspension of the registration / import license, legal actions or other actions as appropriate.

Companies not able to maintain effective quality controls on a consistent basis

- I. **License/Registration suspension or withdrawal of privileges.** Where a company is unable to implement an effective quality management system and maintain their operation in compliance with the standard the import license or registration of the operation will be suspended or, in the case of offshore fish processors, the importation privileges under the applicable bilateral/multilateral agreements will be rescinded
- II. **Enhanced regulatory verification regime.** Where warranted, Canadian operations which are in non-compliance or which are not able to satisfactorily close the regulatory verification process, may maintain their license or registration of the operation. This would require the company to demonstrate the ability to improve their quality management system. Under these special circumstances the Fish Inspection Directorate would apply an augmented regulatory verification regime. The augmented verification regime is characterised by increased frequencies of verification and a greater emphasis on inspection activities.
- III. This would be a temporary arrangement until the establishment demonstrates that it can responsibly operate its quality management system . Companies that are incapable of meeting the regulations will face suspension of their federal registration or license.

Annual Inspection of Domestic Fish Processing Facilities

In addition to the periodic regulatory verifications performed by the Fish Inspection Directorate on domestic fish processing establishments, the Directorate will also perform annual inspections of the physical plant facilities. These annual inspections will be in conjunction with the issuance of the federal registration and all processing establishments will be required to correct all construction deficiencies prior to re-registration.

Product Compliance

- I. Compliance of domestic fish products will be monitored through:
 - A. planned background programs determined through risk analysis and statistical principles. In general, product is not detained, unless there is a history of non-compliance or some other concerns; and
 - B. product samples taken by inspectors as part of the compliance verification audit.
- II. Imported fish products will be monitored via the import product inspection program.

d) Definitions

Regulatory Verification consists of a combination of audit and inspection activities carried out by the Fish Inspection Directorate to verify a company's compliance to regulatory requirements set out in the Fish Inspection Regulations (FIR) and other pertinent regulations or agreements.

Audits are systematic examinations to determine whether quality management activities of companies and the related results comply with planned arrangements (QMP /QMPI Plan & System) and whether these arrangements are implemented effectively and are suitable to achieve objectives. (FIR, safety and commercial fraud).

Systems Verifications are audits carried out by the Fish Inspection Directorate to verify that the company's quality management system meets the agreed upon reference standard. In general, the systems audit will be conducted prior to a plant or an importer being registered or licensed.

Compliance Verifications are audits carried out by the Fish Inspection Directorate to verify that a company's quality management system has been implemented as designed and is effective in meeting all applicable regulatory and agreement requirements as set out in the agreed upon standard. Compliance verification may include the following activities:

- audit of the quality management system, and verification of the company's controls and ability to implement the controls,
- inspection of construction and sanitation of the facility,
- product inspection and
- quantitative field testing, such as determining water supply potability, water chlorine levels, plant light intensity levels, plant sanitation conditions, etc.

Inspections are examinations to directly measure facility, operational, product and system compliance to regulatory requirements.

Background Programs are planned inspection activities carried out for a specified time frame to confirm regulatory compliance. Examples of background activities are product surveys, water quality surveys, plant sanitation and construction surveys.

Enforcement Actions are regulatory actions taken in response to violations of applicable legislation with the goal of promoting compliance.

Quality Management Systems are those systems developed by the industry to control their operations in compliance with the requirements defined in the applicable standards. The Quality Management Program (QMP) is the system applicable to the domestic fish processing industry, the Quality Management Program for Importers (QMPI) is the system applicable for Canadian based importers. The quality management system applicable to offshore processors will be defined in memoranda of understanding or mutual recognition agreements.

Reference Standard is the standard agreed upon by the sector of industry undergoing the regulatory verification and the Fish Inspection Directorate who performs the regulatory verification. The standard will define the requirements that industry's quality management system must meet and will be based on the applicable regulations and terms set out in any applicable bilateral / multilateral fish inspection agreements or arrangements.

Industry refers to the members of the fish processing and fish importing sector

Company refers to an individual fish processor or fish importer.

ANNEX I: NUMBER OF FISH INSPECTION PROGRAMME STAFF

Annex I

26-Aug-97

NUMBER OF FISH INSPECTION PROGRAM STAFF - FY 97/98

REGION	EX	ST	PI	SG(F)	SG(M)	PM	BI	CH	EG	CR	AS	CS	DA	S	EN	TOTAL
Newfoundland	1	2	53	4	2	1	2	1	7	3	1					78
Maritimes	1		73	15	6	1	4	5	15	8	2				1	151
Quebec	1		25	6	3		5	1	6	3	2					52
Central & Arctic	1		16	19	4	1	1	3	8	5		1	1			60
Pacific	1	1	22	10	4	1	1	2	10	4		1	2			59
NHQ	1				10		1				5					17
TOTALS:	6	3	189	54	29	4	14	12	46	23	10	2	3	1	1	397

RGN:	NFL	MAR	QUE	C&A	PAC	NHQ	TOT
Field	57	88	31	35	31	0	242
Laboratory	10	24	12	12	13	0	71
Prog Mgmt	6	9	5	6	7	14	47
Admin Supp	5	10	4	7	8	3	37
Total:	78	131	52	60	59	17	397

NOTE: -- this is a report on the number of staff who were on strength in inspection during FY 96/97, NOT the number of "Full Time Equivalents", or FTEs

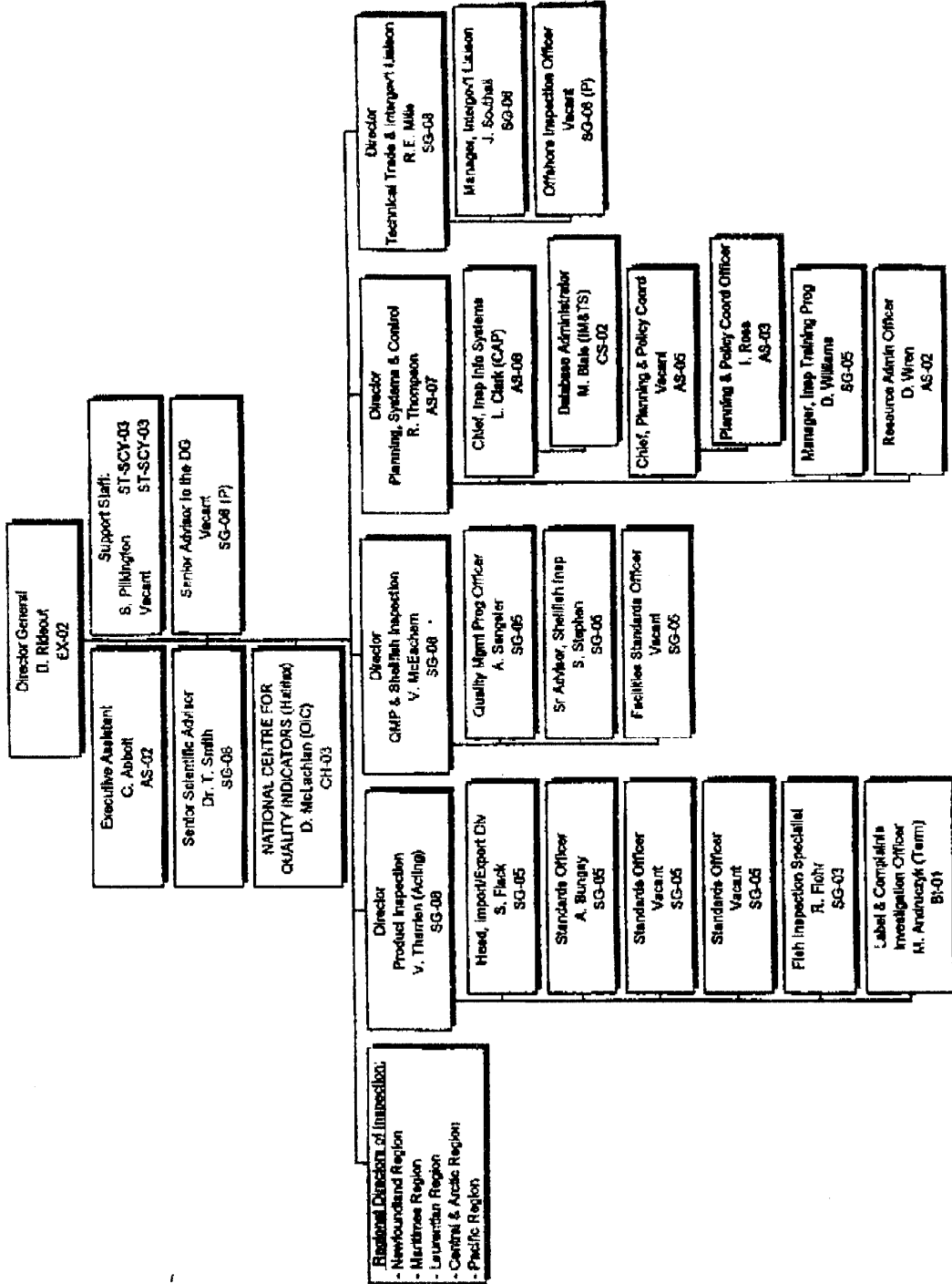
- "Field" includes all PIs, SG 2s to 4s (excl. Training Coordinators), SI, EN.
- "Lab" includes all BIs, CHs, EGs.
- "Prog Mgmt" includes all EXs, SG-5s to 8s, PMs, AS-5s to 7s, plus Training Coordinators.
- "Admin Supp" includes all SCYs, CRs, AS-1s to 4s, CSs, DAs.

ANNEX II: FISH INSPECTION DIRECTORATE - NATIONAL HEADQUARTERS ORGANISATION CHART

March 24, 1999

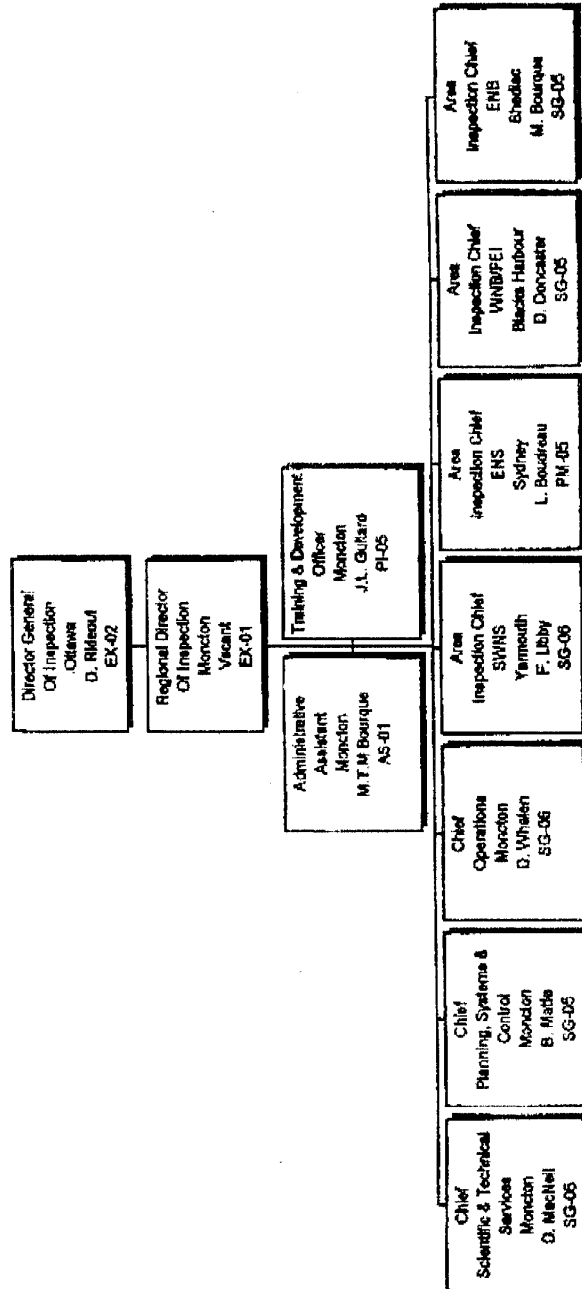
Annex 2

FISH INSPECTION DIRECTORATE - NATIONAL HEADQUARTERS ORGANIZATION CHART



ANNEX III: FISH INSPECTION DIRECTORATE - MARITIMES REGION ORGANISATION CHART

FISH INSPECTION DIRECTORATE - MARITIMES REGION ORGANIZATION CHART



ANNEX IV: THE QUALITY MANAGEMENT PROGRAM (QMP) REFERENCE STANDARD

The Scope

This document sets out the requirements for the documentation and application of a processor's Quality Management Plan. The standard is based on the Fish Inspection Regulations.

Field of Application

Each federally registered fish processing establishment must develop, document and apply a specific QMP Plan for the products and processes carried out in the establishment. The QMP Plan must be based on the requirements set out in this standard. The standard will be used as the foundation of the regulatory verifications performed by government inspectors to verify that a specific QMP plan of a fish processing operation is meeting the standard and the requirements of the regulations.

Definitions

Critical Control Point (CCP): A step at which control can be applied (and is essential) to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical Limit: A criterion which separates acceptability from unacceptability.

HACCP: Hazard Analysis Critical Control Point, A system which identifies, evaluates and controls hazards which are significant for food safety.

HACCP Plan: A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration.

Hazard: A biological, chemical or physical agent or factor with the potential to cause an adverse health affect.

Prerequisite Plan; are programs that control the plant environment elements and recall procedures to ensure compliance with the Fish Inspection Regulations.

QMP Plan: A document prepared by a fish processor in accordance with the QMP Standard which outlines the controls implemented to ensure that the fish products were processed under sanitary conditions and resulted in a safe, acceptable, and fairly traded fish product.

Regulatory Action Point Plan; Are controls established at a processing step(s) to ensure regulatory compliance. They focus on 3 elements of fish processing:

- minimum acceptable fish product standards
- input materials
- labelling of final product

Regulatory Verifications: Activities carried out by Government Inspectors to verify that a fish processing operation’s QMP Plan meets the requirements set out in the QMP Reference Standard and the Fish Inspection Regulations. The Regulatory Verification activities will include, verifying the documented QMP Plan, verifying the application of the QMP plan, inspecting plant conditions and product, investigating corrective actions and performing appropriate tests.

The Components of the QMP Standard

The QMP consists of the following components:

1. Management Roles and Responsibilities (recommended)
2. Background Product and Process Information
3. The Prerequisite Plan,
4. The Regulatory Action Points Plan, and
5. The HACCP Plan.

The Three Control Components of QMP

(1) Prerequisite Plan	(2) Regulatory Action Points Plan	(3) HACCP Plan
I. Plant Environment II. Recall	I. Minimum Acceptable Fish Product Standards II. Input Materials III. Labelling	CCPs - Determined through the application of HACCP principles.

Management Roles and Responsibilities

Processors are recommended to describe how the re-engineered QMP was developed, how it will be implemented and identify the position responsible for the maintenance of the QMP Plan.

The Product and Process Information

Processors are required to identify product and process information in the form of a Product Description, Process Flow Diagram and a Plant Floor Plan where necessary.

1. The Product Description must identify those product attributes and characteristics that are important in ensuring a safe and acceptable fish product.

2. The Process Flow diagram must outline all of the production steps and assists in identifying those steps that are important in processing a safe fish product meeting all regulatory requirements.
3. The Plant Floor Plan identifies cases where hazards are controlled through the application of sanitary or restricted access zones.

The Prerequisite Plan

- I. Processors are required to identify the in-plant controls that provide assurances that:
 - A. the physical plant facilities are designed, constructed and maintained in a condition to allow for the sanitary production of food,
 - B. all potential sources of significant contamination are controlled, and
 - C. product can be rapidly recalled from first shipping destinations.
- II. The Prerequisite Plan is divided into two components:
 - A. Plant Environment Program. As part of the Plant Environment Program processors are required to identify:
 1. the plant environment standard that is applied in the facility (*as a minimum the standard must meet the requirements of the Fish Inspection Regulations*);
 2. the actions that are taken by the processor to ensure the standard is met;
 3. the record keeping system to record corrective actions when problems are identified⁷; and
 4. the corrective action system in place to address deficiencies when they are identified.
 - B. Recall Procedures:
 1. For the purposes of carrying out a product recall processors are required to have a product identification and distribution system that allows for the rapid identification of the 1st shipping destination.
 2. As part of the Recall controls the processor is also required to notify the CFIA of any valid health and safety complaints.

7. Under the Plant Environment Program processors are not required to record the results of monitoring unless there is problem identified. In these cases the processor must record the problem and the corrective action that was initiated.

The Regulatory Action Points (RAP) Plan

Processors are required to establish, document and apply controls that ensure the final product meets the requirements of the Fish Inspection Regulations.

- I. The Regulatory Action Point Plan must describe the controls to ensure that:
 - A. the fish is handled properly during processing and results in a final product that is not tainted, decomposed or unwholesome and meets all applicable sections of the Fish Inspection Regulations;
 - B. any ingredients added to the fish product or packaging material used are acceptable for food and meets all regulatory requirements as specified in the Fish Inspection Regulations and the Food and Drug Act and Regulations; and
 - C. the labelling and coding of all fish products meet the requirements of the Fish Inspection Regulations and are not false misleading or deceptive.
- II. As part of the RAP Plan the processor must identify:
 - A. the fish product standard(s) and the ingredient and packaging requirements (pertaining to the acceptability for use in food processing) that they are processing to (*the minimum fish product standard that must be met are set out in the DFO Fish Products Standard Manual*);
 - B. the actions that are implemented in production to ensure the standards and requirements are met⁸;
 - C. the record keeping system to record corrective actions when problems are identified; and
 - D. the corrective action system in place to address deficiencies when they are identified.

The Hazard Analysis Critical Control Point (HACCP) Plan

Processors must develop, document and implement a HACCP Plan to address any health and safety hazards related to the product or process. The processor must apply the principles of HACCP⁹ to identify any significant hazards and for those significant hazards identified, develop a HACCP plan to prevent, eliminate or reduce the hazard to an acceptable level.

- I. The HACCP Plan must include the following:
 - A. Hazard Analysis;

8. Under the Regulatory Action Points processors are not required to record the results of monitoring unless there is problem identified. In these cases the processor must record the problem and the corrective action that was initiated.

9. Consistent with the CODEX Food Hygiene Committee document, Alinorm 97/13 and the Hazard Analysis and Critical Control Point System by the National Advisory Committee on the Microbiological Criteria for Foods, 1992.

- B. Critical Control Points (CCPs);
- C. Critical Limits;
- D. Monitoring Procedures;
- E. Corrective Action System;
- F. Verification Procedures; and
- G. Record Keeping System.

Verification Requirements

Processors will be required to perform the following verification activities to ensure that their QMP Plan is functioning correctly:

- I. Before implementation the processor will be required to:
 - A. validate the critical limits of CCPs ,where appropriate, and
 - B. verify the QMP Plan to ensure that all of the necessary controls are in place and that it meets the requirements of the QMP Standard.
- II. Once the QMP Plan is implemented the processor is required to:
 - A. perform routine verification of the HACCP Plan to ensure it is functioning effectively (e.g. Record reviews, Corrective Action reviews, review of calibration of equipment),
 - B. verify or validate any changes to QMP controls or CCP critical limits that may occur in the ongoing development of the QMP Plan, and
 - C. verify the QMP Plan at least once per calendar year.

Record Keeping Requirements

- I. The record keeping requirements for the QMP plan areas follows:
 - A. Record keeping requirements for the Prerequisite Plan and the Regulatory Action Point Plan (RAPS) will be “records by exception”. Records will only be required when a deficiency is identified during the monitoring procedures. In these cases the processor is required to record the deficiency and document the corrective action that was taken.
 - B. Record keeping requirements for the HACCP Plan require that all testing, measurements, and monitoring procedure at CCPs are recorded and corrective actions are recorded when the critical limits are exceeded.
 - C. Records must be maintained of all verification actions.

To ensure that the QMP Plan is accurately documented processors are also required to maintain records of the amendments to the QMP Plan.

ESTONIA

OVERVIEW OF ESTONIAN FISH INSPECTION SYSTEM

by Eve Külmallik, Fisheries Department, Ministry of Environment of the Republic of Estonia

I. Description of Competent Authorities and Organisational Structure

First of all, it should be noted that organisational structure of competent authorities is being restructured on and this only gives a picture the current situation.

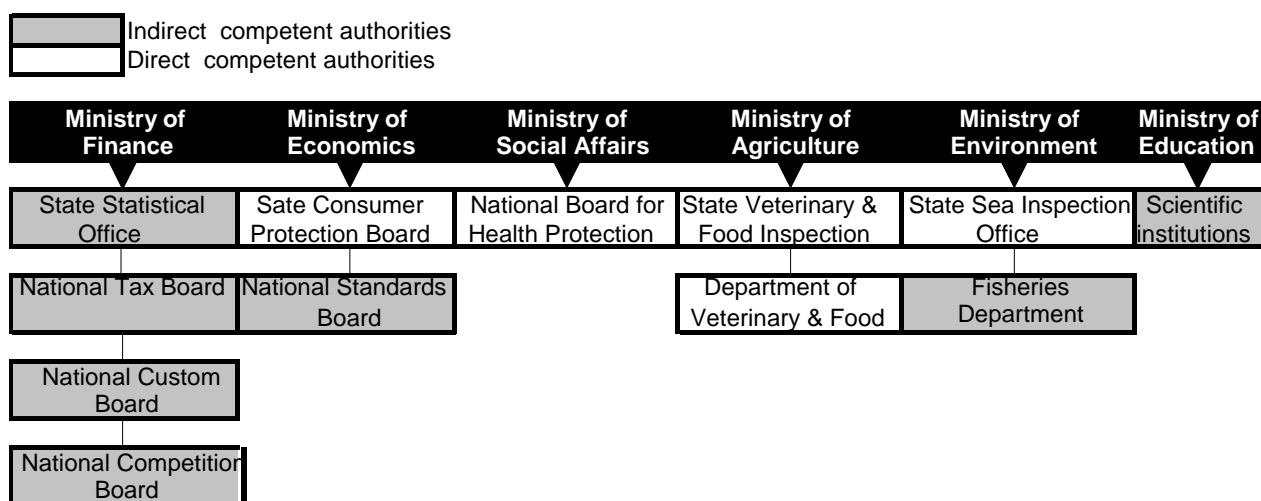
Estonian direct competent authorities are:

1. Estonian State Veterinary and Food Inspection of the Ministry of Agriculture
2. Department of Veterinary and Food of the Ministry of Agriculture
3. Estonian State Sea Inspection Office of the Ministry of Environment
4. National Board for Health Protection of the Ministry of Social Affairs
5. State Consumer Protection Board of Estonia of the Ministry of Economic Affairs.

Estonian indirect competent authorities are:

1. Fisheries Department of the Ministry of Environment
2. Estonian National Standards Board
3. Estonian National Competition Board
4. Estonian National Custom Board
5. Estonian National Tax Board
6. Estonian State Statistical Office
7. Scientific institutions.

Figure 1: **Competent Authorities on Fish Inspection**



Tasks and Roles: Direct Competent Authorities

(1) **Estonian State Veterinary and Food Inspection** - its tasks and rights are determined by its Basic Regulation. Its main area of activity is to execute the State control of safety in the field of veterinary and food. To accomplish this task the Inspection:

- A. organises, co-ordinates and performs the control of legal supervision of safety in the field of veterinary and food in the state and on frontier; accounts, analyses and enforces the efficiency of legal acts and results of surveillance;
- B. supervises the enforcement of legal acts regulating the veterinary service;
- C. issues licenses and activity permits concerning veterinary activity;
- D. organises infectious and non-infectious disease prevention, defence and observe of animals, birds, fish and crustaceans;
- E. supervises the hygienic and safety aspects of food;
- F. supervises the treaty of animal production;
- G. acknowledges and controls animal raw material in processing companies; and
- H. executes veterinary and food control on frontier; etc.

The Inspection has the right to:

- A. prohibit use of inadequate raw material for human consumption and also prohibit the processing of such kind of raw material;
- B. prohibit the taking of inadequate animal production from the processing companies;
- C. prescribe remedial actions to eliminate identified inadequacies;
- D. take samples of production;
- E. stop processing activity until the inadequacies are eliminated;
- F. issue veterinary certificates; and
- G. recall veterinary certificates if reports indicate that the raw material is inadequate.

The Inspection is situated in Tallinn, its departments are in counties of Harjumaa, Hiiumaa, Ida-Virumaa, Jõgeva, Läänemaa, Lääne-Virumaa, Põlva, Pärnu, Rapla, Saare, Tartu, Valga, Viljandi, Võru and also in Narva and Tallinn. The Inspection has 204 employees and it supervises the Veterinary- and Food Control Frontier Service. The latter institution has 48 employees. Under the supervision of the Inspection there are approximately 200 authorised veterinarians.

The Veterinary and Food Inspection conducts control in the fish processing companies, beginning from raw material and working through to analysis of final product. In other words, inspectors keep a check on workshop temperature, ventilation, implementation general hygienic rules, equipment, materials (wood is not allowed), accordance with fish production to production description, etc. As result of the control exercise, the company is added (or not) to the list of the Inspection. The Inspection issues a veterinary control number to the company. The company can not work without this number. This number is issued as “temporary”. If it appears that there is some inadequacy of processing or production then work of the company will be stopped until this inadequacy is eliminated.

The frequency with which Inspection carries out a control exercise depends upon the company’s processing level. For the best companies the frequency of control visits is once or twice a year. The more problems company has, the more it will be controlled. Counties departments report once in quarter to the main office in Tallinn.

In 1997, 100 exporting fish processing companies were registered in the Inspection’s list. The number of companies is expected to decrease this year. The registration is based on EU Council Directive no. 91/493/. Exporting is in accordance of requirements of different countries. The inspection controls given demands. (e.g., some of exporting requirements of Ukraine are different from the requirements of Russia or USA or EU).

The Inspection also executes veterinary control on the frontier. This involves control of documents and analysis of product.

Imported fish and fish products have to be in accordance with EU Council Directive no. 91/493.

(2) **Department of Veterinary and Food of the Ministry of Agriculture.** There are 17 persons employed in this department. Its main functions of this department are to

- A. to develop drafts of food and veterinary laws;
- B. to co-ordinate veterinary- and food quality control in the state and on frontier;
- C. to co-ordinate veterinary- and food safety monitoring programs; and
- D. to analyse veterinary, food safety and quality, food processing situation in the state; to develop food policy; etc.

In this department there are 4 bureaus:

- A. Bureau of Food Safety.
- B. Bureau of Animal Sanitary.
- C. Bureau of Food Control.
- D. Bureau of Food of Animal Origin.

(3) The Sea Inspection Office of the Ministry of Environment has the power to protect the marine environment and co-ordinate and manage the utilisation of the natural resources of the sea-bed. Under the supervision of the Ministry of the Environment, the Sea Inspection Office carries out these functions.

The headquarters of the Sea Inspection Office is situated in Tallinn its departments are in Harjumaa, Läänemaa, Pärnumaa, Virumaa, Saaremaa and the shore of Lake Peipsi. To carry out its tasks within the sea areas and in Lake Peipsi, there are seven patrol vessels based in Tallinn, Pärnu, Haapsalu, Narva and Kallaste as well as twelve motor launches. The Sea Inspection employs 150 people.

The Sea Inspection conducts control of the state of the aquatic environment and the utilisation of natural resources, the protection of marine areas and fish resources within the coastal and territorial waters and Estonia's exclusive economic zone, the Narva River and Lake Peipsi. In environmental protection its activities include control of the operation of ports, harbours, ship repair facilities, ships and other floating craft. The Sea Inspection:

- A. supervises other the enforcement of legal acts, regulations and guidelines on the protection and utilisation of the aquatic environment and water resources;
- B. makes recommendations prescribing compulsory remedial actions in case of non-compliance;
- C. records of violations in a protocol in order to carry out legal sanctions to cover the cost of damages caused to the state;
- D. establishes administrative penalties for violations; and
- E. proposes the initiation of criminal action.

In exercising its control power, inspectors may stop and detain ships and other floating craft.

One of the important tasks is to approve and issue permits for conducting hydrotechnical activities, dumping, conducting geological research, utilisation of natural resources and conducting blasting operations.

Besides the aforementioned tasks also small craft (less than 12 meters in length) has to be registered and technically controlled since, although the owner of such a craft is a professional or an amateur fisherman, a small motor craft may be a potential water polluter on the other hand.

The co-operation agreement with the Estonian Board of Border Guards provides for the exchange of information and experts during inspections, and the participation of observers from the inspection in aerial surveillance. The specialists from the Sea Inspection participate in training the personnel of the board guards in environmental protection issues and in conducting control of the utilisation of natural resources.

Under a co-operation agreement with the Estonian Marine Institute, Sea Inspection patrol vessels participate in marine research activities.

(4) National Board for Health Protection under the Ministry of Social Affairs. The Board has 15 offices of health protection in the counties Harjumaa, Hiiumaa, Ida-Virumaa, Jõgeva, Järvamaa, Läänemaa, Lääne-Virumaa, Põlva, Pärnu, Rapla, Saaremaa, Tartu, Valga, Viljandi and Võru. The Board employs 434 people. The main tasks of the Board are to:

- A. inspect natural and legal persons in following areas of activity; and
- B. use and acquire:
 1. synthetic materials, machinery and facilities unsafe for health;
 2. chemicals and biological preparations unsafe for health;

Its mandate covers importing, selling and production of foodstuffs, food, minerals and drinking water;

Some of the main powers of the Board are the:

- right to take free tests from materials and products and estimate health safety of examined objects;
- right to restrict, cancel or stop the activity of a natural or juridical person who may injure human health;
- right of employer to ban employee who does not pass the health control;
- right to ban the use and acquisition of raw material unsafe for health.

The Board also harmonises product standards, produces specifications for technology and normative documents, and postpones realisation terms (shelf-life or “best before” of canned fish). It harmonises also wrapping materials, building materials and decoration materials. Health protection offices carry out random control of production to compare the accordance of production with standards and specifications.

(5) State Consumer Protection Board of Estonia of the Ministry of Economic Affairs. The main tasks of Consumer Protection Board are to:

- draft consumer protection legal acts, regulations and instructions;
- undertake consumers rights;
- organise control over following demands of goods and service (e.g., checking to ensure that retailers are preserving raw fish in accordance with preserving demands).
- apply responsibility for violation of legal acts in accordance with law; (i.e., applying penalties under the Consumer Protection law);

The powers of the Board include the right to:

- stop the sale of goods or service which are unsafe for consumers and to prevent the production of these goods or eliminate the inadequacies in their production;
- stop or cancel activity license of the company in accordance with law; etc.

The Board has three departments:

- Department of Inspection;
- Department of Information and Consultation
- Department of consumer policy

Tasks and Roles: Indirect Competent Authorities

(1) Fisheries Department of the Ministry of Environment. The National Estonian Board of Fisheries (NEBF) was established under the competency of the Minister of Environment of the Republic of Estonia in 1991. In January 1997 the NEBF was transformed into the Fisheries Department of the Estonian Ministry of Environment in January 1997. The Department employs 14 people. It has 3 sections:

1. Fishery Resources;
2. Development and Co-operation; and
3. Fisheries Economics.

The main tasks of the Fisheries Department are to:

- develop the Estonian fisheries policy and the Estonian Fisheries Management Plan;
- draft the Estonian Fisheries Act and other relevant legislation;

- implement the Estonian fisheries policy and the Estonian Fisheries Management Plan in order to ensure effective management (economic use) and conservation of the living aquatic resources as well as the protection of their environment;
- develop and ensure the establishment of effective mechanisms to monitor and control the compliance with and the enforcement of conservation and management measures;
- promote the maintenance of the quantity, quality, diversity and availability of fishery resources for present and future generations;
- prevent over-harvesting and excess fishing capacity in order to ensure that fishing effort is commensurate with the productive capacity of the resources;
- exercise effective control to ensure that fishing and fishing support vessels flying Estonian flag fulfil their obligations concerning the conservation and management measures taken in accordance with international law and concerning the collection and exchange of data relating to their fishing activities;
- ensure that Estonian fisheries interests, including the conservation and management of the resources, are taken into account in the multiple use of the coastal zone;
- promote the handling, processing and distribution of fish and fishery products in a manner which will maintain the nutritional value, quality and safety of the products, reduce waste and minimise negative impacts on the environment;
- promote international trade in fish and fishery products in accordance with fair practices and relevant international agreements;
- defend the interest of the fisheries sector in negotiations when dealing with cross-sectoral issues, etc.

Figure 2: Relationship between Competent Seafood Inspection Authorities

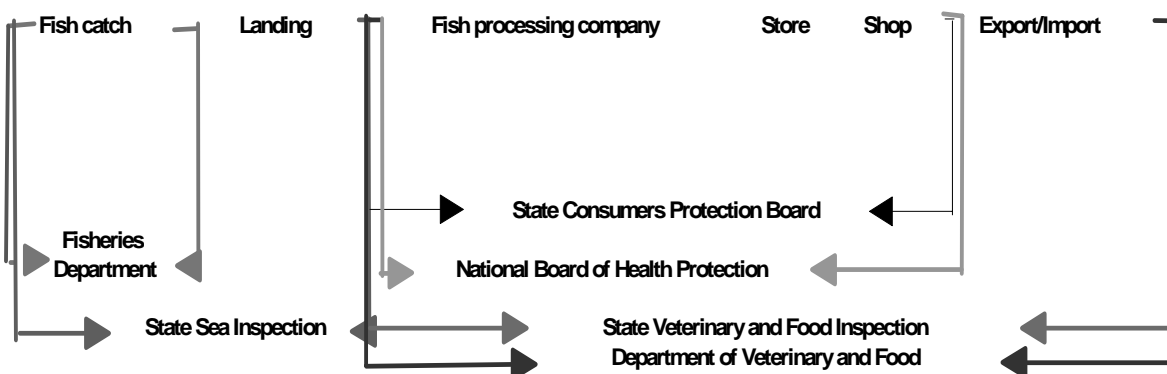
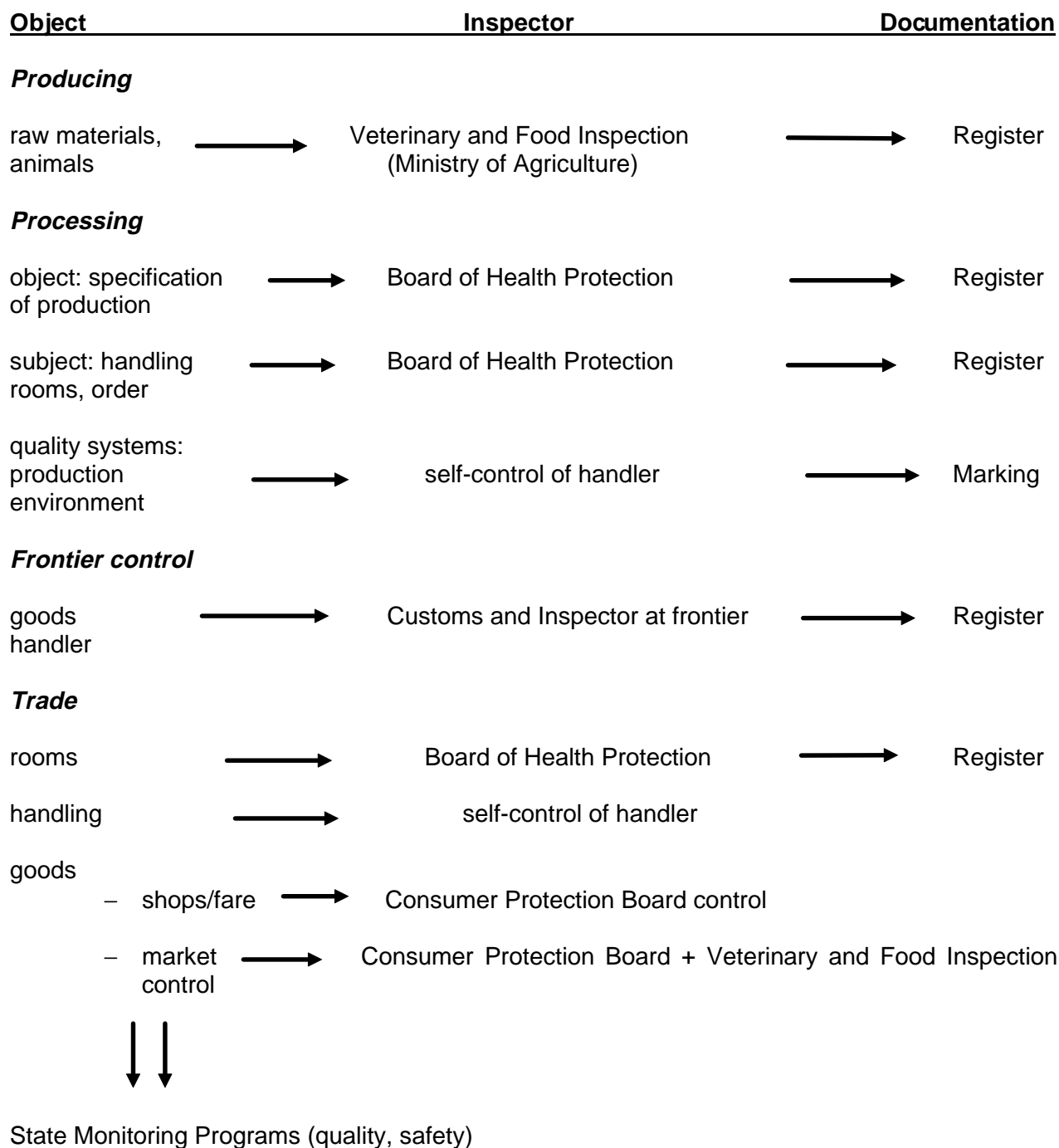


Figure 3: **Food Inspection and Control of Producers**



Legislation

The food inspection legislation of Estonia is complicated. In addition to the Estonia’s own laws and regulations there are some standards which remain in force from the Soviet period. At the end of 1998 for major legal acts, and the remainder by the end of the 2000, the main legislation must be harmonised with EU legislation. Some directives, such as EU Council Directive 91/493, 22 July 1991, are already in force.

Estonian legal acts constitutes the Food Code. Figure 4 illustrates the components of the Food Code.

Figure 4: The Food Code

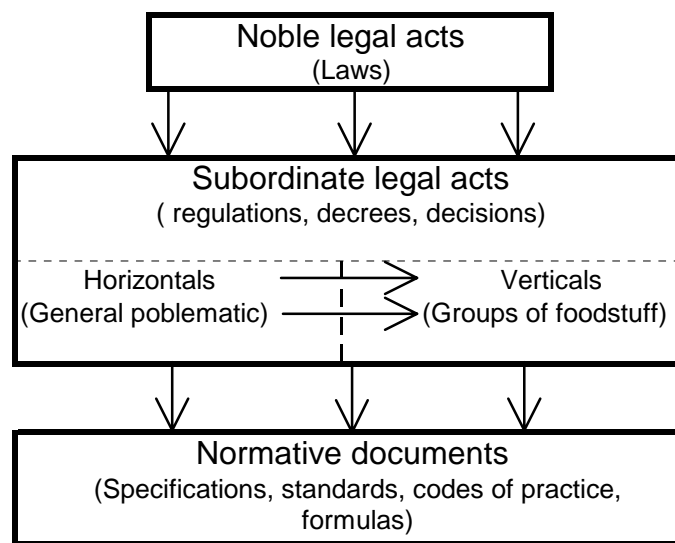
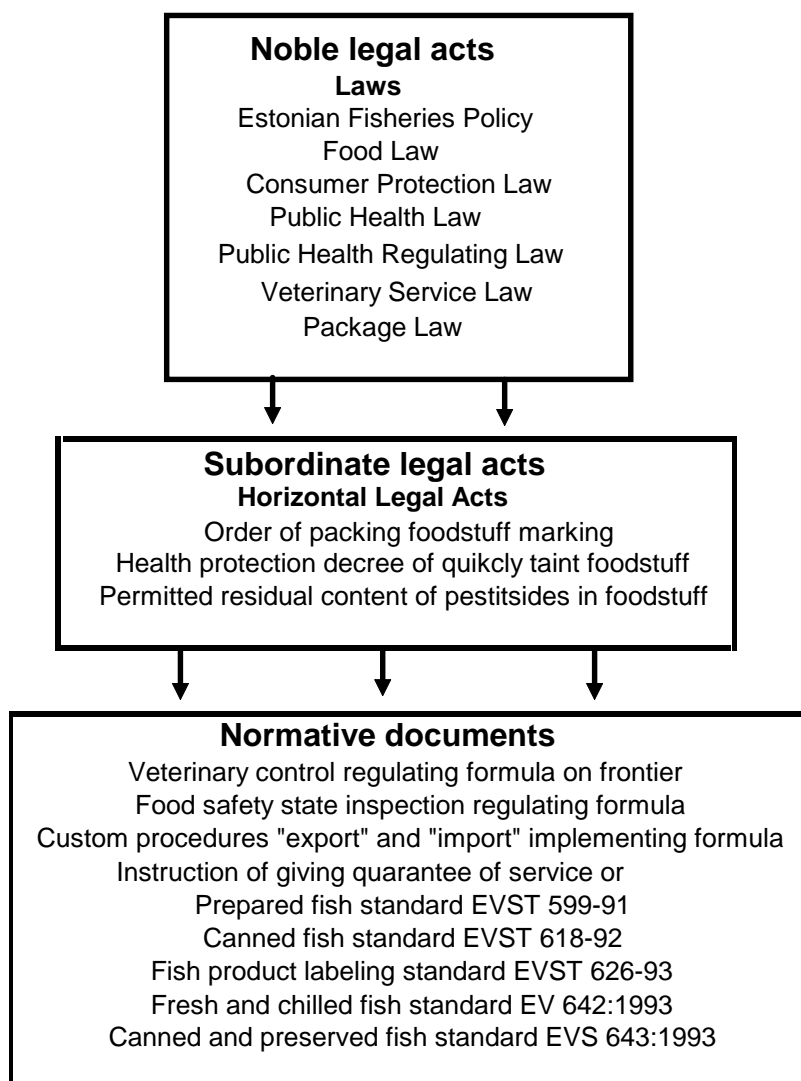


Figure 5 provides an overview of the primary pieces of food inspection legislation used by competent authorities.

Figure 5: Food Inspection Legislation



Laboratories

As one of the most important components of effective food safety control system, great attention is paid to laboratory services. Results of laboratory microbiological and chemical analysis are important when for use in monitoring verification the operation of Critical Control Points (CCPs) and product safety.

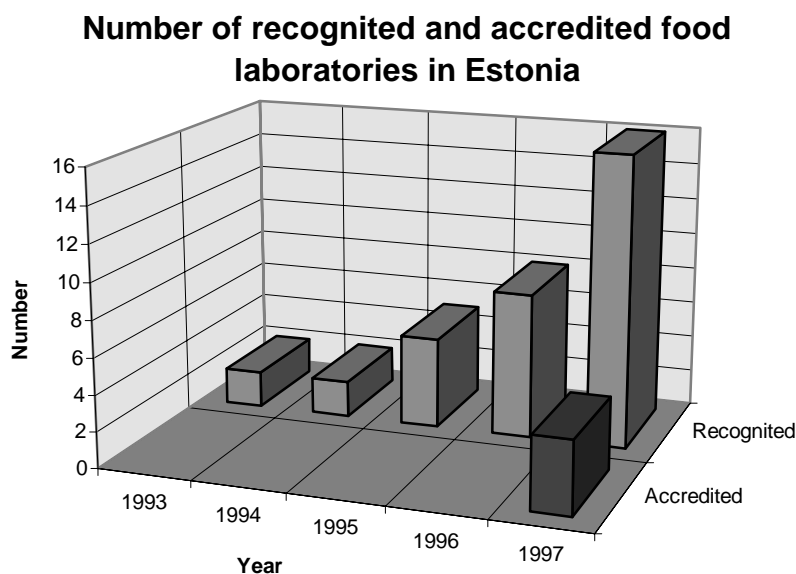
Common problems for Estonian food laboratories include;

- a lack of high-quality equipment and chemicals;
- insufficient funds to run laboratory services and to maintain them; and

- lack of requirements up to date (i.e., lack of up to date information on new methods).

In spite of above problems, the accreditation of laboratories in Estonia commenced. As an illustration of such development Figure 6 presents the growth of accredited laboratories in Estonia since 1993.

Figure 6:



Official recognition, which involves verifying the technical competence, has been Estonian Standardisation Board (ESB) to more than twenty food laboratories analysing methods during last five years. This is the first step in the real accreditation process. In addition, it is important to notice that in 1997 the first 4 food laboratories were accredited by ESB with participation of the external leader-assessors from Sweden and Finland.

These 4 laboratories were accredited in accordance with requirements of EN standard number 45001. The Difference between official recognition and accreditation that:

- official recognition is the first step for accreditation and recognition under EN standard of 45001; whereas
- in official recognition is not considered to measure uncertainty, presentation errors of test results and intercalibration comparison tests.

The 4 accredited laboratories are:

- Commercial laboratory “Areto” — food chemical and microbiological analysis;
- State Veterinary Laboratory — food chemical and microbiological analysis;

- Estonian Grain Board Grain Laboratory ---chemical analysis; and
- Tartu Veterinary Laboratory — food chemical and microbiological analysis, and diagnostic analysis.

Training

A lot of training courses are currently conducted and more are planned for the future. Training topics include: hygiene, quality, HACCP and also the seafood inspection) It is possible to get training courses in following institutions:

- Department of Food Processing of the Technical University;
- Department of Food Hygiene of the Agricultural University; and
- Estonian Maritime Academy, etc.

There are numerous of PHARE training programmes besides domestic training possibilities. One of the most important PHARE training programmes at the moment is “Assistance to Upgrading Efficiency of Estonian Food Processing Industry”. This course is co-ordinated by Ministry of Agriculture. General objective of this training programme is to assist the Estonian industries to meet the demands of domestic and international customers. The course provides advice on implementing quality assurance systems, quality management and investments plans compatible to EU standards. The main task is to implement the Hazard Analysis and Critical Control Point (HACCP) system in pilot companies. From the fisheries sector, two companies were selected: Pärnu Kalamajand Ltd. and Viru Rand Ltd.

At present enterprises, as well as the potential support organisations, are ready for the HACCP. But they are not yet ready for the ISO 9000 level. This is not surprising, as the smallest and many bigger companies in the EU today do not have an ISO certificate (and if they do, then in many cases the ISO standards apply to only a part of their production lines). It should be also noted HACCP systems can be incorporated very well into an ISO system, making it considerably easier to develop the ISO programme.

Useful information on Estonian Fishing Industry can be found in: Aps R., Vaarja, L., Lillipuu, T., *The Fishery Industry in Estonia*, FAO/EASTFISH, Fishing Industry Profile, Vol. 5., Copenhagen, FAO, 1997.

EUROPEAN COMMUNITY

FISHERY PRODUCT INSPECTION SYSTEM IN THE EUROPEAN COMMUNITY

Introduction

Prior to 1 January 1993 and the creation of a Single Market within the European Community, responsibility for regulating health controls for fishery products lay solely with Member States. The first step towards the dismantling of internal border controls within the EC therefore consisted in the harmonisation of existing national regulations. The process was completed in 1991, with the adoption by the Council of Ministers of two framework Directives laying down health conditions, one for live bivalve *molluscs* and the other for fishery products. These two directives were then translated into national law by the individual Member States and the Single Market allowing the free circulation of fishery products which finally came into force on 1 January 1993.

Two further Council Directives established rules with regard to veterinary checks on foodstuffs of animal origin, both within the European Community and -- for imports -- at its external borders.

These four Directives form the legal framework for the harmonisation of fishery product inspection systems in the European Community. Numerous instruments have been adopted in the form of Commission Decisions, laying down the detailed rules of application for these directives. There now exists a coherent body of law which nonetheless retains a degree of flexibility in that EC directives, unlike regulations, are enforced through domestic legislation. Domestic legislation must be adapted to the goals and resources specified in the EC directives.

The boundary between national competence and EC competence is established in accordance with the principle of subsidiarity. The EC inspection system for fishery products, for instance, is subject to three tiers of competence and responsibility, which are described below.

First Tier of Competence/Responsibility: Individual Establishments

The production and marketing of fishery products in the European Community must comply with a set of health rules laying down requirements in terms of resources and performance. The *resource requirements* apply to fishing vessels, production facilities, equipment, warehousing, means of transport and general rules of hygiene. These requirements lay down conditions regarding the structure and development of premises, materials coming into contact with products, preserving techniques, cleaning/disinfection methods, and the hygiene and health of staff handling fishery products. These

conditions are based directly on the FAO Codex Alimentarius recommendations as set out in the various Codes of Practice adopted over the past twenty years.

The *performance requirements* are based on the criteria to be met by fishery products before they can be placed on the market, including freshness and microbiological standards, maximum levels of residues/heavy metals, decomposition amines and marine biotoxins.

The profession owner of the factory, or the manager is responsible for complying with the requirements set out in the regulations. It must ensure at all times that its establishments meet requirements and operate in accordance with the prescribed rules of hygiene. In addition to these broad responsibilities, it also has a duty to set up and implement correctly a programme of “own health checks” based on the principles of Hazard Analysis Critical Control Points (HACCP). Defined by the Codex Alimentarius, these are set out in detail in a Commission Decision dated June 1994. This requires that persons responsible for “own-checks” in a production unit or factory vessel develop them as part of an approach internal to the establishment or use guides of good manufacturing practice drawn up by appropriate professional organisations and acceptable to the competent authorities. All staff affected by “own-checks” receive adequate training in order to participate effectively in their implementation. Laboratories participating in “own-checks” should be approved by the competent authorities on the basis of ISO 9001 standards (EN 45 001).

For establishments with internal laboratories, however, the competent authorities may use the guides for monitoring compliance with the OECD Principles of Good Laboratory Practice.

Establishments must keep detailed and comprehensive records including, for each critical control point (CCP):

- the hazard-control measures introduced;
- critical limits to be controlled;
- methods of control; and
- corrective action to be taken in case of loss of control.

Written record must similarly be kept of observations or measurements, results of the verification activities, and any corrective action taken. A document management system must ensure the traceability of fishery products.

Finally, if the outcome of the “own-checks” process, or any information brought to the attention of the persons in charge of the establishment, reveals or suggests any risk to health, appropriate measures must be taken, including the withdrawal of the identified batches, under the official supervision of the competent authorities. This presupposes that the firm will notify the authorities of any case of fishery products not complying with prevailing health standards. This point has raised legal problems in some Member States.

Second tier of Competence/Responsibility: National Authorities

Every EC Member State must set up a checking and monitoring system to ensure compliance with the provisions set out in EC directives and decisions. This system is the responsibility of the

competent authority, defined as “the central authority of a Member State competent to carry out veterinary checks or any authority to which it has delegated that competence”.

The competent authorities approve fishery product establishments once they have verified that they meet the structural and functional requirements set out in the directives. The establishment is granted a reasonable period of time to adapt to health standards, in particular the introduction of an HACCP system. The approval must be renewed if an establishment decides to carry out activities other than those for which it has received approval (e.g., a fish-filleting unit that decides to smoke its products). The competent authority allocates to each of its approved establishments an official number, which must appear on the packaging of all marketed products to ensure identification and traceability.

The inspection and monitoring of establishments are carried out regularly under the responsibility of the competent authorities, which must at all times have free access to all parts of the establishments, in order to check compliance with requirements.

As well as granting approval, the competent authority must ensure that the control service:

- checks hygiene on fishing vessels during their stay in port;
- checks on the conditions of landing and first sale;
- inspects approved establishments at regular intervals to check whether:
 - the conditions for approval are still fulfilled;
 - the fishery products are handled correctly;
 - the premises, facilities and instruments are clean;
 - whether identification marks are put on correctly; and
- inspects hygiene in wholesale and auction markets, together with packaging, storage and transport conditions.

Thus the entire production chain, from fishing vessel to final sale, is subject to official health inspection by the competent national authority.

Furthermore, the control services reporting to the competent authorities must conduct sampling tests on products placed on the market. They are tested for organoleptics, parasites and chemicals, and also undergo toxicological and microbiological analyses. A monitoring plan must be drawn up for contaminant levels in the aquatic environment, in particular heavy metals and organohalogens and, for aquaculture products, medicinal residues.

Finally, the competent authorities must ensure appropriate training of the inspection staff authorised to perform official checks, allowing them to assess the establishment’s own-checks system on the basis of the documents submitted.

Member States did not wait for EC directives to introduce fishery product inspection systems. In some countries, the checks date back to the Middle Ages. The directives have harmonised the conditions under which inspection takes place, but do not impose structural or functional requirements on

the competent national authorities. This is covered by the principle of subsidiarity. The situation differs markedly from one Member State to another, depending on whether it has a federal or centralised government and whether it is a producer or a consumer country. In some Member States, the competent authority reports to the Ministry of Health (e.g., Germany, Spain and Italy) but in others to the Ministry of Agriculture (e.g., France, the United Kingdom, Denmark and Greece) or the Marine and Natural Resources (e.g., Ireland).

In most Member States, the competent authority is the official veterinary service responsible for health inspections for all products of animal origin.

The inclusion of fishery products under the broad heading of products of animal origin generates major economies of scale in terms of administration and inspection/laboratory staff, as well as optimising resources, particularly when production is seasonal.

The removal of veterinary checks at internal EC borders has made it possible to redeploy inspectors to production sites. Since control services cover all products of animal origin, it is hard to estimate the proportion of human resources given over full-time or part-time to fishery inspection. They belong to official control services at central, regional or local government level. No Member State has recourse to private inspection bodies.

Third tier of Competence/Responsibility: the European Commission

The European Commission has the right to ensure that Member States comply with EC directives.

It can exercise this right, first, by examining the transposition of EC directives into domestic legislation and, second, by on-the-spot checks to ensure the application of those directives. A Member State in whose territory a check is being carried out must give all necessary assistance to the Commission experts in carrying out their duties.

1. Reassigning Competence

Following the bovine spongiform encephalopathy (BSE) crisis, the European Parliament criticised the Commission for the inadequacy of its controls. The Commission responded by re-organising its inspection system and strengthening its capacity for action. The former Office for Veterinary and Plant-Health Inspection and Control became the Food and Veterinary Office (FVO), based in Dublin (Ireland) and reporting to the Directorate General for Consumer Policy and Consumer Health Protection (DG XXIV). The FVO is responsible for food hygiene and consumer health, animal health and welfare, and plant health. Inspection and health checks for fishery products thus fall within its remit.

2. More human resources

35 new inspector posts were created as an emergency measure in 1997. A special competitive examination was held to recruit 120 new inspectors as from May 1998, with a timeframe ensuring adequate training provision for new recruits. Most of the posts are for inspectors with indefinite-term contracts and the status of European Commission officials, thereby ensuring their independence and freedom of judgement and enabling them to develop their expertise on a regular basis. However, in order

to maintain links with the competent authorities in Member States, more is to be done to develop the temporary employment of national inspectors accompanying FVO inspectors on their missions and providing specialist expertise.

3. *Standardised working methods*

In the past, EC inspectors were mainly responsible for inspecting abattoirs to ensure compliance with EC regulations. But the FVO inspectors now have a much broader remit and their working methods must be tailored to the new situation. In particular, their methods require standardisation. A team of over 100 inspectors who spend most of their time on mission are to be given a detailed Manual of Procedures enabling them to organise inspection operations and draw up mission reports in a consistent manner. Work is currently proceeding on the drafting of this Manual of Procedures.

4. *Broader scope*

Inspections will now cover not just a segment of production but the whole of the food chain, from “stable to table”. The FVO’s work will gradually shift towards the creation of multidisciplinary inspection teams covering the various aspects of a given branch, from primary production to the final product.

5. *National authority audits*

Even with its ambitious recruitment policy, the European Commission will not have enough inspectors in the FVO to take over from the competent national authorities. Its role, under the subsidiarity principle, is to assess how competent national authorities are and how well their control systems perform. It should thus be able to check that Member States have sufficient resources to apply EC legislation and that they are effectively doing so. The assessment techniques are based on the principles of auditing. Training in auditing is already being given by an outside provider and will continue as new inspectors are recruited.

Inspectors holding auditing qualifications form the core staff responsible for developing the Manual of Procedures and incorporating principles for the auditing of competent national authorities.

Performance appraisals for control systems include on-site visits to production, storage and distribution establishments in the company of national inspectors. The visits are a means of assessing health conditions in an establishment and the action taken by national inspectors; they include the on-site examination of inspection reports and available records proving that own-checks have been carried out.

6. *Mission priorities*

The broadening of the FVO’s competencies and responsibilities has meant that priorities need to be set for the programme of inspection missions. A formal risk-assessment system has been drawn up for that purpose. The system is a simple, transparent means of grading the risks associated with a group of animals, plants or food products from a particular country. The prioritisation of inspection programmes is based on a range of factors, including the identification and severity of potential hazards, the probability of their appearance or propagation in the European Community, the capacity of national authorities to

control such hazards, the frequency and findings of previous inspections, and the climate and general health conditions in a given country.

7. *Transparency*

To ensure the transparency of its operations vis-à-vis all the parties concerned, i.e. legislators, parliamentarians, industrialists and consumers, the decision has been taken to make FVO inspection programmes and findings available to the public. Subject to Article 214 of the EC Treaty, relating to the disclosure of information, the FVO will communicate the findings of its inspection missions widely in both Member States and third countries. It will also publish an annual report on its activities. Producer and consumer associations will be invited to comment on the inspection findings. Every six months, detailed programmes of its missions will be communicated to the Committees, the European Parliament and the public at large. Where necessary, amendments to these programmes will be published every month, as risks are re-assessed and developments arise. DG XXIV now has a home page on the Internet (<http://www.cc.cec>) to publish its inspection programmes and findings more widely.

Fishery Product Imports

Responsibility for checking fishery products imported into the EC is shared between the competent authorities in exporting countries, the authorities of the Member State through which the products enter the EC, and the European Commission. The requirements applying to imports are equivalent to those for EC products.

The competent authorities in exporting countries must be assessed by FVO inspectors on the same basis as Member State authorities. Once assessed and approved, they are responsible for the application of EC legislation to fishery products exported into the EU. They must therefore submit to the Commission the list of vessels and production units authorised to export fishery products after checking their compliance with EC requirements, including the HACCP-based “own-checks” process. The competent authorities must certify all exported batches of fishery products.

It rests with the competent authorities of Member States to inspect products entering the European Community from third countries. These checks must be carried out in inspection posts approved by the Commission and regularly assessed by FVO inspectors. There are:

- paperwork checks (to inspect certificates and ensure that the facility is on the list of authorised establishments);
- identity checks (to ensure that paperwork and products correspond, and that the products carry identification markings); and
- physical checks which may include laboratory tests.

Physical test findings are used to re-prioritise FVO inspection missions to exporting countries. Border inspection posts must immediately notify other EC inspection centres of any failure in compliance. As soon as the competent authority of a Member State detects a fishery products presenting a risk to public health, it must notify the European Commission via the Rapid Alert System for foodstuffs. Having assessed the risk, the Commission informs the other Member States and may, where necessary, take

measures regarding the origin of the products concerned. This information will also be used to re-prioritise FVO inspection missions.

Conclusions

The inspection and control of fishery products in the European Community falls within the scope of a general system of inspection and control of products of animal origin. Responsibility for such inspection activities lies with producers, national authorities and the European Commission, but is not delegated to any private body. The system is being expanded and the Commission has broadened the scope of its competence in matters of inspection and is acquiring the human and physical resources required to undertake these new responsibilities. Under the subsidiarity principle, EC legislation does not impose the structural or functional harmonisation of fishery product control services, and each Member State must be consulted if information is required on the structures it has set up. However, the efficiency and performance of those inspection systems are assessed by the Commission.

BELGIQUE

SYSTÈME D'INSPECTION DES PRODUITS DE LA PÊCHE EN BELGIQUE

I. Description de l'autorité compétente

a) Personnel

L'expertise est effectuée par des vétérinaires, membres du personnel de l'Institut d'expertise vétérinaire.

b) Législation

- Loi du 15 avril 1965 concernant l'expertise et le commerce du poisson, des volailles, des lapins et du gibier.
- Loi du 24 janvier 1977 relative à la protection de la santé des consommateurs en ce qui concerne les denrées alimentaires et les autres produits ou ses arrêtés d'exécution : cette loi est également applicable aux denrées alimentaires comportant des viandes ou du poisson.
- A.R. du 30 avril 1976 relatif à l'expertise et au commerce du poisson :
 - modifié par l'A.R. du 30 décembre 1992 reprenant les conditions d'installation et d'exploitation fixées aux directives 91/492 et 91/493;
 - modifié par l'A.R. du 19 mai 1995 fixant les exigences hygiéniques pour le poisson à bord des bateaux de pêche et pour ces bateaux de pêche.

c) Organisation

La Belgique est subdivisée en 20 cercles d'expertise. Les chefs de cercle répartissent le travail entre les vétérinaires qui effectuent des contrôles dans les établissements et expertisent les produits de la pêche apportés de la mer ou élevés en eau douce dans les parcs d'élevage. Les poissons importés sont soumis à un contrôle sanitaire dans les postes d'inspection frontaliers.

L'administration et l'organisation de l'expertise et du contrôle sont effectuées par l'administration centrale de l'IEV à Bruxelles (voir annexe 1).

d) Laboratoires

Une liste des laboratoires agréés en vue de l'exécution d'analyses microbiologiques figure à l'annexe II. De plus, un système de monitoring est mis en place en vue de contrôler, dans les produits de la pêche mis sur le marché, l'éventuelle présence de biotoxines et de mesurer les taux de concentration en métaux lourds, en pesticides et en résidus de produits à action pharmaceutique.

e) Formation

Deux centres de formation continue dépendant de deux universités d'Etat organisent des cours pour les vétérinaires de l'IEV en vue de perfectionner leurs connaissances et de les tenir informés. De plus, une quarantaine de vétérinaires (fonctionnaires) sont formés aux techniques de la conduite d'audit des établissements.

II. Description du système d'inspection et de contrôle

L'inspection des produits de la pêche est destinée à déclarer ces produits propres ou impropres à la consommation. Elle est organisée avant la première mise sur le marché, comme l'exige la directive 91/493/CEE et elle a lieu dans les trois minques officiellement agréées sur la côte belge (poisson de mer) ainsi que dans les parcs d'élevage de poisson (poisson d'eau douce).

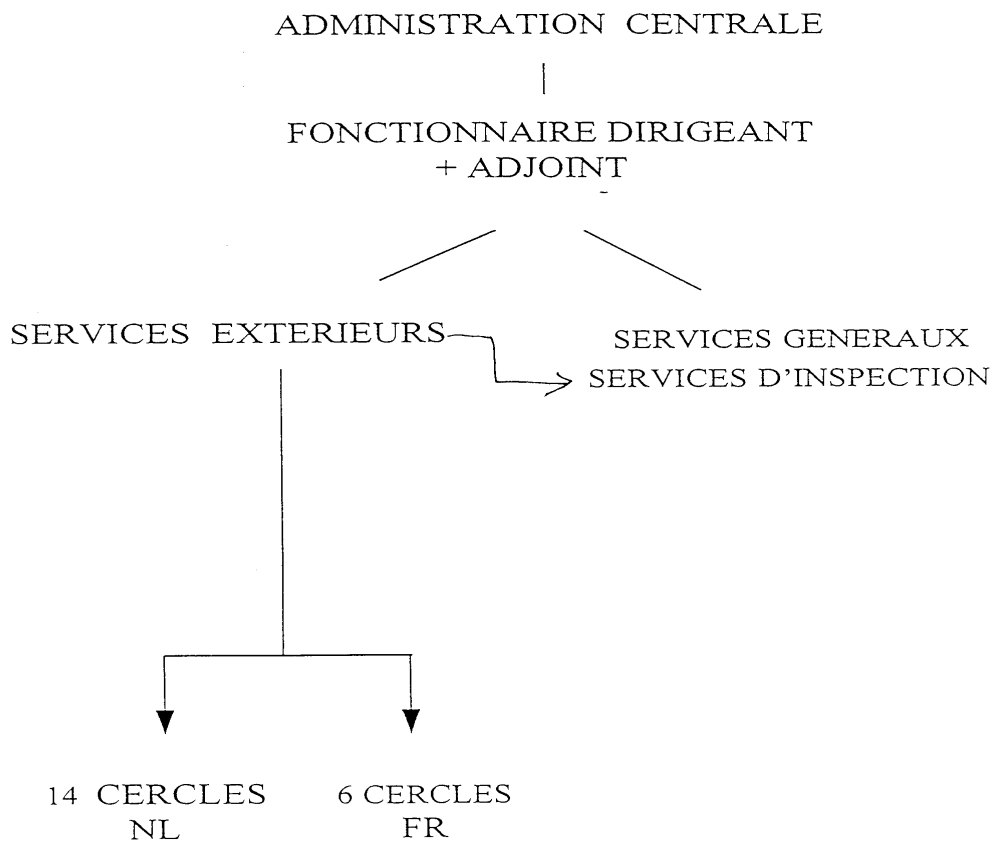
En plus de l'inspection, un contrôle des établissements traitant le poisson est instauré, en vue de vérifier que les conditions structurelles d'installation et d'hygiène pour l'exploitation sont conformes aux directives 91/493/CEE et 92/48/CEE.

Les données relatives aux quantités de poisson capturées, à la consommation de produits de la pêche par habitant et aux quantités de produits de la pêche importés et exportés sont indiquées à l'annexe III.

ANNEXE I : INSTITUT D'EXPERTISE VÉTÉRINAIRE

*Page 1
annex 1*

INSTITUT D'EXPERTISE
VETERINAIRE



SERVICES D'INSPECTION DE L'ADMINISTRATION CENTRALE

I. Matières générales et horizontales :

Le Dr. Lic. R. KEYMOLEN et le Dr. Lic. L. MOOR assurent collégialement :

1. le traitement des matières générales
2. la coordination des cellules, des cercles d'expertise et des matières horizontales : HACCP/qualité, CODEX, C.S.H., Conseil d'expertise, Commission consultative,...
3. les relations avec les services officiels nationaux et internationaux
4. la surveillance et la coordination de la cellule horizontale

DIVISION E : Surveillance CELLULE 9
<ul style="list-style-type: none"> - sur les services de l'IEV : expertise, contrôles, équipes mobiles, coordination, supervision - sur la production : GMP-GHP

II. Matières techniques :

Dr. Lic. R. KEYMOLEN		Dr. Lic. L. MOOR	
DIVISION A : Loi de 52		DIVISION B : Loi de 65	
CELLULE 1	CELLULE 2	CELLULE 3	CELLULE 4
Viandes de boucherie - abattoirs animaux de boucherie - ateliers de découpe - frigorifères - entrepôts - boyauderies - expertise, contrôle - hygiène - plans - agréments - exportation	Produits de viande - ateliers de préparation de viande - boyaux salés - fondoirs - contrôle - hygiène - plans - agréments - exportation - autres produits	Poisson - miniques - piscicultures - produits de la pêche - expertise, contrôle - hygiène - plans - agréments - exportation	Formation continue Commerce national - protection animale - formation continue - détail - commerce ambulants - restauration - transport - épidémiologie-surveillance (coordination) - déchets - exportation
Residus - résidus horm. et arithorm. - résidus autres que les hormones (médicaments) - radioactivité - contaminants		Viandes de volailles - abattoirs de volailles - ateliers de découpe de volaille - produits de volaille - lapins - gibier - expertise - hygiène - plans - agréments - formation continue - exportation	
fussion - laboratoires - prélèvements - bactériologie - parasitologie - additifs - irradiation - toxo-infections alimentaires		Commerce international et importation Pays Tiers - CEE - BENELUX - importation Pays Tiers - postes frontaliers - listes des établissements	
Dr. GUSTIN Dr. VAN DYCK Dr. VAN TONGELEN		Dr. SWARTENBROUX Dr. VAN TONGELEN Dr. VAN CAUWENBERGHE	
Dr. FRANCAUX Dr. VAN DYCK Dr. VAN TONGELEN		Dr. GOUFFAUX Dr. GOUFFAUX Dr. GOUFFAUX	
J. DEGEEST Ch. SCALAIS		Th. VANHOOREN C. SCALAIS	
Dr. CORNELIS Dr. JOURET Dr. GOUFFAUX (Beltest)		Dr. CLYSTERS Dr. TERCLAVERS	
J. DURUISSEAU		J. COUMARD M. ROBERT	

III. Matières administratives :

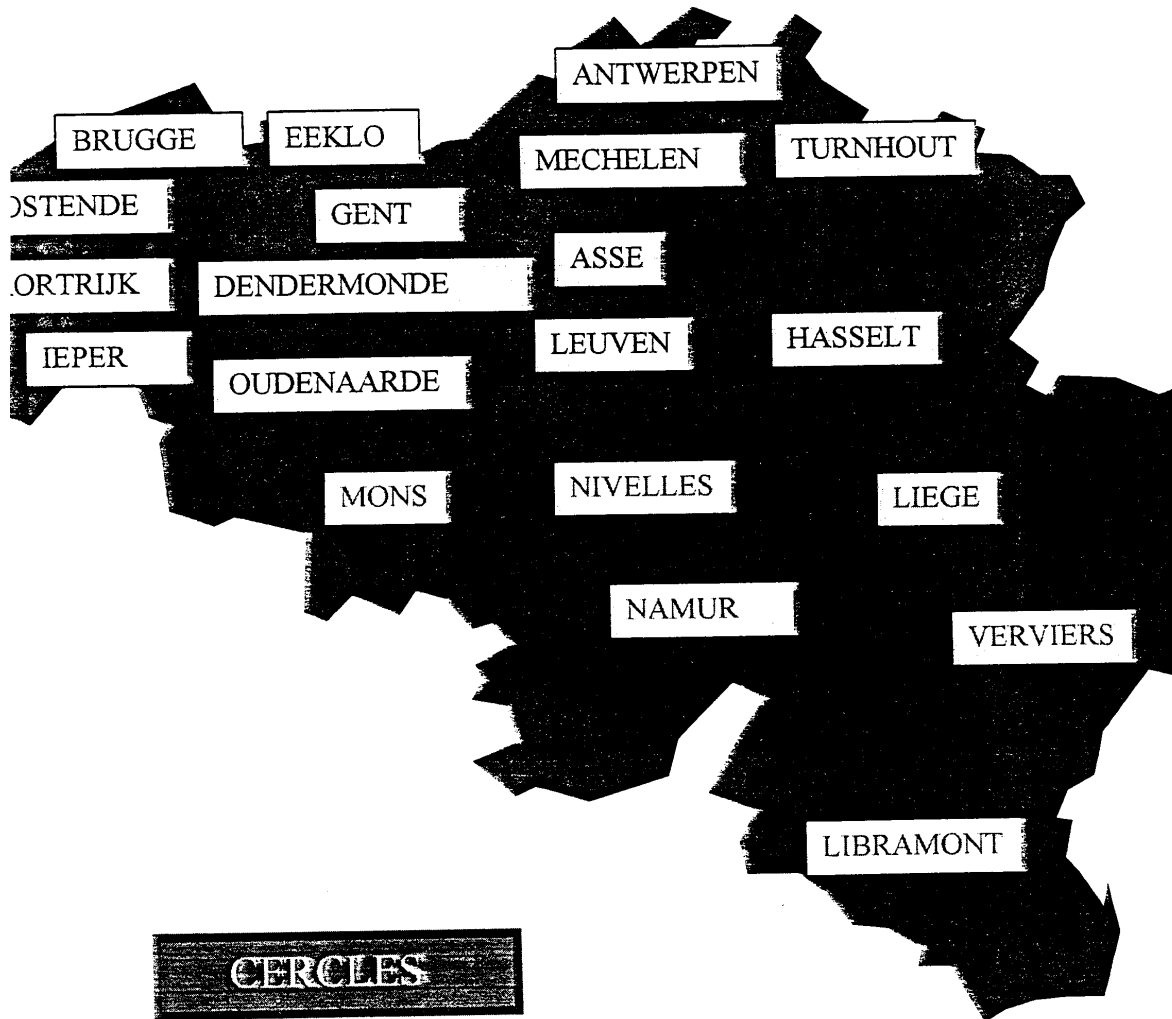
Secrétariat général et coordination : M. TERBINNEN

Traduction : A. VAES

Dactylographie : L. VAN ELSUWEGE

N. WALRAVENS

Ch. DEWIT



ANNEXE II : LABORATOIRES D'ANALYSES MICROBIOLOGIQUES

annexe 2

Ministère des Affaires sociales, de la Santé publique et
de l'Environnement



Institut d'expertise vétérinaire

Rue de la Loi, 56
B-1040 Bruxelles

Administration centrale

Le Fonctionnaire dirigeant

Bruxelles, le 30-06-1997

Rue de la Loi, 56
1040 Bruxelles
Tél. : 02/287.02.11
Fax : 02/287.02.01

Circulaire à Mesdames et Messieurs les :

- **Inspecteurs en chef-directeurs ;**
- **Inspecteurs principaux-chefs de service ;**
- **Inspecteurs-chefs de service ;**
- **Inspecteurs-experts ;**
- **Vétérinaires chargés de missions ;**
- **Contrôleurs.**

Dossier traité par : Dr Lic. M. GOUFFAUX (P 02/287.02.69)

Nos références : 34/IX/BAC/MGX/ 50651
(A rappeler dans toute correspondance).

Annexe(s) : 1.

Objet : Application de l'arrêté royal du 29 janvier 1996 relatif à l'agrément des laboratoires d'analyse des denrées alimentaires et des autres produits.

Veillez prendre connaissance ci-joint de la liste des laboratoires agréés pour les analyses microbiologiques effectuées en application des lois du 5 septembre 1952, du 15 avril 1965 et du 24 janvier 1977, à la demande de l'Institut d'expertise vétérinaire ou du propriétaire des produits.

Cette liste entre en vigueur dès réception de la présente. Elle annule et remplace celle publiée en annexe de la circulaire ministérielle de même objet, datée du 30 septembre 1996 et référencée 35/IX/BAC/MGX/MJ/41217.

Le recours aux laboratoires figurant à cette liste est obligatoire pour toutes les analyses microbiologiques demandées en application des trois lois, à l'exception toutefois de celles demandées dans le cadre de l'autocontrôle.

Le Fonctionnaire dirigeant,

Christiaan DECOSTER.

**LISTE DES LABORATOIRES DE MICROBIOLOGIE AGREES
LIJST VAN DE VOOR MICROBIOLOGIE ERKENDE LABORATORIA**

LABORATOIRE LABORATORIUM	CATEGORIES D'ANALYSES MICROBIOLOGIQUES (*) CATEGORIEËN VAN MICROBIOLOGISCHE ONTLEDINGEN (*)								
	1	2	3	4	5	6	7	8	9
C.A.R.A.H. asbl 11, Rue Pastur, 7800 ATH Tél. : 068/28.21.90 - Fax : 068/28.56.60 Ir. M. VAN KONINCKXLOO	X		X						X
C.V. MEAT-LAB 326, Ieperstraat, 8800 ROESELARE Tél. : 051/20.36.42 - Fax : 051/24.67.22 Dr. Lic. A. ROSSEEL	X		X						
CEAT-HYGANTEC NV 97, Prins Baudewijnlaan, 9100 SINT-NIKLAAS Tél. : 03/766.73.04 - Fax : 03/776.12.09 Dr. Lic. R. ABRAMS	X		X		X	X	X	X	X
CHEMIPHAR NV 4, Lieven Bauwensstraat, 8200 BRUGGE Tél. : 050/31.02.52 - Fax : 050/31.02.54 Dr. Apr. J. CORDONNIER	X		X		X		X	X	X
Dr. L. WILLEMS-INSTITUUT v.z.w. Universitaire Campus, Gebouwen A en C 3590 DIEPENBEEK Tél. : 011/26.92.11 - Fax : 011/26.93.12 Dr Lic. L. HENDRIKS	X		X		X		X	X	X
ECCA NV 24, Klaartestraat, 9052 ZWIJNAARDE Tél. : 09/222.48.43 - Fax : 09/221.72.83 Dr. F. BENIJTS	X		X		X		X	X	X
EURACETA 15, Rue le Marais, 4530 VILLERS-LE-BOUILLET Tél. : 04/259.93.20 - Fax : 04/259.73.74 Mr. L. OLIVIER	X		X						X
FEDERATION DE LUTTE CONTRE LES MALADIES DU BETAIL DU HAINAUT - CENTRE DE DEPISTAGE 2, Drève du Prophète, 7000 MONS Tél. : 065/33.82.91 - Fax : 065/35.63.28 Dr. J. DUREZ	X		X						
INSTITUT PROVINCIAL D'HYGIENE ET DE BACTERIOLOGIE DU HAINAUT 55, Boulevard Saintelette, 7000 MONS Tél. : 065/35.41.21 - Fax : 065/34.74.80 Dr. J.-P. HUBERT	X		X						X
INSTITUT SCIENTIFIQUE DE LA SANTE PUBLIQUE - LOUIS PASTEUR Section Denrées alimentaires 14, Rue Juliette Wytsman, 1050 BRUXELLES Tél. : 02/642.51.11 - Fax : 02/642.50.01 Mme. S. SREBRNIK	X	X							

* Voir légende.

* Zie verklarende tekst.

Page - Bladzijde 1/3

Version mise à jour le 08/04/97.

Versie bijgewerkt op 08/04/97.

LABORATOIRE LABORATORIUM	CATEGORIES D'ANALYSES MICROBIOLOGIQUES (*) CATEGORIEËN VAN MICROBIOLOGISCHE ONTLEDINGEN (*)								
	1	2	3	4	5	6	7	8	9
LABORATOIRE DE MICROBIOLOGIE DES DENREES ALIMENTAIRES D'ORIGINE ANIMALE Faculté de médecine vétérinaire, Université de Liège Bât. 43 bis, Sart Tilman, 4000 LIEGE Tél. : 04/366.40.15 - Fax : 04/366.40.16 Prof. Dr. H. VINDEVOGEL, Dr G. DAUBE	X		X						
LABORATOIRE INTERCOMMUNAL DE CHIMIE - IGRETEC 1, Place de l'Abattoir, 6000 CHARLEROI Tél. : 071/41.58.80 - Fax : 071/42.20.17 Ir.L. PIRMEZ	X		X	X					X
LABORATORIUM HYGIENE EN TECHNOLOGIE VAKGROEP DIERGENEESKUNDIG TOEZICHT OP EETWAREN Faculteit Diergeneeskunde, Universiteit Gent 133, Salisburylaan, 9820 MERELBEKE Tel. : 09/264.74.51 - Fax : 09/264.74.91 Prof. Dr. J. VAN HOOFF	X	X	X		X	X	X		
LARECO Zoning Industriel de Aye 6900 MARCHE-EN-FAMENNE Tél. : 084/32.16.90 - Fax : 084/31.43.31 Ir. W. DE SCHRIJVER	X		X		X		X	X	X
LOVAP 4, Kleinhoefstraat, 2440 GEEL Tel. : 014/58.55.86 - Fax : 014/58.17.06 Ir. W. DE SCHRIJVER	X		X		X		X	X	X
MEAT CONTROL NV 164, Wettersesteenweg, 9520 BAVEGEM Tel. : 09/363.80.14 - Fax : 09/362.04.62 Dr. P. HEEREMAN	X		X						
QUALITY ASSISTANCE 1, Technoparc de Thudinie, 6536 DONSTIENNES Tél. : 071/ 53.47.81 - Fax : 071/53.42.16 Mr. P. DRAUX	X		X	X	X		X	X	X
REGIE VEEMARKT LAR P 27, 8930 MENEN Tel. : 056/42.28.48 - Fax : 056/41.28.48 Dr. Lic. D. LESAGE	X		X						
RIJKSZUIVELSTATION - CENTRUM VOOR LANDBOUWKUNDIG ONDERZOEK MINISTERIE VAN MIDDENSTAND EN LANDBOUW 370, Brusselseseenweg, 9090 MELLE Tel. : 09/252.18.61 - Fax : 09/252.50.85 Dr. Ir. G. WAES	X		X		X		X	X	
SCHEIKUNDIG CENTRUM LOKEREN - BACTERIOLOGIE 95, Kazernestraat, 9160 LOKEREN Tel. : 09/348.14.50 - Fax : 09/349.40.96 B. VAN DOORSSELAERE	X		X						X
SGS AGRILAB NV Haven 407 16, Polderdijkweg, 2030 ANTWERPEN Tel. : 03/545.87.75 - Fax : 03/545.87.79 Dr. Lic. F. JANSSENS	X		X		X	X	X	X	X

* Voir légende.

* Zie verklarende tekst.

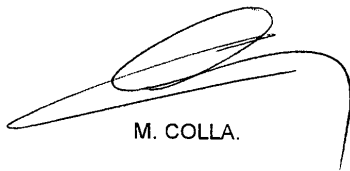
LABORATOIRE LABORATORIUM	CATEGORIES D'ANALYSES MICROBIOLOGIQUES (*) CATEGORIEËN VAN MICROBIOLOGISCHE ONTLEDINGEN (*)								
	1	2	3	4	5	6	7	8	9
STADSLABORATORIUM GENT 8, Baudelokaai, 9000 GENT Tel. : 09/225.03.89 - Fax : 09/233.27.42 Dr. Ir. E. DE MAERTELEIRE	X		X		X		X	X	X
STEDELIJK SLACHTHUIS HASSELT 15, Havenstraat, 3500 HASSELT Tel. : 011/21.10.72 - Fax : 011/23.16.70 Dr. Lic. P. NEVEN	X		X	X					
STEDELIJK SLACHTHUIS LABORATORIUM 68, Slachthuislaan, 2060 ANTWERPEN Tel. : 03/217.29.03 - Fax : 03/235.33.23 Dr. Lic. J. de BORCHGRAVE	X		X						
STEDELIJK SLACHTHUISBEDRIJF GEEL 52, Winkelom, 2440 GEEL Tel. : 014/58.03.11 - Fax : 014/58.58.47 Dr Lic. L. DAEMS	X		X						
VAKGROEP LEVENSMIDDELENTECHNOLOGIE EN VOEDING Faculteit Landbouwkundige en Toegepaste Biologische Wetenschappen, Universiteit Gent 653, Coupure Links, 9000 GENT Tel. : 09/264.61.64 - Fax : 09/225.55.10 Prof. Dr. Ir. J. DEBEVERE					X		X	X	X
WETENSCHAPPELIJK INSTITUUT VOLKSGEZONDHEID - LOUIS PASTEUR 14, Juliette Wytmanstraat, 1050 BRUSSEL Tel. : 02/642.51.11 - Fax : 02/642.50.01 Dr. P. ANDRE			X		X		X	X	

Gezien om te worden gevoegd bij de ministeriële omzendbrief van
Vu pour être annexé à la circulaire ministérielle du

26-06-1997

De Minister van Volksgezondheid
en Pensioenen,

Le Ministre de la Santé publique
et des Pensions,



M. COLLA.

* Voir légende.
* Zie verklarende tekst.

ANNEXE III : QUANTITÉS DE POISSON CAPTURÉES

Wynne 5
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BLZ/PAGE 83

MENSELIJK VERBRUIK VAN ENKELE LANDBOUWPRODUKTEN (KG)

CONSOMMATION HUMAINE DE QUELQUES PRODUITS AGRICOLES (KG)

AANWIJZING / JAAR	PLANTAARDIGE PRODUCTEN								ANNEE / DESIGNATION
	80/81	89/90	90/91	91/92	92/93	93/94	94/95	95/96	
Meel van :									Farine de :
Tarwe	70.15	69.08	69.00	69.32	70.81	70.85	70.10		Froment
Rogge	0.67	1.08	1.09	1.11	1.03	0.93	1.14		Seigle
Gerst	0.10	0.39	0.43	0.33	0.44	0.43	0.36		Orge
Haver	0.16	0.26	0.26	0.17	0.17	0.21	0.34		Avoine
Mais	1.24	1.45	1.68	1.44	1.33	1.36	1.12		Mais
Andere	—	—	—	—	—	—	—		Autres
Totaal meel	72.32	72.20	72.46	72.37	73.78	73.79	73.06		Total farine
Fabriekarjst	1.07	2.02	2.34	2.45	2.57	2.27	2.28		Riz usiné
Breukrijst	3.07	2.38	1.97	1.83	1.53	1.63	1.57		Brisures de riz
Aardappelen	101.00	90.00	96.93	99.00	100.63	99.00	95.15		Pommes de terre
Droge peulvruchten	3.12	2.45	2.70	2.80	2.72	2.69	2.67		Légumes secs
Fruit (- Citrusvruchten)	58.15	59.88	58.60	57.61	63.07	63.11	66.98		Fruits (- Agrumes)
Citrusvruchten	19.73	20.41	22.07	22.79	25.42	30.22	30.23		Agrumes
Totaal fruit	77.88	80.29	80.67	80.40	88.49	93.33	97.21		Total fruits
Gedroogde vruchten	0.83	0.76	1.27	1.27	1.20	1.56	1.52		Fruits séchés
Schaalvruchten	1.78	3.33	3.48	3.91	4.14	4.89	4.90		Fruits à coque
Groenten	73.27	90.10	93.01	103.35	98.30	110.53	109.88		Légumes
Witte suiker	34.84	40.74	40.43	40.52	40.20	40.24	42.11		Sucre blanc
Bijenhonig	0.38	0.38	0.37	0.33	0.30	0.38	0.44		Miel d'abeilles

AANWIJZING / JAAR	1980	1989	1990	1991	1992	1993	1994	1995	ANNEE / DESIGNATION
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VLEES VAN :	DIERLIJKE PRODUCTEN								VIANDE DE :
	1980	1989	1990	1991	1992	1993	1994	1995	
Runderen	24.89	18.41	16.89	18.57	17.09	Bovine
Kalveren	3.11	2.49	2.86	3.09	3.19	Veaux
Runderen / Kalveren	28.00	20.90	19.75	21.66	20.28	21.31	21.75	21.80	Bovine / Veaux
Varkens	41.17	48.76	44.63	47.99	50.38	50.76	49.50	47.36	Porcins
Schapen / Geiten	2.10	1.89	1.97	2.10	2.05	2.08	2.13	2.04	Ovins / Caprins
Paarden	3.51	2.60	2.87	2.42	2.00	1.74	1.82	1.63	Equidés
Kippen	11.30	13.44	13.72	13.83	14.20	14.36	17.89	19.37	Poulets
Ander gevogelte	1.72	2.42	2.82	3.41	3.93	3.88	3.52	3.77	Autres volailles
Konijnen / Wild	1.81	2.50	2.70	2.79	2.56	2.72	2.82	3.00	Lapins / Gibier
Totaal vlees	89.71	90.51	88.46	94.20	95.40	96.85	99.23	98.97	Total viande
Slachtafval	7.13	7.68	7.63	8.31	7.37	6.32	5.18	4.05	Abats comestibles
TOT. VLEES / AFVAL	96.84	98.19	96.09	102.51	102.77	103.17	104.41	103.02	TOT. VIANDE / ABATS
ZUIVELPRODUCTEN :									PRODUITS LAITIERS :
Volle melk	67.80	63.46	63.74	63.63	67.65	68.08	65.01	62.43	Lait entier
Afgeroomde melk	7.45	7.12	7.06	6.84	6.30	6.31	6.13	5.78	Lait écrémé
Yoghurt	4.88	8.06	7.69	8.10	9.00	9.84	11.17	11.90	Yoghourt
Melkdranken	3.35	3.33	3.42	3.22	3.18	2.67	1.85	2.53	Boissons lactées
Andere versas producten	3.65	4.84	5.23	5.85	6.68	7.43	7.51	8.42	Autres produits frais
Verbruiksroom	1.95	3.32	3.41	3.87	4.11	3.84	3.63	3.61	Crèmes de consomm.
Kondensmelk	3.18	1.48	1.28	0.85	1.17	1.08	1.30	2.09	Lait concentré
Vol melkpoeder	1.45	1.62	1.46	1.99	1.78	1.64	1.82	2.18	Poudre de lait entier
Afgeroomd melk poeder	1.42	1.57	1.68	1.47	1.63	1.38	1.30	1.03	Poudre de lait écrémé
Boter	8.55	8.17	7.89	7.97	7.18	7.01	6.67	6.22	Beurre
Kaas	10.22	13.53	14.14	14.36	14.73	15.63	14.44	14.86	Fromage
Smeltkaas	1.43	1.35	1.41	1.44	1.54	1.38	1.69	1.68	Fromage fondu
KIPPEBIJEN :	13.40	12.31	13.92	14.44	14.50	14.30	14.53	14.62	OEUFS DE POULES :

Margarine	VETSTOFFEN								Margarine
	11.35	12.51	12.15	11.91	10.66	11.81	12.82	13.12	
Tafelolie	4.24	5.95	6.70	7.04	7.21	7.32	7.33	7.78	Huile de table
Slachtvet	7.25	9.52	9.42	9.88	9.48	9.11	8.85	9.08	Graisse d'abattage
Spijsvet	4.26	5.74	5.53	4.68	5.67	5.59	5.72	6.40	Graisse alimentaire

Vis	VIS / SCHAAL EN WEEKDIJREN								Poisson
	6.19	6.42	6.68	6.49	6.37	6.28	6.63	7.16	
Schaal / Weekdieren	2.00	2.29	2.33	1.95	2.15	1.93	2.34	2.41	Crustacés / Mollusques

Mineraalwater / Limonade	DRANKEN (liter)								Eau minérale / Limonade
	112.71	162.35	177.41	173.89	188.56	180.85	197.70	203.04	
Bier	133.61	116.62	122.09	112.64	113.41	113.29	109.36	108.51	Bière
Wijn en vermout	19.70	21.69	23.28	22.69	23.70	23.73	24.54	22.01	Vin et vermouth
Alcohol aan 50.	5.16	2.80	2.73	2.72	2.74	2.90	2.68	2.78	Alcool à 50.

BRON : I.E.I.

SOURCE : I.E.A.

B.L.E.U. - BEVOORRADINGSBALANSEN (in ton)

BILANS D'APPROVISIONNEMENT U.E.B.L. (en tonnes)

AANWIJZING / JAAR	1980	1989	1990	1991	1992	1993	1994	1995	ANNEE / DESIGNATION
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ZEEVIS

POISSON DE MER

+ BELGISCHE VANGST (1)	28158	26909	28047	26311	22015	20318	18848	17972	+ PECHE BELGE (1)
waarvan :									dont :
Haringsoorten	2475	438	144	159	164	72	87	11	Sortes de hareng
Rondvissen	14098	8467	7248	5615	5437	4856	4337	4998	Poissons ronds
Platvissen	9111	15784	18663	18737	14494	13557	12631	11207	Poissons plats
Bodemvissen	2474	2220	1992	1800	1920	1833	1793	1756	Poissons de fond
+ Beginvorraad	+ Stock de début
- Eindvoorraad	- Stock final
- Uitvoer	19246	28105	32077	30063	25744	25126	31771	28252	- Exportations
+ Invoer	83829	92638	98957	93864	93772	94551	109450	114292	+ Importations
= BESCHIKBAAR	92541	91442	94927	90112	90043	89743	96527	106012	= DISPONIBLE

ZOETWATERVIS

POISSON D'EAU DOUCE

+ B.L.E.U. VANGST (2)	1500	1500	1500	1500	1500	1500	1500	1500	+ PECHE U.E.B.L. (2)
+ Beginvorraad	+ Stock de début
- Eindvoorraad	- Stock final
- Uitvoer	1694	3651	3800	4426	4500	4944	5803	4730	- Exportations
+ Invoer	10998	19481	20919	23748	22403	22011	22371	20975	+ Importations
= BESCHIKBAAR	10804	17330	18619	20822	19403	18567	18068	17745	= DISPONIBLE

TOTAALBALANS - VIS

BILAN TOTAL - POISSON

+ B.L.E.U. VANGST (A)	29658	28409	29547	27811	23515	21818	20348	19472	+ PECHE U.E.B.L. (A)
+ Beginvorraad	+ Stock de début
- Eindvoorraad	- Stock final
- Uitvoer	20940	31756	35877	34489	30244	30070	37574	30982	- Exportations
+ Invoer	94627	112119	119876	117612	116175	116562	131821	135267	+ Importations
= BESCHIKBAAR (B)	103345	108772	113546	110934	109446	108310	114595	123757	= DISPONIBLE (B)
- Industrie									- Industrie
- Veevoeding	40028	42546	44451	43613	42947	42457	44811	48270	- Aliments pour bétail
- Verliezen									- Pertes
= MENSELIJKE VOEDING (3)	63317	66226	69095	67321	66499	65653	69784	75487	= CONSOMM. HUMAINE (3)
Idem Kg/Inwoner	6.19	6.42	6.68	6.49	6.37	6.28	6.63	7.18	Idem Kg/Habitant
(%) ZELFVOORZIENING (A/B)	28.70	26.12	26.02	25.07	21.49	20.14	17.76	15.73	(%) AUTO-APPROVISION. (A/B)

SCHAAL - EN WEEKDIEREN

CRUSTACES ET MOLLUSQUES

+ BELGISCHE VANGST (1) (A)	2444	2346	2139	1555	1738	1801	1835	1948	+ PECHE BELGE (1) (A)
+ Beginvorraad	+ Stock de début
- Eindvoorraad	- Stock final
- Uitvoer	4153	16208	16232	15584	15888	22013	31709	23981	- Exportations
+ Invoer	47239	66403	67630	58987	63708	65183	84588	78480	+ Importations
= BESCHIKBAAR (B)	45530	52541	53537	44958	49758	44971	54714	56447	= DISPONIBLE (B)
- Verliezen	25042	28898	29445	24727	27367	24734	30093	31045	- Pertes
= MENSELIJKE VOEDING (3)	20488	23643	24092	20231	22391	20237	24621	25402	= CONSOMM. HUMAINE (3)
Idem Kg/Inwoner	2.00	2.29	2.33	1.95	2.15	1.93	2.34	2.41	Idem Kg/Habitant
(%) ZELFVOORZIENING (A/B)	5.37	4.47	4.00	3.46	3.49	4.00	3.35	3.45	(%) AUTO-APPROVISION. (A/B)

(1) B.L.E.U. cijfers uitgedrukt in gelost gewicht.
 (2) Raming.
 (3) Uitgedrukt in verbruiksgewicht.

(1) Chiffres U.E.B.L. exprimés en poids débarqué.
 (2) Estimation.
 (3) Exprimé en poids comestible

BRONNEN : N.I.S. EN L.E.I.

SOURCES : I.N.S. ET I.E.A.

FINLAND

SEAFOOD INSPECTION IN FINLAND

I. Competent Authorities and Organisational Structure

a) Human Resources

In the Ministry of Agriculture and Forestry, Veterinary and Food Department there are four veterinarians, two temporary veterinarians and two lawyers dealing with foodstuffs of animal origin and medication of animals. Out of these four, one veterinarian and one lawyer deal with fish and fishery products. The National Veterinary and Food Research Institute has thirty employees in its Department of Food Hygiene. Out of these three to four work on fish inspection. In six Provincial State Offices there are 13 veterinary officers in all and one to two environmental health officers. There are 256 municipal authority units, in which the municipal or the joint municipal board has the responsibility of food control. The responsible officer in such a unit is usually a veterinarian. The municipal laboratories, 54 in all, are also supervised by a veterinarian in most cases.

b) Legislation

The Act of Food Hygiene of Foodstuffs of Animal Origin (1195/1996) stands for the legal base on the control of fish and fishery products. Additional legislation includes:

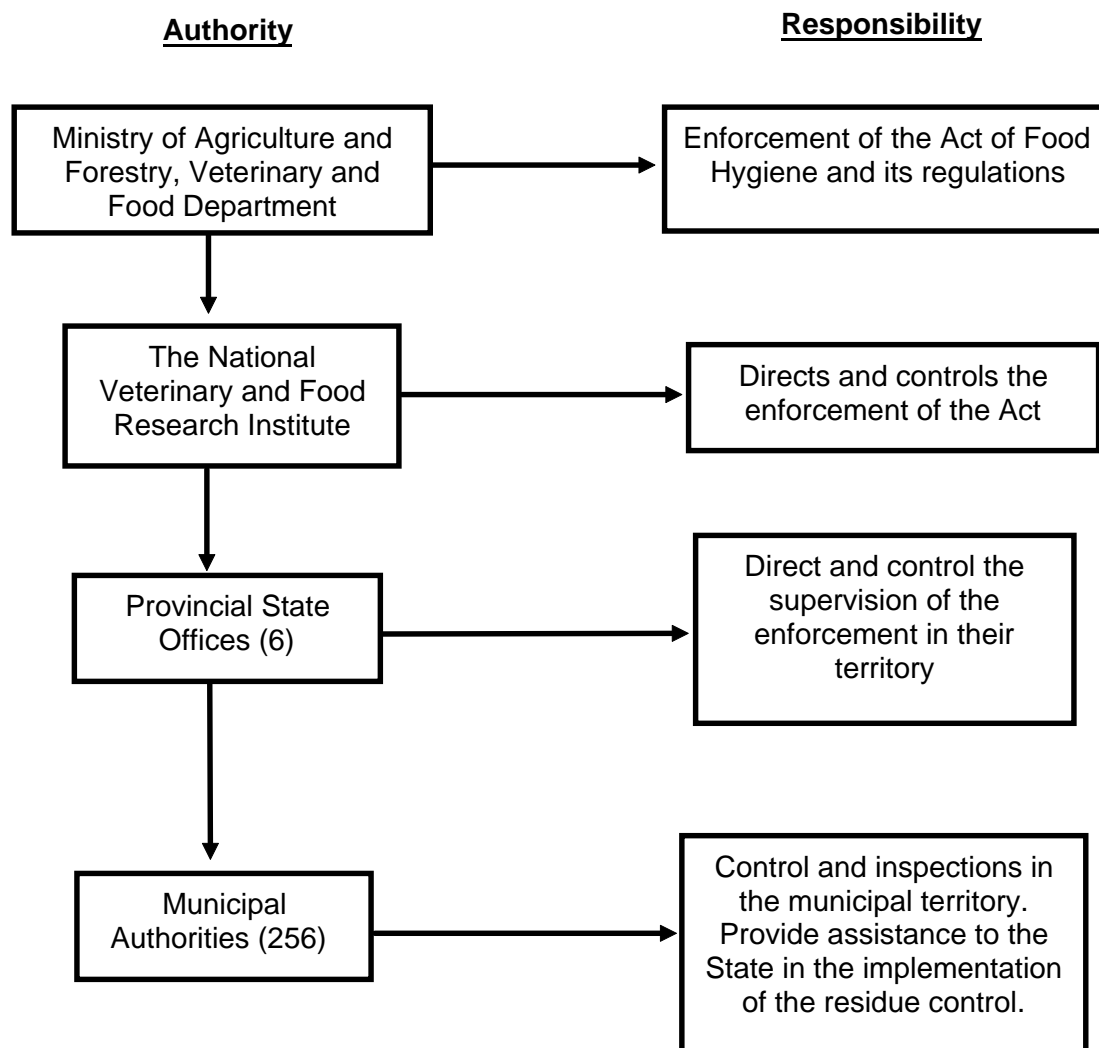
- Act of Infectious Diseases (583/1986) and the Act on Health Protection (763/1994) which specifies requirements concerning the health of the personnel engaged in the handling of foodstuffs of animal origin at the plants, on fishing vessels and production farms;
- Act of Medicating Animals (617/1997) which controls the medication of farmed fish;
- Act of Veterinary Border Inspections (1192/1996) which prescribes the veterinary border inspections and the regulations concerning imports to the European Community from third countries.

More detailed provisions are given in the decisions of Ministry of Agriculture and Forestry. The purpose of the Act of Food Hygiene is to guarantee the safety of the foodstuffs of animal origin. The requirements of the check systems and “own-check” systems are set in the law and the decisions based on it.

c) Organisation

Finland has a four-level administrative model in food safety control. This is summarised in Figure 1.

Figure 1: Organisation of Finland’s Food Safety Control



d) Laboratories

The National Veterinary and Food Research Institute has Central Laboratory in Helsinki and three regional laboratories. The Department of Chemistry and the Department of Food Microbiology take care of the analyses and research of food of animal origin. Besides the Institute serves as a national and international reference laboratory. Most routine analyses are carried out by the municipal food control laboratories. These laboratories are approved and registered by the Institute. The establishments have some laboratories of their own, which are also approved by the Institute.

Use of Third Parties' Inspection Bodies

The Third Parties' Inspection Bodies are not used.

Training

The National Veterinary and Food Research Institute arranges several seminars and courses every year for the food inspectors. In addition, the employees of the Institute give lectures at a large number of occasions arranged by other authorities and organisations. Provincial State Offices arrange training for municipal officers within their territory.

II. Inspection and Control Systems

a) Use of Systematic Inspection Approaches

The inspection and control systems for fish and fishery products are the same whether they are used in domestic consumption or for export. The establishment where fish or fishery products are handled, processed, wrapped, re-wrapped, packed or stored has to carry out an "own-check" system at its own expense. The system must be based on good manufacturing practice (GMP) and good hygiene practice (GHP) and adopt the Hazard Analysis and Critical Control Point (HACCP) principles. The Ministry of Agriculture and Forestry determined the performance and contents of the own-check systems". Where the "own-check" system is properly implemented, there should be the possibility of reducing the official checks. However, the official checks will continue to be necessary.

b) Import Requirements

The control and inspection of foodstuffs of animal origin delivered to Finland from other EU Member States takes place in all the units that first receive the foodstuffs concerned. The control is mainly based on the "own-check" systems of the establishments. The import from third countries is allowed from establishments approved for importing to the European Community. In addition there are some bilateral agreements (e.g., with USA and Estonia).

III. Establishment of Criteria for Determining Equivalency

Imports from outside the European Community is possible for countries approved by the European Community. In addition, the importing establishments in these countries must be approved by the EC or by Finnish authorities. Some delegations have been sent to Estonia to inspect the activities in establishments, especially production conditions, safety and hygiene.

IV. Audit and Verification Methods

The National Veterinary and Food Research Institute audits the municipal authorities and the establishments to check the implementation of legislation.

V. Seafood Production and Utilisation in Finland

In Finland there are a large of small landing places on the coast and inland. In 1996, the estimated number of landing places was 309. On the coast there were 65 fishing posts, 24 of these were of major importance. On interior lakes, there were 41 fishing posts of which 15 were significant.

Out of establishments dealing with fish and fishery products:

- 45 percent have an annual capacity less than 50 tonnes;
- 18 percent have an annual capacity of 50—100 tonnes
- 32 percent have annual capacity of 100—1 000 tonnes.
- 5 percent of establishments have an annual capacity of over 1 000 tonnes.

Total production of farmed fish is 17 000—18 000 tonnes each year. The total harvest of from harvest fisheries is about 44 700 tonnes per year, with interior lakes about 4 600 tonnes each year. The most common fish caught at the sea is Baltic herring, about 70 percent of the catches go to animal feed. In interior lakes the most important species of fish are vendace and powan. Export of farmed fish is about 1 300 tonnes per year and export of harvest fisheries about 11 900 tonnes. About 12 300 tonnes of fish and fishery products are imported from Member States of the European Union and about 22 400 tonnes from countries outside the Union. Thus the domestic consumption of fish and fishery products is about 83 000 tonnes annually and per capita consumption about 16 kg annually.

GERMANY

FISH INSPECTION SYSTEMS IN THE FEDERAL REPUBLIC OF GERMANY

I. Description of Competent Authorities and Organisational Structure

a) *Human Resources*

- Veterinarians (Approbated, often promoted veterinary surgeons having undergone additional special training ending with an examination to fulfil the requirements of the State Veterinary Service or belonging to the staff of veterinary analytical investigation offices).
- Food Inspectors who assist Veterinarians (e.g. sampling, writing reports after joint visits to plants).
- Chemists (in Veterinary and/or chemical analytical investigation offices).

b) *Legislation*

As a Member of the European Union, Germany is bound by EU law. Therefore the national legislation, in principle, transposes EU legislation. Decisions of the European Commission are recommendations unless they are transposed into German national law or made officially known by the Federal Health Ministry.

EC- Legislation

- Directive 91/492/EEC: Live bivalve molluscs
- Directive 91/493/EEC: Fishery products, as modified by Directive 95/71/EC
- Directive 92/48/EEC: Fishing vessels - Freezer vessels
- Decision 93/25/EEC: Heat treatment - bivalve molluscs and gastropods
- Decision 93/51/EEC: Microbiological criteria - crustaceans and shellfish
- Decision 93/140/EEC: Parasites

- Decision 93/351/EEC: Mercury
- Decision 93/383/EEC: Biotoxines - Laboratory
- Decision 94/356/EEC: HACCP (Hazard Analysis and Critical Control Point)
- Decision 95/149/EC: TVBN (Total Volatile Basic Nitrogen)
- Decision 95/328/EC: Health Certificates - Fishery products
- Decision 96/333/EC: Health Certificate - live bivalve molluscs
- Decisions concerning imports of fishery products from certain countries are numerous and are constantly changing due to inspection results or the disease situation (e.g. Cholera)

National Legislation

- Fish Hygiene Regulation (Fischhygiene-Verordnung)
- Food and Commodity Law (Lebensmittel- und Bedarfsgegenständegesetz)
- Official publication of the EC-Decision on HACCP in fishery product plants

The Fish Hygiene Regulation is made under the powers of Food and Commodity Law. The Regulation transposes all three EC directives covering fish and seafood: 91/492/EEC (Live bivalve molluscs), 91/493/EEC (Fishery products) and 92/48/EEC (Fishing vessels - Freezer vessels) into national legislation. The Fish Hygiene Regulation also covers several EC decisions: Decision 93/51/EEC (Microbiological criteria - crustaceans and shellfish), Decision 93/25/EEC (Heat treatment - bivalve molluscs and gastropods) and Decision 93/140/EEC (Parasites). The Regulation also covers several other EC decisions relating to exemptions and certificates. Decision 94/356/EEC (HACCP) has been transposed into by official publication by the Federal Health Ministry, while the contents of other decisions are covered by various national regulations dealing with food in general (e.g., the Regulation limiting harmful substances in food (Schadstoff-Höchstmengen-Verordnung) which limits also the mercury content in fish).

c) Organisation

Germany is a Federal Republic consisting of 16 Laender which are bound by federal laws and regulations. Laender are, however, independent in determining the means of carrying out and enforcing those laws. Federalism and the subsidiary principle are unchangeably rooted in the Grundgesetz (constitution). Law enforcement competencies of the Federal Government are constitutionally restricted to Foreign Affairs and National Defence.

Central Competent Authority

The Central Competent Authority (CCA) is the Federal Health Ministry (BMG) in Bonn. Its responsibilities are to:

- prepare national legislation, especially transposition of EU directives into national legislation;
- Co-ordinate of interpretation of food hygiene legislation within Germany;
- Represent the Federal Republic of Germany at the EU level in Brussels (Foreign Policy); but
- it does not directly supervise, technically or administratively, the Laender in relation to food legislation enforcement!

Competent Authority

The Competent Authorities (CA) are the Ministries of the Laender. These CAs are usually Ministries in charge of Agriculture, Rural Areas, Nutrition, Environment, Social Affairs or Health. Their responsibilities are to:

- execute food legislation and enforce it in the respective land;
- delegate of responsibilities to subordinate administrative bodies (e.g. in some Laender this is the responsibility of approving plants)
- to provide technical supervision of subordinate administrative bodies

In most Laender, however, there is no administrative supervision of subordinate bodies

Regional Competent Authority

The Regional Competent Authorities (RAs) are the Regional District Governments. Regional District Governments do not exist in all the Laender. The RAs responsibilities are to:

- approve of food processing establishments; and
- provide technical supervision of subordinate county veterinarians.

In most Laender there is no administrative supervision of county veterinarians.

Local Competent Authority

The Local Competent Authority is the Veterinary Office of the county. The Veterinary Office is responsible for:

- food law enforcement;
- inspection service (hygiene inspections); and
- training of inspection personnel (veterinarians, food inspectors).

d) Laboratories

State Laboratories

- Federal Laboratories (run by scientifically qualified staff):
 - National Reference Laboratory for Marine Biotoxins at the Federal Institute for Consumer Health Protection and Veterinary Medicine.
- Laender Laboratories:
 - Veterinary / Chemical Investigation Offices (run by scientifically qualified staff).

The State laboratories are responsible for:

- Analytical investigation of food and food-related hygiene (microbiological, chemical, physical and sensory investigations);
- Sampling at the plant in some Laender (in others sampling on the spot is carried out by the Official Veterinary Surgeon (amtlicher Tierarzt);
- Transposition of national residue testing plans; and
- Food monitoring investigations.

Private Laboratories

- Authorised Plant Laboratories
 - Responsible for “own checks” of companies.
- Accredited Private Laboratories
 - Responsible for analysis of samples on behalf of the company within the “own checks” system

e) Use of Third Parties' Inspection Bodies

This is not provided for in the legal framework. Companies are free to use the services of consultant firms to establish their own controls. This is frequently done, especially regarding use of the HACCP systems or quality management programs.

f) Training

Veterinary Staff

Veterinary Offices

Veterinary staff working in Veterinary Offices are required to have:

- five years of university study of veterinary medicine including a final examination (state examination);
- approbation by government body and enlisting in veterinary register (veterinary chamber);
- promotion (in former days required, nowadays optional);
- additional government training course including another final examination (examination for state veterinary service);

Information on changes in, and interpretation of, legislation are forwarded down the veterinary hierarchy to the Veterinary offices in regular intervals and whenever necessary.

Every veterinary surgeon is obliged, by approbation order and veterinary chamber statutes, to keep educating themselves of new developments. Surgeons may demonstrate their compliance with this requirements by joining federal veterinary chamber bodies like Academy for Veterinary Continuous Education (Akademie für tierärztliche Fortbildung (ATF)). This Academy officially recognises the education potential in seminars, meetings, congresses and similar events in all fields of veterinary practice and veterinary service and it certifies participation by surgeons.

Veterinary Investigation Centres:

Veterinary staff working in Veterinary Investigation Centres are required to have:

- five years of University study of veterinary medicine including a final examination (state examination);
- approbation by government body; and
- promotion (in former days required, nowadays optional)

Food Inspectors

The general requirements for food inspectors are laid down in the Food Inspectors Regulation (Lebensmittelkontrolleur-Verordnung). Specification of training courses, final examination and re-training are under the responsibility of the Laender. A food inspector must have:

- successfully completed schooling in a main school;

- successfully completed job training, or at least two years of working experience in a food related job, police administration service or general administration job;
- 24 months of successful training in a food hygiene course (including a final examination); and
- participated in a re-training course at least every 3 years.

II. Description of Inspection and Control Systems

a) Use of Systematic Approaches

- for domestic consumption
- for export

Within the Common Market there is, in principle, no differentiation between domestic consumption and trade between Member States. All fishery product establishments at the processing and trading level, including factory vessels, have to be approved and meet the requirements of the EU Directives (as transposed in the Fish Hygiene Regulation). Exemptions are made for re-wrapping and re-packaging centres which need only be registered by the competent authority as they are not expressly covered by the EU Directives.

HACCP is mandatory in all approved fishery product plants. This concept has been introduced EU-wide by Directive 91/493/EEC, described by Decision 94/356/EEC, and transposed into national legislation. Included are parasite checks, microbiological checks of rooms, equipment, devices and products of all production stages, checks of the Histamin content, on TVBN or heavy metals. Special attention is given to the detection of nematodes which are checked for by candling or digestive methods.

Implementation of a valid and reliable HACCP system, that is adapted to the individual situation of an establishment, is often a painful and time-taking process. This process is underway in most establishments.

The implementation of ISO 9000 Quality Management Systems is voluntary. ISO certification is increasingly implemented by plants to standardise production processes and output quality, and to meet requirements of their customers. ISO certified companies have usually integrated the HACCP concept into their overall quality control concept and can provide an impressive amount of documentation.

In accordance with Directive 91/493/EC, the German Fish Hygiene Regulation does not apply for fish and fishery products:

- at the retail sales level; or
- for direct marketing on local markets of small quantities by fishermen to retailers or consumers.

Retail establishments and direct marketing are covered by the Food Hygiene Regulation (Lebensmittelhygiene-Verordnung). This transposes the requirements of Directive 93/43/EEC (Hygiene

of Foodstuffs). From August 1998, the Regulation will include the requirement for “own checks” in all establishments, in accordance with the principles of HACCP.

Establishments are only approved if they meet the requirements of the Directives as transposed in the Fish Hygiene Regulation. The results of the HACCP and integrated hygiene checks of the establishment, the general and specific hygiene in the establishment and the overall meeting of legal requirements have to be supervised by the veterinary service, which may be assisted by Food Inspectors. In case of non-compliance, injunctions are handed out and the establishment may be fined according to the nature and severity of the shortcoming. The establishment then has to mend the deficiencies or risk suspension of approval.

Additional requirements brought forward by third countries may have to be followed by exporting establishments in order to be allowed to market their products in the respective third country.

b) *Mandatory vs. Voluntary*

The implementation of the HACCP is mandatory in all approved fishery product plants. The concept has been introduced EU-wide by Directive 91/493/EEC, described by Decision 94/356/EEC, and has been transposed by national legislation.

The implementation of ISO 9000 Quality Management Systems is voluntary. ISO certification is increasingly implemented by German fish processing establishments to standardise production processes and output quality, and to meet requirements of their customers. ISO certified companies have usually integrated the HACCP concept into their overall quality control concept.

c) *Import requirements*

Provisions applied to imports of fishery products from third countries are laid down in the aforementioned directives. Import conditions are fixed by the Community taking into account the health situation in the exporting country, the hygienic conditions for production and storage of the products and the result of on-the-spot inspections. In general, conditions in exporting third countries shall be at least equivalent to those governing the production and placing on the market of Community products. There are three different ways to achieve this goal.

1. Listing of countries. For imports into the Common Market, fishery product establishments of the exporting countries have to be approved by their national competent authorities, have to meet the specific import conditions fixed for the country and must be efficiently monitored by national official inspection services. Third countries which are in a position to guarantee fulfilment of these requirements are listed by the European Commission and are free to import into all Member States of the European Communities, including Germany.
2. Listing of establishments. Where a third country is unable to provide the guarantees specified above in (1), imports may be authorised direct from an establishment or factory vessel of this country, provided that the establishment or factory vessel in question has received special approval following an inspection by experts from the Community and Member States.

3. Responsibility of Member States. Until the import conditions for a third country are fixed by the Community it is up to the Member States to ensure equivalency of the imports from a third country with the production and placing on the market of Community products.

Consignments of fishery products or live bivalve molluscs from third countries which are not covered by a specific decision of the Commission have to be accompanied by a health certificate issued in accordance with standards laid down by the Decision 95/328/EC (Health Certificates - Fishery products) and Decision 96/333/EC (Health Certificate - live bivalve molluscs) respectively.

All imported products are subject to inspection at the border inspection post at their point of entrance into the Common Market. This inspection includes:

- visual inspections;
- temperature checks
- checks for parasites
- laboratory investigations like tests for TVBN, Histamin and Algae toxins;
- tests for residues and other harmful substances; and
- microbiological checks (which are carried out following orders of the competent authority).

III. Establishment of Criteria for Determining Equivalency

Establishment of such criteria is up to the discretion of European Commission, in co-ordination with the Member States. The Member States would be bound to the resulting decisions.

IV. Audit and Verification Methods

Auditing methods are in the process of being developed by the European Commission for their inspections in Member States. These methods may be adopted by Member States.

In Germany the Veterinary Services of the Laender are also trying to develop a **standardised** system of supervision procedures including frequency of visits to plants and requested documentation. The system will include checking the presented documents on “own checks” in plants including HACCP. The system will also include carrying out official checks in the processing areas to verify the plant's results. Official checks include visual hygiene inspections as well as microbiological checks to verify the efficiency of the cleaning and disinfection checks of the plant and the condition of the product.

ANNEX I: CITED NATIONAL LEGISLATION

Food and Commodity Law: Gesetz über den Verkehr mit Lebensmitteln, Tabakerzeugnissen, kosmetischen Mitteln und sonstigen Bedarfsgegenständen (Lebensmittel- und Bedarfsgegenständegesetz, LMBG) published version of 8 July 1993, as amended (BGBl. I S. 1169, BGBl. I S. 3538)

Fish Hygiene Regulation: Verordnung über die hygienischen Anforderungen an Fischereierzeugnisse und lebende Muscheln (Fischhygiene-Verordnung - FischHV) of 31 March 1994 (BGBl. I S. 737) as amended on 15 December 1995 (BGBl. I S. 1779)

Official publication of the EC Decision on HACCP: Bekanntmachung über die Entscheidung 94/356/EG der Kommission vom 20. Mai 1994 mit Durchführungsvorschriften zu der Richtlinie 91/493/EWG betreffend die Eigenkontrollen bei Fischereierzeugnissen (ABl. EG Nr. L 156 S. 50) as of 26 September 1994 (Bundesanzeiger Nr. 196, 15.10.1994)

Food Inspectors Regulation: Verordnung über die fachlichen Anforderungen an die in der Lebensmittelüberwachung tätigen, nicht wissenschaftlich ausgebildeten Personen (Lebensmittelkontrolleur-Verordnung) of 16 June 1977(BGBl I S. 1002) as amended

ANNEX II: REGISTERED FISHERY PRODUCT ESTABLISHMENTS IN GERMANY

Table 1: Number of approved or registered fishery product establishments in Germany

(As at 10 July 1997)

Federal Land	EFB*	EFG*	EFS*	EMR ²	EMV ²	EFU ³	Gesamt
Baden-Württemberg	26	0	0	0	0	14	40
Bayern	12	5	0	0	1	6	24
Berlin	7	0	0	0	0	8	15
Brandenburg	0	0	0	0	0	0	0
Bremen	50	1	1	0	0	11	63
Hamburg	41	1	0	0	0	6	48
Hessen	13	0	0	0	0	9	22
Mecklenburg-Vorpommern	16	0	7	0	0	3	26
Niedersachsen	61	1	3	0	1	15	81
Nordrhein-Westfalen	31	25	0	0	3	57	116
Rheinland-Pfalz	6	0	0	0	0	0	6
Saarland	3	0	0	0	0	2	5
Sachsen-Anhalt	3	0	0	0	0	0	3
Sachsen	8	2	0	0	0	1	11
Schleswig-Holstein	60	3	0	1	6	5	75
Thüringen	3	0	0	0	1	1	4
Gesamt	340	38	11	1	12	138	540

Note: some establishments are approved in more than one category

- EFB* = Fish processing establishments
- EFG* = Auction and whole sale markets
- EFG* = Factory vessels
- EMR² = Purification Centres for live bivalve molluscs
- EMV² = Dispatch Centres for live bivalve molluscs
- EFU³ = registered re-packaging establishments

* approved according to the fishery products directive (91/493/EWG),

² approved according to the live bivalve molluscs directive (91/492/EWG)

³ registered according to the German Fish Hygiene Regulation

ANNEX III: OVERVIEW OF THE GERMAN FISHERY SECTOR

About 44 000 people are employed in the German fishery sector. In 1996 the recorded turnover was almost DM 12 billion. The main area of sales turnover in of German fisheries doe not take place in fish production, but in the processing sector and trade.

The German fishing fleet consists of 14 vessels for deep-sea trawler fisheries and 2 310 vessels for cutter and coastal fisheries. The total tonnage of the fleet is about 70 100 GT. The fleet of deep-sea trawler fisheries includes, apart from traditional deep-sea fishing with seven freezers and a fresh fish trawler, two small trawlers and four special vessels for fishing shoaling pelagics (herring and mackerel). The cutter and coastal vessels include 270 shrimp cutters, 410 other types of fish cutters and 1 670 mostly open fishing boats for bottom-set and gillnet and pound net fisheries. In addition, there are 17 special vessels for mussel fisheries.

The volume of catches of German sea fisheries in 1996 amounted to about 251 000 yielding sales proceeds to the amount of about DM 316 million (market price). 80 percent of the total catch is taken from the North and Baltic Seas and the waters to the west of Britain. The largest contribution to producer proceeds was from the catches of shrimps and crabs, cod, mussels, herring, mackerel and saithe. Inland fisheries produced a volume of about 45 000 tonnes of fish for consumption. In terms of value this volume worth DM 210 million corresponded to about two thirds of sales of sea fisheries. With catches of almost 25 000 tonnes, trout farming exceeded carp production as the most important branch of German inland fisheries.

Germany depends on extensive imports both for sea fish and freshwater fish. About 85 per cent of the consumption of fish and fish products, amounting to about 1 240 000 tonnes of catch weight, is covered by imports. In 1996, imports of fish products amounted to about 1 640 000 tonnes of catch weight worth about DM 3.5 billion. Exports amounted to about 693 000 tonnes of catch weight worth about DM 1.2 billion.

The per capita consumption of fish products in Germany is about 14-15 kg. There is particular demand on the German market for sea fish in all presentations, which accounts for about three quarters of total consumption. The remaining quarter is shared by fresh water fish, as well as crustaceans and molluscs. The largest market shares on the German market is assumed by herring and pollack, followed by tuna, cod and redfish. More than half of all fish products are sold in the form of canned products, marinades or as deep-frozen products. Fresh fish takes a 15 percent share of total consumption.

GRÈCE

SYSTÈMES DE CONTRÔLE SANITAIRE EN GRÈCE

L'autorité compétente pour le contrôle officiel des produits de la pêche en Grèce est la Direction Vétérinaire de la Santé Publique de la Direction Générale Vétérinaire du Ministère de l'agriculture ainsi que les services vétérinaires départementaux.

Au niveau du Ministère de la Direction Vétérinaire de la Santé Publique, on trouve la section du lait, des produits laitiers, des produits de la pêche et d'autres aliments. Quatre personnes y sont en charge, dont deux s'occupent exclusivement des produits de la pêche.

La section prend soin de la rédaction des actes législatifs et administratifs nécessaires, de leur harmonisation avec le droit communautaire dans le but de protéger le consommateur du point de vue de l'hygiène des produits de la pêche.

Elle arrête les règles de contrôle sanitaire et s'occupe de leur application depuis la pêche jusqu'au consommateur final.

Elle veille à l'organisation, la surveillance et la coordination de l'application du contrôle sanitaire et technologique, à l'identification des espèces des produits de la pêche à l'importation, l'exportation, la production, la circulation, la conservation, la transformation et la commercialisation.

Elle fixe les conditions et les prescriptions qui doivent être faites du point de vue sanitaire et technologique par les navires, les marchés de vente en gros, les installations de préparation, de conservation, de transformation, les lieux de vente des produits ainsi que les centres d'expédition et de nettoyage des mollusques bivalves.

Elle prend les mesures sanitaires pour améliorer et développer le transfert, l'emballage, la conservation, la standardisation des produits de la pêche en collaboration avec les services coresponsables et les producteurs.

Elle octroie les numéros officiels d'approbation des unités de traitement et de transformation des produits halieutiques.

Elle fixe les formats et les prescriptions microbiologiques, histologiques, biochimiques, biologiques et physicochimiques pour le contrôle de l'hygiène et de la qualité des produits.

Elle participe à la Communauté européenne et aux organismes internationaux afin de faire face aux problèmes de compétence de la section.

Au niveau préfectoral (NOMOS)

Au niveau préfectoral dans chaque direction vétérinaire, il y a une section vétérinaire correspondant à la Direction de la santé publique centrale qui est chargée du contrôle de l'ensemble des produits d'origine animale et qui prend soin de contrôler et d'appliquer la législation vétérinaire arrêtée par le service central.

Elle est aussi chargée de l'approbation d'autorisation d'installation et de fonctionnement des établissements de traitement et de la transformation des produits halieutiques.

Les vétérinaires qui s'occupent du contrôle des denrées alimentaires d'origine animale et des produits de la pêche sont au nombre de 500. Ils doivent avoir obtenu le diplôme de fin d'études vétérinaires délivré par la Faculté des sciences vétérinaires. Seul un petit nombre de vétérinaires est spécialisé.

Le contrôle des produits halieutiques nationaux s'effectue auprès des installations de préparation, de transformation, de congélation, d'emballage et d'entreposage ainsi qu'aux criées, aux marchés de commerce en gros (vente) et dans les bateaux de pêche.

Le contrôle des produits halieutiques provenant des pays membres de l'Union européenne est effectué par échantillonnage dans les entrepôts de destination, tandis que les produits en provenance des pays tiers sont contrôlés aux postes frontaliers de contrôle vétérinaire.

Tous les produits de la pêche de production locale ou non sont soumis également à l'inspection par les services vétérinaires dans les magasins des détaillants.

La mise en œuvre du HACCP aux entreprises est obligatoire comme prévu par la décision communautaire 94/356/CE. Les vétérinaires officiels du service procèdent au contrôle de la perfection des systèmes HACCP et de leur mise en œuvre correcte par les entreprises.

La législation régissant le contrôle sanitaire provient de l'ex-CEE (Directives 91/492/CEE et 92/493/CEE) et est adaptée au droit national. En ce qui concerne le commerce de détail, il est régi par la législation nationale (Décrets présidentiels 786/1978 et 290/1992).

THE NETHERLANDS

SEAFOOD INSPECTION IN THE NETHERLANDS

I. Description of Competent Authorities and Organisational Structure

As an EU Member State the Netherlands has implemented the EU legislation on the field of production and inspection of seafood.

a) Legislation

EU legislation

The relevant EU Directives and Decisions are as follows:

- EU Directive 91/492 (and modification): laying down the health conditions for the production and the placing on the market of live bivalve molluscs;
- EU Directive 91/493 (and modification 95/71): laying down the health conditions for the production and the placing on the market of fishery products;
- EU Directive: 92/48 : health requirements for fishing vessels;
- Decision 94/356: requirements for own checks, Hazard Analysis and Critical Control Point (HACCP);
- Decision 93/25 (modification 97/275): heat treatment- bivalve molluscs and gastropods;
- Decision 93/51: microbiological criteria for cooked crustaceans and shellfish;
- Decision 93/140: parasites;
- Decision 93/383: biotoxines-laboratory;
- Decision 95/149: TVB-N; and
- EU Directive 93/43 on hygiene: for retail sale

Imports from Third Countries

The relevant EU decisions for imports from third countries are as follows:

- Decision 95/328 (modification 97/588): health certificate-fishery products;
- Decision 96/333 health certificate-bivalve molluscs;
- Decision 97/296 (modification 97/758): list of third countries from which the imports of fishery products is authorised for human consumption;
- Decision 97/20: (97/565) list of third countries for imports of bivalve molluscs;
- several decisions about approval of a third country;
- some decisions banning the import of fishery products or bivalve molluscs from a specific country; and
- EU directive 90/675 (to be replaced): organisation of veterinary checks for products entering the EU from third countries.

National legislation

In the Netherlands, EU legislation is implemented in legislation of the Commodity Board for Fish and Fishery products and in the “Commodity Act” of the Ministry of Public Health, Welfare and Sports.

All the requirements for fish handling and hygiene on board of vessels, during landings and in fish auctions, are implemented by the Commodity Board for Fish and Fishery Products. All the requirements on the structure of vessels, auctions and buildings are also implemented by the Commodity Board.

In the Commodity Act of the Ministry of Public Health, Welfare and Sports all the requirements of fish handling and hygiene, including HACCP in plants (establishments), storing, transport, imports from third countries and placing on the market are implemented.

b) Organisation

The Ministry of Health, Welfare and Sports, and the Ministry of Agriculture, Nature Management and Fisheries are responsible for the full implementation of the EU legislation.

The Ministry of Public Health, Welfare and Sports is responsible for public health policy.

The Ministry of Agriculture, Nature Management and Fisheries is responsible for the fisheries policy and policy relating to the production and marketing of fishery products.

The Commodity Board for Fish and Fishery Products is a semi-State organisation with the authority to develop legislation for the fisheries industry. In the case of the implementation of EU legislation, the Commodity Board implements EU legislation with the permission of the Ministry of

Public Health, Welfare and Sports and the Ministry of Agriculture, Nature Management and Fisheries. The Commodity Board can not take action in this field without permission.

There are two main inspection services involved with fish inspection

(1) The National Inspection Service for Livestock and Meat (RVV)

This inspection service is part of the Ministry of Agriculture, Nature Management and Fisheries. Its duties include:

- granting approval to enterprises that meet hygiene and technical requirements;
- repealing approval when enterprises no longer comply with these requirements;
- supervising shellfish production areas, fish handling, hygiene and structure of vessels, fish auctions, fishery products enterprises to ensure they comply to the national legislation (EU legislation);
- import inspection at border inspection posts;
- issuing health certificates and other declarations as proof of health and quality.

(2) The Inspectorate for Health Protection (HIGB)

This inspection service is part of the Ministry of Public Health, Welfare and Sports. Its duty is to monitor throughout the production chain to ensure compliance with the legal requirements for public health. This monitoring takes place through random checks that, in effect, double-check the daily inspections carried out by the RVV. In the case of public health hazards, the RVV usually takes action.

The Inspectorate for Health Protection is also responsible for the inspection of seafood at the retail sale and consumer level.

c) Laboratories

The National Institute for Fisheries Research (RIVO) takes care of the sanitary monitoring program for shellfish production areas. It is also used by the RVV for investigations of fish and fish products. The RIVO is also used for investigations to detect biotoxins in shellfish imports. The national reference laboratory that deals with marine biotoxin is the National Institute for Public Health and Environment Protection (RIVM). When biotoxins are detected, found the reference laboratory is used. It conducts tests including, if necessary the “mice test” for PSP.

The laboratories of the Regional Inspectorates for Health protection are also used for investigation of fish, for example for the material inspection of fish by imports.

d) Use of Third Parties' Inspection Bodies

Some companies use third party inspection bodies like SGS or ISI (International Seafood Inspectorate) when they want to export fish to a third country. The use of third party inspection bodies depends on the requirements in the legislation of the third country.

Usually the RVV inspects fish for export. The export inspection of the RVV is voluntary. If a company needs a guarantee from the RVV to accompany its export products, the RVV inspects the products according to the requirements of the country of destination.

For inspection of fish for the domestic market the Netherlands, and other EU Member States, does not use third party inspection bodies.

e) Training

The personnel of the RVV who deal with fish inspection, and local fish inspectors, are required to complete the course "viskunde A and B". This course is given in fisheries schools. The course are vocational education about the quality of fish, organoleptic criteria, and recognising families of fish.

These course are supplemented by practical "on-the-job" training.

The RVV organises HACCP training for inspectors.

In the border inspection posts, a veterinarian is responsible for all inspection at that specific post. Personnel in border inspection posts dealing with fish inspection also take practical "on-the-job" training.

II. Description of Inspection and Control Systems**a) Use of Systematic Inspection Approaches***For domestic consumption*

The inspection of fish production and marketing the same in the Netherlands and all other EU member states.

All establishments which produce or store fishery products, and also factory vessels, need an approval from the RVV in order to produce fishery products for the EU market. Establishments receive an approval if they meet the requirements of the Commodity Board for Fish and Fishery Products and the Commodity Act. The use of HACCP is mandatory and is a part of the approval requirements for an establishment.

In November 1995, the RVV started the so called "action plan" for fish and fishery products. Main purpose of this action plan is to ensure the compliance of the establishments with the approval requirements. This plan involves:

- regular RVV inspections (followed by reports);

- establishments that do not fulfil the requirements will be:
 - be warned by the RVV;
 - be penalised by the HIGB; and
 - have approval removed by the RVV (if they do not make the necessary changes).

From the beginning of 1997, establishments without a good working HACCP system have the risk of losing their approval.

For export

The relevant legislation is the EU Directives and Decisions and any additional requirements of the country of destination. If establishments require a health certificate, the RVV will provide the necessary verification, provided the products meet the requirements of the country of destination (see also at third party inspection).

b) *Mandatory versus Voluntary*

Some companies use ISO 9000 standards. The use of these standards, and the systems that support them, is voluntary.

The use of HACCP systems is mandatory.

c) *Import requirements*

Companies from third countries that wish to export to EU Member States must fulfil the same conditions as those applies to companies in the EU. The EU requires a guarantee from the competent authority in the country of origin indicated that the products fulfil EU requirements. A health certificate is required.

The exports from many third country is harmonised by EU Decisions. These decisions result from an agreement or understanding between the EU Commission and the competent authority of the country of origin. Under this arrangement, the competent authority provides a list of approved premises that may export to EU Member States. The competent authority in the third country must certify all exports to the EU. In addition, EU Member States conduct import checks on product when it enters their country.

III. *Equivalency*

The EU Commission works on equivalency with third countries, in co-ordination with the Member States.

SWEDEN***FISH INSPECTION SYSTEMS IN SWEDEN*****I. Description of competent authorities and organisational structure****a) *Human resources****National Board of Fisheries*

Control of marketing standards for certain fishery products is in accordance with Council Regulation (EC) 2406/96 of 26 November 1996. Control is in accordance with Council Regulation (EC) 2847/93 of 12 October 1993, which establishes the control system applicable to the common fisheries policy.

Inspection done by Quality Inspectors

Inspection is done by Quality Inspectors. The qualifications for Quality Inspectors include a degree from gymnasium and courses in biology, especially marine biology, or an university degree.

b) *Organisation/Legislation*

The Department of Fisheries Control within the National Board of Fisheries is responsible for the establishment of a fishery control organisations in Sweden (under the EU regulations).

The common organisation of the market for fisheries and aquaculture products is carried out through the Council ordinance 3759/92 (December 17, 1992). The objective of the common organisation is to facilitate trade in fish and fish products.

The member states ensure that the rules of the common market organisation are followed. The controls take place in harbours, at the landing place, at auctions and at first sales. Landings are classified with reference to species, size and freshness according to categories which are common for the European Union. The control should, apart from direct observation of landed quantity, also cover document control (logbooks, landing declarations and sales notes).

The Swedish fisheries control includes the resource management as well as the marketing and structure policies. The main governmental agencies for the fisheries control are the National Board of Fisheries, the Coast Guard, the Police, the Customs and the National Food Administration (NFA).

The National Food Administration is the central supervisory authority for matters relating to food, including drinking-water. The NFA has the task of protecting the interests of the consumer by working for safe food of good quality, fair practices in food trade, and healthy eating habits. Fair practices in the food trade imply that the consumer can rely on the labelling as regards, for example, the composition, weight, keeping qualities and origin of the food. The NFA is directly responsible to the Government. The duties of the National Food Administration are:

- to prepare food regulations;
- to enforce the Food Act and to lead and co-ordinate food control;
- to provide information on important matters concerning food;
- to take an active part in ensuring that the guidelines drawn up by Parliament and the Government on diet and health are followed; and
- to conduct enquiries and practical scientific investigations on food and dietary habits and to develop methods for food control.

The work of the NFA shall be based, as far as possible, on international co-operation, particularly within the European Union (EU).

The work of the National Food Administration can be divided into four fields of activity:

- increasing knowledge;
- establishment of standards and other food regulations;
- supervision and control; and
- information and guidance.

The Food Act has two main purposes to guarantee the consumers:

- safe food;
- fair practices in the food trade.

In order to be able to carry out their standards, supervision and information, the staff of the NFA need to have a very high standard of knowledge and scientific competence. The development of knowledge is a very important activity in the laboratories of the NFA. Here, new and more reliable analytical methods for food control are developed. The NFA is also responsible for quality control of laboratories that analyse foods, including fish and fish products, throughout Sweden.

The NFA leads and co-ordinates the control of about 50 000 food producing establishments, including waterworks, in Sweden. This work is done in close co-operation with the municipal authorities,

who are responsible for most of the supervisory work. The NFA also co-operates with county veterinarians at the county administration. The controls are comprehensive and cover all links in the food-handling chain.

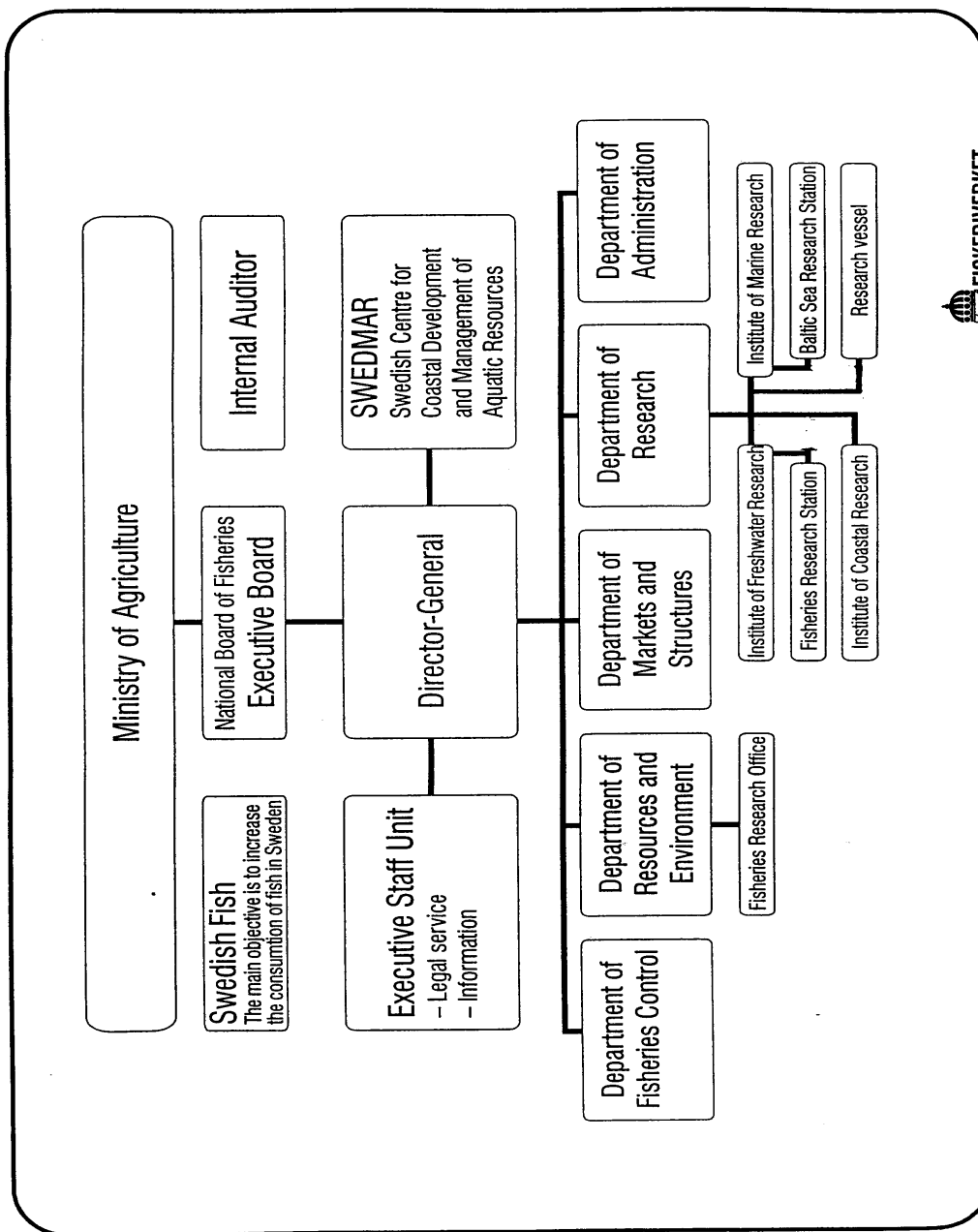
Annex I contains the organisation table of the National Board of Fisheries.

c) *Use of Third Parties Inspection Bodies*

The National Board of Fisheries has agreements with five different municipal authorities in Kiruna, Storlien, Hån Eda and Svinesund. At the border their inspectors have to execute control of marketing standards specified in Article 28 of the Council Regulation (EC) 2847/93 of 12 October 1993 regarding the implementation of a control system for the common fishery policy and in accordance with Council Regulation (EC) 2406/96 of 26 November 1996.

ANNEX I

Organisation
National Board of Fisheries in Sweden



ICELAND

THE FISH INSPECTION SYSTEM IN ICELAND

I. Introduction

Iceland's Fish Products and Monitoring of their Handling Act (no. 93/1992) entrusted the inspection of facilities, hygiene and "own checks" in fish processing establishments to independent inspection bodies approved by the Directorate of Fisheries (DoF). At the same time, inspection bodies were authorised, and virtually obliged, to act as consultants to producers regarding the areas of operations to be supervised. The Act includes provisions on ownership of inspection bodies, permitting them to be owned by of fish processing establishments, with certain limitations.

This system did encounter a certain amount of criticism as the division of tasks between the inspection bodies and the responsible competent authority was not clear. Also, one view was that all surveillance activities and issue of certification should be in the hands of a competent authority to secure competence and impartiality. However, this view can be questioned as no assessment of the competence and impartiality of Government bodies has ever been made; they are automatically regarded as meeting this requirement.

The main reason for the criticism of the previous system was the fact that it allowed inspection bodies to be too closely linked to the establishments being inspected. It was argued that the inspection bodies were not impartial, and their competence for implementation of monitoring could be questioned because their decisions could be influenced by interests other public health and consumer protection. The need for a reform of the new system thus became evident in the early stages of its implementation.

In recent decades, methods have been developed to verify the competence and impartiality of parties conducting inspections, testing and certification. At a global level, these methods have been described in ISO guides, while in Europe CEN (Comité Européene de Normalisation) has described them in its EN (European Standard) 45000 series of standards. These standards have been adopted in Iceland (e.g., ÍST EN 45000).

When the previous inspection system was established, it took into account the above-mentioned methods. But due to the special conditions prevailing in Iceland it was decided to deviate from them in certain respects (e.g., concerning impartiality and consultancy). Initially it was not thought possible to use a method of accrediting inspection bodies, given the lack of clearly defined rules on how inspection should be performed.

Accreditation requires the clear definition of working procedures for inspection bodies. It also demands that inspection bodies, testing bodies and certification bodies operate quality systems in order to

ensure transparency in the implementation of their tasks. This approach also assumes that a separate body should be set up to monitor the competence and activities of inspection bodies, testing bodies and certification bodies (i.e. an accreditation body). The role of the accreditation body is therefore to evaluate and declare the competence and impartiality of parties involved.

Accreditation is performed in Iceland by the Accreditation Department of the Icelandic Metrology and Accreditation Service in accordance with the Weights, Measures and Accreditation Act (no. 100/1992). A special collaboration agreement on the conduct of accreditation in Iceland has been made with a Swedish accreditation body (SWEDAC).

This overview shows the Icelandic authorities are reforming the previous system by insisting on accreditation of those inspection bodies which are approved by the DoF. This insistence ensures that the inspection bodies show impartiality in their inspection work, and that consulting and other activities are kept completely separate from surveillance activities. This paper also explains the division of tasks and responsibilities between the DoF and the inspection bodies.

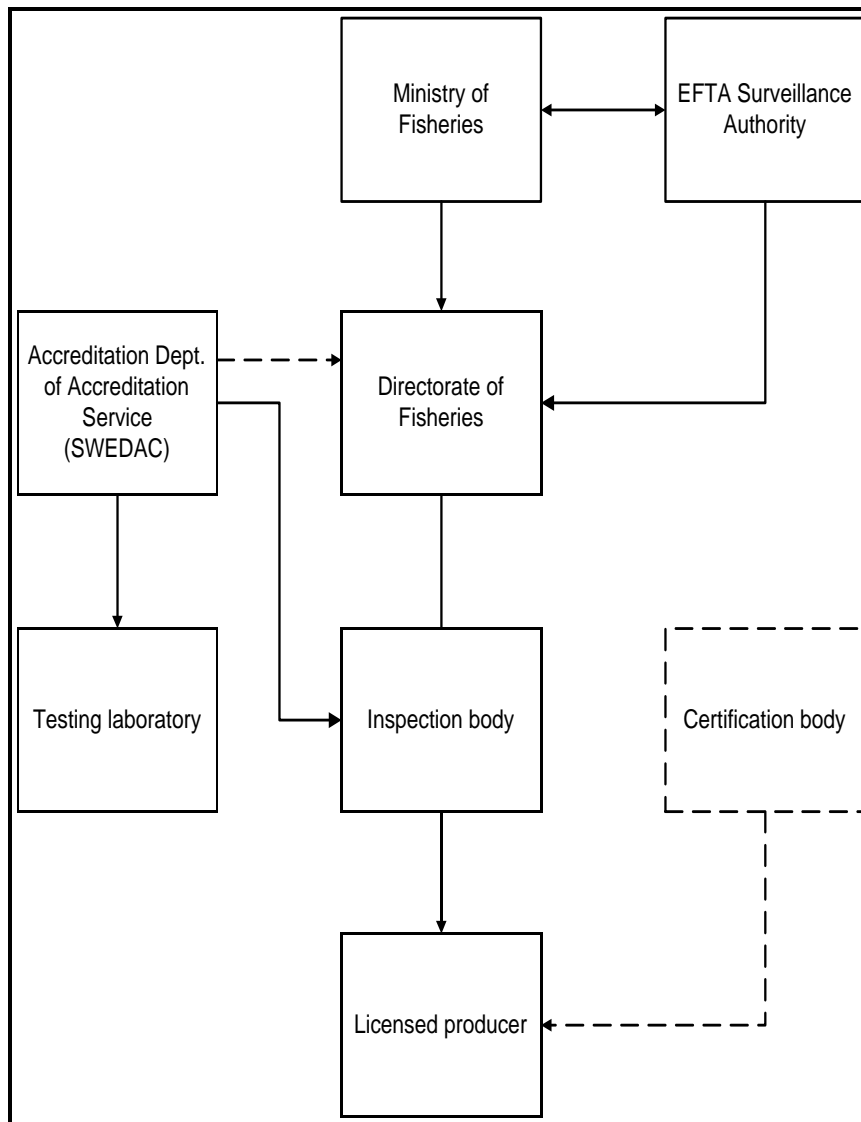
II. Outline of the New System

Inspections of processing establishments have, since 1 January 1998, been performed by accredited inspection bodies acting on behalf of the DoF. Inspection bodies which applied for accreditation on 1 January 1998 had up to 6 months to finalise the accreditation process. The inspection bodies regularly submit the results of their inspections to the DoF. The DoF handles all actions that need to be taken as a consequence of these inspection results.

The main difference between the new system and the previous one is the accreditation of the inspection bodies. This new requirement means that the inspection bodies' can only be engaged in a surveillance role under the responsibility of the DoF, in accordance with predefined procedures. **Inspection bodies must to operate completely independently from the parties being inspected.** Inspection bodies are therefore not be permitted to offer them consulting services or take part in production or sales of fish products. Inspection bodies are expected to demonstrate their competence and impartiality when acquiring accreditation.

The structure of the new system is illustrated on the following figure:

Figure 1: Icelandic Seafood Inspection System



EFTA: European Free Trade Association

The requirement for impartiality and independence of bodies within the surveillance system will result in changes to the surveillance system as a whole.

The tasks of the respective bodies in this figure need to be defined, as do the methods for the tasks. This means that the requirements directed to fish processing establishments must be defined in order to enable inspection bodies to inspect specified points. Furthermore, procedures regarding the methods of inspection need to be drawn up for use by inspection bodies. Accreditation of inspection bodies therefore needs precise definition of all provisions the authorities want the producers to comply with, and the manner in which inspection bodies carry out inspections.

III. Ministry of Fisheries

The Ministry of Fisheries is legally responsible for fish industry activities. The Ministry sets rules and issues the necessary regulations. It has issued:

- Regulation no. 684/1995 which incorporates the provisions of European Council Directive no. 91/493 into Icelandic legislation;
- Regulation no. 450/1997 on the surveillance framework and working methods of accredited inspection bodies in the fish industry (which replaces chapter III of Regulation no. 429/1992 on the arrangement of inspection of marine products); and
- Regulation no. 558/1997 which contains the rules for mandatory “own checks” by fish processing establishments.

IV. Directorate of Fisheries

Role and Tasks

The role of the DoF under the new system is comparable with its previous role in licensing and daily responsibility for surveillance operations. The DoF also assists the Metrology and Accreditation Service with accreditation of inspection bodies by:

- providing the Metrology and Accreditation Service with such technical expertise for the audits as is necessary for the accreditation of inspection;
- undertaking surveillance of inspection bodies and licensed producers (e.g., on the basis of random samples, and thereby measure directly the effectiveness of the system);
- undertaking any aspects of surveillance that cannot be accommodated within the accredited inspection body system which emerge during preparations for the establishment of the system;
- licensing of producers and approval of inspection bodies (cf. Act no. 93/1992; and
- issuing public documents of certification where demanded (cf. Art. 16 of Act no. 93/1992).

Inspection Manual for Fishery Products

Verification of conformance with European Council Directive 91/493 on fishery products

By far the largest task given to the DoF in the implementation of the new system was the writing of the new inspection manual for fishery products.

In the making of the manual, the provisions of European Council Directive 91/493 (which lays down the health conditions for the production and the placing on the market of fishery products) and derived and related EC Acts, were analysed and classified into seven categories. These categories are:

Own Health Checks, Premises and Equipment, Processes, Personnel, Pest Control, Cleaning and Disinfection, and Substances. These seven categories include all requirements for health conditions from catching the fish to processing and placing it on the market.

Within these categories the requirements were grouped into objects of inspection. The objects of inspection contain the requirements identified in the EC legislation. These requirements were interpreted and items of inspection derived: methods of inspection, procedures, limits and rating of non-conformity.

The DoF ensures conformity with all provisions in the manual before issuing new processing licences to fish processing establishments. After that the inspection bodies use the manual when carrying out their regular inspections.

Responsibility

The DoF is:

- responsible for approving inspection bodies (cf. Art. 14 of Act no. 93/1992), providing that the set conditions have been fulfilled (e.g. accreditation), and for rescinding approval if these conditions cease to be fulfilled;
- responsible for licensing of producers providing that conditions have been fulfilled (cf. Art. 12 of Act no. 93/1992) and rescinding their licences if these conditions cease to be fulfilled; and
- professionally responsible for the interpretation of Icelandic Regulations (being consistent with European Council Directive 91/943) and any other legislation which is relevant.

It is planned for the DoF to withdraw from direct inspections of producers wherever possible once the accredited inspection bodies take over. The DoF plans to concentrate instead on monitoring the work of the inspection bodies. To facilitate this monitoring role, DoF software (based on DoF principles) has been used by inspection bodies for the last two years. The software is supplied to the inspection bodies for installation on their computer systems. Their inspectors enter all the results of their inspections in the program and send them on diskette to the DoF every month (or more often if requested). In the near future this facility will have an “on line” computer connection between inspection bodies and the DoF. This enables the DoF to, for example, process statistical information on the state of individual aspects of fish processing establishments and make comparative assessments of them.

V. Inspection Bodies

Role and tasks

The role and tasks of an inspection body is to:

- Undertake inspection of the health conditions for the production and the placing on the market of fisheries products for human consumption, including the inspection of hygiene,

premises, equipment and own checks in fish processing establishments which are licensed as producers by the DoF (c.f. Art. 12 of Act no. 93/1992)

- Supply the DoF with regular information on the state of the licensed producer. In order that this information is presented in the most standardised format possible, the DoF has already developed inspection materials such as Inspection Manual for Fishery Products, inspection forms, check lists and the above mentioned DoF. software.
- Operate in accordance with the ÍST EN 45004 (1995 standard) and is defined, according to Art. 4.2.1 of the standard, as a “type A” inspection body and accredited by the Metrology and Accreditation Service (c.f., provisions of Regulation no. 450 / 1997 on surveillance framework and working methods of accredited inspection bodies in the fish industry).
- Operates as a private company that charges its clients (i.e., licensed producers) an inspection fee.

The reform involved here is that the inspection body shall be accredited and defined according to Art. 4.2.1 of ÍST EN 45004, with the result that it shall be independent of all interested parties (c.f., Appendix A to the standard). Thus the inspection body can never involve consult or promote business for clients of the companies which it inspects.

Responsibility

An inspection body:

- bases its inspections (c.f., ÍST EN 45004) on the requirements made of producers as stated in relevant Icelandic Regulations, together with the interpretation and presentation of individual provisions made by the DoF in the inspection manuals;
- provides the DoF with information about the activities and state of companies (c.f., Art. 14 of Act no. 93/1992) which do not fulfil the defined competence requirements (this information must be provided on request); and
- may not impose unfair conditions upon its clients, or refuse to provide service to specific parties, except in the case of financial default or the failure by that company to fulfil minimum legal requirements.

VI. Producers

The role of the producer is self-explanatory. The new system better-defines the requirements regarding the activities of licensed producers. This gives scope for tailoring the frequency of inspection visits to the state of the individual licensed producer, which has long been one of the DoF's aims.

Responsibility

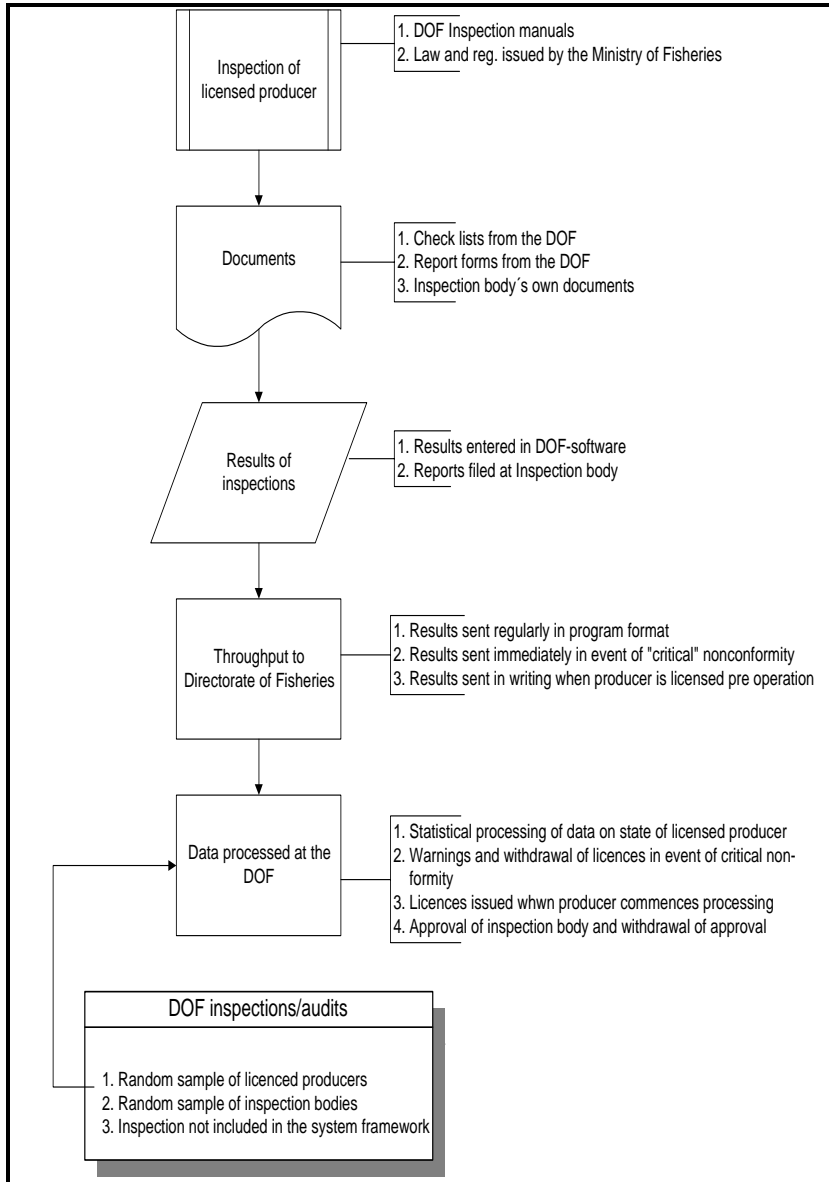
The responsibility of a licensed producer are as follows:

- A licensed producer must have a contract with an accredited inspection body which is approved by the DoF.
- A licensed producer must deal with an accredited testing body for sampling of products, hygiene, etc.
- In the event of disputes with inspection bodies, Icelandic law shall apply where the case is not covered by DoF documents, laws and regulations issued by the Ministry of Fisheries.

The inspection body charges an inspection fee that is negotiated between it and each individual licensed producer.

The relationship between the DoF, inspection bodies and licensed producers during the inspection process is illustrated in Figure 2.

Figure 2: Inspection Process: Relationship between Directorate for Fisheries, Inspection Bodies and Licensed Producers



DoF: Directorate of Fisheries

VII. Accreditation Department of the Metrology and Accreditation Service

Role

The Accreditation Department of the Metrology and Accreditation Services accredits inspection bodies, testing bodies and certification bodies. Accreditation involves an in-depth assessment of the activities of the body in question. This assessment is divided into two parts:

- a systematic assessment in which the body's quality system and impartiality are assessed; and
- a technical assessment in which the technical conduct of inspections is assessed.

Accreditation is granted to inspection bodies, testing bodies and certification bodies whose activities are conducted in conformity with the ÍST EN 45000 standard and Icelandic regulations, and who fulfil the impartiality provisions. The role of the Accreditation Department of the Metrology and Accreditation Service is therefore to assess and declare the competence and impartiality of parties. The DoF provides experts for the assessment team. Accreditation is a prerequisite for DoF's approval of an inspection body as an inspector of fish products.

Accreditation bodies in the European Economic Area (EEA) collaborate on accreditation of inspection bodies. These requests —made to the DoF - can be for inspecting fish industry companies (standard ÍST EN 45004) and for testing laboratories (standard ÍST EN 45001).

Accreditation of fish industry inspection bodies takes into account whether they:

- conduct inspections in accordance competence requirements as defined by the DoF; and
- meet the conditions regarding vested interests (these conditions are stated by the Ministry of Fisheries in its regulations on the surveillance framework).

The Accreditation Department of the Metrology and Accreditation Service uses technical assessors from the DoF for its technical assessments.

VIII. Testing Laboratories

Iceland has incorporated EC provisions into its domestic law with regard to testing laboratories. Producers are obliged to use accredited testing laboratories when testing is conducted by outside parties (see European Commission Decision of May 20, 1994, which lays down detailed rules for the application of European Council Directive 91/493 on hygiene in the processing and marketing of fish industry products). In the case of in-house testing bodies, these shall fulfil the demands stated in European Council Directive no. 88/320, Appendix B, on good laboratory practices.

These provisions have been incorporated in Iceland with Regulation no. 442/1995 on good laboratory practices. Demands concerning the working methods of testing laboratories which serve the fish industry therefore already exist, and all that remains is to issue the appropriate supplementary documents (e.g., documents stating which tests and studies for sampling of licensed producers must be accredited, and the methods they must conform to).

IX. Certification Bodies

Certification bodies cannot perform a direct role in inspection of producers. However, one of the foreseeable consequences of the new system will be an increase in demand for certification of quality systems. In the future, certification bodies may therefore be expected to perform an important role in certification of quality systems under the ISO 9000 and ISO 14000 standards, where part of the certification is conditional upon an “own checks” mechanism based on the principles of HACCP.

X. Implementation and Preparation

The reforms involved with the new system can be summarised as follows:

- Strengthening of producers’ “own check” systems.
- Preparing of inspection bodies for accreditation in accordance with ÍST EN 45004, i.e., production of necessary documents specifying requirements.
- Preparing for accreditation of inspection bodies, i.e., the writing of inspection manual for fishery products.
- Testing of the reformed system.
- Inspections of processing establishments by official DoF inspectors in order to fulfil monitoring requirements during the phase-in period.

Producers’ “own check” systems

Producers’ “own check” systems need to be properly constructed and must operate to allow inspection by accredited inspection bodies to occur along expected lines. Since the adoption of the present system, major advances have been made in the development of “own check” systems in the fish industry. Certain branches of the industry, such as shrimp canning, freezing and fish meal production, have set up their HACCP-based “own check” systems. Progress has also been made in other branches of the industry, although there are certain shortcomings among some producers. For this reason, one of the prerequisites for the reform to the surveillance system was the launching of an awareness campaign to ensure that all producers will have satisfactory “own check” systems by the end of the phase-in period.

Implementation

Implementation of the “own checks” system has involved:

- The regulation no. 558/1997 on mandatory own checks in fish processing establishments was based on the European Commission Decision of May 20, 1994 — which lays down detailed rules for the application of European Council Directive 91/493 — regarding “own checks” on fish products.

- The DoF launched a campaign in January 1997 that focused on producers' "own check" (HACCP) systems. The campaign, which finished at the end of 1997, involved every fish processor being inspected twice by DoF inspectors.

Requirements of testing laboratories, in accordance with ÍST EN 45001

As testing bodies needed some preparation time to be able to fulfil the accreditation requirements, it was considered appropriate to require that they be accredited at the same time as inspection bodies, namely in the second half of 1997 (with a possible 6 months extension).

Official surveillance during the phase-in period

During the phase-in period, the DoF has handled surveillance of licensed producers. In effect, official inspections will continue for as long as the preparatory phase lasts. Inspections will first be entrusted to inspection bodies when the accreditation process is completed. This process will be completed by 1 July 1998 at the latest.

XI. Summary

This overview focuses on the present reform the Icelandic inspection system. This reform includes adding the additional requirement of accreditation to list of the conditions to be fulfilled by privately owned inspection bodies which inspect, on behalf of the competent authority, facilities, hygiene and own checks in fish processing establishments. It is evident that the key to the establishment of the system is the definition of the rules that implement it. Not least, the responsibility of individual parties needs to be clear. It is obvious that, for example, the DoF will continue to be responsible to the Ministry of Fisheries; inspection bodies and licensed producers will still be responsible to the DoF, and so forth.

Regulations issued by the Ministry of Fisheries form the regulatory framework on which these reforms are based with reference to the ÍST EN standards. The largest task in the implementing the new system, was the writing of the new inspection manual for fishery products. This manual is the key to harmonised working methods among inspection bodies and it is the principal document they use in performing their inspections.

JAPAN

I. Description of Competent Authorities and Organisation Structure

a) *Seafood safety and hygiene*

i) *Human resources*

To prevent the occurrence of health hazards arising from human consumption of food, Japan has enforced a Food Sanitation Law (FSL) since 1947. The Ministry of Health and Welfare (MHW) enacts the Food Sanitation Law, Enforcement Ordinance (Cabinet order); Enforcement regulations (ministerial ordinances), and food standards and specifications for food. The MHW also orders intensified inspections on the basis of epidemiological information, data or information from foreign countries. Supervision of fish and fishery products processing facilities in this country is conducted by the MHW, the governor of prefecture, or the mayor of a city which has local health centres.

Under Article 19 of the Food Sanitation Law, the MHW, each prefecture, each large city establishing health centres, and each of Tokyo's 23 wards appoints food sanitation inspectors. These inspectors execute the authority of officials as prescribed in Article 17 of the FSL and perform the duties of instructing and monitoring food hygiene practice.

Under Article 17 of the FSL, the Minister of Health and Welfare, the governor of any prefecture, or the mayor of any city with health centres may: when necessary:

- request necessary forms from a commercial fishery enterprises;
- require the officials concerned to visit places of business. In order to inspect foods or additives intended for sale or for use in the business: inspect the business facilities, books, documents or other articles; and
- require such officials to collect samples of foods or additives intended for sale or for use in business without compensation for such samples within the quantity necessary for performing tests;

Actual inspection of fish and fishery product processing, manufacturing, preparing, and holding facilities, and sampling of fish and fishery products are to be carried out by each prefecture's food sanitation inspectors.

Under the provision of Article 4 of the cabinet order, physicians, dentists, veterinarians, pharmacists, graduates who have studied medicine, dentistry, veterinary science, animal husbandry, the science of fisheries or agricultural chemistry in universities or colleges, those who have completed the

prescribed course in training institutes designated by the Minister of Health and Welfare (supervising nutritionists, etc.), and nutritionists who have been engaged in work related to food sanitation for two years or more are qualified to become food sanitation inspectors. At the end of 1997, we had 845 health centres, and 7,367 food sanitation inspectors.

ii) *Legislation*

The relevant legislation for seafood safety and hygiene is:

- Food Sanitation Law(FSL),
- Food Sanitation Law Enforcement Ordinance (Cabinet order),
- Food Sanitation Law Enforcement regulations (ministerial ordinances),
- Food Standards and specifications,
- Enforcement directives

iii) *Organisation*

In Japan, food safety is the responsibility of the National government; the Veterinary Sanitation Division, Environmental Health Bureau, of the Ministry of Health and Welfare is the only government agency responsible for the interpretation and planning of the FSL, its Enforcement Ordinances and Enforcement Regulations. Actual inspection of fish and fishery product processing facilities is carried out by each prefecture's designated food sanitation inspectors. These laws are implemented by written regulations.

Local self-government is practised by metropolitan and prefectural authorities, due to its importance to national life, but no approval for the self-regulation of food safety has been given to the prefectures. In Japan, such affairs are handled by the national authorities, and the prefectures are to take charge of the affairs on behalf of national agencies (assigned functions).

Supervision, guidance, sampling and inspection based on the FSL are commissioned to the governors of metropolitan areas and prefectures, and the person most responsible for these affairs is the Minister of Health and Welfare, who is also vested with the authority to direct and supervise these affairs.

This organisation is derived from the Law for Establishment of the Ministry of Health and Welfare (the 1949 Law No. 151) which places the Food Sanitation Law under the jurisdiction of the Ministry of Health and Welfare. In addition, Article 148 of the Local Autonomy Law (LAL) stipulates that the management and execution of national affairs are to be commissioned to governors of metropolitan areas and prefectures which function as national agencies of the national government. Article 150 of the LAL also stipulates that national affairs handled by the governors are under the direction and supervision of the relevant minister (the Minister of Health and Welfare for food safety).

The following activities have therefore entrusted by the Central Government to the governors of metropolitan areas and prefectures (and their respective authorities):

- business licensing for a fish and fishery products processing facility based on the Food Sanitation Law;
- supervision and guidance concerning the sanitary control of facilities and operations based on Article 17 of the Food Sanitation Law; and
- sampling of foodstuffs to be offered for testing and inspection; and
- testing and inspection of foodstuff samples.

The execution of these duties remains under the Central Government's direction and supervision. In the metropolitan and prefectural cities where health centres have been established, it is the sanitary authorities that exercise jurisdiction over these duties, and inspection is carried out by the food sanitation inspectors of the health centres.

The Food Sanitation Law provides specific authorities for the MHW with the ability to establish standards pertaining to:

Seafood Safety

Under Article 4 of the Food Sanitation Law, it is prohibited to manufacture and process food for the purpose of sale that:

- is rotten, decomposed, or immature (this provision applies to food items that are generally deemed not to be injurious to human health and fit for human consumption);
- contains or carries toxic or injurious substances, or substances are suspected to contain or carry these substances (provided, however, that this provision applies to cases that are prescribed by the Minister of Health and Welfare as not being injurious to human health);
- is either contaminated with, or suspected to be contaminated, with pathogenic micro-organisms which may injure human health; and
- may injure human health due to uncleanliness, the admixture or addition of extraneous substances, or other causes.

The MHW has standards for judging the violation of Article 4. For example: the Ministry has given instructions to deal with the sale of PSP that exceeds 4 MU/g and DSP that exceeds 0.05 MU/g as a violation of Article 4, judging it to be the sale of food that contains toxic substances (see second dot point above)

In addition, under Article 7 of the Food Sanitation Law, the Minister of Health and Welfare has established standards for food and additives. These are officially announced as a notification from the Ministry of Health and Welfare. In these standards, micro-biological specifications, specifications for veterinary drug residues, pesticide and food additives, and standards for processing, manufacturing and storage are stipulated.

Article 11 of the Law has established labelling standards, and prohibits the sale of food that is not conformity with these standards.

Hygiene and Sanitary Conditions and Practices in Processing Facilities

Under Article 7 of the Food Sanitation Law, the Minister of Health and Welfare, from the view point of public health, has established

- manufacturing standards and storage standards for surimi products;
- processing standards and storage standards for boiled octopus;
- processing standards and storage standards for oysters for raw consumption;
- processing standards for frozen fresh and shellfish for raw consumption; and
- packed food heat-pasteurised under pressure which includes seafood.

Under Article 19, paragraph 18-2 of the Food Sanitation Law, the governor of each prefecture may establish necessary standards relating to public health measures in business facilities for all foods. Where the standards have been established, businesses must comply with them. In a directive sent to the governors of metropolitan areas and prefectures from the Director General of the Environmental Health Bureau of the MHW (similar to the United States Food Code), standards may be established relating to:

- sanitation control at the facility;
- hygienic operations;
- safety of water;
- waste control;
- personnel hygiene of employees;
- testing of products; and
- supervision of sanitation.

The Labelling of Seafood

Under the Article 7 of the Food Sanitation Law, the Minister of Health and Welfare, from the viewpoint of public health, has established standards for the labelling of foods intended for sale. These standards must be complied with.

Licence for Business

Under Article 20 of the Food Sanitation Law, the governor of each prefecture, from the viewpoint of public health, has established standards for the types businesses that have significant influence on public health. For seafood, these types of business are:

- fish retailers;

- fish auctions;
- surimi products manufacturing;
- fish freezing facilities;
- cold storage for fish and fishery products;
- processing “ready to eat” seafood; and
- seafood canning.

Article 21 of the Food Sanitation Law prescribes that. any person who wishes to carry on in any of the businesses listed above, must obtain a license from the governor of the their prefecture. The governor of the prefecture, after receiving an application for a license, will only issue a license when satisfied that the facility of the business concerned complies with the relevant standards.

Other

Standards for the use of veterinary medicines in aquaculture are stipulated in the Pharmaceutical Law.

- prohibited antibiotics and synthetic antibacterial substances, and synthetic chemicals from being contained in residues; and
- excluded Oxytetracycline, Ivermectin, Flubendazole, Closantel, Zeranol, Trenbolone acetate, Isometamidium, Sulfadimidine, Thiabendazole, Carbadox, Albendazole (marker residue : 2-Aminobenzimidazole sulfone)) which have been submitted by manufactures a complete set of data required for evaluating safety and established maximum residue limits.

iv) Laboratories

Under Article 18 of the Food Sanitation Law, the Central Government, the metropolitan areas and prefectures, and cities establishing health centres, must establish the necessary inspection facilities. These inspection facilities are to perform administrative work relating to testing of food samples collected pursuant to Article 17 of the Food Sanitation Law. The MHW has 3 laboratories/research institutes:

- National Institute of Infectious Diseases;
- National Institute of Public Health; and
- National Institute of Health Science.

Any established laboratory may tests to enable the verification of verification of Hazard Analysis and Critical Control Point (HACCP)systems. On samples of raw materials, in-process products, or finished products collected in the fish and fishery product processing facilities by food sanitation inspectors.

Analysis procedure guides are stipulated in the standards and, directives issued by the MHW to the metropolitan and prefectural authorities, and in guidelines for the inspection of food sanitation compiled by the MHW.

The product examination management conducted by the laboratory must comply with the standards established under Ministerial Ordinance Article 186. This standard is based on Good Laboratory Practice (GLP), the ISO/IEC Guide 25's "GLP" found in the section on general requirements for the competence of calibration and testing laboratories.

v) *Use of third parties' Inspection Bodies*

The MHW does not designate non-government organisations as the responsible authorities for seafood safety or seafood inspection.

vi) *Training*

Actual training for food sanitation inspectors is carried out by the local government at beginner', middle and expert levels.

The MHW conducts:

- a three-day HACCP training course;
- a two-day training for those inspecting the facilities authorised to process fish and fishery products for export to the United States;
- a three-day training for those who inspect the facilities authorised to process fish and fishery products for export to EU; and
- HACCP verification training (two-day on-site training) for prefectural food sanitation inspectors

In addition, the National Institute of Public Health, the MHW's education, training and research centre, conducts the Food Sanitation Control course for food sanitation inspectors (one month), which included HACCP and GLP.

b) *Quality of Seafood*

i) *Human Resource*

The quality of seafood is managed by "Japanese Agricultural Standards"(JAS). The JAS is based on the Law Concerning Standardisation and Proper Labelling of Agricultural and Forestry Products (Law for JAS). In this system, only the seafood which passes the quality standards and labelling standards established by Minister of Agriculture, Forestry and Fisheries is permitted to attach JAS mark. Inspection bodies which belong to Ministry of Agriculture, Forestry and Fisheries, prefecture governments and private third parties evaluate quality and labelling these products. Inspection bodies belonging to private third parties are called "registration and ranking bodies."

For registration and ranking bodies, the registration standards are contained in the bulletin of Ministry of Agriculture, Forestry and Fisheries. In these standards, the qualifications to be a registration and ranking body are that the person:

- has experience in inspection of the products concerned for more than 5 years;
- has graduated from high school and has experience in inspection of the products concerned for more than 3 years;
- has graduated from university or similar school, mastered the food production techniques, and has experience in inspection of the products concerned for more than 1 year.

At present, the number of people who are suitably qualified to evaluate the quality and labelling of seafood is:

- inspection body of Ministry of Agriculture, Forestry and Fisheries — 190 persons
- inspection body of prefecture governments — 140 persons
- registration and ranking bodies — 140 persons

ii) Legislation

The relevant legislation regarding the quality of seafood are as follows:

- Law Concerning Standardisation and Proper Labelling of Agricultural and Forestry Products.(the JAS law)
- Enforcement ordinance of Law for JAS.
- Enforcement regulations of Law for JAS.
- Standards for Agricultural Products, including Fisheries Products, and the Labelling of Quality Bulletin of Ministry of Agriculture, Forestry and Fisheries.
- Registration Standard for registration and ranking bodies.

iii) Organisation

JAS system has two parts:

1. the JAS system; and
2. the Quality Labelling Standard System.

All producers have the legal obligation to indicate quality properly accordance with the standard established by Minister of Agriculture, Forestry and Fisheries. The ranking based on JAS is usually done by a registration and ranking body. The registration and ranking bodies survey and direct producers, and survey the food which has the JAS mark.

The Centre for Quality Control and Consumer Service, which is the inspection body of Ministry of Agriculture, Forestry and Fisheries, surveys and directs registration and ranking bodies and producers who produce the food attached JAS mark. The Service also monitors the food to ensure the reliability of the system.

Regional agricultural administration offices and local food agency offices (which belong to Ministry of Agriculture, Forestry and Fisheries), inspect and instruct the producers the quality labelling standards in co-operation with the Centre for Quality Control and Consumer Service. Prefecture governments also oversee, under the mandate of the National Government: labelling; collection of reports; making inspections; consumer requests; and surveillance.

- Centre for Quality Control and Consumer Service — 8 offices.
- Regional agricultural administration offices and local food agency offices — 52 offices.
- Prefecture governments — 47 offices.
- Registration and ranking bodies (third parties) — 5 bodies.

iv) *Laboratories*

The Centre for Quality Control and Consumer Service samples, inspects and analyses the quality of products manufactured in authorised factories. There are five registration and ranking laboratories which inspect, rank and analyse the quality of seafood.

v) *Use of Third Parties' Inspection Bodies*

Because JAS is a system where producers improve quality themselves, the third parties' bodies are utilised. At present, most ranking and inspection are carried out by third parties' bodies. The necessary requirements for a third party inspection body are that:

- it has sufficient ability of human and material resources; and
- it is non-profit organisation.

These conditions must be met before the Minister of Agriculture, Forestry and Fisheries registers an applicant as a third party inspection body.

vi) *Training*

As registration and ranking bodies are registered by items, each body has a training system reflecting to the relevant techniques for ranking the item concerned.

For example: to improve the analysis ability of laboratories, each body carries out cross-checks in the laboratory.

In addition, there is a specific training course which gives the participants the required qualifications to perform ranking (sampling and labelling) as part of a third party body.

II. Description of Inspection and Control System

a) *Seafood Hygiene*

i) *Use of Systematic Approaches, i.e., HACCP, ISO 9000 etc.*

For Domestic Consumption

HACCP was introduced into national legislation in 1995 by an amendment of Food Sanitation Law. This amendment involved introducing an approval system entitled: "Comprehensive Food Safety Controlled Manufacturing Process". Under Article 7-3 of the Food Sanitation Law, this system means that a processing process requires comprehensive measures and sanitation control to prevent the occurrence of food sanitation hazards.

An approval will be granted by the Minister of Health and Welfare provided the applicant complies with standards prescribed by the Ministerial Ordinance Article 4. These standards are based on the General Principle of Food Hygiene and HACCP, and guidelines for its application recommended by the FAO Codex Committee

Once an applicant receives an approval, he or she can diversify his or her manufacturing methods, even though manufacturing standards set according to Article 7 of the Food Sanitation Law. In addition, he or she is not bound by any requirements to appoint exclusive food sanitation supervisors.

This system applies to the manufacture of foods for which standards have been established and which have been designated by Article 1 of the Cabinet Order. Initially, the system applied to the manufacturing of milk, dairy products, ice-cream, yoghurt, ham, sausage, bacon, and packed food heat-pasteurised under pressure. The approval system has been expanded and since 14 November 1997 it applied to surimi products.

The MHW encourages food manufacturers to introduce HACCP system, as an effective tool for control of food safety hazards. In order to facilitate the introduction of HACCP, the MHW has developed a training and education program for official food sanitation inspectors and quality control managers in the food industries.

The MHW has received more than 120 applications for approval (mainly from milk and milk products manufacturers), and has conducted paper reviews and on-site inspection to the facilities. When the applications are approved, the inspection methods will change to emphasise HACCP verification.

In addition to the HACCP-based approval system, the MHW periodically visits the food processing, preparation, and manufacturing sites to inspect food, collect samples, check documents and records in order to confirm conformity with requirements based on the FSL¹⁰

10. Specifications and standards are based on Article 4 and 7 of the FSL, relevant articles of the FSL Enforcement Ordinance and Enforcement Regulations.

For Export

For seafood exports to the EU, and based on equivalency agreement with EU and Japan, the MHW designates seafood processing factories which comply with requirements on EU directives, and sends prefecture-designated food sanitation inspectors, trained in HACCP and EU seafood sanitation requirements. After confirmation by the sanitation inspectors, the MHW issues an export certificate. Follow-up inspections will be done every 2 months.

The MHW is currently discussing an equivalency agreement with the USFDA. In the interim, the MHW temporarily issues certificates affirming that the products are processed in accordance with requirements prescribed in 21 Code of Federal Register part 110, good manufacturing practice (GMP) and part 123 (HACCP). These certificates are issued after confirmation by the prefecture designated food sanitation inspectors, are trained in HACCP principles and US seafood HACCP regulations.

Anyone planning to process fish and fishery products for export to the United States must execute a GMP stipulated in 21 Code of Federal Register part 110 and HACCP provided in part 123, on the basis of directives addressed to governors of prefectural governments from the Director-General, Environmental Health Bureau, MHW.

In addition, processors must themselves take, or require their employees to take, a course of lectures that the MHW conducts, using lecturers trained by the Ministry. The curriculum (three days, lecture and group discussion on: developing hazard lists; HACCP plans; and presentation of the developed HACCP plan) for this course is prepared by the MHW on the basis of the American Seafood HACCP Alliance's curriculum.

The Critical Control Point's (CCP's) monitoring record, corrective action taken, calibration of process control instruments used at the CCP, results of periodic end-point or in-process testing, consumer complaints record, Standard sanitation operation procedure (SSOP) monitoring record, etc. must be recorded in writing.

There will be six inspections a year until fish and fishery product processors become familiar with the implementation of GMP. After processors have demonstrated familiarity with these provisions, the MHW will determine the frequency of future inspections based on results of the previous inspections.

Inspectors determine if facilities are hygienically operated and sanitary conditions are maintained by reviewing the monitoring record and the corrective action records in accordance with SSOP. They also visually inspect the sanitary and maintenance during on-site inspections.

Processors or their employees are trained at seminars on the importance of HACCP as replied in item 1.a) vi).

Prefectural expenses for inspection are covered by local taxes and tax money allocated to local governments for adjusting the financial imbalance among prefectures. As such, inspection costs are not borne by processors. Some prefectures, however, collect the actual expenses incurred in issuing an export certificate from the processors.

ii) *Mandatory vs. Voluntary*

“The Comprehensive Food Safety Controlled Manufacturing Process” is a voluntary system. The MHW encourages the food industry to use HACCP, but this is not mandatory as long as they comply with specifications and standards for food based on Article 7 of the FSL.

However, seafood exports to the EU and the United States must be processed under a HACCP-based system.

iii) *Import Requirements*

Article 16 of the Food Sanitation Laws requires that those who wish to import foods for sale or business use must first submit a notification of food importation form to the Director of Quarantine Stations.

Information from the notification form and attached documents (health certificates, voluntary test results, previous inspection date for the same kind of food) are examined to decide whether to inspect the imported products. Only seafood in compliance with the Food Sanitation Law and relevant requirements are permitted for import into Japan. Food safety/hygienic requirements applied for imported seafood is those applied to seafood processed in Japan.

At this moment, HACCP systems for food safety control are not required for those who wish to export their products to Japan.

b) *Quality of Seafood*

i) *Utilisation of Systematic Inspection Approach (HACCP, ISO9000s etc.)*

For Domestic Consumption

Japan does not use HACCP or ISO. But the JAS system is the standard that helps consumers in their product selection. With the JAS, the ranking of the products consists three processes: sampling; testing; and labelling. This ranking process can be conducted by third party bodies — registration and ranking bodies — authorised by Minister of Agriculture, Forestry and Fisheries. Processing factories which meet the necessary technical standards can be authorised by Minister of Agriculture, Forestry and Fisheries to do their own sampling and labelling. There are technical standards for manufacture facilities, machine, quality management and so on.

Japan is considering to requirements of the ISO 9000 and HACCP systems into the JAS system.

For Export

As the products must fit the standards of the importing countries, inspection based on Law for JAS does not carried out.

i) Obligation or Not

JAS is an optional system and therefore producers are not obliged to use it. When seafood is imported, the labelling must comply with Japan's labelling standards.

ii) Necessary Conditions for Importing

If the label on the imported product does not meet the Japan's required standard, the label must be adjusted.

III. Establishment of Criteria for Determining Equivalency

a) Safety of Seafood

OECD member countries should use the Code of Practice for Fish and Fishery Products — developed by Codex Committee on Fish and Fishery Products — as the international criteria. In addition, the food hygiene part of code of practice for the relevant seafood commodity should be developed in compliance with General Principles of Food Hygiene and HACCP System and the guidelines for its application developed by Codex Committee on Food Hygiene.

Criteria for determining equivalency of inspection system should be developed using appropriate risk assessment. Such assessment should be based the considerations in Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICs), especially the draft guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems¹¹, Section 5 "Equivalence".

b) Quality of Seafood

Seafood quality is required by consumers not only for safety reasons but also because of demands for information about freshness, taste, form, quantity. The provision of such information can therefore promote smooth trade in seafood.

When designing the criteria for the judging "equivalency", it is important to first define what is meant by the term "equivalency" and to consider the criteria for the inspection. Such considerations should take into issues including standards established by international organisation, as well as the differences in the culture, salinity system and quality management system.

IV. Audit and Verification Methods

OECD member countries should discuss this matter based on the:

11. Draft Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (ALINORM 97/30A, Appendix 2).

- draft guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems which contained in the annex to “Guidelines on Procedures for Conducting an Assessment and Verification by an Importing Country of Inspection and Certification Systems of an Exporting Country”; and
- Proposal for Development of a Codex Guideline for the Judgement of Equivalency of Sanitary Measures Associated with Food Inspection and Certification Systems.¹²

With regard to inspection and certification bodies, it is important to utilise third party bodies when the objective is smooth trade of seafood. But there are no definite standards for evaluating the ability and defining the authority of these third parties in each country. International standards should therefore be established for inspection and bodies (e.g. ISO 9000 system).

12. Discussion paper “Proposal for Development of a Codex Guideline for the Judgement of Equivalency of Sanitary Measures Associated with Food Inspection and Certification Systems” (ALINORM 97/30A).

V. General Description of Seafood Production and Utilisation.

The trends in seafood production and consumption in Japan are evident from the following tables.

Table 1: Changes in Marine Fishery Production Volume and Value by type of Fish

Volume: 000 tonnes; Value : 00 million ¥

		1985	1991	1992	1993	1994	1995
	Total	10,877	8,511	7,771	7,256	6,590	6,007
V O L U M E	Tuna, Marlin	439	338	381	391	375	366
	Skipjack and Frigate Mackerel	339	427	350	373	324	336
	Salmon, Trout	203	215	179	230	240	282
	Sardine and Anchovy	4,198	3,466	2,649	2,028	1,505	1,016
	Japanese pilchard	3,866	3,010	2,224	1,714	1,189	661
	Jack mackerel and Scad	225	315	286	362	374	385
	Mackerel	773	255	269	665	633	470
	Saury	246	304	266	277	262	274
	Yellowtails	33	51	55	43	54	62
	Flounders, Halibuts, Soles	214	79	89	88	78	83
	Cod and pollack	1,650	590	574	445	445	395
	Alaska pollack	1,532	541	499	382	379	339
	Sea bream	26	24	25	26	25	27
	Squid and Cuttlefish	531	545	677	583	589	547
	Common squid	133	242	394	316	302	290
Other	2,000	1,904	1,971	1,745	1,684	1,765	
	Total	21,919	19,076	18,272	17,163	15,819	15,112
V A L U E	Tuna, Marlin	4,053	3,046	3,283	3,379	2,811	2,419
	Skipjack and Frigate Mackerel	872	767	723	711	677	602
	Salmon, Trout	1,254	868	1,041	1,106	736	684
	Sardine and Anchovy	1,268	1,399	1,135	944	948	1,069
	Japanese pilchard	717	798	636	435	412	454
	Jack mackerel and Scad	638	688	638	662	570	655
	Mackerel	710	438	347	451	431	425
	Saury	173	233	163	165	166	206
	Yellowtails	268	311	313	305	328	297
	Flounders, Halibuts, Soles	1,059	798	797	754	714	676
	Cod and pollack	1,506	913	790	580	542	459
	Alaska pollack	1,258	765	589	425	396	336
	Sea bream	452	383	390	361	360	333
	Squid and Cuttlefish	2,645	2,123	1,999	1,679	1,768	1,667
	Common squid	939	821	832	715	746	794
Other	7,022	7,111	6,653	6,065	5,768	5,621	

Source: Annual Statistics of Fishery and Aquaculture Production, Ministry of Agriculture, Forestry and Fisheries.

Table 2: Changes in Marine Culture Production Volume and Value by Type of Fish

Volume: 000 tonnes; Value: 00 million ¥

		1985	1991	1992	1993	1994	1995
	Total	1,088	1,262	1,306	1,274	1,344	1,315
V O L U M E	Yellowtails	151	161	149	142	148	170
	Sea breams	28	60	66	73	77	72
	Common Scallop	109	189	208	241	199	228
	Oyster	251	239	245	236	223	227
	Kelp	54	43	73	60	58	55
	"Wakame" seaweed	112	99	112	90	88	100
	"Nori" seaweed	352	403	383	363	483	407
	Others	31	68	71	70	67	56
	Total	5,225	6,407	6,126	6,069	6,270	5,739
V A L U E	Yellowtails	1,427	1,405	1,309	1,372	1,264	1,187
	Sea breams	488	723	667	656	783	755
	Common Scallop	298	395	387	374	377	380
	Oyster	304	401	421	410	427	409
	Kelp	80	135	134	145	119	92
	"Wakame" seaweed	143	182	158	136	159	164
	"Nori" seaweed	1,236	1,173	1,100	1,084	1,336	1,020
	Others	1,249	1,993	1,951	1,892	1,804	1,732

Source: Annual Statistics of Fishery and Aquaculture Production, Ministry of Agriculture, Forestry and Fisheries.

Table 3: Changes in Major Processed Fish Production

000 tonnes¹

	1985	1991	1992	1993	1994	1995
Salted Dried Products	899	909	840	844	806	831
Dried Products	37	44	42	44	46	40
Salted and Dried Products	278	259	254	247	227	233
Boiled and Dried Products	110	111	94	91	92	90
Smoked Products	15	18	14	13	12	14
Fushi ⁴	121	134	135	130	125	127
Salted Products ³	339	343	300	319	304	327
Surimi-based Products	984	874	845	830	823	801
Frozen Food	242	365	382	377	370	359
Oil and Fats Feed	1,678	1,310	1,007	947	786	673
Oil and Fats	404	315	146	107	71	47
Feed	1,275	995	861	840	715	626
Frozen Fishery Products ²	4,173	3,999	3,925	3,878	3,608	3,227
Canned	322	194	198	189	176	158

1. All figures are expressed in terms of the weight of the product. There is one exception: figures for canned fish are expressed in terms of the weight of contents.
 2. Frozen Fishery Products include products for raw materials
 3. Frozen Fishery Products include Salted and other processed products (salted and dried, surimi-based products and so on).
 4. Fushi means boiled, smoked-dried and molded fish fillet.
- Source: "Annual Statistics of Fishery Products Marketing" (Ministry of Agriculture, Forestry and Fisheries and "A time Signal of Canned" (Japan Canners Association).

Table 4: Changes in Fish and Shellfish Domestic Consumption^{1,2}

000 tonnes

	1985	1991	1992	1993	1994	1995 ³
Total	12,263 (11,464)	12,202 (9,268)	11,777 (8,477)	12,030 (8,013)	12,323 (7,325)	11,935 (6,722)
Food	8,416 (7,268)	8,277 (5,857)	8,265 (5,779)	8,464 (5,417)	8,874 (5,232)	8,904 (5,231)
Live, Fresh, Frozen	3,342 (2,100)	3,098 (1,182)	3,154 (1,159)	3,320 (1,106)	4,033 (1,123)	4,143 (1,181)
Salted, Dried, Smoked, Others	2,734 (2,620)	3,100 (2,901)	3,147 (2,883)	3,218 (2,913)	3,203 (2,819)	3,250 (2,813)
Surimi-Based Product (including fish ham and sausage)	1,983 (1,793)	1,634 (1,324)	1,535 (1,283)	1,507 (968)	1,260 (893)	1,179 (869)
Canned	357 (755)	445 (450)	429 (454)	419 (430)	378 (397)	332 (368)
Non Food	3,847 (4,196)	3,925 (3,411)	3,512 (2,698)	3,566 (2,596)	3,449 (2,093)	3,031 (1,491)
Feed(excluding feed for fisheries)	2,017 (2,372)	2,026 (1,494)	1,783 (964)	1,848 (888)	1,845 (513)	1,967 (453)
Feed for Fisheries	1,830 (1,824)	1,899 (1,917)	1,729 (1,734)	1,718 (1,708)	1,604 (1,580)	1,064 (1,038)

1. Figures are converted into raw material and do not include whale and seaweed.

2. Figures in brackets are domestic production.

3. 1995 figures are prompt provisional figures.

Source: "Balance Sheet of Food" (Ministry of Agriculture, Forestry and Fisheries) and Fisheries Agency.

Table 5: Changes Per Capita Family Purchases by Items (all Japan, all households)

Volume: gram; Value: ¥

		1985	1991	1992	1993	1994	1995
V O L U M E	Live, fresh, fish and shellfish total	14,168	13,310	14,009	14,309	13,696	13,989
	Fish subtotal	12,576	11,830	12,446	12,690	12,178	12,350
	tuna	820	883	952	952	1,016	1,059
	horse mackerel	699	683	744	768	747	740
	sardine	681	620	598	575	512	443
	skipjack	337	343	347	434	338	364
	salmon	316	510	545	669	756	828
	mackerel	525	223	246	303	392	388
	saury	746	728	785	697	673	591
	yellowtail	606	599	619	550	584	687
	squid and cuttlefish	1,438	1,515	1,624	1,513	1,368	1,336
	shrimp and prawn	688	937	985	1,020	1,004	973
	other	5,719	4,788	5,000	5,208	4,788	4,941
	Shellfish subtotal	1,592	1,480	1,563	1,619	1,518	1,638
	Salted, dried, fish and shellfish total	3,913	4,013	3,997	3,939	3,758	3,735
	salted salmon	1,030	1,005	952	860	784	731
salted cod roe	302	280	277	285	298	337	
other	2,581	2,728	2,768	2,795	2,675	2,668	
V A L U E	Live, fresh, fish and shellfish total	20,345	22,675	23,717	23,246	21,948	22,247
	Fish subtotal	18,564	20,771	21,657	21,165	20,002	20,203
	tuna	2,239	2,447	2,667	2,613	2,659	2,611
	horse mackerel	832	837	879	856	804	802
	sardine	312	399	392	366	326	313
	skipjack	575	640	689	752	613	622
	salmon	470	784	895	1,031	1,083	1,156
	mackerel	302	149	172	202	253	274
	saury	501	544	541	445	424	401
	yellowtail	1,351	1,267	1,342	1,194	1,224	1,304
	squid and cuttlefish	1,751	1,691	1,675	1,475	1,384	1,367
	shrimp and prawn	1,881	2,277	2,324	2,238	2,124	2,030
	other	8,351	9,737	10,080	9,991	9,108	9,323
	Shellfish subtotal	1,781	1,903	2,061	2,081	1,945	2,045
	Salted, dried, fish and shellfish total	7,337	7,994	8,055	7,620	7,060	6,935
	salted salmon	1,978	1,839	1,771	1,480	1,219	1,080
salted cod roe	970	1,090	1,165	1,203	1,165	1,256	
other	4,390	5,065	5,119	4,937	4,675	4,600	
Surimi-based products	3,460	3,784	4,006	3,840	3,641	3,578	
Other	3,925	4,760	4,860	4,648	4,297	4,179	

Source: "Annual Report on the Family Income and Expenditure Survey", Management and Coordination Agency.

Table 6: Changes in Fishery Product Import Volume and Value by Principal Item

Quantity: 000 tonnes; Value: 00 million ¥

		1985	1991	1992	1993	1994	1995
V O L U M E	Fishery Products Total	786	588	435	385	296	240
	Fish, fresh, chilled or frozen	135	274	268	257	203	159
	Skipjack and Frigate mackerel	33	88	54	57	26	45
	Tuna, Marlin	15	31	48	45	41	37
	Saury	19	38	67	61	41	18
	Fish, Salted, dried or smoked	2	1	1	1	1	1
	Crustacean, Mollusc	15	13	16	17	17	20
	Canned	165	35	28	26	21	11
	Mackerel	59	14	12	11	9	5
	Sardine	69	16	13	11	9	4
	Skipjack	21	3	2	2	1	1
	Tuna	13	2	1	1	1	1
	Fish oil	250	116	45	13	4	3
	Pearl(tons)	213	95	110	84	71	50
	Others	218	148	77	71	50	46
	Surimi-based product	45	16	13	10	10	7
Fish meal	157	113	44	41	21	19	
V A L U E	Fishery Products Total (A)	2,876	1,725	1,632	1,347	1,232	1,108
	Fish, fresh, chilled or frozen	356	380	390	323	294	248
	Skipjack and Frigate mackerel	43	88	42	46	22	35
	Tuna, Marlin	54	81	134	108	100	80
	Saury	33	32	48	35	26	16
	Fish, Salted, dried or smoked	37	30	31	22	21	22
	Crustacean, Mollusc	214	106	89	87	96	90
	Canned	568	122	96	86	61	36
	Mackerel	157	44	37	32	23	12
	Sardine	146	39	34	26	21	11
	Skipjack	130	15	10	11	8	4
	Tuna	108	15	9	9	5	4
	Fish oil	146	42	24	16	10	9
	Pearl (tons)	826	512	528	431	415	390
Others	729	532	474	383	335	313	
Surimi-based product	312	99	91	63	57	43	
Fish meal	150	112	43	30	13	10	
Total Value of Japan's Imports (B)		419,557	423,599	430,123	402,024	404,976	415,309
(A) / (B) (%)		0.7	0.4	0.4	0.3	0.3	0.3

Source: "Japan Trade Statistics", Ministry of Finance.

Table 7: Changes in Fishery Product Import Volume and Value by Principal Item

Quantity: 000 tonnes; Value: 00 million ¥

		1985	1991	1992	1993	1994	1995
	Fishery Products Total	1,577	2,853	2,971	3,124	3,296	3,582
	Live, fresh, chilled or frozen	1,314	2,278	2,344	2,505	2,530	2,540
	Shrimp and Prawn	192	308	294	317	320	312
	Tuna, Marlin	151	258	273	304	298	306
V	Salmon, Trout	116	153	173	229	243	203
O	Crab	34	115	121	110	124	121
L	Cod and Pollack	112	205	273	189	214	216
U	Octopus	99	113	123	131	106	98
M	Squid and Cuttlefish	113	98	101	98	116	86
E	Flounder, halibuts, sole		101	77	82	86	71
	Salted, dried or smoked	42	40	43	45	44	42
	Hard rose of herring	8	10	10	10	9	8
	Hard rose of salmon	10	9	9	10	11	11
	Prepared	64	139	150	162	193	224
	Eel	14	34	36	38	39	36
	Others	158	396	434	412	529	776
	Fish Meal	79	282	331	302	379	588
	Fishery Products Total (A)	11,760	16,881	16,803	16,276	17,091	17,212
	Live, fresh, chilled or frozen	9,659	13,698	13,574	13,074	13,710	13,593
	Shrimp and Prawn	3,386	4,129	3,651	3,595	3,753	3,686
	Tuna, Marlin	860	1,475	1,690	1,893	1,865	1,819
	Salmon, Trout	1,166	1,015	1,299	1,186	1,313	995
V	Crab	335	931	969	991	1,229	1,278
A	Cod and Pollack	265	698	831	417	471	487
L	Octopus	552	639	528	430	435	499
U	Squid and Cuttlefish	649	470	456	468	570	470
E	Flounder, halibuts, sole		361	266	259	261	239
	Salted, dried or smoked	843	584	614	568	516	527
	Hard rose of herring	312	216	205	196	168	173
	Hard rose of salmon	190	151	159	152	157	142
	Prepared	746	1,659	1,739	1,876	2,009	2,199
	Eel	325	691	746	850	872	863
	Others	513	941	876	759	856	893
	Fish Meal	80	224	260	181	202	329
	Total Value of Japan's Imports (B)	310,849	319,002	295,274	268,264	281,043	315,488
	(A) / (B) (%)	3.8	5.3	5.7	6.1	6.1	5.5

Source: "Japan Trade Statistics", Ministry of Finance.

**APPROVAL STANDARD OF COMPREHENSIVE FOOD SAFETY CONTROLLED
MANUFACTURING PROCESS)**

I. Required document preparation

A. Each applicant shall give a full description of the product, including product name (common name), product group names, ingredients, and other pertinent information.

B. Each applicant shall prepare a flow diagram, including manufacturing or processing steps and procedures, with the performance of the equipment and utensils used during manufacturing or processing.

C. Each applicant shall prepare a plant schematic, including construction and design of the facilities, placement of equipment and utensils, product flow, and other pertinent information..

II. Each applicant shall properly identify preventative measures that can be used during manufacturing or processing steps to control food safety hazards; and monitoring systems which can detect control failure at each CCP as follows:

A. Identify food safety hazards which reasonably likely to occur for each product: identify the step/procedure where those hazards must be controlled, and describe preventative measures which can be used at each step/procedures. If an applicant believes that any hazard listed on attached table will never occur, the reasons shall be clearly documented.

B. Of the preventative measures identified according to paragraph A, each applicant shall identify those which must be monitored continuously; or more frequently if continuous monitoring is not possible .

C. Establish monitoring procedures to ensure compliance within critical limits.

- III. Each applicant shall establish all necessary corrective action plans to be followed when monitoring results indicate implementation of preventative measures is not adequate, suggesting loss of control at CCP. All corrective action taken shall be fully documented in the records.**

- IV. Each applicant shall establish written sanitation control procedures, including sanitary control for facilities, equipment and utensils, education/training for workers, exclusion of pests from food plant, control of employee health conditions and other necessary items.**

- V. Each applicant shall establish written verification procedures and plans to ensure that the Comprehensive Sanitation - Controlled Manufacturing Process system is working correctly.**

- VI. Each applicant shall establish record keeping and documentation methods for following records:**
 - A. Monitoring results
 - B. Corrective action
 - C. Sanitation control procedure
 - D. Verification results

- VII. Each applicant or designated representative, shall be responsible for the following manufacturing controls:**
 - A. Review of preventative measures and monitoring results, and maintenance of complete and accurate record of the results
 - B. Maintenance and calibration of process-monitoring instrument, and maintenance of complete and accurate record of the results
 - C. Other necessary duty

- VIII. Each applicant or designated representative, shall be responsible for the following sanitary controls:**
 - A. Performance of periodic raw material, in-process, or end-point testing
 - B. Maintenance and calibration of equipment/utensils used for testing, as prescribed in paragraph A , and maintenance of complete and accurate record of the results
 - C. Other necessary duty

September 30, 1996.

Einyu No. 223

To each Prefectural Governor
mayor of a city designated by ordinance
chief of a special ward

The Director-General of
the Environmental Health Bureau of
the Ministry of Health and Welfare

Approval for Production Processes Subject to Comprehensive Hygiene Controls

Standards for approving foods requiring approval for production processes subject to comprehensive hygiene controls are provided for by the Partial Amendment to the Food Hygiene Law and the Nutritional Improvement Law (Law No. 101, 1995) by the Government Ordinance on Enforcement of Partial Amendments to the Food Hygiene Law (Law No. 109, 1996) and the Ministerial Ordinance on Enforcement Regulations of Partial Amendment of the Food Hygiene Law (Ministerial Ordinance No. 33, 1996) and other laws. Each prefectural governor, mayor of a city designated by ordinance and chief of a special ward have been informed of the Ministerial Ordinance on Enforcement Regulations of Partial Amendment to the Food Hygiene Law and Other Laws by the Notice entitled, "Enforcement of Government Ordinances on Partial Amendment of the Food Hygiene Law and Other Laws" (EISHOKU No. 135, May 23, 1996).

The approval system mentioned here is a food hygiene control method based on the HACCP (Hazard Analysis and Critical Control Point) System, used in food production facilities overseas, which has been introduced for the first time in Japan.

The HACCP System is a system which aims to ensure the safety of products at all stages in the manufacturing and processing of foods, by taking intensive care of points requiring comprehensive control and keeping detailed records on their management. In order to smoothly introduce the above food hygiene control methods into food manufacturing and processing facilities in Japan, it is necessary that food hygiene inspectors in each prefecture, designated city or special ward, provide proper advice and guidance to operators of such facilities and check that appropriate controls are employed in production processes.

For this reason, we have provided the Gist of Enforcement of the Approval System on Comprehensive Hygiene Controls on Production Processes as attached hereto. We request that you operate the system in the proper manner.

(Schedules)

GIST OF ENFORCEMENT OF THE APPROVAL SYSTEM ON COMPREHENSIVE HYGIENE CONTROLS ON PRODUCTION PROCESSES

1. Purpose

The Gist stipulates clerical work to be conducted by the Ministry of Health and Welfare (hereafter the Ministry) and prefectures (including cities designated by ordinance and special wards) and application procedures to be followed by operators of food manufacturing and processing facilities with regard to approval of production processes subject to comprehensive hygiene controls (hereafter "Approval") as specified in Article 7-3 of the Food Hygiene Law (Law No. 233, 1947; hereafter "the Law.").

2. Outline

(1) Any operator of food manufacturing and processing facilities who desires to obtain an Approval shall apply to the Minister of Health and Welfare, submitting the application forms specified in Article 4-2 of the Enforcement Regulations and Article 4 of the Ministerial Ordinance on Ingredients and Standards for Milk and Dairy Products (hereinafter referred to as the "Ministerial Ordinance on Milk") together with documents as specified in Article 4-2-(2) of the Enforcement Regulations and Article 4-2 of the Ministerial Ordinance on Milk.

(2) The Ministry shall check documents so submitted to ensure that the manufacturing and processing methods and hygiene control methods in production processes subject to comprehensive hygiene controls described by the operator making the submission, conform to the standards stipulated in Article 4 of the Enforcement Regulations or Schedule 3 of the Ministerial Ordinance on Milk, and shall notify the operator of its decision.

(3) Each prefecture shall check that any production processes subject to comprehensive hygiene controls for which Approval has been granted are actually being operated.

(4) The Ministry and each prefecture shall provide operators with technical support so that they can implement food manufacturing and processing methods and hygiene control methods in production processes subject to comprehensive hygiene controls for which Approval has been granted.

(5) Operators shall receive training for and endeavour to acquire knowledge about the HACCP System so that they can implement food manufacturing and processing methods and hygiene control methods in production processes under comprehensive hygiene controls.

3. Standards for the Approval

The details of the approval standards of this system stipulated in Article 4 of the Enforcement Regulations and in Article 3 of the Ministerial Ordinance on Milk are stipulated in Schedule 1.

4. Preparation of Application

Any operator who has adequate knowledge of the HACCP System and desires to obtain Approval shall prepare an application for production processes subject to comprehensive hygiene controls taking account of the following:

(1) Organisation of an Expert Team

Any operator seeking Approval shall organise a team of specialists with expertise in hygiene controls (hereinafter referred to as an "Expert Team"). The Expert Team shall play a key role in organising production processes subject to comprehensive hygiene controls.

The Expert Team shall be comprised of people who are acknowledged as having above average knowledge of the HACCP System.

(2) Advice of food hygiene inspectors in each prefecture

When preparing an application for Approval for production processes subject to comprehensive hygiene controls, operators shall be subject to food hygiene inspectors in the prefecture having jurisdiction over their facilities, (hereinafter the "prefecture controlling the facilities.")

(3) Inspection

Operators shall test their production processes subject to comprehensive hygiene controls to ensure food hygiene standards are not compromised.

5. Application procedures, etc.

The details of application procedures for gaining Approval specified in Article 4-2 of the Enforcement Regulations and in Article 4 of the Ministerial Ordinance on Milk are as follows:

(1) Application procedures

(a) An application form in form No. 1.

(b) An operator desiring to obtain approval shall send or submit in person properly completed in application forms to the Veterinary Sanitation Division for milk and meat processing, or to the Food Sanitation Division for the processing of other foods.

Applications shall be sent by registered mail and the words "Application for production processes under comprehensive hygiene controls" shall be written in red ink on the front of the envelope containing said application.

(c) Applications shall be prepared in duplicate ((by each facility)) and according to each food category.

- (d) An application fee shall be paid and a revenue stamp corresponding to that amount shall be affixed to the original application as prescribed in Article 1-2 of the Enforcement Regulations.

(2) *Attached Documents*

The documents to be attached to applications stipulated in Article 4-2 of the Enforcement Regulations and in Article 4 of the Ministerial Ordinance on Milk are specified in ((Schedule 2))

(3) *Applications by foreign operators*

A foreign operator who desires to obtain approval shall appoint a person responsible for the application (hereinafter the "Person Responsible,") whose name shall be written in the applicant's column of the application form.

6. Examination

(1) *Processing on applications*

The Ministry shall check whether manufacturing and processing methods and hygiene control methods in production processes subject to comprehensive hygiene controls described in the documents submitted with the application, conform to the standards stipulated in Article 4 of the Enforcement Regulations or in Schedule 3 of the Ministerial Ordinance on Milk, by referring to the criterion specified in Schedule 1.

(2) *Opinion of the special panel*

The Ministry may ask for an opinion on technical matters related to the Approval, from a panel comprised of people with experience or academic standing established within the Environmental Health Bureau.

(3) *On-site inspection*

- (a) Before granting Approval the Ministry, in co-operation with the prefecture which has jurisdiction over the facilities as the case may be, shall conduct an onsite inspection to verify the contents of the application under consideration or the records of test results.
- (b) The Ministry may commission the prefecture with jurisdiction over the facilities to conduct an onsite inspection to verify the contents of applications and submit a report as the case may be.
- (c) In the case of applications by foreign operators, after consulting with the government of the country of the foreign operator who is exporting goods to Japan, (hereinafter referred to as an "export country") the Ministry shall conduct an onsite inspection of the relevant facilities or commission the government of said export country to do so.

7. Approval

(1) *Grant of a Letter of Approval*

Where the Ministry approves food manufacturing and processing methods for production processes under comprehensive hygiene controls, it shall grant the applicant a Letter of Approval.

In the case of a foreign operator, the Letter of Approval shall be granted through the Person Responsible or the government of the export country.

(2) *Notification of the detail of approval*

The Ministry shall send duplicates of each submitted application and a copy of the Letter of Approval to the prefecture controlling the food production facilities for which the Approval has been granted.

(3) *Approval for foreign operators*

Where the Approval granted relates to a foreign operator, the Ministry shall notify the details of the Approval to each quarantine station.

8. Clerical work after the Approval

(1) *Supervision and guidance*

When the prefecture, which has jurisdiction over the facilities to which Approval was granted, conducts an inspection of said facilities under Article 17 of the Law, it shall ascertain that the approved production processes under comprehensive hygiene controls are actually being implemented.

Where the prefecture finds that the operator of said facilities is involved in production which does not comply approved production processes under comprehensive hygiene control at all, or has altered a part of the facilities without obtaining prior approval, the prefecture shall notify the Ministry.

(2) *Revocation of Approval*

Where the Ministry determines that any operator's actions come under Article 7-3-(5) of the Law, it shall revoke the Approval and notify the operator and the prefecture with jurisdiction over the said operator's facilities, to that effect.

9. Application Procedures for Alteration

Any operator desiring to alter any of the matters specified in Schedule 3 herein regarding approved production processes under comprehensive hygiene controls pertinent to Article 4-2 of the

Enforcement Regulations or Schedule 3-(12) of the Ministerial Ordinance on Milk, shall make an application for alteration which requires the following:

(1) *Observance of application procedures*

- (a) Submission of an application for alteration in form No. 2.
- (b) For other matters 5-(1) mentioned above shall be apply.

(2) *Accompanying documents*

The documents to be attached to an application as stipulated in Article 4-3 of the Enforcement Regulation and in Article 5 of the Ministerial Ordinance on Milk are specified in Schedule 4.

(3) *Notification of alteration*

Where an operator has altered any matters other than those specified in Schedule 3, he is not required to make an application for alteration, but he shall promptly notify the Ministry and a public health centre of the prefecture with jurisdiction over his facilities to that effect.

10. Attendance at lectures

(1) Food hygiene inspectors in the prefecture with jurisdiction over relevant facilities shall attend lectures sponsored by the Ministry, and provide operators with proper supervision and advice regarding production processes subject to comprehensive hygiene controls.

(2) Operators are required to acquire the necessary skills and knowledge about food hygiene, so that they may implement food manufacturing and processing methods and hygiene control methods for production processes subject to comprehensive hygiene controls, and each prefecture shall keep operators under their jurisdiction well informed of the above.

11. Other

(1) *Advice to operators*

When fielding inquiries from operators about production processes subject to comprehensive hygiene controls, each prefecture shall provide them with best available advice.

(2) *Responsibilities of Operators*

Operators shall endeavour to acquire the necessary knowledge regarding hygiene controls under the HACCP System.

Operators shall form an organisation in efforts to upgrade hygiene controls on a self-management basis, and to provide assistance to members by holding seminars on hygiene control under the HACCP System and provide information to operators in general as well as to consumers.

SCHEDULE 1 - APPROVAL STANDARDS

1. Product descriptions

Product descriptions shall include the following items specified in Article 4-1-(a) of the Enforcement Regulations and Schedule 3-1-(1) of the Ministerial Ordinance on Milk:

- (a) name and category of product
- (b) description of raw materials
- (c) names and levels of additives (limited to additives for which standard levels are fixed)
- (d) shape and quality of container and package (limited to cases where special care is required in setting up control standards at concentrated control points to ensure hygienic conditions)
- (e) character and quality (limited to cases where special care is required in setting up control standards at concentrated control points to ensure hygienic conditions.)
- (f) product standards
- (g) best taste period or quality retention period and preservation method (limited to cases where special care is required in setting up control standards at concentrated control points to ensure hygienic conditions.)
- (h) method of consumption (limited to cases where special care is required in setting up control standards at concentrated control points to ensure hygienic conditions)
- (i) targeted consumer level (limited to cases where special care is required in setting up control standards at concentrated control points to ensure hygienic condition)

2. Documents related to manufacturing and processing operations

A. Documents related to manufacturing and processing operations as specified in Article 4-1-(b) of the Enforcement Regulations and Schedule 3-1-(2) of the Ministerial Ordinance on Milk shall describe the following:

- (a) manufacturing and processing operations
- (b) information on the performance of machinery and tools
- (c) details of work, hours of work and job titles of workers involved in each process
- (d) specifications of machinery and tools (limited to cases where they are required to monitor hygienic conditions are maintained.)

B. The documents shall be precise, and written after manufacturing and processing operations in use at the workshop have been checked.

3. Drawings of facilities

A. Drawings of facilities as specified in Article 4-1-(c) of the Enforcement Regulations and Schedule 3-1-(3) of the Ministerial Ordinance on Milk shall describe the following:

- (a) structure of facilities and equipment
- (b) transport routes of products
- (c) position of machinery and tools
- (d) positions of workers on duty and wiring
- (e) classification of workshop area according to sanitary levels (for a highly sanitary zone, this includes levels of air cleanliness and pressure)

B. The drawings shall be precise and they shall be made after the workshop in operation has been examined.

4. Identification of harmful materials

A. When identifying materials which are unhygienic pursuant to Article 4-2 of the Enforcement Regulations and Schedule 3-2 of the Ministerial Ordinance on Milk, all potential dangers likely to occur in manufacturing or processing operations should be listed on scientific grounds

B. Unhygienic materials listed under A above, shall include all those materials which are unhygienic according to the category of foods as specified in Schedule 2-2 of the Enforcement Regulations and the table in Schedule 3-2-(1) of the Ministerial Ordinance on Milk (hereinafter referred to as the "table,") except where data regarding the risk to health for raw materials reveals that no materials capable of causing any such danger are contained.

5. Measures adopted against risk to health

A. Measures to be adopted against health hazard as specified in Article 4-2 of the Enforcement Regulations and Schedule 3-2 of the Ministerial Ordinance on Milk, should be appropriate for each material and each process where health hazard is likely to occur.

B. Measures specified in A above include measures which require consecutive or fairly frequent inspections for their implementation. Such measures shall satisfy the following requirements:

- (a) They shall be measures taken at processing points which require the most concentrated control (concentrated control points) so as to ensure hygienic conditions are maintained.
- (b) They should be measures providing control standards to prevent danger to hygiene occurring, in the light of acceptable levels of harmful materials. As a general rule, control standards should include indicators which promptly show the effectiveness or otherwise of measures taken at concentrated control points to prevent danger to hygiene.
- (c) They should monitor that control standards requiring implementation consecutively or fairly frequently are being so implemented. Any deviation from the control standards should be indicated by the above without delay.

(d) They shall be measures which are clearly effective in preventing health hazards.

C. In the case of monitoring methods under B-(c) above, which monitor the frequency of measures implemented, a person in charge of the monitoring and a method of recording should be established. Frequency of monitoring should be sufficient to prevent health hazards.

6. Rectification measures

A. Rectification measures specified in Article 4-3 of the Enforcement Regulations and Schedule 3-3 of the Ministerial Ordinance on Milk shall satisfy the following requirements:

(a) They should be able to indicate the factors necessary for conditions to return to normal when a monitored value deviates from the control standards.

(b) They should include methods for the proper disposal of products.

(c) Persons responsible for implementing rectification procedures and recording methods should be established.

B. Rectification measures for each item mentioned in (5)-8 should be provided for.

7. Methods of sanitation control

A. Methods of sanitation control as stipulated in Article 4-4 of the Enforcement Regulations and Schedule 3-4 of the Ministerial Ordinance on Milk shall specify details of work, frequency, persons responsible, checks requiring implementation and records taken for each of the following:

(a) sanitation controls for facilities and equipment

(b) hygiene education for workers

(c) maintenance and repairs of facilities, equipment, machinery and tools

(d) measures for prevention of harmful insects entering and for their extermination

(e) sanitation controls for water to be used

(f) sanitation controls concerning drainage and waste disposal methods

(g) sanitation controls for workers

(h) sanitary handling of foods

(i) methods of collecting products

(j) repairs and maintenance of machinery and tools used for testing and inspecting products.

B. Verification

1) Methods of verification as stipulated in Article 4-5 of the Enforcement Regulations and Schedule 3-5 of the Ministerial Ordinance on Milk shall cover the following items to verify that health hazards are prevented:

(a) maintenance and repairs of machinery and tools used for testing and inspecting products (including adjustment of instruments)

- (b) inspections of records on implementation of monitoring systems, rectification measures and sanitation controls for facilities and equipment
 - (c) adjustment of measuring equipment used at concentrated control points
 - (d) (analysis of causes of claims and collection)
 - (e) periodical review of implementation plans
- 2) Each item mentioned above should include details on implementation, including the frequency of such implementation and persons responsible for said implementation.
- 3) The records of test results of products should verify that food manufacturing and processing methods, and sanitation control methods are properly implemented.

9. Records

Methods of recording and periods and methods of retention for items specified in Article 4-6 of the Enforcement Regulations and Schedule 3-6 of the Ministerial Ordinance on Milk shall satisfy the following requirements:

- A. A recorder should be identified as responsible for recording methods, and amendments to records should be clearly identified.
- B. Records of methods of retention should be kept in easily accessible places, the period of retention should be more than one year (for products for which the quality retention period exceeds one year, a period of retention exceeding this is required.)

10. Management system

Management systems for items as specified in Article 4-7 and 8 of the Enforcement Regulations and Schedule 3-7 and 8 of the Ministerial Ordinance on Milk shall include the following:

- A. Systems for guiding workers, evaluating inspection results and properly handling inspections by outsiders so that the monitoring measures for production processes under comprehensive hygiene controls laid down mainly by an operator, the head of facilities, the head of the division related to quality control (including tests and inspections) of raw materials and products, and the head of any division related to management of manufacturing and processing operations, can be properly implemented.
- B. Persons responsible for duties in (5) to (9) above, and the persons in charge of performing such work, must be specified in advance.

SCHEDULE 2 - DOCUMENTS TO BE ATTACHED TO APPLICATIONS

- A. Product descriptions**
- B. Documents related to manufacturing and processing operations**
- C. Drawings of facilities**
- D. Documents describing the following with respect to the identification of materials likely to cause health hazards:**
 - (a) documents specifying materials which are likely to cause health hazards, each process where such materials are used and measures for determining whether health hazard has occurred
 - (b) where no potentially harmful materials are contained, the reasons therefor.
- E. Documents detailing measures against health hazards describing the following with regard to measures which are required to be implemented consecutively or fairly frequently:**
 - (a) concentrated control points and control standards at such points
 - (b) methods for monitoring control standards
 - (c) effectiveness of measures for prevention of health hazards
- F. Documents specifying rectification measures implemented at times when values monitored deviate from control standards for the concentrated control point.**
- G. Documents related to methods of sanitation control**
- H. Documents related to inspections**
- I. Documents related to recording methods**
- J. Documents related to test results for products examined in inspections**

SCHEDULE 3 - MATTERS REQUIRING APPROVAL FOR ALTERATION

- A. Measures adopted for the prevention of health hazards**
- B. Concentrated control points**
- C. Control standards at concentrated control points and methods for monitoring such standards.**

SCHEDULE 4 - DOCUMENTS TO BE ATTACHED TO AN APPLICATION FOR ALTERATION

- A. Any documents required for alterations specified in A to I of Schedule 2 (these must contain a comparison of the original and the altered part)**

- B. Documents related to test results of products examined in inspections after Approval.**

Form No. 1

Date, 199

To the Minister of Health and Welfare

Applicant's address (for a corporate body, the location
of the principal place of business must be shown)
Applicant's name (for a corporate body, the trade name
and the names of representatives)
Applicant's date of birth

Applications for Food Manufacturing and Processing
for Production Processes Subject to Comprehensive Hygiene Controls

I, the applicant, hereby seek to obtain approval for food manufacturing and processing for production processes subject to comprehensive hygiene controls pursuant to Article 7-3-(1) of the Food Hygiene Law by means of the following:

1. Product categories
2. Name and location of manufacturing and processing facilities
3. Outline of production processes subject to comprehensive hygiene controls
4. Documents attached hereto

This form is JIS No. A-4

Form No. 2

199

To the Minister of Health and Welfare

Applicant's address (for a corporate body, the location
of the principal place of business must be shown)
Applicant's name (for a corporate body, the trade name
and the names of representatives)
Applicant's date of birth

Application for Partial Alteration of Food Manufacturing
and Processing in Production Processes Subject to Comprehensive Hygiene Controls

I, the applicant, hereby seek to obtain approval for partial alteration to food manufacturing and processing for production processes subject to comprehensive hygiene controls pursuant to Article 7-3-(1) of the Food Hygiene Law by means of the following:

1. Product categories
2. Name and location of manufacturing and processing facilities
3. Outline of production processes subject to comprehensive hygiene controls
4. Documents attached hereto

This form is JIS No. A-4

KOREA

THE FISHERY PRODUCTS INSPECTION SYSTEM IN KOREA

by Kim Sung Chae, National Fisheries Products Inspection Station, Korea

I. Introduction

There is a vast variety of sea creatures located in the waters surrounding the Korean Peninsula. Fishery products have traditionally been among the most popular food in Korea, and they constitute a major source of protein in the Korean diet.

Korea's rising prominence in the world fishery industry is demonstrated by an annual fish catch of 3.3 million tonnes, fishery products export revenues amounting to US\$1 635 billion and fishery products imports totalling US\$1.08 billion. The total amount of supply-demand for fisheries products was 2.5 million tonnes in 1980, and it steadily increased to reach 4.7 million metric tons in 1995. In 1995, annual seafood consumption per capita was 34.4 kg in fish and shellfish, and 11.6 kg in seaweed. In the same year, production of processed fishery products, which includes frozen products, fish paste, and seaweed products, amounted to 1 692 million tonnes,

In view of these developments, the further improvement of the fishery products inspection system has become one of our most critical concerns, as we seek to continually ensure seafood safety and enhancement of consumer health and hygiene.

The main objective of this paper is to improve the reader's understanding of the history and function of the National Fisheries Products Inspection Station, and to provide an overview of standards related to the inspection system in Korea.

II. Inspection Trends

Fishery products for export

Since the establishment of the Fisheries Products Inspection Law, the National Fisheries Products Inspection Station (NFPIS) has carried out compulsory inspection for all export-oriented fishery products. Its records show that the quantity of goods inspected increased from 34 551 tonnes in 1965 to 43 292 metric tonnes in 1970, and from 185 075 tonnes in 1975 to 203 975 tonnes in 1985. This last

figure is approximately six times the figure for 1965. In 1987, inspection volume reached a peak at 322 628 tonnes.

These numbers may be attributed to the reputation for high quality enjoyed by Korean fishery products throughout the world market. This reputation results from processors' own efforts to enhance product quality, and from stringent inspection by the NFPIS, together with the continuing development of processing and manufacturing technology.

However, due to the recent shift from across-the-board obligatory NFPIS inspection to a largely self-regulated quality control system, inspection volume for these export-oriented fishery products is decreasing: 119 617 tonnes was inspected in 1993; 69 436 metric tons in 1996. Under this self-regulated system, processors and manufacturers have redoubled their efforts to improve product hygiene and quality. With the introduction of this self-regulatory inspection system in April 1993, the number of items for which NFPIS inspection was mandatory was reduced to 31. This number was readjusted to 13 items in October 1994.

The new self-regulatory system notwithstanding, the NFPIS continues to carry out inspections requested by importing countries, and endeavours to ensure the hygienic safety of all Korean fishery products.

Fishery products for import

The inspection of imported fishery products was previously carried out by the Ministry of Health and Welfare in accordance with the Food Sanitation Law. With the revision of regulations in December 1993, the NFPIS became responsible from January 1994 for the examination of fishery products not containing additives.

Accordingly, NFPIS inspection volume in this category increased from 262 000 tonnes in 1994 to 263 000 tonnes in 1995 and to 376 000 tonnes in 1996.

Fishery products for domestic consumption

The Ministry of Health and Welfare and local governments carry out inspections for fishery products processed, manufactured, and distributed domestically, in accordance with the standards stipulated by the Food Sanitation Law.

The NFPIS of the Ministry of Maritime Affairs and Fisheries is responsible for the safety inspection of fishery products which are produced in aquaculture areas or at the point or eventual distribution, and which will be used as raw materials for finished products.

III. Inspection Agency

History and functions

The first official fisheries products inspection began in 1908; these were conducted on seaweed products. Since then, the variety of items subject to inspection has increased to include such products as dried laver and canned fish. Indeed, the inspection system itself has undergone a number of changes since

1933, when the first full-scale inspection was executed by the Fisheries Products Inspection Station. The FPIS became part of the Ministry of Trade and Industry in June 1949 as the Central Fisheries Products Inspection Station (CFPIS). Following an amendment to the Government Organisation Law, the CFPIS was transferred to the Ministry of Agriculture and Forestry in October 1961.

However, with the inauguration in March 1966 of the National Fisheries Administration, the CFPIS became part of the new body as a result of the government organisation improvement measures in November 1981. Its name was changed to the National Fisheries Products Inspection Station at that time. The new Ministry of Maritime Affairs and Fisheries (MOMAF) brought under one administrative body the function of the Fisheries Administration and of the Maritime and Port Administration in August 1996. The NFPIS now operates under the authority of MOMAF.

The NFPIS has three divisions of general affairs, inspection and analysis divisions, and eleven regional inspection stations. There are a total of 205 employees, 135 of whom are inspection specialists, 43 of whom are technicians, and 27 of whom are administrative staff members. Each station is equipped with the modern inspection equipment necessary for effective execution of tasks on a regional level.

The functions of the NFPIS may be divided into three parts. The primary function of this agency is to execute inspections through eleven branch offices in order to assure food safety for consumers by preventing pollution and deterioration of fishery products from harmful substances. The second is to provide technical guidance for the production of sanitary fishery products of high quality. Lastly, the NFPIS dispatches inspection officials to special domestic institutes and to advanced nations for the acquisition of high technology. The agency regularly updates equipment to facilitate the most sophisticated inspection practices possible.

Items subject to inspection

The eleven branches of the NFPIS carry out inspections of fishery items for export and import, including fishery items produced in Korea for domestic consumption.

Products for export

Up until 1992, in accordance with the Fisheries Products Inspection Law, all fishery products for export were subjected to inspection. However, since 1993, only the items designated by MOMAF for inspection (obligatory inspection items), and those designated by importing countries for inspection (desired inspection items) have been subjected to inspection, in line with developments in fish processing technology.

Products for import

In accordance with the Food Sanitation Law, the NFPIS inspects imports of raw materials and simply-processed products such as live fish and shellfish, as well as products that are fresh, chilled, frozen, salted, smoked, or dried, such as processed seaweeds and agar-agar. The Korea Food and Drug Administration and the National Quarantine Station, which are under the Ministry of Health and Welfare, inspect highly-processed products such as canned fish, fish meat paste products, and seasoned products. There are two types of inspection for imported fishery products.

The NFPIS engages in three different kinds of inspection for fishery products: paper inspection, physical inspection, and precision inspection. The use of each depends upon import purpose, inspection history, product country of origin, type of processing and product or species.

Paper inspection involves the examination of all import documents, after which a decision is made concerning importation. Physical inspection involves the examination of product state, taste, smell, and relevant data from precision inspection. Precision inspection is carried out using chemical, microbiological and physical methods.

The NFPIS has reduced the use of precision inspection and increased the use of paper inspection in order that the freshness of goods might not be compromised by the time involved in the inspection process. If goods are determined to present a danger to consumers, the agency is authorised to take measures such as recalling or destroying items.

Inspection methods

In accordance with the Fisheries Products Inspection Law and the Food Sanitation Law, the NFPIS samples among inspection objects and inspects as follows:

- Physical inspection: Product state, taste, smell, colour, markings and packaging state are inspected by an inspection official;
- General analysis: Goods are inspected for moisture, salt, crude protein, crude ash, and foreign substances;
- Microbe analysis: Goods are inspected for the presence of living microbes, *salmonella*, *staphylococcus aureus*, *enteritis Vibrio* microbes, *Vibrio cholera* microbes, and *Listeria*;
- Residual heavy metals: Goods are inspected for the presence of residual amounts of harmful heavy metals such as mercury, lead, cadmium, arsenic, and zinc;
- Radioactivity contamination: Goods are inspected for the presence of radioactive nuclear substances such as $^{134}\text{C}_s + ^{137}\text{C}_s$ and ^{131}I ;
- Antibiotic residuals: Goods are inspected for the presence of residual amounts of antibiotics such oxytetracycline, and synthetic disinfectants such as oxolinic acid;
- Natural toxins: Goods are inspected for the presence of paralytic shellfish poison, laxative shellfish poison, tetrodotoxin, and other substances;
- Parasites: Goods are inspected for the presence of gnathostoma spinigerum and other parasites; and
- Other items: Goods are inspected for the presence of chemical synthetics harmful to the human body (see Annex I).

IV. Shellfish Sanitation Control

In November 1972, the Korean and United States governments concluded an agreement concerning shellfish sanitation control. Since that time, this control has been observed to be steadily improving. The principles comprising the US shellfish sanitation programme, adjusted by the United States Public Health Service, were applied to the production and handling of all fresh and frozen oysters, clams, and mussels intended for shipment between the two countries. The standards, criteria, and guidelines promulgated by the shellfish sanitation programme were incorporated into the relevant sanitary regulations of Korea. The authority concerned has been regularly monitoring shellfish production areas and handling facilities.

For the smooth operation of the agreement, the Ministry of Maritime Affairs and Fisheries applies regulations governing sanitary control of shellfish and their growing areas, and the harvesting and processing of shellfish products for export. The key component of the regulations involves the formal designation of four areas (totalling 20 438 hectares) specifically for the purpose of growing shellfish. In these areas, contamination-level surveys are conducted for various micro-organisms, coliform groups, faecal coliform, pH, DO, and COD.

Surveys are carried out more than 12 times per year on 18 survey points in this category. There are also regular examinations for marine biological toxins such as PSP, ASP, and DSP. In fact, exams are conducted continually throughout the year on 19 survey points in this category. If survey results reveal excessive levels of any of the substances in question, then shellfish harvesting is prohibited.

Those wishing to process shellfish must be registered by MOMAF. Ministry policy outlines equipment standards and sanitary requirements for shellfish processing establishments according to the location of plant or construction facility. The Ministry has also established boat sanitation requirements pertaining to the catching and handling of shellfish, shellfish processing standards, sanitary standards for personnel, quality standards for shellfish products, oyster-seed inspection standards, and inspection standards for exported frozen oysters.

The observance and operational development of the shellfish sanitary agreement over the past twenty five years has made a great contribution to the maintenance of clean areas for growing shellfish through proper management of designated areas. The agreements has also made a significant contribution to the enhancement of product quality and food safety through hygienic management of processing plants, maintenance of skilled staff, and efficient shellfish shucking and storing. The agreement has also resulted in strict inspection applied in relation to shape, colour, odour, selection, foreign matter, viable cell counts, pH levels, deleterious substances, free ammonia, and faecal coliform.

V. Observance of the EU Commission Decision

In October 1995, the EU Commission adopted special conditions for the control of imported fishery products from Korean fishing and aquacultural enterprises.

In the case of shellfish products such as live bivalve molluscs, echinoderms, tunicates, and marine gastropodes originating in the four designated areas mentioned earlier, the Commission recognises the functions of the NFPI in the following fields: inspection execution assurances regarding compliance with the relevant EU regulations including data reports; classification of production; public health control; and production monitoring. The NFPI is now the agency in Korea responsible for

verifying and certifying the requirements of the EU Directive concerning fishery products originating in the four authorised production areas.

In the case of fishery and aquaculture products originating in Korea, the Commission recognises the provisions of Korean legislation on health inspection and monitoring of products as being in keeping with those of the EU Directive. The NFPIS is considered fully qualified to oversee the application of the laws in force, the procedures for EU approval of processing facilities, and the fulfilment of requirements equivalent to those laid down by the Directive.

Accordingly, the Commission recognises the NFPIS as the only competent authority in Korea for verifying and certifying compliance of fishery and aquaculture products with the requirements of the Directive.

Export products must be processed only in plants registered on the EU list and must bear the words "Republic of Korea" on labelling, along with the approval number of the establishment of origin. To ensure full and continuing compliance with EU policy, the NFPIS has composed and distributed a comprehensive manual providing guidelines for registration and control of processing facilities to be used in the preparation of goods for export to EU nations.

- a) The aim of the manual is to define requirements necessary for the establishment of processing facilities (including factory ships), standards for sanitary control, registration of processing establishments, and inspection and certification of related products for the purpose of facilitating the export of all live, fresh, frozen, chilled and canned fish products to EU countries.
- b) Those enterprises which have received a license for fishery processing and manufacturing or food business under the Fisheries Law and the Food Sanitation Law shall be subject to the terms outlined in the manual.
- c) Those wishing to export fishery products to the EU who are registered on the EU list shall ensure that processing facilities, equipment, sanitary control, packing, production processes, and the use of drinking water shall be in compliance with the relevant standards.
- d) The twenty-nine registered processors shall establish working teams, and these will operate the Harvard Analysis and Critical Control Point (HACCP) system to protect products from contamination by hazardous substances at every stage of the manufacturing process. A written record concerning the application and implementation of the HACCP system should be kept for at least two years.
- e) The regional directors of the NFPIS branch offices shall plan and execute a comprehensive inspection once every six months to ensure the sanitary control of processing facilities.

VI. Introduction of the HACCP System

The Codex Commission recommended the application of the HACCP system to assure food safety and protect consumers. Each contracting party to the World Trade Organisation Sanitary and Phytosanitary (WTO/SPS) Agreement should adopt these measures, which constitute the standards and guidelines or recommendations of established international organisations. The Korean government

revised the Food Sanitation Law in December 1995 to add an article authorising the implementation of the HACCP system in addition to the current Good Manufacturing Practices system.

In accordance with the revised law, the HACCP system for Ham and Sausage products was established and published in December 1996. For the HACCP system for fishery products, implementation methods are being monitored and specific standards are expected to be published in December 1997.

VII. Equivalence of Inspection

The NFPIS secures practical equivalence by utilising the relevant country's laws and regulations in carrying out inspections on shellfish and other fishery products, in accordance with the shellfish sanitary agreement between Korea and the USA, and the decision made by the EU Commission.

Article 4 of the WTO/SPS Agreement provides that contracting parties shall enter into consultations with the aim of achieving bilateral and multilateral agreements on the equivalence of specified measures.

Since the basic principle in concluding a bilateral agreement in this field is the high quality of the safety measures assured by each inspection control system, the NFPIS is introducing the Codex standards for food, modern inspection technology and methodology employed by advanced countries, and the supplementing of high-tech equipment with a view toward enhancing its inspection functions. The NFPIS is expected to acquire 57 kinds of precision analysis equipment in the period 1997 to 2004. In addition the NFPIS will be sending and to dispatch 117 special inspectors to national laboratories or to institutes in advanced countries for training.

The NFPIS will further strengthen surveys and inspections pertaining to safety during the fishery-product processing and distributing stages, in addition to the harvesting and shipping stages, in order to comply with the principles of equivalence and non-discrimination stipulated the WTO/SPS agreement.

ANNEX I

Standards for Food Products in General (Common Standards Established by the Ministry of Health and Welfare)*Standards of allowable heavy metal residues*

Substance	Product	Standard allowable
Arsenic	Seasoned food products	1.5 mg/kg max.
Total mercury	Marine fish and shellfish	0.5 mg/kg max.
Lead	Marine fish and shellfish	2.0 mg/kg max.
Lead	Canned fishery products	0.3 mg/kg max.
Heavy metals	Products without separate standards	10.0 mg/kg max.
Tin	Canned fish products	150 mg/kg max.

Food additives

Restricted to those foods indicated in the Official Book of Food Additives.

Food-poisoning bacteria

Salmonella, *Staphylococcus aureus*, *Vibrio parahaemolyticus*, *Clostridium welchii*, *Listeria monocytogenes* shall not be detected in food products.

Antibiotic substances

Antibiotic substances, synthetic antibiotic substances, and synthetic hormones shall not be detected in food products.

No more than 0.1 mg of oxytetracycline per kg of fish or lobster is permissible.

Radioactivity

Iodine 131 → 300 Bq/kg max.

Cesium 134 + Cesium 137 → 370 Bq/kg max.

Paralytic shellfish poison

80 µg/100 g max.

Standards and Regulations by Food Item

Fish flesh products

Standards for composition of constituents

- fish paste, frozen fish paste, semi-processed fish flesh products: fish flesh content 70 per cent min. each;
- mixed fish paste, fish sausage, fish ham, other processed fish flesh products: fish flesh content 60 per cent min. each;
- mixed fish sausage, mixed fish ham: combined content of fish flesh and meat 60 per cent min. (fish flesh content shall be higher than that of meat); and
- fillet fish flesh (surimi): fish flesh content 90 per cent min.

Specifications for constituents

- moisture (%): 10 max. (restricted to dried fish paste);
- nitrous acid (g/kg): 0.05 max. (limited to fish ham and fish sausage);
- tar colouring dye: shall not be detected (sausages excluded);
- coliform group: shall test negative (semi-processed fish flesh products, fillet fish flesh excluded);
- faecal coliform: shall test negative (restricted to semi-processed fish flesh products, fillet fish flesh);
- standard plate count: shall test negative (restricted to sterilised products); and
- preservatives (g/kg): 2.0 sorbic acid, potassium sorbate max. (on the basis of sorbic acid).

Salted-fermented sauce products

Standards for composition of constituents: major materials 60 per cent min.

Specifications for constituents

- Total nitrogen (%): Salted-fermented liquid sauce 1.0 min. salted fermented anchovy liquid sauce only); seasoned-salted-fermented liquid sauce 0.5 min. (seasoned-salted-fermented anchovy liquid sauce only).

- Amino acid nitrogen (mg%): Salted-fermented liquid sauce 600.0 min. (salted-fermented anchovy liquid sauce only), seasoned-salted-fermented liquid sauce 300.0 min (seasoned-salted-fermented liquid sauce only).
- Coliform group: shall test negative (salted-fermented liquid sauce and salted-seasoned-fermented liquid sauce only).
- Tar colouring dye: should not be detected
- Preservatives (g/kg): preservatives other than those listed below should not be detected (salt content restricted to 8% max.)

sorbic acid below 1.0 (as sorbic acid)

potassium sorbate

Pickled products and hard-boiled products

Standard for composition of constituents: According to manufacture's own standards.
Specifications for constituents:

- viable cell counts: should be negative (pasteurised and sterilised-products only);
- coliform group: should be negative (pasteurised and sterilised-products only);
- tar colouring dye: should not be detected.

Dried fish fillets (seasoned dried fish fillets included)

Moisture (%)

- seasoned dried fish fillets: below 28.0 (25.0 max. for semi-roasted fishes, dried and file fish, and 30.0 max. for seasoned white clam and seasoned squid processed with living organism);
- dried fish fillets: 20.0 max. (earshell, 22.0 max.); and
- other items: 23.0 max. (seasoned fish fillets excluded).

Sulphur dioxide (g/kg): 0.03 max.

Coliform group: should be negative (restricted to seasoned and sliced fish).

Seasoned laver

Moisture: below 7.0%

Peroxide value: below 60.0%

Tar colouring dye: should not be detected.

LITHUANIA

THE SEAFOOD INSPECTION SYSTEM IN LITHUANIA

Human resources

In Lithuania there are 111 fish processing industries, three quarters of which are small fish processing industries involved in preparation, salting and smoking. In the fishing industry, a total of about 3 500 people are employed. Of this number approximately 50 have fish processing technology qualifications.

At present the Lithuanian fishing fleet is experiencing a hard period of restructuring. There has been a transfer of ownership from state to private and as a result size of the fleet has decreased from 200 vessels in 1991 to 100 vessels in 1998.

Organisation

Fish resources strategy and the development of fishing industry is under the jurisdiction of the Fisheries Department of the Ministry of Agriculture and Forestry and the Fish Resource Department of the Ministry of Environmental Protection.

Production and trade of fish and fish products for human consumption and animal feeding is controlled by the State Veterinary Service.

Since 1994, all production and storage establishments are obliged to have a veterinary approval number that is given by the State Veterinary Service to enterprises meeting the approval requirements. The State Veterinary Service also appoints an official veterinarian for the supervision and control of the establishment.

Legislation

At present legislation is being reorganised in order to meet the requirements of the European Union (EU) directives.

The Fisheries Department has drafted the Law on Fisheries is working on the basic fishery standards and codes of practice, approved by FAO, for use and implementation in Lithuanian enterprises.

The State Veterinary Service has prepared the veterinary requirements conforming to EU directives 91/493/EEC and 92/48/EEC. The drafts of translated documents have been submitted for expert analysis and are planned for approval in the first part of the current year once co-ordination with the involved agencies is completed.

The State Veterinary Service has been preparing for the implementation of these new requirements. The requirements will establish a new procedure for the control and approval of enterprises and fishing vessels. The requirements will provide for the introduction and implementation of the Hazard Analysis and Critical Control Point (HACCP) system in enterprises preparing fishery products for export. Compliance with the new requirements for local market is expected to be completed before the 2000-2002.

The fishing industry, and the legislation, is moving to the new quality framework. This transition is planned to be completed by the year 2002. From the end of this period only the enterprises meeting the veterinary requirements established in accordance with the requirements of the EU directives will be granted right of preparing products for export. Enterprises wishing to export only be able to do so after they have introduced the HACCP system.

Laboratories

Sanitary, microbiological, chemical-toxicological, parasitological and other analysis of fish, fish products, production, water, facilities, equipment is performed by the veterinary or other approved laboratories. The laboratories try to follow the guidelines for "good laboratory procedures".

At least once a month State Veterinary Service conducts control laboratory analysis on processing and sanitation. The State Veterinary Service also analyses the test results obtained by enterprise laboratories.

Fish caught in internal waters are subjected to radiological, heavy metal residue, pesticide, fish disease and monitoring laboratory tests. The results of these tests condition the further use of the fish caught in water reservoirs.

Border control

In order to protect consumers from fish and fish products that are of low quality or harmful to human health, there is a control procedure for fish imports.

Border veterinary control services take samples of the imported fish and fish products and send them for laboratory analysis. Placing on the market of imported fish and its products is only permitted after an analysis protocol from the laboratory is received recognising the product as suitable for human consumption. For example, in the second half of 1997, 7 355 tonnes from the tested 38 116 tonnes were found to be not satisfying the established norms.

Training

Veterinary inspectors and official veterinarians supervising and controlling the production enterprises are instructed about the principles and control of the HACCP system. This instruction is

provided through courses and seminars. High ranking veterinary officers have completed this training course and are they share their knowledge with the staff in their offices and enterprises.

MEXICO

SEAFOOD INSPECTION IN MEXICO

Legal framework

Basic law

General law of health: Under-law of sanitary control of activities, establishments, products and services. Title sixth: Fishery products.

Regulation: Mexican official standards (NOM)

- NOM-027-SSA1. Sanitary specifications. Fresh, chilled, frozen
- NOM-029-SSA1. Sanitary specifications. Crustacean. Fresh, chilled, frozen
- NOM-031-SSA1. Sanitary specifications. Shellfish. Fresh, chilled, frozen
- NOM-028-SSA1. Sanitary specifications. Fish. Canned
- NOM-030-SSA1. Sanitary specifications. Crustacean. Canned
- NOM-032-SSA1. Sanitary specifications. Shellfish. Canned.
- NOM-129-SSA1. Sanitary specifications. Cephalopods and gastropods. Fresh, chilled, frozen. smoked products.
- NOM-120-SSA1. Good Sanitation Practices
- NOM-129-SSA1. Implementation of HACCP in the fishery products industry.
- NOM-051-SCFI. Labelling for packed food products.

Competent authority

Production

All fish: Harvest areas and aquaculture: Secretaría de Medio Ambiente, Recursos Naturales y Pesca. (Secretariat of Environment, Natural Resources and Fisheries). Subsecretaría de Pesca (Undersecretariat of Fisheries)

Shellfish: Harvest areas: Secretaría de Salud (Secretariat of Health, SSA). Subsecretaría de Regulación y Fomento Sanitario (Undersecretariat of Sanitary Regulations and Promotions). Dirección General de Salud Ambiental (General Directorate of Basic Sanitation).

Processing

Secretariat of Health (SSA). Undersecretariat of Sanitary Regulations and Promotions. Dirección General de Calidad Sanitaria de Bienes y Servicios (General Directorate of Sanitary Quality of Goods and Services).

Sales

Same as above.

Figure 1: **Federal Jurisdiction (competent authority: processors for export)**

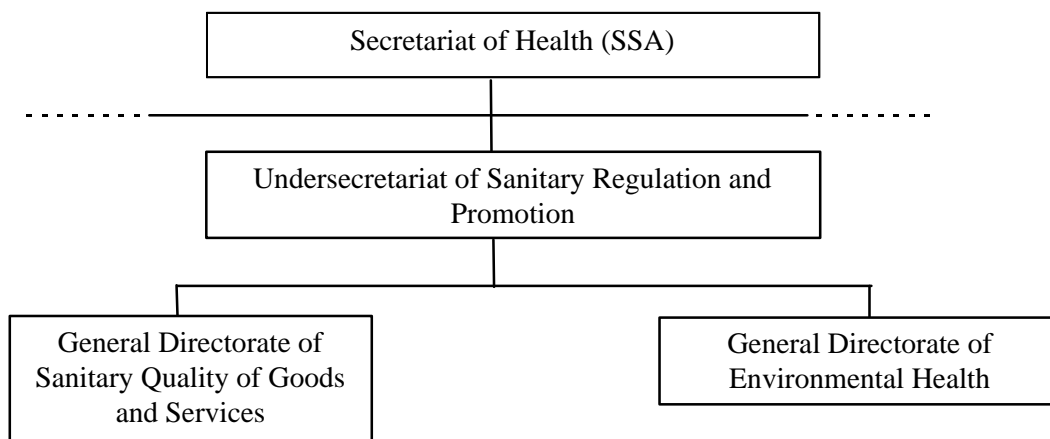


Figure 2: **State jurisdiction (processors for domestic consumption and retailers)**

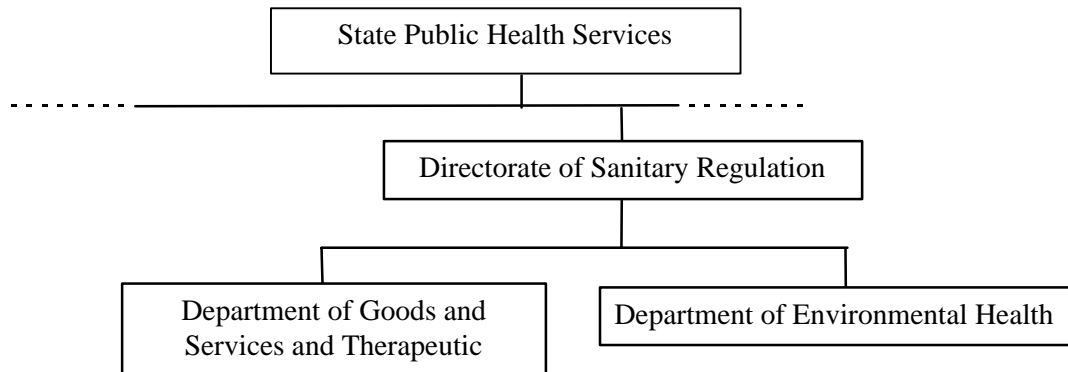
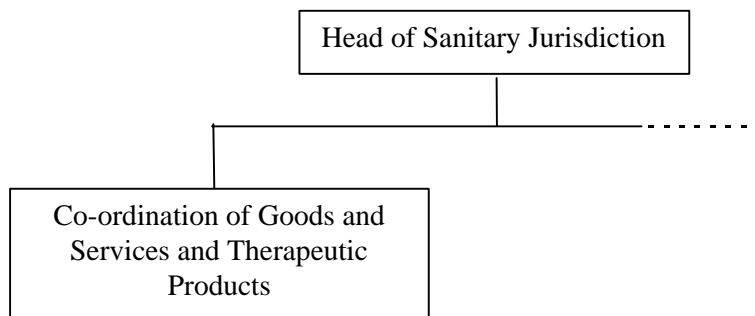


Figure 3: **Local Jurisdiction (processors for domestic consumption and retailers)**



Control Program and Procedures

Program

Computer assisted, focused on problems solution, continuous improvement method, focused on risk

Components

1. Notice of operations by the company for the first time (no license required);
2. Inspection (good sanitation practices, SSOP, samples, labels);
3. Analysis of information (documents, laboratory test, history of compliment);
4. Assessment of compliment (decision making based on regulations) - an assessment of the level of conformance with regulations, evaluation of risk, sanitary history of the company;

5. Notice of inspection;
6. Follow up (program of corrections by the company);
7. Building of compliment history;
8. Seizure of products or suspension of processing line or a plant:
 - Seizure of product proceeds when there is a strong suspicious that a product is not safe. The action stops when there are technical evidence that such probability of hazard do not exist or the product is re-processed to correct the defect or the product is destroyed.
 - Suspension of a processing line or even the whole facility proceeds when evidence exist that there is a potential hazard on the processing line or the plant or when the processing line is not under control. Or there are contaminated production lots resulting from a defective operation. The suspension stops when the plant shows that the defect has been solved or the operation has been controlled.
9. Application of sanctions:
 - Warning letter when Minor defects identified in the inspection;
 - Bid. When there are major defects result the inspection or when defects are identified several times. Or when correction plan with major defects is not solved.
 - Temporarily or permanent close down when the operation represents a major risk to the public health and probability of correction is very difficult:
 - Jail 48 hours.

Facilities, equipment, transportation and communication

Federal offices:

Administrative offices, with computers and software designed controlling the system. Communication by mail, courier, Fax and telephone. Transportation and per diem to visit processing plants are paid by the federal budget. Companies that request for inspections for export paid a fee to cover for expenses to the Secretariat of Treasure.

Short term plans

These include a contract with state authorities to delegate by steps: (1) certification issue; (2) inspection for exports; (3) assessment of compliance and; (4) notice of inspection.

Laboratories

1. National Laboratory of Public Health (Federal laboratory approved for exports)

2. State Laboratories (Sonora and Chihuahua, approved for export)
3. Private laboratories (9 approved for exports)

Approved laboratories are evaluated by an evaluation committee under Law of Metrology and Standardisation.

Personnel

1. Federal inspectors: chemist, biologist, veterinarian, food technologist (6 for fish processing and other areas)
2. Federal assessment of compliance: chemist, biologist, veterinarian, food technologist.
3. Training: all people has been trained in good sanitation practices and HACCP.
4. Supervision:
 - Analysis of previous inspections; and
 - On site supervision

Scope of Fish Inspection Programs

All laws and regulations are applied equally to domestic and foreign products. Table 1 summarises the laws and regulations applied to domestic and exported seafood products.

Table 1: Regulations Applied to Seafood Products

Regulation	Safety	Essential quality	Wholesomeness	Truth of labelling
<u>By-law of the general law of health on sanitary control of activities, establishments, products and services. Title Sixth</u>				
Fish, shellfish, cephalopods, dried fish, smoked seafood	✓	✓	✓	✓
<u>Mexican Official Standards</u>	✓		✓	
027. Fish Fresh. chilled and frozen	✓		✓	
028. Fish. Canned	✓		✓	
029. Crustaceans. Fresh, chilled and frozen	✓		✓	
030. Crustaceans. Canned	✓		✓	
031. Shellfish. Fresh, chilled, frozen	✓		✓	
032. Shellfish. Canned	✓		✓	
120. Good Sanitation Practices	✓		✓	
128. HACCP in the fish processing industry	✓			
051. Labelling				✓

Table 2: **Seafood Inspection in Mexico: Summary**

Risk assessment and management	Infrastructure and procedures	Officially recognised bodies
<p><u>Private companies:</u></p> <ol style="list-style-type: none"> 1. Quality assurance <ul style="list-style-type: none"> – Voluntary: Mexican standards: NMX/ISO 9000 2. HACCP implementation: <ul style="list-style-type: none"> – Prerequisite: mandatory good sanitation practices. NOM-120-SSA1; – Voluntary HACCP for exports to the EU. 91/493/CEE; – Mandatory HACCP. NOM-128-SSA1 by 1 Dec. 1997. <p><u>Government:</u></p> <ol style="list-style-type: none"> 1. Risk analysis: <ul style="list-style-type: none"> – More attention and resources to higher risk; – Preventive regular inspections; – Targeted inspections; – Horizontal regulations; – Sharing responsibilities with industry and commerce to solve safety issues. 2. Responsibility of conformance with specifications. 	<ol style="list-style-type: none"> 1. Legal framework: <ul style="list-style-type: none"> – Basic law; – Regulation; – Competent authority. 2. Production/harvest. 3. Process. 4. Distribution and sale. 5. Control program and procedures: <ul style="list-style-type: none"> – Problem solution focused on risk; – Components; 6. Scope: <ul style="list-style-type: none"> – Safety, wholesomeness, truth of labelling; – Domestic, imports and exports markets. 7. Criteria and decision making: <ul style="list-style-type: none"> – Seizure and suspension; – Sanctions. 8. Facilities, equipment, transport and communications. 9. Laboratories: <ul style="list-style-type: none"> – Federal; – State; – Private. 10. Personnel: <ul style="list-style-type: none"> – Training; – Supervision. 	<ol style="list-style-type: none"> 1. Delegation of authority to state government: <ul style="list-style-type: none"> – Contract between federal and state government; – Stages of delegation. 2. Official accreditation to third parties: <ul style="list-style-type: none"> – Federal law of metrology and standardisation; – Procedures for evaluation and accreditation: <ul style="list-style-type: none"> – Impartiality/requisites; – Demonstration of technical and administrative competence; – Declaration of competence; – Connection to authorities. 3. Audit techniques: <ul style="list-style-type: none"> – ISO-10011-1/ISO-1011-3. Guidelines for auditing quality systems; – Inspection/verification bodies. ISO-IEC.39.

Table 2 (continued): Summary: Seafood Inspection in Mexico

<p align="center">Certification for exports</p>	<p align="center">Equivalence between countries</p>
<p>1. Third party certification:</p> <ul style="list-style-type: none"> - Definition of roles: <ul style="list-style-type: none"> - Test laboratories; - Inspection bodies; - Certification bodies. <p>2. Evaluation and verification of conformance:</p> <ul style="list-style-type: none"> - Method: <ul style="list-style-type: none"> - Evaluation of conformance; - Connection to authorities. <p>3. Types of certificates:</p> <ul style="list-style-type: none"> - Free sale; - Analysis of production lot; - Conformance with GSP; - Listing of certified companies; - Cost effectiveness. 	<p>1. System evaluation. Comparative analysis:</p> <ul style="list-style-type: none"> - Strategic analysis; - Regulations: <ul style="list-style-type: none"> - Product specifications; - Methods of analysis; - GMP/GSP/SSOP/HACCP; - Labelling; - Components of the system; - Supervision and auditing of the system; - Statistics of results. <p>2. Equivalence criteria:</p> <ul style="list-style-type: none"> - % of equivalence; - Evolution of equivalence. <p>3. Equivalence agreement:</p> <ul style="list-style-type: none"> - One way; - Two ways.

NEW ZEALAND

NEW ZEALAND REGULATORY SYSTEMS AND CONTROLS FOR THE EXPORT OF SEAFOOD

I. Overview

The Ministry of Agriculture (MAF) has the legal responsibility for the food safety standards which relate to the export of live animals, plants, dairy products, meat, farmed venison, wild game, fish, shellfish or any part derived thereof from New Zealand.

The Ministry of Health has the legal responsibility for food safety in New Zealand after product is released onto the domestic market (See Annex I).

The Ministry of Fisheries has responsibility for the sustainable utilisation of fisheries. The Ministry of Fisheries split from the Ministry of Agriculture in July 1995.

The Ministry of Agriculture is headed by the Director General. He has control over the four sub unit organisations. These are: MAF Quality Management; MAF Corporate Office; MAF Policy; and MAF Regulatory Authority.

The MAF Regulatory Authority is divided into four generic groups: Meat and Seafood; Dairy; Plants; and Animal Health and Welfare. Each entity is headed by a Chief Officer.

The part of MAF responsible for control over meat and seafood production has two completely separate components (financially as well as administratively).

1. MAF Regulatory Authority (Meat and Seafood) provides policy, specifications and independent audit. MAF Regulatory Authority (Meat & Seafood) is the Controlling Authority for meat, farmed venison, wild game and seafood, and has accountability and responsibility for food safety standards, branding and certification of products and by-products.
2. MAF Quality Management is the Delivery Organisation and as such provides the "hands on" inspection service. MAF Quality Management has responsibility for inspection of product and by-product, ensuring compliance with standards, and providing certification on behalf of MAF Regulatory Authority (Meat & Seafood). The performance of MAF Quality Management in these roles is audited by MAF Regulatory Authority (Meat & Seafood).

II. Ministry of Agriculture

The Ministry of Agriculture administers the legislation relating to the safety and wholesomeness of meat, farmed venison, wild game, seafood or any part derived thereof. The Meat Act 1981 and its regulations provide appropriate regulatory controls of meat, farmed venison, wild game and seafood (products and by-products).

The Minister for Agriculture has accountabilities pursuant to this Act and these accountabilities are delegated to the Director General of the Ministry of Agriculture.

Under the Meat Act 1981 the Director General controls:

- the appointment and powers of Inspectors;
- the requirements for licensing of premises;
- the inspection, production and prerequisites for the sale of meat, farmed venison, wild game, seafood and their products for human consumption prior to their release on the domestic market; and
- the requirements for the export of meat, farmed venison, wild game and seafood.

Primarily, concerns are for the safety and wholesomeness of food, as well as for truth in labelling. The specific legal requirements relate to:

- fish and shellfish are contained in the Fish Export Processing Regulations 1995; and
- delegations of powers are contained in the Ministry of Agriculture and Fisheries Act 1953 and the State Sector Act 1988.

III. Responsibilities of MAF Regulatory Authority

MAF Regulatory Authority (RA) is the only independent competent or controlling authority which has responsibility to:

- Develop and maintain New Zealand's technical and service performance standards. This encompasses services either purchased by Government or for which Government is accountable as the competent authority (for example; export certification).
- Represent the New Zealand Government as the competent authority in relevant international fora (for example; Codex, OIE, IPPC, WTO SPS Committee).
- Negotiate multilateral and bilateral agreements on zoosanitary, phytosanitary and food safety requirements.
- Arrange and administer delivery contracts for services purchased by Government (e.g., disease surveillance, emergency response, animal welfare).

- Audit the compliance to New Zealand and importing country standards, of facilities, quality assurance service providers and industry quality management systems.
- Meet agricultural security and quality assurance reporting obligations to Government and international organisations; and
- Supply technical input to the MAF Policy Group and other Government departments for the development of Government policy in relevant areas.

In addition MAF Regulatory Authority is accountable for both the quality and cost-effectiveness of services purchased by Government, as well as the reliability of Government certification of primary products.

IV. Responsibilities of MAF Regulatory Authority (Meat & Seafood)

MAF Regulatory Authority (Meat & Seafood) is headed by the Chief Meat Veterinary Officer (CMVO), and acts for the Director-General by ensuring that the delegated legislative accountabilities are addressed by:

- producing specifications which are adequate to facilitate the production of safe and wholesome products which are truthfully labelled;
- ensuring that groups/industries involved in the production of animal products comply with the specifications;
- ensuring importing countries certification requirements are met.

The major focus of the Regulatory Authority (Meat & Seafood) is the production, development and enforcement of quality assurance specifications. This involves the design and specification of quality assurance standards on behalf of the Government acting as the mandated competent or controlling authority and covers:

- standards proposed or set in place by international agencies;
- access negotiations (in association with the Ministry of Foreign Affairs and Trade (MFAT));
- sector industry performance and development;
- expert support to Ministers of the New Zealand Government (specifically, the Minister of Agriculture) and servicing designated international agencies;
- servicing designated publication and promotion of agreed policies/standards; and
- contracting, licensing or otherwise arranging for the delivery of agreed policies as appropriate.

It also involves confirmation that delivery groups, such as MAF Quality Management are performing to those standards in the following areas:

- government certification that animal and fish products, production and processing system facilities and personnel meet sanitary, food safety, wholesomeness, and truth in labelling standards; and
- enforcing other statutory responsibilities provided for in MAF administered legislation.

V. MAF Legislation

The responsibilities of the Regulatory Authority are supported by legislation. The Meat Act 1981 governs the slaughter, processing and sale of meat, farmed venison, wild game, fish and shellfish for human consumption. The Act imposes licensing requirements for premises, and confers the powers of Inspectors.

The expected outcomes of compliance with the Act are products and by-products which are fit for purpose and do not present a health risk to animals or humans.

The Act makes provision for the implementation of regulations, the promulgation of directives, and penalties for offences against the Act.

The Act protects importing country requirements. It requires that, as far as shall be practicable, any product intended for export conforms to the requirements of the country to which it is to be exported, and prohibits or restricts the export of any product unless the directions have been complied with.

a) *Meat Act 1981*

In relation to fish, the Meat Act 1981 covers:

- the appointment, qualifications, and powers of the Government appointed Inspectors;
- the requirement that diseased or defective fish or fish product cannot be sold;
- the requirement that all premises (including vessels) associated with seafood be licensed;
- general provisions such as a licence register and record keeping; and
- the offences and penalties.

b) *Fish Export Processing Regulations 1995*

The Meat Act 1981 is supported by the Fish Export Processing Regulations 1995. These regulations cover:

- requirements for the construction and standards of plant and equipment in fish premises;
- obligations on the licensee to maintain hygiene and quality;

- requirements that any fish and shellfish accepted at a fish packing house be fit for human consumption;
- requirements for operation of a premises, storage and transportation;
- requirements that companies carry out regular checks on compliance with the requirements, results are recorded and corrective action taken;
- the Director-General can declare a species or type of fish or an area where fish is taken unsafe due to contamination;
- requirement that no fish and shellfish is exported from NZ unless accompanied by an export certificate;
- providing Inspectors with power to examine and sample fish and to remove and dispose of unfit fish, and to prohibit the use of equipment or premises; and
- providing for exemption from licensing for whole fish processing premises and limited processing fishing vessels.

VI. MAF Regulatory Authority (Meat and Seafood) Group

a) Seafood Group

MAF Regulatory Authority has 4 full-time staff directly involved in the seafood programme, the National Manager (Fish), National Manager (Shellfish), a Technical Advisor and a compliance evaluator. MAF Regulatory Authority also has Veterinary Counsellors based in Brussels and Washington. The purpose of the Seafood group of MAF Regulatory Authority (Meat & Seafood) is:

- to maintain and improve market access for fish and shellfish products through the development of clear objective orientated and technically justifiable food safety standards and specifications; and
- to provide standards/specifications to ensure food safety requirements are met as required by the Meat Act 1981 and where appropriate, for specific markets where government involvement is a prerequisite for market access.

b) Compliance Programme

MAF Regulatory Authority (Meat & Seafood) operates a Compliance Group (CG) whose role is to:

- verify that delivery organisations effectively implement and maintain the CMVO's standards and specifications;
- ensure that corrective action is taken where necessary;

- provide information to the CMVO and National Managers on the efficacy and state of compliance of the relevant specifications;
- provide delivery organisations with specifications adjudication and technical advice on achieving compliance with the specifications; and
- undertake special projects as required by the CMVO.

In relation to fish and shellfish, the CG undertakes audits of the MAF Quality Management Inspectors. Inspectors located at premises, central certifying and regional offices are subject to audit. This is additional to the MAF Quality Management Regional review programme. Audits include verification checks of all premises licensed under the Meat Act 1981.

For seafood the major activity of the CG is to carry out reviews of seafood licensed/approved premises, and any specific activities, disciplines or systems associated with the CMVO's sphere of influence. The findings of the reviews are documented in a standardised manner.

The outcome of the reviews is to achieve uniform application of the specifications and maintain MAF integrity. The delivery organisations are required to resolve deficiencies in the application of the mandatory service.

Specific objectives of the CG's programme include:

- incorporating all appropriate areas of the Meat and Seafood programme into an approved audit schedule;
- ensuring consistency and uniformity amongst reviewers;
- advising delivery organisations and industry of areas that require rectification and assisting in the resolution of these problem areas;
- pursuing a system that will allow quantification of the compliance status and a performance based assessment of premises;
- identifying the need for, and assisting in, the modification of standards/specifications;
- pursuing innovative methods to assess compliance status;
- developing a set of standard responses to commonly occurring major problems; and
- agreeing and implementing competency specifications for delivery organisations and for individuals within the delivery organisation.

c) *Types of Premises*

In the domain of fish and shellfish there are a number of premises types. These premises are under MAF jurisdiction and are required to be licensed by MAF Regulatory Authority (Meat and Seafood) under the provisions of the Meat Act 1981. They are all allocated a unique identifying number. The types of premises comprise:

Packing Houses (PHs):

These are premises which are involved in the processing, packaging, preservation, handling, holding or storage of fish, shellfish and their products. The packing house licence category includes canneries. Fish packing house official numbers are either prefixed with "PH" or "FPH".

d) *Licensing and construction of premises*

The outputs for this team include:

- the development and implementation of standards and specifications for construction and licensing of all premises required to be licensed under the Meat Act 1981;
- the provision of a licensing and approval service to ensure premises seeking licensing and proposed alterations comply with appropriate standards;
- approving material, equipment and building materials used in premises licensed under the Meat Act 1981.

Before a licence is issued to a premises, an initial application must be made which includes information on the type of processing to be carried out, and detailed plans on the construction and operation of the premises including:

- site plans (for land based plants);
- layout plans;
- construction details;
- principal items of plant and equipment;
- product flows and process description;
- details of water supply;
- storage facilities;
- amenities; and
- services.

A licence is granted provided the completed construction of the premises, its equipment and product flows meet the requirements of the legislation. To verify this, routine inspections are carried out by MAF Inspectors during construction of the premises. A final commissioning inspection is undertaken when construction is completed. The licence issued prescribes the restrictions on the premises and also details any special conditions. The official number for the premises is issued at this time, and is shown on the licence.

MAF approves in advance all structural alterations, any additions or changes to plant, fittings or equipment which affect the hygienic condition of the premises or facilities.

Licensing of Fishing Vessels.

Seagoing packing houses (i.e. factory vessels) are licensed in the same manner as land based packing houses. A number of foreign owned vessels operate under charter arrangements in New Zealand. In these instances an inspection upon arrival in New Zealand is carried out before the licence is issued.

Whole Fish Processing Fishing Vessels and Limited Processing Fishing Vessels.

Whole fish processing fishing vessels and limited processing fishing vessels are not licensed but are inspected and issued with an approval before being able to operate in the 200 mile Exclusive Economic Zone (EEZ). Approvals are required for any fishing vessel which wishes to export directly from the fishing vessel including any foreign owned fishing vessels operating in the EEZ either under charter to a New Zealand company or in a joint venture with a New Zealand company. Official numbers are issued for approved fishing vessels.

Whole fish processing premises (which may include fishing vessels) can only chill or freeze and pack certain fish species. Limited processing fishing vessels are restricted to the scaling, gutting, heading, chilling, packing and freezing of fish and the tailing of rock lobsters. Whole fish processing premises are prefixed with "W" and limited processing fishing vessels prefixed with "L".

Official Numbers for Premises

When a premises is licensed an official number is issued. The number has a prefix which indicates the premises type (e.g., PH 12). The specifications for licensing are contained in MAF Manual 1, Licensing. This information is supplemented by MAF circulars and Technical Directives.

Suspension or cancellation of licence

Licences may be suspended or cancelled by the Director General if a premises is considered no longer fit for purpose or if the licensee has failed or refused to comply with any legislative requirements.

VII. MAF Quality Management (Inspection Services)

The inspection of premises licensed under the Meat Act 1981 is carried out by MAF Quality Management (MQM). MAF Quality Management's mission is to:

- protect and promote New Zealand agriculture;
- be internationally recognised as the predominant supplier of quality management services to the agriculture sector; and
- operate a successful business.

MAF Quality Management is the organisation responsible for the delivery of inspection services. In relation to fish and shellfish, MQM performs surveillance of premises and inspection of fish, shellfish and products derived thereof to enable official export certification to be given on behalf of MAF Regulatory Authority

In relation to the export of seafood, this involves delivery of non-contestable market access and quality assurance services including system design, inspection, laboratory analysis, audit and certification.

MQM is divided into three regions each of which has a slightly different structure.

The inspection service consists of veterinarians and trained lay inspectors. Each premises has an official "Inspector in Charge". In a fish packing house or other seafood premises this person is a suitably trained meat inspector.

The line of technical accountability follows up through the veterinary regional structure to the Chief Meat Veterinary Officer.

Inspectors are required to have:

- completed specialist training appropriate to areas of responsibility;
- thorough knowledge of standards and processing techniques;
- high levels of communication, problem solving and conflict resolution skills; and
- commitment to MAF Quality Management operations, goals, and business philosophy.

VIII. Seafood

a) Fishing Industry Inspection and Certification Council

The Fishing Industry Board has set up an advisory council to government. It is, in fact, a co-operative organisation involving representatives from the seafood industry, the Fishing Industry Board and MAF. MAF recognises the Fishing Industry Inspection and Certification Council (FIICC) as the "recognised industry representative organisation" (Advisory Council) for the following purposes:

- where possible participating in negotiating quality assurance requirements with importing country controlling authorities and consequently defining the requirements to be met;
- developing and agreeing with MAF strategies, mandates, and participants for negotiating with importing countries controlling authorities and in multilateral fora;
- developing proposals for seafood safety standards for exports and advising industry of Industry Agreed Implementation Standards;
- developing guidelines or codes of practice for exports and advising industry of them;

- advising of the direction that seafood safety standards should be taking and endorsing strategies and the operational plan of MAF Regulatory Authority in relation to seafood exports;
- communicating to industry developments and trends in seafood safety standards relevant to processors forward planning; and
- providing policy advice to government on appropriate regulations and other controls.

b) *Industry Agreed Implementation Standards (IAIS)*

The Fish Export Processing Regulations 1995 provide for circulars to be issued which specify the means of achieving the standards in the regulations. The circulars are issued by the Director-General and are known as Industry Agreed Implementation Standards (IAIS). If a company wishes, it may make a specific application to the CMVO to have a different method of achieving a standard approved.

IAIS 001.1 Alternative use of Premises

This standard allows fish premises to be used for certain functions other than the processing of fish (e.g. storage of food products).

IAIS 001.2 Fish premises

This standard details the construction and hygiene requirements for fish packing houses. The areas covered include: layout of premises; construction requirements for the buildings; facilities, water, lighting, heating, ventilation; amenities for staff; refrigeration; and design and materials for appliances and equipment.

Layout of premises

The layout of the premises must be such that contamination of product is prevented.

Construction requirements for the buildings

Floors, walls and ceilings must be constructed of appropriate materials and kept clean at all times. Windows must be fly and vermin proof. Doors must, as far as practicable, be self closing. Wood is not permitted in areas where exposed product is processed or in normally wet areas.

Facilities, water, lighting, ventilation

Water used in the premises must be potable. Clean seawater can also be used. The standard specifies the testing that must be carried out on the water supply when the premises is established. Non-potable water may be used in certain instances. Adequate lighting and ventilation must be provided.

Amenities for staff

Amenities such as lunch rooms, changing rooms, toilets and washing facilities must be provided for staff. The amenities must not open directly onto product areas.

Refrigeration

Chillers, freezers and cold stores must be capable of reducing product to or maintaining product at the required temperature. They must be constructed of appropriate materials. Chilled fish is required to be held between minus 1°C and plus 1°C, frozen fish must be held at minus 18°C or colder.

Design and materials for appliances and equipment

Appliances and equipment must be constructed of material which is easily cleaned, durable, inert, and free from cracks.

IAIS 003.1 Operational Requirements for Fish Premises

This IAIS covers the general requirements for operations in fish premises. Provisions relating to the risk of contamination during processing, movement of appliances, movement of personnel are covered. Specific attention must be paid to prevent cross contamination from raw to cooked product and from one process to another. The areas covered include: vermin control; sanitation of premises and equipment; use of water; and ingredients, additives and containers.

Vermin control

A regular and effective vermin control programme is required.

Sanitation of premises and equipment

Each premises is required to have a written cleaning and sanitation programme detailing the areas to be cleaned, frequency of cleaning, special requirements and recording of the cleaning procedures. Only MAF approved cleaners and sanitisers may be used.

Use of Water

Each premises is required to have a written programme covering:

- the monitoring of water in the premises;
- an action plan in the event that non-conformances are detected; and
- records of the analyses and actions taken.

Minimum sampling frequencies and the tests required for the routine surveillance of water (potable and clean seawater) are given.

Ingredients, additives, and containers

Only approved food additives and ingredients can be used in fish products. All additives must be food grade and meet importing country requirements. Fish that are produced by aquaculture can only be treated with approved chemicals or cannot be treated within 8 weeks of harvesting.

The packaging and containers used must protect the fish from contamination and damage and be clean at the time of use.

IAIS 003.2 Personnel Standards

Personal hygiene and health requirements

Workers who are suffering from communicable diseases cannot work as product handlers. Product handlers are required to wear clean protective clothing, refrain from smoking, eating or drinking in product areas and wash their hands thoroughly at the beginning of each shift, after handling contaminated product and after visiting the toilet.

IAIS 003.3 Reception of Fish

Each company is required to check fish on arrival at the fish premises to determine that:

- the fish is fit for human consumption;
- since catching or harvesting the fish have been chilled or frozen;
- fish which is to be alive on arrival at the fish premises is alive; and
- fish is labelled or identified in the correct manner.

Records must be kept of the checks carried out.

Provision has been included for the importation of fish into New Zealand for processing and re-export. Specific approval must be obtained and conditions can be imposed.

IAIS 003.4 Live Eels and Live Rock Lobsters

This standard outlines the approved methods of killing live eels and live rock lobsters in a fish premises.

IAIS 003.5 Fish Processing

Areas covered include: process approvals; training of product handlers; and notification of non-complying fish and fish product and recall of product.

Process approvals

All fish is required to be processed in accordance with an approved process. Processing is required to be carried out so that the possibility of contamination or deterioration of the fish is minimised. It is recommended that companies use the HACCP system as a tool for process control for ensuring food safety.

The IAIS specifies a number of requirements that must be met when limited processing (e.g. filleting, gutting etc.) is carried out. Where further processing (e.g. canning, smoking, drying) is carried out each process is required to have a specific approval from the Inspector. The process approval must contain the critical control points, the checks carried out and the action taken to correct any non-compliances. Adequate records must be kept to demonstrate compliance with the approved process.

Changes have recently been made to the processing standard to align the requirements more closely with the seven principles of HACCP (previously not all of the principles were included). All processors will be required to undertake a hazard identification and where necessary develop a HACCP plan. Competent people are required to be involved in the development of the HACCP plan and the review of process records.

Training of Product Handlers

Each company is required to have a programme that provides for the education and instruction of product handlers in correct product handling, personal hygiene, and sanitary practices.

Notification of non-complying fish and fish product and recall of product

Each company is required to investigate and notify MAF where non-complying product is found in the market, either in New Zealand or overseas. Companies are required to have a recall plan so that any non-complying product can be recalled from the market place.

IAIS 003.6 Storage and Transportation

This IAIS specifies the temperatures and conditions required during storage and transportation.

Frozen fish and fish products must be stored at less than 18°C or colder. Chilled fish must be stored at minus 1°C to plus 1°C. Specific requirements for shellfish are given in IAIS 005.

Fish and fish products must be transported in a manner so that contamination and deterioration of the fish is minimised. Containers and vehicles used to transport fish must be clean.

IAIS 003.7 Release of fish or fish product detained or recalled for marine biotoxin reasons

This IAIS sets out the sampling and testing procedures to be followed when fish has been detained or recalled because of marine biotoxins.

IAIS 003.8 Quality Checks and Records

This standard details the procedures to be carried out by MAF and by companies when undertaking inspections and audits. Companies are required to carry out daily and weekly checks of premises and of the product produced, classify defects and record actions taken to rectify any defects. The emphasis of the programme is on the corrective action for any defect found being carried out in the minimum time. To assist company checkers to determine which category defects fall into, checklist guidelines were developed. The guidelines list common defects found in premises and categorises them into minor, major or critical.

The Inspection is divided into two parts, pre-operative inspections and on-going inspections.

Pre-operative Inspections

Before processing commences on any day, the "pre-op" checks must be carried out by a company checker. During the check, the company checker must ensure the processing area is in a suitable condition to start production. The areas generally covered are:

- cleanliness of area and equipment; and
- the state of repair of area/equipment

If the processing area is unfit to commence processing then no processing can be carried out until the defects are corrected to the satisfaction of the company checker.

Ongoing Inspections

During the day when product is being processed at least one other series of checks must take place. This check must cover, at least, the following items: product, premises, personnel, sanitation, equipment, refrigeration and water/ice.

The types of defects the company checker must look for under these heading are detailed in the "Checklist Guidelines".

Weekly checks

The company is required to undertake the following inspections on a weekly basis: environment; amenities; dry stores; cold stores; and records.

The types of defects the company checker must look for are detailed in the "Checklist Guidelines".

The carrying out of pre-operative and daily checks on any day does not exempt a company from the responsibility of continuous control of processing throughout that day. Any defects found should be recorded in the normal manner and acted upon immediately.

The results of the inspections undertaken by the company checker are recorded on the Company Compliance Checklist. Where defects are found these must be recorded as well as the action taken and time allowed to resolve the defect. When the defect is corrected this must be recorded on the checklist.

Alternative programme

A company may if it wishes develop its own programme for quality checks. The programme must contain the following:

- the name and title of the person responsible for the programme;
- the checks that are to be carried out, including standards and monitoring procedures;
- frequency of checks;
- samples of the documentation used to record the checks, results found and corrective actions; and
- description of plans developed for correcting non-compliances.

MAF Requirements

The MAF requirements are divided into two parts. The first involves inspection of the premises to ensure that the industry agreed implementation standards relating to construction, hygiene and sanitation of the premises, soundness of the product, and certification for export are complied with.

The second part involves ensuring that the company is carrying out the required daily and weekly checks, recording the details and action is taken to correct the defects. Details on the procedures to be followed when non-conformances arise are given. Included in this are penalties to be used if compliance is not achieved.

IAIS 002 Export Fish Certification

All export fish or fish product must be accompanied by an export certificate. This means that certification is required irrespective of the requirements of the importing country. The standard details the procedures that are to be followed for certification, including the use of transfer documents and authorisations. Only approved certificates can be used.

Provision is made for the use of authorised signatories, who are company employees and are appointed by the Director-General. The standard sets out the criteria and training that a person must undergo before being appointed and the auditing procedures that will be carried out.

Where specific certification for a country is required the details are provided. Information on importing countries requirements is also given.

IAIS 004.1 Labelling

This standard details the labelling requirements for any fish or fish product which is exported from New Zealand. Included is a requirement that packages be labelled with the official number of the premises. These requirements are in addition to any labelling requirements of the importing country.

IAIS 004.2 Fish Names

This standard contains a list of the New Zealand commercial fish species, the scientific names and acceptable common names.

IAIS 005 Shellfish Quality Assurance

This standard outlines the requirements for the growing, harvesting, processing and packing, of bivalve molluscan shellfish.

The standard outlines the requirements for the sanitary survey and the classification of growing areas. These are required to be conducted before shellfish can be harvested and include an evaluation of all potential pollution sources, the control plans required for marine biotoxins, provisions for relaying of shellfish, and requirements for the surveillance of harvesting.

There are specific provisions covering the harvesting, handling and transportation of the shellfish including packaging and labelling requirements. There is provision for the temporary wet storage of shellfish.

There are detailed requirements for the depuration of shellfish, including the commissioning and operation of the depuration plant.

Specific provisions relating to the processing of shellfish, for example, requirements for shucking, heat shocking and packing of shellfish are included in the standard.

The standard requires that adequate records are kept so that any shellfish sold can be traced back to the growing area.

Guidelines for the Management of *Listeria* in Fish Packing Houses and IAIS 003.9

In October 1991 an environmental monitoring programme for *Listeria monocytogenes* was introduced for fish packing houses producing cooked or ready-to-eat seafood. Each company is required to have a programme to test the environment in the fish pack house for the presence of *Listeria monocytogenes*. The critical environment in the fish packing house must be tested every two weeks and the non-critical environment every month. Product samples must be tested each month. The programme details the action to be taken if *Listeria monocytogenes* is found.

The "Guidelines for the Management of *Listeria* in Fish Packing Houses" describe the potential risk areas in fish processing operations and how they may be managed to minimise the potential for *Listeria monocytogenes* contamination.

c) *Company Responsibilities*

By law companies are responsible for implementing certain procedures and requirements. The Manager has responsibility to ensure that:

- all requirements appropriate to the premises are met;
- an approved programme is implemented so:
 - regular checks on compliance with the requirements are made;
 - the results of the checks are recorded; and
 - corrective action is taken within an approved period of time if a check reveals non-compliance with a requirement.

The IAIS 003.8 Quality Checks and Records details the company responsibilities in undertaking the inspection and audit of its premises.

d) *HACCP*

The HACCP approach is a scientifically based control system for ensuring food safety. This is achieved by systematically assessing hazards, developing control systems and focusing on preventive measures.

The "Guide to Hazard Analysis Critical Control Point Systems in the Seafood Industry" has been developed to provide:

- background information from which an understanding of the HACCP approach to food safety can be obtained;
- guidance in the design and implementation of a HACCP plan for food safety;
- a template for seafood applications;
- generic models for the application of the template to selected products; and
- guidance on other HACCP-based applications.

It is recommended that all companies use the HACCP system as a tool for process control for ensuring food safety.

e) *Monitoring of Environmental Contaminants*

In the early 1970s MAF started analysing heavy metals in aquatic animal tissues. A programme was set up in 1979 to determine concentrations of mercury, cadmium, lead, copper, zinc and organochlorine residues in commercially important fish. A summary of the data collected was published in 1988.

Most of the marine fish and squid samples were collected at sea but some were supplied by New Zealand processing factories. All species were identified to the species level except for some skates which are difficult to distinguish and are often not separated commercially.

The analytical data was accumulated for each species and the mean, standard error, and range were calculated. Levels recorded in the raw data as trace or below detection limits were treated as zero for statistical purposes. Where known, information on length and weight was included. The marine samples were grouped into geographic area according to the fisheries management areas current in 1979. Samples supplied by the fishing companies were not classified by geographic areas.

This information is used as a basis for ongoing monitoring of environmental contaminants in fish. MAF is currently monitoring a variety of fish from the main fishing areas for mercury and other heavy metals.

Environmental contaminants of shellfish growing areas are investigated as part of the sanitary survey and maintenance of growing area classification.

f) Bivalve molluscs

The Ministry of Agriculture (MAF) is the government agency responsible for the safety of bivalve molluscs destined for export.

In 1980 MAF signed a Memorandum of Understanding with the United States Food and Drug Administration (FDA). The Memorandum states that the MAF assures that molluscan bivalves exported to the United States of America are safe, wholesome and have been grown harvested, transported and processed in accordance with the FDA National Shellfish Sanitation Programme Manuals.

As a result of the 1980 Memorandum, all shellfish growing areas which provided shellfish for export underwent a sanitary survey (as described in Section C.1 and Appendices B & C of the USFDA National Shellfish Sanitation Programme Manuals) and were classified in accordance with the IAIS 005/NSSP Manuals. This work is undertaken by Authorised Health Officers with the Crown Health Enterprise under the surveillance of MAF.

It is a legal requirement that only shellfish which have been grown, harvested and transported in accordance with the IAIS 005/USFDA NSSP Manuals are permitted entry into an export fish packing house. This means that all shellfish that are exported from New Zealand, irrespective of their destination, must comply with the growing area, harvest and transport requirements of the IAIS 005/USFDA NSSP Manuals.

Bivalve molluscs intended for export alive, or after further processing, or after purification/depuration, are required by New Zealand law to be processed under conditions described earlier in this document for the processing of export fish and fish products. More specific requirements for bivalve mollusc processing and purification are described in IAIS 005: Shellfish Quality Assurance.

Legislation

The law specifying the public health standards for shellfish intended for entry into an export fish packing house is found in Clause (4), Part IV of the First Schedule to the Fish Export Processing Regulations 1995. The clause states:

- Fish declared by the Director-General to be subject to this clause under regulation 5(2) of these regulations and received into a product area of fish premises shall have been grown in or taken from a place for which there is an approved monitoring programme to show that the place is not contaminated at the time of catching or harvesting.

Regulation 5(2) of the regulations states:

- The Director-General may by notice to licensees declare that a species or type of fish is subject to clause 4 of Part IV of the First Schedule to the Regulations.

IAIS 003.3, Reception of Fish, lists the species where an approved monitoring programme is required. All edible species of molluscan bivalve shellfish, and scallops which are exported whole must follow the monitoring programme in IAIS 005.1. Scallops which are not exported whole (e.g. meat and roe or meat only) must meet biotoxin requirements (section 3.11 of IAIS 005.1).

The above legislation requires that only shellfish that have been grown harvested and transported in accordance with the IAIS 005/USFDA NSSP Manuals may enter export fish packing houses.

Approval of Shellfish Growing Waters

The location, boundaries and authority to take shellfish for commercial use are controlled by the Ministry or the Regional Government. No person can farm or take shellfish for commercial use unless the person is issued with a permit or licence which delineates the location and boundaries of the growing area.

The public health requirements for growing waters are specified in the IAIS 005/USFDA NSSP Manuals. A brief explanation is that a sanitary survey must be conducted for each shellfish growing area before harvesting is permitted.

The sanitary survey must include:

- A shoreline survey of the growing area to identify and evaluate all actual and potential sources of pollution that may affect the growing area, determine the distance of such sources from the growing area and ascertain the presence of any toxic substances (e.g., industrial and agricultural wastes, heavy metals, pesticides and radionuclides);
- An assessment of the potential effects of bird, animal or boat populations on the water quality; and
- An evaluation of meteorological and hydrographic effects and geographic characteristics that may affect the distribution of pollutants over the growing area.
- The collection of growing area water and flesh samples to effectively evaluate all potential pollution sources. This is collated to form a data profile for periods defining adverse

pollution conditions which reflect adverse meteorological, hydrographic, seasonal and point sources of pollution to provide assurance that growing area classification standards will be complied with; and

- An annual evaluation to assure that data are current and that sanitary conditions in the growing area are unchanged. The evaluation includes the collection of growing water and shellfish samples and their analysis for bacteriological quality.

Purification/Depuration and Relaying

The requirements for these procedures are specified in the Sections 4 and 7 of IAIS 005: Shellfish Quality Assurance.

Polyculture

If bivalve shellfish are farmed with species other than bivalves, the operations need to be approved. The items to be addressed for approval are in section 3.10 of IAIS 005: Shellfish Quality Assurance.

Harvesting and Transport

Specific conditions for harvesting and transport of bivalve molluscs are laid down in Section 5 of IAIS 005: Shellfish Quality Assurance. The conditions address areas such as harvesting vessel hygiene, temperature control between growing area and packing house and labelling.

Marine Biotxin Control

New Zealand complies with the IAIS 005/USFDA NSSP Manual marine biotoxin control requirements. During the 1993 marine biotoxin event New Zealand developed a Marine Biotxin Management Plan (NZMBMP) for the surveillance of shellfish for a variety of shellfish toxins; ASP, DSP, NSP and PSP. All commercial shellfish growing areas have monitoring and management plans in accordance with IAIS 005 and the USFDA NSSP manuals. In June 1996 the National Marine Biotxin Management Plan was completely revised.

Each commercial shellfish growing area is sampled weekly and tested for each of the four marine biotoxins, ASP, DSP, NSP and PSP.

g) *Inspection services*

The inspection of fish premises and fishing vessels is carried out by MAF Quality Management. In relation to the export of fish and shellfish this involves delivery of non-contestable market access and quality assurance services including system design, inspection, laboratory analysis, audit and certification.

The Inspectors carrying out the work are Travelling Meat Inspectors. Each Inspector is required to complete training to achieve a level of competency in meat inspection, as well as a module in the

specific requirements for Travelling Meat Inspectors and have practical experience under the supervision of a senior Inspector before undertaking inspections of fish premises.

Included in the training is a section on fish which covers introduction to fish and fish handling, spoilage of fish, post mortem changes in seafood, freezing and storage of fish, quality assurance, inspection and audit of premises and certification.

Specialist training in areas such as canning, shellfish management and fishing vessel inspection is undertaken where these tasks are required. On-going training is scheduled at a regional level.

Inspectors are required to have:

- thorough knowledge of the standards and processing techniques relating to the fishing industry;
- high level of communication, problem solving and conflict resolution skills; and
- commitment to MAF Quality Management operations, goals, and business philosophy.

Each Inspector reports to a Regional Inspector and for technical accountability to a Regional Manager who is a veterinarian.

Inspections

Inspections of fish premises consist of visits (monthly, fortnightly or more often) for a duration of 30 minutes to three hours on a random basis. The frequency and duration of the visit will depend on the standard of processing operations, size of operation, quality assurance status of the company, and type of processing carried out. Companies undertaking certain types of processing such as canning will be inspected more frequently. At each visit the Inspector audits the Company Compliance Checksheet to ensure they have been completed by the company. Where non-compliances with the standards are found a target time to correct the non-compliance is determined. If further action is required this is done according to the procedures in the Industry Agreed Implementation Standard.

A standard for performance-based audit for seafood premises has been introduced. The standard outlines the principles and mechanisms which will enable the level of surveillance and frequency of audit to be based on an individual premises demonstrate ongoing performance. The standard is optional at this stage.

Inspections of fishing vessels that are licensed or approved are carried out every time the fishing vessel enters port (for whatever reason). For each inspection a report is completed. Fishing vessels can trans-ship product at sea but the fish must be inspected (usually on a carrier vessel) before the fish leaves New Zealand.

Copies of the transshipment reports are sent to the company that owns the fish and the Inspector at the port where the fishing vessel is domiciled.

In all instances significant issues are followed up.

Inspectors are issued with thermometers, protective clothing, inspection stamps, manuals and instructions. Approved laboratory services are available to undertake analyses such as species verification, mishandled product assessments, residue analyses, water testing and microbiological analysis.

Powers of Inspectors

The Meat Act 1981 (sections 6 and 7) gives Inspectors the power to:

- enter any licensed premises and inspect the premises and any fish or fish product on the premises;
- require the condemnation, destruction, disposal or treatment of any fish or fish product which in the opinion of the Inspector is diseased or defective, is incorrectly labelled, is not processed, handled or stored in accordance with the legislation or contains ingredients or contaminants not permitted by the legislation;
- take samples for inspection, testing or analysis and remove or detain any remaining product; and
- prohibit the use of insanitary or unsuitable premises and require the removal of fish from those premises.

The Fish Export Processing Regulations 1995 gives Inspectors the power to:

- dispose of as appropriate fish which is unfit for human consumption;
- issue export certificates, and withdraw a certificate if the statements on the certificate are no longer accurate or true; and
- direct a licensee to discontinue the use of any labelling that is untrue, misleading or unclear.

Industry Agreed Implementation Standards

The Industry Agreed Implementation Standards are circulars issued by the Director-General under the Fish Export Processing Regulations 1995.

Compliance by MAF Quality Management

Each region of MAF Quality Management has a regional compliance audit programme which requires each Inspector location to be audited annually.

MAF Quality Management have an internal national compliance audit programme. This programme requires each Inspector location to be audited annually by the National Meat Service Auditors (Fish) to measure how the programme is delivered. A selection of premises (including fishing vessels) are audited as part of this programme. Land based premises are reviewed at least every two years and a selection of fishing vessels are reviewed annually.

h) Certification

The Fish Export Processing Regulations 1995 requires that all fish and fish products exported from New Zealand be accompanied by an export certificate. The MAF export fish certificate states that:

- the fish are product of New Zealand;
- the fish were processed and packaged under hygienic conditions in premises licensed and inspected by the Ministry of Agriculture in accordance with the Fish Export Processing Regulations 1995; and
- the fish or fish product is fit for human consumption.

Each MAF export certificate is numbered and an official copy kept on file.

Current Certification

For the majority of markets, MAF certificates are prepared by the company that processed the fish and signed by a company person who has been appointed by the Director-General as an authorised signatory.

Each certificate produced by the company is numbered and an official copy kept on file. Audits of the certificates are carried out by Inspectors as part of the inspection of premises. Failure to comply with any of the requirements of certification can result in the signatory or the company losing the right to sign certificates.

ANNEX I: FOOD IMPORTED INTO NEW ZEALAND

The following information provides background on the Ministry of Health's procedures for prospective importers intending to import food into New Zealand.

Overview

The Ministry of Health (MoH) is responsible for the safety, composition and labelling of imported foods on the domestic market. The MoH develops policy, criteria, and procedures to monitor the safety of imported food for human consumption.

Food Product Monitoring

Imported food surveillance is maintained by targeting high risk imported foods. Other foods are monitored from time to time in specific projects. The majority of low risk food enters New Zealand without restriction.

The MoH maintains border surveillance on the following high risk foods. These foods require public health assurances prior to being released into the market place:

- soft cheese and grated cheese;
- ice cream and iced confectionery
- desiccated coconut;
- crustaceans (cooked and raw) including shrimps and prawns and canned product;
- molluscs (cooked and raw) including clams, cockles, mussels, oysters, scallops fish (chilled and frozen);
- canned fish;
- manufactured and minced fish (surmise and marinara mix);
- smoked and smoke flavoured vacuum packed fish;
- meat products (salami and pate);
- canned food (tomato and tomato based products, and mushrooms);
- nut and nut products;
- spices (pepper, paprika, cinnamon and nutmeg);
- dried dates.

A Multiple Release Permit (MRP) can be issued by the MoH to New Zealand importers with the technical skill and experience to manage a quality system for specific food products from specific manufacturers. Customs brokers can then use the MRP to clear specific goods without the usual health clearance requirements. A MRP should use HACCP principles to identify and control the risk factors (hazards) associated with the production, manufacture, packing, storage, and transport of the product.

The Clearance Process and Clearance Options

At the Ministry's request, Auckland Healthcare's Public Health Protection Service, have established a central clearing house to process all imported food applications. A health permit application form is completed by the importer or their customs broker when the foods enter New Zealand. Applications are processed by Auckland Healthcare and foods are either released after the documentation has been examined, or are referred for sampling. A flow diagram of this process is attached with an example of the health permit application form in Attachment 1. Foods may be cleared by one of the following options:

1. **Acceptance of recognised certification** where the Ministry have negotiated certification agreements with other Governments. When clearance is by certification, valid documents must accompany each consignment. Verification of certification is undertaken by sampling at least one consignment every six months or at a reduced rate i.e. 1 in every 20 where consignments are more frequent than 20 in a six month period.
2. **Clearance sampling** on entry to New Zealand. Sampling frequencies are designated as *tightened* (100 per cent), *normal* (20 per cent or 1 consignment in 4), or *reduced* (10 per cent or 1 in 10).

Perishable food products at the *tightened*, *normal* or *reduced* level of inspection may be sampled and released into the market place as the sample results may take some time to become available. Non-perishable products at the *normal* or *reduced* level of inspection may be sampled and released into the market place. Any released product that fails to meet criteria must be recalled.

All shipments of uncertified product are inspected and sampled under the *tightened* regime according to sampling protocols until a credible history is established.

Products from a particular source may be reclassified from *tightened* to *normal* once a credible history has been established. On the *normal* level of inspection 1 consignment in 5 is inspected. Non-perishable products at the *tightened* level of inspection will be sampled and held pending compliant sampling results. An acceptable history requires 5 consecutive satisfactory consignments.

Where food is regularly imported at a steady rate and 2 shipments have been assessed at the *normal* rate without rejection, products may be reclassified to the *reduced* level of inspection. Any unsatisfactory sample returns the product to a *tightened* sampling regime until a further 5N consecutive satisfactory consignments.

Compliance Standards

Importers of both high and low risks foods need to self evaluate, prior to entry, their products to ensure they comply with the New Zealand food legislation in regard to safety, composition and labelling requirements.

New Zealand recognises compliance with the Australian Food Standards Code as a valid alternative to the New Zealand Food Regulations 1984 with the exceptions being standards related to:

- maximum levels for pesticides; and
- veterinary and animal remedies.

For these issues New Zealand requires compliance with the New Zealand Food Regulations.

Food importers into New Zealand may elect to comply with either of these food standards. However, products must comply with all relevant aspects of either the New Zealand Food Regulations or the Australian Food Standards Code, a mix and match compliance approach is not permitted.

The Food Regulations 1984 and the Australian Food Code can be purchased from Bennetts Government Book Shop:

Bennetts Government Book Shop
Cnr. Bowen Street & Lambton Quay
Wellington
NEW ZEALAND
Ph 644 499 34 33
Fax 644 499 33 75

Importers may evaluate their own products or alternatively employ the services of a consultant.

Fees

Costs are recovered for processing imported food applications, sampling and inspecting foods and any analysis subsequently required. The specific costs are set out below:

Assessment and issuing import permit per tariff item	\$33.75
Sampling and inspecting foods	\$73.12 per hour
Assessment of multiple release permit applications	\$73.12 per hour
Travel costs over 40 km from base	\$00.62 per km

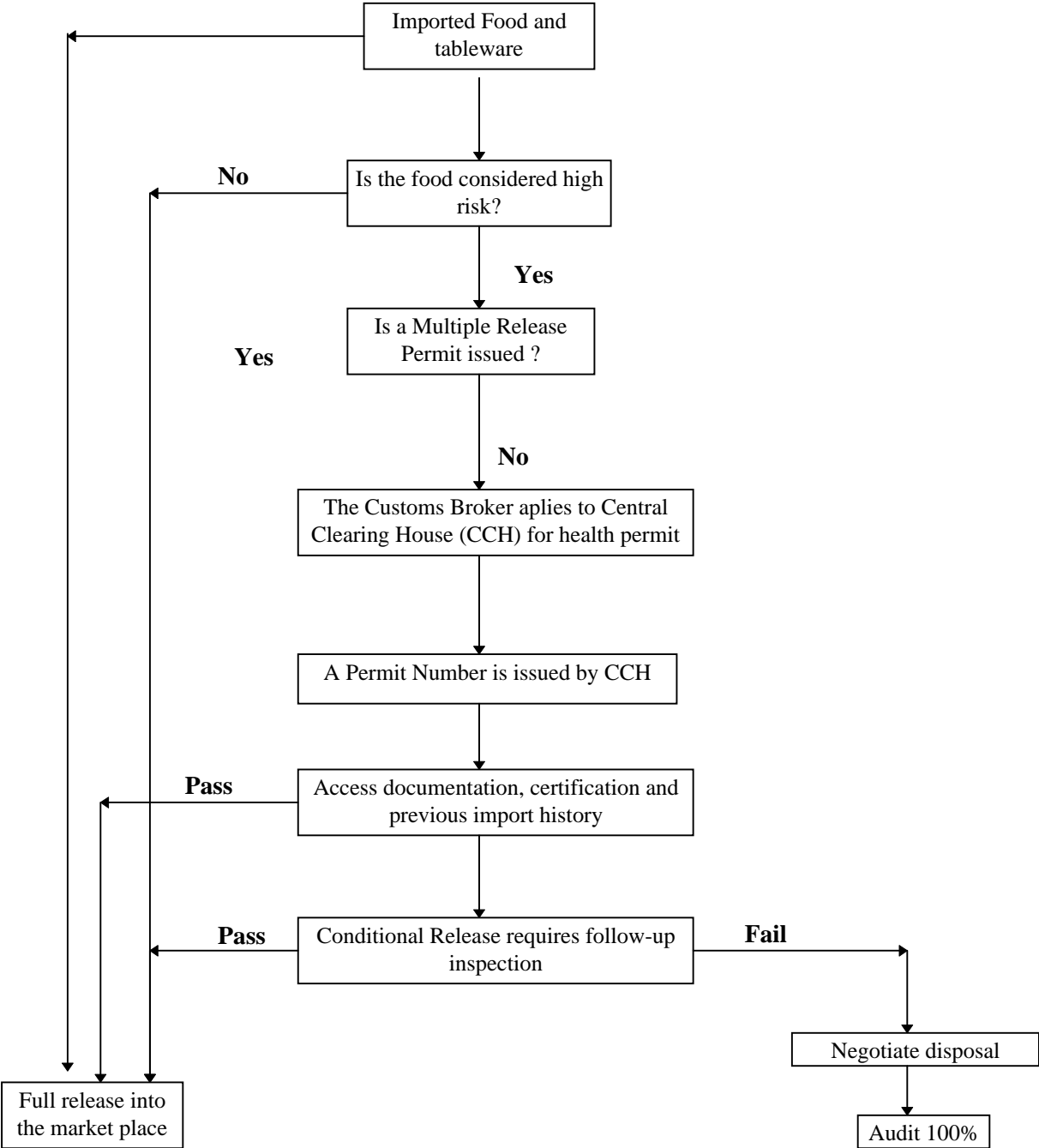
Analysis and testing costs will vary depending on the number of samples and the test(s) completed. Additional costs apply when work is completed after normal office hours.

General

The range of high risk foods monitored, certification arrangements, and testing requirements can change and the most current information should be sought from Auckland Healthcare's Central Clearing House.

The Ministry of Agriculture (MAF) is responsible for animal and plant quarantine requirements.

Figure 1: Imported Food and Tableware Diagram



NORWAY

NORWEGIAN SEAFOOD INSPECTION

by Geir Valset, Chief Inspector, DVM, The Directorate of Fisheries, Bergen

I. Competent Authorities and Organisational Structure

a) *Human Resources/Organisation*

The Ministry of Fisheries is the official authority for fisheries, the fishing industry and the fish farming industry in Norway. The Ministry is the political secretariat of the Minister of Fisheries, performs managerial activities and administers legislative work.

The Directorate of Fisheries was established in 1900 and situated in Bergen. It is the main advisory and executive body for the Ministry in fishing, fish farming and sea-environmental questions. Over 500 people are employed by the Directorate of Fisheries; nearly 300 work outside Bergen. The Department of Quality Control, which is one of six departments of the Directorate of Fisheries, is responsible for quality control of health conditions for the producing, and the placing on the market, of fish products.

The Department of Quality Control employs totally over 140 people. The Department has a central laboratory and an external field service body with around 100 people. These people are distributed among five district offices. The district offices include around 75 inspectors who are situated around the Norwegian coast from the Swedish to the Russian border. The district offices have three regional laboratories.

b) *Legislation*

The quality control of fish and fish products has always been the responsibility of the Ministry of Fisheries. The Norwegian quality regulations relating to fish and fish products are based upon international principles and are consistent with the Codex Alimentarius standards. The Act of Quality Control 1959 gives the authority for quality control. The 1996 Quality Regulations for Fish and Fishery Products (QR) has, in later years, been revised and harmonised with relevant EU Council Directives and Commission Decisions, as well as the new Hazard Analysis and Critical Control Point (HACCP) regulations for seafood in the USA.

In 1996, at the request of the industry, the official quality grading for farmed salmonids and trade categories for saltfish and klipfish was removed from the QR and converted into industry standards.

According to the QR §1-4, the Director General of Fisheries approves establishments (plants and freezing, salting and filleting vessels) and gives them an official approval number. The Director General of Fisheries' List of Approved Establishments are regularly updated and sent to competent authorities in the countries the fish products are exported to.

The Norwegian Food Control Authority (SNT) is responsible for public food control. According to the QR, the SNT has the responsibility for the establishments that produce only for the domestic market or import pre-packed fish products intended for domestic consumption.. The SNT may delegate its authority to the Municipal Food Control Authority.

The Norwegian Animal Health Authority is responsible for animal health, including aquatic organisms, and for the transport and handling of high risk materials.

c) *Laboratories*

The Department of Quality Control has one central laboratory in Bergen and three regional laboratories along around the coast. The laboratories perform chemical, sensory, physical and microbiological analyses. The laboratories:

- support the activities of the competent authority;
- hold scientific knowledge of issues necessary for documenting quality of seafood;
- issue statements based on surveillance activities;
- perform analyses; and
- makes certificates for the fishing industry (what does this mean: do the laboratories certify fishing).

The central, and one of the regional laboratories, have been accredited as meeting the standards EN-45001 and ISO/IEC GUIDE 25-1990. The accreditation is provided by the Norwegian Accreditation and National Measurement Service and covers chemical and microbiological analyses. The other two regional laboratories are expected to apply for accreditation in near future.

d) *Use of Third Parties' Inspection Bodies*

The competent authority does not use third parties' inspection bodies.

e) *Training*

When appointing inspectors, the following qualifications are required (in addition to completing basic school - compulsory elementary school of 12 years):

- higher technical school in food science and hygiene (3 years); or

- technical school in fish processing (3-4 years).

Most inspectors recruited to day have experience from fishing activity, fish industry or inspection/laboratory work within the Municipal Food Control Authority.

The Directorate of Fisheries has internal courses covering: regulations; handling of raw materials; freezing; different types of production and products; hygiene; “own-checks” based on HACCP, etc. Inspectors have participated in external courses for canned food control, ISO-9000 or quality assurance and own-checks system. The duration of courses can be from some days to two weeks.

The quality control is changing from traditional end product control to system control.

Official quality grading and trade categories have been removed from the QR and been replaced by industry standards. The industry is also making codes for quality purpose for different types of fish and fish products. Unless there is training and efforts to preserve knowledge and experience, competence will disappear from the Directorate of Fisheries. When regulations are more general in nature, the possibility of different interpretations exists. Training is important in order to ensure consistent interpretation and use of the regulations of the competent authority of the regulations.

One of the district offices is preparing for the implementation of European Standard EN 45004 - General Criteria for operation of various types of bodies performing inspection. Two laboratories have already been given EN 45001 accreditation. Training is described accurately in the manual.

Training is important to maintain the quality of all the total activities carried out by the competent authority.

Specific training for border control will become important if Norway becomes an EU Member State.

II. Description of Inspection and Control Systems

a) Systematic Inspection Approaches (Mandatory/Voluntary)

Activities

The Department of Quality Control performs quality control and enforces fishery management in co-operation with the Coast Guard. The inspectors are situated around the entire Norwegian coastline and they perform both resource management and quality control functions. This occurs, for example, with of raw material, or at sea on fishing vessels. The Department of Quality Control also has delegated authority, from the veterinary authorities of the Ministry of Agriculture, to control slaughterhouses and wastehandling and to the approve transport of farmed fish (to prevent spreading of fish diseases). Authority is also delegated to the Department of Quality Control, from the Ministry of Agriculture, to control the production of dry fish feed. In addition, in the near future the authority to control the production of fishmeal/oil will be transferred to the Department of Quality Control.

“Own-checks” based on HACCP

Traditionally the quality of fish and fish products has been controlled by random checks on landing, during production, and on the final products. Recently has been replaced by using a “own-checks” system. The QR §1-11 requires “own-checks” based on HACCP in all establishments (plants and freezing, salting and filleting vessels) listed in the Director General of Fisheries' List of Approved Establishments for Fish and Fish Products. The system contains the seven basic principles of HACCP recognised by the international community and described by Codex Alimentarius. The Norwegian “own-checks” system has, among other things, "the basic requirements" (GMP) for sanitation and general factors relating to:

- hygiene and buildings in the establishment;
- registration of calibration procedures and registration of temperature in cold stores;
- control of parasites;
- control of process;
- calibration and control of scales, etc.;
- information procedures for establishments;
- procedures for recall of products and for handling customer complaints;
- description of handling and filing documents and control forms used in “own-checks”;
- description of routines for internal audits of the operation; and
- updating of the “own-checks” system.

The “own-checks” system is mandatory for establishments, whether the product is intended for domestic consumption or whether it is intended for export.

Entrance to Markets

The goal of any export country is to have the easy entrance to all markets of sound and wholesome products fit for human consumption. This will depend on the confidence the authorities in the country of destination have in the national regulations and the control authority in the exporting country.

To comply with existing and expected regulations in EU, USA, Brazil (or any other) market, to follow guidelines and requirements given by Codex Alimentarius, and to have regulations as good as competing fish producing nations (e.g. Canada, Iceland, etc.), the Norwegian “own- checks” system based on HACCP was developed some years ago from the voluntary seafood program from US Food and Drug Administration and the National Oceanic Atmospheric Administration (FDA/NOAA).

A mandatory Norwegian “own-checks” system, based on HACCP, and very similar to FDA's requirements, has been important in the negotiation of bilateral agreements.

Safety hazards and Non-safety Requirements, Other Registrations

The "own-checks" systems for specific safety hazards and non-safety requirements are controlled. In the QR § 1-2, a critical control point (CCP) is defined as "a point or an operation in a production process where lack of control can result in an unacceptable degree of hazard in relation to quality in connection with receiving and handling of raw materials, food safety, hygiene or economic fraud". Quality in connection with receiving and handling of raw materials and economic fraud have therefore been predefined as CCPs.

Guidelines for establishing and controlling the operation of "own-checks" system are outlined in manuals/guidelines given by the Directorate of Fisheries. The manuals/guidelines outline the operation of CCP for various production types.

The FDA has adjusted the HACCP requirements from the original FDA/NOAA voluntary seafood program in the new HACCP regulation of 18 December 1997 for seafood in US. The Directorate of Fisheries is also considering updating and adjusting the "own-checks", building on its practical experience and reflecting the removal from the QR in 1996 of official quality grading for farmed salmonids and trade categories for saltfish and klipfish. It would be appropriate to have a clearer separation between CCP for safety hazards from non-safety requirements and also from "the basic requirements" and other registrations.

Not all people in the fishing industry understand risk analyses, the handling of predefined CCPs with preventive measures, corrective action of non-safety requirements, quality in connection with receiving and handling of raw materials, and economic fraud. Changing two of the predefined CCPs into control points (CPs), but at the having the same control and written registration procedures in these CPs as before, would give the same result. Codex Alimentarius proposes to define defect as "a condition found in a product which fails to meet non-safety requirements" and defect action point (DAP) as "a point, step or procedure at which control can be applied and a defect can be prevented, eliminated or reduced to acceptable level, or a fraud risk eliminated".

Having CCPs just for safety hazards would bring the Norwegian "own-checks" based on HACCP into more harmony with the international community.

Veterinary Drug Residues Control

The Norwegian veterinary drug residues control imposes specific reporting procedures. Drugs for treatment are only obtainable on veterinary prescription. All information from prescriptions is entered into a database contains information the use of medicines in every single fish farm. Regulations impose laboratory control in advance of slaughter for all fish treated with antibiotics or chemotherapeutics during the last 12 months. Residue levels are not accepted. See Annex I.

Database for Pollutants in Fish and Other Seafood

This database documents the normal background levels of pollution and therefore indicates fish resources that have not been polluted by heavy metals, organic pollutants and radioactive compounds. This information serves as basis for statements. See Annex I.

ISO-9000

Several big plants have begun establishing systems to meet ISO 9000 standards. A few of these plants are now certified. It is important that the documents reviewed and approved by the competent (according to the QR), and the documents used for commercial activities, are kept separate.

Sanitary Certificates

Bilateral agreements decrease the need for certificates. In most cases, each country wants to have their own certificate with attestation of specific requirements. It is very difficult finding a minimum standard certificate most markets could agree upon. A Codex sanitary certificate making attestation in relation to a specific Codex standard or a Code could perhaps be such a minimum standard. Re-export of imported consignments is difficult in some cases because of the different requirements in the re-exporting and the importing countries.

Some countries require attestation regarding animal diseases for the import of fish and fish products. Ministry of Agriculture is not necessarily the competent authority for seafood inspection in all countries (e.g. Iceland and Norway).

General statements based on surveillance activities can be issued instead of performing analyses on each individual consignment. The export of frozen pelagic round fish with dead nematodes (not in the muscles) to some countries in eastern Europe can be problematic due to the different regulations in western and eastern Europe.

Contacts and the sharing of information regarding the competent authority and regulations, in addition to visiting production plants, can be sufficient for signing protocols and solving market entrance problems.

c) *Import Requirements*

The QR §1-13 contains import requirements for fish and fish product. Raw materials should also comply with the quality requirements contained in § 5-1,2,3,4, in addition to being sound and wholesome and thus fit for human consumption. Consignments that do not comply with current Norwegian quality regulations may be refused entry, except in cases where Norway is obliged by international agreements, to accept goods produced in accordance with less strict rules (e.g. bleeding of all fish, species exemptions, zero tolerance of veterinary drug residues, etc.).

The Directorate of Fisheries is responsible for the import of fish and fish products. The only exception to this is in the case of imports of pre-packed fish products intended for domestic sale to consumers or institutional households. In this case the SNT is the responsible authority.

If Norway joins the EU, import requirements have to be changed to be consistent with EU Council Directives and Commission Decisions.

III. *Establishment of Criteria for Determining Equivalency*

In recent years, the QR has been revised and harmonised with relevant EU Council Directives and Commission Decisions, as well with the new US HACCP seafood regulations.

Norway entered into the European Economic Area (EEA) agreement with EU some years ago . This agreement made the entrance of Norwegian fish and fish products into EU much easier. The European Free Trade Association (EFTA) Surveillance Authority (ESA) has prepared equivalent lists where Norwegian regulations are compared with EU regulations. Inspectors ESA have visit sites to inspect the competent authority, and the fishing industry, to verify compliance with the EEA requirements.

Brazil and Norway have completed negotiations on a bilateral agreement concerning fish and fishy products. The agreement contains references EU Council Directives and Commission Decisions. The signing of the agreement is imminent.

The Directorate of Fisheries and FDA have agreed upon exchange of letters regarding the control of listeria monocytogenes in smoked salmon produced in Norway for export to United States. Since May 1996, Norway and the US have been developing a HACCP based fish and fish products Memorandum of Understanding (MOU). The intention is that the MOU would be in accordance with Title 21, code of Federal Regulations, part 123.12.

According to the World Trade Organisation (WTO) Sanitary and Phytosanitary (SPS) Agreement, criteria for determining equivalency can be developed for actions relating to safety hazards concerning human health. The benefit of a Norway-US MOU will be a reduction in the import control of fish and fish products from countries with equivalency. Procedures for in the MOU equivalency agreement will be: paper reviews; on-site visits; and official hearings through US Federal Register (FR).

Important principles will include:

- the possibility for the consumers to check the presuppositions in the agreement;
- no reduction in existing standards;
- the same requirement for domestic products as for imported products; and
- verification of compliance with the agreement.

A definition of equivalency may cover productions condition as well as end product specifications. That means a product produced under unacceptable conditions could be prevented from being sold even if there is no demonstration of defect in the end product.

Requirements are provided for the structure of regulations and inspection procedures. For imports into US after 18 December 1997, the importer must have a written verification for ensuring that that products are processed in accordance with requirements of the FR 123.12. This will continue to be required if an MOU or a similar agreement is not established between US and Norway. In the meantime, the FDA has recognises the Directorate of Fisheries certificates that specify that the fish or fish products concerned have been processed in accordance with the requirements of the HACCP regulations.

IV. Audit and Verification Methods

Any quality assurance system needs to be regularly audited to ensure compliance with requirements. The QR §1-11 requires that the “own-checks” system be approved and regularly reviewed

by the competent authority. The implementation of “own-checks” based on HACCP has go through several phases:

1. Directorate of Fisheries writing manuals;
2. training of inspectors;
3. information dissemination and implementation in industry;
4. auditing.

Documentation must have a minimum standard and registration must have been done before auditing, especially the "basic requirements".

It is important to visit each establishments to explain the system and to speed up the process. The implementation takes more time than is often assumed. It is important to try "to keep the “own checks” system as simple as possible, but sufficient".

The inspectors inspect the documentation or the establishments without advance notice. Advance notice is always given before an audit. The best result comes when the establishments make the documentation available and do not leave the entire job to advisers/consultants. Non compliance results in the closing of the establishment concerned. The Directorate of Fisheries has withdrawn the approval of a number establishments who have not implemented the “own-checks” system within the required time limit. It is important that the competent authority makes decisions, makes consistent evaluations and follows up on their own decisions in order to show clear examples for the industry.

The competent authority has no require for quality assurance in the regulations. The laboratories shall according to EU regulations within 01.11.98 be accredited to continue to perform analyses for the authority where result can be followed by decision.

Inspectors from the ESA, FDA, or any other countries:

- perform on-site visit auditing;
- inspect:
 - the competent authority;
 - fishing industry establishments; and
- verify compliance with the terms of bilateral agreements.

Implementing the EN 45004 standard will assure the quality of the work of inspectors from the competent authority. The Department of Quality Control directs the district offices through job descriptions, regulations, instructions, meetings, telephone calls and on-site visiting. Inspectors and districts offices register the type and time of the activities when they perform inspections of fishing industry establishments.

The Department of Quality Control considers quality assurance to be useful for assuring the standard of the activity of the competent authority. The Department has participated at BS EN ISO 9000 Assessor/Lead assessor training courses that were arranged by EU/ESA inspectors.

Without regard to whether mandatory or not, the challenge for the competent authority will in the future be quality assurance.

V. Seafood Production and Utilisation

a) Landings

Norway has 4.5 million inhabitants. The rich fishing grounds off the coast have throughout history been one of the main economic resources of Norway. 11 per cent of the inhabitants live in the northern part of the country; a region that depends on the fisheries and the fishing industry for employment.

An overview of landings, quantities and values of species, is given in the Annex II. The Annex details landings in domestic ports, national landings in foreign ports and foreign landings in domestic ports.

b) Processing

In December 1996, approximately 1150 establishments (900 plants and 250 freezing, salting and filleting vessels) were in the Director General of Fisheries' List of Approved Establishments for Fish and Fishery Products and had been given approval numbers.

Table 1 gives a percentage breakdown of the different processing uses of the catch.

Table 1: **Processing of Catch: Percentage Distribution**

Processing Method	Percentage
Fresh	33
Freezing	17
Salting	11
Meal and oil	37
Drying, canning, etc.	2

c) Domestic consumption

The total domestic Norwegian consumption of seafood was approximately 86 000 tonnes product weight (not live weight) in 1996. In terms of meat consumption, meat made up 66%, poultry 8% and seafood 26 % of the market.

d) Per capita consumption

The consumption per capita in 1996 was approximately 20.7 kg product weight. The figure is the total of sales to consumers and institutional households' consumption.

e) Exports

1 837 000 tonnes of fish and fish products were exported in 1996. The export revenue was Nkr 22 400 million (US\$3 000 million). 90 per cent of Norwegian production of fish products is exported. Approximately 60 per cent is exported to the EU market.

The total production of farmed Atlantic salmon and rainbow trout was 320 000 tonnes in 1996. Atlantic salmon made up approximately 90 per cent of this figure. The export revenues from these farmed fish was over Nkr 6.5 million (US\$900 million).

Aside from the petroleum sector, the fishing industry is the most important export industry in Norway.

d) Imports

568 000 tonnes of fish and fish products were imported into Norway in 1996. The values of these imports was Nkr 3 400 million (US\$450 million).

Table 2: Main Imported Fish and Fish Products

Product	Volume (tonnes)
Fresh cod	65 000
Frozen cod	33 000
Shrimps, cooked	4 500
Shrimps, raw	11 000
Meal/powder	105 000

Table 3: **Origin of Imports**

Country	Volume (tonnes)
Russia	112 000
Denmark	97 000
Iceland	78 000
Chile	72 500
UK	71 000
Canada	8 400

ANNEX I

The Norwegian control of veterinary drug residues in fish etc.

The Director general of Fisheries has made a compilation (issued as a circular, reference "K-melding nr. 4/89", of the laws, regulations, rules and guidelines regarding the way in which the control of veterinary drug residues in fish, shellfish and crustaceans is to be carried out, as well as the action to be taken when infringements are detected.

Electronic data registration:

All drug treatments of fish etc. and results of drug residues analyses are entered into a computer. This facilitates control, and health certificates can be issued quickly without regard to where the fish is farmed, controlled for drug residues or slaughtered. The registration of data from the standardized veterinary prescription forms gives in addition a general overview of outbreaks of disease, epidemiological circumstances, and the total use of drugs in fish farming.

Principles for control:

Fish treated with antibiotics or chemotherapeutic agents during the last 12 months are subjected to control in advance of slaughter. Slaughter fish are also checked in advance when drugs are employed to treat other fish in adjacent net-pens in the farm. Fish that have been treated with drugs are not slaughtered until residues of drug can no longer be detected in the fish. Slaughtered fish are subjected to post-mortem examination for the presence of residues of relevant drugs. Such control is carried out by random sampling and is not notified in advance. Slaughtered fish that contain drug residues are condemned as unfit for human consumption.

Reporting procedures:

Drugs for treatment of fish etc. are only obtainable on veterinary prescription. The Directorate of Fisheries receives, weekly, copies of all such prescriptions which are written on standard forms. Copies of the same prescriptions are sent monthly also from pharmacies or suppliers of medicated feed. The fish farmer is required to notify the Directorate of Fisheries in advance of removal of fish for slaughter, slaughtering and drug treatment during the last 12 months, on a standard notification form. The manufacturer/packer is also required to notify prior to packing. Every two weeks, the Fish Farmers' Marketing Board forward to the Directorate of Fisheries a list of the fish farmers who have slaughtered fish.

Withdrawal periods:

Lists of recommended withdrawal periods have been issued for all types of drugs used to treat slaughter fish. Drugs for which there is no detection method, are not permitted for use.

Analytical methods:

A routine microbiological method is performed for detection of antibiotics or chemotherapeutics in fish, shellfish and crustaceans. Different test bacteria, sensitive to relevant drugs, inoculated in different culture media with different pH, are being employed. If uncertainty exists as to whether the inhibition zone is due to drug residues or other antibacterial substances, the findings are verified using high pressure liquid chromatography (HPLC) or other suitable chemical methods. The Directorate of Fisheries performs annually more than 20 000 analyses with respect to residues of antibiotics or chemotherapeutics in farmed fish. Fifty per cent of the total number of samples are taken for pre-slaughter control and 50% for post-slaughter control.

DATA BASE FOR POLLUTANTS IN FISH AND OTHER SEAFOOD

The pollution of food is often subject to public debate, and the market reacts immediately on the slightest suspicion that the consumption of food represents possible hazards to human health. To take care of the short and long-term interests of the fishing industry it is important to tackle problems regarding pollution on the basis of knowledge. The wild and farmed marine resources shall ideally not be polluted as a result of human activity. This implies that pollutants shall not be detected above a certain background level representing the unpolluted resource. The description of the normal background level is thus seen as a question of vital importance.

The laboratories of the Ministry of Fisheries have established a data base for pollutants in seafood. This will provide a current overview of the concentrations of pollutants in marine food from Norwegians waters, included fish farm locations. The information provided will be used to document good nutritive quality/health, and also to promote fair trade in the export of fish and fishery products.

Aim of the project

To provide data that describe the marine resources living in unpolluted waters. The description shall be sufficiently detailed to permit the handling of existing and future problems on the basis of established knowledge concerning the concentrations of inorganic and organic pollutants.

Sampling for farmed salmon and sandeel

Samples of salmon were collected from each of the nine fishery district along the coast. Five single fish were studied from each location. Small sandeel was caught in the North Sea off Egersund, and two mixed samples were prepared, each consisting of 25 whole fish. Small sandeel is used for the production of oil and meal to be used in fish feed. The material collected is described with respect to catch data and biological parameters permitting statistic comparisons to be made.

Results for farmed salmon

Very low levels of heavy metals, organic pollutants and radioactive compounds were found in the edible parts of the fish. Analyses of mercury showed values ranging from 0,02 mg/kg to 0,05 mg/kg wet weight. This is less than one tenth of the limiting value given by the Codex Alimentarius as the maximum value permitted in fish for human consumption (0,5 mg/kg). The analyses of cadmium gave values less than 0,002 mg/kg wet weight, and results for lead were lower than 0,02 mg/kg. These values are very low compared to international maximum limits. The analyses demonstrated that the concentration of polychlorinated biphenyls (PCB) ranged from approx. 0,0002 mg/kg to 0,005 mg/kg for single congeners. For DDT (sum) a mean value of 0,02 mg/kg was found. Other chlorinated compounds are far below those values that some countries have established as maximum values to protect the health of the consumers. No radioactive cesium was could be detected above the detection limit of 10 Bequerell/kg.

Results for small sandeel

The concentration of mercury was low and comparable to that found in farmed salmon. Lead and cadmium were found at somewhat higher concentration in sandeel compared to farmed salmon, as expected for analyses on whole fish. Radioactive cesium could not be detected. Traces of organic pollutants could be determined at approx. one tenth of the level found in farmed salmon.

Conclusion

Analyses reveal that concentration of pollutants in Norwegian farmed salmon are very low, and without any implications for the health of the consumers.

For further information: Division of Advisory and Information, telephone: 55 23 80 00

DATA BASE FOR POLLUTANTS IN FISH AND OTHER SEAFOOD

COD FROM BORGUNDFJORD (MØRE OG ROMSDAL)

The pollution of food is often subject to public debate, and the market reacts immediately on the slightest suspicion that the consumption of food represents possibly threats to human health. To take care of the short and long term interests of the fishing industry it is important to tackle problems regarding pollution on the basis of knowledge. The wild and farmed resources of the sea should not be polluted as a result of human activity. This means that pollutants over a described background level, representing the unpolluted resource, shall not be detected. An important question will then be what a normal background level is.

The laboratories of the Ministry of Fisheries have established a data base for pollutants in seafood. This will provide a current overview of the concentrations of pollutants in marine food from Norwegian waters, included fish farm locations. The information provided will be used to document good nutritive quality/health, and also to promote fair trade in the export of fish and fish products.

Project aim

To provide data that describe the unpolluted marine resources. The description shall be sufficiently detailed to permit the handling of existing and future problems on the basis of established knowledge concerning the concentrations of inorganic and organic pollutants.

Sampling

It was taken samples of cod from Borgundfjord in April/May 1996. The samples consisted of 25 different fish. The material is described with respect to catch data and biological parameters permitting statistic comparisons to be made.

Results

The analysed cod has low levels of heavy metals and organic pollutants. 50 different metals were analysed and the results for mercury, cadmium, lead and arsenic is described. Analyses of mercury shows an average value of 0,07 mg/kg wet weight. This is low values comparing to the limiting value given by Codex Alimentarius (FAO/WHO) as the maximum value permitted in fish for human consumption (0,5 mg/kg). The analyses of cadmium shows a values less than 0,001 mg/kg wet weight for 23 of 25 fish. The contents of lead in cod was low, lower than 0,01 mg/kg wet weight, while the values of arsenic in fillets showed a range from 0.9 to 19 mg/kg wet weight. The values of the samples is within the normal area for arsenic in fish muscle.

The analyses shows that the contents of polychlorinated biphenyls PCB ranged from <0,00001 to 0,001 mg/kg wet weight for the single congeners. For DDT (sum) it was detected values from 0,0002 to 0,004 mg/kg wet weight. Other chlorinated compounds was lower than 0,001 mg/kg wet weight. All the chlorinated compounds was far below the values that some countries have established as maximum values to protect the health of the consumers.

Conclusion

Analyses reveal that concentration of pollutants in cod from Borgundfjord are very low, and without any implications for the health of the consumers.

For further information: Division of Advisory and Information, the Directorate of Fisheries +47 5523 8000.

DATA BASE FOR POLLUTANTS IN FISH AND OTHER SEAFOOD

PRAWN (*Pandulus borealis*)

The pollution of food is often subject to public debate, and the market reacts immediately on the slightest suspicion that the consumption of food represents possibly threats to human health. To take care of the short and long term interests of the fishing industry it is important to tackle problems regarding pollution on the basis of knowledge. The wild and farmed resources of the sea should not be polluted as a result of human activity. This means that pollutants over a described background level, representing the unpolluted resource, shall not be detected. An important question will then be what a normal background level is.

The laboratories of the Ministry of Fisheries have established a data base for pollutants in seafood. This will provide a current overview of the concentrations of pollutants in marine food from Norwegian waters, included fish farm locations. The information provided will be used to document good nutritive quality/health, and also to promote fair trade in the export of fish and fish products.

Project aim

To provide data that describe the unpolluted marine resources. The description shall be sufficiently detailed to permit the handling of existing and future problems on the basis of established knowledge concerning the concentrations of inorganic and organic pollutants.

Sampling

Samples of prawns were taken from an area outside Spitsbergen September 17, 1995, and in Varangerfjord (Finmark) December 11, 1995. Each sample consisted of 4 KGs, and was frozen and the shell was removed. Two mixed samples of 25 prawns each was taken from each area and described with respect to catch data and biological parameters permitting statistic comparisons to be made.

Results

The analysed prawns has low levels of heavy metals and organic pollutants. 50 different metals were analysed and the results for mercury, cadmium, lead and arsenic is described. Analyses of mercury shows a value of 0,02 mg/kg wet weight. This is 1/25 of the maximum limiting value given by Codex Alimentarius (FAO/WHO) as the maximum value permitted in fish for human consumption (0,5 mg/kg). The analyses of cadmium shows a value on 0,02 mg/kg wet weight. The contents of lead in prawns was 0,01 mg/kg wet weight, while the values of arsenic was 88 mg/kg wet weight (Spitsbergen) and 35 mg/kg wet weight (Varangerfjorden). The values of the samples is within the normal area for prawns.

The analyses shows that the contents of polychlorinated biphenyls PCB ranged from <0,00001 to 0,002 mg/kg wet weight for the single congeners. For DDT (sum) it was detected 0,0002 mg/kg wet weight as an average. Other chlorinated compounds was detected in concentration of 0,001 mg/kg wet weight. All the chlorinated compounds was far below the values that some countries have established as maximum values to protect the health of the consumers.

Conclusion

Analyses reveal that concentration of pollutants in prawns are very low, and without any implications for the health of the consumers.

For further information: Division of Advisory and Information, the Directorate of Fisheries +47 5523 8000.

DATA BASE FOR POLLUTANTS IN FISH AND OTHER SEAFOOD

SPRAT (*sprattus sprattus*)

The pollution of food is often subject to public debate, and the market reacts immediately on the slightest suspicion that the consumption of food represents possibly threats to human health. To take care of the short and long term interests of the fishing industry it is important to tackle problems regarding pollution on the basis of knowledge. The wild and farmed resources of the sea should not be polluted as a result of human activity. This means that pollutants over a described background level, representing the unpolluted resource, shall not be detected. An important question will then be what a normal background level is.

The laboratories of the Ministry of Fisheries have established a data base for pollutants in seafood. This will provide a current overview of the concentrations of pollutants in marine food from Norwegian waters, included fish farm locations. The information provided will be used to document good nutritive quality/health, and also to promote fair trade in the export of fish and fish products.

Project aim

To provide data that describe the unpolluted marine resources. The description shall be sufficiently detailed to permit the handling of existing and future problems on the basis of established knowledge concerning the concentrations of inorganic and organic pollutants.

Sampling for sprat

Samples of sprat were collected from two different catches; Måge in the Sørkjørd (Hardanger) on October 1., and in Fardal in the Sognefjord on October 29. The samples consisted of 25 fish each. The material is described with respect to catch data and biological parameters permitting statistic comparisons to be made.

Results

The analysed sprat has low levels of heavy metals and organic pollutants. 50 different metals were analysed and the results for mercury, cadmium, lead and arsenic is described. Analyses of mercury shows values from 0,01 to 0,02 mg/kg wet weight. This is low values comparing to the limiting value given by Codex Alimentarius (FAO/WHO) as the maximum value permitted in fish for human consumption (0,5 mg/kg). The analyses of cadmium shows a value on 0,02 mg/kg wet weight. This values reflects that the analyses is taken from whole fish. The contents of lead in sprat was 0,01 mg/kg wet weight and lower, while the values of arsenic was 2,6 mg/kg wet weight (Sognefjorden) and 4,5 mg/kg wet weight (Sørkjørd). The values of the samples is within the normal area for sprat.

The analyses shows that the contents of polychlorinated biphenyls PCB ranged from <0,0001 to 0,05 mg/kg wet weight for the single congeners. For DDT (sum) it was detected 0,08 mg/kg wet weight in sprat from Sognefjorden and 0,04 mg/kg wet weight from Sørkjørd. Other chlorinated compounds was detected in much lower concentrations, less than one tenth of DDT. All the chlorinated compounds was far below the values that some countries have established as maximum values to protect the health of the consumers.

Conclusion

Analyses reveal that concentration of pollutants in Norwegian sprat are very low, and without any implications for the health of the consumers.

For further information: Division of Advisory and Information, the Directorate of Fisheries +47 5523 8000.

DATA BASE FOR POLLUTANTS IN FISH AND OTHER SEAFOOD

SPRING SPAWNING COD (*Gadus morhua* L.)

The pollution of food is often subject to public debate, and the market reacts immediately on the slightest suspicion that the consumption of food represents possibly threats to human health. To take care of the short and long term interests of the fishing industry it is important to tackle problems regarding pollution on the basis of knowledge. The wild and farmed resources of the sea should not be polluted as a result of human activity. This means that pollutants over a described background level, representing the unpolluted resource, shall not be detected. An important question will then be what a normal background level is.

The laboratories of the Ministry of Fisheries have established a data base for pollutants in seafood. This will provide a current overview of the concentrations of pollutants in marine food from Norwegian waters, included fish farm locations. The information provided will be used to document good nutritive quality/health, and also to promote fair trade in the export of fish and fish products.

Project aim

To provide data that describe the unpolluted marine resources. The description shall be sufficiently detailed to permit the handling of existing and future problems on the basis of established knowledge concerning the concentrations of inorganic and organic pollutants.

Sampling

It was taken three samples of spring spawning cod in Lofoten in February/March 1995, consisting of 25 fish each. The weight varied from 1 to 5 kilos. It was taken samples of the fish fillet for analyses. The material collected is described with respect to catch data and biological parameters permitting statistic comparisons to be made.

Results

The analysed cod from Lofoten has low levels of heavy metals, organic pollutants and radioactive compounds. 50 different metals were analysed and the results for mercury, cadmium, lead and arsenic is described. Analyses of mercury shows values from 0,03 to 0,24 mg/kg wet weight, giving an average of 0,08 mg/kg wet weight. This is low values comparing to the limiting value given by Codex Alimentarius (FAO/WHO) as the maximum value permitted in fish for human consumption (0,5 mg/kg). The analyses of cadmium shows values from 0,001 mg/kg to 0,002 mg/kg wet weight, which is well beneath the normal concentration level of cadmium in fish muscle. The contents of lead was 0,01 mg/kg as wet weight as average, while the values of arsenic varies from 0,9 mg/kg to 34 mg/kg wet weight. The values of the samples is within the normal area in fish muscle.

The analyses shows that the contents of polychlorinated biphenyls PCB ranged from 0,00001 to 0,003 mg/kg wet weight for the single congeners. For DDT (sum) it was detected values from 0,0002 to 0,004 mg/kg wet weight. Other chlorinated compounds was detected with levels lower than 0,001 mg/kg wet weight. All the chlorinated compounds was far below the values that some countries have established as maximum values to protect the health of the consumers.

Conclusion

Analyses reveal that concentration of pollutants in spring spawning cod from Lofoten are very low, and without any implications for the health of the consumers.

For further information: Division of Advisory and Information, the Directorate of Fisheries +47 5523 8000.

ANNEX II

NORWAYNORVEGE

NATIONAL LANDINGS IN DOMESTIC PORTS / DÉBARQUEMENTS NATIONAUX DANS LES PORTS DOMESTIQUES

	Quant. : tons/tonnes Val. : '000 NKr/KrN				
	1995*		1996*		
	Quant.	Val.	Quant.	Val.	
Salmon	535	26732	531	26669	Saumon
Pink salmon					Saumon rose
Chum salmon					Saumon keta
Sockeye salmon					Saumon rouge
Coho salmon					Saumon argenté
Other salmon	535	26732	531	26669	Autres saumons
Flatfish	15388	244936	18532	287242	Poisson plat
Halibut (all spp.)	14613	237822	17737	280187	Flétan (toutes espèces)
Plaice	537	3464	539	3570	Plie
Other flatfish	238	3650	256	3485	Autres poissons plats
Groundfish	731043	4661478	752510	4339036	Poisson de fond
Cod (Atlantic and Pacific)	363552	2794728	357389	2470365	Morue (Atlantique et Pacifique)
Haddock	79667	440765	96736	481439	Églefin
Saithe	212453	871459	215333	804843	Lieu
Alaska pollack					Morue du Pacifique Occidental
Whiting	329	1428	196	593	Merlan
Hake (all spp.)	777	12813	932	14754	Merlu (toutes espèces)
Redfish	20989	104401	28047	149385	Sébaste
Other	53276	435884	53877	417657	Autres
Pelagics	663331	1466682	751084	2336402	Pélagiques
Horse mackerel	35570	51795	13276	36833	Chinchard
Mackerel	197154	687887	136029	1052145	Maquereau
Herring (Atlantic and Pacific)	411927	666622	581321	1184858	Hareng (Atlantique et Pacifique)
Sardines					Sardines
Other pelagics	18680	60378	20458	62566	Autres pélagiques
Tuna					Thon
Skipjack					Listao
Bluefin tuna (North and South)					Thon rouge (Nord et Sud)
Albacore					Germon
Yellowfin					Albacore
Bigeye					Thon obèse
Other tuna					Autres thons
Other fish	5741	55519	4599	40298	Autres poissons
TOTAL FISH	1416038	6455347	1527256	7029647	TOTAL POISSON
Lobster (rock or European)	34	4472	30	3886	Homard et langouste
Norway lobster (Nephrops)	133	5801	159	6927	Langoustine
Shrimps	33142	638947	40192	617332	Crevettes
Other crustaceans	916	7456	1669	12520	Autres crustacés
TOTAL CRUSTACEANS	34225	656676	42050	640665	TOTAL CRUSTACÉS
Oysters					Huîtres
Mussels					Moules
Scallops	7393	36019	98	644	Coquilles St-Jacques
Clams					Clams
Other shellfish					Autres coquillages
Squid	352	1346	0	0	Calmar
Cuttlefish					Seiche
Octopus					Poulpe
Other molluscs					Autres mollusques
TOTAL MOLLUSCS	7745	37365	98	644	TOTAL MOLLUSQUES
Other marine species					Autres
Pearls					Perles
Seaweed (total)	185000	29200	173160	27464	Algue (total)
Brown seaweed					Algue brune
Red seaweed					Algue rouge
Other seaweed					Autres algues
TOTAL OTHER	185000	29200	173160	27464	TOTAL AUTRES
TOTAL FISH FOR REDUCTION	920919	650007	897566	570578	TOTAL POUR RÉDUCTION
GRAND TOTAL	2563927	7828595	2640130	8268998	TOTAL GÉNÉRAL

NORWAY/NORVEGE

NATIONAL LANDINGS IN FOREIGN PORTS / DÉBARQUEMENTS NATIONAUX DANS LES PORTS ETRANGERS

Quant. : tons/tonnes
Val. : '000 NKr/KrN

	1995*		1996*		
	Quant.	Val.	Quant.	Val.	
Salmon	0	0	0	0	Saumon
Pink salmon					Saumon rose
Chum salmon					Saumon keta
Sockeye salmon					Saumon rouge
Coho salmon					Saumon argenté
Other salmon					Autres saumons
Flatfish	934	18068	1527	28013	Poisson plat
Halibut (all spp.)	6	117	18	429	Flétan (toutes espèces)
Plaice	628	6697	1191	15744	Plie
Other flatfish	300	11254	318	11840	Autres poissons plats
Groundfish	9711	44866	7588	29309	Poisson de fond
Cod (Atlantic and Pacific)	1384	10652	1043	6234	Morue (Atlantique et Pacifique)
Haddock	302	1525	166	749	Églefin
Saithe	6209	21991	5943	18621	Lieu
Alaska pollack					Morue du Pacifique Occidental
Whiting	5	22	14	57	Merlan
Hake (all spp.)	6	62	5	79	Merlu (toutes espèces)
Redfish	1384	6439	255	1957	Sébaste
Other	421	4175	162	1612	Autres
Pelagics	84080	156240	83104	198463	Pélagiques
Horse mackerel			32	41	Chinchard
Mackerel	1597	5865	193	1126	Maquereau
Herring (Atlantic and Pacific)	82414	150225	82222	193880	Hareng (Atlantique et Pacifique)
Sardines					Sardines
Other pelagics	69	150	657	3416	Autres pélagiques
Tuna	0	0	0	0	Thon
Skipjack					Listao
Bluefin tuna (North and South)					Thon rouge (Nord et Sud)
Albacore					Germon
Yellowfin					Albacore
Bigeye					Thon obèse
Other tuna					Autres thons
Other fish	151	1356	72	960	Autres poissons
TOTAL FISH	94876	220530	92291	256745	TOTAL POISSON
Lobster (rock or European)	0	1	0	0	Homard et langouste
Norway lobster (Nephrops)	33	1332	29	1277	Langoustine
Shrimps	5992	135324	942	25831	Crevettes
Other crustaceans					Autres crustacés
TOTAL CRUSTACEANS	6025	136657	971	27108	TOTAL CRUSTACÉS
Oysters					Huîtres
Mussels					Moules
Scallops					Coquilles St-Jacques
Clams					Clams
Other shellfish					Autres coquillages
Squid					Calmar
Cuttlefish					Seiche
Octopus					Poulpe
Other molluscs					Autres mollusques
TOTAL MOLLUSCS	0	0	0	0	TOTAL MOLLUSQUES
Other marine species					Autres
Pearls					Perles
Seaweed (total)					Algue (total)
Brown seaweed					Algue brune
Red seaweed					Algue rouge
Other seaweed					Autres algues
TOTAL OTHER	0	0	0	0	TOTAL AUTRES
TOTAL FISH FOR REDUCTION	36379	18756	74857	41750	TOTAL POUR RÉDUCTION
GRAND TOTAL	137280	375943	168119	325603	TOTAL GÉNÉRAL

NORWAY/NORVEGE

FOREIGN LANDINGS IN DOMESTIC PORTS / DÉBARQUEMENTS ÉTRANGERS DANS LES PORTS DOMESTIQUES

Quant. : tons/tonnes
Val. : '000 NKr/KrN

	1995*		1996*		
	Quant.	Val.	Quant.	Val.	
Salmon					Saumon
Pink salmon					Saumon rose
Chum salmon					Saumon keta
Sockeye salmon					Saumon rouge
Coho salmon					Saumon argenté
Other salmon					Autres saumons
Flatfish	510	3883	631	5685	Poisson plat
Halibut (all spp.)	239	2317	374	3679	Flétan (toutes espèces)
Plaice	237	1397	110	657	Plie
Other flatfish	34	169	147	1349	Autres poissons plats
Groundfish	162075	983694	157731	824367	Poisson de fond
Cod (Atlantic and Pacific)	147410	921537	139074	751028	Morue (Atlantique et Pacifique)
Haddock	11545	47271	13810	52438	Églefin
Saithe	918	2718	1409	5003	Lieu
Alaska pollack					Morue du Pacifique Occidental
Whiting	4	18	4	23	Merlan
Hake (all spp.)	1	4		93	Merlu (toutes espèces)
Redfish	290	1126	567	2446	Sébaste
Other	1907	11020	2856	13336	Autres
Pelagics	85923	232777	125231	530363	Pélagiques
Horse mackerel	949	1349	3447	8769	Chinchard
Mackerel	83903	229806	97777	465544	Maquereau
Herring (Atlantic and Pacific)	977	1385	24007	56050	Hareng (Atlantique et Pacifique)
Sardines					Sardines
Other pelagics	94	237	0	0	Autres pélagiques
Tuna	0	0	0	0	Thon
Skipjack					Listao
Bluefin tuna (North and South)					Thon rouge (Nord et Sud)
Albacore					Germon
Yellowfin					Albacore
Bigeye					Thon obèse
Other tuna					Autres thons
Other fish	42	342	96	844	Autres poissons
TOTAL FISH	248550	1220696	283689	1361259	TOTAL POISSON
Lobster (rock or European)					Homard et langouste
Norway lobster (Nephrops)	2	70	16	510	Langoustine
Shrimps	6658	91150	6327	59703	Crevettes
Other crustaceans					Autres crustacés
TOTAL CRUSTACEANS	6660	91220	6343	60213	TOTAL CRUSTACÉS
Oysters					Huîtres
Mussels					Moules
Scallops	4558	20930	2351	33629	Coquilles St-Jacques
Clams					Clams
Other shellfish					Autres coquillages
Squid					Calmar
Cuttlefish					Seiche
Octopus					Poulpe
Other molluscs					Autres mollusques
TOTAL MOLLUSCS	4558	20930	2351	33629	TOTAL MOLLUSQUES
Other marine species					Autres
Pearls					Perles
Seaweed (total)					Algue (total)
Brown seaweed					Algue brune
Red seaweed					Algue rouge
Other seaweed					Autres algues
TOTAL OTHER					TOTAL AUTRES
TOTAL FISH FOR REDUCTION	3111	2609	10989	6662	TOTAL POUR RÉDUCTION
GRAND TOTAL	262879	1335455	303372	1461763	TOTAL GÉNÉRAL

RUSSIAN FEDERATION

RUSSIAN FEDERATION: FISH AND FISH PRODUCTION QUALITY CONTROL

by Vitalii Korchinski¹³ and Ludmila Mukhina¹⁴

I. Description of Competent Authorities and Organisational Structure

a) Introduction

The fishing industry of Russia is an important provider of food to the Russian population. In 1997 the Russian fisheries catch was 4.7 million tonnes of fish. Of this, 2.6 million tonnes was used produced for human consumption. Fish production quality questions therefore take on special significance.

b) Authorities

The several competent authorities in Russia with responsibility for fish production quality. Annex I indicates the range of authorities involved in this process and their respective roles. The Department of Fisheries is engaged in quality matters from the moment of catch, through processing, and finally with the delivery of the fish product to the market. This department defines the policy with regard to quality and it carries out co-ordination with other state authorities like the State Department of Sanitation and Epidemiological Control, the State Committee for Standards, the Department for Veterinary and State Trade Inspection.

The Department for Fisheries also ensures the quality of fishery products with the European Commission and its member countries. The Department registers establishments in accordance with Scheme No. 1 and sends the list to the European Commission for their registration.

c) Legislation

The following laws are designed to ensure the production of high quality fish products:

-
13. Fisheries Department, Ministry of Agriculture and Foods of Russian Federation, Moscow.
 14. Gosinork Institute, St. Petersburg.

- *Protection of consumers rights;*
- *Veterinary;*
- *Standardisation;*
- *Certification of production and services;*
- *Population sanitary and epidemiological safety;*
- *Ensuring of measurements unity; and*
- *Principles of labour protection.*

In addition, the Sanitary Regulations and Norms [SanPiN 2.3.2.560-96] which specifies the hygienic requirements to the quality and safety of food raw materials and foods. This document lists control indices and standards; safety in epidemiological respects for fish food production on microbiology; heavy metals; toxic substances and pesticides.

In 1996 the *Sanitary Regulations for Practice and Distribution of Fishery Products* were issued and implemented. The regulations were drafted on the basis of the then current Sanitary Regulations issued by State Committee on Sanitary and Epidemiological Inspection of the Russian Federation, and the sanitary requirements contained in key documents from the European Commission.

Russian legislation covers coastal and fish-processing establishments and vessels that manufacture the fish products for both domestic consumption and for export to European Union countries. Competent authorities ensure that these regulations are observed by fish processing establishments and vessels. The competent authorities in the Russian Federation are:

- the State Committee on Sanitary and Epidemiological Inspection and its regional centres;
- the Russian Federation Committee on Fisheries; and,
- other plenipotentiaries to which these rights are delegated.

In addition to the legislative documents mentioned above, the following additional mandatory documents regulate fish production.

- State Standards / GOST/ (contains over 100 items).
- Branch standards /OST/ (53 items).
- Branch technical terms (1300 items).
- Methodological recommendations (more than 200 items).
- Specified technological instructions for every type of production.

The Department for Fisheries of the Ministry of Agriculture and Food finances the development of Branch Standards and other regulating documents. It then refers the documents to the State Authorities

for Surveillance, the State Committee for Sanitary and Epidemiological Inspection (of the Ministry for Health), State Committee for Standards and other authorities. The Department for Fisheries approves the regulations independently, although it may choose to seek assistance from Technical Committees. Such Committees are organised under the auspices of the State Committee for Standards. They comprise specialists from Inspectors Bodies of Russia and branch representatives. The Technical Committees develop standards, make changes to existing standards and recommend improvements to standards.

New regulations have been developed to provide a unified approach to quality control for fish production in establishments and vessels that are exporting to EU countries. These regulations are the:

- *Statute on Registration Procedure for Establishments and Vessels* which produce fish for export to the EU countries and delivery of health certificates for given production type; and
- *Provisional Guide on Organisation Procedure of the System "Own Checks"* on establishments and vessels which produce fish for export to EU countries.

d) Training

High quality fish production specialists play an important role in the fisheries sector. Training staff is therefore of great importance. There are more than 150 institutes in Russia which train specialists for quality control in foodstuffs production.

There are numerous universities, academies and colleges situated in that large port cities of Russia which train specialists for the catching and processing of fish. There are also numerous scientific research institutes in each fishing region of Russia which conduct research on fish production and quality.

Special attention is paid to the re-training staff in the institutes belonging to the Department for Fisheries, the Department of State Sanitation and Epidemiological Surveillance, and the State Committee for Standards.

II. Description of Inspection and Control Systems

a) Inspection

The control over the quality of fish production begins with the drafting of plans for the construction of fishery vessels. After finishing the construction there are procedures for the approval of the enterprise or vessel by the Special Commission with the participation of a sanitation physician.

The factors subjected to control are the:

- application of materials which have contact with fish and fish products;
- supplying of microbiological control of sanitary conditions in fisheries production and personal hygiene of fish product producers;
- quality drinking and seawater for use in disinfection;
- observance of temperature regimes during the process of production; and

- storage and transportation.

In accordance with the regulations, technological services and laboratories or enterprises carry out constant checking of technological parameters, processes and registration of data in journals. The chiefs of enterprises and laboratories are responsible for the quality of production. Control is carried out on critical points of the technological process, the infringement of which might cause the development of microflora in raw or auxiliary materials and create food safety problems for consumers. Thus the main principles of Hazard Analysis and Critical Control Point (HACCP) analysis are not absolutely new for the Russian Federation.

Russia regards HACCP in its entirety as a system ensuring the quality of products exported to the international market. A great deal of work is taking place in the Russian Federation regarding the use of the system based on HACCP to ensure the safety of the fish and fish products.

From end of the 1960s/beginning of 1970s there was factory control in the coastal fish-processing establishments and vessels in the fishing industry. This involved the control of technochemical and microbiological parameters of production that might influence the quality of the finished product.

In conformity with the requirements of normative documents, establishment laboratories have been continually carry out the control of these parameters with obligatory recording of the data in journals. As a rule control has been carried out at those stages (points) of production process where there is risk of the development of microflora of the raw or auxiliary materials and therefore create food safety problems for consumers.

Given this experience, the fishing industry is able to adopt a new control system relatively easily. The establishments organise groups for introduction of HACCP. Much attention is given to qualification of experts and their knowledge in technology and hygiene requirements. The group leaders develop a technological control scheme with an indication of critical points, hazards and preventive measures. The technological control scheme is approved by establishment director. For each critical control point under bacteriological evaluation of technological conditions, the establishments elaborate their maximum admissible microbiological ratings according to specific methods.

At the establishment, the program of measurements and observances is draw up with the regard for technological scheme. In conformity with this program, the Inspection Body carries out an assessment of the work of system of “own-checks” based on the principles of HACCP at the establishment. The scheme for organisation of the safety control of food fish production in the Russia Federation is given in the Annex I to this paper

Sanitary and epidemiological surveillance is carried out in the Russian Federation by the Department of Sanitary and Epidemiological Surveillance (Ministry of Health) and the State Sanitary and Epidemiological Service institutions; subordinate territorial State Sanitary and Epidemiological Surveillance centres; centres of territories, regions, towns of federal significance, autonomous regions and territories, regions with water and air transport.

The State Committee for Standards gives the following regional branch centres the right to take act as laboratories in the quality assessment of the fish products: Centre for Certification Tests, Certification Body “Vostok-Test” Dalrybssystemotekhnika, Vladivostok; Central Technological Laboratory, Certification Body “Sakhalinryba”, Yugno-Sakhalinsk; Technological Laboratory, Certification Body “Intekham”, Petropavlovsk-Kamchatskiy; Test Centre Giprorybflot, Saint-Petersburg;

Test Centre Scientific and Industrial Association “Kaspribtechcentre“, Astrakhan; Test Centre “AtlantNIRO“, Kaliningrad; and Test Centre, Certification Body VNIRO, Moscow.

For exports of fish products, the State Committee of Fisheries¹⁵ of the Russian Federation, in co-operation with the State Committee of Sanitary and Epidemiological Surveillance¹⁶ of the Russian Federation, is the Russian competent authority.

In the period from 1996 to 1997 the State Committee of Fisheries registered a number of certain establishments and vessels. These establishments and vessels then obtained a provisional registration number in the European Commission in Brussels. At present more than 140 Russian establishments are registered with both the Department for Fisheries and the European Commission. These include the Far East fishing vessels, from the Murmansk, Kaliningrad, Arkhangelsk and Astrakhan regions and also a number of coastal establishments.

Registered establishments are required to carry out the quality control in strict conformity with new sanitary requirements regardless of which market, whether it product for export or domestic use.

The reception of Health certificate remains a complicated question. In some establishments the Health certificate is signed by veterinary services without indication of name, position, or date. However, in reality only the state bodies of Ministry of Health and State Committee of Fisheries actually have the authority to sign the Health certificate. The Health certificate for each shipment should be received by the manufacturer, not by intermediary. Accordingly the establishment is required to be submitted for registration by the manufacturer.

The export of Russian fishery products to the world market is not possible without direct technical co-operation with other states. Furthermore, such exports are not possible without co-operation between manufacturers of the fishery products (coastal fish-processing establishments and vessels) with co-ordinating and the controlling bodies of State Sanitary and Epidemiological Surveillance Federal Centre (Ministry of Health), centres for certification of the fishery products and regional branch laboratories. Co-operation is required in order to fulfil a number of conditions, one of which is the delivery of Health certificate in conformity with the Commission Decision 93/185/EEC to the Council Directive 91/493/EEC.

As the bulk of approved establishments are fish-processing vessels, it is necessary to prepare and establish a special control system with:

- self-recording and transmission of information on the production state;
- parameters for appropriate technological processes; and
- sanitary and microbiological manufacture assessment.

Such systems will guarantee the manufacture of competitive, high quality products, and ensure that the necessary information is efficiently transmitted from establishment-manufacturer to its controlling body.

15 At present the Fisheries Department of the Ministry of Agriculture and Foods of the Russian Federation.

16 At present Department of Sanitary and Epidemiological Surveillance of Ministry of Health of the Russian Federation.

On location (ship) testing on fishing freezing trawlers, for the purpose of obtaining of Health certificate for exports to the EU countries, without stopping at home ports directly on the open sea, has shown the efficiency and reliability of elaborated system of “own checks”. These systems have used the self-recording of temperature parameters of the technological process and rapid methods for assessment of the sanitary state of the products in real fishery conditions.

This testing has shown that in Russia there is hardware, software and organisational and technical provision of the efficient communication systems, that permit establishments-manufacturers of the fish and fish products to receive Health certificates from controlling (co-ordinating) bodies whilst operating on the open sea.

b) *Falsification*

In the process of checking the quality of fish products, inspectors sometimes discover falsification. Therefore the Department for Fisheries has appointed seven laboratories and institutes in different regions of Russia for the evaluation of fish product quality and, if necessary, identification of their origin. These authorities were confirmed by the State Committee for Standards. These organisations can confirm the quality of product issued by fishery plants and by signing contracts, in order to prevent the delivery of falsely labelled product to markets.

At present there exist two kind of product falsification: concealed and evident. For instance, one Belgium firm began production of crab cans after buying "Chatka" labels in Russia. At the same time technology and quality of products had changed in accordance with new Russian standards. Under the new standards, such cans must be produced from fresh crabs without any additions. The cans must a correct proportion of dryweight and liquid and the quality of crab meat is strictly regulated. Because of the infringement of the requirements by the Belgium firm, the consumer perception of finished crab production was changed negatively.

In spite of severe demands on food exports to European market, in 1996-97 Turkey delivered sturgeon caviar from unknown producers (in volumes which exceeded the total quantity of caviar exported from the Russia Federation). It must be stressed that, in the management of this fishery, Turkey never had allocations for sturgeon catch.

From Russia's perspective the matter of falsification is be of special attention.

e) *Organisational Structure*

The organisational structure of branch system for the quality management has been created to achieve the following objectives.

- Ensuring and improving of fish product safety.
- Ensuring and improving the systems which provide fish product safety.

The Fisheries Department, which determines policy in the quality field, is at the head of the fisheries branch system. It has co-ordinating duties for implementing this policy, in the future, will be imposed on the Russian Centre for Quality Management and its regional branches.

The Co-ordinating Microbiological Centre for the fish and fish products makes up part of this branch structure. The accreditation of its test laboratory in the *Accreditation system for test laboratories of State Sanitary and Epidemiological Service of the Russian Federation* has been carried out for technical competence and independence in such principal spheres as:

- inspection of “own checks“ systems; and
- developing systems for voluntary certification of the quality systems in the manufacture of fish production based on the principles of HACCP.

At present the main task is the accreditation and state registration of the system for the voluntary certification of quality systems and manufacture of fish products based on HACCP principles.

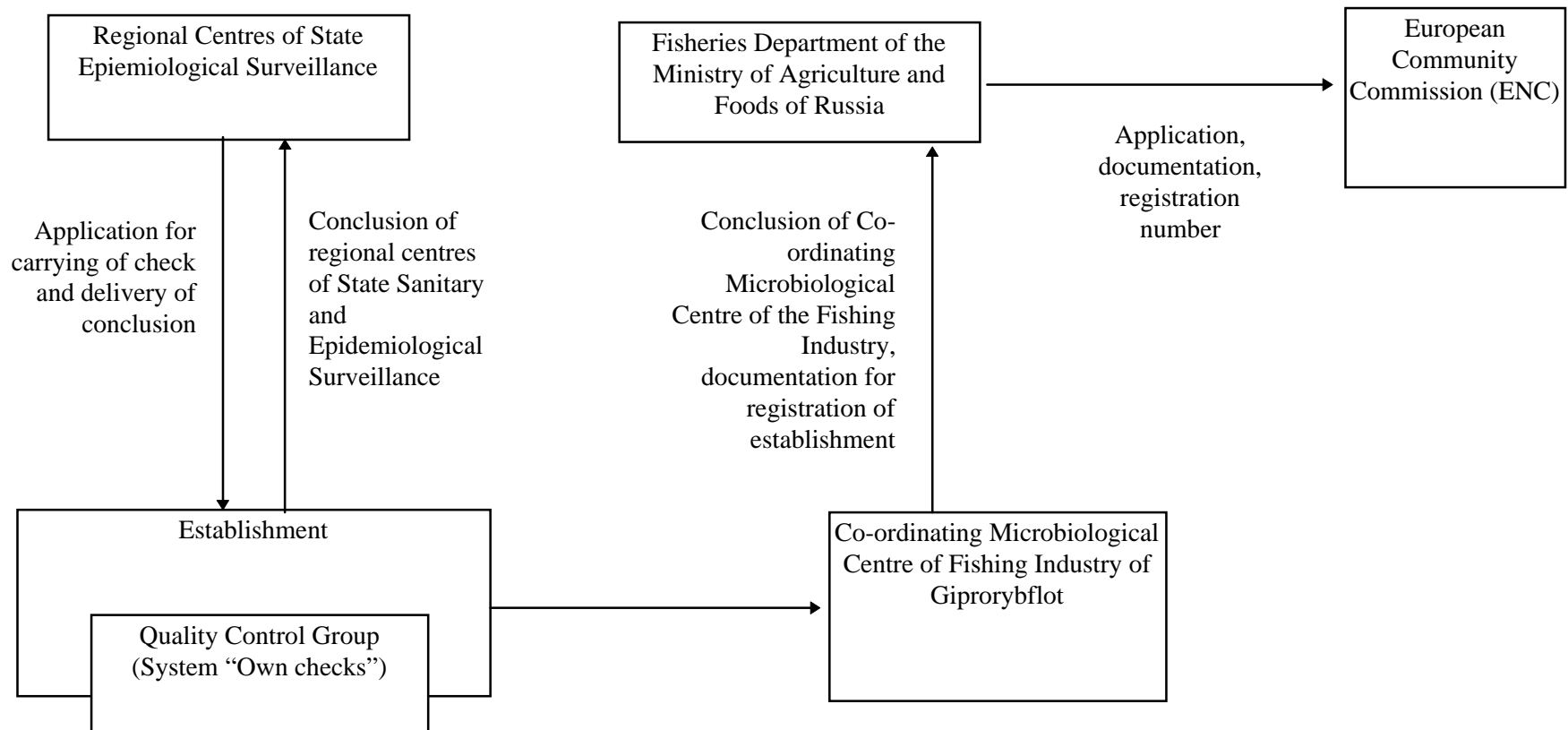
ANNEX I: THE ORGANISATIONAL STRUCTURE OF THE FOOD SAFETY PRODUCTS IN THE RUSSIAN FEDERATION

Production control at the establishment	State inspection of the Russian Federation authorities							
	Department of State Sanitary and Epidemiological Surveillance of Russia	State Committee for Standardisation of Russia	Ministry of Agriculture and Foods of Russia				State Trade Inspection of Trade Committee	Public control Consumers' Union of Russia
			Veterinary Department	Fisheries Department				
				Coordinating Microbiological Centre of Gipro-rybflot (CMCFI ¹)	Research Institutes and CMCFI of Gipro-rybflot	Regional branch centres		
Continuous control of food raw materials along technological line of the end product	State surveillance of observance of sanitary regulations and norms in the production of foods	1. State surveillance of observance of standards and technological process 2. Production quality control	Veterinary phytosanitary spot control of production quality and its manufacture conditions	Giving of number for registration of establishments in EC, state inspection of work of systems on the basis of HACCP and observance of sanitary regulations and norms for production and realisation of fish production. Training of specialists, preparation of experts-auditors	Elaboration of state standards, instructions, sanitary regulations and other normative documentation	Carrying out of arbitration analyses of the fish production	Spot control of end product quality in the trade shops	Spot control of end product quality

1. Co-ordination Microbiological Centre of the Fishing Industry.

ANNEX II: THE ORGANISATION SCHEME FOR THE CONTROL OF THE FOOD FISH PRODUCTION SAFETY IN THE RUSSIAN FEDERATION

Registration procedure for establishments and vessels manufacturing the fishery products for export to the European Community countries



UNITED STATES OF AMERICA

FISH INSPECTION SYSTEMS IN THE UNITED STATES

I. Description of Competent Authorities and Organisational Structure

a) *Human Resources*

The Food and Drug Administration (FDA) is comprised of over 9 000 professional, scientific, and support staff. Approximately 3 200 of these individuals operate in the Office of Regulatory Affairs (ORA) which includes all of the field investigators. Of these, the equivalent of approximately 340 positions are assigned to seafood related activities (excluding research). These positions are equally divided to domestic and import activities.

Approximately, 835 employees operate out of FDA's Centre for Food Safety and Applied Nutrition (CFSAN). The equivalent of some 97 positions are delegated to seafood activities at CFSAN, of which approximately 54 work for the Office of Seafood.

Thus, approximately 394 FDA employees from ORA and CFSAN are involved in seafood related regulatory activities. Additional activities at the Seattle Seafood Products Research Centre and headquarters offices such as the Office of Policy, Office of International Affairs, the Office of Chief Counsel, etc., are not accounted here.

The focus of FDA personnel resources is somewhat flexible and can be altered to address changing regulatory demands between programme areas or within a specific discipline, such as seafood, as required to protect the public from newly arising concerns.

Individual US States conduct inspections of fishery related operations within their jurisdictions. FDA contracts with 38 of the States to assist in doing food inspections; seafood inspections are part of the contracts with 33 of these States. FDA also has approximately 57 food safety related inspection partnerships with the States. These partnerships are expected to become all the more of a valuable tool as the Hazard Analysis and Critical Control Point (HACCP) requirements go into effect.

The National Marine Fisheries Service (NMFS), under the National Oceanic and Atmospheric Administration of the US Department of Commerce, operates a voluntary, fee-for-service, Seafood Inspection Programme and is a recognised competent authority to conduct inspection, grading, and certification of fish and fishery products. The Seafood Inspection Programme is staffed by 179 professionals, scientists and support personnel. Of these, eight are located at headquarters and the

remaining 171 are located in the field or support offices throughout the US, Puerto Rico, and American Samoa.

b) Legislation

The majority of US federal regulatory authority and activity for seafood regulation is vested with FDA within the Department of Health and Human Service. FDA's mission is to enforce laws enacted by the US Congress and regulations promulgated by the Agency to protect the consumer's health, safety, and pocketbook. A few of the principal laws associated with seafood safety are:

- The Federal Food, Drug, and Cosmetic Act of 1938, as amended (21 USC. 301-392);
- The Fair Packaging and Labelling Act (15 USC. 1451-1461); and
- The Public Health Service Act, relating to biological products for human use (42 USC. 262-263) and control of communicable disease (42 USC. 264).

Section 704 of the Federal Food, Drug, and Cosmetic Act (21 USC. 374) provides the basic authority for FDA investigators to enter and inspect establishments or vehicles being used to process, hold or transport seafood. Section 702 of the Act (21 USC. 372) authorises the taking of samples for examination and investigation purposes.

Regulations enforced by FDA in association with these laws are promulgated under Title 21 Code of Federal Regulations (CFR). Notices of new, revised or proposed regulations are published daily in the Federal Register. These laws and regulations are publicly available on the Internet.

A summary of these laws and regulations is assembled for simplified reading in a document titled Requirements of Laws and Regulations Enforced by the US Food and Drug Administration. While the document is not a substitute for the actual laws and regulations it should serve the Workshop purposes of describing regulatory expectations in the US and it should assist the individuals making comparisons in understanding FDA's approach to regulation of seafood and food in general. The document is not currently available as a hard copy but can be accessed on the FDA Internet home page (<http://www.fda.gov>) under the 'Industry' heading.

Although the document was recently revised in April 1997, it does not capture all of the pertinent regulation. One very important regulation for US purposes is 21 CFR Part 123 addressing the FDA's HACCP approach to Fish and Fishery Products (Annex I). Also attached is a short CFSAN Handout which briefly describes the FDA's authorities and activities related to seafood regulation (Annex II).

Contracts and partnerships with States are based on similar overlapping laws and regulations to those of the federal government. Many US States have enacted a basic Uniform Food, Drug, and Cosmetic Bill, and other States have adopted at least a part of the bill. The provisions of these laws are very similar to the 1938 provisions of the Federal Food, Drug, and Cosmetic Act. Most States without the Uniform Bill, have laws based on the 1906 Food and Drug Act. Most larger cities also have their own ordinances and regulations.

The NMFS voluntary seafood inspection programme operates primarily under the authority of the Agricultural Marketing Act of 1946, and subsequent amendments. Other useful authorities are provided through the following Acts:

- Fish and Wildlife Act
- Lacey Act
- Racketeer Influenced and Corrupt Organisations Act
- Federal Trade Commission Act
- Magnuson-Stevens Fishery Conservation and Management Act

Brief descriptions of these authorities are provided in Annex III titled “The National Oceanic and Atmospheric Administration Seafood Inspection Programme.”

Member firms or individuals contracting under the Seafood Inspection Programme must meet the applicable FDA, state, and local requirements as a baseline to having products or facilities inspected.

c) *Organisation*

Much of the seafood policy development and inspection programming takes place at the Office of Seafood within the Centre for Food Safety and Applied Nutrition (CFSAN).

At the field (inspection) level of the FDA, each of the 21 district directors reports to the appropriate five regional directors who, in turn, report to the Associate Commission of Regulatory Affairs (ACRA) at headquarters. The Offices of Regional Operations, Enforcement, and Criminal Investigations also report to the ACRA.

The ACRA and the director of CFSAN, report to the Deputy Commissioner for Operations who then reports to the FDA Commissioner. The Commissioner reports to the Secretary of the Department of Health and Human Services who, in turn, reports to the US President. The President, of course, reports to the people of these United States.

Pertinent details on the organisation of the FDA can be found at http://www.fda.gov/ora/inspect_ref/iom/97ch2/iom39.html. Attached is an organisational chart for the NOAA/NMFS Seafood Inspection Programme (Annex IV).

d) *Laboratories*

FDA currently maintains seventeen regulatory laboratories across the nation. Each has the ability to conduct seafood related analyses for a vast array of defects including microbial pathogens and parasites, chemical contaminants, decomposition, filth, illegal or undeclared food or colour additives, drugs, pesticides, radionuclides, marine toxins (e.g., saxitoxins, domoic acid, etc.), specie substitutions and net weight falsification or other misbrandings. However, some laboratories have specialised expertise that can be utilised in the absence of the necessary expertise at a particular laboratory or for confirmation purposes when desired.

FDA has several laboratories dedicated to seafood safety research: the Gulf Coast Seafood Laboratory Branch at Dauphin Island, Alabama; the Seafood Products Research Centre in Bothell, Washington; and the Centre for Food Safety and Applied Nutrition headquarters' laboratories in Washington, D.C.

The Division of Science and Applied Technology, in the Office of Seafood at CFSAN, plans and co-ordinates the research activities at these facilities and also co-ordinates research with other agencies such as the National Marine Fisheries Service, Fish and Wildlife Service, and others.

Procedures and methodologies for conducting analyses for enforcement purposes are well documented and controlled at FDA.

e) Third Party Inspection Bodies

FDA does not generally approve or accredit inspection bodies or laboratories to assure the acceptability of the products it regulates. However, the use of reliable third-party information to assist FDA in making regulatory decisions is becoming more attractive in light of pressures on the availability of federal funds and resources coupled with improving communications and capabilities of external interests.

For fishery products, FDA currently reviews third-party laboratory analyses submitted for import entries subject to "detention without physical examination" due to historical violations associated with the products, the country of origin, the manufacturer, or the importer. The third-party results are submitted to remove the appearances of a violation to gain entry of the detained goods. In addition to the analytical results, FDA carefully reviews the submissions for suitability of sample collection and representation, background of the analysts, analytical method suitability and application, etc. The Agency frequently audits the results of such submissions by also sampling and analysing the subject entries. FDA's Laboratory Procedures Manual details the criteria that are considered when reviewing results from, or auditing, a third-party laboratory. The Agency maintains a list of third-party laboratories found to produce unreliable data for specific analyses. Data submitted by such labs, as evidence demonstrating the acceptability of goods, are rejected.

FDA establishes contracts with state health agencies to assist with the inspection of food plants, including seafood plants. These contracts are written to result in an extension of FDA activities rather than the acceptance of third-party activities. However, FDA has also recently been entering into and pursuing state "partnerships" to increase the efficiency and avoid the redundancy of state and federal inspections of the same plants by co-ordinating, accepting and relying on state inspection activities under some circumstances.

In addition, a couple of domestic programmes which have been largely successful at providing a level of public protection from harmful seafood and which involve non-FDA entities are the National Shellfish Sanitation Programme (NSSP) and the Salmon Control Plan. The NSSP programme ensures the proper and safe growing, harvesting, handling and distribution of molluscan shellfish. In this programme, the opening and closing of harvest waters is monitored and enforced by individual State governments that possess shellfish harvesting waters. FDA administers and provides oversight of the NSSP including audits and evaluations of the State programmes. The Salmon Control Plan is administered through the National Food Processors Association and provides assurances of the safety and quality of domestically processed canned salmon. Canned salmon and molluscan shellfish must still meet all of the requirements of the Federal Food, Drug, and Cosmetic (FFD&C) Act and its regulations.

Reliance on foreign government programmes to help ensure the safety of US imports is also gaining momentum. For years FDA has entered into co-operative agreements or Memorandum of Understanding (MOU) with foreign governments to evaluate the suitability of food to be delivered to the US. There are several such agreements with countries that have demonstrated laws or regulations consistent with the provisions in the NSSP Operations Manual along with personnel, infrastructure, and other resources needed to effectively implement the programme. FDA's seafood HACCP initiative, effective December 18, 1997, encourages the application of MOUs or similar agreements to establish HACCP equivalent inspection and enforcement systems as a means for importers to assure the safety of imported seafood. Also, legislation was recently proposed that would hold food offered for import adulterated if it is not prepared, packed, and held under a system, conditions, or measures that achieve the level of protection for food within the US. While regulations clarifying this law have not yet been developed, it is speculated that the exporting countries' inspection and enforcement practices will be weighted heavily in permitting entry of food from those countries into the US.

Consequently, while FDA is actively pursuing ways of placing reliance on other governmental inspection bodies (i.e., States and foreign governments) to contribute to the overall protection efforts of the public, there are still reservations about the use of non government entities. When any function is performed by a non government entity, such as a private inspection organisation, there must be sufficient government oversight of the private organisation to ensure that the relevant regulatory functions are being carried out adequately and in a manner that preserves the integrity and credibility of the functions. Ultimate regulatory responsibility must continue to rest with the government.

f) Training

Newly hired investigators to FDA are required to have successfully completed a full 4-year course of study in an accredited college or university leading to a bachelor's or higher degree, which included at least 30 semester hours in one or a combination of the following fields: biological sciences, chemistry, pharmacy, physical sciences, food technology, nutrition, medical science, engineering, epidemiology, veterinary medical science, or related scientific fields; or a combination of education and experience which consists of at least the 30 semester hours of study in the above sciences plus appropriate experience or additional education. Laboratory personnel will generally be required to have a bachelor's or higher degree consistent with the field of analyses the employee is expected to conduct.

All newly hired investigators are required to take FDA courses in Food and Drug Law, Interviewing Techniques, Evidence Development, and Quality Auditing. They are exposed to other nationally offered courses depending on the types of investigations they will be conducting. For example, in seafood, an investigator may be exposed to FDA courses in Food Microbiology, Seafood Safety, Seafood HACCP, Organoleptic Analysis of Seafood, Canning Technology, Nutritional Labelling, etc. The investigators may also be exposed to regionally provided training or specialised, non-FDA, training as necessary. Laboratory personnel may also take nationally available training such as Analytical Techniques for Seafood or Organoleptic Analysis of Seafood, or specialised training by the Centres or non-FDA sources as necessary.

Additionally, with the advent of the HACCP regulations, FDA has reached approximately 6,000 federal, state, local, and foreign government regulators, as well as industry participants, through an Alliance training effort co-ordinated between FDA, academia, and industry. The Alliance has trained an additional 530 individuals, including 90 foreign officials, in "Train the Trainer" courses to further disseminate understanding and compliance with the seafood regulation. Another 2 500 or more

individuals have been directly exposed to the requirements of the seafood HACCP regulations through FDA's "town hall meeting" and "import workshop" efforts.

FDA provides technical assistance to the States through its State Training and Information Branch and annually conducts seafood training of state and local regulators as part of its mandatory seafood and shellfish programmes. This training in inspection and analysis of samples traditionally reaches over 100 state and local inspectors and analysts per year.

To provide a sound scientific approach for its inspections, FDA also conducts in-house training through its Education and Training Staff. The Agency operates small business assistance and consumer affairs functions at the District, Regional and Headquarters levels to foster compliance with its regulations, to provide a greater understanding of the need for industry controls, to help exchange information among FDA, consumers and regulated industry, and to provide consumer advisories. FDA provides extensive technical assistance in the area of seafood safety and sanitation to foreign governments, through direct contacts and through the World Health Organization (WHO) and the Food and Agriculture Organization (FAO).

Hiring qualifications for NMFS inspectors are similar to FDA's. The training specialists of Technical Services, and the Quality Team are continually updating their training activities to reflect changing needs of the inspectors and their related industry functions. Areas of training include inspection procedures for fishery products, low-acid canned foods, sensory analysis, HACCP principles and implementation, auditing practices, European Union requirements, and retail food safety. These may be presented as formal group sessions, home study, or individual exercises according to the need.

II. Description of Inspection Approaches

a) Use of Systematic Inspection Approaches

In the US, the manufacturer or owner of the goods is responsible for the safety, wholesomeness, and truthful labelling of the products in his control. FDA inspects food operations and samples products to ensure the food is neither adulterated nor misbranded.

An establishment inspection is a careful, critical, official examination of a facility to determine its compliance with laws administered by FDA. Inspections may be used to obtain evidence to support legal action when violations are found. FDA routinely inspects all food processing, handling and storage operations involved in interstate commerce. Facilities are inspected for sanitary conditions and processes, safe product handling practices, and general adherence to Good Manufacturing Practices (21 CFR Part 110). Beginning on December 18, 1997, all fish and fishery product processors will also be inspected for compliance with the HACCP regulations (21 CFR Part 123, Annex I). Thermally processed, hermetically packaged seafood has been subject to HACCP-derived regulations for over two decades (21 CFR Part 113). Products may be examined on the premises for such things as filth, decomposition, short weight, and labelling violations. Samples of products are collected for further laboratory analysis, for surveillance purposes, or if there is reason to suspect non-compliance for some other reason. Those operations which produce seafood products deemed to be of higher risk (e.g., ready-to-eat products) are targeted for inspection more frequently than lower risk operations (e.g., fresh fish filleting and packing operations).

Each year, the programme offices at FDA, the Office of Seafood at CFSAN in the case of seafood inspections, prepare Compliance Programmes which direct the field inspection, surveillance

activities. The Programmes describe the product areas to emphasise, the types of products to target, the make-up of samples, the types of analyses to conduct on the specific products, the analytical methods to be used, and the regulatory parameters to determine compliance. If, during the course of the year, concerns about specific products arise, assignments are written to address inspection and/or sampling to investigate the particular concerns.

Some of the areas of safety concern in seafood are:

- Pathogens — *Salmonella*, *Clostridium botulinum*, *Vibrio* spp., *Listeria* spp., *Staphylococcus aureus*, enterotoxigenic *E. coli*.
- Parasites — nematodes, cestodes, trematodes.
- Marine Toxins — paralytic shellfish poisoning, neurotoxic, shellfish poisoning, diarrhetic shellfish poisoning, amnesic shellfish poisoning, and ciguatera fish poisoning.
- Decomposition — histamine, putrescine, cadaverine.
- Environmental Contaminants and Pesticides — including methyl mercury and radionuclides.
- Aquaculture Drugs — unapproved drugs or unapproved applications.
- Food and Colour Additives — unapproved or improperly declared; sulphites, borates, nitrate/nitrite, cyclamate, safrole, FD&C Yellow n° 5, FD&C Red Approaches n° 4.
- Foreign objects - metal fragments.

Most of the commonly recognised safety related concerns in seafood are addressed in an FDA publication called the Fish and Fishery Products Hazards and Control Guide. Processors are encouraged to use the Guide in developing and maintaining their HACCP programmes.

FDA also inspects seafood products for spoilage decomposition, filth, mold, proper labelling (including nutritional labelling), and economic deception such as short weights or specie substitution (the latter having the potential to cause serious allergenic effects in sensitive individuals). Approved or unapproved applications of additives to mask decomposition have also recently become of great concern to FDA.

FDA seeks to prevent entry or remove violate goods from commerce via advisory actions (warning letters and untitled letters), administrative actions (citations, detentions, administrative meetings), judicial actions (seizure, injunction and prosecutions).

The inspection and control systems are the same for exported products as they are for domestic products. However, section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 USC. 381(e)(1)) does not deem food intended for export to be adulterated or misbranded if it:

- a) accords to the specifications of the foreign purchaser;
- b) is not in conflict with the laws of the country to which it is intended for export;
- c) is labelled on the outside of the shipping package that it is intended for export; and

d) is not sold or offered for sale in domestic commerce.

The inspection services provided by NMFS/NOAA include HACCP related activities, sanitation inspections for vessels, shore-based processing facilities, warehouses, distribution and retail facilities; product evaluation in-process or by end item examination for compliance with minimum safety, wholesomeness, and labelling criteria, processor or buyer specifications, federal or state procurement specifications, US Standards for Grades, and foreign country requirements, and domestic and international consultative or training services.

Products inspected and certified by NMFS/NOAA for export must be at least in compliance with the requirements of the country to which they will be exported, and the buyers requirements, when known.

b) *Mandatory vs. Voluntary*

FDA requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder are mandatory.

The NMFS/NOAA Seafood Inspection Programme is a voluntary, fee-for-service programme, paid by the persons using the service. However, anyone using the service must comply with all the regulations governing the programme, including all regulations pertaining to seafood promulgated by FDA and the US Fish and Wildlife Service. If an individual chooses to export to another country, all the import requirements of that country must be met before an official United States Department of Commerce (USDC) Export Health Certificate may be issued.

c) *Import Requirements*

Section 801 of the Federal Food, Drug, and Cosmetic Act (21 USC. 381) authorises FDA to examine food offered for entry into the US through US Customs, either prior to entry or after secured delivery to importers/brokers.

Importers, or their representatives, are required to file a notice with the US Customs to gain entry of each shipment of goods. Importers are also requested to provide copies of Customs entry documents, together with an invoice of the items in each entry, to FDA. Recent electronic filing advancements are simplifying this procedure. Customs notifies FDA of notices received for all FDA regulated products. FDA decides which entries need to be examined and samples collected accordingly.

All imported seafood is required to meet the same standards as domestic goods. Products which appear to be adulterated, misbranded, or manufactured, processed, or packed under insanitary conditions may be refused admission.

Due to a number of foodborne outbreaks which have been associated with imported goods in recent years, FDA's procedures for protecting the public from unsafe imported food has raised many concerns among the American public and its legislators. Consequently, efforts are being made to improve the confidence in imported goods by assuring that foreign suppliers and their governments are taking appropriate measures to safeguard the integrity of the food being delivered to the US. One of these efforts is the implementation of 21 CFR § 123.12 (see Annex I) setting forth requirements for the determination and verification that imported fishery products are processed under HACCP conditions. FDA has an interest in establishing memoranda of understanding (MOU) with foreign governments to assist importers

in meeting this requirement. When importing fish or fishery products from a country with whom FDA does not have an MOU, the importer must have written product specifications that ensure safe and sanitary product and take some type of affirmative step that demonstrates that measures are being taken to ensure that the imported product is in compliance with the regulation (e.g., lot specific HACCP records, continuing or lot-by-lot government or third-party certification, records of manufacturer's HACCP plan and guarantee, inspection records, product testing records, etc.).

III. Establishment of Criteria for Determining Equivalency

FDA is currently preparing guidance documents to describe the Agency's criteria for evaluating the equivalency of regulatory systems used by foreign countries to ensure the safety of foods exported to the US. A copy of a June 4, 1997, Federal Register Notice soliciting public comment on the criteria best describes FDA's current direction on this issue.

IV. Audit and Verification Methods

FDA has traditionally conducted auditing and verification procedures where third-party laboratory results are submitted as evidence to gain the release of detained imported food shipments or parts of the shipments. In addition to established procedures for submitting such evidence, past experience with the third-party laboratory influences the confidence in the submitted results. FDA may conduct audits by sampling and analysing the tested shipment and/or by visiting the laboratory to verify the results and capabilities of the laboratory.

FDA auditing is also integral to the initiation and maintenance of MOUs to assure that the circumstances supporting the basis for an agreement continue to exist. This policy is described in FDA's Compliance Policy Guide Section 100.900. FDA conducts such audit and verification exercises in association with MOUs with foreign governments on the safety and wholesomeness of molluscan shellfish. Such exercises may include periodic visits by FDA observation teams to ensure the parameters of the MOU are being met.

Similarly, FDA could rely on various tools to audit and verify equivalency arrangements with foreign governments. In addition to the initial establishment of equivalency described in the attached document, FDA communication with the foreign government will help provide confidence in the measures and on-going activities being taken to ensure compliance of the imported goods. FDA may also request on-site visits to examine foreign processors and/or the activities of the foreign government to ensure the obligations of the agreement are being met. In addition, FDA will likely always need to engage in some level of import product sampling and testing for verification that all systems are working. The frequency of the testing would be influenced by the confidence established in the previous approaches. It is FDA's desire, as well as the importers', the foreign manufacturers', and the foreign governments', for FDA to be able to minimise the amount of verifying necessary to ensure that the seafood delivered to the US is safe, wholesome, and truthfully labelled.

ANNEX I: CODE OF FEDERAL REGULATIONS, PART 123: FISH AND FISHERY PRODUCTS

General Provisions

Sec. 123.3 Definitions

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) and in part 110 of this chapter are applicable to such terms when used in this part, except where they are herein redefined. The following definitions shall also apply:

- a) **Certification number** means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish processor.
- b) **Critical control point** means a point, step, or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels.
- c) **Critical limit** means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.
- d) **Fish** means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all molluscs, where such animal life is intended for human consumption.
- e) **Fishery product** means any human food product in which fish is a characterising ingredient.
- f) **Food safety hazard** means any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.
- g) **Importer** means either the US owner or consignee at the time of entry into the United States, or the US agent or representative of the foreign owner or consignee at the time of entry into the United States, who is responsible for ensuring that goods being offered for entry into the United States are in compliance with all laws affecting the importation. For the purposes of this definition, ordinarily the importer is not the custom house broker, the freight forwarder, the carrier, or the steamship representative.
- h) **Molluscan shellfish** means any edible species of fresh or frozen oysters, clams, mussels, or scallops, or edible portions of such species, except when the product consists entirely of the shucked adductor muscle.
- i) **Preventive measure** means physical, chemical, or other factors that can be used to control an identified food safety hazard.

- j) **Process-monitoring instrument** means an instrument or device used to indicate conditions during processing at a critical control point.
- k) 1) **Processing** means, with respect to fish or fishery products: Handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labelling, dockside unloading, or holding.
- 2) The regulations in this part do not apply to:
 - (i) Harvesting or transporting fish or fishery products, without otherwise engaging in processing.
 - (ii) Practices such as heading, eviscerating, or freezing intended solely to prepare a fish for holding on board a harvest vessel.
 - (iii) The operation of a retail establishment.
- l) **Processor** means any person engaged in commercial, custom, or institutional processing of fish or fishery products, either in the United States or in a foreign country. A processing includes any person engaged in the production of foods that are to be used in market or consumer tests.
- m) **Scombroid toxin-forming species** means tuna, bluefish, mahi mahi, and other species, whether or not in the family *Scombridae*, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that permit the growth of mesophilic bacteria.
- n) **Shall** is used to state mandatory requirements.
- o) **Shellfish control authority** means a Federal, State, or foreign agency, or sovereign tribal government, legally responsible for the administration of a programme that includes activities such as classification of molluscan shellfish growing areas, enforcement of molluscan shellfish harvesting controls, and certification of molluscan shellfish processors.
- p) **Shellstock** means raw, in-shell molluscan shellfish.
- q) **Should** is used to state recommended or advisory procedures or to identify recommended equipment.
- r) **Shucked shellfish** means molluscan shellfish that have one or both shells removed.
- s) **Smoked or smoke-flavoured fishery products** means the finished food prepared by:
 - 1) Treating fish with salt (sodium chloride), and
 - 2) Subjecting it to the direct action of smoke from burning wood, sawdust, or similar material and/or imparting to it the flavour of smoke by a means such as immersing it in a solution of wood smoke.

- t) **Tag** means a record of harvesting information attached to a container of shellstock by the harvester or processor.

Sec. 123.5 Current good manufacturing practice

- a) Part 110 of this chapter applies in determining whether the facilities, methods, practices, and controls used to process fish and fishery products are safe, and whether these products have been processed under sanitary conditions.
- b) The purpose of this part is to set forth requirements specific to the processing of fish and fishery products.

Sec. 123.6 Hazard Analysis and Hazard Analysis Critical Control Point (HACCP) Plan

- a) **Hazard analysis.** Every processor shall conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed by that processor and to identify the preventive measures that the processor can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest. A food safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls.
- b) **The HACCP plan.** Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, as described in paragraph (a) of this section. A HACCP plan shall be specific to:
 - 1) Each location where fish and fishery products are processed by that processor; and
 - 2) Each kind of fish and fishery product processed by the processor. The plan may group kinds of fish and fishery products together, or group kinds of production methods together, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are identical for all fish and fishery products so grouped or for all production methods so grouped.
- c) **The contents of the HACCP plan.** The HACCP plan shall, at a minimum:
 - 1) List the food safety hazards that are reasonably likely to occur, as identified in accordance with paragraph (a) of this section, and that thus must be controlled for each fish and fishery product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:
 - (i) Natural toxins;
 - (ii) Microbiological contamination;

- (iii) Chemical contamination;
 - (iv) Pesticides;
 - (v) Drug residues;
 - (vi) Decomposition in scombroid toxin-forming species or in any other species where a food safety hazard has been associated with decomposition;
 - (vii) Parasites, where the processor has knowledge or has reason to know that the parasite-containing fish or fishery product will be consumed without a process sufficient to kill the parasites, or where the processor represents, labels, or intends for the product to be so consumed;
 - (viii) Unapproved use of direct or indirect food or colour additives; and
 - (ix) Physical hazards;
- 2) List the critical control points for each of the identified food safety hazards, including as appropriate:
 - (i) Critical control points designed to control food safety hazards that could be introduced in the processing plant environment; and
 - (ii) Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest;
 - 3) List the critical limits that must be met at each of the critical control points;
 - 4) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;
 - 5) Include any corrective action plans that have been developed in accordance with Sec. 123.7(b), to be followed in response to deviations from critical limits at critical control points;
 - 6) List the verification procedures, and frequency thereof, that the processor will use in accordance with Sec. 123.8(a);
 - 7) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.
- d) **Signing and dating the HACCP plan.**
- 1) The HACCP plan shall be signed and dated, either by the most responsible individual onsite at the processing facility or by a higher level official of the processor. This signature shall signify that the HACCP plan has been accepted for implementation by the firm.

- 2) The HACCP plan shall be dated and signed:
 - (i) Upon initial acceptance;
 - (ii) Upon any modification; and
 - (iii) Upon verification of the plan in accordance with Sec. 123.8(a)(1).
- e) **Products subject to other regulations.** For fish and fishery products that are subject to the requirements of part 113 or 114 of this chapter, the HACCP plan need not list the food safety hazard associated with the formation of *Clostridium botulinum* toxin in the finished, hermetically sealed container, nor list the controls to prevent that food safety hazard. A HACCP plan for such fish and fishery products shall address any other food safety hazards that are reasonably likely to occur.
- f) **Sanitation.** Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with Sec. 123.11(b) they need not be included in the HACCP plan, and vice versa.
- g) **Legal basis.** Failure of a processor to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary, otherwise operate in accordance with the requirements of this part, shall render the fish or fishery products of that processor adulterated under section 402(a)(4) of the act. Whether a processor's actions are consistent with ensuring the safety of food will be determined through an evaluation of the processors overall implementation of its HACCP plan, if one is required.

Sec. 123.7 Corrective actions

- a) Whenever a deviation from a critical limit occurs, a processor shall take corrective action either by:
 - 1) Following a corrective action plan that is appropriate for the particular deviation, or
 - 2) Following the procedures in paragraph (c) of this section.
- b) Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with Sec. 123.6(c)(5), by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:
 - 1) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and
 - 2) The cause of the deviation is corrected.
- c) When a deviation from a critical limit occurs and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:

- 1) Segregate and hold the affected product, at least until the requirements of paragraphs (c)(2) and (c)(3) of this section are met;
 - 2) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review. Adequate training may or may not include training in accordance with Sec. 123.10;
 - 3) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;
 - 4) Take corrective action, when necessary, to correct the cause of the deviation;
 - 5) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with Sec. 123.10, to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.
- d) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with Sec. 123.8(a)(3)(ii) and the recordkeeping requirements of Sec. 123.9.

Sec. 123.8 Verification

- a) Overall verification. Every processor shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented. Verification shall include, at a minimum:
- 1) Reassessment of the HACCP plan. A reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. Such changes may include changes in the following: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with Sec. 123.10. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of Sec. 123.6(c).
 - 2) Ongoing verification activities. Ongoing verification activities including:
 - (i) A review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;
 - (ii) The calibration of process-monitoring instruments; and,
 - (iii) At the option of the processor, the performing of periodic end-product or in-process testing.

- 3) Records review. A review, including signing and dating, by an individual who has been trained in accordance with Sec. 123.10, of the records that document:
 - (i) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within 1 week of the day that the records are made;
 - (ii) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with Sec. 123.7. This review shall occur within 1 week of the day that the records are made; and
 - (iii) The calibrating of any process control instruments used at critical control points and the performing of any periodic end-product or in-process testing that is part of the processor's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made.
- b) Corrective actions. Processors shall immediately follow the procedures in Sec. 123.7 whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.
- c) Reassessment of the hazard analysis. Whenever a processor does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes that could reasonably affect whether a food safety hazard now exists. Such changes may include, but are not limited to changes in: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with Sec. 123.10.
- d) Recordkeeping. The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with paragraphs (a)(2)(ii) through (iii) of this section shall be documented in records that are subject to the recordkeeping requirements of Sec. 123.9.

Sec. 123.9 Records.

- a) General requirements. All records required by this part shall include:
 - 1) The name and location of the processor or importer;
 - 2) The date and time of the activity that the record reflects;
 - 3) The signature or initials of the person performing the operation; and

- 4) Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed.
- b) Record retention.
 - 1) All records required by this part shall be retained at the processing facility or importer's place of business in the United States for at least 1 year after the date they were prepared in the case of refrigerated products and for at least 2 years after the date they were prepared in the case of frozen, preserved, or shelf-stable products.
 - 2) Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility or the importer's place of business in the United States for at least 2 years after their applicability to the product being produced at the facility.
 - 3) If the processing facility is closed for a prolonged period between seasonal packs, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack but shall be immediately returned for official review upon demand.
 - c) Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying at reasonable times.
 - d) Public disclosure.
 - 1) Subject to the limitations in paragraph (d)(2) of this section, all plans and records required by this part are not available for public disclosure unless they have been previously disclosed to the public as defined in Sec. 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in Sec. 20.61 of this chapter.
 - 2) However, these records and plans may be subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic-type HACCP plans that reflect standard industry practices.
 - e) Tags. Tags as defined in Sec. 123.3(t) are not subject to the requirements of this section unless they are used to fulfil the requirements of Sec. 123.28(c).
 - f) Records maintained on computers. The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

Sec. 123.10 Training

At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to fish and fishery product processing at least

equivalent to that received under standardised curriculum recognised as adequate by the US Food and Drug Administration or who is otherwise qualified through job experience to perform these functions. Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardised curriculum.

- a) Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan, that is appropriate for a specific processor, in order to meet the requirements of Sec. 123.6(b);
- b) Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in Sec. 123.7(c)(5), the HACCP plan in accordance with the verification activities specified in Sec. 123.8(a)(1), and the hazard analysis in accordance with the verification activities specified in Sec. 123.8(c); and
- c) Performing the record review required by Sec. 123.8(a)(3); the trained individual need not be an employee of the processor.

Sec. 123.11 Sanitation control procedures

- a) Sanitation SOP. Each processor should have and implement a written sanitation standard operating procedure (herein referred to as SSOP) or similar document that is specific to each location where fish and fishery products are produced. The SSOP should specify how the processor will meet those sanitation conditions and practices that are to be monitored in accordance with paragraph (b) of this section.
- b) Sanitation monitoring. Each processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 of this chapter that are both appropriate to the plant and the food being processed and relate to the following:
 - 1) Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice;
 - 2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;
 - 3) Prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product;
 - 4) Maintenance of hand washing, hand sanitising, and toilet facilities;
 - 5) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitising agents, condensate, and other chemical, physical, and biological contaminants;
 - 6) Proper labelling, storage, and use of toxic compounds;
 - 7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and

- 8) Exclusion of pests from the food plant. The processor shall correct in a timely manner, those conditions and practices that are not met.
- c) Sanitation control records. Each processor shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b) of this section. These records are subject to the requirements of Sec. 123.9.
- d) Relationship to HACCP plan. Sanitation controls may be included in the HACCP plan, required by Sec. 123.6(b). However, to the extent that they are monitored in accordance with paragraph (b) of this section they need not be included in the HACCP plan, and vice versa.

Sec. 123.12 Special requirements for imported products

This section sets forth specific requirements for imported fish and fishery products.

- a) Importer verification. Every importer of fish or fishery products shall either:
 - 1) Obtain the fish or fishery product from a country that has an active memorandum of understanding (MOU) or similar agreement with the Food and Drug Administration, that covers the fish or fishery product and documents the equivalency or compliance of the inspection system of the foreign country with the US system, accurately reflects the current situation between the signing parties, and is functioning and enforceable in its entirety; or
 - 2) Have and implement written verification procedures for ensuring that the fish and fishery products that they offer for import into the United States were processed in accordance with the requirements of this part. The procedures shall list at a minimum:
 - (i) Product specifications that are designed to ensure that the product is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act because it may be injurious to health or have been processed under insanitary conditions; and
 - (ii) Affirmative steps that may include any of the following:
 - (A) Obtaining from the foreign processor the HACCP and sanitation monitoring records required by this part that relate to the specific lot of fish or fishery products being offered for import;
 - (B) Obtaining either a continuing or lot-by-lot certificate from an appropriate foreign government inspection authority or competent third party certifying that the imported fish or fishery product is or was processed in accordance with the requirements of this part;
 - (C) Regularly inspecting the foreign processor's facilities to ensure that the imported fish or fishery product is being processed in accordance with the requirements of this part;

- (D) Maintaining on file a copy, in English, of the foreign processor's HACCP plan, and a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of the part;
 - (E) Periodically testing the imported fish or fishery product, and maintaining on file a copy, in English, of a written guarantee from the foreign processor that the imported fish or fishery product is processed in accordance with the requirements of this part; or
 - (F) Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.
- b) Competent third party. An importer may hire a competent third party to assist with or perform any or all of the verification activities specified in paragraph (a)(2) of this section, including writing the importer's verification procedures on the importer's behalf.
 - c) Records. The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in paragraph (a)(2)(ii) of this section. These records shall be subject to the applicable provisions of Sec. 123.9.
 - d) Determination of compliance. There must be evidence that all fish and fishery products offered for entry into the United States have been processed under conditions that comply with this part. If assurances do not exist that the imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors under this part, the product will appear to be adulterated and will be denied entry.

Subpart B--Smoked and Smoke-Flavoured Fishery Products

Sec. 123.15 General

This subpart augments subpart A of this part by setting forth specific requirements for processing smoked and smoke-flavoured fishery products.

Sec. 123.16 Process controls

In order to meet the requirements of subpart A of this part, processors of smoked and smoke-flavoured fishery products, except those subject to the requirements of part 113 or 114 of this chapter, shall include in their HACCP plans how they are controlling the food safety hazard associated with the formation of toxin by *Clostridium botulinum* for at least as long as the shelf life of the product under normal and moderate abuse conditions.

Subpart C--Raw Molluscan Shellfish***Sec. 123.20 General***

This subpart augments subpart A of this part by setting forth specific requirements for processing fresh or frozen molluscan shellfish, where such processing does not include a treatment that ensures the destruction of vegetative cells of micro-organisms of public health concern.

Sec. 123.28 Source controls

- a) In order to meet the requirements of subpart A of this part as they apply to microbiological contamination, chemical contamination, natural toxins, and related food safety hazards, processors shall include in their HACCP plans how they are controlling the origin of the molluscan shellfish they process to ensure that the conditions of paragraphs (b), (c), and (d) of this section are met.
- b) Processors shall only process molluscan shellfish harvested from growing waters approved for harvesting by a shellfish control authority. In the case of molluscan shellfish harvested from US Federal waters, the requirements of this paragraph will be met so long as the shellfish have not been harvested from waters that have been closed to harvesting by an agency of the Federal government.
- c) To meet the requirements of paragraph (b) of this section, processors who receive shellstock shall accept only shellstock from a harvester that is in compliance with such license requirements as may apply to the harvesting of molluscan shellfish or from a processor that is certified by a shellfish control authority, and that has a tag affixed to each container of shellstock. The tag shall bear, at a minimum, the information required in Sec. 1240.60(b) of this chapter. In place of the tag, bulk shellstock shipments may be accompanied by a bill of lading or similar shipping document that contains the information required in Sec. 1240.60(b) of this chapter. Processors shall maintain records that document that all shellstock have met the requirements of this section. These records shall document:
 - 1) The date of harvest;
 - 2) The location of harvest by State and site;
 - 3) The quantity and type of shellfish;
 - 4) The date of receipt by the processor; and
 - 5) The name of the harvester, the name or registration number of the harvester's vessel, or an identification number issued to the harvester by the shellfish control authority.
- d) To meet the requirements of paragraph (b) of this section, processors who receive shucked molluscan shellfish shall accept only containers of shucked molluscan shellfish that bear a label that complies with Sec. 1240.60(c) of this chapter. Processors shall maintain records that document that all shucked molluscan shellfish have met the requirements of this section. These records shall document:

- 1) The date of receipt;
- 2) The quantity and type of shellfish; and
- 3) The name and certification number of the packer or repacker of the product.

ANNEX II: CFSAN HANDOUT: THE FOOD AND DRUG ADMINISTRATION'S SEAFOOD REGULATORY PROGRAMME¹⁷

The US national regulatory authority for public protection and seafood regulation is vested in the Food and Drug Administration (FDA). The FDA operates an oversight compliance programme for fishery products under which responsibility for the product's safety, wholesomeness, identity and economic integrity rests with the processor or importer, who must comply with regulations promulgated under the Federal Food, Drug and Cosmetic (FD&C) Act, as amended, and the Fair Packaging and Labelling Act (FPLA). In addition, FDA operates the Low-Acid Canned Food (LACF) programme which is based on the Hazard Analysis Critical Control Point (HACCP) concept, and is focused on thermally processed, commercially sterile foods, including seafood such as canned tuna and salmon.

Most FDA in-plant inspections consider product safety, plant/food hygiene and economic fraud issues, while other inspections address subsets of these compliance concerns. Samples may be taken during FDA inspections in accordance with the agency's annual compliance programmes and operational plans or because of concerns raised during individual inspections. The FDA has laboratories around the country to analyse samples taken by its investigators. These analyses are for a vast array of defects including chemical contaminants, decomposition, net weight, radionuclides, various microbial pathogens, food and colour additives, drugs, pesticides, filth and marine toxins such as Paralytic Shellfish Poison (PSP) and domoic acid.

In addition, FDA has the authority to detain or temporarily hold food being imported into the US while it determines if the product is misbranded or adulterated. The FDA receives notice of every seafood entry, and at its option, conducts wharf examinations, collects and analyses samples, and where appropriate, detains individual shipments or invokes "Automatic Detention," requiring private or source country analysis of every shipment of product when recurring problems are found, before the product is allowed entry.

Further, FDA has the authority to set tolerances in food for natural and man-made contaminants, except for pesticides, which are set by EPA. The FDA regulates the use of food and colour additives in seafood and feed additives and drugs in aquaculture. FDA also has the authority to promulgate regulations for food plant sanitation (i.e., Good Manufacturing Practices (GMP) regulations), standards of identity, and common or usual names for food products.

The agency has in force a set of GMP regulations for LACF and Acidified Foods (AF), including seafood. FDA also conducts risk assessments and other laboratory evaluations through experts at its Centre for Food Safety and Applied Nutrition.

FDA has the authority to take legal action against adulterated and misbranded seafood and to recommend criminal prosecution or injunction of responsible firms and individuals.

FDA conducts both mandatory surveillance and enforcement inspections of domestic seafood harvesters, growers, wholesalers, warehouses, carriers and processors under the authority of the FD&C Act. The frequency of inspection is at the agency's discretion, and firms are required to submit to these inspections which are backed by federal statutes containing both criminal and civil penalties.

17. Office of Seafood Centre for Food Safety and Applied Nutrition, FDA, 1995.

FDA provides financial support by contract to state regulatory agencies for the inspection of food plants, including seafood. Additionally, FDA provides technical assistance and training to the states through its State training and Information Branch. To provide a sound, scientific approach for its inspections, FDA conducts training through its Education and Training Staff. The agency operates small business assistance and consumer affairs functions at the District, Regional and Headquarters levels to foster compliance with regulations, to provide a greater understanding of the need for industry controls, to help exchange information among FDA, consumers and regulated industry, and to provide consumer advisories. To these same ends, the Centre for Food Safety and Applied Nutrition (CFSAN) provides assistance directly to the industry and the consuming public through staffs dedicated to information and education activities. FDA provides extensive technical assistance in the area of seafood safety and sanitation to foreign governments through direct contacts and through the World Health Organisation (FAO), both United Nations organisations.

The FDA also operates two other specific regulatory programmes directed at seafood - the Salmon Control Plan and the National Shellfish Sanitation Programme (NSSP), recently augmented by the Interstate Shellfish Sanitation Conference (ISSC). These are voluntary programmes involving the individual states and the industry.

The Salmon Control Plan is a voluntary, co-operative programme among the industry, FDA and the National Food Processors Association (NFPA). The plan is designed to provide control over processing, plant sanitation, and to address concerns about decomposition in the salmon canning industry.

Consumer concerns about molluscan shellfish are addressed through the National Shellfish Sanitation Programme ((NSSP). It is administered by FDA and provides for the sanitary harvest and production of fresh and frozen molluscan shellfish (oysters, clams and mussels). Participants include the 23 coastal shellfish-producing states and nine foreign countries.

The NSSP was created upon public health principles and controls formulated at the original conference on shellfish sanitation called by the Surgeon General of the US Public Health Service in 1925. These fundamental components have evolved into the National Shellfish Sanitation Programme Manual of Operations. A prime control is proper evaluation and control of harvest waters and a system of product identification which enables trace back to harvest waters.

FDA conducts reviews of foreign and domestic molluscan shellfish safety programmes. Foreign reviews are conducted under a Memorandum of Understanding (MOU) which FDA negotiates with each foreign government to assure that molluscan shellfish products exported to the US are acceptable.

The FDA conducts research in support of its seafood programme. This research is directed to understanding the nature and degree of severity posed by various safety hazards, and other defects which may affect quality and economic integrity. Research also finds means to defect and to control these identified hazards. The FDA laboratories specialising exclusively in seafood research are located on the Atlantic, Gulf, and Pacific coasts in order to better address unique, regionally associated problems of toxins, contaminants, decomposition, and unsafe or deceptive harvest and processing practices.

ANNEX III: THE NATIONAL OCEANIC & ATMOSPHERIC ADMINISTRATION SEAFOOD INSPECTION PROGRAMME

The Seafood Inspection Programme of the National Marine Fisheries Service (NMFS) is an agency of the National Oceanic and Atmospheric Administration (NOAA) within the US Department of Commerce (USDC), and is a competent authority at the Federal level to conduct inspection, grading, and certification of fish and fishery products for domestic or export purposes. With this authority, NOAA has been inspecting and certifying seafoods for export to foreign markets for several decades.

Competency

NOAA is a competent authority at the Federal level to conduct inspection, grading, and certification of fish and fishery products for domestic or export purposes. NOAA also has formal operating agreements with fourteen US states to conduct inspections/certifications on its' behalf. Under such agreements, NOAA provides the necessary training to state inspectors, and licenses them to act on its behalf, and issue official USDC certificates. The licensed state inspector is under the technical supervision of NOAA when operating in this capacity.

NOAA recognises the competency of State inspection programmes in specific areas (e.g., controls relative to molluscan shellfish under the US National Shellfish Sanitation Programme (NSSP)). Thereby, NOAA may cite compliance with the criteria of such a programme as fulfilling, or partly fulfilling as the case may be, specific certification requirements. Such conditions will be clearly identified on the official USDC certificate.

Legislative Authorities

The seafood inspection, grading and certification services are authorised by the Agricultural Marketing Act of 1946, as amended, and the subsequent Fish and Wildlife Act of 1956, as amended, which transferred the functions related to fish and fishery products to the Department of the Interior, Fish and Wildlife Service. The President's Reorganisation Plan No. 4 of 1970, later transferred specific functions from the Department of Interior to a newly formed agency, the National Oceanic and Atmospheric Administration (NOAA) within the US Department of Commerce.

The Agricultural Marketing Act directed the Secretary of Agriculture (and through subsequent reorganisations the Secretary of Commerce):

"...to inspect, certify, and identify the class, quality, quantity and condition of agricultural products when shipped or received in interstate commerce, under such rules and regulations as the Secretary of Agriculture [Commerce] may prescribe, including assessment and collection of such fees as will be reasonable and as nearly as may be to cover the costs of the services rendered, to the end that agricultural products may be marketed to the best advantage, that trading may be facilitated, and that consumers may be able to obtain the quality product which they desire, except that no person shall be required to use the service authorised by this subsection. Any official certificate issued under the authority of this subsection shall be received by all officers and all courts of the United States as prima facie evidence of the truth of the statements therein contained."

The NOAA Seafood Inspection Programme is referred to as "voluntary" because no individual is required to use the inspection service. However, anyone using the service must comply with all the regulations governing the programme, including all regulations pertaining to seafood promulgated by the US Food and Drug Administration (FDA) and the U. S. Fish and Wildlife Service (FWS). Similarly, if an individual chooses to export to another country, all the import requirements of that country must be met before an official USDC Export Health Certificate may be issued.

All persons who use the service must reimburse the Department of Commerce of the cost for providing the service. Hourly rates for the various services are published annually in the Federal Register, a publication of the US Government used to inform the public about federal regulations and other federal actions.

Other authorities provided to NOAA under the Agricultural Marketing Act include the development of standards of quality, condition, quantity, grade, and packaging; the development of federal agency or state procurement standards and specifications; conducting and promoting research to determine the most efficient and practical means, methods, and processes for handling, storing, preserving, protecting, processing, and distributing of products.

In addition to Agricultural Marketing Act functions cited above, additional mandates and authorities were provided to NOAA through the Fish and Wildlife Act. These include involvement in the development of fair trade standards, better health and sanitation standards and the improvement of production and marketing practices in regard to commercial species, and the ability to conduct undercover enforcement operations necessary for the detection and prosecution of violations of any laws administered by NOAA relative to fish.

The Lacey Act, as amended is another extremely significant law which is enforced by the NOAA. The Lacey Act prohibits illegal interstate commerce in fish or fishery products if they violate any law, treaty, or regulation of the United States, or of the place of shipment or receipt (e.g., the laws of a foreign country). The criminal penalties under this Act include a fine of not more than \$20,000, or imprisonment for not more than five years or both. Each violation is considered a separate offence.

NOAA has used its authorities for example under the Lacey Act to aid state enforcement agencies and FDA in successful investigations and prosecutions regarding the illegal harvesting, sale, and distribution of molluscan shellfish. In addition to the previously identified authorities, other federal statutes and regulations can be used depending on the circumstances of the case. They include the Racketeer Influenced and Corrupt Organisations Act, the Federal Trade Commission Act, and the Magnuson Fishery Conservation and Management Act.

NOAA requires that, as a condition of participation in its programme, the conditions of the firm and the product must at least meet the requirements established by FDA and does not provide firms with any dispensation from state or local requirements. Therefore, illegal activities observed or uncovered by NOAA may be acted on jointly with other agencies or referred to another agency for specific action. It is not uncommon in the United States for multiple agencies to co-ordinate actions against a violator and for charges to be filed against that violator citing violations of the respective statutes and regulations of the agencies involved.

Human Resources

The Inspection Services Programme of NOAA is headquartered in Silver Spring, Maryland, and has facilities and inspectors located throughout the United States, Puerto Rico, and American Samoa. The division has a current inspection staff of 179 employees; eight of which are located in the headquarters office in Silver Spring, Maryland with the remaining 171 being stationed in the field or support offices throughout the US, Puerto Rico and American Samoa. The inspection staff is complimented by over 100 cross-licensed inspectors through agreements with 14 states and the US Department of Agriculture. The cross-licensed personnel are trained for specific commodity inspections.

Training Requirements

The minimum qualification requirements for GS-696 series consumer safety officers are the following:

A. Degree which includes at least 30 semester hours in one or a combination of the following: biological sciences; chemistry; pharmacy; physical sciences; food technology; nutrition; medical science; engineering; epidemiology; veterinary medical science; or related scientific fields that provide knowledge directly related to consumer safety work. The 30 semester hours can include up to 8 semester hours in statistics or course work that includes the principles, theory or practical application of computers or computer programming.

OR

B. Combination of education and experience--courses consisting of at least 30 semester hours in the fields of study described in A above, plus appropriate experience or additional education."

The training specialists of Technical Services, and the Quality Team are continually updating their training activities to reflect changing needs of the inspectors and their related industry functions. Areas of training include inspection procedures for fishery products, low-acid canned foods, sensory analysis, HACCP principles and implementation, auditing practices, European Union requirements, and retail food safety. These may be presented as formal group sessions, home study, or individual exercises according to the need.

Services

The inspection services provided by NOAA include HACCP related activities, sanitation inspections for vessels, shore-based processing facilities, warehouses, distribution and retail facilities; product evaluation in-process or by end item examination for compliance with minimum safety, wholesomeness, and labelling criteria, processor or buyer specifications, federal or state procurement specifications, US Standards for Grades, and foreign country requirements, and domestic and international consultative or training services.

The regulations under which these services are provided currently comprise Parts 260 through 267 of Title 50 of the US Code of Federal Regulations (i.e., 50 CFR Parts 260-267). Part 260 contains the general regulations of the NOAA inspection programme and includes the requirements for admission to the programme, identification and use of official marks, as well as debarment and termination procedures. Parts 261 through 267 contain the various US Standards for Grades of Fishery Products. These regulations are further delineated through the policies, procedures, and inspectors instructions which are

found in Fish Inspection Manual 25 composed of three parts. This manual provides the detailed procedures the NOAA inspectors follow when conducting inspections; laboratory procedures will be in concert with recognised good laboratory practices and the methods used will be the official methods of the Association of Official Analytical Chemists, other recognised international analytical methods, or identified modifications of these methods.

All fish processors in the United States are required under the laws and regulations enforced by the FDA to produce safe, wholesome, properly labelled products. The processing and storage of these products must be in compliance with FDA's 21 CFR Part 110 Current Good Manufacturing Practices regulations and Part 123 Fish and Fishery Products HACCP Requirements. As previously stated, no firm may participate in the NOAA inspection programme if it is not in compliance with the minimal requirements established by FDA.

Firms that wish to use official USDC Processed Under Federal Inspection or US Grade marks, or firms which require certification of processing conditions to meet buyer or foreign country requirements must pass NOAA sanitation evaluations using Federal Standard 369-Federal Sanitation Standard for Fish Plants or applicable foreign requirements. Compliance with Federal Standard 369 requires a score of 90 percent or higher with no critical deficiencies noted. This standard is used by NMFS to evaluate production, storage, and distribution facilities.

Products inspected and certified by NOAA for export must be at least in compliance with the requirements of the country to which they will be exported, and the buyers requirements, when known. Therefore, it is important that NOAA be advised as soon as possible by responsible agencies of foreign governments when changes are made or scheduled to be made in their import requirements.

Since the programme's beginning in 1946, it has provided inspection services to seafood processors, brokers, exporters and importers. During 1995 NMFS inspected/certified over 1.2 billion pounds of fishery products, of which over 150 million pounds were certified for export. US exporters use the service to comply with regulations of those importing countries which require certification by a competent authority of the exporting country. The Official USDC Export Health Certificate has been used for many years, and bilingual Export Certificates have been created in several languages for exports to foreign countries.

In July 1992 NOAA implemented an inspection programme based on the Hazard Analysis Critical Control Point (HACCP) concept. This voluntary programme, which was developed to meet the HACCP-based requirements recently established by the EU and continued industry interest, now has approximately 100 facilities enrolled nation-wide and including all types of processors and product forms. In addition to basic safety oversight, the NOAA HACCP-based programme also monitors defect action points to assure wholesomeness and economic integrity including label reviews. If the plant desires to hire trained individuals to perform the functions required in 21 CFR Part 123.10 that reflect HACCP expertise, NOAA inspectors assigned to the plant may fulfil this role. Other industry services include, lot inspections of products for domestic and export sale, sanitary reviews, and consultative services.

NOAA publishes semi-annually (October and April) an Approved List of Fish Establishments and Products which identifies US firms that satisfy NOAA inspection service requirements and participate in its programme for in-plant inspection services. In order to maintain this status, facilities under the traditional programme are monitored not less than once per week for compliance with sanitation standards; whereas facilities under the HACCP-based inspection service undergo a systems audit for sanitation and records review of critical control points at a frequency based on their level of compliance.

In the HACCP-based inspection service, a level IV plant would receive a systems audit once every 2 weeks, level III once a month, level II once every 2 months, and level I once every 6 months.

Export Certification

USDC Export Health Certificates are controlled documents (i.e., each bears a unique number, bears the embossed seal of the US Department of Commerce, and can only be issued by an inspector of NOAA or authorised cross-licensed state or Federal government inspector). Before an Export Health certificate may be issued, the product must be in compliance with requirements of the importing country. The certificate identifies the individual products as to type, package size and count, and the official findings of the inspector. Analytical results may appear in the remarks section of the certificate or noted as an attachment to the certificate. Analytical reports from non-governmental laboratories, which are noted on the certificate as attachments, are recognised by NOAA as providing credible results. These certificates are available in several bilingual formats to meet the specific import requirements of several importing countries or trading blocks.

ANNEX IV: NOAA/NMFS ORGANISATIONAL CHART FOR NOAA SEAFOOD INSPECTION PROGRAMME

