Causes of detentions and rejections in international fish trade

FAO
FISHERIES
TECHNICAL
PAPER
473

by
L. Ababouch
Chief
Fish Utilization and Marketing Service
Fishery Industries Division
FAO Fisheries Department
Rome
Italy

G. Gandini
Veterinarian
Ministry of Health
Ufficio Veterinario Adempimenti CEE
Bologna
Italy

and

J. Ryder
Consultant
Teddington Manor, Teddington, Tewkesbury
Gloucestershire
United Kingdom of Great Britain and Northern Ireland

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
Rome, 2005

ISBN 92-5-105286-7

Preparation of this document

The Fish Utilization and Marketing Service (FIIU) of the Food and Agriculture Organization (FAO) of the United Nations is mandated to assist Member States to strengthen fish safety and quality programmes and to promote the use of harmonized systems and standards developed by the *Codex Alimentarius* using scientifically based techniques such as risk assessment.

For a long time, FIIU resources and activities focused on training and assisting Member States, especially developing countries, in strengthening fish inspection and implementing Hazard Analysis Critical Control Point (HACCP)-based safety and quality systems. This has helped many developing countries secure and expand market shares for their seafood export and it is currently estimated that over 50 percent of international fish trade (in value) originates in developing countries. However, much remains to be done to generalize HACCP systems and promote a harmonized approach to fish control in international trade.

This paper is based on a study that was undertaken to identify the major causes of detentions and rejections at borders and assess the control procedures of the main importing countries/regions, namely the European Union, the United States of America, Japan and Canada. Developing a good understanding of the control procedures and the causes of detentions/rejections is very useful for FAO, which can use the gained insights to tailor its assistance programme in the exporting developing countries and focus its work on the real issues for international harmonization and promotion of equivalence among seafood trading partners. It can also be beneficial for trading partners in their quest to reduce seafood wastages and fishborne illnesses, as well as for donors in their assistance programmes.

This study was initiated in late 2000 and took over three years to finalize in its present form. A major difficulty was accessing essential data and in a format useful for their exploitation. A significant volume of data was collected through personal contacts of the authors and their collaborators. Other data were collected from the Internet as they became available. However, the nature and volume of data available on the Web sites of the major importing countries are still insufficient and not fully adapted for this type of study. This report makes several recommendations for improving the data and their dissemination which would enable FAO to monitor the situation on a regular basis and adapt its international programme in fish safety and quality accordingly.

Abstract

Fish and fishery products are among the most traded food commodities today and this trade is likely to increase to meet the ever increasing-demand for fish and seafood. Yet, one of the most serious difficulties facing exporters is the different quality and safety standards and policies imposed by importers. These disparities concern regulations, standards and procedures, including border controls where seafood products can be rejected, destroyed or detained. In order to promote harmonization and equivalence among seafood-trading nations, such differences need to be reduced and ultimately removed and replaced by international control systems and standards based on scientific techniques such as risk assessment.

This document analyses seafood detentions and rejections in international trade focusing on the four largest fish and seafood importers – Canada, the European Union, Japan and the United States of America. It includes a general introduction, followed by a description of the international regulatory framework and current import regulations for each area. Examples of problem border cases are given, covering a wide range of factors from the type of problem (i.e. microbial, chemical), to species, geography and product category (i.e. fresh, frozen, cured), and an analysis of the relevant data for trends and patterns is made. The document ends with a view towards the future, providing recommendations on what should change in order to improve fish safety and quality controls in international trade and examining the potential role of industry, governments and international bodies in this process.

Ababouch, L.; Gandini, G.; Ryder, J.
Detentions and rejections in international fish trade.
FAO Fisheries Technical Paper. No. 473. Rome, FAO. 2005. 110p.

Acknowledgements

The authors wish to thank C.A Lima Dos Santos[1] and S. Subasinghe[2] for their valuable contributions to the collection and analysis of border data, respectively for the United States of America and Japan.

Further thanks are given to Tina Farmer and Françoise Schatto for excellent assistance in the preparation of the final document.

[1] C.A. Lima dos Santos. Rua Cel. Eurico de Sousa Gomes Filho No. 510/cob, Barra da Tijuca, 22620-320 Rio de Janeiro, Brazil

[2] S. Subasinghe, Director, INFOFISH, 1st Floor, Wisma PKNS, Jalan Raja Laut, PO Box 10899, Kuala Lumpur 50728, Malaysia

Contents

Preparation of this document iii
Abstract iv
Acknowledgements v
Acronyms and abbreviations xiii

1. Introduction 1
1.1 International trade in fish 1
1.2 Current impediments to trade 1
1.3 This report 2

2. Rules and regulations governing fish and seafood safety and quality 5
2.1 International context 5
2.2 The European Union 8
2.2.1 Border control 10
2.2.2 Checks at border inspection posts 10
2.2.3 The rapid alert system 12
2.3 United States of America 13
2.3.1 Detention without physical examination 15
2.3.2 Automatic detention 15
2.3.3 Import alerts 16
2.4 Japan 16
2.4.1 General principles for food imports 16
2.4.2 The process for fish and fish products on arrival in Japan 17
2.4.3 Consignments requiring prior approval 18
2.4.4 Labelling requirements 18
2.5 Canada 19
2.5.1 Import product control system 19
2.5.2 Inspection testing 21
2.5.3 Monitoring frequencies 22
2.6 Summary of border control systems for fish and seafood 22

3. Border cases in the European Union, North America and Japan 25
3.1 Introduction 25
3.1.1 Data sets used 25
3.2 European Union 26
3.2.1 Imports of fish and fish products 27
3.2.2 Border cases 29
3.2.3 Border cases in the European Union in the context of import volume 34
3.3 United States of America 35
3.3.1 Imports 35
3.3.2 Border cases 36
3.3.3 Filthy as a reason for seafood detention 38
3.3.4 Border cases in the United States in the context of import volume 39

3.4 Japan 39
3.4.1 Imports of fish and fish products 39
3.4.2 Import notifications for foods including marine products 40
3.4.3 Border cases for seafoods 41
3.4.4 Border cases in the context of import volume 44
3.5 Canada 44
3.5.1 Imports 44
3.5.2 Border cases 46
3.5.3 Border cases in Canada in the context of import volumes 50
3.6 Comparison of border cases among major importers 52
3.6.1 Relative frequency of border cases 52
3.6.2 Border case patterns and trends 53
3.6.3 Performance of continents 54
3.6.4 Access to data for border cases 56
3.6.5 Type of data recorded for border cases 57
3.6.6 Ease of analysis of data for border cases 59
3.6.7 Requirements for harmonization and equivalency schemes 59
3.6.8 Trade and economic implications 65
3.6.9 The case of aquaculture 69

4. Conclusions and recommendations 71
4.1 Border inspection systems 71
4.2 Border control data 73
4.3 Export performance and development assistance 74

References 77

Annexes 79

Relevant regulations, procedures, guidance or standards used by the European Union 79
A.1 Directive 97/78 Annex II – Border inspection posts (European Union) Approved requirements for border inspection posts 79
A.2 Levels of physical checks on products of animal origin (European Union) 80
A.3 Documentary requirements (United Kingdom/European Union) 81
A.4 Microbiological standards (European Union) – existing and upcoming standards 84
A.5 Flow chart for transmission of information in Rapid Alert Network (European Union) 88

Relevant regulations, procedures, guidance or standards used by the US FDA 89
A.6 A summary of procedures that United States importers must follow when handling food products 89
A.7 FDA/EPA guidance levels in seafoods 91
A.8 Import refusal report (United States of America) 93

Relevant regulations, procedures, guidance or standards in use in Japan 94
A.9 Fish designated by the Convention on International Trade in Endangered Species (CITES) or Washington Convention (Japan) 94

A.10 Food Sanitation Law and Quarantine Law (Japan) 95
A.11 Procedure of import notification of foods and related products (Japan) 99
A.12 Inspection systems (Japan) 100
A.13 Allergic labelling (Japan) 101

Relevant regulations, procedures, guidance or standards in use in Canada 102

A.14 Bacteriological and chemical guidelines for fish and fish products 102
A.15 Summary of required testing frequencies (Canada) 104
A.16 Example alert notifications (European Union) 106
A.17 Oasis example report (United States of America) 107
A.18 Example of import alert list (Canada) 108
A.19 Definitions of product types (European union) 109
A.20 FDA guideline on insects as filth 110

Tables

1. Total imports for major importing nations/regions (MT) 1
2. Lists of third countries from which import of fishery products is authorized for human consumption (EC) 9
3. New European Union hygiene package of regulations and directives 10
4. Border inspection posts in the European Union (EU) – after May 2004 11
5. Consignment checks at European Union borders 11
6. Summary of physical checks at border inspection posts 12
7. Regulations applying to fishery products and prepared products – Japan 17
8. Japanese "Import Notice" Item 1: Principal Import Quota Items 18
9. Japanese "Import Notice" Item 2 – Goods originated in or shipped from certain specific area 18
10. Comparison of fish import systems in the European Union, United States of America, Japan and Canada 23
11. Information notifications in the European Union (EU) according to categories of source of contamination – 2003 27
12. Residues of veterinary medicinal products – 2003 27
13. Information notifications in the European Union (EU) according to the food groups involved, 2001–2003 27
14. Top ten exporters to the European Union 1999–2002 (2002 basis) (tonnes) 28
15. Total European Union imports by exporting continent 1999–2002 (tonnes) 28
16. Total European Union imports by product type and species group 1999–2001 (tonnes) 29
17. Border cases in the European Union from 1999 to 2002 by risk and exporting region 30
18. Border cases in the European Union from 1999 to 2002 – microbial risks 30
19. Border cases in the European Union from 1999 to 2002 – chemical risks 32
20. Border cases in the European Union from 1999 to 2002 – other causes 33
21. Border cases in the European Union from 1999 to 2002 – product types and species groups 33
22. Combined border cases in the European Union from 1999 to 2002 – by cause and product type/species 33
23. Border cases in European Union per unit volume of imports, 1999–2002 – by continent 35
24. Border cases in the European Union per unit volume of imports, 1999–2001 – by product types and species groups 35
25. Top ten exporters to the United States 1999–2002 (2002 basis) – tonnes 36
26. Total USA imports by exporting continent 1999–2002 (tonnes) 36
27. Total USA imports by product type and species group 1999–2002 (tonnes) 37
28. Seafood import refusals by US FDA from July 2001 to June 2003 38
29. Annual evolution of seafood imports' detentions 38

30. Top ten exporters to Japan 1999–2002 (tonnes) 40
31. Total Japanese imports by exporting continent 1999–2002 (tonnes) 40
32. Total Japanese imports by product type and species group 1999–2001 (tonnes) 40
33. Import notifications, inspections/rejections of food items – 2000 41
34. Import notifications by exporting continent for all foods – 2000 41
35. Rejections of seafood Imports in Japan by exporting continent – 2000/2001 and 2001/2002 42
36. Border cases in Japan by risk category – 2000/2001 and 2001/2002 43
37. Breakdown of reasons for border cases in Japan – 2000/2001 and 2001/2002 43
38. Border cases in Japan – chemical risks – 2000/2001 and 2001/2002 43
39. Japanese imports - categories of fish products rejected – 2000/2001 and 2001/2002 44
40. Border cases in Japan per unit volume of imports, 2000 – by continent 45
41. Top ten exporters to Canada 1999–2002 (2002 basis) 45
42. Total Canadian imports by exporting continent 1999–2002 45
43. Total Canadian imports by product type and species group 1999–2001 46
44. Border cases in Canada from 1999–2002 by cause and exporting region 47
45. Border cases in Canada from 1999–2002 – chemical causes 48
46. Border cases in Canada for 1999-2002 – "other causes" 48
47. Border cases in Canada from exporting regions – "other causes" for period 1999–2002 combined 49
48. Border cases in Canada from 1999–2002 – by product types and species groups 49
49. Combined border cases in Canada from 1999-2002 – by cause and product type/species 50
50. Border cases in Canada per unit volume of imports, 1999–2002 – by continent 51
51. Border cases in Canada per unit volume of imports, 1999–2001 – by product types and species groups 51
52. Performance of continents in exporting to the European Union, Canada and Japan 55
53. Border case data available on the World Wide Web 56
54. Recording of cause, product and species data in European Union, the United States and Canadian Web sites 58
55. How border case data are held on the World Wide Web 58
56. Estimates of volumes and value of border cases for Japan 69

Figures

1. Total border cases for European Union, United States, Canada and Japan 1999–2002 relative to import quantities 53
2. Relative frequency of causes of border cases for the European Union, United States, Canada and Japan 54

Acronyms and abbreviations

ACS	Automated Commercial System (United States Customs)
ADI	Acceptable daily intake
BIP	Border Inspection Post (European Union)
BPCS	Better Process Control School (in the United States of America)
BSE	Bovine Spongiform Encephalopathy
CA	Competent Authority
CAC	Codex Alimentarius Commission
CCFFP	Codex Committee on Fish and Fishery Products
CCFH	Codex Committee on Food Hygiene
CCFIEICS	Codex Committee on Food Import and Export Inspection and Certification Systems
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods
CFIA	Canadian Food Inspection Agency
CFSAN	Centre for Food Safety and Applied Nutrition (United States of America)
CVC	Certificate of Veterinary Checks (United Kingdom)
DSP	Diarrhetic Shellfish Poisoning
DWPE	Detention Without Physical Examination (United States of America)
EC	European Commission
EEA	European Economic Area
EFSA	European Food Safety Authority
EFTA	European Free Trade Area
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration (United States of America)
FD&C	Food, Drug and Cosmetic colours
FRAN	F-specific RNA coliphage of bacteriophage
GAO	General Accounting Office (United States of America)
GHP	Good Hygienic Practice
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis Critical Control Point
HTML	Hyper Text Markup Language
IAL	Import Alert List (Canada)
IDR	Import Detention Report (United States of America)
IRR	Import Refusal Report (United States of America)
JECFA	Joint FAO/WHO Expert Committee on Food Additives

JEMRA	Joint FAO/WHO Expert Meetings on Microbiological Risk Assessments
LACF/AF	Low Acid Canned Food/ Acidified Food (United States of America)
MHLW	Ministry of Health, Labour, and Welfare (Japan)
MOU	Memorandum of Understanding
MRA	Mutual Recognition Agreement (Canada)
OASIS	Operational and Administrative System for Import Support (United States of America)
PDF	Portable Document Format (file format developed by Adobe)
ppb	parts per billion
QMPI	Quality Management Programme for importers (Canada)
RASFF	Rapid Alert System for Food and Feed (European Union)
RTE	Ready to Eat
SPS	Sanitary and Phytosanitary
SSOP	Sanitation standard operating procedures
TBT	Technical Barriers to Trade
TDH/TRH	Thermostable direct haemolysin /Thermostable direct related haemolysin
USDA	United States Department of Agriculture
WTO	World Trade Organization

1. Introduction

1.1 INTERNATIONAL TRADE IN FISH

International trade in fishery commodities reached US$ 58.2 billion in 2002 (export value), a 5 percent improvement relative to 2000 and a 45 percent increase since 1992. In volume terms, exports were reported to be 50.0 million tonnes (live weight equivalent), having grown by 40.7 percent since 1992. Many countries, developed and developing, export some fishery products with revenues often being a major source of foreign currency. In 2002, 95 countries were net exporters of fish and fishery products with Norway, Thailand, Viet Nam, Chile, Canada reporting net export values of more than US$1.5 billion each and with Indonesia, India, Iceland, Taiwan Province of China, Denmark and Peru having net exports worth more than US$1 billion each. Within this global trade in fish, developing countries registered a net fishery trade surplus of about US$17. 5 billion in 2002 and accounted for 49 percent by value and 55 percent of fish exports by volume. (FAO, 2004)

In 2002, fish imports reached more than US$61 billion in value (a new record) and around 51 million tonnes (live weight equivalent) in volume. Developed countries accounted for about 82 percent of the total value of imports of fish products. In volume terms, developed countries imported over 32 million tonnes (live weight equivalent) of which 68 percent was fish for human consumption, while developing countries imported 19 million tonnes (live weight equivalent) of fish, of which 47 percent consisted of fish for food. About 74 percent of the import value was concentrated in three main areas: the European Community, Japan and the United States of America. These three dominate the world markets both in terms of prices and market access requirements (Table 1).

Japan was once again the largest importer of fish and fish products, accounting for some 22 percent of the world import value in 2002 (US$13.6 billion). The EC further increased its dependency on imports for its fish supply by 10 percent since 2000, with Spain, (US$3.9 billion, the world's third largest importer), France (US$3.2 billion), Italy (US$2.9 billion), Germany (US$2.4 billion) and the United Kingdom (US$2.3 billion) as the main importers. The United States, besides being the world's fourth largest exporting country, was the second largest importer, with imports remaining rather stable at US$10 billion since 2000.

TABLE 1
Total imports for major importing nations/regions (MT)

World rank	Country/region	Imports (MT)			
		1999	2000	2001	2002
1	European Union*	7 478 808	7 739 115	8 080 969	7 901 021
2	Japan	3 298 137	3 432 517	3 627 677	3 667 318
3	USA	1 730 352	1 745 460	1 860 852	1 976 025

* Includes intra European Union (EU) imports (EU country to EU country) and extra European Union (EU) imports (non EU countries into the EU). The split is approximately 50:50.

1.2 CURRENT IMPEDIMENTS TO TRADE

In the international market of fish and fishery products, one of the most serious difficulties faced by exporters is that different standards and regimes are being imposed by importing countries on producing countries to ensure that products meet the requirements of the target market. Even after the ratification of the Agreement on

Sanitary and Phytosanitary (SPS) measures and the Agreement on Technical Barriers to Trade (TBT), under the World Trade Organization (WTO), differences among various national standards and inspection systems may maintain or create new non-tariff trade barriers.

Globalization of food trade, coupled with technological developments in food production, handling, processing and distribution, and the increasing awareness and demand of consumers for safe and high quality food have put food safety and quality assurance high in public awareness and a priority for many governments. This is exacerbated by the series of food safety scares in the 1990s (e.g. bovine spongiform encephalopathy (BSE) and dioxins) and by concerns over technological innovations from biotechnology (genetically modified organisms). Consequently, many countries have tightened food safety controls, imposing on imports additional costs and requirements that are not always technically or scientifically supportable.

Sanitary and hygienic regulations have come to play an increasingly important role during recent years due to negative public perceptions that have grown in major importing markets (Ahmed, 1991). Developing countries have often complained that they are penalized by the complexity of sanitary and quality regulations of 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 implementation of the regulations and the lack of consistent and harmonized criteria have inhibited trade.

The differences between importing countries regulations, standards, organization and function of inspection services, and the *modus operandi* of such services are among the most important practical difficulties of compliance faced by developing countries. A key problem is the border control where products are rejected or put in detention awaiting resolution or destruction.

1.3 THIS REPORT

This report analyses the detentions and rejections in international trade and focuses on the three largest fish importers – North America, European Union and Japan. The availability of data is a key consideration in such an exercise, and each of these countries/regions maintains records of detentions and rejections at their borders. The study focuses, at a macro-level, on international trade among countries rather than trade among companies. The latter aspects are mentioned in the study, but only where it contributes to the analysis.

The first chapter outlines the background to the report. Chapter 2 details the regulations in force for the European Union, the United States of America, Japan and Canada providing a picture of what exporters face in each of these importing territories. This chapter also outlines the regulations that govern international trade, specifically the World Trade Organization and the Codex Alimentarius Commission (CAC).

Chapter 3 considers each major importing country/region separately examining the border cases across a range of parameters: problem type (microbial, chemical and other causes), fish species, geography, product type (fresh, frozen, cured, etc.). The chapter will then analyse the data collectively for trends or patterns in the border cases. The case of aquaculture products is mentioned, though available data on production methods (thus allowing specific conclusions to be made about aquaculture) is limited. The chapter also specifically examines the scientific basis for the border cases. Finally, this report attempts to examine the costs to fish trade as a result of border detentions and rejections, but only for Japan for which data on the quantities or values of rejected shipments are available.

The final chapter looks to the future and provides recommendations on what could change to improve controls in international trade in fish and fish products at borders and looks at the potential role of industry, governments and international bodies in this process.

As a final note on terminology, the term "border case" is used to cover any situation where a product is detained, rejected, destroyed, returned to sender or otherwise removed, even if only temporarily, from the trade flow. Our purpose is to focus on the removal of products from trade for whatever reason, and the final destination of the product is less relevant to the discussion than the fact that trade flow has been interrupted, causing an economic impact on the participants in trade. While it is recognized that "refused" products can re-enter into trade flows, such data are not considered in this report.

2. Rules and regulations governing fish and seafood safety and quality

2.1 INTERNATIONAL CONTEXT

As early as 1980, there was an international drive towards reforming fish inspection systems to move away from end-product sampling and inspection into preventative Hazard Analysis Critical Control Point (HACCP)-based safety and quality systems. This preventative approach requires that:

- fish products are prepared/processed in certified plants and establishments. The certification process requires that the plant meets minimal requirements in terms of layout, design and construction, hygiene and sanitation;
- the industry takes responsibility in fish safety control and implements HACCP-based in-plant quality control programmes;
- a regulatory competent authority is in charge of certifying fish plants and establishments, approving and monitoring HACCP-based in-plant quality control programmes and certifying fish and fishery products before distribution;
- where necessary, national surveillance programmes of the harvesting areas should be in place to control the threats of biotoxins and other biological and chemical pollutants; and
- for export, an additional control can be exercised by the importing party and involves an audit of the national control system of the exporting country to ensure that it meets the requirements of the importing country. This should lead to the signing of mutual recognition agreements between trading countries.

While there is growing and strong evidence that the implementation of HACCP-based systems have contributed to improve fish safety and quality, there has been an increasing awareness of the importance of an integrated, multidisciplinary approach to food safety and quality throughout the entire food chain. FAO defines the food chain approach as that where the responsibility for the supply of safe, healthy and nutritious food is shared along the entire food chain – by all involved with the production, processing, trade and consumption of food. (FAO, 2003a).

In fisheries, stakeholders include farmers, fishers, food processors, transport operators, distributors – and consumers, as well as governments obliged to protect public health. The holistic approach to food safety along the food chain differs from previous and present models in which responsibility for food safety is mainly concentrated on the food processing sector and government control services. The implementation of the food chain approach requires an enabling policy and regulatory environment at national and international levels with clearly defined rules and standards, establishment of appropriate food control systems and programmes at national and local levels, and provision of appropriate training and capacity building.

In fisheries, there are five broadly-defined needs on which a strategy in support of a food chain approach to food safety should be based:

1. Fish safety and quality from a food chain perspective should incorporate the three fundamental components of risk analysis – *assessment, management and communication* – and, within this analysis process, there should be an institutional separation of science-based risk assessment from risk management, the latter being the regulation and control of risk.

2. Tracing techniques *(traceability)* from the primary producer (including animal feed and therapeutants used in aquaculture), through post-harvest treatment, processing and distribution to the consumer must be improved.
3. Harmonization of fish quality and safety standards is necessary, implying increased development and wider use of internationally agreed, scientifically-based standards.
4. Equivalence in food safety systems – achieving similar levels of protection against fishborne hazards and quality defects whatever means of control are used – must be further developed.
5. An increased emphasis is needed on "risk avoidance or prevention at source" within the whole food chain – *from farm or sea to table*. In the farmed sector, this includes development and dissemination of good aquaculture practices and safety and quality assurance systems (i.e. HACCP) to complement the traditional approach to fish safety and quality management based on regulation and control.

The principles of achieving harmonization of standards and equivalency in food control systems and the use of scientifically-based standards are embodied in two binding agreements of WTO – the SPS and TBT Agreements. The SPS agreement confirms the right of WTO member countries to apply measures necessary to protect human, animal and plant life and health.

The purpose of the SPS Agreement is to ensure that measures established by governments to protect human, animal and plant life and health in the agricultural sector, including fisheries, are consistent with obligations prohibiting arbitrary or unjustifiable discrimination on trade between countries where the same conditions prevail and are not disguised restrictions on international trade. It requires that, with regard to food safety measures, WTO members base their national measures on international standards, guidelines and other recommendations adopted by the Codex Alimentarius Commission (CAC), where they exist. This does not prevent a member country from adopting stricter measures if there is a scientific justification for doing so or if the level of protection afforded by the Codex standard is inconsistent with the level of protection generally applied and deemed appropriate by the country concerned. The SPS Agreement states that any measures taken that conform to international Codex standards, guidelines or recommendations are deemed to be appropriate, necessary and not discriminatory. Finally, the SPS Agreement requires that SPS measures are to be based on an assessment of the risks to humans, animal and plant life using internationally accepted risk assessment techniques.

The objective of the TBT Agreement is to prevent the use of national or regional technical requirements, or standards in general, as unjustified technical barriers to trade. The agreement covers standards relating to all types of products including industrial products and quality requirements for foods (except requirements related to SPS measures). It includes numerous measures designed to protect the consumer against deception and economic fraud. The TBT Agreement basically provides that all technical standards and regulations must have a legitimate purpose and that the impact or cost of implementing the standard must be proportional to the purpose of the standard. It also states that, if there are two or more ways of achieving the same objective, the least trade restrictive alternative should be followed. The agreement also places emphasis on international standards, WTO members being obliged to use international standards or parts of them except where the international standard would be ineffective or inappropriate in the national situation. The aspects of food standards that TBT requirements cover specifically are quality provisions, nutritional requirements, labelling, packaging and product content regulations, and methods of analysis. Unlike the SPS Agreement, the TBT Agreement does not specifically name

the international standard setting bodies, whose standards are to be used as benchmarks for judging compliance with the provisions of the Agreement.

Risk analysis is widely recognized today as the fundamental methodology underlying the development of a food safety standard that provides adequate health protection and facilitates trade in food (WHO, 1995). There is a fundamental difference between a hazard and a risk. A hazard is a biological, chemical or physical agent in, or condition of food, with the potential to cause an adverse health effect. In contrast, risk is an estimate of the probability and severity in exposed populations of the adverse health effects resulting from hazard(s) in food. Risk analysis is a process consisting of three components: risk assessment, risk management and risk communication. Risk assessment is the scientific evaluation of known or potential adverse health effects resulting from human exposure to food-borne hazards. Risk management is the process of weighing policy alternatives to accept, minimize or reduce assessed risks and to select and implement appropriate options. Risk communication is an interactive process of exchange of information and opinion on risk among risk assessors, risk managers, and other interested parties.

The responsibility for the supply of fish that is safe, healthy and nutritious should be shared along the entire chain from primary production to consumption. Development and implementation of Good Aquaculture Practices (GAP), Good Manufacturing Practices (GMP), Good Hygienic Practices (GHP) and Hazard Analysis Critical Control Point (HACCP) are required in the food chain step(s). Government institutions should develop an enabling policy and a regulatory environment, organize the control services, train personnel, upgrade the control facilities and laboratories and develop national surveillance programmes for relevant hazards. The support institutions (academia, trade associations, private sector, etc.) should also train personnel involved in the food chain, conduct research on quality, safety and risk assessments and provide technical support to stakeholders. Finally, consumers and consumer advocacy groups have a counterbalancing role to ensure that safety and quality are not undermined by political considerations solely when drafting legislation or implementing safety and quality policies. They also have a major role in educating and informing the consumer about the major safety and quality issues.

The general principles of GHP/HACCP have been adopted by the *Codex Alimentarius* Commission (CAC) in 1997, 1999 and 2003 (FAO/WHO, 2003). They include requirements for the design and facilities, control of operations (including temperature, raw materials, water supply, documentation and recall procedures), maintenance and sanitation, personal hygiene and training of personnel. Similarly, the Codex Committee on Fish and Fishery products is working on a draft code of practice for fish and fishery products, including aquaculture products, which integrates these general principles and adapts them to the fish industry (FAO, 2003b). This Code is not intended to cover extensive fish farming systems or integrated livestock and fish culture systems that dominate production in many developing countries.

Control and prevention of chemical pollutants and biotoxins require the implementation of appropriate monitoring and surveillance programmes. This is particularly important for mollusc culture as filter feeders can concentrate pollutants, biological agents and biotoxins. The Codex Code of Practice describes the requirements for surveys and monitoring of growing areas to determine sources of domestic and industrial pollution, classification of growing areas as suitable for harvesting and relaying or non-suitable for growing or harvesting, and the frequency and methods of monitoring.

The following sections examine how this international framework for fish and seafood safety and quality is applied in international fish trade by the major importing countries/regions, with a particular focus on border controls.

2.2 THE EUROPEAN UNION

The principle behind assuring the safety of imported fish and seafood to the European Union is that of certifying Competent Control Authorities in the third countries exporting to the European Union. The European Union (EU) delegates the control of food safety to a Competent Authority in each country, who in turn ensures that exporting farms, vessels and processors are producing safe food under a system equivalent to that in the European Union – the principle of equivalence. National laws are "harmonized" with those in place within the European Union.

When the laws of any third country are harmonized and systems to monitor and control food (fish) processing establishments and vessels are deemed equivalent, the exporting country is approved for export to the European Union. Individual companies are checked by the Competent Authority and, if deemed appropriate, are listed as approved in a national register, with a certification number. This register is passed to the European Commission (EC) who make the information public via its website and other public documents.[1] These are the so-called List I countries. Other countries that are in the process of gaining approval but are deemed to be producing safe foods are shown in List II. Shipments from List II countries are, however, subject to 100 percent border checks (Table 2).

Unfortunately for processors, these are the only routes by which processors can export to the European Union. Even if a processing establishment is meeting international standards of safety and quality, it can only export if the country in which it operates is recognized and certified by the EC on List I or List II. This has caused problems for qualified processors in several countries who then have to wait for the government to complete the process of recognition by the European Union.

In addition to the certification requirements from exporting countries, the European Union operates a border inspection system to verify regularly that the European Union requirements are effectively implemented in the exporting country.

During recent years, the European Union has completed a recast of the legislation governing food hygiene and laying down specific hygiene rules for food of animal origin. EC Regulation 178/2002 is of very broad scope; it establishes the general principles and requirements of food law, lays down procedures on matters of food safety, and establishes the structure and role of European Food Safety Authority (EFSA). It also covers the basic concepts of equivalence and traceability.

The Regulation applies to all stages of production, processing and distribution of food and animal feed, setting the basic principle of "the farm to table" approach. It lays down the general principles of food law including risk analysis, the precautionary principle and protection of consumers' interests plus the general obligations of the different bodies in the food chain and their consequent liabilities. It also lays down the requirement for transparency rules (for public access to information), systems for data analysis, the rapid alert system and establishment of an organizational framework including the audit and control systems applicable to the EFSA.

EFSA's function is to provide the European Union (EU) with independent scientific and technical advice to underpin policymaking and legislation in the area of food safety and in related areas of plant health, animal health and environmental protection. The Regulation also states that third countries with which the European Union has concluded agreement might participate in EFSA.

One development has been regarding the concept of "equivalence" (Art 1123). The Regulation was revised as part of a review of Food Law and drawing on Art 11 of Directive 91/493 (on fish and fish products). Under this revision, in circumstances where a country may not have its own facilities, European Union authorities may accept as "equivalent" health certification issued by acceptable bodies in another

[1] http://forum.europa.eu.int/irc/sanco/vets/info/data/listes/ffp.html

TABLE 2
Lists of third countries from which import of fishery products is authorized for human consumption – EC*

List I. Countries and territories covered by a specific decision under Council Directive 91/493/EEC

Albania	Cuba	India	Mexico	Poland	Taiwan Prov. of China
Argentina	Czech Republic	Indonesia	Morocco	Romania	Thailand
Australia	Ecuador	Iran	Mozambique	Russian Federation	Tunisia
Bangladesh	Egypt	Jamaica	Namibia	Senegal	Turkey
Belize	Estonia	Japan	Netherlands Antilles	Serbia & Montenegro (1)	Uganda
Brazil	Falkland Islands	Kazakhstan	New Caledonia	Seychelles	United Arab Emirates
Bulgaria	French Polynesia	Kenya	New Zealand	Singapore	United Rep. of Tanzania
Canada	Gabon	Latvia	Nicaragua	Slovakia	Uruguay
Cape Verde	Gambia	Lithuania	Nigeria	Slovenia	Venezuela
Chile	Ghana	Madagascar	Oman	South Africa	Viet Nam
China	Greenland	Malaysia	Pakistan	Rep. of Korea	Yemen
Colombia	Guatemala	Maldives	Panama	Sri Lanka	Zimbabwe
Costa Rica	Guinea Conakry	Mauritania	Papua New Guinea	St Pierre & Miquelon	
Côte d'Ivoire	Guyana	Mauritius	Peru	Suriname	
Croatia	Honduras	Mayotte	Philippines	Switzerland	

* (as of 13/4/2004). Not including Kosovo as defined by the United Nations Security Council Resolution 1244 of 10 June 1999.

List II. Countries and territories meeting the terms of Article 2(2) of Council Decision 95/408/EC*

Algeria	Azerbaijan (3)	Cameroon	Fiji	Israel	Solomon islands
Angola	Bahamas	Cyprus	Grenada	Malta	St Helena
Antigua and Barbuda (2)	Belarus	El Salvador	Hong Kong SAR	Myanmar	Togo
Armenia (1)	Benin	Eritrea	Hungary (5)	Congo (4)	USA

* COMMISSION DECISION 2004/359/EC of 13 April 2004 amending Decision 97/296/EC drawing up the list of third countries from which the import of fishery products is authorized for human consumption.
(1) Authorized only for imports of live crayfish (*Astacus leptodactylus*) intended for direct human consumption.
(2) Authorized only for imports of fresh fish.
(3) Authorized only for imports of caviar.
(4) Authorized only for imports of fishery products caught, frozen and packed in their final packaging at sea.
(5) Authorized only for import of live animals intended for direct human consumption.

country. The most quoted cases are Namibia, which can be certified by South Africa health certification bodies, and New Zealand, which can certify establishments in certain Pacific Islands.

A new regulation, EC/853/2004, lays down the food hygiene requirements for product of animal origin, including HACCP systems and procedures. New hygiene rules have been introduced that will adapt the concept of "*farm to table*" to hygiene policies and will, for the first time, create a single, transparent hygiene policy applying to all food operators including agreed steps to protect food safety. This new legislation will replace the patchwork of rules for specific sectors and types of product, which have gaps notably at the farm and primary production levels.

The new legislation gives food producers primary responsibility for the safety of food through self-checking and modern hazard control techniques. It integrates 16 existing product specific Directives and Directive 93/43 into a new "Food Hygiene Package" (Table 3).

The three regulations cover general hygiene of foodstuffs, hygiene of food of animal origin and official controls on products of animal origin (intended for human consumption). Part four of the package (animal health rules for products of animal origin) will apply no earlier than 1 January 2006 and will strengthen animal health requirements both within the Community and for imports. The last part of the package will remove a large number of previous regulations from the statute book.

TABLE 3
New European Union hygiene package of regulations and directives

Package	Regulation /Directive	Covering
Hygiene 1	European Parliament and Council Regulation (CE) 852/2004 on the hygiene of foodstuffs	general requirements primary production, technical requirements, HACCP, registrations/ approval of food businesses, national guides to good practice
Hygiene 2	European Parliament and Council Regulation (CE) 853/2004 laying down specific hygiene rules	specific hygiene rules for food of animal origin (approval of establishments, health and identification marking, imports, food chain information)
Hygiene 3	European Parliament and Council Regulation (CE) 854/2004 laying down specific rules for the organization of official controls on products of animal origin intended for human consumption	detailed rules for the organization of official controls on products of animal origin (methods to verify compliance with Hygiene 1 & 2 and animal by-products regulation 1774/2002)
Hygiene 4	Council Regulation (CE) 882/04 laying down health rules governing the production, processing, distribution and importation of products of animal origin	veterinary certification, compliance with European Union rules
Hygiene 5	European Parliament and Council Directive 2004/ 41/EC repealing 17 existing Directives	

2.2.1 Border control

Council Directive 97/78/EC of 18 December 1997 lays down the principles governing the organization of veterinary checks on products entering the European Union from third countries. Under the recent overhauls of controls by the EC [2], these rules will remain in place since they are very specifically designed for the organization of the official controls on feed and food of animal origin. This Directive requires that all products of animal origin imported into the European Union from third countries must be checked at an approved Border Inspection Post (BIP) to verify their compliance with European Union legislation. Annex A.3 details the approved requirements for border inspection posts (taken from Annex II of Directive 97/78).

Within the expanded European Union there are 278 BIPs operated by national authorities (Table 4). These posts are at the point of first contact with the European Union. Most of these are ports and airports, others are road or rail links located in particular at the eastern borders of the Union.

The accession of the ten new Member States in May 2004 has extended the eastern frontier with the Russian Federation and moved the frontier eastwards to border with Belarus, Ukraine, the Republic of Moldova and Turkey. New BIPs equally have to be established along the borders with Croatia, Macedonia , Montenegro and with Serbia. Candidate countries proposed a total of 87 BIPs to be approved for checking imports into the Union. As of May 1 2004, 37 new BIPs were approved from the ten new Member States. At the same time, several BIPs in Italy, Germany and Austria disappeared, mostly road and rail BIPs. Table 4 shows the status of BIPs in the European Union.

2.2.2 Checks at border inspection posts

At these BIPs, there are three main types of veterinary check on all consignments; documentary, identity and physical.

Documentary

A documentary check is carried out on all consignments. This involves checking that the appropriate veterinary documentation (including the health certificate) exists and has been completed properly.

[2] The recent overhaul includes the development of a new and integrated approach towards official food and feed control in the European Union. The proposed Regulation EC/52/2003 was adopted by the Commission on 5 February 2003.

TABLE 4
Border inspection posts in the European Union (EU) – after May 2004

Country	No. of Border Inspection Posts				
	Port	Rail	Road	Airport	Total
Austria	-	6	10	2	18
Austria (after May 1)	-	1	2	2	5
Belgium	4	-	-	4	8
Cyprus	1*	-	-	1	2*
Czech Republic	-	-	-	1*	1*
Denmark	11	-	-	2	13
Estonia	2*	-	1	-	3*
Finland	2	-	2	1	5
France	15	-	3	16	34
Germany	9	3	10	10	32
Germany (after May 1)	8*	1	2	10	21
Greece	2	3	6	2	13
Hungary	-	-	4	1*	5*
Ireland	1	-	-	2	3
Italy	17	2	4	15	38
Italy (after May 1)	17	2	2	15	36
Latvia	-	-	2	-	2
Lithuania	3*	3*	5*	1*	12*
Luxembourg	-	-	-	1	1
Malta	-	-	-	1	1
Netherlands	6	-	-	2	8
Poland	3*	-	4*	1*	8*
Portugal	10	-	-	5	15
Slovakia	-	1*	1	-	2*
Slovenia	-	-	1	-	1
Spain	21	-	-	19	40
Sweden	5*	-	-	3	8
United Kingdom	22*	-	-	9	31
	133	11	35	99	278

Source: Commission Decision 2003/831 (EU15) and Commission Decision 2004/273 (new EU10). * these are new figures from a draft Commission Decision which updates the numbers published in Commission Decision 2004/273 and are put into the table for completeness. Countries in italics are new entrants to the European Union.

TABLE 5
Consignment checks at European Union borders

Consignments that do not arrive in containers	Check on some of the packages to ensure that the stamps, official marks and health marks identifying the country and establishment of origin are present and conform to those on the certificate or document.
Consignments that arrive in containers with official seals	Documentary and identity checks for all consignments. Some may not need to be opened in order to complete an identity check provided official seals have been used in the country of dispatch and the seal numbers are clearly recorded in official veterinary certification.
Consignments that arrive in containers with no official seals	If official seals have not been used, or there is doubt over whether the seal number was recorded by the certifying veterinarian, the container would need to be opened and a check made on the packages therein to ensure that the stamps, health marks and other marks identifying the country and establishment of origin are present and conform to those on the certificate or document.

Identity
Every consignment is subject to an identity check to verify that the consignment matches that described in the documentation (Table 5) and check the health mark, which typically identifies the country and company identity.

Physical
In principle, a physical check is required on all consignments. However for the majority of products where import rules are fully harmonized a physical check is carried out on a percentage of consignments. The percentage varies according to the product and country of origin (Table 6). A physical check involves an inspection of the contents of

TABLE 6
Summary of physical checks at border inspection posts (Dec 94/360/EC)

Category I - 20 percent of consignments of: Fish products in hermetically sealed containers (stable at ambient temperature), fresh/frozen fish, dried/ salted fishery products
Category II - 50 percent of consignments of: Other fishery products other than those in Category I and bivalve molluscs
Category III - minimum 1 percent - maximum 10 percent of all consignments of: No fish products in this category

the consignment to ensure that it presents no animal or public health risk or quality defect. It may also involve the taking of samples for laboratory tests.

Physical checks on products of animal origin are categorized by the animal product being imported and the level of sampling required. Some countries have special arrangements with the European Union. Table 6 summarizes the situation for fish and related products. The full table of animal products is shown in Annex A.2.

Some countries are exempt for instance, veterinary checks are not required for fishery products from Iceland and are not usually required for any animal products from Norway and the Faeroe Islands.

As a result of the above checks, consignments may be sent for further testing. The professional judgement of the inspectors will identify the tests to be carried out, for instance, histamine and heavy metals for tunas, various specific bacteria for a variety of at-risk products, or malachite green for farmed fish. Non-statutory tests for residues are also carried out periodically for chemicals such as veterinary drugs.

There is also a general rule of 1–5 percent random sampling. These tend to be sent for analysis for indicator organisms such as *E. coli* and faecal coliforms rather than the more specific tests already mentioned. Annex A.3 details an example of the documentary requirements for animal products (including fish) at a United Kingdom (UK) BIP. The UK procedures are based on European Community legislation.

Presently, samples are subjected to sensory, chemical (histamine, mercury, Total Volatile Bases TVB-N, etc.) or biological (total flora, indicator organisms, parasites, etc.). However, most microbiological testing standards and criteria are still not harmonized within European Union members, except for the following fish and fish products: *Salmonella* and *E. coli* in live bivalve molluscs, echinoderms, tunicates and gastropods; fRNA bacteriophages in live bivalve molluscs, and; *Salmonella, S. aureus, E. coli* and *Vibrio parahaemolyticus* in cooked crustaceans and molluscan shellfish (Decision 93/51/EEC and Directive 91/492). Consequently, several European Union members' countries use different microbiological criteria for the other seafoods, which creates confusion amongst exporters as to which standard or criteria to follow. Upcoming legislation, which is still debated and is currently in draft form is supposed to circumvent this problem. Annex A.4 details the existing and upcoming microbiological criteria for fish and fishery products.

Once a problem consignment has been identified at the border, the member state has an obligation to notify all other member states of the cause of the border case. This is now done via the Rapid Alert System of the European Union.

2.2.3 The rapid alert system

The Rapid Alert System for Food and Feed (RASFF) was established originally under Article 8 of Directive 92/59/EEC (superseded by Directive 2001/95), the directive on general product safety. Products in this case covers "any product, including in the context of providing a service, which is intended for consumers….", so the Directive is much broader than food and feed. This Directive provides for a procedure to inform the European Union Member States when a product presents a serious risk for the health and safety of consumers.

When *Regulation 178/2002,* which lays down general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, came into force, the food procedure covered by Article 8 of the General Product Safety Directive ceased to apply and was instead called the Rapid Alert System for Food and Feed (RASFF). The legal basis of the RASFF is to be found in Article 50 of Regulation 178/2002/EC. This new legal basis extends the rapid alert system for food to include animal feeds and includes the Border Inspection Posts network.

Basically, the purpose of the RASFF is to provide the European Union control authorities with an effective tool for exchange of timely information on measures taken to ensure food safety.

The RASFF is effectively a network of the relevant European Union member states authorities, but also includes other countries such as the EFTA/EEA states. Whenever a member of the network has any information relating to the existence of a serious direct or indirect risk to human health, this information is immediately notified to the Commission under the RASFF. The Commission immediately transmits this information to the members of the network. Article 50.3 of the Regulation gives further details on when a RASFF notification is required. (Annex A.5 details a flow chart for the process).

Basically, Member States shall immediately notify the Commission, under the rapid alert system, of:

(a) any measure they adopt which is aimed at restricting the placing on the market or forcing the withdrawal from the market or the recall of food or feed in order to protect human health and requiring rapid action;
(b) any recommendation or agreement with professional operators which is aimed, on a voluntary or obligatory basis, at preventing, limiting or imposing specific conditions on the placing on the market or the eventual use of food or feed on account of a serious risk to human health requiring rapid action;
(c) any rejection, related to a direct or indirect risk to human health, of a batch, container or cargo of food or feed by a competent authority at a border post within the European Union.

These latter notifications are called *Information Notifications.* Information notifications concern a food or feed for which a risk has been identified, but for which the other members of the network do not have to take immediate action, because the product has not reached their market. These notifications mostly concern food and feed consignments that have been tested and rejected at the external borders of the European Union. Products subject to an information notification have not reached the market or all necessary measures have already been taken.

The RASFF also issues *Alert Notifications.* These are sent when the food or feed presenting the risk is already on the market and when immediate action is required. Alerts are triggered by the Member State that detects the problem and that has initiated the relevant measures, such as withdrawal/recall. As of 26 May 2003 the European Union began posting a weekly internet report with information on all notifications from the Rapid Alert System[3].

2.3 UNITED STATES OF AMERICA

The majority of United States Federal regulatory authority and activity for seafood regulation is vested with the Food and Drug Administration (FDA) within the Department of Health and Human Service. The FDA's mission is to enforce laws enacted by the United States of America Congress and regulations promulgated by the

[3] http://europa.eu.int/comm/food/food/rapidalert/

Agency to protect the consumer's health, safety, and pocketbook. Among the principal laws associated with seafood safety there is the Federal Food, Drug and Cosmetic Act (the Act) of 1938, as amended (21 USC.301-392).

A Federally Mandated Seafood Rule (FDA, 1995) promulgated in 1995 constitutes the basis for the sanitary procedures for processing and importing fish and fishery products into the United States of America, including Good Hygienic Practices and HACCP.

Section 801 of the Federal Food, Drug, and Cosmetic Act (21 USC.381) authorizes FDA to examine food offered for entry into the United States of America through United States Customs, either prior to entry or after secured delivery to importers/brokers. Importers, or their representatives, are required to file a notice with the United States 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.

Section 702 of the Act (21 USC.372) authorizes FDA to take food samples for examination and investigation purposes. Each year, the Programme offices of FDA and the Office of Seafood at the Centre for Food Safety and Applied Nutrition (CFSAN) prepare Compliance Programme that direct the field inspection and surveillance activities. The Programme describe the product areas to emphasize, the types of product to target, the make-up of samples, the types of analyses to conduct on 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* spp., *Clostridium botulinum*, *Vibrio* spp., *Staphylococcus aureus*, enterotoxigenic *Escherichia 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, putrecine, 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, saffron, FD&C Yellow no. 5. FD&C Red Approaches No.4 and
- foreign objects – metal fragments.

The FDA also inspects seafood products for spoilage decomposition, filth, mould, 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 or safety problems). Approved or unapproved applications of additives to mask decomposition have also recently become of great concern to the FDA. Annex A.5 details a flowchart for importing foods into the United States of America and Annex A.7 provides the FDA/Environment Protection Agency EPA guidance levels for contaminants in seafoods.

In the United States of America, the manufacturer or owner of the goods (including seafood) is responsible for the safety, wholesomeness, and truthful labelling of the

products in his control. The FDA seeks to prevent entry or remove violative goods from commerce via advisory actions (warning letters and untitled letters), administrative actions (citations, detentions, and administrative meetings), judicial actions (seizure, injunction and prosecutions).

The Food, Drug and Cosmetic Act authorizes the FDA to detain a product that appears to be out of compliance with the Act. The FDA district office involved will issue a "*Notice of Detention and Hearing*" specifying the nature of the violation cited to the owner or consignee, who is entitled to an informal hearing to provide testimony and/or documentation on the suitability of the product for import to the United States. A "*Notice of Detention and Hearing*", although not providing information on the final disposition of the products, do show the type and nature of the violations cited by FDA and the products, countries and industry involved. If the owner fails to submit evidence that the product is in compliance or fails to submit a plan to bring the product into compliance, FDA will issue a "Notice of FDA Action" refusing admission to the product. The product then has to be exported or destroyed within 90 days.

Each month, an Import Refusal Report (IRR) (Annex A.8) is published based on data generated by the FDA's Operational and Administrative Import Support (OASIS). This report replaces the FDA Import Detention Report (IDR). The IDR gives an incomplete picture in that it only reflected the initial action by the Agency and not the ultimate determination of the compliance status of the product. Through the new IRR data are sorted by country and by product based on the industry code with a clear indication on products that have been found to appear in violation of the Act, the origin of the product and the reason to refuse admission of the product. The data are available (including on the Internet) by country and by product commodity (FDA, 1999).

2.3.1 Detention without physical examination

In some instances a product may be detained as soon as it is offered for entry into the United States. This procedure is the administrative act of detaining a product without physical examination and is based on past history and/or other information indicating the product may be violative. A product may be subject to a *Detention Without Physical Examination* (DWPE) recommendation until the shipper or importer proves that the product meets FDA guidelines or standards.

2.3.2 Automatic detention

Occasionally, the FDA identifies products from an entire country or geographic region for DWPE when the violative conditions appear to be geographically widespread. Detention recommendations of this breadth are rare and are initiated only after other avenues for resolving the problem have been exhausted (see vFDA Regulatory Procedures Manual, Chapter 9-25-00 for details on Detention Without Physical Examination – formerly known as Automatic Detention).

In 1979, the FDA was confronted by a serious and growing problem with Asian shrimp. The FDA's testing disclosed that a high percentage of shrimp entries from various Asian countries were contaminated by *Salmonella*, or decomposed, or contained filth or often a combination of the three.

Between March and August 1979, the FDA sampled and tested 835 entries of shrimp from six Asian countries. Of the total, 387, or 46 percent, were found violative and consequently denied entry. Decomposition accounted for 164 or 20 percent, and the remaining were detained for filth. The percentage of denied shrimp entries from each of the six countries ranged from 31-78 percent and a considerable number of violative samples for each country were found over a six-month period. The volume of incoming shrimp shipments and FDA's obligation to sample and test the shrimp created an overload in FDA's laboratories and shifted personnel from other health protection

duties. FDA considered that it was fast becoming a "de facto" quality control agent for foreign shippers for these countries.

This deteriorating situation prompted FDA to consider carefully, and then implement countrywide blacklisting of the commodity. Two criteria must be reached before FDA will implement this action: 25 percent of the entries from a shipper or a country is violative for a single attribute and at least 10 violative samples have been found in a six-month period. Each of the six countries met the criteria and all shrimp shipments from all shippers in each of the six countries were blacklisted in October 1979.

The term "blacklisting" was soon changed to "automatic detention", which better reflects the nature of the action. Commodities or products automatically detained are not allowed to enter the United States commercial channels.

2.3.3 Import alerts

Import alerts have been developed to communicate guidance to FDA field offices. The purpose of an import alert is to identify and disseminate import information (problems, violative trends, etc.) to FDA personnel thus providing for more uniform and effective import coverage. Import alerts identify problem commodities and/or shippers and provide guidance for import coverage.

To assure the expeditious handling of imported products, FDA has automated its import operations. By combining FDA's Operational and Administrative System for Import Support (OASIS) and Customs' Automated Commercial System (ACS), an FDA reviewer will be able to more efficiently evaluate and process each import entry. The import filer transmits the required shipment-specific FDA data into the ACS. Within several minutes, the filer receives notification that either their shipment has been released or FDA wishes to review it. This system provides FDA with immediate data on imported products, provides information on potential problems, and maintains national historical data files to develop profiles on specific products, shippers, and manufacturers. Eventually all filers processing entries through Customs' ACS will provide FDA information electronically.

Of particular interest is the 2003 FDA Interim Final Regulation (21 CFR Parts 1 and 20) promulgated under the *Public Health Security and Bio-terrorism Preparedness and Response Act*. This regulation, which became mandatory in December 2003, requires that domestic and foreign facilities that manufacture/process, pack or hold food for human or animal consumption in the United States of America register with FDA and submit, electronically, prior notice to FDA before the shipment is due to arrive into the United States of America. It is feared by several fish exporting countries that the implementation of these requirements may disrupt fish trade flows from exporting countries into the United States of America.

2.4 JAPAN

2.4.1 General principles for food imports

Much less information is available on Japanese safety and quality requirements for fish and fishery products, not least because of language constraints. However, information gathered by the authors during several international meetings and conferences indicate that application of HACCP-based food control regulations has been introduced for some years now, including sanitary and hygienic requirements for fish handling and processing establishments and conditions for storage and transport. Risk analysis principles are being incorporated along with spot checks at the border and with the quality control schemes that often control imports at the source.

The main laws controlling entry of food products are the Food Sanitation Law and Quarantine Law (Table 7).

Other laws are relevant to control of food imports and these include the Plant Protection Law, the Domestic Animal Infectious Diseases Control Law, Customs

TABLE 7
Regulations applying to fishery products and prepared products – Japan

Harmonized System Code	Items	Relevant Regulations
03-01	fish, (live)	Food Sanitation Law and Quarantine Law
03-02	fish, (fresh or chilled, except fillet)	
03-03	fish, (frozen, except fillet)	
03-04	fish fillets	
03-05	fish, (dried, salted, or smoked) or fish flour and meal	Food Sanitation Law
03-06	crustaceans, (live, fresh, frozen, dried, or salted,)	Food Sanitation Law and Quarantine Law
03-07	molluscs,(live, fresh, chilled, frozen, dried, salted, or smoked)	
16-03	extracts of fish, crustaceans and molluscs	
16-04	prepared fish, caviar and caviar substitutes prepared from fish egg	Food Sanitation Law
16-05	prepared crustaceans and molluscs	

Notes:
1 Herring, codfish, sardine, horse mackerel, saury, scallop, adductors of shellfish, cuttlefish and squid are Import Quota items.
2 Fish (live) in 03-01 include those fish whose import is controlled by the Washington Convention (see Annex A.9).
3 Quarantine - No prohibited area is designated for the import of marine products. However, marine products from areas contaminated by cholera or from suspected areas shall be subject to inspection under the Quarantine Law.

Law and for labelling, the Law Concerning Standardization and Proper labelling of Agricultural and Forest Products (JAS Law).

Under the Food Sanitation law[4] (AnnexA.10), all importers of food must submit an "import notification" to the Ministry of Health, Labour, and Welfare (MHLW) that a consignment is intended to be imported. Without such a notification, the imported food cannot be sold or used for business purposes.

The "Notification Form for Importation of Foods" is submitted to a *quarantine station* of the Ministry. All the entry points in Japan have such quarantine stations. There are some 31 quarantine stations at seaports and airports throughout the country.

A flow chart for the whole procedure of import notification of foods and related products is given in Annex A.11.

Postal cargoes from abroad are also subject to the Food Sanitation Law and an import notification must be submitted. Items that are imported for personal uses are exempted from import notification.

In recent years and in response to an increasing consumers' uneasiness concerning foods because of the problems of BSE, false labelling and pesticide residues, etc. the food sanitation law has been updated. As a result, sales and imports of food items may be prohibited without inspection when the Minister of Health, Labour and Welfare deems it necessary to protect consumers.

2.4.2 The process for fish and fish products on arrival in Japan

When a consignment arrives at a Japanese port, a "Notice of Customs Clearance (i.e., Arrival Notification)" is sent to the addressee from a customs office, and the customs clearance procedure is initiated. The import notification form must be submitted before the end of custom clearance procedures. In some cases a sanitary or health certificate from the exporting country must be attached to the import notification form (for instance puffer fish).

At the quarantine station, food sanitation inspectors carry out document examination and inspection to confirm that the foods comply with the Food Sanitation Law. This will include validation as to:

- whether the imported food, etc. complies with the manufacturing standards regulated under the Food Sanitation Law;

[4] Article 16 indicates that "Those who wish to import food or food additives, for sale or for use in business, shall notify the Ministry of Health, Labour, and Welfare on each occasion as prescribed by the Ministerial Ordinance."

TABLE 8
Japanese "Import Notice" Item 1: Principal Import Quota Items

*** Non-liberalized items** Live inshore fishes (herring, cod, yellow-tail, sardine, horse mackerel, saury), fresh or chilled inshore fishes and cod roe, frozen inshore fishes and cod roe, fish fillets and other fish meat (fresh, chilled or frozen), inshore fishes (dried, salted, or in brine), fish meal, cod roe, dried sardines, scallops, adductors of shellfish, cuttlefish and squid except for mongo, edible seaweed, prepared foods of seaweed.
*** Items controlled by international convention or agreement** Plant and animal species and their derivatives listed in Appendix I of the Washington Convention (Convention on International Trade in Endangered Species of Wild Fauna and Flora – CITES), controlled substances listed in the Montreal Protocol.

TABLE 9
Japanese "Import Notice" Item 2 – Goods originated in or shipped from certain specific area

Whales and their preparations	Non-member countries of the International Whaling Convention, Brazil, Republic of Korea, Peru, Ireland, Norway, etc.
Salmon, trout and their preparations	China, Democratic People's Republic of Korea and Taiwan Province of China
Bluefin tuna and their preparations	Belize, Honduras and Equatorial Guinea
North Atlantic swordfish and their preparations	Belize, Honduras
Marine mammals and their preparations, fish, crustaceans, other aquatic animals and preparations thereof	Items shipped from outside of Japanese territorial waters

- whether the use of additives complies with the standards;
- whether poisonous or hazardous substances are present; and
- whether the manufacturer or the place of manufacturing has a record of sanitation problems in the past.

There are clearly two possibilities at this stage.

(a) The consignment is deemed to comply with the law. In these cases, the consignment can complete customs clearance, be passed onto the importer and be moved into domestic distribution.

(b) The consignment needs to be further examined. This may happen to consignments with a record of non-compliance with the law in the past, or for imported puffer fish, for example. In such cases, an "inspection order" will be issued out in order to confirm compliance. (Annex A.12 provides further details of this and other inspection systems used in Japan). The importer is responsible for the cost of this inspection. Again, there are two possibilities:

(i) The consignment is judged to comply with the law and can thus complete customs clearance as in (a).

(ii) The consignment is judged to not comply with the law and cannot be imported into Japan. The MHLW quarantine station notifies the importer how the cargo violates the Food Sanitation Law, and the importer must take necessary measures by following the instructions from the quarantine station.

2.4.3 Consignments requiring prior approval

There are certain fish and fish products that require approval for import prior to customs clearance procedures. The *Import Notices* are either non-liberalized items governed by import quotas or items covered by international convention or agreement (Table 8) or designated goods originating in or shipped from certain specific areas and items controlled by international convention or agreement (Table 9).

2.4.4 Labelling requirements

Allergy Labelling under Food Sanitation Law

Requirements for labelling of foods containing allergenic substances were regulated in April 2002. Furthermore and specific to fish, it is recommended that foods that contain

abalone, cuttlefish, salmon roe, shrimp, crab, salmon and mackerel as raw materials are labelled as such. Refer to Annex A.13 for further details on labelling of allergens.

JAS Standard System

(1) Quality Labelling

The names of foods and country of origin for fresh fish and the names of foods, raw materials, content quantity, manufacturer, open date, and preservation method for processed marine products shall be contained on the label.

(2) Affixation of JAS mark

(a) A JAS mark may be affixed by applying to the JAS standard grading organizations after the customs clearance for marine products including fish, meat, hams, sausages, etc. Using a JAS mark is at the discretion of the manufacturer (importer) and not mandatory. Processed marine products include specially packaged boiled fish pastes, processed sea urchin, flavour seasonings, mixed and dressed sea urchin, Kezuribushi (shavings of dried bonito), fish ham and sausage, kamaboko (flavoured boiled fish paste), dried small sardines, etc.

(b) JAS standard grading is available using inspection data from a "Designated Foreign Testing Organization", accepted by the Japanese Ministry of Agriculture, Forestry, and Fisheries.

2.5 CANADA

The Canadian legislative framework for fish safety (including imported fish and foreign consumers of Canadian fish and fish products) addresses not only consumer safety but also product packaging and labelling requirements.

The main body is the Canadian Food Inspection Agency (CFIA), which was set up through the Canadian Food Inspection Agency Act in 1997. Under the *CFIA Act*, the CFIA is responsible for the administration and/or enforcement of all federal legislation related to food inspection, agricultural inputs and animal and plant health. The legislation covered includes the *Fish Inspection Act,* the *Fish Inspection Regulations* as well as the *Consumer Packaging and Labelling Act* as it relates to food and the *Food and Drugs Act.*

The main vehicle used by the CFIA to control the safety, quality and integrity of fish and fish products is the National Fish and Fish Products Inspection and Control System.

At the federal level, food safety is a shared responsibility between two ministries – the Ministry of Agriculture and Agri-Food and the Ministry of Health. The Ministry of Agriculture and Agri-Food, through the CFIA, conducts all federal food inspection activities. The Ministry of Health is responsible for establishing policies and standards relating to the safety and nutritional quality of food sold in Canada. The body responsible is Health Canada.

2.5.1 Import product control system[5]

The Canadian Import Product Control System uses a variety of controls to ensure that all fish and fish products coming into Canada meet Canadian requirements.

To start with, all importers of fish and fish products must be licensed. This requires that the importer must maintain all records of recalls and complaints and must notify the CFIA if the results of an investigation indicate that the fish may be unsafe. In addition, importers of ready-to-eat and canned products must have further documentation that proves that processing conditions used have resulted in production of a safe product.

[5] The description of the systems employed borrows heavily on the information provided on the Canadian Food Inspection Agency website at the time of publication (http://www.inspection.gc.ca).

Importers must notify the CFIA within 48 hours of the importation of a product. The CFIA then decides whether the product should be inspected or not. The CFIA maintains a database of all fish imports – by processor and product description – and includes compliance data for any inspection undertaken.

In Canada, the importer can also take on this responsibility of inspection through a Quality Management Programme for importers (QMPI). The QMPI importer must develop a quality management system and provide details of that system to the CFIA. Once accepted by the CFIA, the importer must implement and comply with the written programme. The activities under the QMPI must meet or exceed the frequencies and type of analyses that would be performed on a lot by the CFIA. All microbiological and chemical analyses must be conducted by an accredited laboratory. The QMPI system targets larger importers as the system has significant costs associated with licensing and maintenance. However, the QMPI importer has total control over the imported fish and this can mean significant savings in time, often a critical aspect in the trade process. Currently there are 18 QMPI importers (out of a total of approximately 1 000 fish importers in Canada) who bring in around 40 percent of the fish imports into Canada. This system also allows the CFIA to target its inspection resources to areas of non-compliance.

In general, inspection rates will vary from 2 to 100 percent depending on the inherent risk of the product, additional controls placed on the product by the exporting country, the history of compliance of the product/processor and the quality management programme in place by the importer.

Less inspection effort is targeted at foreign exporters/processors with a history of good compliance. Consistent compliance (at least ten consecutive inspections) with Canadian regulations means that the foreign processors will be considered for the "A" List. The following criteria define an "A" List processor:

- a minimum of 30 lots imported in the last two years of the selected product category type (i.e. canned, ready-to-eat, fresh or other [frozen, raw, dried, etc.]);
- acceptable results for all analyses conducted, except minor label infractions in the last ten consecutive inspections, for products imported in the selected product category type, within the past two years.

Processors meeting the above criteria will be placed on the "A" List and selected for random inspection by processor, at the following frequencies for standard tests:

- canned product – 10 percent (instead of 15 percent);
- ready-to-eat-product – 10 percent (instead of 15 percent);
- other (not fresh) product – 10 percent (instead of 15 percent);
- fresh product – 1 percent (instead of 2 percent);
- raw molluscan shellfish – not applicable to the A List

Products from processors on the "A" List will be randomly sampled at a lower frequency than normal. The CFIA maintains the "A" List on its Web site[6]. As of April 2004, this list contained 37 companies, 26 from United States of America, 5 from Thailand, 3 from China, 1 from India, 1 from Norway and 1 from Japan.

In addition, where the relevant authority in an exporting country places additional controls on its exporters and these controls are recognized by the CFIA through a Mutual Recognition Arrangement, the CFIA will then also reduce the inspection effort on imports from those countries. Such agreements (or Memoranda of Understanding MOU) exist with Australia, Ecuador, Iceland, Indonesia, Japan, New Zealand, Philippines and Thailand.

When an imported product fails to comply with the *Fish Inspection Regulations*, *Food and Drug Regulations* or the *Consumer Packaging and Labelling Regulations*,

[6] http://www.inspection.gc.ca/english/anima/fispoi/import/listae.shtml

it is listed on the CFIA Import Alert List (IAL) which is searchable on the CFIA Web site. All subsequent importation of this product from the same producer will be subject to mandatory inspection until such time as four consecutive shipments pass import inspection requirements. Products that are failed by an importer operating under the QMPI also are listed on the IAL. Imported fish products that do not conform to Canadian requirements are not permitted entry into Canada. In such cases, the importer is notified on the refusal of entry and subject to the appeal process, the product must be destroyed, removed from Canada, or brought into compliance through culling, reworking or re-labelling.

2.5.2 Inspection testing

As indicated in the previous section, the system established for conducting inspections is dependent on a number of factors already discussed. However, when an inspection takes place, the imported products are subjected to microbiological, chemical, bioassay and/or sensory examinations depending on the product type, foreign country standards and Canadian standards. The products are assessed by the CFIA, by the importer under the QMPI programme or by a recognized foreign authority under an Arrangement. Whoever does the inspection, the procedures are the same.

The tests on random samples are divided into two categories:

- *standard testing* that is to be applied to all products; and
- *specialized testing* that normally depends on the safety risk implications of the product.

Standard tests include:

- labelling – which involves examination of the label, packaging and code markings to evaluate compliance to Canadian requirements;
- net content – examination to evaluate conformity to all weight declarations (e.g., net and/or drained weight, including fluid measure where applicable);
- sensory – examination to evaluate sensory and physical compliance to quality standards for taint (rancid or abnormal), decomposition, foreign matter, undesirable parts and parasites, and to evaluate conformity to all other content declarations such as style, count, composition, etc; and
- container integrity inspection to determine compliance of canned fish to Canadian standards for container integrity.

Specialized tests include:

- composition analyses to ensure that non-permitted or non-declared ingredients or additives are not present and to determine that declared ingredients/additives do not exceed regulatory guidelines;
- chemical analyses to determine that chemical contaminants do not exceed regulatory limits. This would include toxic elements, pesticides, industrial chemicals and drug residues;
- natural toxin analyses to determine that natural toxins do not exceed regulatory limits. Examples would include histamine, paralytic shellfish poison, domoic acid and other biotoxins such as ciguatoxin, okadaic acid and tetramine;
- bacteriological testing to ensure absence of pathogenic organisms. Examples would include analyses for organisms such as *E. coli, Listeria monocytogenes*, *Salmonella* sp., and *Staphylococcus aureus*; and
- safety parameter testing to determine that fish packed in containers sealed to exclude air and which do not depend solely on heat sterilization, freezing or refrigeration for safety have adequate pH and/or water activity and/or salt content to ensure product safety.

Other tests include tests done as part of an investigation or special project. Examples would involve monitoring of products from countries where commercially harvested fish may be exposed to chemical or microbiological contamination.

Annex A.14 details the Canadian guidelines for microbial and chemical presence in fish and fish products.

2.5.3 Monitoring frequencies

Standard testing

Standard tests are conducted on products on the Import Alert List as required and products that have not been recommended for inspection in the past two years at a frequency of 100 percent. All other products will be monitored randomly at a frequency of 15 percent, with the exception of fresh fish, which will be inspected at a frequency of 2 percent (see Annex A.15 for a more detailed breakdown of test frequencies).

Specialized testing

Microbiological and chemical analyses will be conducted on products on the Import Alert List and not inspected in the last two years, as required. Otherwise, products will be conducted randomly at a frequency of 5 to 15 percent, depending on the product history and the nature of the product.

Product from MOU/MRA processors

A lower random inspection frequency may apply to products from preferred status plants that are recognized under a Memorandum of Understanding (MOU) or a Mutual Recognition Agreement (MRA).

Product from "A" List processors

Products from "A" List processors are subject to random monitoring at a rate of 10 percent for all standard tests. Fresh fish will be monitored at a frequency of 1 percent.

2.6 SUMMARY OF BORDER CONTROL SYSTEMS FOR FISH AND SEAFOOD

In compiling the regulations for this study, it became apparent that these four importing countries/regions examined employ different systems to protect their marketplaces from unsafe and substandard fish and seafood. An attempt was made to summarize the main similarities and differences between them in Table 10.

The table shows that there are major differences between the border control systems used by different importing countries. These differences in procedures are further complicated by differences in the type of biological, chemical or physical tests to which samples are subjected, as well as the methods of analysis and standards applied as discussed further in Chapter 3. This can only have a negative impact on the free flow of trade between exporting and importing countries as exporters have to become knowledgeable about several (or more) systems, which are often not well substantiated, in order to get their products to market. This wastes time, adds cost and will lead to mistakes (incorrect or missing documents, most likely). Therefore it is less efficient than it could be.

Clearly then, it would be advantageous to harmonize not only the systems of border control, but also the standards, criteria and testing methods. This need has been recognized internationally, and the work of the Codex Alimentarius Commission is very important in this area.

Codex has published the combined texts for *Food Import and Export Inspection and Certification Systems.* This covers:

- Guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems. CAC/GL 26 - 1997.
- Guidelines for the development of equivalence agreements regarding food import and export inspection and certification systems. CAC/GL 34 - 1999.
- Guidelines for the exchange of information in food control emergency situations. CAC/GL 19 – 1995;

TABLE 10
Comparison of fish import systems in the European Union, United States of America, Japan and Canada

Exporter (s)	Importing country or region			
	European Union (EU)	**United States (USA)**	**Japan**	**Canada**
Role of exporting government for exports to the importing country/region	EU certifies a Competent Authority in exporting country	Can voluntarily create an agreement with United States of America None exists to date	No official agreements with exporting countries known so far	Can voluntarily create an agreement with Canada, e.g. Thailand, Indonesia, Iceland, etc.
Role of exporters for exports to the importing country/ region	Apply GHP/HACCP (own checks) to be certified by their own country's Competent Authority following physical inspections, documentation review and final product checks	Have SSOP/ HACCP based programme and make necessary documentation available to FDA through importer	Have a GHP/HACCP based programme but it is not clear whether and how it is implemented aboard. Major importing companies have their QC staff work with exporting companies	Have GHP/HACCP based programme
Can an exporter export to the importing country/region without the existence of a Competent Authority in their own country	No	Yes	Yes	Yes
Role of importing governments in the importing country/ region	Run inspection system to ensure European Union legal and technical requirements are met Has border inspection posts	Run inspection system to ensure United States legal and technical requirements are met, but not mandatory as for European Union Has border inspection posts	Run inspection system to ensure Japanese legal and technical requirements are met, but to a much lesser extent than European Union Has border inspection posts	Run inspection system to ensure Canadian legal and technical requirements are met Has border inspection posts
Role of importers in the importing country/ region	Receive cleared import	Check SSOP/HACCP plans of exporting firms and make them available to FDA inspectors Notify authority of all imports (under Bioterrorism Act)	Notify authority of all imports Major importing companies have their QC staff work with exporting companies on grading and hygiene	Become licensed Notify authority of all imports Can become QMPI approved and do own inspections. QMPI importers have obligations to CFIA
Frequency of paper and identity checks at the border in the importing country/region	All imports	All imports	All imports	All imports on Import Alert List or not tested during the last two years. Otherwise, all lots taken for testing (see Annex A.15)
Frequency of physical checks at the border in the importing country/ region	Variable frequency depending on the status of the country of origin and company's history (see Table 6)	Variable frequency depending on the status of the country of origin and company's history	Variable frequency depending on the status of the country of origin and company's history	All imports on Import Alert List or not tested in last 2 years. Otherwise, all sampled (see Annex A.15)
Frequency of microbiological and chemical analyses carried out at the border in the importing country/region	At discretion of inspector given evident quality, product type, species, country of export and company's history (see Annex A.4)	At discretion of inspector and/or depending of the yearly targetting programmes	At discretion of inspector and/or depending of the yearly targetting programmes	2, 5 or 15 percent depending on the product/species. (see Annex A.15)
Any requirement or guidance for microbial testing	Yes. For ready-to-eat seafoods, live molluscs and cooked crustacea and molluscan shellfish (see Annex A.4)	Yes. See Annex A.7	Yes	Yes. (See Annex A.14)
Type of microbiological tests done when required in the importing country/ region	At discretion of inspector but includes *L. monocytogenes, E. coli, Salmonella, S. aureus, Vibrio* spp. (see Table 18 for actual examples)	See Annex A.4	Indicator organisms and total counts (see Table 37 for actual examples)	L. monocytogenes *E. coli* *Salmonella* *S. aureus* (see Annex A.14)

TABLE 10 Cont'd

Exporter (s)	Importing country or region			
	European Union (EU)	**United States (USA)**	**Japan**	**Canada**
Type of chemical tests done when required in the importing country/ region	At discretion of inspector but includes histamine, heavy metals, veterinary drugs, pesticides (see Table 19 for actual examples)	Includes histamine, heavy metals, veterinary drugs, pesticides	Antioxidants, preservatives, veterinary drugs, colouring and bleaching agents and biotoxins (see Table 38 for actual examples)	Includes histamine, heavy metals, veterinary drugs, pesticides (see Table 45 for actual examples)
Standards and guidelines used for microbial hazards	See Annex A.4. Otherwise, as per country requirements	See Annex A.7	See Annex A.10	See Annex A.14
Standards used for chemical hazards	See Annex A.4	See Annex A.7	See Annex A.10	See Annex A.14
Can integrity for LACF/ AF	Performed by companies and controlled by Competent Authorities in exporting countries	Specific requirements under BPCS and/or addressed under HACCP for LACF/AF	Not available	Controlled at borders. Canning - wrinkle > 20 percent is unacceptable

- Guidelines for the exchange of information between countries on rejections of imported food. CAC/GL 25 - 1997.

The role of appropriate risk assessment in the development of food standards and control systems is a common theme throughout the texts. However, these basic safety principles still need to find their way into practical application for the promotion of harmonization and equivalency. The discrepancies between importing countries as regards the types of control, control procedures and standards are discussed in more details in chapter 3 under 3.6.7.

3. Border cases in the European Union, North America and Japan

3.1 INTRODUCTION

Each year the major importing countries of fish and fish products reject or detain imports for a variety of reasons. Indeed, the previous chapter outlined the regulations and procedures governing the import of fish into the three largest fish importers – European Union, North America and Japan.

In most cases, the statistics held for these detentions or rejections have not been easy to come by unless you had contacts with the various authorities responsible for food or fish inspection. Where the data are available, they are often similar, but not identical, in terms of the type of information collected or the classification of the causes for rejection/detention. Importantly, the ability to access these data easily as a member of the public (or industry) varies considerably between importing countries. This latter issue is discussed in some detail in Chapter 4, including recommendations as to how to improve the situation.

On a global scale, it would be nice to be able to present a table summarizing the total number of detentions and rejections of food at borders worldwide, but this is not possible as the data available are still limited.

The rest of this chapter considers fish and seafood imports into the European Union, United States of America, Japan and Canada markets. Each market is considered separately, laying out the facts on border cases, and also putting the border cases into perspective as regards import volumes. It analyses the data for trends or patterns in rejections/detentions across a range of parameters – problem type (microbial, chemical, other causes), species, geography and process type (fresh, frozen, cured, etc.). The case posed by aquaculture products is covered and the chapter also specifically examines the scientific basis for rejection/detentions.

3.1.1 Data sets used

There are two main sets of data used in this document – border case data and import data. Currently, border case data are not held centrally anywhere, and thus data have to be sourced from the importing countries themselves. Import data are held centrally by FAO and also by the countries themselves. However, a single data set for imports is not always examinable from both a product basis (i.e. imports broken down by products) and a country basis (i.e. imports broken down by exporting country).

The study covers the period 1999 to 2002 for which attempts were then made to get the border case and import data from the four countries/regions considered.

Border case data

As highlighted earlier, the types of data and the periods covered differed from one country/region to another. Thus, for the European Union and Canada, detailed line-by-line data for the border cases from 1999–2002 was compiled in spreadsheets with subsequent breakdown by risk category, products and exporting regions.

The data collected for the United States of America cover a two-year period from mid-2000 to mid-2002, but line-by-line data were not available.

The data collected for Japan were more varied. Publicly available data (Web based) were restricted to an annual summary for 2000 for foods in general. However, border

case data for fish were obtained from the Japanese authorities directly but were restricted to two periods – April 2000/October 2001 and November 2001/0ctober 2002. For ease of comparisons, the 19-month period was averaged to provide a monthly figure and then aggregated to give a 12 month estimate. Again, the level of detail was not as good as for the European Union and Canada with only summary data available.

As has been noted in the previous chapter, the latest border case data is available on the internet for the European Union, United States of America and Canada. An annual summary for all foods (for 2000 at the time of writing) is available for Japan. Example extracts of the information available on the internet can be found in Annex A.16 for the European Union, Annex A.17 for the United States of America and Annex A.18 for Canada. However, though data is available publicly, and this should be applauded, there are limitations with regard to the data fields recorded, the ease of extraction of the data for later analysis and access to archived information.

Putting border cases into perspective

In the present study, border case data were analysed considering two issues: impact on consumer safety and international economic and trade implications, with the understanding that protection of consumer safety cannot be compromised by any consideration whatsoever. Absolute number of border cases were used to assess the extent of fish safety and quality aspects, whereas relative comparisons between exporting and importing regions, or between risk categories and products types used border case data weighted in relation to the volume of trade.

For instance, if Region 1 exports to Region 2 and ends up with 100 border cases in Region 2, and Region 3 exports to Region 2, and ends up with only ten border cases, then it is inappropriate to say that Region 1 is performing poorly compared to Region 3 without knowing the quantities of imports involved. Thus we have used the volumes of trade in tonnes to provide a comparative figure. This is a crude figure, as the border cases do not indicate how many kilograms were involved in each border case – so a "case" could involve a shipment of 100 kg or 10 tonnes. When the latter were known, a rough calculation was made to estimate the total value of border cases to trade disruption. However, the number of border cases per unit volume does give an indication of the relative importance of various factors in border cases. This calculation is not possible in all circumstances due to data gaps.

3.2 EUROPEAN UNION

In the European Union in 2003[7] there were a total of 4 286 notifications of food related problems from internal production and imported foods. This rose from 3 024 in 2002. This is for all food and feed products and represents a 41.7 percent increase over 2002. Of these, 454 were alert notifications and 1 856 were information notifications (see Chapter 2.2 for an explanation of the differences).

Significant specific notifications during the year included aflatoxins in nuts (763), cadmium (103) and mercury (24) in fish (mostly swordfish), industrial dyes in chilli powder (119) and dioxins (26) mostly in animal feeds. Table 11 breaks down the notifications (which are mostly information notifications and these are mostly border cases of imported foods). As noted above, a large number of notifications were due to mycotoxins (95 percent were aflatoxins) in nuts. Of the remaining categories, chemical contaminants dominate (pesticides, veterinary drugs, heavy metals and others) with microbial contamination the next most important group.

[7] Taken from the RASFF Report for 2003 available at http://europa.eu.int/comm/food/food/rapidalert/index_en.htm.

TABLE 11
Information notifications in the European Union (EU) according to categories of source of contamination – 2003

Cause of notification	Information notifications	Alert notifications	Total
Mycotoxins	770	35	805
Microbiological contamination	323	155	478
Chemical contamination (other)	225	175	400
Veterinary drug residues	293	60	353
Heavy metals	155	21	176
Pesticide residues	54	10	64
Labelling problems	39	1	40
Others	116	38	154

Source: European Union RASFF Report 2003.

TABLE 12
Residues of veterinary medicinal products – 2003

	Meat and products	Poultry and products	Fish & crustacea and products	Confectionary, honey and royal jelly	Eggs and egg products
Nitrofuran metabolites		41	50		9
Lasalocid					4
Nitrofuran metabolites and chloramphenicol	22		13		
Mainly sulphonamides				17	
Mainly nitrofuran metabolites		11	29		
Malachite green			11		
Other				5	5
Totals	22	52	103	22	18

Source: EU RASFF Report 2003.

TABLE 13
Information notifications in the European Union (EU) according to the food groups involved, 2001–2003

	2001	2002	2003	Percent average
Fish, crustacean and molluscs	232	480	545	29.3
Nuts	157	251	744	23.7
Fruit and vegetables	76	212	211	11.3
Meat and poultry	53	234	249	11.2
Other foods	105	74	162	8.9
Herbs and spices	35	30	113	3.9
Eggs and dairy	16	63	77	3.3
Animal nutrition	0	90	69	3.0
Beverages	27	28	68	2.9
Confectionery, honey and royal jelly	7	53	72	2.5
Totals	708	1515	2310	

Source: EU RASFF Report 2003.

Veterinary drug residues were a special case. Table 12 gives a breakdown of the drug or metabolites and the food associated with the contamination, and it is apparent that fish and crustacea dominate as the carrier for these contaminants.

The main culprits as regards food groups were fish, crustacea and molluscs followed by nuts. The other main food groups responsible for notifications are shown in Table 13. It is very evident that the total numbers have also been increasing over the period quite significantly and across all the food groups.

Of course, care has to be exercised in taking too much from this data, as the import volumes can vary significantly, and thus as a percentage of trade, some of these groups may increase or decrease in importance. This being said, border cases impacting on consumer safety should be considered in absolute terms, especially in relation to the severity of the hazard.

3.2.1 Imports of fish and fish products

The European Union is a huge importer of fish and fish products. This is a necessity as total community production of fish, from both capture and farmed methods, falls

way short of the demand in the member states. Over the last few years the European Union has imported around 3.5-3.8 million tonnes annually from all countries outside of the European Union. Intra European Union trade amounts to around 3 million tonnes annually.

The main exporter to the European Union is Norway with around 600 000 tonnes annually, nearly three times the next major exporter (in 2002), the United States of America. The trend for Norwegian exports, however, has been downward over the four- year period, 1999 to 2002. United States exports to the European Union on the other hand have increased over the same period, with the United States now ranked second in 2002 from 5th in 1999. China had a dramatic drop in 2002 after quite significant increases from 1999 to 2001. This was due to a ban on imports from China because of chloramphenicol contamination (European Union Decision 2002/69).

The total imports are also broken down by continent (Table 15), as this allows a later comparison with the border cases from these same regions. The most important exporting region was Europe (non EU), which accounted for some 36–40 percent of imports into the European Union. The next most important exporting regions were Africa, Asia and Central and South America.

Table 16 breaks down the imports into species groups and into main product types, again for comparative reasons when examining the border case data. The data also only cover the period from 1999 to 2001, as the FAO statistics provide this breakdown, and 2002 data were not available at the time of writing. The data also cover both extra and intra European Union trade. Annex A.19 defines the product types (prepared, processed, etc.) according to EC Directive 91/493.

The dominant species group imported was fish, followed by cephalopods, shrimp and molluscs. The main fish species imported are canned and frozen tunas, fresh and frozen salmon and ground fish (cod, Alaska pollack, hake), in a mixture of forms (frozen, chilled, salted). Pelagic species are also important (mackerel, herring, sardines).

TABLE 14
Top ten exporters to the European Union 1999–2002 (2002 basis) (tonnes)

Country	1999	2000	2001	2002
Norway	675 455	647 398	594 934	580 471
United States of America	143 058	123 735	180 958	215 723
Iceland	197 712	198 499	205 760	206 227
Russia	182 341	212 150	215 631	180 251
Argentina	208 630	164 194	192 708	177 062
Morocco	133 614	171 808	174 971	174 937
Faeroe Isles	98 545	90 816	127 923	136 849
Thailand	123 294	105 891	109 776	121 926
China	127 363	162 355	217 130	115 072
Greenland	51 497	57 052	62 662	93 564
Totals – all imports	3 457 587	3 483 458	3 811 565	3 787 655

Source: European Commission.

TABLE 15
Total European Union imports by exporting continent 1999–2002 (tonnes)

Continent	1999	2000	2001	2002
Europe (not EU)	1 389 199	1 407 948	1 399 060	1 384 995
Africa	625 754	701 361	764 677	777 015
Central and South America	606 590	561 386	634 152	638 891
Asia	548 266	569 718	677 160	634 459
N.America	218 699	195 927	268 359	288 928
Oceania	69 079	47 120	68 157	63 367
Totals	3 457 587	3 483 458	3 811 565	3 787 655

Source: European Commission.

TABLE 16
Total European Union imports by product type and species group 1999–2001 (tonnes)

	1999	2000	2001
Products of edible fish			
Frozen fish, shellfish, crustacea, cephalopods	2 951 167	2 969 863	3 362 283
Fresh fish, shellfish, crustacea, cephalopods	1 824 580	1 819 575	1 898 050
Prepared fish	822 645	897 946	1 031 924
Canned fish, shellfish, crustacea, cephalopods	896 495	983 289	977 817
Cured fish, shellfish, cephalopods	319 672	302 945	313 406
Processed fish	148 792	150 468	158 945
Live fish, shellfish, crustacea	40 084	44 289	49 374
Species groups			
Fish	4 714 032	4 772 094	5 116 132
Cephalopods	534 703	544 201	620 587
Shrimp	495 293	546 751	584 921
Molluscs	294 322	270 491	277 749
Crabs	58 549	60 724	65 699
Lobsters	69 781	65 183	65 199
Caviar	7 767	7 651	9 625

Source: FAO. Note that for some products several types, e.g. prepared and frozen, are used to categorize the product.

3.2.2 Border cases

General

From 1999-2002, the European Union recorded just under 900 border cases for fish and fish products reaching its borders. However, the distribution is skewed, with just under 50 percent of cases occurring in 2002 (Table 17). The reason for this is a dramatic increase in chemical risks that occurred in 2002. This will be discussed in more detail later. It is also possible that some non-reporting occurred during the first years as European Union member states were starting to implement the RASFF.

A detailed data set is available for the four years that allows a more detailed breakdown of the border cases. Table 17 shows the border cases by year (1999–2002), by risk and by exporting region.

The main exporting region that gave rise to border cases in the European Union was consistently Asia, varying from around 50 to 75 percent of cases each year with no trend evident. Africa and central and south America were the next main exporting regions to have problems with products imported into the European Union. There is a notable trend of decreasing relative importance for exports from Africa dropping from 34 percent of cases in 1999 to just over 11 percent in 2002. Overall, for the period from 1999–2002, Asia accounted for 66 percent, Africa for 18 percent and central and south America for 11 percent with these three regions accounting for 95 percent of border cases.

These figures do not take into account the volume of imports from these respective regions. A later section in this chapter puts the border cases into perspective, comparing the border cases with the volume of exports from each region.

For the European Union, it becomes apparent that, until 2002, the dominant cause of border cases was microbial in origin. Chemical risks though were becoming more important and by 2002, chemical risks dominated. It is worth noting that "other causes" only played a small role in the cause for border cases throughout the European Union.

Microbial risks

The microbial risks that caused most problems at European Union borders were *Vibrio* spp. and *Salmonella* accounting for around 66 percent of cases between them (Table 18). There were no significant rises or drops, except, perhaps, in the appearance

TABLE 17
Border cases in the European Union from 1999 to 2002 by risk and exporting region

	Microbial	Chemical	Other causes	Totals	Percent by year
1999					
Asia	49	19	3	71	55.9
Africa	34	9	1	44	34.6
C&S America	7	4		11	8.7
Europe			1	1	0.8
N America				0	0.0
Oceania				0	0.0
Totals	90	32	5	127	100.0
2000					
Asia	63	12	4	79	52.0
Africa	26	11	3	40	26.3
C&S America	19	5	3	27	17.8
Europe	0	3	1	4	2.6
N America	1	1		2	1.3
Oceania				0	0.0
Totals	109	32	11	152	100.0
2001					
Asia	54	49	8	111	63.8
Africa	14	10	10	34	19.5
C&S America	11	3	4	18	10.3
Europe	1	3		4	2.3
Oceania	3	1		4	2.3
N America	1	2		3	1.7
Totals	84	68	22	174	100.0
2002					
Asia	86	232	9	327	76.2
Africa	27	14	7	48	11.2
C&S America	16	20	2	38	8.9
Europe	2	12		14	3.3
N America	1	1		2	0.5
Oceania				0	0.0
Totals	132	279	18	429	100.0

Source: European Rapid Alert System.

TABLE 18
Border cases in the European Union from 1999 to 2002 – microbial risks

	1999	2000	2001	2002	Totals	Percent
Vibrio spp	32	42	39	52	165	39.8
Salmonella	31	37	19	28	115	27.7
Enterobacteria	17	6	2	16	41	9.9
Total counts		15	9	15	39	9.4
Parasites	1		13	14	28	6.7
Staphylococcus	7	2	1	2	12	2.9
E coli	1	2	1	5	9	2.2
Other	1	5			6	1.4
	90	109	84	132		

Source: European Rapid Alert System.

of parasites as a cause in 2001 and 2002. However, it is interesting to note the complete absence of *Listeria* spp. as a cause for border cases. This is probably because the EC and several European Union countries, are not supportive of zero tolerance stance, do not have specific control programmes for *Listeria monocytogenes*.

It is important to note that the only harmonized microbial criteria in the European Union so far are for cooked crustaceans and molluscs and live bivalve molluscs, as noted in the previous chapter (see Annex A.4). For all other fish and fish products, the individual member states use their own criteria for the common indicator and specific bacteria, with France and Spain having the most detailed requirements for various

products, but quite different in terms of the product groupings, and the criteria used (Eurofish, 1998). This causes a confusing picture for exporters who may be exporting to different countries within the European Union. This has been recognized by the EC which has initiated efforts to harmonize the microbial standards of fish products. These interim draft standards and guidelines are presented in Annex A.4. However, these efforts need to be expanded using scientifically based risk assessment for the products in question.

Vibrios provide an interesting case in this respect. Although the EC has no harmonized criteria for *Vibrios* yet, they are clearly being tested for on a regular basis. In examining the data, it is evident that mainly two members (Italy and Norway) of the Rapid Alert System are responsible for 75 percent of the *Vibrio* notifications from 1999–2002, with 75 percent of cases due to frozen shrimp. Indeed, the major shrimp import markets of the UK and Germany did not notify at all during this same period. This shows major differences within the European Union towards the testing of *Vibrios* and presents a confusing picture for exporters. The data does not allow determination of the criteria used for the notifications, so care must be taken in drawing conclusions as regards testing criteria used. However, products are being removed from trade based on *Vibrio* counts at some level. This contrasts with recommendations from the "EC Expert Opinion on *V. parahaemolyticus* and *V. vulnificus* in raw and undercooked seafood" (EC, European Commission 2001) which states the following:

- "The practice of judging seafood exclusively based on total *Vibrio* counts as indicative for the presence of pathogenic vibrios is not appropriate and should be discontinued.
- The practice of judging seafood exclusively based on total *V. parahaemolyticus* counts without consideration of the virulence factors TDH/TRH (or *tdh/trh*) is not appropriate and should be discontinued.
- Currently available scientific data do not support setting specific standards or microbiological criteria for pathogenic *V. parahaemolyticus* and *V. vulnificus* in seafood. Codes of practice should be established to ensure that GHP has been applied."

This question is elaborated upon further in this chapter (section 3.6.7).

Chemical risks

As regards the chemical cases, some notable trends appear (Table 19). Prior to 2001, the main risks were from heavy metals, with mercury and cadmium accounting for nearly 70 percent of border cases in 1999 and 2000. However, in 2001 and 2002, two new chemical agents, chloramphenicol and nitrofuran, appeared dramatically in border cases. In 2001 and 2002, these two chemicals accounted for over 65 percent of the border cases, with the heavy metals now accounting for only 14 percent of cases.

This increase in these two veterinary drugs is due to rigorous testing regimes imposed in 2001 and 2002 on shrimp (and other food) imports from various south-east Asian countries by the European Union. China was most affected as Commission Decision 2002/69 suspended the import into the European Union of Chinese products of animal origin intended for human consumption or for use in animal feed. The main products affected by the suspension in volume terms were honey, rabbit meat, poultry and crustaceans such as shrimps and prawns. During this period, Viet Nam, Thailand and Pakistan were also requested to submit each seafood shipment for analysis for chloramphenicol and nitrofurans.

Later in 2002, the European Union decided to lift the import restrictions due to guarantees by exporting authorities and the results of further tests. It is worth noting that similar stringent testing regimes were imposed by other importers, such as the United States of America, Canada and Japan. However, a significant difference was the lower limit of detection of the analytical method used, which was very low for the European Union and Canada (less than 1 part per billion (ppb)) as compared to 5 ppb

TABLE 19
Border cases in the European Union from 1999 to 2002 – chemical risks

	1999	2000	2001	2002	Totals	Percent
Chloramphenicol			44	102	146	35.3
Nitrofuran				89	89	21.5
Mercury	14	11	11	19	55	13.3
Cadmium	12	7	5	12	36	8.7
Bacterial inhibitors				21	21	5.1
Histamine	4	8	1	3	16	3.9
Polyaromatic Hydrocarbons			3	11	14	3.4
Residues	1	1		9	11	2.7
Sulphite		2		7	9	2.2
Diarrhetic Shellfish Poison		2	4	2	8	1.9
BADGE *	1	1	1		3	0.7
Lead				3	3	0.7
Carbon Monoxide		1			1	0.2
Malachite green				1	1	0.2
Phenol	1				1	0.2
	33	33	69	279	414	

* Biphenol A diglycidyl ether - a component in plastics manufacture.
Source: European Rapid Alert System.

level for the United States of America. Later, the United States detection limits were lowered to be more in line with the European Union and Canadian limits.

Other causes

Other causes of border cases in the European Union only averaged at around 6 percent of incidents over the period studied, although the percentage varied between 4 and 12 percent year on year. Of the other causes for border cases, the main problem, and pretty consistently each year, was with the certificates that accompany imports, accounting for just over half of the cases (Table 20). From the data it is not possible to discover which certificates are involved in these incidents. It is likely that the problems centre on the health certificate. This is an absolute requirement and is prescribed by the European Union for all fish and fish product imports and the certificate is generally known to be examined in some detail. Given that these certificate problems only account for around 2–3 percent of all border cases, this is not a big concern for developing countries, and is one that is easily remedied should it become an issue for a particular country.

The other two types of problems were sensory tests revealing quality problems or with a temperature abuse of the imported product, for instance a thawed frozen product or a problem in the time-temperature history.

Border cases by product and species

Table 21 breaks down the border cases by product type and species group for the period 1999–2002. The predominant forms of product causing border cases are frozen and prepared products. It is interesting that for the European Union, canned and processed fish does not constitute a major problem for European Union importers, and the fresh and cured fish accounts for only around 5 percent of border cases during the four-year period and that caviar accounts for 2 percent.

The main problem species group is shrimp, not surprisingly given that they were the species responsible for the chloramphenicol and nitrofuran border cases that dominated in 2001 and 2002. Fish and cephalopod come in second and third. Other groups (crab, lobster and bivalves) account for only 7 percent of border cases. However, it will be interesting to note the relative frequency when trade volumes are considered in the next section.

A final analysis that is possible with the data collected for the European Union is to determine the causes for border cases according to the species or products imported (Table 22). Not surprisingly, histamine is restricted to fish species, and is mostly found

TABLE 20
Border cases in the European Union from 1999 to 2002 – other causes

	1999	2000	2001	2002	Totals	Percent
Certificate problems	3	6	12	8	29	54.8
Sensory		1	2	7	10	18.9
Species Identification			3	1	4	7.5
Temperature problems	1	1	2		4	7.5
Use not allowed		2			2	3.8
Package damage			1	1	2	3.8
Moisture			1		1	1.9
Insects				1	1	1.9
	5	11	22	18	56	100.0

Source: European Rapid Alert System.

TABLE 21
Border cases in the European Union from 1999 to 2002 – product types and species groups

	1999	2000	2001	2002	Totals	Percent
Product types						
Frozen	79	71	107	211	468	56.3
Prepared	41	32	26	97	196	23.6
Processed	3	12	15	54	84	10.1
Canned	13	14	5	11	43	5.2
Fresh	3	9	8	20	40	4.8
Caviar	1	0	0	0	1	0.1
Cured	0	0	0	0	0	0
Species groups						
Shrimp	39	47	76	243	405	46.6
Fish	60	59	57	125	301	34.6
Cephalopod	23	20	20	34	97	11.2
Bivalve	4	15	15	17	51	5.9
Crab	1	2	3	7	13	1.5
Lobster	0	1	0	1	2	0.2

Note that for some products several types e.g. prepared and frozen, are used to categorize the product and for some none are used.
Source: European Rapid Alert System.

TABLE 22
Combined border cases in the European Union from 1999 to 2002 – by cause and product type/ species

	Microbial	Chemical	Histamine	Other causes	Totals	Percent
Frozen	268	181	1	18	468	56
Prepared	96	90	3	7	196	24
Processed	29	46	0	9	84	10
Fresh	19	9	4	8	40	5
Canned	6	21	10	6	43	5
Cured	0	0	0	0	0	0
Caviar	1	0	0	0	1	0
Shrimp	167	229	0	9	405	47
Fish	147	104	15	35	301	35
Cephalopod	64	28	0	5	97	11
Bivalve	27	19	0	5	51	6
Crab	5	8	0	0	13	1
Lobster	1	1	0	0	2	0

Note that for some products several types e.g. prepared and frozen, are used to categorize the product and for some none are used.

Source: European Rapid Alert System.

in canned fish imported into the European Union. Shrimp border cases are split fairly equally between microbial and chemical causes, but, as discussed earlier, veterinary drugs account for a huge rise in border cases in 2001 and 2002, and if viewed by year, the dominant cause in 1999–2000 is microbial and chemical for 2001–02. Fish species also account for the bulk of the "other causes" detailed earlier in this section.

3.2.3 Border cases in the European Union in the context of import volume

Comparative studies of border cases between exporting and importing regions, or between risk categories and products types, etc. require the use of a figure that allows a relative comparison. Thus, we have used the volumes of trade in tonnes to provide a comparative figure and have expressed the data as the number of border cases per unit volume to indicate the relative importance of various factors in border cases.

We can compare the border cases arising from exporting regions for the four-year period, 1999–2002. For border cases arising from problems associated with products or species, comparisons were restricted to the years 1999–2001 because of data availability. Table 23 breaks down the border cases per 100 000 tonnes from various exporting regions.

The picture changes little from earlier indications of absolute numbers of border cases. Asia still tops the list with consistently over twice as many cases per unit volume as the next nearest regions (Africa and central and south America) from 1999 to 2001, and in 2002, following the dramatic increase in shrimp border cases, the figure jumps threefold to 52 cases per 100 000 tonnes of imports. Good performers are non-European Union Europe, North America and Oceania.

It is interesting to note that non-European Union Europe, the region that exports the most product to the European Union, has also the least border cases/trade volume, possibly because of the efficiency of their fish control systems. Indeed, these countries are renowned for their food control and surveillance systems. Another possibility can be linked to the fact that those exporting countries that trade the largest volumes are likely to have larger consignments, thus the number of border cases per unit volume would be lower, but absolute *volumes* of border cases (in kg of rejected product, for instance) per unit volume of import may be comparable.

A useful figure to note is the total number of border cases per unit volume (100 000 tonnes) arising in the European Union from all imports each year. This figure can be compared to other regions later in the analysis section. From 1999 to 2002, the figure ranges from 4-11 border cases/100 000 tonnes imports, with the higher figure appearing in 2002. This is due to the increase in the absolute number of border cases for 2002, as import volumes have remained essentially static.

As regards products and species, a different situation arises where the higher absolute numbers of border cases for a product category or species are no longer the main problem relative to the amount of trade in those species/products (Table 24), though the changes are not dramatic. Frozen products do now become a lesser problem, with processed products becoming more predominant in the relative importance of border cases in 2000 and 2001. Prepared products also generate a significant level of cases.

The high levels of caviar cases per unit volume of trade for 1999 is notable, but with the very low amounts traded, a single case dramatically inflates the figure. In 2000 and 2001, there were no border cases and hence a zero figure for these years. Again, cured and fresh products prove to be low risk products. For the European Union, canned products also pose very few problems.

Likewise for species trends. Fish are no longer the main problem, with shrimp dominating the tables each year, and becoming more pronounced in 2002. The reasons for this have already been discussed. Bivalves, crab and cephalopods also give rise to varying levels of border cases throughout the three-year period. The reasons for bivalve cases are mainly microbial (ten cases – elevated total counts, hepatitis virus, *E. coli* and *Staphylococcus* spp.) with two cases each of diarrheic shellfish poisoning (DSP) and cadmium.

Given that a significant amount of bivalves are eaten raw, controls are likely to be more stringent, given a higher risk factor in eating raw products. Indeed, Huss, Ababouch and Gram (2004) ranked the risk associated with seafoods by product type and identified raw or live molluscan shellfish, amongst others, as a high risk product. This is why the European Union (and other countries') legislation imposes

TABLE 23
Border cases in European Union per unit volume of imports, 1999–2002 – by continent

	1999			2000			2001			2002		
	tonnes	cases	cases/ 100 000 tonnes	tonnes	cases	cases/ 100 000 tonnes	tonnes	cases	cases/ 100 000 tonnes	tonnes	cases	cases/ 100 000 tonnes
Asia	548 266	71	13	569 718	79	14	677 160	111	16	634 459	327	52
Africa	625 754	44	7	701 361	40	6	764 677	34	4	777 015	48	6
C&S America	606 590	11	2	561 386	27	5	634 152	18	3	638 891	38	6
Europe (not EU)	1 389 199	1	0	1 407 948	4	0	1 399 060	4	0	1 384 995	14	1
N America	218 699	-	-	195 927	2	1	268 359	3	1	288 928	2	1
Oceania	69 079	-	-	47 120	-	-	68 157	4	6	63 367	-	-
	3 457 587	127	4	3 483 458	152	4	3 811 565	174	5	3 787 655	429	11

Source: European Rapid Alert System.

TABLE 24
Border cases in the European Union per unit volume of imports, 1999–2001 – by product types and species groups

	1999			2000			2001		
	tonnes	cases	cases/ 100 000 tonnes	tonnes	cases	cases/ 100 000 tonnes	tonnes	cases	cases/ 100 000 tonnes
Processed	148 792	3	2	150 468	12	8	158 945	15	9
Prepared	822 645	41	5	897 946	32	4	1 031 924	26	3
Frozen	2 951 167	79	3	2 969 863	71	2	3 362 283	107	3
Canned	896 495	13	1	983 289	14	1	977 817	5	1
Fresh	1 824 580	3	0	1 819 575	9	0	1 898 050	8	0
Live	40 084		-	44 289		-	49 374		-
Cured	319 672	-	-	302 945	-	-	313 406	-	-
Caviar	7 767	1	13	7 651	-	-	9 625	-	-
Shrimp	495 293	39	8	546 751	47	9	584 921	76	13
Bivalves	294 322	4	1	270 491	15	6	277 749	15	5
Crab	58 549	1	2	60 724	2	3	65 699	3	5
Cephalopod	534 703	23	4	544 201	20	4	620 587	20	3
Fish	4 714 032	60	1	4 772 094	59	1	5 116 132	57	1
Lobster	69 781	-	-	65 183	1	2	65 199	-	-

Note that for some products several types e.g. prepared and frozen, are used to categorize the product and for some none are used.
Source: European Rapid Alert System.

a requirement for monitoring programmes of microbial and biotoxins contamination of the harvesting areas of bivalves and well defined conditions for processing and distribution, including traceability. Thus, the number of countries authorized to export are limited, and any exports from these approved areas should be carefully tested for biotoxins and bacterial counts.

Salmonella spp. and *Vibrio* spp. dominate the cases for cephalopod species and various microbes for the limited number of crab cases.

3.3 UNITED STATES OF AMERICA

3.3.1 Imports

The United States America is the second largest importing country in the world for fish and fish products, importing a huge variety of seafood from across the globe. Its main trading partners for imports are Canada, China and Thailand (Table 25). In fact the bulk of the top ten exporters are Asian or American (South and North). It is interesting to note the emergence of China and Viet Nam as important exporters, and increasing exports from all other countries over the period, with the exception of Thailand (fairly static) and Mexico (decreasing). The increasing Chinese imports is doubly interesting as it contrasts with the dramatic fall off of Chinese exports to the European Union in 2001 and 2002 due to the chloramphenicol problem (see previous section).

TABLE 25
Top ten exporters to the United States 1999–2002 (2002 basis) – tonnes

Country	1999	2000	2001	2002
Canada	304 490	311 062	331 191	353 565
China	148 422	180 078	186 929	259 017
Thailand	256 431	258 304	249 962	247 511
Chile	76 415	98 314	117 855	135 512
Ecuador	100 423	77 637	80 290	100 428
Viet Nam			62 251	85 745
India	38 001	45 072	46 049	57 654
Mexico	66 981	63 047	54 770	47 410
New Zealand	35 915	32 817	31 931	41 916
Brazil	13 288	18 065	23 446	34 549

Source: US Government statistics.

TABLE 26
Total USA imports by exporting continent 1999–2002 (tonnes)

Continent	1999	2000	2001	2002
Asia	783 222	813 939	851 866	927 990
N.America	458 722	466 664	484 642	495 839
S.America	273 142	284 481	308 998	352 724
Europe Non EU	133 998	113 001	85 768	91 420
Oceania	57 607	68 965	76 633	89 251
European Union (15 countries)	35 593	29 957	28 589	29 654
Africa	21 252	27 510	24 156	21 258
	1 763 536	1 804 517	1 860 652	2 008 136

Source: US Government statistics.

The total imports are also broken down by continent (Table 26), which also shows a steady increase in total imports over the four-year period reaching 2 million tonnes in 2002. The most important exporting region was Asia, with almost double the amount imported from the next most important source, its neighbouring countries in North America. In 2002, Asian exports accounted for 46 percent of United States imports of fish and fish products. The next most important exporting regions were South America, Europe and Oceania. It is interesting to note that within Europe, the European Union (fifteen countries) only provided around a quarter of total European exports to the United States.

Table 27 breaks down the imports into species groups and into main product types, again for comparative reasons when examining the border case data.

The dominant species group imported was fish in a variety of forms, followed by shrimp and other crustacea. Similarly, the dominant form was as frozen/fresh accounting for over 80 percent of imports on average over the four-year period. The next most important product group was canned with around 14 percent of all imports on average.

3.3.2 Border cases

Available published information and/or officially disclosed data by FDA indicates that FDA seafood detentions averaged 3 559 per year during 1991–92. During the period January through October 1999 the FDA has issued 3 904 "*Notices of Detention and Hearing*" for fishery/seafood products. The number of notices issued ranged from a low of 171 in January 1999 to a high of 506 in June in 1999, with a numerical average slightly exceeding 390 detentions notices per month.

In this study, data were available for July 2001 to July 2003 and in order to determine any trends (though it is recognized this is limited data sets), we are breaking down the period to split year periods. During the period July 2001 to June 2002 seafood import

TABLE 27
Total USA imports by product type and species group 1999–2002 (tonnes)

Species	Product	1999	2000	2001	2002
Whole/gutted fish	Fresh/frozen	502 003	482 117	472 681	465 873
Shrimp	Fresh/frozen	330 371	343 418	398 398	427 454
Fish fillets and steaks	Fresh/frozen	296 789	333 263	360 848	418 462
Canned fish & shellfish	Canned	247 870	252 332	244 610	286 815
Other fish & shellfish	Fresh/frozen	163 073	172 602	192 625	205 267
Fish blocks and slabs	Fresh/frozen	97 229	92 490	66 534	66 692
Lobster	Fresh/frozen	36 771	42 918	41 600	45 304
Cured fish & shellfish	Cured	30 137	31 250	32 507	34 918
Scallop	Fresh/frozen	19 994	24 335	18 006	21 866
Other fish & shellfish		16 744	14 252	14 216	16 794
Crabmeat	Fresh/frozen	7 963	9 648	12 914	10 316
Surimi	Fresh/frozen	9 786	786	745	3 559
Caviar	Cured	2 483	2 603	2 338	2 412
Prepared meals	Prepared	2 323	2 505	2 630	2 404
		1 763 536	1 804 519	1 860 652	2 008 136

Source: US Government statistics.

detentions reduced to 1 158 per year showing an impressive decrease. However, the latest data disclosed by FDA show a new marked annual increase to 2 415 for July 2002 to June 2003.

Caution should be taken when using IRR (Import Refusal Report) data to compare annual figures of product/country quality and safety levels. IRR provide only a rough indication of product/country quality and safety levels because: (1) with the exception of products on Automatic Detention, the FDA randomly selects which shipments to examine and (2) the agency may focus on testing for certain hazards and not others.

Table 28 shows a summary of import border cases extracted from published FDA data. On average seafood accounts for around 10–11 percent of all food border cases.

A direct comparison between the two one-year periods is shown in Table 29. The main causes of border cases in the United States of America were from other causes (mainly filthy), accounting for around 72 percent of all cases (33.1 percent for filthy). Microbiological (approx. 23 percent) and chemical (approx. 5 percent) agents were of less importance.

The FDA has only five categories that specify microbial causes for a refusal - *Salmonella*, *Listeria*, *Shigella*, Hepatitis A and the general term Bacteria. Of interest are the substantial increases in *Salmonella* incidents. *Salmonella* increases seem to be related to particular control attention dedicated to some products from Asia during the months of October 2002 and April 2003.

The increase by almost five that occurred in the poison category reflected the FDA decision to introduce additional controls, e.g. analyses for chemical (polycyclic aromatic hydrocarbons, sulphites) and veterinary drug (chloramphenicol and nitrofurans) residues. The main problem was shrimp from Asian countries, especially China. It should be noted that the FDA detection limits for the veterinary drug residues were set at higher limits (5 ppb) than the European Union and Canada (1 ppb). Later, the United States detection limits were lowered to be more in line with the European Union and Canadian limits.

The category "other" covers a large number of different reasons such as mislabelling and lack of description of the process. The United States has over 170 descriptors for the classification of the cause for a border case for all foods. Many of them reflect possible microbial or chemical problems but are not specified as such. The dramatic inflation in numbers appears to be the result of inspection for compliance with requirements

TABLE 28
Seafood import refusals by US FDA from July 2001 to June 2003 (FDA 2002)

Border Cases			No. of seafood products refused according to:					
Year	Month	Number	Filth	*Salmonella*	Listeria	Histamine	Poison	Other
2001	Jul	122*	74	20	5	2	4	21
	Aug	146	79	40	3	3	4	25
	Sep	59	27	14	7	0	2	11
	Oct	136	59	50	2	3	4	26
	Nov	121	51	39	4	0	1	26
	Dec	83	57	18	2	2	5	7
2002	Jan	177	84	71	2	6	1	42
	Feb	184	84	35	12	4	0	64
	Mar	213	90	38	8	4	4	73
	Apr	126	60	20	0	0	5	43
	May	174	72	41	1	1	5	64
	Jun	143	80	41	3	2	2	34
	Jul	136	87	53	1	12	3	126
	Aug	121	66	27	1	3	6	74
	Sep	115	58	39	5	3	2	50
	Oct	260	72	108	1	3	17	103
	Nov	125	71	15	5	2	8	57
	Dec	153	58	30	2	0	16	82
2003	Jan	298	77	42	11	7	14	197
	Feb	194	55	27	4	0	20	143
	Mar	210	61	37	11	1	18	145
	Apr	320	54	119	4	0	11	200
	May	281	88	76	7	2	19	181
	Jun	202	79	57	3	4	10	115

* Note that for some products several reasons, e.g. both "filthy" and "Salmonella", are given as reasons for rejection but computed as one border case only. This explains why number of border cases is not the total of causes presented horizontally.
Source: US FDA Office of Regulatory Affairs.

TABLE 29
Annual evolution of seafood imports' detentions

	June 2001/June 2002		June 2001/June 2002		2 year total	
	Numbers	percent	Numbers	percent	Numbers	percent
Microbiological	**476**	**26.5**	**685**	**21.6**	**1161**	**23.4**
Salmonella	427	23.8	630	19.9	1057	21.3
Listeria	49	2.7	55	1.7	104	2.1
Chemical	**64**	**3.6**	**181**	**5.7**	**245**	**4.9**
Poison	37	2.1	144	4.5	181	3.7
Histamine	27	1.5	37	1.2	64	1.3
Other causes	**1253**	**69.9**	**2299**	**72.6**	**3552**	**71.6**
Others	436	24.3	1473	46.5	1909	38.5
Filthy	817	45.6	826	26.1	1643	33.1
Totals	1793		3165		4958	100.0

Source: US FDA Office of Regulatory Affairs.

such as the HACCP legislation and the labelling of catfish. However, the descriptor "insanitary"[8] was responsible for the bulk of the increase.

3.3.3 Filthy as a reason for seafood detention

Based on FDA official Seafood Import Refusals statistics "filthy" is the most common reason for seafood import refusal in the USA. According to the FDA Violation Code

[8] Defined as "The article appears to have been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health".

Translation (last revision dated of 17 March 1999) "filthy" is defined as a condition when ("sic") *The article appears to consist in whole or in part of a filthy, putrid, or decomposed substance or be otherwise unfit for food*." Although details are not given for the individual products, Huss, Ababouch and Gram (2004) assumed that microbial spoilage is the major reason for this type of refusal. However, previous FDA data clearly indicate that "filthy" was mainly related to product contamination by insect and/or insect parts (Annex A.20).

In the case of developing countries, pre-processing operations, when carried outside the plants under rather poor technical, hygienic and sanitary conditions, can be the main cause for contamination by insect, rodents and other animals. This includes shrimp grading, heading and peeling; cephalopods (squid) grading and cleaning; crab meat picking; shellfish (mussels, clams) shucking, are carried out in sandy beaches, in the ground floor of fish landing places, fish farms, sheds or family homes.

Despite dramatic improvements in a number of countries, sufficient effort is still needed to educate workers in basic principles of personal hygiene. Education and training is very difficult to achieve in countries where the labour force does not remain for a significant period of time in a single plant, for instance, the case of the utilization of daily-paid or piece-work personnel.

There is no doubt that during the last 5 to 10 years the situation has improved significantly and more and more industries have well established and efficient quality control systems based on HACCP principles.

3.3.4 Border cases in the United States in the context of import volume

Unfortunately, we have been unable to make this comparison for exporting area or species or products, as the data sets used were already partly consolidated – there was no line by line data that would allow geographic areas and fish species and products for each border case to be identified. Macrolevel analysis, i.e. no of cases per unit volume, for all border cases is presented in the next section (Analysis) for comparative purposes between countries.

3.4 JAPAN

3.4.1 Imports of fish and fish products

Japan depends heavily on imports to satisfy the nation's high fish consumption requirements. Total fish imports have been around 3 million tonnes annually (Table 30). China was the key exporter of fish and fishery products to Japan, with increasing amounts exported over the 1999–2002 period. Other major exporters are the United States, Thailand, Norway and the Russian Federation. It is interesting to note the increasing importance of Thailand and Chile, while other countries have been decreasing in importance – the Russian Federation, the Republic of Korea and Norway.

Total imports are also broken down by continent (Table 31), as this allows a later comparison with the border cases from these same regions. Not surprisingly, the major continent exporting to Japan is Asia, which dominates the imports accounting for 47 percent of all fish imports in 1999 to 54 percent in 2002. Europe and the United States are the next most important exporting regions, though Europe is becoming less important. Central and South America is becoming a more important source of fish for Japan, though Chile accounts for over half of the exports from this continent.

Table 32 breaks down imports by species groups and product categories for the period 1999–2001 for which data were available at the time of the study. Fish species dominate imports, accounting for around two-thirds of imports. The main fish species imported are frozen Alaska pollack mince blocks, tunas (frozen, fresh and canned), salmon (fresh and frozen) and pelagic species (mackerels, herring, sardines) and canned eels. Frozen shrimp accounted for around 10 per cent of the total imports. The dominant molluscan

TABLE 30
Top ten exporters to Japan 1999–2002 (tonnes)

Country	1999	2000	2001	2002
China	468 871	529 374	627 287	630 412
USA	338 272	337 911	362 042	355 856
Thailand	207 236	219 926	238 634	255 925
Norway	288 772	277 074	280 321	251 250
Russian Federation	217 148	219 281	199 865	188 822
Chile	111 383	133 298	185 623	174 529
Republic of Korea	170 756	184 890	161 763	156 520
Indonesia	115 239	110 388	122 367	127 493
Viet Nam	65 308	68 731	75 192	87 440
Canada	67 209	60 192	52 460	65 489
Totals	2 925 229	3 042 764	3 122 056	3 126 515

Source: FAO.

TABLE 31
Total Japanese imports by exporting continent 1999–2002 (tonnes)

Continent	1999	2000	2001	2002
Asia	1 390 114	1 504 662	1 594 344	1 666 305
Europe	682 344	658 925	642 016	584 476
North America	405 587	398 104	414 631	421 346
Central and South America	209 646	226 902	259 991	260 988
Oceania	109 146	110 223	103 821	104 511
Africa	128 389	143 946	107 253	88 889
Totals	2 925 229	3 042 764	3 122 055	3 126 515

Source: FAO.

TABLE 32
Total Japanese imports by product type and species group 1999–2001 (tonnes)

	1999	2000	2001
Products of edible fish			
Fresh fish, shellfish, crustacea, cephalopods	1 466 090	1 517 896	1 656 425
Frozen fish, shellfish, crustacea, cephalopods	556 246	573 915	509 949
Cured fish, shellfish, cephalopods	399 249	422 382	404 641
Live fish, shellfish, crustacea	278 870	283 628	287 119
Canned fish, shellfish, crustacea, cephalopods	210 771	231 315	205 964
Processed fish	2 101	1 736	428
Species groups			
Fish	1 946 420	2 044 469	2 180 078
Shrimp	280 971	285 364	287 547
Cephalopods	225 814	242 440	198 668
Molluscs	222 355	222 407	177 556
Crabs	135 202	136 784	120 775
Caviar	90 843	86 378	89 387
Lobsters	11 722	13 030	10 515

Note that for some products several types e.g. prepared and frozen, are used to categorize the product.
Source: FAO.

import was fresh clams, accounting for over 50 percent of imports. The remaining molluscs spanned the most common commercial species (abalone, mussels, oysters, scallops). Squid, cuttlefish and octopus also form an important group in fish imports.

3.4.2 Import notifications for foods including marine products

The MHLW provides information on its website about importation of all foods which is broken down into the number of cases imported (each consignment must be notified to the authorities), the inspection frequency and number of rejections. The data on the Web is only available for 2000.

TABLE 33
Import notifications, inspections/rejections of food items – 2000

Category of food	Notification (No of cases)	Import inspection (No of cases)	Rejection (No of cases)
Live stock products	211 446	7 228 (3.4 percent)	21 (0.29 percent)
Processed live stock products	130 869	6 579 (5 percent)	69 (1.04 percent)
Marine products	230 490	17 762 (7.7 percent)	69 (0.38 percent)
Processed marine products	135 011	19 594 (14.5 percent)	146 (0.77 percent)
Agri products	201 267	18 102 (9 percent)	298 (1.65 percent)
Processed Agri products	221 967	16 317 (7.35 percent)	157 (0.96 percent)
Other foods	114 224	12 094 (10.6 percent)	155 (1.28 percent)
Total	1 131 050	85 582 (7.6 percent)	915 (1.06 percent)

Source: MHLW, Tokyo.

TABLE 34
Import notifications by exporting continent for all foods – 2000

Continent	Notification (No of cases)	Percent
Asia	490 536	43.4
Europe	293 960	26.0
North America	227 793	20.1
Others	118 761	10.5
Totals	1 131 050	100.0

Source: MHLW, Tokyo.

A total of 1 131 050 cases of import notifications[9] were submitted (Table 33) for a total of over 29 million tonnes of food and related products. Among the notified cargoes, an average of just over 7 percent were subject to inspection. Marine products (including processed products) were inspected at a higher frequency of 10.2 percent. In 2000, the number of notifications had increased by 10.5 percent (3.8 percent by weight) compared to the previous year.

Among all cargoes that went through inspection just over 1 percent were reshipped or disposed of after being rejected due to non-compliance with the Food Sanitation Law (Table 33). However, this reduced to 0.5 percent for marine products (including processed products), indicating a higher standard of imported fish and fish products as against other imported foods, despite a higher inspection rate.

When the numbers of import notifications in 2000 were analysed according to the region of export, Asia accounted for the largest number with cases (Table 34), not too surprising given the dominance of Asian countries in the import volumes (Table 31). The next largest exporting regions were Europe and North America. These three regions accounted for nearly 90 percent of all import notifications by number. Given the dominance of Asian countries in term of volumes, the number of notification cases (a single shipment) is low when compared to the other continents whose volumes are significantly smaller. This may infer that there is a better control at source before shipping due possibly to good understanding of the Japanese requirements by Asian exporters and/or to in plant advice from importers who visit regularly the exporting companies. It may also infer that the shipments from Asia are significantly larger. If so, any rejections may have larger economic repercussions on the exporters. However, this is a supposition that cannot be confirmed from the available data.

3.4.3 Border cases for seafoods

We have also obtained more detailed data from the MHLW specific for seafood imports. This information is not available on the Web. From the data on border cases, we can

[9] An import notification alerts the authorities to the arrival of an import.

break down the incidents to the reason, exporting region and to the product type/ species. For this data we have access to two periods, as mentioned in Section 3.1.1.

With respect to marine products and processed marine products, the border cases were based on the following non compliance of the regulations:

(a) Decomposed, hazardous or poisonous (Article 4)
(b) Products without a complete sanitation/health certificate (Article 5)
(c) Products with undesignated additives used (Article 6)
(d) Food or additives that do not meet specifications and standards (Article 7)
(e) Apparatus or containers/package that do not meet specifications and standards (Article 10)

Table 35 breaks down border cases by exporting region. By far and away the largest number of border cases came from Asia, not surprisingly, as this region is the largest exporter to Japan. Border cases from all other continents accounted for only around 7-9 percent of all cases. Contrast this with the total number of notifications of imports above (Table 34) for all foods, where Asia accounted for only 43 percent of import notifications. There will be further discussion of this in the next section.

Also of note is the almost doubling of border cases over the two periods. This has been attributed to increased inspections and stricter controls (Infofish, pers.comm.), no doubt in response to significant food safety events in Japan during the period studied with subsequent media and consumer pressure.

Table 36 breaks down the border cases by the major risk category for comparative reasons with earlier data. In Japan, microbial risks predominate with chemical risks also being significant. Ninety-seven percent of all risks are accounted for by these two categories. This is a similar profile to that of the European Union, where these two categories also dominated. However, the main risk category remained microbial in origin for both periods, whereas in the EU, chemical causes became dominant in 2002 due to the rapid appearance of veterinary drugs as an issue in imports.

Table 37 details the reasons for the border cases during 2000/2001 and 2001/2002. All microbial incidents are accounted for by one of three categories during the year with coliforms accounting for around half of microbial cases. It is apparent that all the microbial cases in Japan arise from tests for indicator organisms or indicative tests (high counts). Specific pathogenic bacteria do not account for any border cases, for instance, *Listeria* spp., *Staphylococcus*, *Vibrio* spp. etc. This will be further discussed in the analysis section at the end of this chapter.

The chemical risks are also a significant factor in border cases. The variety of risks identified under this category is numerous. Table 38 expands on the chemical groupings shown in Table 37. Over 80 percent of border cases due to chemical risk result from contamination with antioxidants, preservatives or biotoxins.

The bulk of the latter group come from ciguatera poisoning from various groupers, red snapper and carpet cod. This group are distinctive in that they are not additives,

TABLE 35
Rejections of seafood Imports in Japan by exporting continent – 2000/2001 and 2001/2002

Exporting continent	Number of border cases		As a percentage of total	
	Average 12 month period in Apr 2000–Oct 2001	Nov 2001–Oct 2002	Average 12 month period in Apr 2000–Oct 2001	Nov 2001–Oct 2002
Asia	106	208	91	93
Oceania	4	6	4	3
Central and South America	2	4	2	2
North America	2	2	2	1
Europe	2	2	1	1
Africa	0	1	0	0
	116	223	100	100

Source: Compiled by INFOFISH based on data from MHLW, Tokyo.

TABLE 36
Border cases in Japan by risk category – 2000/2001 and 2001/2002

Category	Number of border cases		As a percentage of total	
	Average 12 month period in Apr 2000–Oct 2001	Nov 2001–Oct 2002	Average 12 month period in Apr 2000_ Oct 2001	Nov 2001–Oct 2002
Bacterial	63	143	54	64
Chemical	50	76	43	34
Others	3	4	3	2
	116	223	100	100

Source: Compiled by INFOFISH based on data from MHLW, Tokyo.

TABLE 37
Breakdown of reasons for border cases in Japan – 2000/2001 and 2001/2002

Category		Number of border cases		As a percentage of total	
		Average 12 month period in Apr 2000–Oct 2001	Nov 2001–Oct 2002	Average 12 month period in Apr 2000–Oct 2001	Nov 2001–Oct 2002
Bacterial	Coliforms	33	69	28	31
	High count/live bacteria	26	43	22	19
	E. coli	4	31	3	14
Chemical	Antioxidants	13	40	11	18
	Preservatives	12	4	10	2
	Colourings	4	7	3	3
	Bleaching agents	1	1	1	0
	Biotoxins	17	14	15	6
	Antibiotics	3	10	3	4
Other causes	Violation of storage/ preparation	2	4	2	2
	Spoilage	1	-	1	-
		116	223	100	100

Source: Compiled by INFOFISH based on data from MHLW, Tokyo.

TABLE 38
Border cases in Japan – chemical risks – 2000/2001 and 2001/2002

Chemical		Number of cases	
		Average 12 month period in Apr 2000-Oct 2001	Nov 2001-Oct 2002
(a) Antioxidants			
	Sulphur dioxide (> 0.03 g/kg)	14	11
	Carbon monoxide	3	6
	TBHQ	2	1
	EDTA (>0.25g/kg)	1	0
(b) Preservatives			
	Sorbic acid (>1.0g/kg)	9	11
	Benzoic acid	5	9
	Nitrite residue (0.005g/kg)	3	2
	Hexamethylene Tetra Amine	1	0
	Sodium iodide	1	0
	Boric acid	0	1
	Polyphosphate	0	1
	Undisclosed/unregulated	0	4
(c) Colourings			
	Orange II	1	0
	Yellow No 4	3	2
	Yellow No 5	2	2
	Red 40	0	1
(d) Bleaching agents			
	Hydrogen peroxide	2	1
(e) Biotoxins			
	Ciguatoxin	24	10
	Diarrhetic shellfish poison	2	0
	Paralytic shellfish poison	1	3
	Histamine	0	1
(f) Antibiotics			
	Oxytetracyline	5	10
Total		79	76

Source: Compiled by INFOFISH based on data from MHLW, Tokyo.

TABLE 39
Japanese imports - categories of fish products rejected – 2000/2001 and 2001/2002

Category	Number of border cases		As a percentage of total	
	Average 12 month period in Apr 2000-Oct 2001	Nov 2001-Oct 2002	Average 12 month period in Apr 2000-Oct 2001	Nov 2001-Oct 2002
Frozen*	84	174	73	78
Preserved/ dried/ seasoned/ cured	11	28	9	12
Fresh	16	15	14	7
Canned	4	4	3	2
Live	1	2	1	1
Total	116	223	100	100

* includes a wide range of fin-fish /crustacea/cephalopods/ fish fillet and minced products.
Source: Compiled by INFOFISH based on data from MHLW, Tokyo.

but are occurring naturally and thus need to be carefully monitored. The main culprits from the additives are sulphur dioxide and sorbic acid.

Table 39 breaks down the border cases by product type and species group for the periods 2000/1 and 2001/2. The predominant forms of product causing border cases are frozen products accounting for around three-quarters of all detentions. It is interesting that canned and live fish does not constitute a major problem for Japanese importers, and that fresh and cured fish account for only around 20 percent of border cases on average.

3.4.4 Border cases in the context of import volume

We can compare the border cases arising from exporting regions for 2000/2001 and 2001/2002 in the context of export volumes. We can also look at relative border cases arising from problems associated with products, however, this analysis is not possible for species categories as we do not have the border data available. There are some difficulties with the data which is discussed later.

Table 40 breaks down the border cases per 100 000 tonnes from various exporting regions. However some reservation must be exercised with this data, as the border cases are for non-calendar years and the import figures are broken down into calendar year periods. Thus, the import figures for 2001 and 2002 are used for the two periods, as these year groups best represent the period for the border case data.

The picture changes from earlier indications of absolute numbers of border cases. Asia still tops the list, but Oceania has a significant number of cases per unit volume. These two regions (geographically the closest to Japan) are significantly larger in relative border cases than the other continents. Better performers are Europe, North America, Central and South America and Africa. However, as we have noted before, care must be taken in these relative figures where the border cases are low, as changes of one unit in the number of border cases can make significant changes to the relative figure.

3.5 CANADA

3.5.1 Imports

Canada is a significant importer of fish and fish products and, importantly for this study, it also collects and records detailed information on rejections and detentions at borders. It has also been, along with other countries, on the forefront for developing and implementing HACCP-based fish safety and quality approaches.

From 1999 to 2002, Canada imported over half a million tonnes of fish and fish products annually, including meal and oils (Table 41). In the region of half of the imports came from its neighbour, the United States. The next main exporters were Peru, Thailand, China, Norway and the Russian Federation, accounting for a further 35 percent of imports.

The total imports are also broken down by continent (Table 42), as this allows a later comparison with the border cases from these same regions. Not surprisingly

TABLE 40
Border cases in Japan per unit volume of imports, 2000 – by continent

Continent	Average 12 month period in Apr 2000–Oct 2001			Nov 2001–Oct 2002		
	Tonnes (2001)	Border cases	Cases/100 000 tonnes	Tonnes (2002)	Border cases	Cases/100 000 tonnes
Asia	1 594 344	106	6.6	1 666 305	208	12.5
Oceania	103 821	4	3.9	104 511	6	5.7
Central & South America	259 991	2	0.8	260 988	4	1.5
Africa	107 253	0	0.0	88 889	1	1.1
North America	414 631	2	0.5	421 346	2	0.5
Europe	642 016	2	0.3	584 476	2	0.3
Totals	3 122 056	116		3 126 515	223	

TABLE 41
Top ten exporters to Canada 1999–2002 (2002 basis)

Country	1999	2000	2001	2002
United States	196 671	207 157	226 749	228 754
Peru	48 470	80 749	111 002	68 071
Thailand	44 090	39 829	45 495	50 253
China, People's Republic	17 538	19 688	22 807	28 056
Norway	16 596	18 535	21 971	20 719
Russian Federation	24 351	17 371	15 969	20 666
Iceland	33 398	26 488	19 108	15 438
Chile	19 606	17 977	11 108	15 251
Philippines	6 946	5 365	4 508	8 804
Taiwan Province of China	7 497	9 874	7 215	8 354
Totals - all imports	488 422	525 783	576 484	546 214

Source: Fisheries and Oceans Canada (http://www.dfo-mpo.gc.ca/communic/statistics/trade/canadian_trade/import_data/index_e.htm).

TABLE 42
Total Canadian imports by exporting continent 1999–2002

Continent	1999	2000	2001	2002
North America (USA in this case)	197 495	207 986	228 521	229 758
Asia	94 881	98 664	104 387	125 032
Central & South America	79 037	109 789	140 423	103 184
Europe	111 174	103 871	97 696	81 291
Oceania	4 393	4 502	4 413	5 547
Africa	1 442	971	1 044	1 402
Totals – all imports	488 422	525 783	576 484	546 214

Source: Fisheries and Oceans Canada.

North America dominates, with Asia and Central and South America as the next two most exporting regions. Worthy of note is that the only continent that has decreased in volume exported to Canada year on year over the four-year period is Europe. The shortfall from Europe has been more than made up from increased exports from the United States, the Americas and Asia.

The following table[10] (Table 43) breaks down the imports into species groups and into main product types, again for comparative reasons when examining the border case data. These data do not include fishmeal and oil. The data also only cover the period from 1999–2001, as the FAO statistics provide this breakdown, and 2002 data were not available at the time of this study. The table uses the same definitions for product types (prepared, processed, etc.) as was used for the discussions about the European Union – for comparative reasons.

[10] The data set used (Canadian) that allows a breakdown by exporting country (Table 42) does not allow breakdown by product or species. A second data set from FAO statistics does allow such a breakdown but did not have 2002 data at the time of this study (Table 43).

TABLE 43
Total Canadian imports by product type and species group 1999–2001

	1999	2000	2001
Product types			
Frozen fish, shellfish, crustacea, cephalopods	172 360	176 754	185 477
Fresh fish, shellfish, crustacea, cephalopods	79 224	88 424	94 619
Canned fish, shellfish, crustacea, cephalopods	61 501	53 769	60 959
Prepared fish	38 537	36 209	44 098
Live fish, shellfish, crustacean	18 269	19 997	19 302
Processed fish	13 267	16 414	17 782
Cured fish, shellfish, cephalopods	16 219	19 995	16 918
Caviar	437	647	1 071
Species Groups			
Fish	243 415	245 765	256 203
Shrimp	61 115	69 650	77 198
Molluscs	18 821	17 179	19 053
Lobsters	16 231	18 292	17 009
Cephalopods	13 049	14 350	14 690
Crabs	7 772	9 470	9 833

Note that for some products several types e.g. prepared and frozen, are used to categorize the product.
Source: FAO.

The main species group was fish, and within this group, the main species imported are tunas, salmon and cod in a mixture of forms (frozen, chilled, live, processed, etc).

3.5.2 Border cases

During the 4 year period studied (1999–2002), Canada recorded just under 600 border cases where imported fish and shellfish were detained for inspection. Peak years were 1999 (170 cases) and 2002 (174 cases). However, no trends are identifiable from this data set.

As mentioned earlier, the data set for the border cases in Canada is detailed and thus further examination of the border cases is possible. Table 44 details the border cases by year (1999-2002), by risk and by exporting region.

As can be seen from these data, the main exporting continents from which border cases in Canada arose were Asia, Europe (both European Union and non-EU) and Central and South America. Overall, some 36 percent of cases during the 1999-2002 period were from exports from Asia, 32 percent from Europe and 18 percent from Central and South America. What is interesting when examining the European data is that the European Union exporters had more border cases in Canada than non-EU European exporters.

However, these figures do not take into account the volume of imports into Canada from these respective regions and this is an important point. A later section in this chapter puts the border cases into perspective, comparing the border cases with the volume of exports from each region.

Border cases due to microbial problems were relatively low over the 1999-2002 period accounting for only 5 percent of all cases in the four-year period. Where problems occurred, it was due to *Listeria* spp. (13 cases), *E.coli* (10 cases) and *Salmonella* (4 cases) with these 3 bacteria accounting for 93 percent of cases. It is also interesting to note that Asia (with 14 cases) and the European Union (with 10 cases) accounted for over 80 percent of the microbial based cases.

As can be seen from the data however, the main causes of concern were chemical (22 percent) and "other causes" (73 percent). The relative frequency of border cases arising for chemical or other reasons was not consistent for exporting regions or annually. For instance, Asian exporters in 1999 and 2000 had most problems with other causes

TABLE 44
Border cases in Canada from 1999–2002 by cause and exporting region

	Microbial	Chemical	Other causes	Totals	Percent by year
1999					
Asia	0	10	54	64	38
European Union	3	17	21	41	24
Europe (not EU)	0	0	29	29	17
C&S America	0	1	24	25	15
Oceania	0	2	3	5	3
Africa	0	1	3	4	2
N America	0	0	2	2	1
Totals	3	31	136	170	100
2000					
Asia	2	7	35	44	36
C&S America	0	3	18	21	17
European Union	2	4	14	20	17
Europe (not EU)	0	0	17	17	14
Africa	0	1	9	10	8
Oceania	0	5	3	8	7
N America	0	0	1	1	1
Totals	4	20	97	121	100
2001					
C&S America	4	13	19	36	29
Asia	6	9	19	34	27
European Union	1	3	16	20	16
Africa	0	4	11	15	12
Europe (not EU)	1	0	7	8	6
N America	0	1	5	6	5
Oceania	0	4	2	6	5
Totals	12	34	79	125	100
2002					
Asia	6	27	38	71	41
European Union	4	4	23	31	18
C&S America	0	9	17	26	15
Europe (not EU)	0	2	18	20	11
Africa	0	1	14	15	9
Oceania	0	2	6	8	5
N America	0	1	2	3	2
Totals	10	46	118	174	100

Source: Canadian Food Inspection Agency.

(five times more other causes than chemical), whilst in 2001 and then 2002 this relative frequency was shifting towards almost a 1:1 relationship.

It is worth breaking these two categories down further.

Table 45 shows the breakdown of border cases, from 1999–2002, where a chemical risk was identified as the reason for detention or rejection.

Two things become apparent when examining this table. First, there are three main chemical causes identified – mercury, sulphites and histamine – and these appear every year as a significant chemical contamination associated with imports. A second trend, or lack of one, is the fact that other chemical based risks appear in one year and then not again, or re-appear a second time in a later year. It will be important to understand the cause for this so that proper advice can be given to exporters, especially those in the developing world. Further discussions on this appear in Annex A.14.

By far and away the largest category of risks identified by Canadian authorities was that classified as "other causes". As a reminder, this category is applied for risks other than microbial and chemical risks. In the case of Canada, it is clear that these other causes predominate in border cases, though some risks in this category can be indirectly relevant to microbial risks, for instance, can integrity.

Table 46 details the breakdown of reasons for border cases classified as other causes from 1999–2002. The main problem is classified as "sensory evaluation", accounting

TABLE 45
Border cases in Canada from 1999–2002 – chemical causes

Chemical risk	1999	2000	2001	2002	Totals
Sulphite	3	5	11	10	29
Mercury	4	5	14	5	28
Histamine	8	3	6	8	25
Colourants present	11				11
Carbon monoxide				9	9
Nitrate	4			5	9
Chloramphenicol				4	4
Phosphate		1	1	1	3
Borate			2	1	3
Ascorbate		3			3
Tocopherol				2	2
Medicines		1		1	2
Gluco-deltalactone		1			1
Sorbate	1				1
Sorbitol		1			1
Totals	31	20	34	46	131

Source: Canadian Food Inspection Agency.

TABLE 46
Border cases in Canada for 1999-2002 – "other causes"

Risk - other causes	1999	2000	2001	2002	Totals	Percent
Sensory evaluation	62	46	39	54	201	47
Net weight	41	29	17	32	119	28
Can integrity	27	19	15	22	83	19
Moisture	5	1	3	3	12	3
Safety Parameters		1	3	6	10	2
Missing Canadian code	1		2	1	4	1
Species Identification		1			1	0
Totals	136	97	79	118	430	100

Source: Canadian Food Inspection Agency.

for 47 percent of cases. Under Canadian procedures, sensory evaluation is used to determine quality attributes, though if decomposition is suspected, then samples are analysed for histamine.

Net weight problems are next in importance (28 percent). This problem, however, does not always imply a health hazard to consumers and is often an issue of economic fraud (whether intentional or not), except for canned low acid seafood where underweight can result in a safety hazard. However, the can integrity test (19 percent) is used to protect consumers from possible health hazards, specifically from the anaerobic bacteria, such as *Clostridium botulinum*. This test is performed at the border in Canada and can detect minor faults in cans and the seals. As the requirements for can integrity checks at the border are systematic in Canada but not in other countries, and the standards used, especially regarding wrinkle measurements, are more stringent, companies unaware of these differences do not set their seaming machines and double seam control to the Canadian requirements and their products can be penalized at the Canadian border.

This does not however imply that other importing countries do not control can integrity. To the contrary, the United States and the European Union rely more on the control (prevention) at the source to protect against can integrity problems rather than quality control at their borders only. Indeed, the United States has a specific regulation[11] for low acid canned food and acidified food (LACF/AF) which requires the exporting establishment to be registered with FDA and to carry out can seaming operations under a Better Process Control School (BPCS) certified supervisor. The BPCS programme certifies supervisors of thermal processing systems, acidification,

[11] 21 CFR Parts 113 "Thermally processed low-acid foods packaged in hermetically sealed containers". USFDA. Washington, DC.

TABLE 47
Border cases in Canada from exporting regions – "other causes" for period 1999–2002 combined

Risk – other causes	Africa	Asia	European Union	Europe (Non EU)	North America	C&S* America	Oceania
Sensory Evaluation	16	74	12	35	3	53	7
Net weight	7	48	33	11	2	14	4
Can integrity	13	11	25	24	2	5	3
Moisture	0	3	1	0	4	4	0
Safety Parameters	0	8	2	0	0	0	0
Missing Canadian code	1	1	1	1	0	0	0
Commercial sterility	0	1	0	0	0	0	0
Species Identification	0	0	0	0	0	1	0

* Central and South.
Source: Canadian Food Inspection Agency.

TABLE 48
Border cases in Canada from 1999–2002 – by product types and species groups

	1999	2000	2001	2002	Four year totals	Percent of totals
Product type*						
Frozen	78	56	49	52	235	35
Prepared	60	24	31	26	141	21
Canned	45	32	19	36	132	20
Processed	43	15	26	43	127	19
Fresh	0	11	10	14	35	5
Caviar	2	0	4	3	9	2
Cured	0	1	0	0	1	0
Species groups						
Fish	69	61	66	102	298	65
Bivalves	25	10	12	12	59	13
Shrimp	17	6	17	16	56	12
Lobster	7	2	2	2	13	3
Cephalopod	2	8	3	1	14	3
Crab	4	0	2	4	10	2

* Note that for some products several types e.g. prepared and frozen, are used to categorize the product.
Source: Canadian Food Inspection Agency.

and container closure evaluation programmes for low-acid and acidified canned foods. Likewise, in the European Union, can integrity is part of the HACCP system and any testing is carried out by the Competent Authority of the exporting country.

This may also reflect differences in the types of products exported from the different regions. For example, a region exporting mainly canned products, is likely to have higher border cases of can integrity. Unfortunately, the available data do not permit to refine the analysis further.

Table 47 breaks down the other causes by exporting region. The trend differs between the regions. Asia, Oceania and the Americas mirror the overall trend of sensory evaluation being the main cause of border cases, followed by net weight and can integrity problems. Europe (non-European Union) and Africa also have sensory evaluation issues as their main area of concern but net weight issues and can integrity issues are swapped. However, the European Union has most problems with net weight and can integrity issues, possibly because of the differences in standards evoked before (see Table 10).

This may also reflect differences in the types of products exported from the different regions. For example, a region exporting mainly canned products, is likely to have higher border cases of can integrity. Unfortunately, the available data do not permit to refine the analysis further.

Table 48 breaks down the border cases by product type and species group for the four-year period 1999–2002. The predominant forms of product causing border cases are frozen, prepared, processed and canned. It is interesting to note that fresh and cured fish accounts for only around 5 percent of border cases during the 4 year period and that caviar accounts for 2 percent.

TABLE 49
Combined border cases in Canada from 1999-2002 – by cause and product type/species

	Microbial	Chemical	Histamine	Other causes	Totals	Percent
Frozen	0	45	6	184	235	35
Prepared	0	13	0	128	141	21
Processed	17	22	16	72	127	19
Canned	0	14	1	117	132	19
Fresh	2	20	3	10	35	5
Caviar	0	3	0	6	9	1
Cured	0	0	0	1	1	0
Fish	21	62	24	191	298	66
Bivalve	6	8	0	45	59	13
Shrimp	0	17	0	39	56	12
Lobster	0	2	0	11	13	3
Cephalopod	0	0	0	14	14	3
Crab	2	2	0	7	11	2

The main problem species group is "fish", with bivalves and shrimp coming in a distant second and third. Other groups (crab, lobster and cephalopods) account for only 8 percent of border cases. However, it will be interesting to note the relative frequency when trade volumes are considered in the next section.

Finally, the data set allows us to determine the causes for border cases according to the species or products imported (Table 49).

3.5.3 Border cases in Canada in the context of import volumes

As the data sets come from different sources, the periods studied are restricted to those where both border cases and import volumes are known. For Canada, we can compare the 1999–2002 period for the border cases arising from exporting regions. For border cases arising from problems associated with products or species, we are restricted to the years 1999–2001.

Table 50 breaks down the border cases per 100 000 tonnes from various exporting regions. The picture changes dramatically from earlier indications of absolute numbers of border cases. It becomes clear that in exports to Canada, Africa performs poorly relative to other continents, by some considerable margin. The European Union and then Oceania are the next two regions that most give rise to border cases.

As was noted for the European Union, it is interesting to note that the four regions that export the most product to Canada are also the best performing. As before, it is not possible to determine the exact reasons for this, but the same possibilities present themselves i.e. it is probable that those exporting countries that trade the largest volumes with Canada are likely to have larger consignments, thus the number of border cases per unit volume would be lower, but absolute volumes (in kg for instance) would be high as the problem consignment is larger. Also, these exporting regions are more likely to be familiar with the Canadian regulations thus reducing the likelihood of problem consignments.

In the Canadian system, once an exporter is found to be responsible for a problem shipment, then the exporter is checked systematically for four consecutive consignments. This increases the chances that future problems, if any, will be found. It also should provide incentive to get things right, though.

A useful figure to note is the total number of border cases per unit volume (100 000 tonnes) arising in Canada from all imports each year. This figure can be compared to other regions later in the analysis section. From 1999 to 2002, the figure ranges from 22 to 35 border cases/100 000 tonnes imports.

As regards products and species, a similar situation arises where the higher absolute numbers of border cases for a product category or species are no longer the main problem relative to the amount of trade in those species/products (Table 51).

TABLE 50
Border cases in Canada per unit volume of imports, 1999–2002 – by continent

	1999			2000			2001			2002		
	tonnes	cases	cases/ 100 000 tonnes	tonnes	cases	cases/ 100 000 tonnes	tonnes	cases	cases/ 100 000 tonnes	tonnes	cases	cases/ 100 000 tonnes
Africa	1 442	4	277	971	10	1 030	1 044	15	1 437	1 402	15	1 070
European Union	20 560	41	199	11 179	20	179	10 084	20	198	12 635	31	245
Oceania	4 393	5	114	4 502	8	178	4 413	6	136	5 547	8	144
Asia	94 881	64	67	98 664	44	44	104 387	34	33	125 032	71	57
Europe – not EU	90 614	29	32	92 692	17	18	87 612	8	9	68 656	20	29
C & S* America	79 037	25	32	109 789	21	19	140 423	36	26	103 184	26	25
USA	197 495	2	1	207 986	1	1	228 521	6	3	229 758	3	1
All regions	488 422	170	35	525 783	121	23	576 484	125	22	546 214	174	32

* Central and South America.
Source: CFIA and FAO.

TABLE 51
Border cases in Canada per unit volume of imports, 1999–2001 – by product types and species groups

	1999			2000			2001		
	tonnes	cases	cases/ 100 000 tonnes	tonnes	cases	cases/ 100 000 tonnes	tonnes	cases	cases/ 100 000 tonnes
Caviar	437	2	458	647	0	0	1 071	4	373
Processed	13 267	43	324	16 414	15	91	17 782	26	146
Prepared	38 537	60	156	36 209	24	66	44 098	31	70
Canned	61 501	45	73	53 769	32	60	60 959	19	31
Frozen	172 360	78	45	176 754	56	32	185 477	49	26
Fresh	79 224	0	0	88 424	11	12	94 619	10	11
Cured	16 219	0	0	19 995	1	5	16 918	0	0
Live	18 269						19 302		
Bivalves	18 821	25	133	17 179	10	58	19 053	12	63
Crab	7 772	4	51	9 470	0	0	9 833	3	31
Fish	243 415	69	28	245 765	61	25	256 203	66	26
Shrimp	61 115	17	28	69 650	6	9	77 198	17	22
Cephalopod	13 049	2	15	14 350	8	56	14 690	3	20
Lobster	16 231	7	43	18 292	2	11	17 009	2	12

Note that for some products several types e.g. prepared and frozen, are used to categorize the product.
Source: FAO.

Frozen products now rank lower, with processed[12] products predominating in the relative importance of border cases. The very high levels of caviar cases per unit volume of trade may not be relevant and some care must be taken with the relative figures due to the very low amounts traded – very high figures for 2000 and 2002, and zero for 2001. What is maybe interesting is that smoked products (classified under cured), which have hit headlines in recent years, prove to be low risk products. Maybe this is the result of the considerable exposure of *Listeria* spp. in smoked fish products having an effect on the processors and is indicative of greatly improved processing conditions for cured products in general.

Likewise for species trends, fish do no longer rank highest, with bivalves consistently predominating (for border cases). However, the most obvious reason for this does not hold true. It might be expected that microbial or chemical problems would predominate for bivalves, but in fact sensory evaluation, net weight and moisture problems cause the border cases. However, this is against a backdrop of a low level of microbial cases in Canada in border inspections.

[12] See Annex A.18 for EU definitions of product types used in this publication.

3.6 COMPARISON OF BORDER CASES AMONG MAJOR IMPORTERS

Each year, thousands of tonnes of products are detained, rejected or destroyed at national borders. The preceding sections have detailed the facts behind border cases in recent years for the three most important importing regions in the world, namely the European Union, North America and Japan.

As the data indicate, there are major differences between the importing regions studied, both in terms of numbers and nature of cases. It is important however to realize that, beyond shear numbers, the type of border case (safety, quality or economic fraud) and its direct macro and microeconomic impacts are different and need to be taken into consideration when comparing the different cases and strategies to reduce them. Unfortunately, the available data do not always enable this type of refined analysis. Recommendations are provided later as to how data collection and dissemination can be modified to improve the analysis.

It should be also noted that beyond differences in control systems, standards and analytical techniques, importing countries may devote different human and financial resources to border controls. This is likely to play an important role in the efficiency of border controls. Unfortunately, this information is not available to enable refinement of the analysis when comparing the different importing control regimes.

3.6.1 Relative frequency of border cases

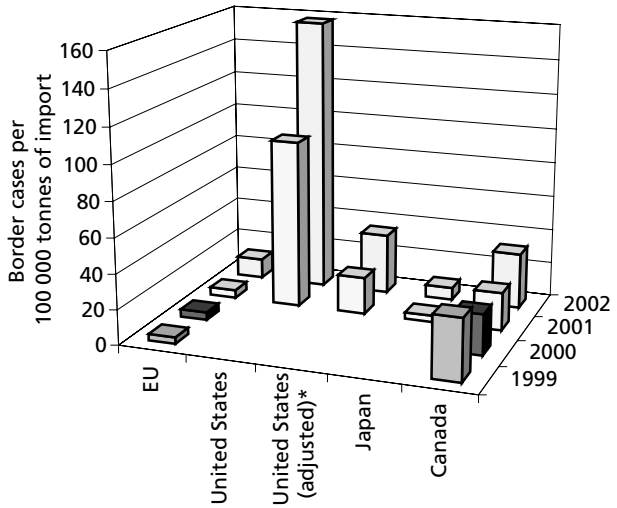
Figure 1 shows a quite dramatic difference in the absolute numbers of border cases in the various importing countries/regions when shown relative to import quantities. These highlight some important differences, even though it is not possible to determine the absolute quantities of border cases per unit weight of imports.

At first glance, the United States of America has around ten times as many border cases per 100 000 tonnes as the European Union or Japan, and 3-4 times as many as Canada. This should not be taken to indicate necessarily that the United States have a higher performance in border controls or that products exported to the United States have more non conformity problems.

In fact, the data need to be adjusted and substantiated to enable comparisons of performance between the regions studied. Firstly, a high percentage of United States cases end up with the product actually entering the United States after re-examination, sorting, re-packing, new documentation and information or new labelling. During 1999-2001, 78 percent of detained shipments were released for import into the United States (Allshouse *et al.*, 2003). Therefore, only around 22 percent of the cases in the United States can be considered in comparing the different regions as the other 78 percent ended up being accepted. Taking this into account, the United States has now around twice more border cases than the European Union and Japan and 60 to 80 percent as many as Canada (see Figure 1, adjusted United States graphs).

Secondly, the other countries/regions, especially the European Union, use some sort of "prevention at source" approach. Indeed, Chapter 2 explains that the European Union relies on national Competent Authorities (CAs) in exporting countries to examine establishments and products to assess their conformity to European Union requirements prior to shipments. By so doing, several non conformity cases are detected and stopped in the exporting countries. This approach has proven to be more preventative and cost effective than relying only on controls at the border. But it can also be penalizing for well managed seafood companies that cannot export to the European Union because they are in a country that does not have the resources and the capacity to put together a competent authority that meets the European Union requirements. Likewise, Canada and to some extent Japan, have adopted a "prevention at source" approach, although less formalized and less actively in comparison to the European Union. Canada has developed MOU/MRAs with a limited number of countries – Australia, Ecuador, Iceland, Indonesia, Japan, New Zealand, Philippines

FIGURE 1
Total border cases for European Union, United States, Canada and Japan 1999–2002 relative to import quantities. *Adjusted data represent 22 percent of total United States border cases



and Thailand, whereas Japanese importing companies have a long tradition of fielding quality controllers to work at the exporting sites. In both cases, some non conformity cases are eliminated before consignments are shipped.

More and more countries, including the United States (National Academy of Sciences, 2003), are advised to adopt a "prevention at source" approach because of its higher performance and cost effectiveness. However, care must be exercised to ensure that exporting developing countries are assisted in their efforts to build national capacity in safety and quality. This can only be a win–win situation both for the exporter and for the importer. While reducing safety and quality problems, their inherent costs and damages are reduced for exporters. At the same time, resources for control at borders are reduced significantly and target better problem cases, increasing their efficiency. Also, reducing losses due to rejections and detentions should result in greater supply of safe fish and less illnesses due to unsafe foods.

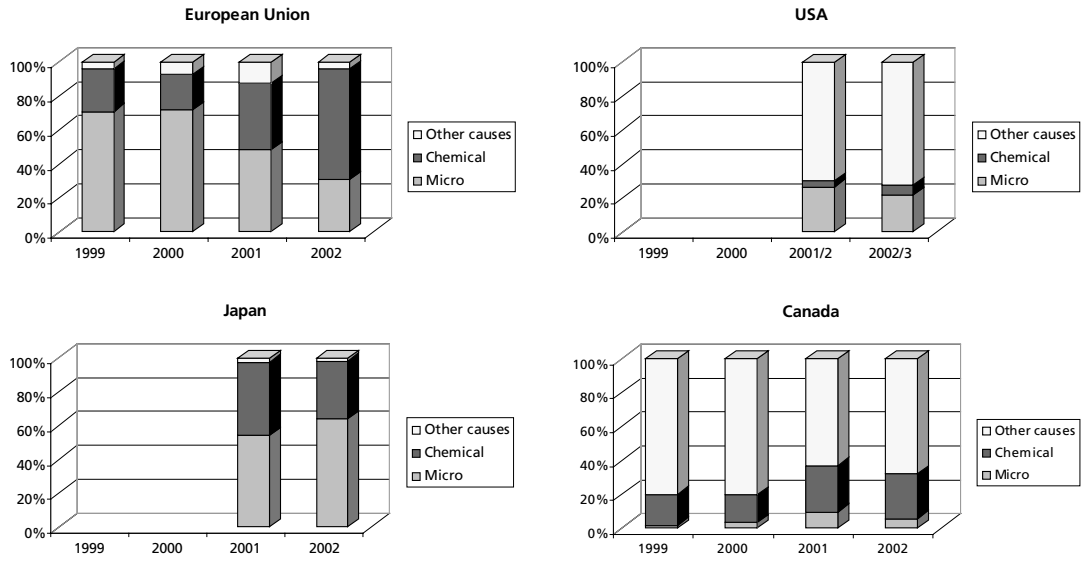
A third difference is the types and methods of control and standards applied at border. Chapter 2 shows that in the different importing countries studied, not only are border checks different (see Table 10), but the analytical techniques used can be different and the criteria or standards applied to judge conformity or non conformity are different (e.g. histamine, *Salmonella, Listeria monocytogenes*, etc.). Most importantly, these criteria and standards are not always based on fully fledged scientific risk assessments. Not only can this create arbitrary barriers to trade, but it is also costly as safe products may be refused in some regions while unsafe products may be distributed in others. Consequently, there is a need to harmonize the procedures and the standards between these majors markets, using risk assessment methodologies where applicable. This is further developed under section 3.6.7.

3.6.2 Border case patterns and trends

The previous sections broke down the causes of border cases into three main categories – microbial, chemical and other causes.

The breakdown for the four countries/regions covered in this publication is summarized in Figure 2. The differences in the profile of each country are quite obvious, with both the European Union and Japanese border cases being predominately

FIGURE 2
Relative frequency of causes of border cases for the European Union, United States, Canada and Japan



microbial or chemical in origin, while these causes only account for a quarter to a third of border cases in the United States and Canada. The previous sections on each country detail the types of "other causes" for both Canada and the United States. Given the well publicized increase in 2001/2 of chemical (veterinary drugs) contamination from Asia (especially for shrimps), it is interesting to note that this becomes evident in the European Union data, where chemical contamination becomes a dominant category, while for other major importers, this trend is not noticeable. These other regions were importing large quantities of shrimp from Asia during this period, but were clearly handling the imported products differently, or recording the data differently.

Section 3.6.5 discusses in more detail the disparity between the data recorded for the causes of border cases, and the difficulty this poses for comparison between importing regions.

However, the obvious differences highlighted again point to the significant variations in approaches to controls at the borders of the countries being studied. For an exporter, it would be helpful if these procedures were harmonized, and that if they export a product, it should be treated the same way irrespective of who the importing country is. The extra costs imposed on traders by these differences may be significant, but are difficult to quantify due to the absence of relevant data, most importantly the quantities and value of rejected products and costs of controls.

3.6.3 Performance of continents

Again, we have a crude analysis here, but the results do provide a useful reference for discussion. The only two importing regions with full data over the four year period, 1999-2002, to allow comparison of the performance of exporting continents are the European Union and Canada. The Japanese data allow this comparison for the two periods 2000/2001 and 2001/2002 (Table 52). The underlying data are important and readers are referred to Table 23 for the European Union, Table 40 for Japan and Table 50 for Canada.

It is first apparent that there are some significant differences in the "relative" performance of the exporting continents dependent on whether fish is being sent to

TABLE 52
Performance of continents in exporting to the European Union, Canada and Japan

		1999		2000		2001		2002	
		cases/ 100 000 tonnes	Rank	cases/ 100 000 tonnes	Rank	cases/ 100 000 tonnes	Rank	cases/ 100 000 tonnes	Rank
Oceania	to EU	-	1	-	1	5.9	5	-	1
North America	to EU	-	1	1.0	3	1.1	2	0.7	2
Europe (not EU)	to EU	0.1	3	0.3	2	0.3	1	1.0	3
C&S* America	to EU	1.8	4	4.8	4	2.8	3	5.9	4
Africa	to EU	7.0	5	5.7	5	4.4	4	6.2	5
Asia	to EU	12.9	6	13.9	6	16.4	6	51.5	6
USA	to Canada	1.0	1	0.5	1	2.6	1	1.3	1
C&S* America	to Canada	31.6	2	19.1	3	25.6	3	25.2	2
Europe (not EU)	to Canada	32.0	3	18.3	2	9.1	2	29.1	3
Asia	to Canada	67.5	4	44.6	4	32.6	4	56.8	4
Oceania	to Canada	113.8	5	177.7	5	136.0	5	144.2	5
EU	to Canada	199.4	6	178.9	6	198.3	6	245.4	6
Africa	to Canada	277.4	7	1,029.9	7	1 436.8	7	1 069.9	7
Europe	To Japan					0.3	2	0.3	1
North America	To Japan					0.5	3	0.5	2
Africa	To Japan					0.0	1	1.1	3
C&S* America	To Japan					0.8	4	1.5	4
Oceania	To Japan					3.9	5	5.7	5
Asia	To Japan**					6.6	6	12.5	6

* Central and South.
** 2001 detention figures used are an average 12 month period in Apr 2000-Oct 2001, 2002 figures are from Nov 2001–Oct 2002. See Table 40.

the European Union, Canada or Japan. This fact alone is worthy of comment. There are two main reasons why this might occur. One, the importing regions apply different criteria for border actions (whether sampling frequencies, limits for contamination levels or other procedures) and/or the exporting continents send different volumes and products (either different risk categories or of varying quality) to the export markets.

If the latter is the case, and given that the product forms are fairly similar (frozen fish dominates, significant numbers of crustacea, cephalopods, molluscs, etc.) for the European Union and Canada, it would seem that individual exporters must recognize the differences and target their products to suit the market criteria. This certainly does happen, but it is probably more likely that importing regions treat the imports (as a whole) in different ways resulting in different border actions. In the case of Japan, it is possible that the higher risk products that Japan imports may have originated from its neighbouring countries, as the species are similar. However, this is conjecture with the data available.

Being more specific, Oceania ranks as the best exporting region when exporting to the European Union, but ranks very poorly when exporting to Canada and Japan. Africa is the poorest performer in exports to Canada and second poorest to the European Union, however performs quite well in exports to Japan. The poorest performer by some margin in exporting to the European Union is Asia, exacerbated in later years with the veterinary drug issue alluded to in earlier sections. It is also the poorest performer in exports to Japan. However, Asia outperforms both Oceania and the European Union in exporting to Canada, though still only performs moderately. Central and South America perform very well in exports to Canada but less well when

exporting to the European Union and Japan. North America is consistently a top performing exporter.

It is not easy to determine the significance of these differences and their causes. It was noted earlier that there seemed to be a tendency for those exporting the least amounts relatively to have more border cases per unit volume, and this certainly applies in the case of exports to Canada, though not in order. However, this does not apply to the European Union, as Oceania is the smallest exporter but is one of the top performers, or Japan, as Asia is the largest exporter, but is a poor performer.

It may be misleading to research in more detail as to why these differences occur, mainly because the importing nations use different procedures (sampling plans, analytical techniques, type of defect) and/or criteria on imports and the products exported differ from one importing region to the other. Again, for the benefits of international trade and ultimately the consumer, it is desirable that the importing rules are harmonized both in terms of the governing legislation and in implementation to enable proper evaluation of performance.

3.6.4 Access to data for border cases

The ease of access to data is variable. Three of the countries/regions in this study hold individual border case information on the internet, making access to data easy, as long as users have Internet access (see section 3.6.6). This initiative is to be applauded, and more countries should follow this example, though the type of information available on the three Web sites was variable. Japanese data is available on a Web site, but it is only held as annual summary tables at a macrolevel (main food commodities and exporting regions) and cannot be queried to individual border actions.

Table 53 compares the border case information available on the individual Web sites for the European Union, the United States and Canada.

As can be seen, the data available are similar. A notable exception is that the European Union reports do not include company details, whereas both the United States and Canadian sites do include these details. Also, the European Union records the importing country (of course, this is irrelevant for Canada or the United States). This information is useful for exporters, as there are differences in the way in which European Union member states perform some border controls for imports of fish and fish products. This has been mentioned earlier.

Missing data from all the Web sites includes Latin names (for identification), actions taken (e.g. re-exported, destroyed, reworked) and, importantly, the quantity and values of the lots in question. The latter data would allow calculations for the costs involved at both the country level and company level. This data would be very useful for policy makers, and for industry also. Presently, most of the economic studies costing implementation of safety and quality requirements can estimate fairly accurately the cost of appraisal (inspection and inspection management, analysis), the cost of prevention (training, maintenance, validation) but lack the data to assess the cost of failure (detention, rejection, scraps, re-work, destruction). The true performance

TABLE 53
Border case data available on the World Wide Web

Country	date	reference number	exporting country	importing country (EU) or district	company	cause	species	production method	product	product code	Latin name	action taken	quantity involved	value involved
EU	✓	✓	✓	✓	×	✓	✓	×	✓	×	×	×	×	×
USA	✓	✓	✓	✓	✓	✓	✓	×	✓	✓	×	×	×	×
Canada	✓	×	✓	×	✓	✓	✓*	×	✓*	×	×	×	×	×

* sometimes this is not specified, e.g. when "all products" is used. ✓: yes. ×: no

of safety and quality assurance systems can only be seen in light of costs (appraisal, prevention) and benefits (reduction or elimination of failure).

Another key field missing in all data is the method of production. This is important as it is useful to be able to differentiate between farmed and wild fish in international trade and therefore in border actions where trade is interrupted (see also section 3.6.9). It is very likely that the causes for border cases will be different, e.g. veterinary drugs for farmed fish and histamine for wild fish (scombroids). In looking at border case data as potential lessons to be learned, it would be useful to provide specific recommendations to fish farmers and to fishermen based on actual border cases.

3.6.5 Type of data recorded for border cases

It is worth looking at the type of data recorded in more detail. Of course for the date and country fields[13], the data kept are going to be very similar in each database of records (United States, Canada, European Union, etc.). For instance, if Australia is the exporting country this will be noted in the same way in each database. Similarly the date will be understandable in all databases (though the United States and European models are different for date format, but this is a minor issue).

However, and more importantly, the data recorded for the cause of the border case are different between countries/regions, and this makes it much more difficult to make comparisons at both the micro- and macrolevels. The European Union and Canada use free text entries for the cause while the United States use a coding system, choosing from one of over 170 codes to detail the reason why the product was detained.

Given the wide acceptance of HACCP based principles in ensuring food safety worldwide, it would make sense to adopt the approach used in hazard analysis using microbial, chemical and physical hazard categories for the categorization of the causes for border cases. Given the preponderance of other causes outside of the pure safety hazards in border cases, then an "other causes" category could be added, or could be further sub-divided into, say, documentation, labelling, and so on.

Considering the "cause" data in more detail, there are also differences seen in causes of border cases. For example, in microbial terms, specific (and normally pathogenic) bacteria are commonly cited in European Union border case records as the reason for an action taken at the borders, but a lot less so in Canada and the United States and not all in Japan, where indicator organisms are used for taking actions on suspect consignments. Also, there is a preponderance of more rapid and cheap tests e.g. sensory tests in Canada and the United States, rather than analytical tests with definable limits as used in the European Union (e.g. heavy metals, microbial limits). In a very specific example, the can integrity test is used systematically at the borders in Canada but not anywhere else and, not surprisingly, can failure is often cited as a problem at Canadian borders, but not elsewhere.

There is a separate, but important, issue to the use of inspection to control food imports and that is the argument about whether control systems should be limited to safety issues only, and that other quality issues (where public health is not in question) should be left to the market place. Here is not the place to decide upon this issue, but it is an issue that needs to be addressed to provide consistency between importing regions.

Similarly, the species and products are detailed in different ways, using different classifications. For instance, the European Union combines the product, species and cause into one field, while the United States and Canada split the product/species and cause fields, though the product and species fields are combined (Table 54). It would be useful, at little or no extra work when compiling, to record these data separately,

[13] In database terminology, a record is a single entry, for instance, one border case, while a field is a single type of information collected in a record. A record can have any number of fields; for instance, date, country of origin, product are all potential fields for a record of a border case.

TABLE 54
Recording of cause, product and species data in European Union, the United States and Canadian Web sites

Importing country/region	Example of text recorded for product and species
EU	*Listeria monocytogenes* in smoked salmon *Salmonella enteritidis* in eggs Fumonisins in maize meal *Listeria monocytogenes* in saint nectaire cheese Ochratoxin a in spices/curry Unauthorized additive (Annato/bIxin/Norbixin - e-160b) and colour Sudan 1 in sweet pepper
USA	Fermented silver fish (monamon) Canned baby eels Mackerel in tomato sauce Mackerel in tomato sauce hot chilli
Canada	Frozen shrimps and prawns, shell-on, headed, raw Frozen shrimps and prawns, peeled and deveined, raw Scallops - frozen meat, raw Frozen shrimps and prawns, peeled, raw Scallops – frozen meat, raw Frozen: shrimps and prawns

TABLE 55
How border case data are held on the World Wide Web

Country	Web site address and how data are held	Easily cut and paste into spreadsheet for analysis?	Notes
EU	*http://europa.eu.int/comm/food/food/rapidalert/index_en.htm* – Separate downloadable PDF* file for latest week for all foods and feeds. – Archived to Week 21 in 2003 (when first started). – Annual summary produced once a year (PDF file)	No. Text cannot be cut and paste into spreadsheet to automatically create appropriate columns and rows.	See Annex A.16 for example report. Reports are only for all foods and cannot be sorted for, say, fish only.
USA	*http://www.fda.gov/ora/oasis/ora_oasis_ref.html* – Monthly Import Refusal Reports held as HTML text. Can choose between product report (e.g. fishery/seafood products) or exporting country report. – Only archived for one year. No access to older data. – Also has definitions for violation codes used in the Import Refusal Report.	No. Text cannot be cut and paste into spreadsheet to automatically create appropriate columns and rows.	See Annex A.17 for example report. Fish can be pulled out as a separate report.
Japan	*http://www.mhlw.go.jp/english* – Gives access to predefined summary tables about rejections (presently for 2000) categorized by food commodity and region of export. Macro data only. – Links to laws governing inspection – Examples of violations given on Web site	No. Text cannot be cut and paste into spreadsheet to automatically create appropriate columns and rows.	No reports of "live" data for rejections. Only annual summary data.
Canada	*http://active.inspection.gc.ca/active/IALFront.asp?l=E* – Gives access to the Import Alert List for fish and fish products – an online searchable database. – Can search by exporting country (drop down list), product category (drop down list), processor (free text), product (free text), date (free text), last rejection (free text) and can specify maximum number of lines to show. – Reports go back to 1998 at least, maybe earlier.	Can be cut and paste into spreadsheets and can easily be sorted using database functions. Hyperlinks become a nuisance.	See Annex A.18 for example report Fish can be pulled out as a separate report.

PDF - Portable Document Format. Readable with free Adobe Acrobat software (www.adobe.com).
HTML - Hyper Text Mark up Language. The method used to layout Web pages.

i.e. fields for product, species and cause, and to harmonize products and species under defined categories allowing easier comparisons across importing regions. It is also advisable to harmonize this data with import and export data categories, so that relative importance of border cases can be easily obtained. The next chapter will make further recommendations about these and related issues.

3.6.6 Ease of analysis of data for border cases

Having said that the information is available on the Web sites, the ease with which this information can be manipulated and analysed is different. Table 55 summarizes the way the data are held on the four Web sites. The Canadian reports are by far and away the easiest dataset to transfer to spreadsheets for later analysis, as the data can be easily cut and paste into spreadsheets, and be immediately available for sorting and other database operations. Thus, to compile all the available data from the Canadian Web site into a spreadsheet would take minutes rather than hours. Also, fish data can be pre-selected on the Canadian Web site, separating these data from data on other foods. This is useful.

The data from the European Union and United States Web sites are not so readily usable. To transfer European Union data into a spreadsheet requires some further processing, as the text tool used in the PDF file will copy the data, but pasting into the spreadsheet creates mixed columns, which then need to be re-aligned properly under the headings. This takes some time. Also, non-fish records need to be removed.

The United States data are even more problematic, as the data will only allow cut and paste into a spreadsheet on a word by word (or phrase by phrase) basis, taking some minutes for each record. This would make it a very laborious task to convert even a months worth of records, and would increase the chances of human error in the transfer process. However, fish data can be pre-selected on the Web site, so these data come clean of data on other foods.

Japanese data are restricted to annual summaries (available only for 2000 at the time of writing) of detention data, and is across all foods sources (livestock, marine products, etc.) and does not break down data further to seafood detentions. This is a further area that needs to be harmonized for importing countries.

3.6.7 Requirements for harmonization and equivalency schemes

The present study shows that "*the prevention at source*" approach is not generalized and that all the major importing countries rely on end product control at the borders despite the deficiencies related to end product sampling and analyses.

Limitations of end product sampling and analyses

The following limitations have been reported for end product control methods (Huss, Ababouch and Gram, 2004):

- The chances of finding a hazard will be variable, but most often very low as explained later. Nevertheless, the laborious and costly work of sampling and testing will give a sensation of "being in control" and create a strong but false sense of security.
- It may take several days before results from end-product testing are available. This makes the method inapplicable for fresh fish and short shelf life products.
- The results are retrospective - if hazards are identified in the end-product testing programme and product needs to be destroyed, then there is significant loss as the production costs and expenses have already been incurred.
- It is costly. Decently equipped laboratories are needed as well as trained personnel. The running costs of a laboratory are high, as are often the costs of products "lost" to testing.

In most cases, there is no test that gives an absolutely accurate result with no false positives and no false negatives. This is certainly the case for many microbiological testing methods.

Furthermore, there are the principles of sampling and the concept of probability to consider. Indeed, the number, size and nature of the samples taken for analysis greatly influence the results. In some instances, it is possible for the analytical sample to be truly representative of the "lot" sampled. This applies to liquids such as milk

and water. However, in cases of lots or batches of food such as seafood, this is not the case, and a food lot may easily consist of units with wide differences in microbiological or chemical quality. Even within the individual unit (i.e. a retail pack), the presence of a hazard (pathogen or toxic chemical) can be very unevenly distributed, and the probability of detecting the hazard may be very low. For example, it has been estimated (Mortimer and Wallace, 1988) that for a heterogeneously distributed contamination by *Salmonella* (at a rate of 5 cells/kg and assuming that the contamination is restricted to 1 percent of the batch), the probability of detecting the hazard by taking 10 samples of 25 g would be lower than 2 percent. This assumes 100 percent effectiveness for the detection test and most are less than 90 percent.

Therefore, even the most elaborate sampling and testing plans of end-products cannot guarantee safety of the product. There is no way to avoid some degree of risk and error in each acceptance and each rejection of lots unless the entire lot is tested, in which case no edible seafood will be left. This is obviously not acceptable both from practical and economic points of view. More worrying is the sense of false security it creates.

What is needed is to promote wider application and recognition, through equivalence schemes, of the "*prevention at source*" approach, anticipating safety hazards and building safety into the product and the food chain right from the start.

Lack of harmonization of control methods, criteria and standards

Border case data and epidemiological data have indicated that the major safety concerns involving fish and seafood are bacterial pathogens and chemical toxins or contaminants. Yet, there is a major discrepancy between the major importing countries as to how to stop these undesirable pathogens and chemicals from entering the seafood or crossing borders. These discrepancies persist despite the fact that they have been recognized for many years. The following are most relevant to international fish trade and illustrate the magnitude of the discrepancies.

Histamine: Histamine poisoning is a food-borne chemical intoxication occurring a few minutes to several hours following the ingestion of foods that contain unusually high levels of histamine.

Histamine poisoning occurs throughout the world and is perhaps the most common form of toxicity caused by the ingestion of fish. Japan, the United States of America and the United Kingdom are the countries with the highest number of reported incidents, although this possibly implies better reporting on their part. Less frequent incidents have been reported elsewhere in Europe, Asia, Africa, Canada, New Zealand and Australia (Huss, Ababouch and Gram, 2004).

There is uncertainty regarding the threshold toxic concentration of histamine because potentiators of toxicity, such as cadaverine, putrescine and spermine may be present in fish and lower the effective dosage compared with pure histamine. Different fish could contain different potentiators, and the levels of potentiators could also vary considerably from one individual fish to another.

A review (Shalaby, 1996) of the oral toxicity to humans of histamine and other biogenic amines in foods concluded that histamine-induced poisoning can be considered, in general, slight at 8–40 mg/100 g, moderate at > 40 mg/100 g and severe at >100 mg/100 g. Based on an analysis of poisoning episodes, the review suggested the following guideline levels for histamine content in fish:

– < 5 mg/100 g (safe for consumption)
– 5–20 mg/100 g (possibly toxic)
– 20–100 mg/100 g (probably toxic), and
– >100 mg/100 g (toxic and unsafe for human consumption).

Because of the recurrence of histamine poisoning in many parts of the world and the importance of international trade of the concerned fish species, many countries

have imposed maximum limits or produced guidelines on histamine levels in traded fish. But these limits are not harmonized and none have been based on a thorough risk assessment.

Thus, the US FDA guidelines, established for tuna, mahi-mahi and related fish, specify 50 mg/100 g (500 ppm) as the toxicity level, and 5 mg/100 g (50 ppm) as the defect action level because histamine is not uniformly distributed in a decomposed fish. Therefore, FDA considers that if 5 mg/100 g is found in one section, there is a possibility that other units may exceed 50 mg/100 g . FDA requires the use of the Association of Official Analytical Chemists (AOAC) fluorometric method.

The European Union requires Competent Authorities to take nine samples from each batch of fish species of the following families: *Scombridae, Clupeidae, Engraulidae* and *Coryphaenidae*. These samples must fulfil the following requirements:

– the mean value must not exceed 10 mg/100 g (100 ppm)
– two samples may have a value of more than 10 mg/100 g (100 ppm) but less than 20 mg/100 g (200 ppm)
– no sample may have a value exceeding 20 mg/100 g (200 ppm).

However, fish belonging to these families and which have undergone enzyme ripening treatment in brine may have higher histamine levels but not more than twice the above values. For example, in salted anchovies, a major traded commodity, European Union accepts a mean value as high as 200 to 400 ppm (instead of 100 to 200 ppm required for non ripened products). Examinations must be carried out in accordance with reliable, scientifically recognized methods, such as high-performance liquid chromatography (HPLC).

In Australia and New Zealand, the level of histamine in a composite sample of fish or fish products, other than crustaceans and molluscs must not exceed 10 mg/100 g (100 ppm). A 'composite sample' is a sample taken from each lot, consisting of five portions of equal size taken from five representative samples. This clause, which came into force in October 1994, was under review in 2002, with a proposal to increase the maximum allowable level of histamine in fish and fish products to 20 mg/100 g (200 ppm).

In Canada, the level of histamine in enzyme-ripened products (e.g. anchovies, anchovy paste, fish sauce) should not exceed 20 mg/100 g. For all other scombroid fish products (e.g. canned or fresh or frozen tuna, mackerel, mahi-mahi), samples are collected according to sampling plan 1 (AQL 6.5) for inspection. Any sample exceeding 50 mg/100 g will result in the lot being rejected with no right to re-inspection. The acceptance number is that corresponding to the number for decomposition.

Salmonella: Many countries, especially the major seafood importing countries, view the presence of *Salmonella* in raw frozen fish and crustacea as a form of adulteration, based on the fact that species of *Salmonella* are not usually found in clean marine environments and would only be found in products which have been exposed to poor standards of hygiene during handling and processing.

However, more and more fish and crustacea are produced by aquaculture. Aquaculture practices in many countries, especially Asian countries which produce almost 90 percent of world aquaculture fish and crustacea, involve pond fertilization with chicken and animal manure which are a source of faecal organisms. Environmental conditions in fish ponds in the tropics are conducive for growth and proliferation of bacteria such as *Salmonella.*

Likewise, many studies (Reilly, Twiddy and Fuchs, 1992) have shown that *Salmonella* and other enterobacteria can be present as part of the natural bacterial flora of water ponds and that specific serotypes of *Salmonella* can be frequently isolated from cultured shrimp. Usual processing of raw fish and shrimp such as washing, grading, chilling and freezing will not eliminate *Salmonella* if it is naturally present in cultured fish or shrimp. However, cooking quickly destroys this pathogen.

It is therefore legitimate to question whether a zero tolerance for *Salmonella* in aquaculture shrimp and fish is justifiable and useful for health protection. A risk assessment will help clarify the issue and remove any injustifiable barrier to the ever increasing trade of aquaculture shrimp and fish.

Vibrio species: *Vibrio* species are typical of marine and/or estuarine environments and are commonly isolated from fish and crustacea. Most of the species are mesophilic and their numbers tend to increase during the warm seasons. The genus comprises 34 species of which 13 species can cause human disease. Seafood-borne diseases are primarily caused by *Vibrio parahaemolyticus*, *Vibrio vulnificus* and *Vibrio cholerae.* These pathogenic *Vibrio* spp. are ubiquitous in warm (>15 °C) seawater environment. They can be found at levels of up to 10^2–10^3 cells/g in shellfish and up to 10^4–10^8 cells/g in the intestines of shellfish-eating fish. They are indigenous to the aquatic environment and their presence and numbers are influenced by factors such as temperature, salinity and algal density.

The major importing countries use different *Vibrio* standards, ranging from absence of *V. cholerae* (United States of America and Canada) and *Vibrio vulnificus* (USA) in ready to eat seafoods, to <100/g *V. parahaemolyticus* in cooked crustacea (European Union) or (Japan) (RTE) to < 10^4 (FDA) in RTE seafood (see Annexes A.4, A.7, A.10, A.14).

This again has created important trade flow disruptions despite repeated concerns raised by scientists regarding the subjectivity of these standards. For instance, the EC Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) recommended that (EC 2001):

- The practice of judging seafood exclusively based on total *Vibrio* counts as indicative for the presence of pathogenic vibrios is not appropriate and should be discontinued.
- The practice of judging seafood exclusively based on total *V. parahaemolyticus* counts without consideration of the virulence factors TDH/TRH (or *tdh/trh*) is not appropriate and should be discontinued.
- Currently available scientific data do not support setting specific standards or microbiological criteria for pathogenic *V. parahaemolyticus* and *V. vulnificus* in seafood. Codes of practice should be established to ensure that GHP has been applied.

Regarding cholera, an ongoing FAO/WHO risk assessment on *Vibrio* spp. in seafood addresses the issue of *Vibrio cholera* in warm water shrimp imported by United States of America, Europe and Japan. The justification for taking up this risk assessment is that several millions of tonnes of warm water shrimp are traded annually and this trade is generally adversely affected whenever there are outbreaks of cholera in shrimp-producing tropical countries.

The hazard identification concluded that *V. cholerae* is a heterogeneous species comprising of more than 200 serotypes. Of these only serotypes O1 and O139 are known to cause cholera. Non-O1/non-O139 serotypes are rarely associated with the sporadic cases of gastroenteritis. Therefore the agents involved in cholera need to be clearly identified as choleragenic *V. cholerae*.

Furthermore, a series of studies conducted in several countries in Asia during the late 1980s reported an absence of choleragenic *V.cholerae* in warm water shrimp, making it difficult to predict the distribution of choleragenic *V. cholerae* in warm water shrimp. On the other hand, frequent testing is done on warm water shrimp at the port of entry in importing countries. The FAO/WHO risk assessment team considered this data. Over 20 000 samples were tested in Japan during 1995–2000. Data on 181 samples were available from the US FDA and findings from a survey of 752 samples were available from Denmark. Of the total of 21 857 samples tested only two samples imported into Japan from India were positive for choleragenic *V. cholerae*.

This risk assessment has concluded that even if all imported shrimp is consumed without any further cooking, the risk of cholera is about 2–4 cases in 100 years. This is an over-estimate because (a) imported volumes has been taken as edible volume and (b) it is common that shrimp are generally consumed after cooking – this would reduce the bacterial numbers by greater than six logs. Thus the risk would be very low or near to zero. This inference is supported by epidemiological data. Cholera is a reportable disease and good surveillance mechanisms exist in most developed countries importing warm water shrimp. The data show that there are no cases of cholera reported due to imported shrimp in these countries.

Shrimp intended for export is a high value item. It is produced using GHP/HACCP in the producing countries. Adoption of such procedures greatly reduces the risk of contamination of shrimp with choleragenic *V. cholerae*, and the risk assessment confirms this.

Listeria monocytogenes: Owing to the widespread occurrence of *L. monocytogenes,* some experts consider that it is extremely difficult (and expensive) to produce ready-to-eat (RTE) foods, including RTE seafood such as smoked fish, without sporadic occurrence of the organism at low levels (FAO, 1999). The dose-response relationships (and resulting risk estimate) indicate that such low levels constitute a very low risk. Yet there is currently no international agreement on "acceptable levels" of *L. monocytogenes* in seafoods. Some countries, such as the United States, Austria, Australia, New Zealand and Italy, require the absence of *L. monocytogenes* in 25 g of seafood (referred to as zero tolerance). Other countries (Germany, Netherlands, France) have a tolerance of < 100/g at the point of consumption. Others (Canada, Denmark) have a tolerance of < 100/g for some foods and zero tolerance for others – especially those with extended shelf lives and that can support the growth of *L. monocytogenes*. In addition, differences exist in the analytical methods adopted by different countries.

A recent FAO/WHO risk assessment on *L. monocytogenes* in RTE foods has prompted several countries to review food safety objectives regarding this bacterium. The risk assessment concluded that in the case of fish and fishery products, zero tolerance is not always appropriate. This work and other similar studies have led several countries to revise standards on *L. monocytogenes* in RTE foods. For example, the US FDA has recently called for public comments regarding requests that the agency establish a regulatory limit of 100/g for *L. monocytogenes* in foods that do not support the growth of the micro-organism.

Chemical contaminants: The present study shows that a major cause of border cases in 2001/2002 was due to chemical residues. This is because at the end of 2001 and during the first months of 2002 several control laboratories in Europe detected trace amounts of chloramphenicol and nitrofurans in imported animal products (e.g. shrimps and chicken). Following the safeguard provisions as foreseen in the European Union regulations for food imports of animal products, some producers and producing countries were temporarily withdrawn from the list of approved exporters and others were forced to rapidly implement drastic measures (e.g. analysis lot by lot). North America and Japan adopted similar controls, although using less sensitive analytical techniques.

In Europe, this increase was triggered mainly by improvements in analytical methods which significantly lowered the levels of detection for residues of these drugs. However, several producers and exporters argued that the products were not produced using these drugs, and that the trace amounts were at such low levels that they could not result from the illicit use of drugs but from environmental contamination. Some also argued that very low levels would pose no risk to consumers.

At the international level (FAO, 2004a), the Joint FAO/WHO Expert Committee on Food Additives (JECFA) is responsible for developing acceptable daily intake (ADI) values and maximum residue levels (MRLs) for veterinary drugs which are compatible with Good Veterinary Practices (GVP). These are adopted by the *Codex Alimentarius* Commission usually after one round of comments from member countries at the Codex Committee on Veterinary Drugs in Foods (CCRVDF). Due to the nature of toxicity (chloramphenicol, furazolidone) or lack of data (nitrofurazone), JECFA did not establish ADIs for these compounds. Consequently, CAC did not adopt MRLs for these compounds. Recently, JECFA re-considered chloramphenicol and concluded that there was no sufficient evidence that low level contamination of animal products could result from the occurrence in the environment.

The affected exporting countries were forced to take appropriate measures which include, for example, destruction of animal products, tighter controls on the use of illegal drugs, high investments into modern analytical equipment, and training of laboratory personnel. Most countries could meanwhile resume their exports.

It is important to distinguish between zero tolerance and a *de minimis* limit. The term *zero tolerance* is used for residues of substances which are considered to be unacceptable at any concentration, whereas concentrations below *de minimis* limits constitute only a theoretical risk that can be ignored (i.e. the presence below *de minimis* levels is acceptable).

While development of analytical chemistry continues to lead to significant improvements in the sensitivity of methods applied by research and control laboratories (for chloramphenicol, the limit of detection has decreased since 1970 by five orders of magnitude), problems continue to exist and the impact on trade is considerable. For example, it was recently revealed that trace amounts of a certain substance that had initially been identified as one of the nitrofuran metabolite markers indicating drug use had instead originated from other food ingredients, for example, flour and the packaging of foods.

It should be recognized that at the very low levels at which limits of detection and quantification (LOD/LOQ) are set, the uncertainty of analytical results increases. This needs to be respected when such results are communicated.

More importantly, the increased sensitivity of analytical methods raises the probability of finding trace amounts of substances that may originate from other routes than the administration of veterinary drugs to animals. Such routes could be environmental contamination, cross-contamination at the feed mill or the farm, or contamination from other sources like ingredient or packaging. An inventory of such substances without an ADI/MRL that potentially could cause problems in trade and are used under conditions of good veterinary practices is needed. For such compounds the nature of the existing data and the potential gaps in the data bases supporting their use should be identified and discussed.

Finally, modern analytical equipment is very expensive and requires resources and considerable theoretical knowledge and practical expertise which are not created overnight. The use of modern analytical methods puts considerable burden on the shoulders of control laboratories of exporting countries. Ways and means for proactive capacity building should be considered, instead of the current reactive approach for capacity building which starts after products have been rejected.

Conclusions

It is now universally agreed that food standards and control systems should be scientifically-based using risk assessment methods. While this approach has been used for some time for setting the MRL of pesticides, chemical contaminants and additives, it is relatively new for biological hazards and these unfortunately represent a major concern in fish trade. In fact, international guidelines are still being developed and only

a few countries, with significant scientific and financial resources, have been able to initiate fully fledged food microbiological risk assessments. Of these, only a few deal with seafood hazards. To have international value, these risk assessments will need, where appropriate, to incorporate data from different countries and regions where the fish species concerned are produced, traded and/or consumed. Unfortunately, developing countries, which lack the necessary human and financial resources, are not able to contribute adequately despite their important role in international fish trade.

To fill this gap, the thirty-second session of the CCFH identified, in 1999, a list of pathogen-commodity combinations that require expert risk assessment advice. In response, FAO and WHO jointly launched a programme of work. The ad hoc Joint Expert Meetings on Microbiological Risk Assessment, JEMRA, have the objective of providing expert advice on risk assessment of microbiological hazards in foods to their member countries and to Codex. This involved the implementation of a number of activities including the establishment of expert drafting groups to examine four of the 21 pathogen-commodity combinations identified in 1999 as priority issues (*Listeria monocytogenes* in ready to eat foods, *Salmonella* spp. in broilers and eggs, *Campylobacter* in poultry and *Vibrio* spp. in seafoods). The *Salmonella* and *Campylobacter* risk assessments have been recently finalized and the others are in the final stages. Among the other 17 pathogen-commodity combinations identified as priority issues, only *Salmonella* in fish is relevant to fish trade. Biotoxins in bivalve molluscs have been addressed recently through an international expert consultation called for by the CCFFP. The consultation completed risk assessments regarding the various biotoxins and its main recommendations will be debated during the next session of the CCFFP in 2005. Other similar mechanisms therefore need to be initiated to assess the risk of other pathogenic agents such as histamine, heavy metals, viruses and parasites relevant to fish trade and consumption. But important resources need to be mobilized for this to take place.

In the meantime, the major trading countries/regions are using microbiological criteria as interim measures. These are presented in various annexes to this study. Annex A.4 presents the draft EC regulation on microbiological criteria for foodstuffs that has been in development since 1999. Once approved, these will be used as interim measures awaiting formal risk assessments.

Finally, the present study seems to indicate that control at the borders, despite its limitations and doubtful performance, is given more priority over the "prevention at source" approach using GHP/GMP and HACCP based systems. These systems are presently widely recognized and industry has experimented with them and enjoyed their perceived benefits. Therefore, it seems appropriate that trading partners should be collaborating to build equivalent schemes based on the HACCP approach, using appropriate safeguards to protect consumer health. This way, the resources presently spent on border controls can be used more cost effectively.

3.6.8 Trade and economic implications

While international efforts are focussing on harmonization, several development agencies and donors have been exploring ways and means, both financial and technical, to assist developing exporting countries build national and regional capacity to meet international safety and quality standards. Proper assessment of the extent of assistance needed is key in decision making. Therefore costing the impact of substandard quality and safety products would be of interest not only to producers, processors, quality control authorities and consumers, but also to governments, donors, public health authorities and development agencies. In addition to the economic losses incurred because of fish spoilage, product rejections, detention and recalls and the resulting adverse publicity to an industry and even to a country, fish-borne illnesses cost billions of dollars to the community because of their costly adverse health effects, the loss of productivity and the medical expenses.

Furthermore, risk managers who will be weighing different mitigation options need economic data to assess the cost effectiveness of the different options presented to them. Unfortunately, the detention/rejections data, as they are collected, cannot be exploited to assess the cost of border cases. It is important to have access to such information in future for the reasons mentioned above.

The few studies which have looked at the economic impact of detentions and rejections have addressed it both at the macro- and microlevels. At the macroeconomic level, analysis focused mostly on estimating the economic costs of trade flow disruption cases. Whereas, at the microeconomic level, studies addressed mostly the implementation and maintenance costs of HACCP-based systems and maintenance. Fewer of these studies used the PAF (Prevention-Appraisal-Failure) model.

Macroeconomic level

Macroeconomic studies carried out by FAO (Cato *et al*., 1998) and others (Casewell, 2001; Allshouse *et al*., 2003) reported on specific trade flow disruptions that gave rise to international disputes over seafood safety and affected trade opportunities for producers, exporters and importers with the resulting economic impact. These cases have been discussed as to their relevance and technical and scientific justification in section 3.6.7. Following are key examples to illustrate the macroeconomic impact.

In 1997, the European Commission (EC) banned shrimp imports from Bangladesh because processing plants in Bangladesh did not meet EC standards. The estimated net cost of this August–December 1997 ban after considering shipments diverted to other countries was US$14.7 million to the Bangladesh frozen shrimp processing industry. As in many other less developed countries (LDCs), many plants in Bangladesh had difficulty meeting the required quality and safety standards because of a lack of sufficient funds to invest in quality control measures, more adequately trained staff, and expensive equipment. The Bangladesh Department of Fisheries, Fish Inspection and Quality Control had verified and certified compliance for only 20 percent of the seafood processing companies that previously were shipping to the European Union (EU). This ban affirms the apprehension of some LDCs that evolving standards can be a major market access issue.

During the period 1997–1999, Kenya and some other countries surrounding Lake Victoria have faced a series of food safety related restrictions of their fish exports. *Salmonella* contamination in Nile perch from Kenya in April 1997 led to border testing of all Nile perch consignments. Later, a cholera epidemic in East Africa in December 1997 resulted in a European Commission ban of imports of fish products from Kenya, Mozambique, the United Republic of Tanzania and Uganda until June 1998. The World Health Organization and FAO issued statements that the ban was not scientifically justifiable and the restrictions were lifted in June 1998. For Mozambique alone, the ban resulted in a loss of US$60 000 in trade per month while the ban was in place, equating to about 30 tonnes of fish that were not exported to the European Union market. Following reports of pesticide contamination of fish from Lake Victoria, another round of restrictions began in April 1999 that prohibited all fish exports from Lake Victoria to the European Union. As a result of these events, employment in the sector declined and industrial fish processing companies reduced capacity or closed.

In January 2002, the European Union suspended shrimp and prawn imports (and other products of animal origin) from China because of residues of chloramphenicol, and because of general deficiencies in the Chinese residue control system. Chloramphenicol has been linked to fatal leukemia and anaemia in humans. At the same time, FDA stepped up surveillance for chloramphenicol residues and residues of other unapproved aquaculture drugs in shrimp and crayfish imports from all countries and modified its testing methods so as to be able to detect the antibiotic at 0.3 part per billion or ppb, equal to that of Canada and the European Union. Subsequently,

products with detectable levels of chloramphenicol were refused entry into the United States, which temporarily suspended shrimp imports from China.

Although some of these seafood safety incidents appear to have resulted in relatively limited and short-term interruptions of trade and economic impacts, costs could continue to accrue from continued market diversions (i.e., lost market share), loss of momentum in the sector, decreased prices, and reduced capacity due to temporary or permanent plant closures. The above examples illustrate that food safety restrictions can act as barriers to trade as they can for any type of food. Despite the advantages of some developing countries in terms of preferential trading arrangements, food safety incidents can impose costly requirements on developing countries beyond their ability to afford compliance.

Microeconomic level

At the micro-level, the PAF model divides production costs relevant to quality and safety into three categories:

- **prevention costs** are the costs of any action taken to investigate, prevent or reduce defects and failures. They include the costs of planning and documentation, training, maintenance, personnel incentives;
- **appraisal costs** are the costs of assessing and recording the quality achieved. These are generally the easiest to measure and include: costs of inspection and control of raw materials, ingredients and packaging, costs of in-plant process inspection, laboratory costs and recording costs;
- **failure costs** are the costs arising from failure to achieve the quality specified. They can be divided into internal and external costs, depending on whether they are produced within the plant or after the transfer of product ownership to the customer. Internal failure costs include scraps, reprocessing, additional laboratory analysis, extended cold storage, low yield. External failure costs include product rejection, detention, recall, liability, bad publicity, etc.

The PAF model theory demonstrates clearly that the failure costs decrease significantly with an increase in prevention and appraisal expenditure. But, for each process and situation, there is a point at which total quality and safety costs will be at their optimum and any extra expenditure in prevention and/or appraisal will not bring additional improvement.

Public health managers have been more specifically interested in safety implications and their costs for public health. They studied food safety valuation by attempting to measure the effectiveness levels of a food safety public programme and the extent to which this programme achieved its goals. An example would be to measure the effectiveness of a programme designed to educate consumers on the safety of seafood, or of nutritional attributes of seafood, or the cost and benefits of a seafood HACCP programme.

In this respect, two estimation methods have been used: Cost of illness (COI) and the willingness to pay (WTP) method. The COI approach estimates the resources that society will save by avoiding food-borne illness. Social costs include costs to individuals, industry costs and public health surveillance costs. Costs to individuals can be measured through documenting medical costs, income or productivity loss, pain and suffering, leisure time costs, child care costs, risk aversion costs, travel costs, and vocational and physical rehabilitation costs, among others. Industry costs include product recalls, plant closings and cleanups, product liability costs, reduced product demand and insurance administration. Public health surveillance costs include disease surveillance costs, costs of investigating outbreaks and costs of cleanup. The WTP method actually measures peoples' willingness-to-pay for the reduced risk of death or illness in a specified population from consuming food. For example, FDA estimated benefits of implementing the HACCP programmeme for seafood ranging

from US$1.435 to US$2.561 billion. This represents total discounted benefits beyond the fourth year after implementation using a discount rate of six percent. Benefits included those derived from safety (cost savings resulting from reduction in illnesses from a variety of hazards), nutrition, increased consumer confidence, expert advice and reduced enforcement costs.

Estimates from the present study

As mentioned earlier, the above-mentioned studies need to be expanded beyond country cases to assess the economic implications of border cases in the main markets. Following is an attempt to estimate the cost of border cases in Japan using data presented in Chapter 2 and available on the MHLW Web site. Unfortunately, similar data were not available from the other importing countries.

Fish and seafood detentions cases in Japan, posted on the Web for 2000, numbered 201 for a total of 445 tonnes, yielding an average of 2.2 tonnes/case. Assuming that for the period covered under the present study, the organizational structure of fish trade to Japan (types of products, container size, shipment routes, means, duration, packaging, etc.) have not seen major changes, this figure was used to estimate 2001 and 2002 volumes and costs of border cases for Japan as follows:

Estimated Volume (in tonnes) of border cases for each product category = Number of cases for the product category x 2.2 (t/case)

$$\text{Estimated Value of border cases for each product category} = \frac{\text{Volume x total import value}}{\text{Total import volume}}$$

Table 56 estimates at 255.2 tonnes and 490.6 tonnes the total volume of Japan border cases respectively for 2001 and 2002. These represent a small fraction (respectively 0.0083 percent and 0.016 percent) of total imports to Japan in 2001 and 2002. They were valued at U.S$1 159 870 and US$2 230 465 (or 0.009 percent and 0.017 percent) of total import values respectively for 2001 and 2002. For the period 2001–2002, the average cost was estimated at US$4546 per ton detained and US$10 000 per border case.

These costs are much greater than the prevention costs that would have enabled the concerned companies to avoid these border cases. This is confirmed by several studies, compiled by Cato (Cato, 1998), which estimated the costs of implementing GMP and HACCP. In the United States, 1995 cost estimates of HACCP implementation for seafood processing plants averaged US$23 000 the first year and US$13 000 per year the subsequent years. In parallel, prices for seafood were also estimated to increase by less than one percent in the first year and less that 0.5 percent in subsequent years with the larger cost increase expected to decrease consumption by less than 0.5 percent.

Other studies estimated the costs of implementing in the United States of America the HACCP-based Model Seafood Surveillance Programme (MSSP) in the crab industry at US$3 100 per plant or US$0.04 per kg, representing 0.33 percent of processor price. Compliance costs were estimated at US$6 100 per plant. Investment costs averaged US$3 200 for large plants and US$1 700 for small plants. All in all, added cost per kg of product for compliance was US$0.02 for small plants and insignificant for large plants. For molluscan shellfish (oysters, mussels, clams), these costs were estimated at US$5 500 per plant. Annualized compliance costs per kg were estimated at US$0.11 for small plants and US$0.01 for larger plants.

In Bangladesh, costs per kg for the shrimp industry were estimated between US$0.26 and 0.71 for upgrading the plant and implementing HACCP and between US$0.03 and 0.09 for its maintenance. Those were higher than the figures estimates in the United States, mainly because the Bangladesh shrimp industry had to start from scratch and also had more small and medium enterprises than in the United States. It is well established

TABLE 56
Estimates of volumes and value of border cases for Japan

Product type	Import			Border cases		
	Volume (tonnes)	Value (US$ million)	Unit cost (US$/tonne)	Number	Volume (tonnes)	Value (US$)
2001						
Fresh fish	375 000	1 849	4 931	16	35.2	173 571
Frozen	2 344 000	8 647	3 689	84	184.8	681 727
Canned	281 000	1 786	6 356	4	8.8	55 933
Cured	34 000	320	9 412	11	24.2	227 770
Live	37 000	351	9 486	1	2.2	20 869
Total 2001	**3 071 000**	**12953**		**116**	**255.2**	**1 159 870**
2002						
Fresh fish	329 000	1 603	4 872	15	33	160 776
Frozen	2 362 000	8 730	3 696	174	382.8	1 414 829
Canned	353 000	2 033	5 759	4	8.8	50 679
Cured	36 000	329	9 139	28	61.6	562 962
Live	38 000	356	9 368	2	4.4	41 219
Total 2002	**3 118 000**	**13 051**		**223**	**490.6**	**2 230 465**

that economy of scale lowers the costs of safety and quality systems in large enterprises. But even though high, these costs represent only 0.31 percent (implementation) and 0.85 percent (maintenance) of 1997 price. (Cato and Lima dos Santos, 1998).

More importantly, these costs remain very low in comparison with the cost of border cases estimated in the present work at US$4.55 per kg. Indeed, the per kg costs of implementing and maintaining HACCP or HACCP-based systems would represent between 1.46 percent and 3.4 percent (United States of America) or 6.45 percent to 17.6 percent (Bangladesh) of the costs of border cases. Furthermore, and as stated before, these costs should be considered only as the visible part of the iceberg. The cost of transportation, the resulting adverse publicity, the requirements for systematic physical checks of subsequent shipments, the loss of clients confidence and ensuing market shares, market diversions, loss of momentum, decreased prices, reduced capacity due to temporary or permanent closures, are certainly additional costs with far reaching impact, but unfortunately difficult to quantify.

3.6.9 The case of aquaculture

Aquaculture has been the fastest growing food production sector in many countries for nearly two decades, with an overall growth rate greater than 11.0 percent per year since 1984, compared with 3.1 percent for terrestrial farm animal meat production, and 0.8 percent for landings from capture fisheries. The majority of the food fish production comes from land-based freshwater culture, and in some countries it exceeds that from freshwater capture fisheries.

Production in 2002 reached 51.4 million tons including aquatic plants, with 71 percent from China. Developing countries accounted for around 90 percent of production. All continents showed increases in production during 2000–2002 with the exception of Europe where production remained relatively unchanged (0.1 percent annual decrease).

The rapid growth in aquaculture production and trade has made the sector important to the economies of many countries, especially developing countries, both for food security and trade. Over the years, aquaculture products have helped to stabilize traded fish supplies and to bring down fish prices.

However, aquaculture products have been subject to close scrutiny for their safeness for consumption within international fish trade, i.e. the recent issue on veterinary drugs residues discussed in details previously in the present study. Likewise, aquaculture

products are target for *Salmonella* reduction strategies and there is increasing concern about organic contaminants in farmed fish products. Indeed, the farming of fish high up in the food chain leads to a concentration of contaminants. For example, "fishmeal and fish oil were found to be the most heavily dioxin contaminated feed materials with products from European fish stocks contaminated more heavily than those from South Pacific" (EU, 2000).

Consequently, it would be very beneficial to examine border cases from the perspective of the production method (i.e. farmed fish or captured fish). Unfortunately, the data does not allow this either in the trade data or the border case data. The increasing importance of aquaculture should be considered a good opportunity for better control over the whole food chain. However, this is still not the case for several hazards, most notably the chloramphenicol issue with farmed shrimp. Clearly, the introduction of good aquaculture practices will certainly improve the performance in this respect and it would be very nice to support this with actual and verifiable border case data. This requires that we are able to differentiate the production methods in both trade and border case data. It is now mandatory in the European Union to inform the consumer on the label on the production method, but trade statistics do not differentiate aquaculture from capture fisheries yet.

4. Conclusions and recommendations

The two preceding chapters have detailed the regulations governing imports into the European Union, the United States of America, Japan and Canada and have presented and discussed the data available about the border cases (detentions, rejections, re-exports, etc.) in the same countries/regions.

Key issues coming from these chapters have included a need to harmonize the procedures and methods used to govern imports, to base the actions taken on risk assessment where consumer safety is in question, and importantly to communicate the actions taken to all interested parties in a manner that is unambiguous, transparent and easily obtained and analysed. The final section of the previous chapter discussed several issues in more detail and provided recommendations as to how to improve harmonization.

This final chapter will make recommendations about what governments, and industry also, can and should do to facilitate trade in fish and fish products. It will also suggest further work that needs to be undertaken in this important, and not well studied, part of international trade.

4.1 BORDER INSPECTION SYSTEMS

The ultimate goal must surely be to have safe fish and fish products freely crossing borders with no impediments to trade unless the product will have a negative impact on consumers. Negative impact includes safety risk, quality defect or economic fraud.

As indicated earlier, there is growing and strong evidence that the implementation of HACCP-based systems have contributed to improve fish safety and quality, but there is also a growing awareness of the need for an integrated, multidisciplinary approach to food safety and quality, considering the entire food chain. The implementation of the food chain approach requires an enabling policy and a regulatory environment at national and international levels with clearly defined rules and standards, establishment of appropriate food control systems and programme at national and local levels, and provision of appropriate training and capacity building.

Likewise, fish safety and quality from a food chain perspective should incorporate the three fundamental components of risk analysis – *assessment, management and communication* – and, within this analysis process, there should be an institutional separation of science-based risk assessment from risk management – which is the regulation and control of risk.

As with the advent of HACCP and the move away from end product testing towards quality assurance techniques, it would seem that the same arguments about the failure of sampling to find failed products should apply to border control. Also, the HACCP/risk analysis approach is equally valid for use at borders – find what is critical to control in the whole trade system and then control those risks at the appropriate point. This may not necessarily be at the border. Where the control point is a border then put in systems to make sure the process does not go out of control. This requires measurement and limits.

For food safety issues, this would mean a move away from random sampling at borders. However, it would also necessitate a more complete understanding than we have at present of the main points in the food chain where a risk to consumer health is both high and likely to happen. This is where good science will provide answers, and

why governments must put such science as a priority for funding. The limited number of risk assessments to date needs to be expanded rapidly and internationally to provide the framework to ensure that unsafe food is not produced, or if it is, it is removed from the food chain. However, the systems used must also strive to remove the possibility of interrupting trade flows unnecessarily through inappropriate border actions.

Recently, a report from the Institute of Medicine and the National Research Council of the National Academies in the United States has concluded:

"The report also addressed safety criteria and concerns surrounding produce and seafood. Rather than rely on random screening of a small percentage of seafood imports, FDA should take steps to increase the understanding and application of its comprehensive guide for seafood safety in international commerce of fish and shellfish to ensure that safety hazards are properly detected and addressed prior to shipment".

In a separate study, examination of United States data concluded that *Salmonella* is a potential target for risk reduction efforts (Allshouse *et al*., 2003), and that most *Salmonella* contamination detentions are for shrimp. From the wider examination of border case data in this report and the discussions in the previous section, these conclusions can be rather limiting in that *Salmonella* in cultured shrimp may not be a significant safety risk (see 3.6.8) and that other contaminants are more worthy of risk reduction efforts, for instance, veterinary drugs in aquaculture products, heavy metals in some larger species, histamine in some fish species, etc.

Recommendation 1: Governments should commit to examining their inspection procedures and move towards the risk analysis approach where consumer health is at risk along the food chain from "farm or sea to table". This should ideally be done through sharing experiences between countries and communicating best practices to other countries. This would assist in harmonizing procedures and promoting equivalence schemes between importing regions. The Codex Alimentarius Commission should be provided with the means to strengthen its role in this process building on the work of the *Codex* Committee on food import and export inspection and certification systems CCFIEICS and the *Codex* Committee on fish and fishery products CCFFP.

Recommendation 2: The FAO Committee of Fisheries Sub Committee on Fish Trade should be asked to endorse further work by FAO in better understanding the impact of border actions on fish trade allowing targeted recommendations for improved trade flow between exporting and importing nations.

Recommendation 3: Governments and international bodies (World Health Organization, FAO and donors' community) should commit to continuing, and indeed expanding, the work into risk assessment of foods to provide the international framework for the assurance of food safety.

In addition to safety issues, many governments consider it their duty to control food to protect consumer from fraudulous practices and provide for fair trade practices. Unfortunately, several countries advocate presently the use of HACCP-based approaches to control safety hazards and end product control (whether at the border or before) for quality defects and economic frauds. The control of quality defects and economic fraud should also adopt a similar approach so that the control is at the points where the fraud is most likely to happen.

However, it must be recognized that the risk analysis approach does not have all the data yet needed to use this approach exclusively and several gaps still exist in the scientific literature. Also, some aspects of inspection do not always involve risks to human health, for instance, labelling, species substitutes and documentation issues. Therefore, the current practices of inspection will continue in the near future, mostly based on physical inspection with further examination of suspect lots.

However, as alluded to earlier, whether non-safety issues are handled by the same systems as food safety issues is an important point to be agreed upon internationally for consistency in international trade building on the ongoing work of the CCFFP on the Code of Practice for Fish and Fishery Products. This Codex committee recommends HACCP to deal with all safety and quality issues, using mandatory Critical Control Points (CCP) for safety hazards and voluntary Defect Action Points (DAP) for quality issues.

Recommendation 1: Governments should commit to examining their inspection procedures with respect to quality defects (freezer burn, honeycombing, etc) and economic frauds (net weights, species identification, etc) and decide whether border control is the best place to detect these problems, building on the ongoing work of the CCFFP and the CCFIEICS.

4.2 BORDER CONTROL DATA

Irrespective of the system employed, border control and inspection takes place on a daily basis and will continue to be so for some time before a fully-fledged "prevention at source" approach is harmonized and traceability schemes are well implemented to provide transparency among trading partners. This data is clearly valuable to the industry, but is also valuable to the inspection agencies to improve their systems, and to policy-making or advising bodies that can advise on best practice.

Unfortunately, the data is not both readily available and easily analysed with the exception possibly of Canada, though even these data are not complete in an ideal world. The previous chapter also noted the main fields that are completed for each record, though it varied slightly between the four countries/regions studied, and also noted the complete absence of either quantity or value of consignments where border actions were taken, important information to put figures to the costs involved in border control.

The paucity of this information in the public domain is a constraint to an understanding of the facts about border cases and their effect on trade. It also suggests a lack of transparency by those countries that do not make the data known. Without this data, it becomes more difficult to make sensible recommendations about what both importing and exporting countries can do to improve the situation. However, given the data available and analysed in this document, some recommendations can be made to improve the current situation.

Recommendation 1: All importing countries' governments should follow the example of the European Union, United States, Japan and Canada in making their border case data available, preferably on the internet. This should include archive information going back for as many years as is possible, given data availability.

Recommendation 2: Each record for a border action should preferably include at least the following data.

- date of action
- country of origin of product (i.e. exporting country)

– importing country (for European Union only)
– company name
– cause for action taken (e.g. cadmium, *Vibrio*, *Salmonella,* etc.)
– method of production (farmed or captured)
– species involved, including, ideally, the Latin name
– product form involved (e.g. frozen, canned, smoked, etc*.)
– action taken (re-export, destruction, sorting, re-packing, etc)
– quantity of consignment
– value of consignment (would be very useful, but could be commercially sensitive)

* for the product field, general terms such as *processed* should be avoided and a more specific term used. Different interpretations of the word *processed* causes ambiguity. Again, the CCFFP definitions should be adopted when applicable

Recommendation 3: The data made available on Web sites need to be harmonized between Web sites and need to be presented in a form that is easily further analysed. The suggested format is to present the data record by record in a spreadsheet using the fields above, as a minimum. Useful other fields include a category field to supplement the species field, e.g. crustacea, molluscs, cephalopods, etc., the product field, e.g. frozen/fresh, heat processed, cured, etc. and the cause field, e.g. chemical, microbial, labelling, documentation, etc. The terms used for these latter two category fields need to be both defined and universally accepted.

The Codex Alimentarius Commission has already published the combined texts for *Food Import and Export Inspection and Certification Systems* in the late 1990s. This provides guidelines for food import and export inspection and certification systems, including how to exchange information. It would be sensible for the CAC to extend these guidelines to take into consideration the above issues.

4.3 EXPORT PERFORMANCE AND DEVELOPMENT ASSISTANCE

The globalization and further liberalization of world fish trade, while offering many benefits and opportunities, also presents new and emerging safety and quality challenges. Fish safety and quality assurance in the new millennium requires enhanced levels of international cooperation in setting up standards and regulations. The SPS/TBT agreements of the WTO and the benchmarking role of the Codex provide an international platform in this respect. Consequently, the major fish producing, exporting or importing countries have launched, in the early 1990s, an overhaul of fish inspection regulations to set up the foundations for the implementation of the HACCP-based quality and safety systems. This is in conformity with the guidelines of the CAC. Regulations enacted by the European Union and the United States of America have increased the pace and set the trend for many other countries, especially the major commercial partners of the European Union and the United States of America. This highlights the need for better harmonization and recognition schemes. More recently, several countries have initiated national works on microbiological risk assessment, but several gaps and differences still exist. These differences provoke questions such as:

- How can we achieve common understanding of equivalence and of recognition/equivalence schemes?

- Why is the progressive implementation of HACCP not always leading to a gradual decrease in end-product sampling and inspection, including at borders?
- Is it realistic to expect a harmonization of microbiological standards for fish and fishery products?

On many of these issues, developing countries are at a disadvantage because of insufficient/inadequate national capacities and resources. International organizations such as FAO will need more resources to address the increasing requests from member countries.

What does also become evident, is that we could do with more data. This has already been concluded in the previous section.

However, with increasing demand for fish and seafood, the importance of the fisheries sector to the economies of many developing nations and the importance of developing nation exports to world trade in fish and fish products, the data does suggest that further assistance in safe seafood production is warranted.

Recommendation 1: **International development agencies** should continue to support developing nations in the production of high quality and safe fish and fish products. This effort should continue to focus on the basics (Good Hygiene Practice, Good Manufacturing Practice, Good Aquaculture Practice and HACCP) but also build capacity in the risk analysis approach to ensuring food safety.

Recommendation 2: Exporting nations' **governments** need to put, or keep, food safety as a priority for their food production both for domestic and exporting sectors and to expand support to the industry. Likewise, exporting **companies** need to continue to put food safety as their top priority in company business strategies.