FOOD AND FEED IMPORT PRACTICES OF FOREIGN GOVERNMENTS TO IMPROVE FOOD SAFETY

Final

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* Revisions were made only to Appendix F, based on feedback from Japan. In addition, in December 2012 the Australian Quarantine and Inspection Service (AQIS) name was replaced by references to the Australian Government Department of Agriculture, Fisheries and Forestry (DAFF). All references to AQIS in this report now refer to DAFF. No other changes were made.
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- Canada Food Inspection Agency (CFIA)
- Health Canada
- The Government of Chile Servicio Agrícola y Ganadero (SAG)
- The Government of Chile Ministry of Foreign Affairs, Office of Economical Direction (Dirección General de Relaciones Económicas Internacionales (DIRECON))
- The Government of Chile Ministry of Health
- Agencia Chilena para la Calidad e Inocuidad Alimentaria (ACHIPIA)
- Food Safety Authority of Ireland
- Ireland Department of Agriculture, Food, and the Marine
- The State of Israel Ministry of Agriculture and Rural Development
- The State of Israel Ministry of Health
- Japanese Ministry of Health, Labour and Welfare (MHLW)
- Japanese Ministry of Forestry, Fisheries and Agriculture
- Mexico Comisión Federal Para La Protección Contra Riesgos Sanitarios (COFEPRIS)
- Mexico Servicio Nacional De Sanidad Inocuidad Y Calidad Agroalimentaria (SENASICA)
- New Zealand Ministry of Agriculture and Forestry
- The Republic of South Africa Department of Agriculture, Forestry & Fisheries
- The Republic of South Africa National Department of Health
- National Regulator for Compulsory Specifications of South Africa
- The Netherlands Voedsel en Waren Autoriteit, VWA
- Customs Administration of the Netherlands
- United States Food and Drug Administration (FDA)

* In December 2012, the Australian Government notified FDA that the Australian Quarantine and Inspection Service (AQIS) name has been replaced by references to the Australian Government Department of Agriculture, Fisheries and Forestry (DAFF). All references to AQIS in this report now refer to DAFF.
EXECUTIVE SUMMARY

Under contract to the U.S. Food and Drug Administration (FDA), Eastern Research Group, Inc. (ERG) in collaboration with Catherine Carnevale, Louis Carson, and Robert Lake, independent subject matter experts, undertook this study of imported food and feed practices of foreign governments. The objectives of the study were:

- To determining what practices are currently used by other mature food safety systems that have similar goals and public health outcomes to that of the U.S. food safety system via:
  - Reviewing published literature, and
  - Interviewing country officials involved in the importation of food and feed using a validated semi-structured interview protocol.
- To performing a qualitative analysis of those practices identified.

The countries selected for the study included: Australia, Canada, Chile, Ireland, Israel, Japan, Mexico, New Zealand (NZ), the Netherlands, and South Africa. The interviews conducted with each country’s officials – either in-person or via digital video conference (DVC) – focused on a variety of topics ranging from government authorities and private sector involvement in the safety of imported food and feed to meeting World Trade Organization (WTO) obligations. Below is a brief synopsis of key findings related to each of the topic areas covered in these discussions.

ES.1 Roles and Functions of Agencies Responsible for Imports of Human Foods and Animal Feed

While several countries’ food and feed safety systems originated from export programs designed to promote market access and meet trading partner standards, each of the countries has legal frameworks and laws with the objective of protecting the country’s consumers from hazards in food, whether produced domestically or imported, assuring safe feeds for animals, and facilitating trade.

Each of the countries has government ministries or authorities functioning at multiple levels to help ensure the safety of imported foods and feed. Depending on the governmental structure of the country, authorities at the federal, state/territory, regional, and/or local levels might regulate and monitor imported food safety.

The variations in the administrative process of importing food can generally be categorized into differences in pre-border activities, such as importer registration and import licensing, import controls at the border, and post-border import controls.
ES.2 Inspection Programs

All countries studied use risk assessment to prioritize their regulatory efforts. Most countries identify high risk foods (Australia, Mexico, Israel, New Zealand, the Netherlands, Ireland and Canada), and some countries also place foods into categories of high, medium, and low risk (South Africa and Chile).

Other special inspection and monitoring requirements are imposed on an as needed basis when a foodborne outbreak has occurred in the exporting country. For example, each country has processes in place to impose additional requirements on trading partners in cases where foodborne disease has occurred, including animal related diseases that could impact human or animal health.

The regulatory authorities differ in their requirements for examinations, reviews and sampling/testing. Generally, countries perform testing for chemicals (pesticide residues, residues of veterinary drugs, additives [rarely], micro and macro nutrients [rarely], heavy metals, marine toxins, mycotoxins, and other contaminants) and microbiological pathogens.

None of the countries conduct individual inspections of food or animal feed manufacturers or shippers in other countries as part of routine surveillance activities.

All countries notify the public when a food safety issue of public health significance (imported or domestic) is occurring. Further, countries generally notify foreign governments when an imported food from that country affects human or animal health. However, countries differ in their notification procedures.

ES.3 Audits and Certification

Some country authorities assess the effectiveness of their import programs on a regular basis (Canada, Israel, Ireland, and the Netherlands), while an independent group, the Food and Veterinary Office of the European Commission, serves a similar function for EU Member States.

All of the countries rely to some extent on their trading partners’ programs to ensure that imported food and feed are safe.

Countries perform audits of foreign systems. However, these are mostly focused on high-risk products and/or on those products/countries where agreements exist. Few foreign audits are conducted in conjunction with equivalence agreements for FDA regulated products, but they are conducted for some animal products.

Reliance on third parties to carry out inspection or certification of imported food or feed is limited, as this role is largely undertaken by country officials, including state, territorial and local offices.
Most of the countries studied rely heavily on importers to ensure the safety of imported food and feed, and as such, importers are required to be registered in several countries (e.g., Israel, New Zealand, Mexico, and Ireland).

Several countries provide some form of guidance to promote good importer practices (Canada, New Zealand, Ireland, South Africa, and Australia).

Several countries recover some of the cost of operating their import system (New Zealand, Israel, the Netherlands, Ireland, Chile, Canada, and South Africa). Furthermore, Australia recovers all of the cost of running its inspection system by charging user fees.

**ES.4 Laboratory Support**

Governments use networks of public/private sector laboratories to support their food safety programs. All countries employ accredited laboratories to check compliance and conduct market surveillance. Some countries offer an approved list of government and private accredited laboratories that may be contracted to meet compliance requirements.

Most countries’ laboratories are accredited using ISO 17025 or a similar standard to qualify for testing of imported foods and feed.

**ES.5 Enforcement at Border**

When food or feed shipments are found to be non-compliant with safety or quality standards, countries reject the products and do not allow them to enter the country as is. When a product is rejected, the country food and feed authority notifies the importer or owner of the non-compliant product(s), and a determination is made as to whether the product should be destroyed, reconditioned, returned to the country or origin, or re-exported to another country.

The countries interviewed do not have product detention lists similar to FDA. If contaminants are repeatedly found in specific foods or feeds, the country food and feed authority might establish an additional set of requirements and testing to ensure product compliance.

Most countries do not have specific programs that address the intentional contamination of imported products.

**ES.6 Food-related Illness Outbreaks**

All countries have foodborne illness tracking capabilities and recall systems in place. Countries perform regular food and feed sample testing to assure compliance and occasional surveys of food safety. Some countries establish foodborne illness patterns using the national health system data.

None of the countries studied have a dedicated system solely for tracking imported foods after they clear customs. Rather, national capabilities to track imported foods derive from:
- Registration & recordkeeping rules for importers, and
- Traceability requirements for food and feed operators

ES.7 Export Programs

All countries have export certification programs which focus on assuring market access for country food/feed exports, and most of these programs focus on high-risk foods. Some of these programs include exporter registration, exporter licensing, and/or export certification.

ES.8 World Trade Organization (WTO) Obligations

All of the countries are sensitive to the need to document their risk-based rationale for import-related decisions.

While some countries are not involved in equivalence determination in any form (e.g., South Africa), other countries have equivalence agreements for particular products or product categories within a food safety system (e.g., New Zealand, Mexico, Canada). Most countries, however, do not have equivalency agreements for FDA-regulated foods.
1 INTRODUCTION

The US Food and Drug Administration (FDA) is currently shifting away from an intervention and response-focused model for assuring the safety of imported food and feed to focus on prevention, with producers and importers held accountable for the safety of imported foods. The enactment of the Food Safety Modernization Act (FSMA) on January 4, 2011 has provided FDA with additional tools and authorities to support this transition. FSMA aims to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it. Specific topics and areas of food safety addressed in FSMA will require further measures relating to imported food and feed to be implemented. Some of these topics to be addressed include:

- Tracking and tracing of foods,
- Intentional adulteration of food,
- Foodborne illness surveillance,
- Targeting inspection resources for ports of entry and foreign facilities,
- Certification of certain imported foods,
- Foreign supplier verification,
- Inspection of foreign facilities,
- Voluntary qualified importer programs,
- Prior notice of imported food shipments,
- Accreditation of third party auditors,
- Neutralizing import program costs, and
- Building capacity of foreign governments with respect to food safety.

While the study reported here was initiated prior to the enactment of FSMA, information gathered in the study may help to inform the process as FDA works to refine and develop a modernized, prevention-based food safety system for domestic and imported foods. The goal of the study was to gather information about the food and feed import programs developed and used by other governments, including those that are recognized to be at the forefront of good import practices. Foreign governments vary in their approaches to ensuring the safety of imported food and feed, and they implement a range of import controls, many of which are directly applicable to the newly established import safety requirements under FSMA.
2 STUDY OBJECTIVE

This study was designed to help FDA determine the range of practices currently employed by other countries to ensure the safety of food and feed imports by:

- Determining what practices are currently used by other mature food safety systems that have similar goals and public health outcomes to that of the U.S. food safety system via:
  - Reviewing published literature, and
  - Interviewing country officials involved in the importation of food and feed using a validated semi-structured interview protocol.
- Performing a qualitative analysis of those practices identified.

3 STUDY METHODOLOGY

This study relied on two primary data sources, 1) review of publically available literature on the statutes, regulations, guidelines, procedures, and agreements pertaining to the countries studied; and 2) semi-structured discussions (that were based on a validated protocol) with food and feed safety government officials in other countries. Countries were invited by FDA to participate in the study, with selection based on common sense criteria, including: 1) neighboring countries with which the U.S. has strong relationships; 2) inclusion of a range of economies; 3) consideration of countries where FDA has international offices; and 4) consideration of countries included in the United Nations Food and Agriculture Organization (FAO) “Mature Food Safety Systems” study. Table 1 depicts the countries that participated in the study.

<table>
<thead>
<tr>
<th>Country</th>
<th>Type of Country Discussion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Digital Video Conference (DVC)</td>
</tr>
<tr>
<td>Canada</td>
<td>Digital Video Conference (DVC)</td>
</tr>
<tr>
<td>Chile</td>
<td>In-person</td>
</tr>
<tr>
<td>Ireland</td>
<td>In-person</td>
</tr>
<tr>
<td>Israel</td>
<td>In-person</td>
</tr>
<tr>
<td>Japan</td>
<td>Paper Review</td>
</tr>
<tr>
<td>Mexico</td>
<td>In-person</td>
</tr>
<tr>
<td>The Netherlands</td>
<td>In-person</td>
</tr>
<tr>
<td>New Zealand</td>
<td>Digital Video Conference (DVC)</td>
</tr>
<tr>
<td>South Africa</td>
<td>In-person</td>
</tr>
</tbody>
</table>

It should be noted that due to unforeseen country circumstances, Japan was unable to participate in the country interview portion of the project but provided written information pertaining to the research topics. Given the timing and other constraints, information obtained from Japan is presented in Appendix F but is not incorporated into the analysis presented in the main body of this report.
FDA also provided the study team with import practice topics of interest that should be addressed during discussions with food safety authorities in each country and subsequently in the qualitative analysis. These topics included:

- Government authorities and private sector involvement in the safety of imported food and feed,
- Inspection programs,
- Audits and certification programs,
- Laboratory support,
- Enforcement activities at the border,
- Food-related illness outbreak surveillance systems,
- Export programs, and
- World Trade Organization (WTO) obligations.

One parameter of the study was to approach the aforementioned topics with an FDA lens; researching measures as they apply to the FDA regulated foods.¹

Using the FDA topics of interest as guidance, the study began with an extensive literature review of each selected countries’ publically available statutes, regulations, guidelines, procedures, government-to-government agreements and other literature addressing the topic of imported food and feed safety practices. We then compiled the information for each country into a background research document that served as a starting point for country discussions (see Figure 1).

The discussions with the competent authorities for food and feed safety for each of the nine countries included in the study were conducted over a three-month period.² Former FDA officials serving as subject matter experts (SMEs) on our project team facilitated each of the discussions. The discussions with Australia, Canada, and New Zealand were conducted via digital video conference (DVC) at the FDA White Oak facility. For the remaining countries, two project team members traveled to each country to conduct in-person discussions.

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¹ FDA regulated foods include: seafood, dairy and shell eggs, fruits and vegetables, processed foods, dietary supplements including vitamins and minerals, and foods for special dietary uses.

² Not all countries had animal feed officials present during the interviews.
discussions with the country’s food and feed safety officials.

The country discussions were intended to be semi-structured in nature; guided by the topics of interest, but allowing for free-flowing conversation that could adjust to the information provided by participating officials. During some country visits, officials also made informational presentations or took the project team on site visits to see the implementation of import practices first-hand.

We then integrated the information obtained through these country discussions with the background research compiled from the literature review into a separate Annex for each country. Each country’s Annex was then provided to the participating government officials for review and comment. The revised Annexes are provided as appendices to this report.

4 RESULTS

This section presents a qualitative analysis of imported food and feed practices of the nine countries. Further information on each country’s practices can be found in the country appendices attached at the end of the report. While the comparative analysis and country appendices address the same informational topics, the section numbering and headings in each are not identical.

The remainder of this report refers to the term “country food and feed authority(ies)” where the authority and implementation/operations consist of a combination of national and local, district or state officials.

4.1 Roles and Functions of Agencies Responsible for Imports of Human Foods and Animal Feed

4.1.1 Governmental and Private Sector Involvement in Ensuring the Safety of Imported Food and Feed

Each of the participating countries has government ministries or authorities functioning at multiple levels to help ensure the safety of imported foods and feed. Depending on the governmental structure of the country, authorities at the federal level, state/territory, regional, and/or local levels might regulate and monitor imported food safety. Countries’ imported food safety systems are overseen by a range of authorities.

At the federal level, the primary oversight for food safety might rest with a department or ministry of health (Chile, South Africa, and Israel), health and agriculture
In addition to the primary food safety authorities, many countries have other collaborative authorities to help ensure the safety of imported food (see Figure 2). These authorities might be responsible for specific types of products such as seafood (e.g., South Africa and Chile) or agricultural products\(^5\) (e.g., Chile and Mexico), or they might oversee specific import-related issues such as foodborne illness outbreaks (e.g., Canada and Australia).

In nearly half of the participating countries (the Netherlands, Australia, New Zealand, and Canada), the same regulatory authorities governing imported food also govern animal feed. In other countries (Ireland, Israel, Chile, Mexico, and South Africa) a federal agriculture-based ministry or department is the primary regulatory authority for imported feed. Regardless of the country’s structure for the safety and oversight of imported food and feed, authorities share many of the same responsibilities including: development of safety regulations, coordinating surveillance activities, and risk assessment.

In addition to the primary food safety authorities, many countries have other collaborative authorities to help ensure the safety of imported food (see Figure 2). These authorities might be responsible for specific types of products such as seafood (e.g., South Africa and Chile) or agricultural products\(^5\) (e.g., Chile and Mexico), or they might oversee specific import-related issues such as foodborne illness outbreaks (e.g., Canada and Australia).

National customs departments also help control and monitor imported goods at the border. Still other government ministries or authorities help monitor imported goods once they have been cleared for entry into the country, including local health authorities (e.g., Mexico and South Africa).

Private sector involvement in countries’ official imported food and feed safety systems is limited. Some companies operate laboratories for food-related testing and analyses (e.g., New Zealand). The Netherlands also has semi-autonomous public/private bodies that assist in food safety operations by helping to provide export certification.

### 4.1.2 The Food Importation Process

The variations in administrative process of importing food can generally be categorized into differences in pre-border activities, such as importer registration and import licensing,

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\(^3\) New Zealand is in the process of integrating its food and import safety programs under the umbrella of one agency through legislation expected to be in place in 2012.

\(^4\) As Member States of the European Union (EU), Ireland and Netherlands also operate under broader health, food safety, and veterinary authorities of the EU.

\(^5\) Fruits, vegetables, meat, or feed might be classified as agricultural products, depending on country.
import controls at the border, and post-border import controls. The common import controls implemented by countries at each phase in the import process can be seen in Table 2.

Table 2: Common Approaches to Food Import Controls

<table>
<thead>
<tr>
<th>Import Process Phase</th>
<th>Common Approaches</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Border Controls</td>
<td>Require importers to:</td>
</tr>
<tr>
<td></td>
<td>• Register or be listed</td>
</tr>
<tr>
<td></td>
<td>• Obtain licenses</td>
</tr>
<tr>
<td></td>
<td>For import shipments, require importers to:</td>
</tr>
<tr>
<td></td>
<td>• Submit import applications</td>
</tr>
<tr>
<td></td>
<td>• Obtain country import documentation</td>
</tr>
<tr>
<td>Border Controls</td>
<td>Customs review of documentation</td>
</tr>
<tr>
<td></td>
<td>Customs inspection of food and feed</td>
</tr>
<tr>
<td></td>
<td>• physical inspection may be also done by:</td>
</tr>
<tr>
<td></td>
<td>– Agricultural agency</td>
</tr>
<tr>
<td></td>
<td>– Food safety agency</td>
</tr>
<tr>
<td>Sampling and Testing Practices</td>
<td>Risk-based identification of “high-risk” foods</td>
</tr>
<tr>
<td></td>
<td>• Evaluation of inherent food risk</td>
</tr>
<tr>
<td></td>
<td>• Evaluations of importer history</td>
</tr>
<tr>
<td></td>
<td>• Product information from other countries</td>
</tr>
<tr>
<td></td>
<td>High-risk foods require, at most inspection locations, additional sampling and testing</td>
</tr>
<tr>
<td>Post-Border Controls</td>
<td>• Quarantine or controlled storage until testing and approval process is completed</td>
</tr>
<tr>
<td></td>
<td>• In-country food surveillance systems</td>
</tr>
<tr>
<td></td>
<td>• Traceback, emergency response capability</td>
</tr>
</tbody>
</table>

Some countries have pre-border or pre-entry requirements for importers as well as foods and feeds to be imported. Some require importers to be registered, licensed, or listed with the national food and feed authority (e.g., Ireland, the Netherlands, Canada, Israel, and New Zealand). Other countries might require the importer to submit an import application (e.g., Mexico) or country entry documents (South Africa, the Netherlands, and Ireland) to the national food and feed authority before products are imported. For example, South Africa requires import permits, while Australia requires import permits for foods with a high risk categorization, termed “restricted.”

For goods arriving at the border, some countries (e.g., the Netherlands and Ireland) have specified points of entry for animal origin products and non-animal origin products with increased risks, while other countries do not require product-specific points of entry for imported goods. Food or feed arriving at the border for importation might be handled by the country’s customs officials and/or the country’s food and feed authorities for food and feed safety. The overlapping, yet often separate, import responsibilities of customs and food and feed safety authorities might be made explicit through memoranda of understanding (MOU) or detailed in import or food and feed safety-related legislation.

Customs authorities are involved to varying degrees in countries’ systems for ensuring the safety of imported food and feed. While some countries utilize Customs as the primary check of imported goods entering the country (e.g., Mexico), others might utilize Customs for specific
tasks that work in conjunction with the efforts of food and feed safety authorities. For example, most countries’ customs or quarantine authorities review product documentation at the border (Canada, Mexico, Chile, Australia, Israel, Ireland, and the Netherlands) and refer physical checks of products to food and feed safety officials (an exception being Mexico). Some countries’ customs authorities provide a preliminary assessment about the admissibility of products into the country after their initial paperwork or product review (Canada and Mexico), while countries such as Ireland refer non-compliant products to food health and safety officials for further inspection. Countries such as Ireland, the Netherlands, and Canada use computerized databases that contain product-specific information that can be accessed by food and feed safety authorities, as well as Customs, to help communicate potential import issues or product concerns requiring targeted surveillance at the border.

At the border, product handling varies according to the product itself and/or level of risk to human or animal health. Country food and feed authorities for food/feed safety or customs officials might use the preliminary information obtained through importer or product registration to identify products as high or low risk goods (e.g., Israel, Australia, New Zealand, and Chile) or as agricultural products (e.g., Mexico and Chile). Product categorization might be determined by a review of tariff codes (e.g., New Zealand), product testing (e.g., Israel), or matching product regulations requiring increased import controls (e.g., Ireland).

Foods categorized as presenting higher risk to human health might undergo increased inspection or sampling. Most of the countries studied require, at a minimum, a review of product documentation at the border, regardless of risk categorization. Documentation might include health certificates, especially for high risk products like fish or animal-based products (e.g., the Netherlands). In some countries’ (e.g., Ireland) food of non-animal origin or other foods that are considered to be of low risk to human health might enter the country freely, without further import controls.

Countries have varying practices for sampling and inspecting imported goods usually based on product risk categorization, previous compliance history of the product, or if the product is a new product never before imported into the country. Some countries’ customs officials refer products requiring testing to food safety authorities, and those officials might then take samples for laboratory analysis (Ireland and South Africa). For example, importers of high risk or “prescribed” foods imported into New Zealand must obtain a conditional release permit and the products cannot be sold until the product’s test criteria are met and approved by a Food Act Officer. In Chile, however, all food products enter controlled storage after quarantine and customs, where application must be made to Health for release and distribution of the product. In contrast, countries such as Canada sample imported products through annual sampling and monitoring plans after border clearance.

While the majority of countries destroys or returns foods or feed that are determined to be non-compliant, some countries may allow products to be brought into compliance and then allowed entry. Other non-complying products may be directed to a non-food use and allowed entry. Non-complying products that don’t pose a risk to health may be allowed entry with a “commitment to correct” (e.g., Canada).
Thus, while importers bear primary responsibility for the quality of imported goods, countries verify product compliance with pre-border, border, and post-border food safety mechanisms.

4.1.3 Laws, Regulations for Imported Food and Feed Safety

The laws and regulations with relevance to the safety and oversight of imported food and feed can be, generally, grouped into the following categories (also see Table 3):

- Consumer protection in terms of food safety and/or public health,
- Granting authority for the oversight of imported food and/or feed,
- Product-specific, and
- Import-specific.

### Table 3: Country Legislation Relating to Imported Food Safety

<table>
<thead>
<tr>
<th>Type of Law/Regulation</th>
<th>Examples of Countries Having Type of Law/Regulation [a]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Consumer Protection</strong></td>
<td></td>
</tr>
<tr>
<td>Food Safety and/or Public Health</td>
<td>Australia  Mexico  Ireland</td>
</tr>
<tr>
<td></td>
<td>Canada  The Netherlands  South Africa</td>
</tr>
<tr>
<td></td>
<td>Chile  New Zealand  Israel</td>
</tr>
<tr>
<td><strong>Granting authority for the oversight of imported food and/or feed</strong></td>
<td></td>
</tr>
<tr>
<td>Using one piece of legislation</td>
<td>Mexico  Chile  The Netherlands</td>
</tr>
<tr>
<td>Using more than one piece of legislation [b]</td>
<td>Israel  South Africa  Ireland</td>
</tr>
<tr>
<td><strong>Product-specific</strong></td>
<td></td>
</tr>
<tr>
<td>Agricultural Goods</td>
<td>South Africa</td>
</tr>
<tr>
<td>Meat</td>
<td>Canada  Ireland  The Netherlands</td>
</tr>
<tr>
<td>Seafood</td>
<td>Canada</td>
</tr>
<tr>
<td>Feed</td>
<td>South Africa  Israel  Canada</td>
</tr>
<tr>
<td></td>
<td>New Zealand  The Netherlands  Ireland</td>
</tr>
<tr>
<td><strong>Import-specific</strong></td>
<td></td>
</tr>
<tr>
<td>General Importation of Food and Feed</td>
<td>Australia  The Netherlands</td>
</tr>
<tr>
<td>Import/export certificates</td>
<td>South Africa  Ireland</td>
</tr>
<tr>
<td>Import controls</td>
<td>Canada</td>
</tr>
<tr>
<td>Internal guidance policies</td>
<td>Ireland  The Netherlands</td>
</tr>
<tr>
<td></td>
<td>Canada  Australia</td>
</tr>
</tbody>
</table>

[a] List of countries having particular laws and/or regulations is not comprehensive.

[b] Legislation for each ministry or agency having authority in the import process.

While the legislative content may vary, all countries have policies intended to ensure overall human health and safety of food. The overarching aim of this legislation across countries is to ensure that food is safe and fit for human consumption. In addition to laws that address basic food safety, countries also have legislation or regulations pertaining to the quality and safety of particular product categories such as agricultural goods (e.g., South Africa), meat (e.g.,
Canada, the Netherlands, and Ireland), seafood (e.g., Canada), and feed (e.g., South Africa, New Zealand, Canada, Israel, the Netherlands, and Ireland).6

Legislatively, countries also provide for the authority or oversight of imported food and feed. While some countries (e.g., Mexico) may use one piece of legislation to grant these authorities, other countries (e.g., Israel) might have more than one piece of authority-granting legislation; one for each ministry or agency authorized to provide oversight in the importation process. The authority, and to whom it is granted, for oversight and responsibility for the imported food and feed process also varies by country.

For example, while the Netherlands has integrated responsibility for enforcing all imported food legislation under the umbrella of one national authority for food and feed, and New Zealand is currently undergoing this process, other countries divide the responsibility among multiple authorities; each overseeing the implementation of policies for certain types of products (such as agricultural goods) or regulations (such as labeling requirements) under their jurisdiction.

Lastly, some countries have legislation and regulations that are specific to imported food and feed. Some countries have legislation which broadly addresses the importation of food and/or feed products (Australia, South Africa, the Netherlands, and Ireland). Countries also have policies and regulatory guidelines that address more specific import-related issues such as: import/export certificates (e.g., Canada), import controls (e.g., Ireland and the Netherlands), and a range of internal guidance policies (e.g., Canada and Australia).

4.1.4 Handling of Products Transshipped Through a Third Country as Compared to Directly Imported Products

Most countries (e.g., EU countries, NZ and Australia, Israel, Mexico) capture country of origin information on import documentation that can then be used to trace transshipped products should it be necessary. EU countries, such as the Netherlands and Ireland, require country of origin information for export certificates, which are required for exported and transshipped products. Contrastingly, South Africa views transshipments as cargo-in transit, and it is handled differently than imports in that it passes, shipment intact in the same packaging, through the country without being imported. In general, most countries do not have explicit transshipment procedures.

6 Netherlands and Ireland have a different legislative structure than the other countries interviewed, as their import related laws and regulations are primarily dictated at the EU level and incorporated on the country level through the adoption of statutory instruments.
4.2 Inspection Programs

4.2.1 Mechanisms to Prioritize Food and Feed Import Surveillance Activities

All countries studied use risk assessment to prioritize their regulatory efforts. Most countries identify high risk foods (Australia, Mexico, Israel, New Zealand, the Netherlands, Ireland, and Canada), and some countries also place foods into categories of high, medium, and low risk (South Africa and Chile).

The criteria and methods that countries use for determining high risk foods differ (see Table 4). For example, Canada has been using FDA’s iRisk software, a web-based risk ranking tool currently being beta tested by FDA. Canada is utilizing this software to synthesize information from multiple sources (e.g., combination of foods and the hazards that they present). Chile uses water content as one criterion, with foods having a high water content presenting a higher risk than dry foods. European countries categorize animal origin foods, including meat, dairy, seafood, honey, as high risk for their ability to transmit diseases to humans and animals. As a general rule, the countries view meat, poultry, seafood, and dairy products as high risk and shelf stable processed products as low risk.

High risk foods might require more testing and/or pre-import notification, certification, and verification than goods considered low risk. Most countries have control plans on how these foods should be inspected and tested and whether those measures should occur prior to export, upon entry to the importing country, or both. For example, in Australia, all foods that are considered “risk” foods (defined as having a medium to high risk to public health) are held pending inspection and testing for contaminants and pathogens (not all tests are performed on each). After five consecutive shipments have passed testing requirements, the inspection rate falls to 25 percent of consignments and, after 25 consecutive passes, the inspection rate falls to five percent of shipments. For non-risk foods (“surveillance foods”), Australia applies a five percent inspection rate to shipments, and consignments are not held pending analysis. Regardless of risk categorization, if a food fails an inspection or test, 100 percent of shipments of a particular product entity (e.g., oranges from a particular importer sourced from a specific farm) are inspected and tested as they undergo the previously described 100%-25%-5% inspection regimen.

For certain products, or in particular countries (e.g., Chile), food or feed consignments might clear Customs’ documentation checks and move into controlled storage facilities before the food safety authorities take charge. This enables control of the products until the food safety authorities make their decisions to inspect, sample or test the shipments, as the owner of the products must apply to the food safety authority for release of the product into domestic commerce.
Table 4: Product Risk Determination and Inspectional Priorities [a]

<table>
<thead>
<tr>
<th>Country</th>
<th>Foods Categorized as</th>
<th>Inspectional Frequency Affected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia [b]</td>
<td>Risk or Surveillance Foods</td>
<td>All risk foods inspected/tested</td>
</tr>
<tr>
<td>Canada</td>
<td>Food requiring increased surveillance</td>
<td>Meat and fish undergo increased surveillance</td>
</tr>
<tr>
<td>Chile</td>
<td>High, Medium, Low Risk</td>
<td>Inspectional frequency determined by level of risk.</td>
</tr>
</tbody>
</table>
| Ireland [c]   | • Non-animal origin foods or feed not subject to increased controls  
                • Non-animal origin foods or feed subject to increased controls  
                • Animal origin foods or feed                                  | • Non-animal origin foods or feed not subject to increased controls may freely enter the country  
                • Non-animal origin foods or feed subject to increased controls are inspected according to regulation  
                • Identity and physical check rates are determined by the EU regulations and vary between 5 to 50% of a shipment  
                • Animal origin foods or feed are inspected as directed by annual inspection program or documented procedures |
| Israel        | Sensitive or Regular                         | • 100% of fish products  
                • 5% of “regular” foods inspected daily                                                         |
| Mexico        | High Risk (for hazardous foods)             | High risk products receive the greatest scrutiny                                                 |
| The Netherlands [c] | • Non-animal origin foods or feed not subject to increased controls  
                     • Non-animal origin foods or feed subject to increased controls  
                     • Animal origin foods or feed                                  | • Non-animal origin foods or feed subject to increased controls are inspected according to regulation for each food type  
                • Identity and physical check rates are determined by the EU regulations and vary between 5 to 50% of a shipment  
                • Animal origin foods or feed are inspection depends on the product and place of origin  
                • 1%, 20% or 50% of the product is physically checked |
| New Zealand [b] | Prescribed foods                             | • All risk foods inspected/tested  
                • Food Act Officer must be satisfied that prescribed food is in compliance with relevant regulations and standards |
| South Africa  | High, Medium, Low Risk                       | Inspectional frequency determined by level of risk.                                               |

[a] Information in this table is based on country discussions and may not be exhaustive of each country’s methods or practices for each table category.  
[b] Food Standards Australia New Zealand (FSANZ) determines food risk levels for both Australia and New Zealand, so while the terminology between countries may differ; both countries adhere to similar risk standards.  
[c] The Netherlands and Ireland adhere to the same EU standards, regulations, and guidance for imported foods. Any difference in informational content in the table is the resultant of information provided during the country discussion rather than a difference in country requirements.
None of the countries studied performed food facility inspections in foreign countries, as a general rule, unless the inspections were part of an arrangement with the government of the foreign country, such as equivalence or mutual recognition agreements. In such cases the inspections were part of looking at that country’s food control system, as opposed to inspecting a single facility.

### 4.2.2 Special Screening and Trading Partner Requirements where Disease or an Outbreak has Occurred

Other special requirements are imposed on an as needed basis when a foodborne outbreak has occurred in the exporting country. For example, each country has processes in place to impose additional requirements on trading partners in cases where foodborne disease has occurred, including animal related diseases that could impact human or animal health.

Bovine spongiform encephalopathy (BSE, “mad cow disease”) is a disease for which countries have special import screening requirements in place. All countries studied have special screening for BSE. Generally, countries do not allow animal feed of bovine or ruminant, in some cases mammalian origin, in ruminant feeds.

Country food and feed authorities may apply restrictions or screening procedures for emergency situations concerning emerging food safety issues. Several of the countries mentioned handling specific international food safety issues such as foods containing colorings not intended for human consumption (e.g., Sudan Red), contaminants (e.g., melamine in food and animal feed), radiation, and foodborne disease outbreaks. Mexico has the authority to set an emergency six-month standard where conditions have changed in an exporting country, prohibiting imports from that country.

### 4.2.3 Percentage of Imported Food Shipments Examined and the Relationship between Risk-ranking of Foods and Volume of Imported Foods Examined

Each of the countries participating in this study described a somewhat different, risk-based approach to managing the safety of imported foods (see Section 4.2.1). The approaches discussed include:

- Shipment examinations (by customs, quarantine, agriculture, health, sometimes national or state/provincial authorities), and
- Sampling and testing at the border or when in domestic commerce.

The regulatory authorities differ in their requirements for examinations, reviews and sampling/testing. Generally, countries perform testing for chemicals (pesticide residues, residues of veterinary drugs, additives (rarely), micro and macro nutrients (rarely), heavy metals, marine toxins, mycotoxins, and other contaminants,) and microbiological pathogens. Import documents are examined by customs, quarantine or the food safety authority in all cases for completeness, mandatory certificates, or possible fraud, but there might not always be verification of consignment identity and integrity. Most countries also examine labeling.
There are also differences in product surveillance that are based on the risk associated with the particular food and source of the food. Israel, for example, focuses on foods of animal origin, with every shipment inspected to ensure that it has the required veterinary certificate, refrigerated car license, temperature verification and labeling. These verifications are made at the municipal veterinary inspection points at the health district level. Ireland stated that microbiological testing is of primary interest for imports. Chile emphasizes labeling checks within its regulatory program.

Most countries require customs officials (e.g., Canada, Chile, Mexico, and the Netherlands), quarantine officials (e.g., Australia), food and feed safety authorities (e.g., Ireland) or their health department (e.g., Israel) to review 100 percent of the import food and feed documentation. The documents required for review vary in all of the countries and, often, depend on the food type. For example, in the Netherlands and Ireland, all importers of food and feed of animal origin or foods of non-animal origin presenting increased risk must submit a Common Entry Document or a Common Veterinary Entry Document to the national food and feed authority with jurisdiction over that food product to be reviewed before product entry. Additionally, animal products must have health certificates which are reviewed at Border Inspection Posts by national food and feed authorities for each shipment. EU regulations specify the identity and physical check rates for foods of non-animal origin, bulk and bagged feeds, and animal products from countries where an equivalence agreement is in place (i.e., reduced physical checks).

Not all countries were able to provide estimates of the number of visual examinations and sampling/testing efforts they undertake, but some numbers were available. For example, Chile stated that of the 55,000 samples taken in the annual market survey of food products, 30 percent are tested for chemicals such as pesticide residues, illegal additives and veterinary drugs; while 70 percent are tested for microbiological pathogens. Canada’s post border testing of foods (other than meat and poultry) for 2010-2011 covered 8,594 samples tested for microbial contaminants (including bacteria, viruses and parasites) and 16,085 samples tested for multiple chemical hazards.\(^7\)

In several countries products categorized as presenting increased risk to human or animal health are also subjected to mandatory examination or physical checks (e.g., Chile, the Netherlands, Ireland, Mexico, Israel, New Zealand, South Africa, and Australia). In South Africa, for example, all canned meat and canned fish and 90 percent of frozen fish are inspected. In New Zealand, 100 percent of “prescribed” foods are initially inspected and the rates fall if no shipment failures are found; for non-prescribed foods, consignment inspection and test rates are low unless concerns are raised. In Israel, 100 percent of seafood shipments are sampled. Frozen fish and ready to eat products undergo laboratory tests, while fresh fish are sampled at the border. This is in contrast to requirements for non-high risk foods, which are certified by the import department, with five percent of the applications inspected, three percent of the shipments inspected at the quarantine station, and the remainder released.

\(^7\) Additional data can be found in the individual country appendices.
4.2.4 Types of Examination and Testing Processes Used for Ensuring Animal Feed and Feed Ingredient Safety

Most countries regulate animal feeds somewhat differently than foods for humans. While the health ministry is often the primary regulatory agency for foods, agriculture departments or quarantine services often regulate animal feeds (see Section 4.1.1). For example, in Australia, animal feeds are regulated as quarantine materials and are highly regulated on this basis. Quarantine products must come from an approved source and must undergo a risk-based assessment before entry. Many countries require that feed exporters or the feeds themselves be registered, approved, and/or accompanied by safety/health certificates (e.g., the Netherlands, Ireland, Australia, South Africa, and Canada). This may be true for both livestock feeds and pet foods.

Imported feeds might be monitored for the presence of chemical residues, pesticides, heavy metals, mycotoxins, salmonella, drug residues, drug guarantees (in the case of medicated feed), or BSE, depending on the importing country. In some countries, feeds might be tested for the presence of ruminant protein and checked for ruminant DNA (e.g., Australia).

For EU countries, including the Netherlands and Ireland, the EC Food and Veterinary Office inspects countries intending to export to the EU to verify the effectiveness of national control systems to implement EU standards.

4.2.5 Inspections of Food or Animal Feed Manufacturers or Shippers in Other Countries

None of the countries conduct individual inspections of food or animal feed manufacturers or shippers in other countries as part of routine surveillance activities. Circumstances where countries might undertake foreign inspection include:

- Follow-up investigations for a foodborne illness outbreak ostensibly caused by an imported food, or

- An assessment of the exporting country’s food control system (e.g., to establish a preclearance arrangement or to assess equivalence). In such cases, individual facilities are not inspected by the importing country except as part of assessing how the exporting country inspects such facilities.

Some countries studied have numerous agreements with other countries and conduct foreign site visits. For Ireland and the Netherlands, the European Commission’s Food and Veterinary Office (on behalf of all of the 27 EU Member States) audits “third country” control systems for high risk products and perform site visits in this regard. Other countries find foreign inspections to be costly and mentioned that insufficient resources preclude inspections of food manufacturers or food control systems in other countries (e.g., South Africa), and, in Australia’s case, the exporting country must be charged if such an assessment is performed.
4.2.6 Notifying Foreign Governments of Unsafe Food and Feed Products

Countries generally notify foreign governments when an imported food from that country affects human or animal health. Countries differ, however, in their notification procedures.

- All EU Member States, including Ireland and the Netherlands, participate in the Rapid Alert System for Food and Feed (RASFF), an electronic notification system managed by the European Commission DG-SANCO in Brussels. With RASFF, the EC notifies non-EU countries when one of their products exported to an EU country (or Norway, Liechtenstein, or Iceland) is non-compliant with EC food safety requirements. This notification requests that the exporting country take corrective action. Notifications are for routine violations, as well as those of health significance.

- Canada contacts foreign government officials when a food safety problem involving an imported food is of public health significance or has public health implications for that country.

- New Zealand notifies the government food and feed authority when imports of food covered by a government-to-government agreement fail verification testing, as does Australia.

All countries notify the public when a food safety issue of public health significance (imported or domestic) is occurring. For example:

- In Mexico, the health ministry manages a national alert system, Rapid Alert, which communicates information about foodborne illnesses or contamination problems. This system notifies government officials and industry, as well as the public and media.

- Canada’s food recall process categorizes food found to be unsafe into three classes. When a food product is categorized as Class I (where there is a reasonable probability that the consumption to the food will lead to serious or life-threatening health consequences or the probability of a foodborne outbreak situation is considered high), the Canadian Food Inspection Agency notifies the public through a newspaper and media release, and posts the notification on the CFIA website.

- New Zealand’s Ministry of Agriculture and Forestry publishes information to consumers on significant food safety risks that might involve domestic or imported foods.

- In South Africa, if a recalled food product has been offered for sale to the public, a public notification is made.
4.3 Audits and Certification

4.3.1 Assessing and Measuring the Effectiveness of Food and Feed Safety Import Programs

Some country authorities assess the effectiveness of their import programs on a regular basis (Canada, Israel, Ireland, and the Netherlands), while an independent group, the Food and Veterinary Office of the European Commission, serves a similar function for EU Member States (see 4.3.2). For instance, the European Union (EU) regularly assesses the performance of national food and feed authorities in Ireland and in the Netherlands (as well as other EU Member States). Other countries might perform evaluations of agencies with responsibility for portions of the import process (e.g., South Africa) or for specific programmatic product areas (e.g., Mexico).

Information regarding the criteria used for import program evaluation is limited, though Canada indicated that factors considered in evaluating programs include the following:

- Compliance with relevant food policies,
- Health and safety standards, and
- Program design and delivery.

Programmatic measures considered by officials in Ireland include:

- Impartiality, quality and consistency of controls,
- Adequate laboratory capacity,
- Sufficient number of suitably qualified and experienced staff,
- Adequate facilities and equipment,
- Adequate legal powers,
- Food and feed business operators cooperate with staff performing official controls,
- Documented procedures are available, and
- Records are maintained.

4.3.2 Extent of Reliance on Trading Partners’ Food Safety Programs to Ensure that Imported Foods or Animal Feed are Safe

All of the countries rely to some extent on their trading partners’ programs to ensure that imported food and feed are safe. Several countries rely, considerably, on the food safety systems of other countries (Mexico, the Netherlands, and Ireland). Australia explicitly relies on the exporting country’s food safety programs where certification arrangements exist. Canada and
New Zealand rely on importers to ensure that imported foods are safe, and Israel relies to some degree on the risk assessments performed by other countries in determining product safety.

Some countries use additional measures (e.g., audits of producers, exporters and shippers) to verify the safety of trading partners’ food and animal feed. For example, South Africa employs a system of “horizon scanning” which involves assessing various information sources, e.g. media, internet, etc., of food safety challenges, incidents, and outbreaks in order to assess the likelihood of those issues affecting South Africa.

For EU Member States Ireland and the Netherlands, the EU’s Food and Veterinary Office (FVO) conducts audits of equivalence agreement partners (i.e., third countries outside the EU) to verify systems standards. The FVO also audits the work of the Member States on a regular basis. EU’s FVO assesses the performance of the Member States’ food and feed authorities, countries aspiring to join the EU (referred to as candidate countries), and non-EU countries intending to export to the EU (referred to as non-EU countries), to verify the effectiveness of national control systems for meeting EU standards in the areas of food safety, animal health and welfare, and plant health.

4.3.3 Use of ISO, Global GAP or Other Assurance Systems

Most countries rely on the International Organization for Standardization’s (ISO) standard 17025 for accrediting laboratories (Canada, the Netherlands, Ireland, Mexico)8. South Africa and Chile’s laboratories for agricultural testing are certified to ISO 17025, while their food testing under the jurisdiction of health departments/ministries are currently in the process of obtaining certification.

New Zealand utilizes ISO 17020, the international standard for inspection bodies, and Australia accepts the use of Global Gap9 to help provide quality assurance for imported goods. Israel recognizes ISO 9000, ISO 9001, and ISO 22,000 as well as the Hazard Analysis and Critical Control Points (HACCP) system of preventive controls.

4.3.4 The Nature and Frequency of Foreign Food Audits

As mentioned in Section 4.3.2, the European Commission’s FVO conducts audits for animal origin products in countries with which they have equivalence agreements. These audits include dairy and seafood. Generally, however, countries do not conduct foreign audits for the types of food and feed products regulated by FDA.

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8 ISO 17025 specifies the “general requirements for the competence to carry out tests and/or calibrations, including sampling” (ISO, 2005).
9 Global Gap is a voluntary standard-setting body for the certification of production processes of agricultural (including aquaculture). More information can be found on the Global Gap website at: http://www.globalgap.org/cms/front_content.php?idcat=9
Some countries perform government-to-government assessments of food and feed safety control systems and subsequent audits of those systems. These types of assessments might be used to establish pre-clearance or recognition arrangements with the exporting government, and it is often the responsibility of the exporting country to designate the facilities that are able to meet the specific criteria and conditions of the arrangement. Thus, when audits are conducted subsequent to the arrangements, they might be conducted at those designated facilities.

Few foreign audits are conducted in conjunction with equivalence agreements for FDA regulated products, but they are conducted for some animal products. As an example, equivalence is the basis for importing meat and poultry in Canada, but not for fish. Similarly, Mexico has an equivalence agreement with the U. S. on meat and poultry, but not on FDA regulated foods.

4.3.5 Utilization of Third-parties to Conduct Inspections and/or Product Certification

Reliance on third parties to carry out inspection or certification of imported food or feed is limited, as this role is largely undertaken by country officials, including state, territorial and local offices. Some countries (e.g., Australia, New Zealand, and Chile) rely on approved third-party laboratories for testing and analysis of imported food and feed products. In Australia, third-party assurances are used for some other purposes for imported foods, for example, manufacturers’ declarations about the ingredients and processing of a food. Third-parties have also been relied on in the context of Hazard Analysis and Critical Control Points (HACCP), a widely recognized preventive control system used to ensure that food is safe (Australia and South Africa).

4.3.6 Arrangements and Agreements with Other Governments Relating to Imported Foods or Animal Feed

Several of the countries have Memoranda of Understanding (MOU) or reduced inspection agreements with other countries (Canada, Australia, New Zealand, and the Netherlands). For instance, the Netherlands has reduced physical check agreements with some countries for several categories of food (fish, dairy, meat, honey, poultry, gelatin, eggs, and mollusks). Australia and New Zealand have a mutual recognition agreement in place which limits the imported foods requiring inspection at their respective borders to those classified as risk category foods. South Africa has technical cooperative agreements in place with several countries, for example agreements concerning health guarantees and inspector training. Australia has arrangements with other countries involving the certification of particular products. Countries having these certification agreements with Australia may have their system re-evaluated when the agreement is about to expire or be renewed.

For the Netherlands and Ireland, arrangements such as MOUs pertaining to food and feed imports are made on behalf of Member States through EU agreements.
4.3.7 **Registration or Licensing of Firms that Import and/or Export Foods or Animal Feed**

Most of the countries studied rely heavily on importers to ensure the safety of imported food and feed, and as such, importers are required to be registered in several countries (e.g., Israel, New Zealand, Mexico, and Ireland). Countries vary as to with whom importers are required to register. For instance, New Zealand requires firms that import food and feed to register with Customs. Ireland requires importers of animal products and feed to register with agricultural authorities, while importers of most foods of non-animal origin are required to register with health authorities.

In Canada, importers of certain cheeses, seafood, and fresh fruits and vegetables are required to obtain a license from the country’s food and feed authority.

4.3.8 **Surveys of Imported Foods and Feed**

Some countries perform surveys of imported food and feed that are distinct from targeted sampling and testing programs. Several countries perform national food surveys that include the surveillance and testing of risk products (e.g., Mexico), or product areas of emphasis that change annually (e.g., Chile). Canada performs two programs, one directed at chemical residues and one on microbiological pathogens. Other countries perform surveys of particular products. For example, South Africa samples fish and fishery products for pesticides and PCBs. In Australia, surveys of imported goods are performed at the state level, and the federal authorities support these efforts through funding the testing of imported foods included in the surveys.

4.3.9 **“Good Practices” Programs for Foods and Feed Importers**

Several countries provide some form of guidance to promote good importer practices (Canada, New Zealand, Ireland, South Africa, and Australia). For example, Canada has general guidance for food importers, but also has a voluntary code of practice based on HACCP guidelines for importers wanting to go beyond the minimum import controls. New Zealand provides importers with guidance documents pertaining to import standards and clearance procedures, and the Netherlands provides a help desk to assist importers.

### Figure 3: Import Program Cost Recovery

<table>
<thead>
<tr>
<th>Country</th>
<th>Percentage</th>
<th>Cost Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mexico</td>
<td>11%</td>
<td>Recover Some Cost of Operating Import Program</td>
</tr>
<tr>
<td>Australia</td>
<td>11%</td>
<td>Recover Some Cost of Operating Import Program</td>
</tr>
<tr>
<td>Canada</td>
<td>78%</td>
<td>Recover All Costs of Operating Import Program</td>
</tr>
<tr>
<td>Chile</td>
<td></td>
<td>Topic not Addressed</td>
</tr>
<tr>
<td>Israel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ireland</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The Netherlands</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New Zealand</td>
<td></td>
<td></td>
</tr>
<tr>
<td>South Africa</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4.3.10 **Description of Import Program User Fees and Cost Recovery Systems**

Several countries recover some of the cost of operating their import system (New Zealand, Israel, the Netherlands, Ireland, Chile, Canada, and South Africa). Canada recovers a small amount of its costs through user fees, and South Africa charges for re-testing of imports. Australia recovers all of the cost of running its inspection system by charging user fees. In particular, Australia is authorized to charge fees for services.
that include:

- Quarantine risk profiling (cargo import clearance),
- Inspection, surveillance and treatment of imported goods,
- Inspection and clearance of sea containers,
- Fumigation monitoring of imports,
- Lodgment of quarantine entries,
- Applications and assessments of import permits,
- Overtime and shift services by an officer outside the ordinary hours of duty,
- Registration of premises for the purposes of performing quarantine inspections, and
- Audits to ensure compliance with program procedures and regulations.

### 4.3.11 Incentives to Increase Industry Involvement in Ensuring that Imported Foods Meet Safety Standards

Country incentives for encouraging industry participation in ensuring the safety and quality of imported food are primarily in the form of:

- Decreased regulatory involvement, and
- Simplified or streamlined importation process.

For example, both South Africa and Australia noted that importers who have good compliance records for food and feed imports were not as likely to be inspected or tested as those who had poor compliance histories. Australia also has an assurance-based arrangement that allows qualifying importers to avoid having their food held pending inspection and sampling. Aside from decreased regulatory involvement, the Netherlands streamlines the import process by providing importers with a “one-window operation” which allows them to interact with a single entity during the import process rather than multiple government agencies. Several countries also attempt to increase industry awareness and involvement by providing educational materials or training to the industry (New Zealand, Canada, Ireland, and Mexico).

### 4.3.12 Obstacles to Industry Participation in Ensuring that Imported Foods Meet Safety Standards

Obstacles to industry participation in ensuring the safety standards of imported food were not gleaned from most country conversations. Canada and New Zealand both posited that the importers’ lack of understanding of importer requirements and their responsibilities for meeting those requirements may be considered obstacles by industry.
4.4 Laboratory Support

All countries participating in this study use laboratories as part of their food import program to measure compliance with applicable standards and conduct post-market surveillance. National food and feed authorities have government laboratory facilities at federal and/or state/local levels but, at times, rely upon academic or other government laboratories outside of their jurisdiction to provide unique expertise, analysis, equipment or technology (also see Table 5).

Most countries indicated that their laboratories are accredited using ISO 17025 or a similar standard to qualify for testing of imported foods and feed (see Section 4.3.4 and Figure 4). The accreditation is usually overseen and implemented by an independent, government-recognized or government entity, where laboratories must pay a fee and seek accreditation for specific microbiological, chemical, filth or other methodological capabilities. For example, Standards Council of Canada (SCC), International Accreditation New Zealand (IANZ), the South African National Accreditation System (SANAS), and the Irish National Accreditation Board (INAB) serve as accreditation bodies.

Table 5: Private Laboratory Support for Import Testing

<table>
<thead>
<tr>
<th>Country</th>
<th>Country Activity or Practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Accredited third party laboratories are identified by government to perform import testing/sampling. The laboratories work directly with importers and charge the importers for their services.</td>
</tr>
<tr>
<td>Canada</td>
<td>Accredited third party laboratories are contracted for testing of imports, including product verification, compliance, and detection of harmful organisms.</td>
</tr>
<tr>
<td>Chile</td>
<td>Accredited private laboratories participate in import testing.</td>
</tr>
<tr>
<td>Ireland</td>
<td>The private laboratory sector includes nearly 40 government approved laboratories that offer routine food safety analytical laboratory services to industry.</td>
</tr>
<tr>
<td>Israel</td>
<td>Accredited private laboratories are allowed to participate in import testing.</td>
</tr>
<tr>
<td>Mexico</td>
<td>Accredited laboratories are also audited against national laboratory norms and then their results can be accepted in enforcement, certification, or equivalence agreements.</td>
</tr>
<tr>
<td>The Netherlands</td>
<td>While accredited third-party laboratories supply data in support of imported food requirements, government must confirm these test results through their own testing before deciding on the shipment’s status.</td>
</tr>
<tr>
<td>New Zealand</td>
<td>Approved and accredited laboratories can be used for testing of food imports.</td>
</tr>
<tr>
<td>South Africa</td>
<td>One part of the government, the National Regulator for Compulsory Specifications, will work with private laboratories but the rest of the government relies on its own laboratories.</td>
</tr>
</tbody>
</table>

In some countries (Mexico, Canada, South Africa, New Zealand, Australia and Chile), government, academic, and private laboratories are accredited and recognized by food and feed safety authorities to fully participate in the imported food and feed program. In other countries (Ireland, Israel, and the Netherlands), accredited private laboratories provide services only to industry. Some countries also require verification of third party laboratory results. For example, in cases where Chile, Ireland and the Netherlands require importers to submit private laboratory
testing results to show compliance for imported foods and feeds, the government laboratory must also complete a confirmatory test for release of the imported shipment.

Country food and feed authorities often use research institutes or national standard-setting facilities to conduct research supporting their imported food and feed programs. For example, Institute for Food Safety (RIKILT), is an independent research institute located in the Netherlands which is contracted as an EU reference laboratory providing services to all EC members.

4.5 Enforcement at Border

4.5.1 Handling Foods That Do Not Meet Requirements and Preventing the Importation of Unsafe Foods

As described throughout this report, country food and feed authorities employ multifaceted programs to ensure the safety and compliance of imported foods and feeds, both pre-arrival as well as after product arrival at the border or port of entry (see Section 4.1.3 for Steps in the Importation Process and Section 4.2 on Inspection Programs).

When food or feed shipments are found to be non-compliant with safety or quality standards, countries reject the products and do not allow them to enter the country as is. When a product is rejected, the country food and feed authority notifies the importer or owner of the non-compliant product(s) and a determination is made as to whether the product should be destroyed, reconditioned, returned to the country or origin, or re-exported to another country. In some countries (e.g., Ireland and the Netherlands), officials negotiate with the owner of the consignment and the country of dispatch, where appropriate, about how the non-compliant product will be handled. While all countries might permit the destruction of non-compliant goods, not all countries (e.g., Canada, New Zealand) allow for non-compliant goods to be reconditioned for re-entry. For product violations where equivalence or export certifications are concerned, the country authorities for food and feed notify the trading partner, as well as the importer and/or owner.

The countries interviewed do not have product detention lists similar to FDA, but in all cases where violations are found, corrective actions are initiated to assure that future shipments will be in compliance with requirements. In certain cases, for example where contaminants are repeatedly found in specific foods or feeds, the country food and feed authority may establish an additional set of requirements and testing to ensure product compliance. In Ireland and the Netherlands, products of increased risk are listed in Annex I of EC 669.
Some countries’ importers and registered producers (e.g., Ireland, the Netherlands, and Mexico) are required to have traceability systems in place to locate and recall suspect goods when requested.

4.5.2 Programs for Investigating and Responding to Intentional Contamination of Foods

While most countries in this study recognize the possibility of intentional contamination of food, few countries indicated that structured processes or programs were in place for dealing with the issue. Canada was the only country to note specific intelligence efforts to address the intentional contamination of food. Some countries have authorities or programs that are charged with addressing intentional contamination of food as part of their responsibilities (e.g., Israel and South Africa); however, these countries do not necessarily have established programs or protocols for investigating the issue. Other countries’ food safety programs (e.g., Mexico and Chile) do not address the topic of intentional contamination of food, but officials indicated that the problem would be addressed by the proper authorities if detected (see Figure 5).

National food and feed authorities in Ireland indicated that intentional contamination was not currently part of their food and feed safety risk assessment methodology due to the low occurrence of such issues and the focus on current food/feed safety risk priorities, such as animal origin hazards. Some countries also noted that current surveillance, emergency response, and recall procedures have been used to respond to prior incidences of intentional contamination (such as melamine in pet food and milk products) and were deemed satisfactory. Most of the country food and feed authorities indicated that intentional contamination, such as product tampering, was more appropriately undertaken by law enforcement, intelligence or national defense agencies, and they would provide expertise and support as required.

Several countries stated that it is the port/border operations officials that establish and oversee security procedures and operations for imported foods and feeds, while country food and feed authorities are responsible for focusing on product documentation, identification, safety and quality.
4.6 Food-related Illness Outbreaks

4.6.1 System for Tracking Imported Foods after Entry

The ability to track imported foods once they are cleared at the point of entry depends on two related components:

- Registration and recordkeeping requirements for importers, and
- Traceability requirements for food and feed operators.

None of the countries studied have a dedicated system solely for tracking imported foods after they clear customs. Rather, authorities rely on each of the above components to track imported foods in case of recall or outbreak investigations.

Most of the countries studied (Ireland, the Netherlands, Canada, Australia, New Zealand, and Mexico) require importers to register with Customs and/or another competent government authority. While in some countries the registration requirement applies only to the importer, other countries (e.g., Ireland and the Netherlands) also require the registration of products that the importer is bringing into the country. The importer is often required to maintain records related to its suppliers, such as contact information, lot/batch numbers, etc. and to produce these records in a timely fashion for any recall or outbreak investigation. Further, in some countries (Australia), imported foods are required to be labeled not only with the importer but also the original supplier information, including the lot/batch numbers of the original supplier for the given product.10

Once the imported food is released into commerce, the ability to track it relies on the traceability requirements in place for all food and feed operators in the country. Ireland, the Netherlands, Mexico, Australia, and New Zealand all require that food and feed operators maintain the capability to trace food shipments (imported and domestic) “one step forward and one step back.” Food and feed operators are required to maintain records that document the names and addresses of their suppliers and customers, as well as the nature of the product and date of delivery. The EU countries included in the study (Ireland and the Netherlands) further encourage operators to keep information on the volume and quantity of a product; the batch number, if there is one; and a description of the product, such as whether it is raw or processed.

Thus, when an imported food is implicated in an outbreak investigation, the importer of the product is a critical link in identifying customers who bought the products. However, the speed with which food authorities can track any food or feed implicated in a recall or outbreak

10 It is unclear how this applies to imported bulk goods, such as dry grains and produce.
appears to depend on the ease of access to records (e.g., computerized records) and the records’ accuracy and completeness.

4.6.2 Systems for Identifying Foodborne Illness Outbreaks

In the countries studied, the majority of foodborne illnesses are identified through: 1) consumer complaints, 2) illnesses recorded by local health authorities, and/or 3) regular disease surveillance efforts, often at the national level.

Health authorities generally identify foodborne illnesses, and these authorities function at the district (Israel), provincial (South Africa), state/territory (Mexico, Australia, New Zealand), regional (Chile) and national (Canada, Ireland, the Netherlands) levels. Some countries (e.g., Ireland, the Netherlands) utilize established networks, such as inter-agency computerized information networks, to communicate foodborne illness issues to other relevant authorities and agencies. Most of the countries studied noted efforts to track foodborne illnesses back to a source (Australia, Canada, Ireland, Israel, the Netherlands, New Zealand, and South Africa).

Country systems for tracing illnesses back to a potential source have varying components, but generally revolve around an incident or outbreak investigation conducted by government officials at all levels. Investigations might be conducted on local or national levels, depending on the scale of the foodborne illness outbreak. Outbreak investigations concerning imported food might be headed by health authorities (e.g., South Africa), the country food and feed authority(s) for food safety (e.g., Chile, Mexico), or a combination thereof (e.g., Ireland, Canada). Where countries have multiple agencies with responsibility over food (Australia, Mexico), government agencies with jurisdiction over the particular food product or food type concerned in the outbreak are typically involved in investigating the cause of the foodborne illness.

Foodborne illness investigations that implicate imported food may require review of product documentation such as importer registration information, product registration, product certifications, or transshipment records by country food and feed authorities. Results of foodborne illness investigations are used to inform future import practices and requirements. For example, previously implicated food or feed items might be given additional scrutiny before being granted an import certificate or country entry document. Food products determined as having an increased level of risk or associated with previous food safety outbreaks or incidents might undergo increased sampling at the border or become subject to a product ban.

4.7 Export Programs

All of the countries studied have programs for ensuring the safety of food and feed exports. These programs may include:

11 Some countries perform surveillance activities on more than one scale.
Each country issues paper (e.g., the Netherlands, South Africa) or electronic (e.g., New Zealand, Australia) export certificates to provide assurance to importing countries that their food exports should be accepted. In most countries, food and feed safety authorities issue export certificates directly, while other countries, such as New Zealand and the Netherlands, utilize third parties as part of the country food and feed authority’s certification process. Mexico allows eight of its states to issue export certificates.

Countries might require certification for the export of:

- Meat and meat by-products (Australia, Canada, Ireland, and the Netherlands),
- Fresh produce (Israel and Australia)
- Eggs and egg products (Ireland and Australia),
- Dairy products (Australia, Israel, and Ireland),
- Fish and fish products (Canada, Australia, and Israel), and
- Feed (the Netherlands)

Countries also issue official export certificates upon request. For example, upon request, Chile issues food export certificates, South Africa will certify consignments of fish products and Canada will certify animal feed.

Countries might attest in the export certificate that the importing country’s standards have been met (e.g., Chile, Israel, and New Zealand). Canada issues such certificates for animals and animal products, including fish. South Africa certifies that fish exports to the EU meet EU requirements and that exported fresh fruit and vegetables meet the importing country’s phytosanitary standards. Some of the studied countries also provide lists of establishments that meet the listing requirements of importing countries (Australia, Ireland, the Netherlands, and South Africa) or meat exporters (Israel). Other countries certify that exports of non-animal origin food meet their own standards. (Canada, Ireland).

Countries (e.g., the Netherlands, Ireland, and South Africa) issue certificates that include information such as:

- Product name,
- Quantity,
- Unique certificate identification,
- Exporter name and address,
- Date,
- Name and address of receiving party, and
- Statement indicating that the food is safe.

Several of the countries studied have licensing or registration requirements for exported goods in addition to export certification requirements. For example, Israel requires food exporters to be licensed. New Zealand requires that exporters of animal derived products intended for human or animal consumption be registered. Australia requires facility registration and export permits for some exported foods, mostly those that are derived from animals.

4.8 World Trade Organization (WTO) Obligations

There are several topics of interest concerning national import practices and World Trade Organization (WTO) obligations. One such topic is consistency of measures and requirements pertaining to domestic and imported products. To help ensure that policies regarding domestic and imported products are consistent, countries enforce the same standards for both domestic and imported goods. During discussions, several of the countries mentioned the importance of internationally recognized food safety standards, such as those adopted by the Codex Alimentarius Commission and recognized by the WTO.\(^\text{12}\)

Another topic of interest regarding import practices and WTO obligations relates to the obligation to document the scientific justification for any food safety measures that may restrict imports. Article 5 of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)\(^\text{13}\), requires that measures are based on an assessment of risk, as appropriate to the circumstance. Most countries document their requirements for scientific justification of specific measures through regulations or policies that encompass imported food and feed products. For example, Ireland and the Netherlands document their scientific justification in European Commission regulation (EC No. 178/2002). Australian imported foods must meet the foods standards code which is support by risk assessment. Canada’s Regulatory

\(^{12}\) The Codex Alimentarius Commission (CAC) is jointly sponsored by the World Health Organization and the Food and Agriculture Organization of the UN. Over 180 nations are members of the CAC which establishes consensus standards for food and feed in international commerce.

\(^{13}\) The SPS Agreement aims at “1) Recognize the sovereign right of Members to provide the level of health protection they deem appropriate; and 2) Ensure that SPS measures do not represent unnecessary, arbitrary, scientifically unjustifiable, or disguised restrictions on international trade (WTO, 2011).
5 CONCLUDING REMARKS

Process Guide requires that proposed regulations, including those for imported foods, be published with a Regulatory Impact Analysis Statement (RIAS).

Equivalency of countries’ food and feed safety systems is also a topic of interest related to WTO. Equivalence is covered in Article 4 of the SPS Agreement. While some countries are not involved in equivalence determination in any form (e.g., South Africa), other countries have equivalence agreements for particular products or product categories within a food safety system (e.g., New Zealand, Mexico, Canada). Equivalence agreements pertaining to entire food safety systems are less common. Member States of the EU are one example of countries that are considered to have mutually equivalent food safety systems.

Lastly, some countries have formal procedures for recognizing the competency of the regulatory systems of trading partners. Canada uses Mutual Recognition Agreements to recognize other countries’ inspection systems as providing adequate oversight. For Ireland and the Netherlands, system recognition requirements are detailed in EU regulation which states that the adequacy of a foreign country’s food safety system is based on its comparability to the food safety system and standards of the EU. In New Zealand, foreign countries can apply for an initiation of an equivalency assessment and pre-clearance arrangement, which, if granted, would signify that adequacy of the producing country’s regulatory system for food safety.

5 CONCLUDING REMARKS

This report is based on a review of publically available literature for the nine countries studied, site visits and discussions conducted with national authorities responsible for ensuring the safety of food and feed, and contributions of subject matter experts having knowledge of food and feed safety systems. After the compilation of all information on a given country’s programs, a draft report was provided to the participating authorities, providing an opportunity to submit comments and changes for clarification and correction for the respective country report. While the number of country systems included in this study is small, there was sufficient information and exchange with country officials to gain insights and a general understanding of each country’s imported food and feed practices.

The nine import systems contained in this study have matured and taken shape within political, cultural, trade and budgetary environments that may be unique to the country itself and/or its affiliated members. In many cases, these factors have resulted in the streamlining and innovation of the importation process for importing food and feed; moving country food and feed authorities to focus on the greatest food and feed safety risks. While several countries’ food and feed safety systems originated from export programs designed to gain market access, each the countries has legal frameworks and laws with the objective of protecting the country’s
consumers from hazards in food, whether produced domestically or imported, assuring safe feeds for animals, and facilitating trade.

While it is difficult to mark trends in country practices because of the larger context in which each country operates, the following list points out some important and valuable commonalities in the nine countries studied.

1. **Efficient Import Program Operations.** Each country has adapted and changed to meet the growing volume of imported entries without corresponding new or additional resources. Most of these countries charge user fees or have a cost recovery system. While one country’s imported food and feed safety system is wholly funded through these fees, other countries assess fees for specific import services such as registration, inspection or laboratory analysis. To meet an ever-increasing number of entries, country food and feed authorities are approaching imported food and feed safety enforcement from a farm-to-table paradigm, similar to domestic food safety, rather than as strictly a border enforcement issue. With this paradigm, and particularly for high risk foods and feeds, country food and feed authorities are:

   - **Requiring pre-arrival or pre-clearance trading partner agreements.** These might be equivalence or another form of a country recognition agreement and can require certification. Generally under such agreements, the exporting country assumes responsibility for ensuring that the products will be acceptable to the importing country and deciding which food or feed facilities are able to export to the importing country. Audits or other verification procedures are carried out to maintain the agreement and admissibility of products is usually enhanced by having such agreements in place.

   - **Placing greater responsibility on importers and exporters.** Countries may require importers and trading partners to play a primary and integral role in ensuring safe food and feed and keeping records to enable traceback. Most countries require importers to register, to be licensed, to file import permits or file applications for release of the food.

   - **Finding avenues for enhanced inter-governmental cooperation to enable efficient import food/feed inspections.** For example, some countries’ food and feed authorities share responsibilities for inspection and testing with state and local authorities at the border or post-border when processes allow. Moving from paper-based systems to interactive electronic systems allows government and private sector users to access data related to inspection process and shipment entry status.

   - **Relying on post-border inspectional and laboratory surveillance networks, including federal, state/provincial/local bodies.** Food safety inspections at the border are limited in most countries because of other mechanisms to ensure that only safe foods are exported (e.g., importer accountability, agreements with foreign government or certificates for high risk foods). General surveillance of imported foods is often carried out post border by national or sub-national bodies.
2. **Risk Assessment.** All countries employ risk assessment-ranking to focus resources and utilize the rankings to establish risk management strategies. Each country uses risk assessment methods to target and manage its resources more effectively. All countries are consistent in ranking higher risk foods and feeds as those of animal origin, including seafood, and lower risk foods and feeds usually of non-animal origin.

3. **Testing by Accredited and Approved Laboratories.** For almost all countries studied, laboratory accreditation was overseen and administered by a separate, independent entity, often a National Board or Council. This independent entity, for a fee, using standards such as International Organization for Standardization (ISO) 17025, accredited government and third party/private laboratories for specific analytical/testing capabilities, such as pesticides, mycotoxins and pathogens. In addition, some country food and feed authorities compile a list of approved accredited labs for specific tests that industry could employ. In some countries, food and feed authorities accept government and/or private accredited laboratory test results for enforcement /bilateral agreement requirements.

4. **Foreign Facility Inspections versus System Audits.** Countries generally do not conduct foreign facility inspections, unless part of government-to-government recognition arrangements, or subsequent to a foodborne illness incident. Some country food and feed authorities have dedicated audit units to conduct regular reviews of their agreements with trading partners. In these cases, system audits are conducted and not individual food facility inspections. Additionally, some countries have dedicated audit units to review internal adherence to policies and procedures and progress for implementing changes/improvements.

5. **Foodborne Illness Detection and Response.** All countries have foodborne illness outbreak alert systems. In some countries these functions are conducted at state, local or territorial level on a routine basis. If the outbreak becomes regional/national, then federal agencies assume control and manage the response.

In addition to the above practices that were common to a number of the countries studied, it is important to point out practices that seemed to work well and which are different from practices traditionally carried out under FDA’s programs. These “novel” practices stood out during the review of participating countries’ programs.

1. Requiring food and feed importers to be registered or licensed and receive training about their food and feed safety responsibilities. Clarifying importer responsibilities and expectations could lead to a public-private team approach and positive changes between importers and their suppliers.

2. Establishing independent entities to fulfill laboratory accreditation, export certification and importer/exporter training. Food and feed safety authorities can recognize private bodies that are qualified to carry out these functions.

3. Use of accredited laboratories approved by food safety authorities to perform analyses for the authorities. Accredited laboratories can take the place of government laboratories for routine analytical work by prescribed methods.
4. Establishing an independent (i.e., high level independent group), but interagency group to regularly review the level of partnership and coordination among all of the federal, state and local agencies involved with imports and, where necessary, facilitate interagency improvements.

5. Negotiating agreements with other countries requiring that each country certify the safety of its food and feed exports to the other. The challenge of ensuring food safety in food exports and imports, within the confines of food and feed safety authorities’ missions, legal authorities, and resources requires that countries talk and negotiate agreements. One size cannot fit all country systems.

6. Maintaining a publicly available list of high risk foods and feeds and requiring imports of such foods to have advance authorization or certification. Transparency of the risk rationales used to develop the list is important and could provide a basis for any additional protective measures that may be required.

7. Moving high-risk products to controlled storage and requiring an application for their release. While import documentation control and quarantine issues are handled in most countries by Customs and agriculture authorities, requiring food importers to request release from country food and feed authorities provides clarity of purpose for this step of the process. The requirement for controlled storage assures that product does not accidentally enter the market before release.

8. For lower risk foods and when collecting statistical sampling data, releasing shipments to the marketplace, rather than detaining them pending analysis. Foods that are randomly sampled or have no previous history of regulatory non-compliance should be allowed to enter commerce directly (sometimes referred to as “test and release”).
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OVERVIEW OF INTERVIEW AND FOOD SAFETY SYSTEM

Australia imports about 15 percent of food products consumed domestically. Imported foods are categorized as either “risk foods” that present a medium to high risk to public health and safety, or “surveillance foods” that present a low food safety risk. The import process for food safety purposes depends on the food’s risk category. Animal feeds, further distinguished as livestock feeds and pet food, are considered “biologic materials” and thus, classified as quarantine material.

Importers must ensure that their products meet quarantine and food safety requirements prior to importation. Some products have quarantine restrictions, and importers wishing to import restricted items must obtain an import permit prior to importation.

The owner, or the owner’s agent, must enter for home consumption most imported goods with a Customs value that exceeds the import entry threshold (currently A$1,000). If cargo is targeted for intervention by The Australian Quarantine and Inspection Service (AQIS), the Formal Import Declaration (FID) will be referred across to the AQIS Import Management System (AIMS).

The Australian Customs and Border Protection Service (ACBPS) refers all risk food to AQIS, where initially all of it is inspected and tested. After five consecutive consignments have passed inspection, the inspection rate is reduced to 25 percent; after a further 20 consecutive passes, the inspection rate is reduced to five percent.

Risk foods are subject to 'test and hold' direction and are not released for sale until test results are known. Consignments of risk food that do not meet Australian standards cannot be imported. These foods must be brought into compliance; otherwise the food will be re-exported or destroyed.

Government agencies and other authorities with oversight of imported food and animal feed include:

- Food Standards Australia New Zealand (FSANZ), part of the Australian Government's Health and Ageing portfolio, acts as the risk assessor for the safety of imported food.
- The Australian Quarantine and Inspection Service (AQIS), within the Department of Agriculture, Fisheries and Forestry (DAFF), performs inspections at the border for quarantine and food safety purposes.
- The Australian Customs and Border Protection Service (ACBPS) manages the security and integrity of Australia's borders. It works closely with other Australian government and international agencies.
- State and territorial governments are responsible for enforcing Food Standards Code standards once food has entered Australia.
- Third party laboratories are identified by DAFF to perform import testing/sampling.
- The laboratories work directly with importers and charge the importers for their services.
1 ROLES AND FUNCTIONS OF AGENCIES RESPONSIBLE FOR IMPORTS OF HUMAN FOODS AND ANIMAL FEED

1.1 Governmental Ministries and Subunits (Including National/Regional/Local, as Appropriate) With Responsibility for Assuring the Safety of Imported Food

The Australia and New Zealand Food Regulation Ministerial Council makes policy decisions pertaining to food. The council is chaired by the Australian Government Minister for Health and Ageing (or delegate), and the council includes Ministers for each state and territory government and the New Zealand Government (DAFF, 2011a).

Food Standards Australia New Zealand (FSANZ) is an independent statutory agency established by the Food Standards Australia New Zealand Act 1991 (Australia and New Zealand share the same food standards). FSANZ is part of the Australian Government's Health and Ageing portfolio, and the Parliamentary Secretary to the Minister for Health and Ageing has executive responsibility for the agency. Structurally, FSANZ is governed by a Board with a wide range of expertise and experience in food matters, with members drawn from Australia and New Zealand. FSANZ has offices in Canberra, Australia, and Wellington, New Zealand. The responsibilities of FSANZ include:

- Developing the Australia New Zealand Food Standards Code which regulates the use of ingredients, processing aids, colorings, additives, vitamins and minerals;
- Developing standards for primary production and processing and for food hygiene;
- Determining the risk food poses to public health and safety following a food safety risk assessment. FSANZ categorizes food as 'risk' if it has the potential to pose a medium to high risk to public health. FSANZ advise AQIS of the risk category for food, which determines the frequency with which it will be inspected and the appropriate testing regime;
- Labeling for both packaged and unpackaged food, including specific mandatory warnings or advisory labels;
- Coordinating food surveillance and food recall systems;
- Conducting research; and
- Supporting the Australian Quarantine and Inspection Service in its duty to inspect imported foods.

(FSANZ, 2011)

Previously titled the Australian Customs Service, the Australian Customs and Border Protection Service (ACBPS) manages the security and integrity of Australia's borders. It works closely with other government and international agencies, in particular the Australian Federal Police, the Australian Quarantine and Inspection Service, the Department of Immigration and Citizenship
and the Department of Defense, to detect and deter unlawful movement of goods and people across the border. The agency is a national organization employing more than 5,500 people in Australia and overseas, with its Central Office in Canberra. (ACBPS, 2011)

The Department of Agriculture, Fisheries and Forestry (DAFF) safeguards Australia’s animal and plant health status in order to protect the economy and environment from the impact of exotic pests and diseases through risk assessment, inspection and certification, and the implementation of emergency response arrangements for Australian agricultural, food and fiber industries.” (DAFF, 2011d)

Responsibilities of DAFF that relate to food imports and export certification include:

- Protecting Australia's agriculture, food, fisheries and forestry industries by providing quarantine and inspection services and export certification
- Providing independent research, policy analysis, forecasts and advice on economic issues affecting agriculture, food, fisheries and forestry industries
- Providing independent scientific advice, social analysis and science-based quarantine and policy advice

(DAFF, 2011d)

The Department of Health and Ageing has a variety of responsibilities pertaining to the health of Australians, but in terms of the current study, their primary role is leading a whole-of-government approach to strengthening Australia’s readiness for disease threats, national emergencies and other large scale health incidents (Department of Health and Aging, 2011).  

The Department of Health and Ageing established OzFoodNet in the year 2000 as a collaborative initiative with Australia's State and Territory health authorities to provide better understanding of the causes and incidence of foodborne disease in the community and to provide an evidence base for policy formulation. It is a member of the Communicable Diseases Network Australia, and is supported by technical assistance from the National Centre for Epidemiology and Population Health at the Australian National University, Food Standards Australia New Zealand, the Department of Agriculture Fisheries and Forestry and the Public Health Laboratory Network (OzFoodNet, 2011).

State and territory authorities have responsibility for all food available for sale, including imported food. Each state and territory authority has its own food legislation that is based on the national Model Food Act developed by FSANZ. State and territory action on food is different from, but complementary to, the Federal Imported Food Inspection Scheme. State and territory authorities work closely with FSANZ and AQIS to resolve issues on matters involving imported food.

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1 For a more comprehensive list of the Department’s responsibilities, see: http://www.health.gov.au/internet/main/publishing.nsf/Content/health-overview.htm
foods that AQIS has not inspected or that have later been found not to be in compliance with federal standards (DAFF, 2011).

The Imported Food Control Act also allows for analysts, or private laboratories, to have a role in the safety of Australia’s food. DAFF approves these analysts to perform import testing/sampling, and the laboratories must be accredited. The analysts work directly with importers and charge the importers for their services. A list of laboratories is available for importers to select from (DVC, 2011).

1.2 Agencies Responsible For Animal Feed and/or Pet Foods

The import of animal feeds meet the Quarantine Act 1908. Further distinguished as livestock feeds and pet food, these imported products are classified as quarantine material. Furthermore:

- At the border, quarantine officials oversee feed imports only for quarantine.
- Livestock feeds are highly regulated on the basis of quarantine.
- Feeds undergo a risk-based assessment before import.
- Quarantine products must come from an approved source.
- State and territorial governments enforce feed standards once feed is in the country.

Additional information required for livestock feed includes:

- Stock feed, pet food, and aquaculture questionnaire (to be completed by manufacturer).
- Microalgae questionnaire (to be completed by manufacturer).
- Dependent on the type of livestock feed, further detailed information (such as origin of ingredient) may also be required.²

Additional information required for pet food includes:

- Pet food declaration application (to be completed by manufacturer).
- Stock feed, pet food, and aquaculture questionnaire (to be completed by manufacturer).

(AQIS, 2011a)

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Throughout the remainder of this document, animal feed is addressed only where specifically noted, and otherwise, "food" refers to food for human consumption.

1.3 Food Importation Process Steps and the Government Units That Oversee Each Step

There is currently a 44 member staff managing Australia's Imported Food Control Act 1992 functions. Australia's import process depends on the risk categorization of the food. Australia divides food into two categories as follows:

- Risk Foods are those that present a medium to high risk to public health.
  - These foods are initially inspected at a rate of 100 percent.
  - Risk food is held while being tested.
  - There are approximately 21 risk foods currently listed.

- Surveillance Foods are those that present a low risk.
  - This category captures all non-risk foods.
  - Surveillance foods are monitored for compliance with the Food Code.
  - There is a 1 in 20 chance for surveillance foods to be inspected.

(DVC, 2011)

Importers must ensure that their products meet quarantine and food safety requirements prior to importation. Products having quarantine restrictions include:

- Eggs and egg products
- Dairy products
- Meat and seafood
- Seeds and nuts
- Fresh fruit and vegetables

Importers wishing to import any of the restricted items listed above must obtain an import permit prior to importation (See Section 1.2 for additional feed requirements). An import permit may be obtained by submitting an Application for Permit to Import Quarantine Material to the Australian

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3 Information on the types of food products imported into Australia is available at: http://www.daff.gov.au/egis/import/food/inspection-data
Quarantine and Inspection Service (AQIS), the group within DAFF responsible for administering
the Quarantine Act 1908. AQIS assesses the application and, on the basis of that assessment, may
decide to grant an import permit subject to any conditions deemed necessary for safe importation,
use and disposal of those products (AQIS, 2011m).

Most imported goods with a Customs value that exceeds the import entry threshold (currently
A$1,000) must be entered for home consumption by the owner of the goods or the owner's agent.
An entry is made by submitting an import declaration into the Integrated Cargo System (ICS). 4 If
cargo is targeted for AQIS intervention for quarantine or imported food, the Formal Import
Declaration (FID) will be referred across to the AQIS Import Management System (AIMS). FIDs
may also be referred to AIMS under the Broker Accreditation Scheme arrangements, or by non-
tariff based profiles. FIDs that are in AIMS are called "AIMS Entries" (or 'Entries') for all AQIS
purposes" (AQIS, 2011b).

The remainder of the import declaration process is as follows:

- Cargo Reporter5 reports goods to Customs.
  - Customs requires import declarations to be submitted into the Integrated Cargo System (ICS).
    There are three options for submitting declarations.
- Fill in the import declaration form (Customs Form B650) and present it to a Customs Officer.
- Purchase a digital certificate which allows you to communicate with Customs electronically using the Customs Interactive website.
- Use the services of a Customs broker who will complete the Customs requirements for you based on the information you provide.
- Evidence of Identity (EOI) check is completed at a Customs counter.
  - Customs will accept the declaration after EOI check and process it using Customs Interactive.
- ICS will allocate an import declaration ID. This is recorded on the form
- ICS entered information will identify errors when saved.
  - If there are errors, when the owner contacts Customs errors on the declaration will be advised. Written amendments are then required.

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4 "The Australian Customs and Border Protection Service (Customs) Integrated Cargo System (ICS) is the means that allows
for the electronic lodgment of Formal Import Declarations (FIDs) by brokers and/or importers for imported goods" (AQIS,
AIMS and ICS, 2011).
5 Cargo Reporter may be the shipping company, slot charterer, freight forwarder or other participant.
- Custom submits the declaration.
  - Community protection, tariff, reference data, securities and other checks are performed.
  - ICS checks and returns any errors. Any errors must be rectified and resubmitted.

- Community protection and lodgment questions are asked, if any.
  - Owner must answer community protection and lodgment questions in writing before Customs lodges the declaration. (Must be the same day as it was submitted)

- Finalization and payment.
  - When the ICS has processed the import declaration the declaration is ready for payment.
  - Owner pays liabilities.

- Information passed to AQIS.
  - Owner must respond to AQIS concerns/questions if any before Customs lodges the declaration.
  - Risk food is referred to AQIS by Customs at a rate of 100 per cent of consignments. Risk food is initially inspected and tested at a rate of 100 percent against a published list of potential hazards, including micro-organisms and contaminants. Once five consecutive consignments have passed inspection, the inspection rate is reduced to 25 percent; after a further 20 consecutive passes, the inspection rate is reduced to five percent.
  - Risk foods are subject to 'test and hold' direction and are not released for sale until test results are known. Consignments of risk food which fail inspection, and therefore do not meet Australian standards, cannot be imported. These foods must be brought into compliance otherwise the food will be re-exported or destroyed (AQIS, 2011m).
  - Product tests are allocated within AQIS Information Management System (AIMS) for various commodities (most of these being risk categorized foods or those on Holding Orders) and the results provide a history for each producer and food. This history determines the inspection rate of those foods, with compliant producers benefiting from lower inspection rates and those with compliance problems remaining on or elevated to higher rates of inspection (AQIS, 2008).

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6 When food needs to be tested, "importers are responsible for nominating a laboratory of their choice from the list of analysts appointed under the Imported Food Control Act 1992" (AQIS, Tests Applied to Risk Foods, 2010).
• When all Customs and AQIS concerns are addressed and no examinations are required, an "Authority to Deal" is issued by Customs and Border Protection.

If further information or examination is required, then the goods can be released after satisfactory examination results/information have been supplied (ACS, 2005).

1.4 Assistance, Cooperation or Contributions from Other Government Bodies (National or Local) in the Imported Food and Feed Process

Customs, FSANZ, and DAFF work cooperatively in the import process (See Sections 1.1 and 1.3).

1.5 Laws and Regulations that Provide Authority for the Oversight of the Safety of Imported Foods and Animal Feed, and the Policies and Procedures that Guide Import Officials

Australia New Zealand Food Standards Code (the Code) is the primary legislation for the safety of domestic and imported foods for human consumption. It sets forth requirements for labeling, processing, quality, and production that apply generally as well as to particular categories of food (e.g. fruit, dairy). (FSANZ, 2011a)

The Imported Food Control Act 1992 and its subordinate legislation (see below) provides, "the legal basis for the food safety inspection of imported food. Under the Act, importers are responsible for ensuring that all food imported into Australia complies with relevant standards in the Code. This legislation allows AQIS to run a food safety inspection program known as the Imported Food Inspection Scheme (IFIS). "(AQIS, 2011m)

Imported Food Control Regulations 1993 "provides for the inspection and control of food imported into Australia, and for related purposes".

Imported Food Control Order 2001 "lists imported food that is required to be inspected, or inspected and analyzed as risk food, or active surveillance food, under the Imported Food Inspection Scheme."

Quarantine Act 1908 and its subordinate legislation (see below) requires that all imports of food comply with the quarantine conditions for their import (i.e. conditions preventing the introduction of pests and disease that could cause significant harm to people, animals, plants and other aspects of the environment). It also allows for the laboratory testing and emergency quarantine of goods not meeting criteria set forth in the Act.

Quarantine Proclamation 1998 sets out restrictions on imported goods, including imported food or feed, to prevent the establishment or spread within Australia of human, animal or plant pests and diseases. The basic law is contained in the Quarantine Act 1908, which creates a system by which things that are likely to introduce pests or disease can be prevented from entering Australia. It also makes it possible to prevent the spread of a pest or disease by preventing the movement within Australia of things likely to spread the pest or disease. The basic way to
impose these restrictions is by proclamation. Quarantine Proclamation 1998 contains these restrictions.

1.6 Handling of Products Transshipped Through a Third Country as Compared to Directly Imported Products

Cargo transshipped through a third country is handled as described below:

- When foods have been transshipped through other countries, for quarantine purposes, DAFF assesses:
  - Whether or not the food item requires an import permit (i.e. Does it contain plant or animal product?)
  - Whether or not the food presents a quarantine concern.
- The country of origin is taken from the ICS and compared to the information on the product. Importers must provide an explanation if these two countries of origin do not match. (DVC, 2011)

2 INSPECTION PROGRAMS

2.1 Mechanisms to Prioritize Food/Feed Import Surveillance Activities, such as Product Sampling and Testing, Inspections at the Border, and Facility Inspections of the Exporting Country

The Imported Food Control Act 1992 and subordinate legislation have two inspection categories that determine the frequency of inspection: risk, and surveillance. As mentioned above, FSANZ advises DAFF on whether food should be classified as ‘risk’ food, all other food is managed as surveillance food. All foods categorized as risk foods are inspected and tested, whereas all referred surveillance foods are inspected, but not all are tested. End-point inspection and testing are the main basis for determining the compliance of imported foods with the applicable standards.

Risk foods

"Food Standards Australia New Zealand (FSANZ) is responsible for the determining the risk food poses to public health and safety following a food safety risk assessment. FSANZ categorizes food as ‘risk’ if it has the potential to pose a medium to high risk to public health. FSANZ advises AQIS of the risk category for food, which determines the frequency with which it will be inspected and the appropriate testing regime" (AQIS, 2011m).

"Risk food is referred to AQIS by Customs at a rate of 100 percent of consignments. Risk food is initially inspected and tested at a rate of 100 percent against a published list of potential hazards—including micro-organisms and contaminants. Once five consecutive consignments have passed inspection, the inspection rate is reduced to 25 per cent; after a further 20 consecutive passes, the inspection rate is reduced to 5 percent" (AQIS, 2011m).
“Risk foods are subject to 'test and hold' direction and are not released for sale until test results are known. Consignments of risk food which fail inspection and therefore do not meet Australian standards cannot be imported. These foods must be brought into compliance otherwise the food will be re-exported or destroyed. Any consignments that fail result in a return to 100 per cent testing of that product until a history of compliance is re-established for the producer of the food” (AQIS, 2011m).

**Surveillance foods**

“All other foods are considered by FSANZ to pose a low risk to human health and safety and are known as ‘surveillance foods.’ Each consignment of surveillance food has a five percent chance of being referred by Customs to AQIS for inspection to assess its compliance with Australian food standards. Samples of surveillance foods may be analyzed for pesticides and antibiotics above accepted levels, microbiological contaminants, natural toxicants, metal contaminants and food additives.”

“The selection of surveillance food consignments is random, and the referral of those consignments is done using electronic profiles in the Customs Integrated Cargo System. Information such as the importer, producer or the country of origin of the goods does not affect the random selection and referral of a surveillance food. There is the possibility that an importer who regularly imports similar consignments of surveillance foods (i.e. low risk food in the same tariff group) will increase the chance of these consignments being referred by the random profiling.”

“As the surveillance foods are considered by FSANZ to be low risk, they are subject to a 'test and release' direction and can be distributed for sale before test results have been received. However, if AQIS receives adverse test results, the relevant state or territory food regulatory authority is advised so they can determine if a recall is required. Any action, such as a recall or withdrawal taken on goods released by an importer is at the importer's expense.”

“The inspection rate for surveillance food that fails inspection is also increased to 100 percent until a history of compliance is established for the producer or importer of the food. The process for increasing inspection of surveillance food is referred to as applying a Holding Order. A holding order remains in place until favorable test results are received. Instead of test and release, foods subject to a holding order are subject to a 'test and hold’ direction. Once a history of five consecutive passes is established, the rate of referral returns to five percent of consignments” (AQIS, 2011m).

Product tests are allocated within AQIS Information Management System (AIMS) for various commodities, and the results provide a history for each producer and food. This history determines the inspection rate of those foods, with compliant producers benefiting from lower inspection rates and those with compliance problems remaining on or elevated to higher rates of inspection (AQIS, 1998).
Inspection data is published by AQIS biannually. This detailed data describes the volumes and types of inspections performed for various commodities and countries (AQIS, 2011).7

2.2 Special Screening Requirements and Trading Partner Requirements where Disease or an Outbreak has Occurred

Risk foods are subject to certain analytical tests or certification requirements. The list of screening requirements for these foods can be found in *Tests Applied to Risk Category Foods* (2010).8 “Food products from foreign producers with a consistent history of compliance are inspected less frequently than products from new suppliers or those with a history of failure against Australian standards” (AQIS, 2008).

Occasionally, FSANZ is alerted to an emerging risk issue or concern (such as melamine) which leads them to establish a standard for a specific set of products. This information is then passed onto AQIS. AQIS Imported Food Notices highlight emerging issues for importers and any coinciding testing or sampling that should occur for the products in question.9

"All food referred for inspection is subject to visual and label inspections. This may include a visual inspection of the food and a check of the government to government certification as is required to demonstrate Bovine Spongiform Encephalopathy (BSE) free status for imports of beef and beef products. Some foods are also subject to analytical testing-for microbial, chemical or other hazards. AQIS has Imported Food Notices (IFN), specific to each category of food, that advise what tests are applied to particular foods" (Productivity Commission, 2009).

2.3 Percentage of Imported Food Shipments Examined and the Relationship between Risk-Ranking of Foods and Volume of Imported Foods Examined

Documentation and visual inspection of products is performed by AQIS (See Sections 2.1 and 2.2 for types of review). Testing and sampling of products is performed by NATA certified laboratories that are approved by AQIS (See section 3.7).

It appears that a similar number of documentation versus analytical tests are performed for products being referred to inspection. For example, the following inspection activities occurred over the period of January to June 2010:

- 6,969 entries of imported food were referred to AQIS for inspection under the Imported Food Inspection Scheme

- 10,781 lines of imported foods were inspected

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• 42,664 tests were applied, including label and visual checks and broken down as follows:
  
  – 15,279 label assessments
  
  – 13,246 analytical tests
  
  – 14,139 other$^{10}$ tests

(AQIS, 2010b)

2.4 Types of Review, Examination and/or Testing of Imported Products Performed by Food Safety Inspectors

Australia examines imported foods as follows:

• All imported foods referred to the imported food inspection scheme are subject to documentation and label checks.

• The documents and labels may contain nutrition information, lot codes and shipment information that may prove helpful in tracing products if necessary.

• Not all foods sampled are tested for all standards.

• There is a strict pass/fail arrangement for products that have been inspected/tested.

Australia relies heavily on test results for imported food:

• Tests are recorded as the total number of analyses run.

• Tests are based on lot and batch codes.

• A range of types of sampling and analysis are performed such as chemical, pesticide, and microbiological testing.

• Products having foreign certifications are tested once per year.

Imported feed is assessed against requirements in the Quarantine Act 1908. Under the Quarantine Act 1908, stock and aquaculture feeds are assessed for the likelihood of the presence of ruminant protein. A number of higher risk stock and aquaculture feeds are tested for the presence of ruminant DNA. Testing is conducted on a per consignment basis, and, when applied, it is conducted on 100 percent of imported consignments of that specific commodity. Also, the

$^{10}$ "Other" tests refer to an array of tests (such as physical and additive tests) that are not otherwise identified.
Agricultural and Veterinary Chemicals Code Act 1994 requires feeds or feed supplements that make a therapeutic claim to be registered (DAFF, 2011e).

2.5 Frequency of Documentation and Labeling Checks as Compared to Analytical Examinations

All imported foods referred to AQIS for inspection under the Imported Food Control Act 1992 are subject to documentation and labeling checks. The information contained may include nutrition information, lot codes, and shipment information that may prove helpful in tracing products if necessary.

Not all foods are sampled and tested for all standards. When samples are collected they can go through a range of tests such as chemical, pesticide, and microbiological.

2.6 Types of Examination and Testing Processes Used for Ensuring Animal Feed and Feed Ingredient Safety

Countries wanting to import pet food into Australia undergo an assessment for any TSE (including BSE). In addition:

- The pet food industry in Australia is self-regulating.
- The pet food industry is overseen by a primary industries group at the Ministerial level.
- There is a voluntary code of practice for pet food which is closely adhered to in practice.

(DVC, 2011)

2.7 The Dependence of Examination and Testing Requirements on Conditions (such as the Presence of BSE or Other Zoonotic Diseases) in the Exporting Country

Australia has additional requirements for countries with known feed-related issues:

- BSE was used as an example regarding additional requirements for countries with known outbreaks.
- BSE policy parameters were outlined in 2001 and revised in 2009. Australia is now implementing the OIE standard and performing risk assessments of ESE-relevant countries in order to categorize their risk level.

For example, New Zealand, Lithuania, the US, and Croatia applied to have FSANZ assess their BSE risk level. Australia is currently undertaking risk assessments for other countries, such as the United States (DVC, 2011).
2.8 Inspections of Food or Animal Feed Manufacturers or Shippers in Other Countries (including Selection Criteria and Frequency)

The following information about foreign inspections was provided by Australian officials:

- DAFF does not often perform inspections of foreign facilities for imported food. Inspections of this variety usually pertain to foreign certification arrangements for particular products of which Australia has very few (see Table 1 in section 3.3). Interviewees noted that foreign inspections are rarely performed for imported food safety purposes. The imported food inspection scheme is fully cost recovered from importers. Inspections of government to government certification arrangements are outside the scope of cost recovery arrangements so funding these types of inspections is difficult. Foods managed under certification are tested at the rate of 5% of consignments and competent authorities notified where food fails (see section 2.7 below).

- For quarantine purposes, there are specific commodities that do require facility inspections and audits, importers are directly charged for these inspections and audits, for example inspections of stock feed and pet food manufacturing facilities.

(DVC, 2011)

2.9 Notification System(s) to Directly Notify Foreign Governments When Foods or Animal Feed Manufactured in their Countries are Found to be Unsafe; and to Notify the Public When Imported Products do not Meet Safety Standards

Australia notifies foreign governments about food/feed issues in several situations, including:

- Governments with foreign certification agreements are notified when their certified products do not meet the five percent testing requirements.
- Governments are notified when their surveillance foods do not meet Food Code standards, although DAFF doesn’t necessarily expect the government to take action in these types of cases.

DAFF maintains communication with FSANZ in case a foreign government notification is necessary (DVC, 2011).

The test results for foods that fail inspections and testing for analytical reasons are available to the public. Additionally, the government officials notify the public of problems with foods that need to be recalled, (FSANZ, 2008; DVC, 2011).

At the request of States and Territories, FSANZ is responsible for coordinating recall action. This means that when FSANZ is notified of a recall, it liaises with the food business and State and Territory authorities to gather and collate all necessary information. This information is then disseminated to State and Territory governments, other government agencies and the food
industry. FSANZ also monitors the effectiveness of food recalls on behalf of the Australian Competition and Consumer Commission (ACCC) (FSANZ, 2008).

"Where a food incident is associated with human illness, the [National Food Incident Response] Protocol will be used to coordinate the response of food regulatory agencies under the broader management of the human illness outbreak. In these incidents, the Protocol may be activated as a result of activity under the National Guidelines for Managing National Outbreaks of Foodborne Illness. The Protocol may also be activated via the Agricultural Emergency Plan or Australian Veterinary Plan in the event of a zoonotic disease being detected in food-producing animals or via the National Counter-Terrorism Plan in the event of a terrorist threat." (ISC, 2009)

"FSANZ's Food Industry Protocol says that the roles and responsibilities of the sponsor (i.e. "the food business with primary responsibility for the supply of a food product"), include: 1) notifying the public (generally by press advertisement) in the event of a consumer level recall, and 2) for imported product, contacting overseas supplier/manufacturer when initiating recall action." (FSANZ, 2008)

Additional protocols that may be involved in the notification process for unsafe foods include:

- Food Safety Emergencies -a Communication Protocol (FSANZ and the Retail and Manufacturers Liaison Committee)
- State/Territory food incident/emergency response plans (which differ according to state/territory)

(ISC, 2009)

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11 Emergency response plans of other government agencies include:
- National Counter-Terrorism Plan (Australian Government Attorney General's Department);
- Commonwealth Disaster Response Plan (Emergency Management Australia);
- Agricultural Emergency Plan (Australian Government Department of Agriculture, Fisheries and Forestry);
- Coordination between the Department of Health and Ageing and Commonwealth Government Agencies for Health Incident Management (Australian Government Department of Health and Ageing);
- Australian Veterinary Emergency Plan (AUSVETPLAN) (Australian Government Department of Agriculture, Fisheries and Forestry);
- SAFEMEAT Incident coordination plan (Australian Government Department of Agriculture, Fisheries and Forestry and SAFEMEAT); and
- Guidelines for the detection, investigation and management of multi-jurisdictional outbreaks of foodborne illness (OzFoodNet);
- Food Safety Emergencies -a Communication Protocol (FSANZ and the Retail and Manufacturers Liaison Committee);
- Food Industry Recall Protocol;
- State/Territory food incident/emergency response plans. (ISC, 2009)

12 This protocol is an internal document (ISC, 2009)
AUDITS AND CERTIFICATION

3.1 Assessing and Measuring the Effectiveness of the Food/Feed Safety Import Program (e.g., Self Audits of the Program, Public Health Outcomes, Surveillance Sampling Results, Number/Rates of Refusals, Periodic Program Evaluations)

A Survey of Chemicals in Imported Seafood (2008), carried out under the Imported Food Control Act, reviewed the management of imported seafood testing. During the study, “the Australian Quarantine and Inspection Service (AQIS) tested 100 samples of seafood for residues of 88 agricultural and veterinary compounds. These samples were volunteered by importers and collected by AQIS between April 2006 and March 2007. [The survey found that] residues of one or more antimicrobial chemicals were detected in 31 of the seafood samples tested. The levels were all low and posed no significant safety concerns”. (AQIS, 2008)

3.2 Extent of Reliance on Trading Partners’ Food Safety Programs to Ensure That Imported Foods or Animal Feed are Safe

Foods defined as risk foods (determined by tariff code) are always referred to AQIS by Customs and initially monitored by AQIS until they meet reduced surveillance requirements. Once satisfying import requirements for risk foods, the primary responsibility for food safety returns to the food safety program of the trading partner until/unless the risk food violates regulatory requirements, and then it restarts the cycle of AQIS monitoring and compliance for risk foods. (See also Section 2.3)

Responsibility for the safety of imported products determined to be low risk as well as those from countries where certification arrangements are in place falls primarily on the on the food safety program of trading partners (See Table 1). As stated in the Review of the Imported Food Control Act (1998), “Ultimately, it is the responsibility of industry to provide safe food. The government sets safe food standards and puts a mechanism in place to monitor compliance, while industry should be responsible for implementing an internal process to ensure those standards are met” (AQIS, 1998; DVC, 2011).

3.3 Requirements for Food and/or Animal Feed Export Certificates Issued by the Exporting Country’s Competent Authority, and Types of Inspection or Testing for Each

Feed

Although manufacturers are required to sign declarations for livestock feed and pet food exported to Australia, certificates issued by that country’s competent food/feed safety authority is not required (AQIS, 2011f).

Food

Beef products are currently listed as requiring certificates. “BSE certification issued by the national competent authority in the country of origin, is assessed by AQIS IFP authorized
officers to determine if the imported beef or beef products meet Australia's food safety requirements. Once AQIS is satisfied these requirements have been met, the food is allowed entry but is still subject to the inspection rate applicable to the food's category.” (AQIS, 2010a).

Table 1 also shows the countries with specific imported products requiring certification. Information that must be included on the certificate is also presented in the table.

3.4 Use of ISO, Global Gap or Other Assurance Systems and Confidence in the Assurance System(s) Utilized

Global GAP is not used at the present. Importers may, however, use Global Gap or ISO accreditation to demonstrate to AQIS that they have an effective food safety system under compliance agreements with importers that are permitted under the Imported Food Control Act 1992 (DVC, 2011).

Laboratories performing testing of imported foods must be accredited by The National Authority of Testing Authorities, Australia (NATA). NATA’s “criteria for determining a facility's competence is based on the relevant international standard (e.g. ISO/IEC 17025, ISO 15189, ISO/IEC 17020)” (NATA, 2011).

3.5 The Nature and Frequency of Foreign Food Safety Systems Audits Performed

There has been little systematic audit of the controls or systems that underpin certification, except in relation to fumigation. For quarantine purposes, offshore systems audits are an example of pre-border audit and verification that is occasionally conducted. (Quarantine and Biosecurity, 2008)

3.6 Equivalence Agreements Requiring Periodic Audits/Reevaluations of Exporting Countries’ Food Safety Programs

Australia has no equivalence agreements requiring periodic audit.

3.7 The Utilization of Third-Parties (Within the Exporting or Importing Country) to Carry out Inspections and/or Product Certification (Nature and Extent of Programs) and Methods for Verifying the Adequacy and Reliability of the Third Party Work

Product inspection and certification of goods to be imported into Australia is carried out by members of the food safety system of the competent authority in the exporting country. Third party assurances are used for quarantine purposes for some imported foods, for example, manufacturers’ declarations about the ingredients and processing of a food.
<table>
<thead>
<tr>
<th>Country</th>
<th>Food</th>
<th>Certificate Type</th>
<th>AIMS/ICS Codes and Certificate Requirements</th>
<th>Competent Authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thailand</td>
<td>Cooked Chilled/Frozen Crustaceans, Mollusks &amp; other seafood products</td>
<td>Health Certificate</td>
<td>DOFHCTH Products must be sourced from factories registered with, and under supervision of, DoF.</td>
<td>Ministry of Agriculture and cooperatives - Department of Fisheries (DoF)</td>
</tr>
<tr>
<td>France</td>
<td>Roquefort Cheese</td>
<td>Sanitary Certificate</td>
<td>SCER Sanitary Certificate to Export Roquefort from France to Australia The Sanitary Certificate must be accompanied by test results for <em>E. coli</em> specific to the consignment.</td>
<td>Ministere De L’Agriculture Et De La Pêche</td>
</tr>
<tr>
<td>Canada</td>
<td>All seafood products</td>
<td>Certificate of Origin and Hygiene, and/or Canned Salmon Inspection Certificate</td>
<td>CI or CIOH</td>
<td>Certificates issued by the Canadian Food Inspection Agency (CFIA)</td>
</tr>
</tbody>
</table>
| New Zealand  | Non-viable Uncanned Salmon (includes smoked salmon)                  | AU301 (Replaces AP1247)           | Certification Statements must include:  
  '..have been produced in accordance with IAIS 003.9 designed to ensure Australian import requirements relating to *Listeria monocytogenes* are met. As such I have no reason to believe the product contains *Listeria monocytogenes*.'  
  | New Zealand Food Safety Authority (NZFSA)                           |
| New Zealand  | Fish or Fish Products (includes risk fish, crustaceans & molluscs)   | AU300 (Replaces AP1564)           | Certification Statements must include:  
  '..were processed in establishments operating with New Zealand law'  
  '..were processed in accordance with New Zealand regulatory requirements for items intended for human consumption'  
  '..are of New Zealand origin'; OR  
  '..were partly derived from product of New Zealand origin and partly derived from product imported into New Zealand from and further processed in approved premises'; OR  
  '..were derived from product imported into New Zealand from and further processed in approved premises.'  
  | New Zealand Food Safety Authority (NZFSA)                           |

Source: DAFF Foreign Government Certification Notice, 2010
The Imported Food Control Act 1992 allows for analysts within private laboratories to have a role in the safety of Australia’s food. DAFF approves appropriately qualified analysts to perform import testing of samples collected by DAFF’s AQIS officers. The laboratories must be accredited by NATA. Importers are charged directly by the laboratories for any samples tested. The laboratories report results directly to DAFF via an electronic system linked to AIMS. A list of laboratories is available for importers to select from (DVC, 2011).  

Australia also uses Food Import Compliance Agreements (FICAs), which can give importers a bypass through the border inspection scheme by recognizing importers’ product assurance schemes. Importers must demonstrate that their goods meet Australia’s standards. For example, an importer can show that their supplier has a documented HACCP system. FICAs also remove some duplication that occurs when importers check with suppliers to ensure that they are sourcing food that will meet Australia’s standards. These arrangements have been possible for about the last year and a half (DVC, 2011).

3.8 Arrangements with other Governments Relating to Imported Foods or Animal Feed (such as Memoranda of Understanding, Mutual Recognition Agreements, etc.)

Under the Tasman Mutual Recognition Arrangement between Australia and New Zealand (TTRMA), "the only New Zealand foods that are subject to inspection at the border are those classified as risk category foods. Equivalence determination of food safety systems covering dairy products was reached in 2007, enabling dairy products to be brought under the TTMRA and the removal of border inspection for these products. Each remaining risk food is now being assessed for equivalence of the food safety management systems in each country" (AQIS, 2011a).

Australia has foreign arrangements involving the certification of particular products. Countries having these certification agreements with Australia may have their system re-evaluated when the agreement is about to expire or be renewed. Codex guidelines are used to help gauge the effectiveness of the other countries’ systems. Australian officials noted that if these certificate agreements are not frequently used by importers, it is not worth the time or monetary investment, on Australia’s part, to renew them.

"FSANZ has established Memoranda of Understanding (MOUs) with regulatory authorities in several countries. Although these MOUs vary in their intended purpose, they aim to encourage cooperation on food standards development, risk assessment, improved communication and to allow sharing of non-public food safety information. FSANZ currently has MOUs with:"

- Canadian Food Inspection Agency
- Health Canada

References on third party laboratories for imported food available at:
• Chinese Ministry of Science and Technology
• Chinese State Food and Drug Administration
• New Zealand Environmental Risk Management Authority
• New Zealand Food Safety Authority
• United Kingdom Food Standards Agency

FSANZ and the United States Food and Drug Administration (US FDA) have also recently signed a confidentiality commitment which will facilitate sharing of non-public food safety information. The commitment allows the agencies to share information on emerging food incidents and food recalls, and permits FSANZ to share confidential commercial information for enforcement or recall purposes (AQIS, 2009).

3.9 Registration or Licensing of Finns That Import and/or Export Foods or Animal Feed to the Country or for Finns That Import Foods or Animal Feed

Firms importing quarantine-restricted items (which include all feed products) are required to obtain an import permit before exporting their product to Australia (See Section 1.3). Information from the competent authority of the exporting country regarding the manufacturing of the product may be included with the import permit application, but it is not noted as a requirement (AQIS, 2011j).

3.10 Use of Sampling Surveys of Imported Foods/Feed (as Opposed to Targeting Specific Products/Producers for Inspections and/or Testing) to Gather Information and Identify Trends and Potential Areas of Difficulty

Imported food not classified as "risk food" undergoes a random surveillance process (See Section 2.1, Surveillance Foods). The Imported Food Control Act does not allow AQIS to sample foods for survey purposes, but AQIS supports the surveys undertaken by the states and FSANZ, by paying for testing for any imported food included in the surveys. "The surveys aim to gather information to inform the risk assessment processes undertaken by Food Standards Australia New Zealand, and to provide data to assist in determining the most appropriate routine testing of imported food." Surveys listed on the AQIS website include:

• Imported horticultural products survey
• Imported seafood survey
• Imported spices survey

(AQIS, 2011n)
3.11 "Good Practices" Programs for Foods/Feed Importers

There is currently no government sponsored good practices program for importers. AQIS has previously worked with industry organizations to provide an advisory role to the industry on training curricula and guidance. From a quarantine perspective, good manufacturing practices are recognized (DVC, 2011).

3.12 Description of Import Program User Fees and Cost Recovery System

"The Australian Government requires AQIS to recover 100 percent of the cost of running its inspection system, and this is achieved by charging fees for services provided. The Quarantine Service Fees 2006\textsuperscript{14} and the Imported Food Control Regulations 1993 provide for the type and level of fees that can be levied on imported food. Specifically, chargeable services provided under the legislation include:

- Cargo import clearance related quarantine risk profiling
- Inspection, surveillance and treatment of imported goods
- Inspection and clearance of sea containers
- Fumigation monitoring of imports
- Lodgment of quarantine entries
- Applications and assessments of import permits
- Overtime and shift services by an officer outside the ordinary hours of duty
- Registration of premises for the purposes of performing quarantine inspections
- Audits to ensure compliance with program procedures and regulations."

(Productivity Commission, 2009)

3.13 Incentives to Increase Industry Involvement in Ensuring That Imported Foods Meet Safety Standards

*Inspection Rate*

Product tests are allocated within the AQIS Information Management System (AIMS) for various commodities. The majority of tests are allocated for "risk foods" or those on Holding Orders, and the test results are used to establish a history for each producer and food. This history determines the inspection rate of those foods, with compliant producers benefiting from

\textsuperscript{14} For Customs Notice of Fees, see: http://www.customs.gov.au/webdata/resources/notices/ACN0621.pdf
lower inspection rates. Those producers and products having compliance problems maintain higher rates of inspection (AQIS, 1998).

**Food Import Compliance Agreements (FICA)**

“Since February 2010 food importers have been able to participate in a Food Import Compliance Agreement (FICA) with the Australian Quarantine and Inspection Service (AQIS). FICAs offer food importers an alternative regulatory arrangement to inspection and testing of their products under the imported food inspection scheme (IFIS). FICAs are an assurance based regulatory arrangement undertaken through formal recognition and audit of an importer’s food safety management system by AQIS.” The incentive for importers to take up FICAs is greater control over their supply chain with no requirement to hold consignments until AQIS inspection and sampling has occurred (AQIS, 2011g).

3.14 Obstacles to Industry Participation in Ensuring That Imported Foods Meet Safety Standards

Information on this topic was not gleaned from publically available information or country interviews.

4 LABORATORY SUPPORT

4.1 The Role of Laboratories in Supporting the Imported Food and Feed Programs and Description of Laboratory Capabilities

When an imported food is directed for testing under the Imported Food Inspection Scheme (IFIS), the testing must be conducted by a laboratory appointed by AQIS. Importers select an AQIS-approved laboratory to perform any required testing. Prior to nominating a laboratory, the importer must contact them to confirm that: 1) they are able to perform the tests assigned in the Food Control Certificate, and 2) they are able to collect samples from AQIS collection sites, as some laboratories do not service all areas. Eleven laboratories are currently listed as performing tests for AQIS (AQIS, 2011h).

Australian officials did not feel that the process of laboratory selection by importers posed challenges, as the laboratories are set up to work with AQIS. Most third party AQIS approved laboratories offer similar basic tests, and officials felt that importers appreciate having a choice of laboratories that are capable of performing the necessary product testing (DVC, 2011).

4.2 Methods for Laboratories to Achieve Quality Assurance (such as Voluntary or Mandatory Accreditation)

Laboratories performing testing of imported foods (including non-government laboratories) are accredited by The National Authority of Testing Authorities, Australia (NATA). NATA’s

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15 Laboratory testing capabilities are detailed in the Appointed Analysts Testing Capability Matrices which are available from the AQIS website.
"criteria for determining a facility's competence is based on the relevant international standard (e.g. ISO/IEC 17025, ISO 15189, ISO/IEC 17020)" (NATA, 2011).

5 ENFORCEMENT AT BORDER

5.1 Approach to Visual Inspections and Analysis of Imported Foods (e.g. Risk-Assessment and Prioritization Schemes, Documentation Review, Sample Collection)

See Section 2.1 regarding surveillance of imported food.

For quarantine, 100 percent of consignments are referred to AQIS for clearance. Requirements to clear consignments for quarantine purposes vary from minimal, where little quarantine risk exists (for example, canned soft drinks, canned fruit and vegetables) to requiring import permits, government certification, pre clearance inspections, and post arrival inspections for products like fresh produce where there is real potential for pests and diseases to be introduced.

5.2 The Process that Occurs When an Imported Food is Found to be Contaminated or does not Meet Standards

For foods required to clear quarantine, food not meeting import requirements cannot be imported. The food must meet all required conditions, otherwise it must be re-exported or destroyed. Food that has not cleared quarantine cannot be moved without AQIS approval.

For non-quarantine foods (risk and surveillance foods), consignments that fail inspection, and therefore do not meet Australian standards, are also unable be imported. Where goods cannot be brought into compliance, for example, by correctly labeling the product, AQIS oversees the destruction or export of products. Where surveillance foods fail testing, subsequent consignments will also be placed on a test and hold direction until five consecutive passes are achieved.

For food that has been distributed, state and territory food authorities are advised of the failure, and they will determine if action needs to be taken. AQIS does not have the power to recall food that has passed quarantine requirements and been distributed by the importer. Once products are past the border, state and territorial governments oversee the safety processes related to food products (DVC, 2011).

5.2.1 The Procedure and Outcome for Imported Foods that are Refused Entry (Including Efforts to Prevent them from Mistakenly Entering Domestic Commerce)

See Section 5.2 concerning refusals. During the DVC the following points were made about the possibility of refused imports mistakenly entering domestic commerce (DVC, 2011):

- It is possible for affected import shipments to enter the domestic food supply, but interviewees noted that this is uncommon.

- Interviewees noted they are improving their current IT systems in order to help ensure affected products do not enter domestic food supply.
5.2.2  **Entry of Detained Products Based on Further Testing or Reconditioning of the Product**

Foods not initially meeting import requirements may be released after coming into compliance with the specific requirements for that product. Most product failures pertain to non-compliance of labeling standards. Importers are able to address label non-compliance before requesting an AQIS inspection. Where foods fail because their composition does not meet Australia's standards (for example, a non-approved additive or coloring) or because the food contains unacceptable levels of a natural toxicant or microbiological contaminant, it may not be possible to make the food compliant for entry. In these cases, the importer has the option of re-exporting the food to a country that is willing to accept the food, knowing the reason why the food is being exported, or having it destroyed. The food is re-exported or destroyed under AQIS supervision. (DVC, 2011)

5.2.3  **Process for Identifying and Tracking Producers or Countries that have Repeated Violations**

Australia does not have a formal method for tracking importers or suppliers who repeatedly violate Australian standards, however, regional inspectors may be aware of repeat violators due to the frequency of inspections performed. Officials commented that a tracking element for importers and suppliers will be considered when establishing forthcoming IT changes and updates (DVC, 2011).

5.3  **Program for Investigating and Responding to Intentional Contamination of Foods**

Efforts to investigate and respond to the intentional contamination of food stem from refusal, recall and foodborne illness-related procedures (See Sections 2.7, 5.2, and 6.2). In addition:

- Emergency management’s “all hazard approach” encompasses issues such as intentional contamination of food.
- There is a group within DAFF that has an intelligence focus to help promote food safety.

(DVC, 2011)

In responding to intentional contamination:

- Most recalls are voluntary.
- Recalls are mandatory if an importer allowed a food to leave its premises without authorization.
- State and territorial governments, AQIS16, and Customs try to determine the extent of affected products and the action that is most appropriate to the circumstance.

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16 AQIS is involved when imported food is implicated
• DAFF coordinates national recalls if more than one jurisdiction is involved.

(DVC, 2011)

6 FOOD RELATED ILLNESS OUTBREAKS

6.1 System for Tracking Imported Foods once they are Cleared at the Point of Entry

Once food has cleared the border, imported food is managed by state and territory food authorities. All food must be labeled with importer details, and lot and batch information enables food to be recalled, should it be required. State and territory law places requirements on food businesses, including importers and distributors, to have systems in place to recall food (DAFF, 2011e).

6.2 Systems for Identifying Foodborne Illness Outbreaks

According to the National Food Incident Response Protocol, OzFoodNet is developing Guidelines for the detection, investigation and management of multi-jurisdictional outbreaks of foodborne illness. The protocol also provides a list of agencies and government or industry groups/committees that could be involved in a national food incident, including:

Federal Government Agencies and Authorities

• Australian Government agencies responsible for food issues or food safety;
• Australian Government agencies responsible for human health, agriculture, environment, consumer affairs or trade;
• State and Territory Government agencies responsible for food issues or food safety;
• State and Territory Government agencies responsible for human health, agriculture, environment or consumer affairs, including jurisdictional public health units; and
• Local government authorities, including jurisdictional public health units.

Other Organizations and Committees

• Australian Health Protection Committee and its subcommittees;
• The Communicable Diseases Network Australia;
• OzFoodNet;
• Food Surveillance Network (FSN);
• Animal Health Australia;
• Food Chain Assurance Advisory Group;
• Food Regulation Standing Committee;
• Government Food Communicators Group;
• Retailers and Manufacturers Liaison Committee; and
• SAFEMEAT (ISC, 2009)

"Health departments conduct surveillance diseases that are foodborne and potentially transmitted by food in order to monitor trends in illness, detect outbreaks, inform preventative measures and evaluate the efficacy of intervention efforts. State and territory health departments record details of notified patients in surveillance databases. These surveillance datasets are aggregated into a national database—the National Notifiable Diseases Surveillance System (NNDSS)—under the auspices of the National Health Security Act 2007. Surveillance data are used to monitor trends in the incidence of disease and to detect outbreaks and clusters of disease. Long-term trends in surveillance data also enable the efficacy of public health interventions to be assessed."

"In Australia, state and territory health departments conduct surveillance for between 10 and 15 different diseases that may be transmitted through food. Most of these diseases are transmitted by the fecal-oral route and as such may also be transmitted by contact with infected animals or people, or through consumption of contaminated water. In addition, health departments collect summary data on all outbreaks of foodborne diseases, which provide robust information on contaminated foods causing illness in Australia."

Currently, "OzFoodNet aggregates and analyses national-level information on the incidence of diseases caused by pathogens commonly transmitted by food, as well as foodborne disease outbreaks. The OzFoodNet network includes collaborators from the Public Health Laboratory Network, Food Standards Australia New Zealand (FSANZ), the Department of Agriculture, Fisheries and Forestry and the National Centre for Epidemiology and Population Health at the Australian National University. OzFoodNet is a member of the Communicable Diseases Network Australia (CDNA), which is Australia's peak body for communicable disease control" (OzFoodNet, 2009).

6.3 Procedure for Tracking Illnesses back to the Food Source when a Foodborne Illness Outbreak Occurs

Procedure for tracing the source of foodborne illnesses:

• As foodborne illness-related issues arise through the surveillance work of OzFoodNet (see above), FSANZ and applicable health agencies and industries are informed. For international concerns, AQIS is also involved in working with importers to trace back to the source product.

• The health arm investigates the public health aspect and notifies food-related agencies if the issue is food-related.
Australian officials felt that this system of tracing works well in Australia (DVC, 2011).

6.4 How Consumers Notify the Government and/or Importers of Food Problems

Information on this topic was not distilled from publically available information or country interviews.

7 EXPORT PROGRAMS

7.1 Programs for Ensuring Safety Requirements of Export Destination Countries

“AQIS operates under the conditions and restrictions of the Export Control Act 1982. Certain goods are subject to the provisions under the Act and associated Regulations and Orders when they are prepared or processed for export.” Export requirements are product-dependent, and as a general rule, AQIS only assists in the export of prescribed goods. The Act specifies that goods are ‘prescribed’ or ‘non-prescribed’.

Prescribed goods include:

- Dairy
- Live animals
- Fish and fish products
- Plants and plant products
- Eggs and egg products
- Meat and meat products
- Grain
- Animal food (frozen raw meat)
- Food labeled as organic
- Fresh fruit and vegetables
- Dried fruit
- Pharmaceuticals (raw animal material)

All other goods are classified as non-prescribed, and provisions may still apply if government to government certification is required” (AQIS, 2011e).
“Some prescribed goods intended for export must be prepared at registered premises. This means that the premises must be constructed, equipped and operate in an effective and hygienic manner, and be approved by the Australian Quarantine and Inspection Service (AQIS).

To register the premise, [the producer] must apply to AQIS for assessment. The application will be assessed for technical, financial and fit and proper compliance as per the relevant export legislation. Export operations can begin when notification of approval by AQIS and (where required) overseas government authorities is received. [Producers] are given a registration certificate and number, which must be displayed at your premises. A review of registration occurs regularly.”

All Prescribed Goods require an export permit prior to departure from Australia. AQIS is the permit issuer for goods prescribed under the Export Control Act (1982). The export permit number (EPN) is mandatory for prescribed goods to gain clearance via Australian Customs and Border Protection Service. All goods require an export declaration number (EDN) for clearance through the Australian Customs Service EXIT system. They may also require export certification to enable entry into the importing country. For edible meat, hides, and skins, fish, dairy, horticulture, grains, eggs and inedible meat products documentation may be lodged electronically with AQIS via the EXDOC system (See Section 7.1.1) (AQIS, 2011i).

7.1.1 Use of Export Certificates to Provide Assurances to the Importing Country

Under the Control Act (1982) export documentation includes the export permit and/or the export certificate. DAFF is responsible for providing export documentation for exported goods under the Export Control Act 1982, and the agency uses a software program, EXDOC, for managing export documentation. EXDOC covers the following product categories:

- Edible Meat
- Dairy
- Seafood
- Grains
- Eggs
- Horticulture
- Skins & Hides
- Wool
- Inedible Meat Products

(AQIS, 2011i)
7.1.2 Providing to the Import Country Lists of Establishments that Meet the Importing Countries’ Food Safety Requirements

Where there are specific importing country requirements, in addition to those specified in the Export Control Act (1982), a separate country listing may be required. The registered establishment must apply to AQIS for assessment to confirm compliance with the importing country’s listing requirements. Products may only be produced for export once listing has been granted.17

The main listing of establishments for other countries involve meat (DVC, 2011).

7.1.3 Authorized Third Party Issuance of Export Certificates

Information indicates that third parties do not issue export certificates.

8 WORLD TRADE ORGANIZATION (WTO) OBLIGATIONS

8.1 Methods for Ensuring Consistency between Domestic and Imported Food Safety Requirements

The Review of the Imported Control Act (last updated 2008), states: “To achieve the balance of regulation between importers and local manufacturers, inspection of local manufacturing processes must produce the same outcomes as end-point inspection, certification agreements and quality assurance-type systems (compliance agreements with the importer) for imported food. This is particularly difficult to determine, and precise determination will require a considerable amount of research and judgment. Ultimately, the answer may lie in the determination of equivalence. Currently, the Committee believes that, on the information available, the balance has been appropriately struck.”

8.2 Methods of Documenting the Scientific Justification for Import Practices with regard to Article 5 of the SPS Agreement, which Requires that Measures are based on an Assessment of Risk, as Appropriate to the Circumstance

“Successive Australian Governments have maintained a conservative, but not a zero-risk, approach to the management of biosecurity risks. This approach is consistent with the World Trade Organization’s (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

Annex A of the SPS Agreement defines the concept of an ‘appropriate level of protection’ (ALOP) as the level of protection deemed appropriate by a WTO Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory. Australia expresses its ALOP in qualitative terms.

17 For listing of importer requirements for Dairy by country, see http://www.daff.gov.au/aqis/export/dairy/country-requirements.
[Australia’s] ALOP, which reflects community expectations through Australian Government policy, is currently expressed as providing a high level of sanitary and phytosanitary protection, aimed at reducing risk to a very low level, but not to zero.

Consistent with the SPS Agreement (Article 5, paragraph 3), in conducting risk analyses Australia takes into account as relevant economic factors:

- The potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease in the territory of Australia
- The costs of control or eradication of a pest or disease
- The relative cost-effectiveness of alternative approaches to limiting risks.” (DAFF, 2011b)

Australian officials also noted that:

- All imported foods must meet the foods standards code. There is a publically available risk assessment behind each of these standards.
- If officials believe that trade will be affected, the WTO is notified.

(DVC, 2011)

8.3 Involvement in Article 4 of the WTO SPS Agreement Regarding Equivalence Determination

“Australia is under an obligation (via its participation as a Codex member country) to recognize other countries' inspection/certification systems if those systems deliver outcomes which are equivalent to those delivered by Australian systems. Under the current legislation, AQIS can enter into certification agreements with specified foreign government agencies; allowing those agencies to certify that the subject goods met Australian food standards at the time of their production. Shipments are accompanied by a certificate from the overseas authority” (AQIS, 2008).

Australia is not currently engaged in equivalency determinations, although officials highlighted:

- Equivalence is currently addressed through foreign government certifications for specific products.
- Australia also participates in the Trans Tasman Mutual Recognition Arrangement (TTRMA) agreement with New Zealand, which also cover products and services beyond food.

(DVC, 2011)
8.4 Process for Recognizing a Foreign Country’s Food Safety System as having Adequate Regulatory Oversight

AQIS refers to the Codex guidelines CAC/GL 34-99 and CAC/GL 53-2003 when determining the adequacy of another country’s regulatory system.
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OVERVIEW OF FOOD AND FEED SAFETY SYSTEM

The Canadian Food Inspection Agency (CFIA) is the primary agency associated with the inspection of foods and feed\(^1\) imported into Canada. The CFIA was established in 1997 and consolidated all food and feed inspection related resources at the federal level. Reporting to the Minister of Agriculture and Agri-Food, the CFIA is responsible for administering and/or enforcing 13 federal statutes and 38 sets of associated regulations, which govern the safety, nutritional quality and labeling of food and feed sold in Canada and support a sustainable plant and animal resource base. The CFIA is responsible for the enforcement of the health and safety provisions of the *Food and Drugs Act*, the administration and enforcement of the *Feeds Act*, and the delivery of federal food and feed inspection and enforcement activities\(^2\).

With regard to food safety, Health Canada (reporting to the Minister of Health) is responsible for establishing policies and standards governing the safety and nutritional quality of all food sold in Canada. More specifically, Health Canada is responsible for the administration of the *Food and Drugs Act* and *Regulations*, the core federal legislation which regulates the safety and nutritional quality of all food sold in Canada. Health Canada is also responsible for assessing the effectiveness of CFIA’s activities related to food safety (section 11(4) of the *Canadian Food Inspection Agency Act*).

The *Food and Drugs Act* and *Regulations* is the primary legislation that applies to all food sold in Canada, whether produced domestically or imported. This legislation sets out minimum health and safety requirements, as well as provisions for preventing fraud or deception in labeling, composition, packaging, treatment, processing, sale or advertising.

In addition, there are other Canadian statutes that apply to food. These statutes include:

- The *Consumer Packaging and Labeling Act* (CPLA) and associated *Regulations* establish labeling and net quantity requirements for consumer packaged goods for sale in Canada.

- The *Canada Agricultural Products Act* (CAPA) and associated *Regulations*, the *Fish Inspection Act* (PIA) and *Regulations* and the *Meat Inspection Act* (MIA) and *Regulations* set out further requirements for products that are imported, exported or traded inter-provincially.

Food commodities regulated under CAPA, PIA, and MIA include dairy products, fresh fruit and vegetables, honey, organic products, maple products, eggs, processed fruit and vegetable products, fish and seafood, and meat. Establishments that prepare or process these commodities and trade inter-provincially or internationally are generally referred to as the "federally registered" food sector, as most must be registered.

\(^1\) "Food" and "feed" include food products and food ingredients and feed products and ingredients

\(^2\) The Canada Border Services Agency (CBSA) provides initial inspection services at the border and makes risk management decisions regarding admissibility of imported goods, based on CFIA recommendations
Food and food facilities regulated under the *Food and Drugs Act* and the CPLA but not subject to MIA, CAPA and FIA are commonly referred to as the “non-federally registered” sector. This sector covers a wide range of products, including fats and oils, juices, bakery products, infant formula, cereals, spices and seasonings, coffee and tea, confectionary, and alcoholic and non-alcoholic beverages. The sector also includes dairy, honey, maple, eggs, meat, fresh fruit and vegetables, processed fruit and vegetable products and seafood products that are only traded within a province (i.e., do not trade across provincial and international boundaries). The responsibility for inspection of foods in the non-federally registered sector is shared between the CFIA and provincial and territorial governments, with the CFIA focusing on internationally and interprovincially traded products. Approximately 70 percent of food products in the Canadian marketplace fall within the non-federally registered sector. (CFIA, 2011ee)

Livestock feed is regulated under the *Feeds Act* and associated Regulations and under certain provisions of the *Health of Animals Act* and associated Regulations. The CFIA administers and enforces the legislation and verifies that livestock feeds manufactured and sold in Canada or imported are safe, effective and are labeled appropriately.

Other federal statutes are designed to protect Canadian agriculture, aquatic animals, forestry, industry and wildlife from the introduction of animal and plant diseases and pests, and include the *Health of Animals Act* and related Regulations, and the *Plant Protection Act* and Regulations. These statutes restrict the importation of certain foods and feeds from specific areas of concern or require relevant certificates, permits or other documentation, depending on the disease/pest status of specific countries.

CFIA promotes its imported food safety system as being a “robust, risk-based system” (CFIA, 2011bb). Surveillance activities are prioritized with regard to importers’ history of regulatory compliance as well as the hazard levels “posed by particular products (e.g., microbial concerns, veterinary drugs), combined with high volumes of consumption and trade” (NAS, 2010). Importers bear the primary responsibility for ensuring that their products meet Canadian standards (CFIA, 2011p).

1 **Roles and Functions of Agencies Responsible for Imports of Human Foods and Animal Feed**

1.1 Governmental Ministries and Subunits (Including National/Regional/Local, as Appropriate) With Responsibility for Assuring the Safety of Imported Food

*The Canadian Food Inspection Agency (CFIA)*

When CFIA was created in 1997, Canada consolidated all federally mandated food, plant, and animal inspection and quarantine services formerly provided by the Departments of Agriculture and Agri-Food Canada, Health Canada (HC), Fisheries and Oceans Canada, and Industry Canada (National Academy of Sciences, 2010) in CFIA. Canada migrated to a singular food enforcement agency in order to improve effectiveness (e.g., consistency of inspections, clarification of responsibilities), efficiency (e.g. reducing duplication and overlap in food safety activities), and reducing federal spending (GAO, 2005).
The CFIA is structured as a corporation. The Minister of Agriculture and Agri-Food is responsible for and has overall direction of the Agency. As of March, 2010, the CFIA employed over 7,000 workers, 4,700 of whom served in “inspection positions such as chemists, risk assessors, supervisors and scientific researchers”. Of the 4,700 inspection positions, 3,300 employees served as “front-line inspectors and inspection managers who work in food processing plants, import service centres and field offices across the country” (CFIA, 2011q).

“The CFIA Agency Import Coordination Committee (AICC) was established to ensure consistency in the delivery of import programs and to provide a forum for Policy and Programs, and Operations to address key issues with respect to import control. The AICC brings together subject matter experts from the different CFIA commodity areas to make commodity-specific decisions. “The AICC is not an executive decision-making body and does not provide strategic direction”, but rather committee meetings typically address linkages, relationships and issues with external parties (e.g. CBSA, United States Food and Drug Administration) and internal matters such as resourcing and day-to-day operational issues”. The committee is in the process of being revived after having gone through a recent dormant period. (CFIA, 2008; DVC, 2011)

Health Canada

With regard to food, Health Canada is responsible for establishing policies and standards governing the safety and nutritional quality of all food sold in Canada, as well as assessing the effectiveness of CFIA’s activities related to food safety. Groups within Health Canada that participate in maintaining the safety of imported food and feed include:

- The Food Directorate is the federal authority responsible for establishing standards and policies governing the safety and nutritional quality of all food sold in Canada. It also engages in research, food safety risk assessment, pre-market review, and evaluation of all issues related to food safety and nutrition.

- The Veterinary Drugs Directorate evaluates and monitors the safety, quality and effectiveness of veterinary drugs and sets maximum residue limits for food products derived from food-producing animals.

- The Pest Management Regulatory Agency evaluates, registers, and sets maximum residue limits for agricultural chemicals in foods. (Health Canada, 2011b)

Department of Foreign Affairs and International Trade (DFAIT)

DFAIT sets tariff rate quotas (TRQs) for the importation of certain agricultural products under the authority of the Export and Import Permits Act. (DFAIT, 2011)

Canada Border Services Agency (CBSA)

The CBSA reviews import documentation (such as permits and licenses), and also inspects shipments to ensure that they align with the documentation presented. The import inspections performed by the CBSA are typically visual in nature, such as performing document checks and visual inspections of goods (the CFIA oversees laboratory testing as it relates to the inspection of
imported goods). For commercial goods, the CBSA provides a range of import and export services to help ensure that trade flows smoothly. (CFIA, 2011p)

In 2003, the CBSA assumed responsibility for the initial import inspection services in respect of the Acts and Regulations administered by the CFIA to the extent that they are applicable at Canadian border points. The CFIA retains responsibility for the enforcement of those Acts to the extent that they apply within Canada. The CFIA and the CBSA have a Memorandum of Understanding (MOU) which outlines the administrative and operational roles and responsibilities of the two agencies with respect to the import, export and in-transit movement of food, plants, animals and related products.³

The CBSA Border Service Officers are designated as inspectors under CFIA Acts under section 9(2)(b) of the Canada Border Services Agency Act to ensure that initial port of entry inspection requirements are effectively implemented.

**Provincial and Territorial Governments**

The responsibility for inspection of intra-provincially traded foods is shared between the federal and provincial/territorial governments.

The federal *Food and Drugs Act* (FDA) and associated *Regulations* and the *Consumer Packaging and Labeling Act* (CPLA) and associated *Regulations* are applicable to all food manufactured and imported for sale in Canada, including the intra-provincial food sector. Provincial and Territorial governments may enact legislation governing food produced and sold within their respective jurisdiction. Such legislation is complementary to federal statutes. As such, most provincial/territorial food safety legislation does not cover the provisions of the federal FDA and CPLA.

Although provinces and territories have no direct responsibility for imported foods or inter-provincially traded foods, they can sample and test food that has been imported or inter-provincially traded, when that food is distributed/sold within their territory. If that food is found to be non-compliant with their provincial/territorial legislative or regulatory requirements, they can take enforcement action on the affected food or dealer (CFIA, 2011p).

**Private Sector**

In Canada the importer is held responsible for ensuring that all imported food and feed meet Canadian regulatory requirements.

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1.2 Agencies Responsible for Animal Feed and/or Pet Foods

Livestock Feed

The importation of livestock feeds is regulated by the CFIA under the *Feeds Act* and *Feeds Regulations*, whereby all imported feed must be approved (i.e., listed in a positive list of ingredients in the *Feeds Regulations*) and/or registered before it can be imported or used in feed in Canada, thus, providing import controls. Compliance is verified by the CFIA (CFIA, 2011ee). Authority to regulate feed and the importation of any animal product or animal by product is also provided by the *Health of Animals Act* and associated *Regulations* (See Section 1.5).

Pet Food

The importation of pet food is also regulated by the CFIA under the *Health of Animals Regulations*. Generally, pet food and feed for exotic animals are regulated differently from food intended for food producing animals.

See also Section 2.2 for import requirements regarding BSE.

1.3 Food Importation Process Steps and the Government Units That Oversee Each Step

According to the CFIA *Guide to Importing Food Products Commercially* (2011), there are several steps that an importer must take to import food into Canada, including:

- Import/Export businesses must register with and obtain a business number (BN) from the Canada Revenue Agency (some exceptions apply). The import/export account number must be provided on customs documents submitted to CBSA. The CBSA does not register foreign facilities (CFIA, 2011ee)

- The importer provides the CBSA with the following information/documentation:
  - Cargo control document. This document may be a manifest, waybill or some other approved document obtained from the carrier or freight forwarder.
  - Invoice to support the value of the goods. This invoice provides information concerning the shipment including: details regarding the importer and exporter, a description of the goods, the value of the goods, the country of origin and destination of the goods, and the currency of settlement. A Canada Customs’ invoice or a commercial invoice containing all the required information is necessary for goods with a value of $1,600 or greater. An additional copy of the invoice is required in cases where the importer or broker intends to transmit the final accounting data through CADEX (Customs Automated Data Exchange).
  - B3 form which is used for duty and tax purposes.
- Permits, certificates, licenses or other documentation required by the CBSA or other government departments for the release of food shipments. Generally, original documents are necessary.

- The importer/broker accesses the Automated Import Reference System (AIRS) to determine the requirements to import CFIA-regulated commodities. AIRS is an electronic “reference system that provides detailed information on import requirements for all Canadian Food Inspection Agency commodities”.

- The importer/broker sends an electronic message to the CBSA, which then forwards it to the CFIA, through the CBSA Electronic Data Interchange (EDI). The CFIA reviews the information submitted and sends recommendations to the CBSA regarding actions to be taken. Instructions are based on the commodity and risk of the shipment.

- When imported products arrive at Canada’s Border:
  - The CBSA checks each shipment for the associated product/importer documentation, but they do not conduct direct sampling of imported foods and feed.
  - Imported food sampling and testing is generally part of joint domestic-imported monitoring and survey programs that are prompted by risk-based or scientific sampling plans, intelligence regarding food safety, and/or responsiveness to consumer issues. While foods being sampled/tested as part of regular monitoring activities are not held during testing, those products targeted as the result of intelligence activities, for example, are held during sampling/testing (See Section 2) (DVC, 2011).
  - Based on the CFIA’s recommendations and program requirements, the CBSA may:
    - Release the shipment for sale (i.e., product is admitted into Canada)

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4 “Special programs exist to speed the transit time through Customs.
- The Pre-Arrival Review System (PARS) allows Customs to process release information before the goods arrive, thus accelerating release or referral of goods when they do arrive.
- The Customs Self Assessment (CSA) Program is designed for low-risk, pre-approved importers, carriers and registered drivers. The CSA program simplifies many of the import border requirements so that low-risk shipments can be processed more quickly and efficiently at the border. It also allows the CBSA to better focus its resources on identifying high-risk shipments that pose a potential threat to the health, safety or economic well-being of Canadians.
- Release on Minimum Documentation Option is another program offered by Canada Border Services Agency, to importers or brokers who post security with Canada Border Services Agency for release of goods prior to payment of duties. Importers or brokers requesting this option provide specified minimal documentation rather than the complete information otherwise required. When goods are released on minimum documentation, the importer or broker must present or transmit confirming accounting data within five full business days from the date the goods are released.” (CFIA, 2011p)
- Release the shipment to destination where it will be held pending an inspection decision (e.g., meat, fish), i.e., the product is released to the importer for inspection at the importer’s warehouse

- Hold the shipment for inspection at the border

- Reject the shipment

- Food commodities not meeting regulatory criteria:

  - Are not allowed into Canada and details of the shipment are posted on the CFIA website (the posting refers to the product and country of origin rather than the specific importer of that good)

    - Importers are instructed to destroy or remove from Canada products not meeting regulatory criteria

    - If a particular product or lot is found not to be in compliance with regulations, the CFIA may put a border look-out in place to ensure that the product/lot is not imported

  - In some situations, e.g., where the non-compliance relates to non-health and safety labeling issues, the shipment may be allowed into Canada with a “commitment to correct.”

(CFIA, 2011p)

*Animal Feed*

In addition to the CBSA process related to importation of food (Section 1.3), importers of animal feeds must (Feeds Act, 2011):

- Register their livestock feed product\(^5\),

- Ensure that the product’s information, composition, and labeling meet Canadian regulation, for the specified product,

- Demonstrate that a plan for tracking the product is in place with respect to products under the enhanced feed ban, and

- Implement a procedure for controlling products that do not meet import requirements

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\(^5\) CFIA requires the following types of imported feed to be registered: “

- Mixed livestock feeds manufactured outside Canada
- Single ingredient feeds listed in Part II of Schedule IV of the Feeds Regulations, such as mineral complexes, viable microbial cultures

(CFIA, 2011aa)
1.4 Assistance, Cooperation or Contributions from Other Government Bodies (National or Local) in the Imported Food and Feed Process

The Canada Border Services Agency (CBSA) and the Canadian Food Inspection Agency (CFIA) share responsibility for enforcing acts and regulations that govern the import, export and in-transit movement of food, plants, animals, and related products (these include agricultural inputs such as fertilizers, livestock feed and agricultural products). A memorandum of understanding between the CFIA and the CBSA establishes respective roles and responsibilities (refer to Section 1.1). The CBSA provides initial inspection services at the border and makes risk management decisions regarding admissibility of imported goods based on the CFIA’s recommendations (CFIA, 2011p). According to the Guide to Importing Food Products Commercially (2011), the Customs Act gives the CBSA the authority to detain goods that to not meet the Act’s requirements. The guide goes on to describe the duties of customs officials as including:

“The review of import documentation, ensuring that all required permits, certificates and licenses (including those for other government departments) are presented before the goods are released; and perform examinations of food shipments to verify that the information/documents being presented at the time of release are relevant to the goods.”

CFIA Programs (Food, Animal, Plant business lines) input the import requirements information on the Automated Import Reference System (AIRS) and update it regularly so that it accurately reflects import conditions by commodity type and country of origin. The CBSA Border Service Officers check AIRS and if they have questions on specific import requirements, verify with either the National Import Service Center (NISC), the online import procedures web pages by business line or the local CFIA office. Certain shipments or products may need to be targeted for inspection or testing by CFIA staff and this is indicated by the statement “Refer to CFIA veterinary inspection” or “Refer to CFIA-ISC” in the recommendations to CBSA portion of AIRS.

Provincial and Territorial governments have jurisdiction over public health issues, which includes food prepared, sold and manufactured within their borders (See Appendix B for complete list of Provincial and Territorial governments) (Section B, Guide to Importing Food Products Commercially, 2011). Once imported food is distributed within their borders, they could sample and take action at the intra-provincial level. A study by the National Academy of Sciences titled, Enhancing Food Safety: the Role of the Food and Drug Administration states that, “[the] Canadian provinces play a large role in ensuring the safety of food products within their jurisdictions, but not in the regulation of food imports/exports” (NAS, 2010).

1.5 Laws and Regulations that Provide Authority for the Oversight of the Safety of Imported Foods and Animal Feed, and the Policies and Procedures that Guide Import Officials

The Food and Drugs Act and Regulations is the primary legislation that applies to all food sold in Canada, whether imported or produced domestically. The legislation sets out minimum health
and safety requirements, as well as provisions preventing fraud or deception. The Act applies to food, drugs, cosmetics, medical devices, and natural health products. (CFIA, 2011p)

The Consumer Packaging and Labeling Act and Regulations establish labeling and net quantity requirements for consumer packaged goods for sale in Canada (CFIA, 2011p).

The Pest Control Products Act (PCPA) and Regulations is the primary federal legislation for the regulation of pesticides in Canada and governs their importation, manufacture, sale and use. Maximum residue limits (MRLs) which are set for each pesticide used on food sold or imported into Canada are established by the PMRA under the authority of the PCPA and enforced by the CFIA under the Food and Drugs Act.

The Agriculture and Agri-Food Administrative Monetary Penalties Act includes provisions for administrative monetary penalties for the enforcement of the Health of Animals Act and the Plant Protection Act. (CFIA, 2011p)

The Canada Agricultural Products Act (CAP Act) and associated regulations are "designed to set national standards and grades for agricultural products and to regulate the marketing of agricultural products in import, export, and interprovincial trade. They provide for the licensing of dealers in agricultural products; the inspection, grading, labeling, and packaging (including standardized sizes) of regulated products; the registration of establishments; standards governing the construction, maintenance and operation of establishments; and mechanisms to settle disputes over transactions between dealers of fresh fruits and vegetables."

The following regulations fall under the CAP Act: 

- Dairy Products Regulations
- Egg Regulations
- Fresh Fruit and Vegetable Regulations
- Honey Regulations
- Licensing and Arbitration Regulations
- Maple Products Regulations
- Processed Egg Regulations
- Processed Products Regulations
- Livestock and Poultry Carcass Grading Regulations

While this Act primarily deals with food quality issues, commodity-specific regulations under this act incorporate by reference the safety provisions of the Food and Drugs Act.
The Fish Inspection Act and Regulations establish composition, quality, labeling and packaging requirements for fish and fish products traded internationally and interprovincially. Regulations also set standards of construction, operation and maintenance for processing establishments.” (CFIA, 2011p)

The Feeds Act and Regulations provide the CFIA with authority to verify that livestock feeds manufactured and sold in Canada or imported into Canada are safe, effective and are labeled appropriately. The Act sets requirements for the registration of imported feeds, and the associated regulations set standards for composition and labeling of feeds manufactured for livestock.

The Health of Animals Act and Regulations including the Reportable Diseases Regulations regulates the movement of live animals and things derived from them, such as animal feeds, with the intent of minimizing the introduction of animal diseases, or diseases transmissible to humans from animals into Canada. The Act and Regulations also provide for the registration, operation, and maintenance of private quarantine premises. The Act and Regulations apply to both Aquatic and Terrestrial animals as defined within the legislation. This Act also provides the authority for orders to remove from Canada animals and things derived from them that do not meet Canadian import requirements or that were imported in contravention of the Regulations. Other authorities include forfeit or seizure by the crown, with disposal as determined by the Minister. (CFIA, 2011p; CFIA, 2011ee)

The Plant Protection Act and Regulations prevents the import and export of pests that can be harmful to plants. The Act covers fresh fruits and vegetables that may be subject to phytosanitary import requirements. (CFIA, 2011p)

The Fish Health Protection Regulations of the Fisheries Act are intended to prevent the spread of fish diseases by” inspecting fish stocks and controlling the movement of fish stocks.” (CFIA, 2011p)

Export and Import Permits Act (EIPA) gives the Minister of International Trade the authority to control the import and export of certain goods through the establishment of a series of criteria-based lists such as Import Control List (ICL), the Export Control List (ECL) and the Area Control List (ACL). In terms of food imports, agricultural products may be controlled by the Act. Each control list established under the Act is briefly described below.

Area Control List (ACL)

The ACL grants the Governor in Council the authority to establish a list of countries to which he deems the control of exported goods necessary (Export Control List, 2011). The current ACL list was not found in publicly available information.
Import Control List (ICL)

The ICL is designed to help control the supply and distribution of imported goods, some of which may be competitive with Canadian products (EIPA, Section 5, 2011). EIPA (Section 5 defines the products to be included on the ICL as imported goods that “the Governor in Council deems it necessary to control” for reasons such as ensuring supply and demand, implementing agricultural-related regulations, and maintaining intergovernmental trade arrangements. The rather extensive list (20 pages) includes a range of food products including some processed animal and dairy products, grains such as barley, and certain types of pasta (Import Control List, 2011).

Export Control List (ECL)

The ECL is intended to help control the export of various products including those in the categories of: technology, medical products, forestry products, and agricultural products. More specifically, Section 3 of EIPA states that ECL gives the Governor in Council the ability to control exported products in order to ensure supply and demand of goods, uphold intergovernmental trade arrangements, and promote the use/processing of Canadian goods. Major agricultural products covered in by the ECL include: peanut butter, sugar-containing products, roe, and syrups and molasses (Export Control List, 2011).

(CFIA, 2011p) See also Section 1.1

The Customs Act provides the authority for goods not meeting the Act’s criteria to be detained (CFIA, 2011p).

The Meat Inspection Act regulates the international and interprovincial slaughter, processing, packaging, and trading of meat and meat products. In Canada, meat is the product coming from a “food animal” which “means any animal in the class of mammals or birds that is slaughtered and processed as a meat product for human consumption and for which an inspection system has been established” (Meat Inspection Regulations, 1990). Thus, meat includes both meat and poultry (CFIA, 2011p).

The Weights and Measures Act “establishes net quantity requirements for commodities sold on the basis of measure”. The Weights and Measures Act applies to bulk items that may be sold to institutions or businesses (CFIA, 2011p).

Internal Policies and Guidance

Grouped according to the legislative and regulatory requirements described above, the CFIA organizes many of its activities “around nine food commodity programs: meat, fish and seafood, eggs, dairy, maple, honey, fresh fruits and vegetables, processed products, and products in the non-federally registered sector)” (CFIA, 2008). Publically available import guidance documents are available for the following:
Canada's Forthcoming Regulation and its Status

Canada has proposed an import-related regulation that stems from the food component of the Government’s Food and Consumer Safety Action Plan (FCSAP)\textsuperscript{12}. Currently in draft form, the forthcoming regulation has already gone through the prepublication review. The CFIA conducted a pre-consultation in the fall of 2010 and expects the regulation to be pre-published in the *Canada Gazette*, Part I, in 2012.

The CFIA is proposing to enhance the safety of imported food products in the non-federally registered sector (NFRS; refer to Overview by supporting a modern and stronger approach to food safety that focuses on proactive action to identify and control risks and hazards. The proposed Regulation is designed to strengthen the accountability of Canadian importers with respect to the safety of their products as well as outline general food safety and importer licensing provisions to ensure that all NFRS products sold in Canada meet Canadian requirements, enhance the CFIA’s ability to communicate important food safety information, and increase consumer confidence in the safety of Canada’s food supply.

The regulatory proposal will require Canadian importers of NFRS products to develop and implement preventive food safety control systems, as a condition of licensing, to ensure that food is safe, fit for human consumption, and conforms to food safety and labeling requirements as outlined in the relevant Acts and Regulations.

The CFIA is working on the development and implementation of this regulatory initiative.\textsuperscript{13}

\begin{itemize}
  \item Automated Import Reference System (AIRS)\textsuperscript{7}
  \item Food\textsuperscript{8}
  \item Animals\textsuperscript{9}
  \item Plant\textsuperscript{10}
  \item Guidance to food importers by food program\textsuperscript{11}
  \item Manuals of procedures and other internal guidance documents provide further detailed inspection procedures for inspection field staff.
\end{itemize}

\textit{Canada’s Forthcoming Regulation and its Status}

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\end{itemize}

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\textsuperscript{7} http://www.inspection.gc.ca/english/imp/airse.shtml
\textsuperscript{8} http://www.inspection.gc.ca/english/fssa/impe.shtml With further guidance documents by commodity type
\textsuperscript{9} http://www.inspection.gc.ca/english/anima/impe.shtml
  \begin{itemize}
    \item Terrestrial: http://www.inspection.gc.ca/english/anima/heasan/pol/pole.shtml#prod
    \item Aquatic: http://www.inspection.gc.ca/english/anima/aqua/imp/impe.shtml
  \end{itemize}
\textsuperscript{10} http://www.inspection.gc.ca/english/plaveg/impe.shtml
\textsuperscript{11} http://www.inspection.gc.ca/english/fssa/impe.shtml
\textsuperscript{12} FCSAP is a five-year plan announced by the Prime Minister at the end of 2007 and which includes a food safety portion often referred to as “Food Safety Action Plan”.
\textsuperscript{13} Further information on this initiative is available at: http://www.inspection.gc.ca/english/fssa/imp/lic/proe.shtml
1.6 Handling of Products Transshipped Through a Third Country as Compared to Directly Imported Products

There are two sources of shipment information for imported foods and feeds: 1) paper or Electronic Data Interchange (EDI) information/data submitted by the carrier, and 2) the release request submitted by the importer/broker. (CBSA, 2011i)

On a release request, which is required from the importer or their broker prior to the CBSA releasing a shipment, the country of origin must be provided for each commodity in the shipment. There are defined rules for origin and normally this is the country where the majority of the value of the product was created. Transshipment in itself does not impact the country of origin. (CBSA, 2011i)

If goods shipped from destination “A” to “B” are transshipped through an intermediate destination, this may be identified through the shipping document or the electronic equivalent, transmitted from the carrier to the CBSA, pre-arrival of the shipment. (CBSA, 2011i)

On a release request, only seller, buyer, and consignee details are required, and the manufacturer details, if a different party, are not required. The CBSA is also considering mandating these data elements in the future to help with the issue of imports losing their identity due to trans-shipment. (CBSA, 2011i)

With respect to animal or plant products/by-products, specific requirements may apply for transshipments through a 3rd country. For example, any animal product or by-product that requires veterinary certification for import from the country of origin if transshipped through a 3rd country, must be accompanied by the country of origin certification as if it were being shipped directly. In such cases, the commodity must also have a re-export veterinary zoosanitary certificate from the country of export (3rd country) stating that the product was legally imported, and was not commingled or changed in any way while in their territory.

2 Inspection Programs

2.1 Mechanisms to Prioritize Food/Feed Import Surveillance Activities, such as Product Sampling and Testing, Inspections at the Border, and Facility Inspections of the Exporting Country

The CFIA uses information gathered from inspections and sampling of imported goods to help prioritize product focus in terms of risk.

Canada prioritizes surveillance activities based on the degree of each importer’s compliance with the country’s import regulations (See Section 1.3). In addition to “unbiased sampling” to “assess human dietary exposure, perform risk assessments, monitor trends, identify potential problems and at-risk population groups, set standards and guidelines, and evaluate the effectiveness of programs”, Canada also conducts “directed sampling” or “biased sampling,” that is, “directed at targeted sample populations . . . to investigate and verify any suspected problems of potential health risk suggested by the monitoring program” (CFIA, 2005 as cited in NAS, 2010).
“Inspection frequencies are adjusted to reflect the history of compliance associated with importers and products” (CFIA, 2011q).

Particular imports, such as meat and fish, undergo increased surveillance activities as compared to other foods and feeds. Meat consignments require pre-import notification and verification before shipment to Canada. Countries eligible for importing meat products have their first 10 shipments inspected, and if they meet Canadian standards, one in ten shipments, thereafter, is inspected. If an importer’s meat product does not pass inspection, each shipment from that importer will continue to be inspected until ten consecutive shipments have passed inspection. (CFIA, Meat Import Control Program, 2011). Imports of fish and seafood must be notified to the CFIA within 48 hours of their import. Fish which fail inspection are posted on a public Mandatory Inspection List (MIL). Subsequent imports of these products from the same processor are subject to mandatory inspection until four consecutive lots are found acceptable. Fish which the CFIA has determined may be unsafe or unwholesome, based on collected information are posted on a public Enhanced Inspection List (EIL). Imports of these products are subject to inspection until it is determined that the relevant issue has been addressed (CFIA, 2011q).

Inspection programs, including sampling activities, have a combined focus that includes domestic and import programs.

There are three main drivers for the testing of imported goods. They are:

- **Planned Work (e.g. sampling plans)**

- Sampling and testing are designed to meet objectives set by the regulatory requirements, priorities set by ranking hazards/food combinations in terms of the relative risk they represent and trade requirements. Sampling for monitoring purposes is also used to verify policies and programs effectiveness, etc. Targeted surveys complement the monitoring programs in areas that are not addressed by these programs, with a focus on fresh produce and imported ingredients that are sampled in the retail.

- Sampling and testing requirements are set out in annual plans designed to assess compliance of domestic and imported food and feed. The plans include activities related to inspection, sampling and labeling, and are developed taking into consideration the compliance history/data for the food or feed commodity, the country of origin and, where applicable, the compliance history of the particular importer/exporter of record.

- The Food Safety Science Committee, which is a panel of food safety experts, also provides general direction on priority areas through a qualitative approach to risk ranking.

- Information is also gathered from CFIA “border blitzes”
The CFIA implements the National Chemical Residue Monitoring Program (NCRMP) that gathers information pertaining to contaminants on domestic and imported agricultural products that enter into the food supply. Products monitored are prioritized in terms of factors such as the quantity of the product consumed by the population and goods that have a greater potential to have toxic elements. The four purposes of the program are to:

- Determine the extent to which there is deviation from Good Agricultural Practices (GAP) or Good Practice in Veterinary Medicine (GPVM) related to use of pesticides, veterinary drugs, and other agricultural inputs and contaminants (including heavy metals). This is assessed from the violations rates found in the monitoring phase. When rates of violation exceed acceptable levels, usually one percent, further control activities might be triggered (further explained below).
- Prevent the distribution of adulterated food products containing illegal residues.
- Growers and distributors of food which violate Canadian standards are placed on an enhanced inspection list in order to identify causes and reduce or prevent re-occurrences
- Provide data for calculation of comparative risk associated with domestic and imported sources of foods. This allows an estimation of equivalency of the various foreign residue control programs with those of Canada.

A positive test for contamination of a food product does not necessarily indicate a health risk for the consumer. Residue levels at or below the MRLs are in compliance and do not require regulatory action. The Agency takes appropriate action when a violation is identified through more elevated residue findings. These actions include follow-up inspections, further directed sampling according to a surveillance plan, or even seizure and recall of products when the health risk is considered unacceptable. (CFIA, 2011, CFIA 2011)

The design of the NCRMP is based on Codex principles. For chronic risks, the CFIA uses a sampling and testing strategy designed with sufficient statistical sensitivity to catch a one percent violation rate 95 percent of the time. CFIA follows up on all violations, however, the degree and depth of the follow up will depend on multiple factors including: relative risk to human health, history of compliance, and results of the investigation. The form of the follow up can also take multiple forms and is based on the level of risk posed by the non-compliant food.

The CFIA also implements the National Microbiological Monitoring Program (NMMP) which randomly selects and tests a variety of domestic and imported products for high-risk pathogens such as *E. coli*, *Listeria monocytogenes*, *Salmonella* and *Shigella*. (CFIA, 2011h)

Through the food component of Canada’s Food and Consumer Safety Action Plan, the CFIA performs targeted surveys to test “foods that are considered to have the greatest potential for health risks for a variety of pathogens. These surveys focus on areas not covered by the CFIA’s regular monitoring activities, specifically on the following

- Emerging hazards,
- New foods, and
- New sources of foods”

(CFIA, 2011h)

The national feed inspection program includes random and directed (targeted) sampling plans for feed, including imported feed (e.g. aflatoxins). Feed inspection and sampling plans are developed for each fiscal year. Inspectors determine which products are sampled, within the parameters of the sampling plan. (DVC, 2011)

The CFIA does not have an established program for conducting inspections of individual food and feed facilities in exporting countries. In certain circumstances, such as situations associated with significant food borne illness, or as part of an overall examination of a country’s food safety system, site visits may be conducted. For food or feed derived from animal products, site inspections may be conducted in foreign countries to gather data relevant to the evaluation of the country’s control systems with respect to animal health requirements.

### 2.2 Special Screening Requirements and Trading Partner Requirements where Disease or an Outbreak has Occurred

Canada has imposed additional requirements for trading partners in cases where disease has occurred, depending on circumstances. The CFIA performs “ongoing scanning of new and emerging risks, including food borne illnesses or outbreaks in foreign countries and other contaminants and [their] risk[s]” (Green, 2011). Examples of CFIA screening efforts include:
The CFIA works with the Canadian Animal Health Surveillance Network (CASHN) and animal detection programs to detect, diagnose, and trace animal-related diseases including those that could impact human health through foods and animal health through feed.

Canada implemented a BSE Enhanced Surveillance Program in 1993. “The program tests a sample of animals from the national cattle herd and focuses on higher-risk animals that are most likely to be affected by the disease. The surveillance program’s objectives are to determine and monitor the level of BSE present in Canada and to confirm the effectiveness of the suite of measures Canada has implemented to protect human and animal health from the disease.” (CFIA, 2011b)

For food and feed products of animal origin, and with respect to animal health issues, the CFIA evaluates regions and countries on an individual basis to qualify for Country Freedom Recognition; classifying them as officially recognized as “free” of the disease of concern in terms of certain animal (including fish/shellfish) diseases.

The evaluation of a country, or a region(s) or zone(s) within a country is reviewed by the CFIA on a case-by-case basis and is dependent on factors such as the epidemiology of the disease for which the country is being evaluated, the geographical or physical barriers which are present in a particular country or zone within the country, surveillance used in relation to the disease of concern, and the veterinary infrastructure of that country. The recognition of disease freedom by the CFIA is not solely dependent on the World Organisation for Animal Health (OIE) status or country self-determination. The CFIA utilizes risk assessment approaches in order to determine if a hazard is present in a country, and to evaluate the risk of transmission of that hazard resulting from the importation of animals, animal products or by-products. Canada accepts OIE country classification for Bovine Spongiform Encephalopathy (BSE) risk categorization.

On site visits are often required to evaluate whether import conditions will be required.

For live aquatic animals (which include finfish, mollusks, crustaceans), the country evaluation happens before import regardless if there is a disease outbreak. The CFIA determines the risk of disease based on country health status. This is then used to determine import conditions.

Imported foods and feeds of animal origin must be in compliance with all applicable terrestrial and aquatic animal health import requirements. Similarly, relevant phytosanitary import requirements must be satisfied for imported foods and feeds of plant origin.

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16 The list of countries officially evaluated and the diseases for which they were evaluated, can be found at the following site: http://www.inspection.gc.ca/english/anima/disemala/recotab/recotabe.shtml
17 Further information is available at: http://www.inspection.gc.ca/english/anima/heasan/pol/ie-2003-3e.shtml
(See also Section 1.2)

**Pet Foods**

Specific import requirements pertain to pet foods containing ingredients from bovine animals as well as pet foods not containing ingredients from bovine animals that are sourced from countries with low, controlled, or undetermined BSE risk. In some cases a pet food facility in the exporting country will need to be inspected. Manufacturers that produce pet foods and use bovine products may need to have separate production lines for pet foods with and without bovine ingredients. (CFIA, 2011r)

Pet food containing ingredients of animal origin must meet all applicable requirements of the *Health of Animals Act*, depending of the diseases of concern for each species from which the product is derived.

For countries not recognized as having negligible risk for BSE, and not recognized as free of diseases of concern, importation is subject to a case by case evaluation by the CFIA and an import permit is issued only after the successful completion of a risk assessment. A questionnaire, *Importation of Commercially Prepared Pet Food from Countries of Controlled or Undetermined BSE Risk*, must be completed and submitted with the import permit application and a visit to the exporting country may be required to collect additional information. (CFIA, 2011r)

For countries recognized as having negligible risk of BSE by the OIE as recognized by CFIA, the following documentation is required:\(^{18}\):

- Zoosanitary export certificate endorsed by an official full-time, salaried veterinarian of the country of origin, stating the origin of the product.
- Canada Customs Invoice (CCI) clearly describing the product.

(CFIA, 2011r)

2.3 **Percentage of Imported Food Shipments Examined and the Relationship between Risk-Ranking of Foods and Volume of Imported Foods Examined**

This section separates the discussion of risk-ranking and product examination by those products classified as food and those classified as animal feed. Imported food products are discussed first.

The CBSA provides initial inspection services at the border and makes risk management decisions regarding admissibility of imported goods based on CFIA recommendations. These recommendations are outlined in the Automated Import Requirements System (AIRS) and

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commodity-specific import procedural directives and are verified by the CBSA (refer to Section 1.3).

Inspection and sampling of imported food and feed occurs post entry into Canada, e.g., at the importer’s warehouse, at the manufacturer, at retail. Monitoring requirements are set out in annual plans designed to assess compliance of domestic and imported food and feed. The plans include activities related to inspection and sampling activities and are developed taking into consideration the compliance history/data for the food or feed commodity, the country of origin and, where applicable, the compliance history of importers/exporters of record.

**Food**

Canada’s import program is multifaceted (further explained below) and not designed on imported line items (i.e., shipments/lots within shipments). The CFIA import policy functions at three levels: 1) pre-border, 2) at the border, and 3) post border. The extent and scope of authorities varies by food commodity and program.

- Pre border activities are generally undertaken where the product must be produced under equivalent safety provisions, and can include foreign food safety audits or assessments.
- Border activities generally include review of the documentation of import shipments and release to importer. They also include border blitzes and look outs.
- Post border activities can include mandatory holds at importers’ warehouses, until either an inspection is completed (e.g. fish; meat program) or an inspector releases the product. It can also include random sampling of imports at the import warehouses, at retail, or at other locations.

The CFIA conducts three types of food sampling and testing activities as part of its compliance verification activities:

- Monitoring,
- Directed sampling and
- Compliance testing.

Sample testing can be grouped into three major categories based on scientific discipline and volume: chemical residues, food microbiology (including extraneous matter) and other (e.g., composition, nutrition, allergens and irradiation). Reports of the chemical monitoring program are posted on the CFIA website. Reports of the microbiological monitoring program will also be posted in the future.

A 2007-2008 report for the National Chemical Residue Monitoring Program (NCRMP) noted “over 190,000 tests for residues of veterinary drugs, pesticides, environmental contaminants, mycotoxins, and metals on monitoring samples of domestic and imported dairy, eggs, honey,
meat and poultry, fresh and processed fruit and vegetable commodities and maple syrup” were completed through the program (CFIA, 2011w). This number reflects multiple tests performed on a single sample, such as multi-residue tests. This number of tests also combines testing for domestic and imported foods. (DVC, 2011)

The CFIA also verifies imported and domestic products for:

- Container integrity,
- Ingredients,
- Labels,
- Nutrition labeling, where appropriate, e.g., retail packages
- Net quantity and
- Grade (for some commodities)

As previously indicated, sampling activities in Canada are post-border. The number of samples of imported foods (not including meat and poultry) collected and analyzed for chemical residues and microbial contaminants in 2010-2011 were:

- Microbial contaminants: 8,594 samples. This includes testing for bacteria, viruses and parasites, with a significant emphasis on fresh produce (e.g., leafy green vegetables, tomatoes, sprouts, onions, berries).
- Chemical residues: 16,085 samples comprising foods of plant and animal origin as well as manufactured foods. These are tested for multiple chemical hazards such as pesticide residues, veterinary drug residues, environmental or natural toxin as well as environmental contaminants.

**Animal Feed**

Under the *Feeds Act and Regulations*, a feed must be approved (i.e., listed on a positive list of ingredients) and/or registered before it can be imported or used as livestock feed in Canada. All verification activities by CFIA, including sampling and testing programs, occur post-border.

Animal feed sampling programs broadly target feed ingredients and products available in the Canadian marketplace. During the development of the sampling plans, the risk and compliance history of the feed is taken into consideration by CFIA officials. CFIA inspection staff can identify feeds from non-domestic sources by way of sample submission and documentation processes. In 2010-2011, there were 32 imported feeds sampled and tested. (CFIA, 2011ee)
2.4 Types of Review, Examination and/Or Testing Of Imported Products Performed By Food Safety Inspectors

See Sections 2.1 and 2.3.

2.5 Types of Examination and Testing Processes Used for Ensuring Animal Feed and Feed Ingredient Safety

According to the CFIA Livestock Feed webpage, CFIA: “

- Monitors feeds for the presence of residues of chemicals, pesticides, contamination by heavy metals, mycotoxins and salmonella and - verifying drug guarantees in feeds;
- Investigates detections of feed related contamination of meat, milk or eggs and producer complaints;
- Reviews labels of medicated feeds for compliance so that all applicable cautions and warnings are provided for safe use;
- Inspects commercial feed mills and farms involved in the production of medicated feeds.”

(CFIA, 2011u)

The national feed inspection program includes sampling and testing of domestic and imported livestock feed. The type and quantity of samples to be collected is based on available resources and an annual workplan. Testing of imported feeds includes random testing and targeted testing (e.g., for aflatoxins in imported corn). It is up to the inspector as to what they choose to sample, within the parameters of the sampling workplan (DVC, 2011). Examining and testing requirements change depending on country conditions. See also Sections 1.2, 2.2, and 2.3.

2.6 Inspections of Food or Animal Feed Manufacturers or Shippers in Other Countries (Including Selection Criteria and Frequency)

The CFIA does not have an established program for conducting inspections of individual facilities in exporting countries for most commodities. In certain circumstances, such as situations associated with significant food borne illness, or as part of an overall examination of a country’s food safety system, site visits may be conducted (See Section 2.1).

With respect to imported meat and meat products, the exporting country's inspection and certification systems along with the establishments operating under that system, must be approved by the CFIA, before meat products are allowed to be imported to Canada. Evaluations include an on-site review of the inspection system and meat producers (abattoirs and processing), if preliminary evaluation findings are acceptable. On-site reviews require: “1) visitation of a representative sample of establishments to observe application of the required standards, controls and official oversight, interviews with officials and plant employees, and 3) examination of documented control and official oversight procedures.” (CFIA, 2011n)
With respect to fish and seafood, the CFIA regulates over 1,000 fish and seafood importers and audits and inspects importers to ensure they are meeting the conditions of their license. The CFIA performs site visits in exporting countries with the purpose of auditing the exporting country’s safety system. (CFIA, 2011s)

2.7 Notification System(s) to Directly Notify Foreign Governments When Foods or Animal Feed Manufactured in their Countries are Found to be Unsafe; and to Notify the Public When Imported Products do not Meet Safety Standards

Canada contacts foreign government officials when a food safety problem involving an imported food is of public health significance and/or has public health implications for that country. Foreign governments are not notified of routine importer findings (Canada DVC, 2011). Similarly, Canada will contact foreign officials when a feed safety problem involving an imported feed of public or animal health significance is identified.

The CFIA uses an Incident Command Structure (ICS), which is an international model for the command, control, and coordination of emergency response. ICS combines facilities, equipment, personnel, procedures and communications operating within a common organizational structure” (CFIA, 2010).

Section 19 (1) of the Canadian Food Inspection Agency Act provides for mandatory recall authority for any product regulated under an Act or provision that the Agency enforces and administers, including food and feed, specifically: “Where the Minister believes on reasonable grounds that a product regulated under an Act or provision that the Agency enforces or administers by virtue of section 11 poses a risk to public, animal or plant health, the Minister may, by notice served on any person selling, marketing or distributing the product, order that the product be recalled or sent to a place designated by the Minister.”

The CFIA had rarely had to use that mandatory recall authority since most recalls are initiated voluntarily by industry/importers.

Canada’s food recall process categorizes food that is found to be unsafe into the following classes:

“Class I — represents a situation in which there is a reasonable probability that the consumption/exposure to a food will lead to adverse health consequences which are serious or life-threatening, or that the probability of a foodborne outbreak situation is considered high.

Class II — represents a situation in which there is a reasonable probability that the consumption/exposure to a food will lead to temporary or non-life threatening health consequences or that the probability of serious adverse consequences is considered remote.”
Class III — represents a situation in where there is a reasonable probability that the consumption/exposure to a food is not likely to result in any adverse health consequences.”

(CFIA, 2011i)

When a food product is categorized as “Class I”, CFIA notifies the public through a newspaper and media release, posts the notification on the CFIA website, and emails the information to the CFIA email subscriber list (CFIA, 2011i).

For importers, the CFIA provides guidance on all aspects of a food recall, including methods for tracking the distribution of their product and for controlling products that deviate from Canadian requirements (see response 1.3). As part of this product control plan, importers should have a product recall plan which incorporates the following elements:

- Forming a recall management team that will be responsible for: “Decision making, Quality assurance / technical advisory, Media communication, Complaint investigation, Contacting accounts, Contacting the CFIA, and Legal Counsel”.
- Maintaining a complaint file that records product complaints, complaint investigations, and actions taken to address the complaint.
- Recall contact list that has appropriate contact information for CFIA officials and offices
- Ability to trace products by maintaining product and distribution records and tracking product codes, distributors, and shipments containing specific lot numbers, etc
- Maintaining records of product recalls

(CFIA, 2011i)

3AUDITS AND CERTIFICATION

3.1 Assessing and Measuring the Effectiveness of the Food/Feed Safety Import Program (e.g., Self Audits of the Program, Public Health Outcomes, Surveillance Sampling Results, Number/Rates of Refusals, Periodic Program Evaluations)

Section 11(4) of the Canadian Food Inspection Agency Act, gives the Minister of Health the statutory responsibility to assess the effectiveness of the CFIA's activities related to food safety. The mandate of Health Canada’s Food Safety Assessment Program is to assess the effectiveness of CFIA's activities related to food safety with the objectives of:

- Providing advice and guidance to the CFIA on its food safety activities; and
- Providing feedback to Health Canada to assist in carrying out its role of developing food safety and nutrition policies and standards (regulations, guidelines, etc).
The Food Safety Assessment Program covers all of CFIA’s activities related to food safety and nutritional quality\textsuperscript{19}. In the context of the Food Safety Assessment Program, this covers assessing the:

- Program rationale;
- Program design and delivery; and,
- Compliance with relevant food safety policies and standards.

(Health Canada, 2011)

The CFIA also performs internal evaluations of various aspects of the food and feed import program. Examples of CFIA programmatic audits and evaluations include:

The Audit of the Management of Imported Food Safety (2008) focused on “assessing how the CFIA manages food inspection activities to reduce risks associated with imported foods, including the management control framework in place for imported food safety”. The audit used interviews with CFIA staff and documentation reviews to assess activities for the nine commodity groups in the federally registered food sector. The audit found that: 1) “The type of [import-related] performance information gathered, maintained, and assessed varies from Area-to-Area and Region-to-Region, 2) the information that is compiled is not being analyzed to assess the effectiveness of program delivery or management controls, 3) Management reports tend to focus on urgent priorities, with information (such as, trends or details of food imports) to support management decision-making not as readily available.” (CFIA, 2008)

In 2010, the CFIA created business lines to improve the integration and coordination in the management of its programs across all parts of the Agency. The Food Business Line has improved oversight and governance for all food-related activities, including for imports.

In addition, the CFIA is improving performance reporting through the implementation of an agency-wide system that supports the agency's Performance Measurement Framework.

The Evaluation of Feed Program (2007) focused on the relevance, success, program design and delivery and continuous improvement of the feed program (which includes, but is not solely focused on, imported feed) from years 2001 to 2007. Findings relevant to this study include\textsuperscript{20}: 1) “The Feeds Regulations are outdated. The feed inspection program is based on a process-based model; however, it is not fully HACCP-based; 2) Feed Program coordination between internal CFIA units is poor, and 3) Product assessment procedures and sampling are well-documented and understood. Processes, frequency and monitoring are clearly understood and followed for

\textsuperscript{19} A full listing of assessments conducted under the Food Safety Assessment Program are listed on the Health Canada website at: http://www.hc-sc.gc.ca/fn-an/securit/eval/reports-rapports/index-eng.php

commercial mills and rendering plants, but there is a lack of clarity related to the frequency and follow-up procedures for retail establishments and for farms which mix feeds.”

Since the publishing of the Evaluation of the Feed Program, significant steps have been taken towards development and implementation of performance monitoring and reporting to monitor the effectiveness of the Program and inform decision making. The inspection approach was revised and implemented in 2009. The key elements include:

- The incorporation of facility risk profiles to better allocate resources towards facilities that are considered to be of higher risk
- Comprehensive training of feed inspection staff on the new inspection system, assessing compliance and documentation requirements
- The development of a manual of procedure for facility inspection
- Uniformity in responding to non-compliance through documentation and follow-up

3.2 Extent of Reliance on Trading Partners’ Food Safety Programs to Ensure That Imported Foods or Animal Feed are Safe

A key principle in Canada’s import controls is to hold the importers responsible for the products they sell in Canada. Importers are responsible for ensuring that imported products meet Canadian safety and quality requirements.

For meat and meat products, equivalency of the foreign country’s meat inspection system is a pre-requisite to importation. For other food commodities or feed, CFIA may enter into arrangements with other countries, whereby the control systems of the trading partner are taken into account within the CFIA’s import controls activities.

For example, there is an arrangement between Canada and the European Union on sanitary measures to protect public and animal health in respect of trade in live animals and animal products (including fish and seafood). The arrangement establishes a mechanism for the recognition of equivalence of sanitary measures maintained by the two Parties consistent with the protection of public and animal health. There are also other commodity-specific arrangements (e.g., for fish and seafood; for low acid canned vegetables) with certain countries.

Seafood importers are required to be licensed and to demonstrate that they have food safety preventive practices in place. The licensing of importers of fish and seafood products was introduced in 1986 when the fish inspection program was part of the Department of Fisheries and Oceans and, thus, the rationale for having licensing provisions for seafood and not for other foods was a result of the amalgamation of several food inspection groups into the CFIA. The CFIA is introducing import licensing requirements for the non-federally registered sector, and other import licensing regimes are under consideration.

According to the Audit of the Management of Imported Food Safety (2008), “While initial foreign country equivalency assessments were conducted with some countries (e.g. United
States), periodic foreign country equivalency audits are only partially delivered and no foreign country equivalency controls are in place for food commodity programs other than meat, fish and seafood, and egg. Imports of other food commodities rely almost exclusively on destination inspections and projects.”

The control of imports was facilitated by the release in April 2011 of a web-based, enhanced Import Control Tracking System (ICTS). This system is updated as imports enter Canada and contains shipment details such as: the product’s description, exporter, importer, country of origin, lot size and destination, which allows inspectors to track and target shipments according to work plan requirements. ICTS also has the capability to capture inspection results.

Animal feed is regulated under the Feeds Act and Regulations, whereby all imported (and domestic) feed must be approved (i.e., single ingredients allowed for use in feed manufacture or as livestock feed must appear in the positive list of ingredients in the Feeds Regulations) and/or registered (for any combination of ingredients that would be considered a mixed feed) before it can be imported or used in feed in Canada, thus, providing import controls. Compliance is verified by the CFIA.

(CFIA, 2011ee)

### 3.3 Requirements for Food and/or Animal Feed Export Certificates Issued by the Exporting Country’s Competent Authority, and Types of Inspection or Testing for Each

Certificates serve as a regulatory tool for certain imported products. Requirements for certification are specified by CFIA product categories and also consider product areas that have posed previous problems with regard to food or feed safety. Mandatory certification by the exporting country’s competent authority is only required for imported meat products, and, as relevant, for foods or feeds of animal origin or plant origin with respect to applicable animal or health requirements, respectively.

Certification by the exporting country’s competent authority can be either lot by lot certificate or foreign establishment certification. The use and approach to certification varies by food commodity program and takes into account the risks posed by a food as well as the safety controls implemented in the exporting country.

Examples of certifications or agreements include:

- Canada requires Californian leafy greens and Mexican cantaloupes to have mandatory government certification and requires that the handler for leafy greens and the name of the grower packer for cantaloupes be identified on import documentation.

- Canada has an agreement by which Vietnam certifies that seafood is free from specific veterinary drugs.

- Canada also has agreements with a number of countries regarding establishment certification, whereby it recognizes their food safety systems (e.g. Canada-EU
veterinary agreement; Thailand (seafood)) and where imports from plants approved by the competent authorities are allowed to enter Canada.

Import licenses are required for importers of fish, seafood and cheese. The CFIA is developing new regulations for a licensing regime for Canadian importers bringing food and ingredients in the non-federally registered sector (NFRS) into Canada by 2013. Consideration is being given to licensing all importers.

Dealers of fresh fruits and vegetables must also be licensed, albeit for trade and commerce purposes.

Animal Feed

The registration process confirms that the livestock feed products comply with Canadian regulatory requirements and are eligible for importation and legal sale in Canada. Once a feed is registered, lot-by-lot certification is not required. (See also Section 1). Registrations must be renewed every three years.

In addition, relative to preventing the entry of zoonotic or other animal diseases, imports into Canada of any product of a rendering plant as defined under the Health of Animals Act (e.g. bone meal, fish meal, other animal origin meals, animal derived fats, oils, digests or hydrosylates, etc), must be imported under an import permit issued by the CFIA under the authority of the federal Health of Animals Regulations. Conditions specified on import permits vary by commodity and country of origin, and commodities other than fish oil, require per shipment veterinary zoosanitary certification or certificates of analysis. Records of distribution within Canada must be maintained for a minimum of 10 years for all (imported and domestic) rendered products (down to the retail level). The import permit authorizes and prescribes the legal use in Canada (CFIA, 2011).

3.4 Use of ISO, Global Gap or Other Assurance Systems and Confidence in the Assurance System(s) Utilized

The CFIA laboratories are accredited to the ISO/IEC 17025 standard. Third party laboratories (outside the Government system) contracted by the CFIA for product verification, compliance, and detection of harmful organisms must also be accredited to the ISO/IEC 17025 standard (refer to Section 4.1).

For fresh produce, individual companies, farms, warehouses, and packers have begun to implement international certification schemes, including GlobalGAP, SQF (Safe Quality Foods), BRC Global Standard for Food Safety, Primus and DavisFresh. CanadaGAP is a national, voluntary HACCP based program covering on-farm production and packers for fresh produce (also pertains to flowers and ornamental plants) and is administered by the Canadian Horticultural Council. In 2010, CanadaGAP obtained benchmarking by GFSI (Global Food Safety Initiative) and has applied to GlobalGAP (Produce Safety Project, 2010).
Certain National Industry Organizations (or equivalent organizations) in Canada have developed or are developing and implementing national food safety programs for their sectors. These include initiatives all along the food supply chain, such as CanadaGAP, the Canadian Horticultural Council’s on-farm food safety program and the Packaging Association of Canada’s PacSecure food safety program. These industry-developed, national food safety programs are sector specific, auditable and are based on HACCP principles and ISO standards.

3.5 The Nature and Frequency of Foreign Food Safety Systems Audits Performed

The CFIA periodically audits meat inspection programs of other countries. Country audits from 2007-2010 include:

- Argentina/Uruguay: Residue Control Program (2010)
- Brazil: Poultry Meat Products (2007)
- Chile: Residue Control Program (2008)
- United States: Evaluating the Food Safety System Governing the Production of Meat and Poultry Products Intended for Export to Canada (2010); New USDA-FSIS E. coli O157:H7 Policy and Follow-up of the Corrective Actions Taken (2007); Meat and Poultry Meat Products (2007); Complete system audit (beef; pork; poultry processing (2010)

(CFIA, 2011a)

3.6 Equivalence Agreements Requiring Periodic Audits/Reevaluations of Exporting Countries’ Food Safety Programs

Equivalence is the basis for importing meat and poultry, and Canada has equivalence agreements in place with some countries for the importation of these commodities, pursuant to the provisions of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures. In addition, Canada has an equivalence agreement in place with the EU for all products of animal origin, (e.g., meat, poultry, seafood, ova, serum). Agreements include provisions for audits and verification.
Canada has also entered into equivalency agreements with several trading partners for fish and seafood. These agreements authorize periodic audits of exporting countries’ food safety programs. However, given the large number of countries from which Canada imports fish and seafood, the primary import control mechanism in this sector is the licensing of importers.

Where Canada assesses the food safety system in the country of origin, it also takes into account that country’s import performance. In addition, emergency assessments can also be undertaken, should they be required because of an increased risk for a particular product or country. (CFIA, 2011n)

3.7 The Utilization of Third-Parties (Within the Exporting or Importing Country) to Carry out Inspections and/or Product Certification (Nature and Extent of Programs) and Methods for Verifying the Adequacy and Reliability of the Third Party Work

Third-parties are not generally utilized for inspections and/or product certification, with some exceptions (e.g., organic certification). (DVC, 2011)

3.8 Arrangements with other Governments Relating to Imported Foods or Animal Feed (such as Memoranda of Understanding, Mutual Recognition Agreements, etc.)

Canada has memoranda and trade agreements with a range of other countries that relate to food imports.

For example, the CFIA has developed mutual recognition or equivalence-type arrangements whereby Canada’s food safety control systems for commodity groups (e.g., animals and animal products) or specific commodities are recognized as equivalent, e.g., under the framework of the Canada-EU Veterinary Agreement. There are also such agreements specific to fish and seafood, whereby Canada’s control system has been recognized as being equivalent to that of other countries e.g. Australia, New Zealand, Thailand, Indonesia.

Mutual recognition arrangements provide increased confidence that products produced under the inspection system of the exporting country comply with Canadian requirements. This is a consideration for CFIA inspectors in determining which imported products to inspect and allows allocation of monitoring resources to higher risk areas. Mutual recognition of systems arrangements have a number of service obligations and provisions associated with them, including face-to-face meetings and audits/verification processes

There are also a number of bilateral agreements with other countries pertaining to the exchange of food safety information, including information relating to the safety of imports, (e.g., a memorandum between the CFIA and the U.S. Food and Drug Administration to cooperate on food recalls and exchange information) (GAO, 2005).
3.9 Registration or Licensing of Firms That Import and/or Export Foods or Animal Feed to the Country or for Firms That Import Foods or Animal Feed

Import/Export businesses must register with and obtain a business number (BN) from the Canada Revenue Agency. The importer must obtain a business number for each import/export account appearing on customs form, (CFIA, 2011p). Registration of the importing food and feed businesses is free (CFIA, 2011p) and does not require the participation of the competent authority in the country of origin, although product standards required for importation post-registration may require their participation (CBSA, 2011g). If products are subject to an import or export quota, a permit must be obtained through DFAIT. (See also Section 1.1).

Fish and Seafood

Under the CFIA’s Fish Import Inspection Program, importers of fish and seafood for human consumption and for commercial sale must hold either a Fish Import License or a Quality Management Program Import License from the CFIA. Importers are responsible for ensuring that their products meet Canadian regulatory requirements including the food safety standards established by Health Canada. Non-compliant shipments are not permitted to be sold in Canada. The CFIA regulates over 1,000 fish and seafood importers and audits and inspects importers to ensure they are meeting the conditions of their license. (CFIA, 2011s)

A basic fish import license costs $500 and a Quality Management Program Import (QMPI) license costs $5,000. Both types of license must be renewed annually and are not transferable. The system verification “process focuses on an assessment of the Fish Import License application form, the importer's understanding of their license responsibilities and on the processes to meet regulatory requirements.” (CFIA, 2011q)

Cheese

Importers of cheese must hold an import license. The Dairy Products Regulations describe the requirements that must be met to apply for and maintain a cheese import license as well as the conditions for suspension or cancellation of a license (cost, renewal, duration). As previously mentioned, importers are responsible for ensuring that their products meet Canadian regulatory requirements including the food safety standards established by Health Canada. Non-compliant shipments are not permitted to be sold in Canada. The CFIA inspects importers to ensure they are meeting the conditions of their license. (Refer to the Dairy Import Program).

Fresh Fruit and Vegetables

The Canadian importer is required to be licensed with the CFIA and/or be a member of the Dispute Resolution Corporation. Importers that are retailers selling directly to consumers with sales under $230,000 per year are exempted from this requirement. A CFIA license and/or membership with the DRC provides a mechanism for dispute resolution of any quality or payment issues in produce transactions and is renewable annually. The Licensing and Arbitration Regulations describe the requirements that must be met to apply for and maintain a license to import fresh fruits and vegetables and the conditions for the suspension or cancellation
of a license. As well, the regulations require the importer to post a bond or other security and state the causes for forfeiture of the bond or other security.

Other information

CFIA officials interviewed voiced their preference for licensing all importers. The CFIA is currently proceeding with licensing importers in the non-federally registered sector, as part of a forthcoming regulation. The decision to, first, license importers of products in the non-federally registered sector is part of the Government of Canada’s priorities under the Food and Consumer Safety Action Plan. Details of licensing requirements resulting from the new regulation are currently being determined and may resemble some aspects of the fish licensing requirements. (DVC, 2011)

3.10 Use of Sampling Surveys of Imported Foods/Feed (as Opposed to Targeting Specific Products/Producers for Inspections and/or Testing) to Gather Information and Identify Trends and Potential Areas of Difficulty

See Sections 2.1 and 2.3

3.11 “Good Practices” Programs for Foods/Feed Importers

The CFIA has good importer practice programs that are advisory in nature. For example, Good Importing Practices for Food (GIP) is a “voluntary code of practice to be used as a guideline for Canadian importers.” These HACCP-based guidelines go beyond the minimum requirements for food and feed importers. (CFIA, 2011; Canada DVC, 2011)

The CFIA also provides a range of guidance documents to importers (See Section 1.5).

3.12 Description of Import Program User Fees and Cost Recovery System

Cost recovery activities (domestic, import, and export-related activities) cover an estimated seven to eight percent of the CFIA budget. These can include registration fees, inspection fees, safety/efficacy assessment fees, inspection fees and other fees for service21.

3.13 Incentives to Increase Industry Involvement in Ensuring That Imported Foods Meet Safety Standards

As previously indicated, Canada holds the importer responsible for ensuring that imported products meet Canadian safety and quality requirements. Inspection programs are designed to verify that importers are meeting requirements. The CFIA’s activities to encourage industry compliance include education and guidance documents on good importing practices and guidance on importing foods commercially.

21 Further information on the full range of fee-based activities can be found at: http://www.inspection.gc.ca/english/reg/cfiaacia/feesfrais/feesfraise.shtml
The CFIA undertakes various activities to increase industry involvement in meeting regulatory requirements including: 1) publication of guidance; 2) importer training and outreach; and 3) recognition that increased importer compliance may result in reduced inspection by the CFIA. (DVC, 2011)

3.14 Obstacles to Industry Participation in Ensuring That Imported Foods Meet Safety Standards

Industry obstacles may include the importers’ lack of understanding of the import requirements and their responsibilities in meeting requirements (DVC, 2011).

4 LABORATORY SUPPORT

4.1 The Role of Laboratories in Supporting the Imported Food and Feed Programs and Description of Laboratory Capabilities

The food and feed import process relies on laboratories in Canada as well as the imported product’s country of origin. For laboratories in Canada and abroad, the majority of laboratory testing involving imported food deals with product verification, compliance, and detection of harmful organisms.

Laboratories in Canada dealing with imported foods may be CFIA laboratories or third party laboratories (i.e., laboratories outside the government system). All CFIA laboratories and third party laboratories must be “accredited by the Standards Council of Canada (SCC) under the Program for Accreditation of Laboratories better known by its bilingual acronym PALCAN”22.

Accredited CFIA laboratories are equipped to perform a range of tests on multiple commodities (e.g., meat and non-meat). CFIA laboratories perform the analyses associated with the National Microbiological Monitoring Program (NMMP), the National Chemical Residue Monitoring Program (NCRMP) and the feed monitoring program (See Section 2.2) as well as all compliance and enforcement testing (DVC, 2011). The majority of the NCRMP testing is conducted in third party laboratories. The CFIA laboratories also have a research component for regulatory purposes (e.g., to develop methodology to enforce standards).

The CFIA requires third party laboratories be accredited to the ISO/IEC 17025 standard (as per SCC info above), and these laboratories are audited. The CFIA has an agreement with the SCC to accredit testing laboratories under a Program Specialty Area (PSA) for Agricultural Inputs, Foods, Animal Health and Plant Protection. The SCC is the accrediting body and incorporates specific CFIA requirements into the assessments.

22 Program requirements for SCC accreditation are outlined in the PALCAN Handbook (CAN-P-1570) (SCC, 2011). As a signatory to several international and regional arrangements, SCC accreditation is recognized around the globe. Under these arrangements, each organization recognizes the equivalence of accreditations performed by its counterparts, and promotes the acceptance of test results from such accreditations within its own country.
To venture into a contract with a third party laboratory, the CFIA employs a competitive bidding process as set out by the Government of Canada where the CFIA posts its requirements and the condition of the contracts on the Public Works and Government Service Canada web site (http://www.merx.com). Accredited third party laboratories are able to bid on the process for a defined period of time on the MERX website. Once a third party laboratory has been assessed as meeting specific requirements, an extensive contract is put in place to ensure that the tests are performed to the CFIA’s standard and in accordance to the CFIA’s methods of analysis. All contracts and results are managed by the CFIA’s Science Branch. The third party laboratories input the results into a database which is sent to the CFIA on a regular basis. For microbiology and allergens, non-compliance results are immediately reported to CFIA with a similar Record of Analysis to that of the CFIA Record of Analysis. These third party laboratories are subject to audit by the CFIA to ensure oversight of the terms and conditions of the contract.

5 **ENFORCEMENT AT BORDER**

5.1 **Approach to Visual Inspections and Analysis of Imported Foods (e.g. Risk-Assessment and Prioritization Schemes, Documentation Review, Sample Collection)**

According to Green (2011), Canada’s food import system utilizes a preventative, systems-based approach that focuses on the processing of safe food rather than the border inspection of goods.

The CFIA targets potentially high risk products and shipments prior to importation. The importer enters product information and documentation into the Electronic Data Interchange (EDI) prior to goods being imported. The CFIA reviews the importer and product information entered into EDI and then sends recommendations to the CBSA about shipments or products that may need to be referred to the CFIA.

At all points of entry into Canada, the CBSA checks documentation associated with imported items. Although The CBSA does not perform direct sampling of imported foods and feed, they may inspect goods to:

- Detect prohibited or restricted items, or smuggled goods;
- Fulfill the requirements of other government departments (e.g., confirm presence of import permits); or
- Ensure that the goods comply with customs legislation (i.e., to verify that the description, value, quantity and markings of the goods match the information on the invoice).”

(CBSA, 2011c)

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23 AIRS is an electronic “reference system that provides detailed information on import requirements for all Canadian Food Inspection Agency commodities.”
“The CFIA does land border inspections, also known as border blitzes. They are done at selected strategic land border crossings. The CFIA does these inspections in partnership with the CBSA. The CBSA has a Border Lookout system that the CFIA uses to target products and/or importers at the border. The Border Lookout system automatically informs the CFIA of the arrival of these products in Canada. It provides officials with the information and direction they require to reduce or manage imports that have been identified as a risk.” (CFIA, 2011k)

Imported food sampling and testing is generally part of the CFIA’s annual sampling plans that cover both domestic and imported products. Sampling of imported food and feed is not done at the border but is conducted at varying locations post entry (e.g., importer’s warehouse, retail, manufacturing), depending on the commodity. Monitoring and survey programs are risk-based, scientific inspection and sampling plans, and take into account intelligence regarding food safety issues, and/or responsiveness to consumer issues. Sampled food and feed products are not detained pending results unless the sampling is targeted based on intelligence that the food is likely to be contaminated. (DVC, 2011)

See Sections 2.1-2.4 for further information.

5.2 The Process that Occurs When an Imported Food is Found to be Contaminated or does not Meet Standards

Any goods, including food products, not meeting proper import documentation standards may be refused entry into Canada. Refused goods will either be ordered to be removed by the importer or seized by the CBSA (CBSA typically seizes serious import regulation infractions or undeclared goods). Goods that are not permitted entry as per the CFIA’s Automated Import Reference System (AIRS) may “only be imported under exceptional circumstances, i.e., with the presentation of an exemption letter or a CFIA special permit, etc” (CBSA, 2011).

Where there are issues or concerns that relate to animal health or plant protection, further evaluations are carried out by CFIA program specialists to make an import decision/recommendation.

As previously indicated, sampling of imported food and feed is part of annual monitoring plans for all food and feed in Canada, domestic and imported, and occur once the food or feed is in the country. For most commodities, sampled products are not held pending laboratory analysis. Where the food or feed are found to be non compliant, the following steps are taken:

- The food or feed product is evaluated to determine whether or not it violates Canadian health standards and/or poses a risk to human health or animal health, as applicable.
- When a violation occurs, actions vary according to the magnitude of health risk presented and may include: “
  - Seizure and recall of products when the health risk is considered unacceptable
  - Follow-up inspections,
Further directed sampling according to a surveillance plan

(CFIA, 2011w)

5.2.1 Procedures for Refusing Imported Foods Based on a Finding that they do not Comply with Requirements

“CFIA recommends that CBSA refuse entry of shipments that are not compliant with Canada’s requirements (e.g., documentation, importer verification). Non-compliance may be a result of food safety, animal health or plant protection requirements. CBSA may issue a refusal before the product reaches the Canadian border [or port of entry].” (CFIA, 2011k)

Where Canada determines an imported food or feed to be non-compliant, Canada may refuse subsequent shipments of those products, may require analysis and inspection of future shipments, or may seize or recall those products (where the product has been distributed). The action taken will depend on the risks posed, the circumstances (e.g., has the product already been distributed) and the relevant legislation.

Canada does not have the authority to invoke a country-wide ban on specific imported foods and feeds, even when a particular problem is found to be widespread. Further, the CFIA has found that these issues are usually related to specific importers/exporters or manufacturers of the product.

Canada may also issue border lookouts, which is a process used to flag products of potential concerns or severe or repeated non compliances to published import conditions by particular commodity, or importers/exporters. (DVC, 2011)

Where there are specific concerns, importers may be required to provide evidence to the CFIA (e.g., analytical results) that the products meet Canadian requirements

See also Sections 1.3 and 5.2.

5.2.2 The Procedure and Outcome for Imported Foods that are Refused Entry (Including Efforts to Prevent them from Mistakenly Entering Domestic Commerce)

If an imported food or feed product does not meet the import requirements, the product may be rejected at the border (Canada DVC, 2011). However, there may be some situations where the shipment may be allowed into Canada or released to importers with a “commitment to correct” and requirement for inspection by CFIA, e.g., for a labeling infraction that may only require additions to the label or re-labeling. (Refer to previous sections)
5.2.3 Process for Identifying and Tracking Producers or Countries that have Repeated Violations

Import/Export business registration with the Canada Revenue Agency allows identification of importers via the business number that is assigned to each importer, and subsequently to identify products that they have imported. (DVC, 2011)

According to Audit of the Management of Imported Food Safety (2008), “Imported food-related information systems for the Meat, Fish and Seafood, and Egg programs are integrated and provide tracking and control mechanisms. For Fish and Seafood, an automated copy function has been incorporated into the Import Control and Tracking System (ICTS) in 2010, to effectively use information from CBSA. The Fish and Seafood Program has also implemented a system and tool set to provide management information.

Canada is currently expanding the use of management information tools to other commodity programs. In 2011, the ICTS Phase II project provided the tools to enable Agrifood (fresh fruits and vegetables, dairy, processed fruits and vegetables, honey, maple), Animal (including feed) and Plant Health Programs to track imported products electronically.

The CFIA has recognized that the information provided by the CBSA may lack the specificity and details; particularly with respect to product in the non-federally registered sector (i.e. not all available data is transferred). A strategic plan for development of information systems related to imported food and food commodity programs is currently under development within the Import Control Division of the CFIA.”

The CFIA also assesses the results of its annual inspection and sampling programs, and readjusts priorities based on importer and product compliance and other information.

5.3 Program for Investigating and Responding to Intentional Contamination of Foods

The CFIA has emergency response procedures designed to protect food, plants and animals from accidental or intentional events. In the event of intentional contamination of food or feed, the CFIA uses established plans and procedures to carry out a response. For example, in cases of food tampering the CFIA would coordinate a response from a food safety perspective, while a criminal investigation of the incident would be carried out by local police authorities. The CFIA and the company involved will work with the local police. The CFIA’s food safety investigation can include retail and plant level inspections of the food manufacturing, health and safety risk assessments, detention of products, and follow-up activities into the scope of distribution. If there is a threat to the public, the CFIA will inform the public.

Intelligence efforts are also conducted to gain information on issues such as intentional contamination. (CFIA, 2011m; DVC, 2011)

(See also Section 2.7)
6  **FOOD RELATED ILLNESS OUTBREAKS**

6.1  **System for Tracking Imported Foods once they are Cleared at the Point of Entry**

The Import Control Tracking System (ICTS) enables CFIA personnel to trace shipments from the point of arrival to their final destination, which could include one or more of the following: importer’s warehouse, manufacturer, vendor, purchaser, consignee, shipper, and/or exporter. It allows for effective scheduling of inland inspections and monitoring of import activities.

ICTS provides the ability for the CFIA to track and monitor all shipments entered into EDI from the time the shipment is declared to the CFIA to the final disposition of goods (i.e., final outcome of product based on inspection results: market product, return, recondition, destroy etc.), while also providing the ability to capture and retrieve detailed information on imported commodities regulated by the CFIA, including results of inspections where applicable.

ICTS also specifically:

- Allows the CFIA to determine eligibility of entry for shipments ahead of arrival at the border and recommend to the CBSA to refuse entry, where necessary, or to make release recommendations.

- Captures and displays information from EDI. EDI allows Importers and/or Brokers to electronically submit transactions and receive automated decisions by both the CFIA and the CBSA. EDI requirements are determined by the requirements set in the CFIA Automated Import Reference System (AIRS).

- Enhances the CFIA’s import tracking and intelligence to risk manage import resources by allowing the combination of multiple queries and the assignment of local office or inspector to a specific Plant Health, Animal Health, Live Animal, Feed, Fresh Fruit & Vegetable, Processed Fruit & Vegetable, Honey, Maple, or Dairy shipment for inspection, once the shipment arrives at the importer’s warehouse or other specified destination.

- Provides the ability (through manual entry) to capture all paper based transactions & inspection results into an electronic database for the Live Animal commodity section

- Serves front-line inspection staff, program design specialists and operation planners which provide them the ability to facilitate their daily inspection activities/workload and ability to plan/review agency work plans.

- Enables the CFIA to determine whether or not to inspect a product/shipment using EDI and Non-EDI (manually entered) transactions.

- Allows for the manual entry of inspection decisions for the Meat and Egg programs and links with the Multi Commodity Activity Program (MCAP) to complete inspection plans for the Fish Program.
6.2 Systems for Identifying Foodborne Illness Outbreaks

Canada has a Foodborne Illness Outbreak Response Protocol (FIORP, 2010) that set out the key guiding principles and operating procedures for the identification and response to multi-jurisdictional foodborne illness outbreaks in order to enhance collaboration and coordination among partners, establish clear lines of communication, and improve efficiency and effectiveness of response. The FIORP describes activities beginning with the determination of a potential for multi-jurisdictional foodborne illness outbreak and ending with either the containment of the risk/resolution of the outbreak. It also includes a post-outbreak review process.

The FIORP (2010) also outlines the roles and responsibilities of all federal, provincial and territorial partners involved in responding to a foodborne illness outbreak in Canada that involves more than one province, territory or another country.

At the federal level, the Public Health Agency of Canada (PHAC), Health Canada and the CFIA have legislated responsibilities for responding to food-borne illness related events.

Human health surveillance activities occur at the local/regional, federal/provincial/territorial, and international levels. Increased or unusual cases of human illness will trigger investigations to determine a common source. National surveillance programs include the National Enteric Surveillance Program (NESP) and PulseNet Canada. International outbreaks are monitored through network activities with groups such as the World Health Organization (WHO), the International Food Safety Authorities Network (INFOSAN), and notification from foreign bodies such as the WHO International Health Regulations (IHR) focal points, which are national centres designated to communicate with the WHO IHR Contact Points under the regulations.

Under the leadership of the Chief Public Health Officer, the Public Health Agency of Canada (PHAC) delivers on the Government of Canada’s commitment to promote and protect the health and safety of all Canadians. Among its activities is responding to multi-jurisdictional infectious disease outbreaks and acting as the National IHR (2005) focal point.

The PHAC is usually the first point of contact for notification by partners of issues related to actual or potential food-borne illness outbreaks, and requests for epidemiologic expertise/support for food-borne outbreak investigation.
The CFIA’s Office of Food Safety and Response acts as a single point of contact for both domestic and international food-related issues and emergencies. The CFIA conducts food safety investigation, testing and recall activities. If imported food is believed to be the source of an outbreak, the CFIA will lead the food safety investigation and report safety concerns to the country from whence the food originated. The CFIA may call upon Health Canada to conduct health risk assessments on food related hazards.

6.3 How Consumers Notify the Government and/or Importers of Food Problems

Consumers can report food safety concerns and issues to the CFIA or their Provincial Public Health Authority via contact information on the CFIA website. The CFIA has the consumer website categorized by type of food issue, such as pre-packaged food or restaurant concerns in order to direct consumers to the appropriate contact information. (CFIA, 2011y)

Similarly, producers can report feed-related concerns to the CFIA through the local inspection office or via the CFIA website.

7 Export Programs

7.1 Programs for Ensuring Safety Requirements of Export Destination Countries

Canada’s domestic system for food and feed safety provides confidence to trading partners and enables market access for the export of Canadian commodities. Canada does not have a separate stream/program for oversight of commodities intended for export that would treat food and feed commodities differently from its oversight of domestic food/feed for safety purposes.

Certificates may be requested by importing countries for public health (HACCP, FSEP programs), animal health (e.g., freedom from an animal disease), or plant protection (e.g., free from a plant pest) objectives. The focus of the CFIA’s export program is to ensure that only products and by-products which meet the import requirements of an importing country are exported from Canada. (CFIA, 2011)

Canada also provides information to some trading partners such as the European Union (DG SANCO) and to the US (USDA’s Food Safety and Inspection Service) on the annual results of its chemical and/or microbiological monitoring programs. Export certificates are provided by the CFIA as a Canadian legislative requirement for some commodities (i.e., for meat and poultry, rendered products), or at the request of the importing country (conditions are established by negotiations with the individual country’s Central Competent Authority). The main commodities that the CFIA certifies for export include:

- **Meat**—The CFIA requires export certificates to be issued for the export of meat products under Canadian legislation (CFIA Exports, 2011f; CFIA Meat Hygiene Manual of Procedures, 2011v).

- **Fish**—“Fish export certificates provide a means for the CFIA to advise the importing country’s inspection authorities that the consignment was processed by an establishment operating in compliance with Canadian requirements. Fish export
certificates will only be issued for consignments of fish when the consignment is available for inspection in Canada. Fish will be certified when it satisfies the requirements of the Fish Inspection Regulations, and if applicable, requirements set out by the importing country.” (CFIA, 2011z)

- **Dairy**-Dairy products require export documentation that attests to their quality and processing, however, certificates are not necessarily issued (CFIA Food Imports, 2011g)

- **Fresh and processed fruits and vegetables and honey** - Export certificates attesting to quality are available upon request.

- **Processed fruits and vegetables and honey** – A statement of free sale may be issued upon request for products produced in a registered establishment

- **Non-federally registered food sector**- The” Manufacturer's Declaration to Cover the Export of Food Products Manufactured in Canada” may be issued for the exportation of food products

- **Feed**- The CFIA may, upon request, issue a certificate attesting that a product meets Canadian standards and would be permitted for sale in Canada (i.e., a certificate of free sale) (DVC, 2011). Export certificates are required for products which contain ingredients from a rendering plant (e.g., feed, pet food, fertilizer). Certification must be obtained prior to the product leaving Canada and product must meet the requirements of the destination country.

- **Rendered products** - Under Canadian legislation, the CFIA requires export certificates to be issued for the export of anything originating from a rendering plant, as defined under the Health of Animals Act.

### 7.1.1 Providing to the Import Country Lists of Establishments that Meet the Importing Countries’ Food Safety Requirements

In some circumstances, the CFIA will provide to an importing country a list of Canadian establishments that meet the importing country’s requirements. This is usually done where Canada has an arrangement with the importing country (e.g., Canada-EU Veterinary Agreement) (DVC, 2011). The CFIA may also provide to importing countries the list of registered fish and seafood establishments and establishments with HACCP-based controls recognized under the CFIA’s Food Safety Enhancement Program.

### 7.1.2 Authorized Third Party Issuance of Export Certificates

CFIA does not have a system whereby official export certificates can be issued by authorized third parties. (DVC, 2011)
8  WORLD TRADE ORGANIZATION (WTO) OBLIGATIONS

8.1  Methods for Ensuring Consistency between Domestic and Imported Food Safety Requirements

The Government of Canada’s 2007 Cabinet Directive on Streamlining Regulation requires federal regulatory authorities to make use of all or parts of relevant international standards, guidelines, and recommendations as a basis for technical regulations and for conformity assessment procedures where they fulfill intended policy objectives and achieve the intended regulatory outcomes sought by Canada.

Canada is an active participant in the World Trade Organization’s SPS committees and notifies its regulatory measures to the WTO through the WTO and the North American Free Trade Agreement (NAFTA) Enquiry point, under the responsibility of the Standards Council of Canada.

8.2  Methods of Documenting the Scientific Justification for Import Practices with regard to Article 5 of the SPS Agreement, which Requires that Measures are based on an Assessment of Risk, as Appropriate to the Circumstance

Government departments and agencies are subject to the government's policy on the publication of proposed regulations. The Regulatory Process Guide requires that proposed regulations be published with a Regulatory Impact Analysis Statement (RIAS). The RIAS is published in the Canada Gazette, Part I (where draft regulations are published for public consultation), then in the Canada Gazette, Part II, along with the final publication of the regulations. The RIAS is prepared by the department or agency sponsoring the regulations and includes the justification for the proposed measures.

8.3  Involvement in Article 4 of the WTO SPS Agreement Regarding Equivalence Determination

Canada participates in equivalency agreements with other countries; sometimes at the request of the other country. Details of the equivalency agreements are country and issue-dependent.

Equivalency of meat inspection systems is a prerequisite to Canada’s evaluations for potentially authorizing meat imports (DVC, 2011). Also required is an evaluation of the terrestrial animal health veterinary infrastructure and zoosanitary health status of the country of origin (details of this evaluation are commodity dependent).

The Canada – EU veterinary agreement is one example of such a formal evaluation of equivalence in veterinary infrastructure.
8.4 Process for Recognizing a Foreign Country’s Food Safety System as having Adequate Regulatory Oversight

Mutual Recognition Agreements between Canada and other countries recognize a foreign country’s commodity specific inspection system as being competent with adequate regulatory oversight. Details as to how the assessment of the foreign country’s inspection systems as being competent and having adequate oversight vary by commodity.
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OVERVIEW OF INTERVIEW AND FOOD AND FEED SAFETY SYSTEM

The Ministry of Health, SAG (within the Ministry of Agriculture) and SERNAPESCA are the main agencies responsible for regulating food and feed safety in Chile. The Ministry of Health and SAG have regional offices called SEREMIs. Most of the work related to food safety is delegated to the respective SEREMI.

The Ministry of Health has primary responsibility for domestic and imported human food safety. Since the Ministry of Health encompasses the Chilean health care system as well as the food safety function, the imports program is limited by budget constraints.

SAG is responsible for assuring that no exotic pests and diseases in imported plant and animal products enter the country; domestic food production practices; veterinary drug and pesticide approval and controls; regulation of animal feed; and providing necessary assurances for exports of food and agricultural products. SAG is present at the Chilean borders, primarily for quarantine and export functions.

SERNAPESCA (within the Ministry of Economics) is responsible for fisheries and aquaculture, but it has no import regulatory responsibilities.

Most of the food consumed in Chile comes from domestic sources. The majority of Chile’s domestic fruit production is exported, as is a substantial portion of pork and poultry production. As a result, the Chilean food safety and phytosanitary programs are centered on the safety of exported foods. The country has built institutions to enable the success of their export trade. Chile’s knowledge of and success in meeting, the specific SPS requirements of each of their export country’s markets has contributed to Chile’s success as a food exporter.

Currently, Chile is working on further advancing the imports program to meet the standard set by the export program. As part of this effort, ACHIPIA was created. ACHIPIA is intended as a high level coordinating body comprised of the ministries responsible for food safety. Although not yet formally established by law, this body has existed since 2005, and has already developed several multi-year plans, the goals of which are being implemented despite changes in the structure of ACHIPIA’s funding.

Chile has a network of public and privately owned laboratories. The SEREMIs send all food samples that need to be tested to one of these laboratories. Chile also accredits laboratories to ISO 17025 standards, although not all of the laboratories are accredited at present.

1 ROLES AND FUNCTIONS OF AGENCIES RESPONSIBLE FOR IMPORTS OF HUMAN FOODS AND ANIMAL FEED

1.1 Governmental Ministries and Subunits (Including National/Regional/Local, as Appropriate) With Responsibility for Assuring the Safety of Imported Food

The Ministry of Health (Ministerio de Salud) and the Ministry of Agriculture (Ministerio de Agricultura) are the two main institutions in charge of food safety in Chile.
The Ministry of Health (Department for Nutrition and Foods) is responsible for food sanitation (including rules for meat and poultry) and the approval of food ingredients, labels, and packaging of processed foods. As a general rule, the Ministry of Health has primary responsibility over food imports, and the Ministry of Agriculture has more responsibility over food exports. There are some exceptions to this rule (such as the certification of processed or fresh foods), and institutional responsibilities often overlap. (Ministry of Health, 2011)

The Agricultural and Livestock Service (Servicio de Agricultura y Ganado, SAG) is the part of the Ministry of Agriculture that is responsible for enforcing Chile’s import regulations concerning alcoholic beverages, feedstuffs, organic foods, as well as animal and plant quarantine (USDA, 2010). SAG is also responsible for ensuring the safety of exported goods that are from agricultural or animal origin (ACHIPIA, 2011a).

The Plant Protection Division of SAG operates the Good Agricultural Practice programs for specific horticultural crops; registering, monitoring, and managing farms for such programs, performing field research and audits, and allowing export to countries¹. The Division also carries out pesticide monitoring programs on vegetables for export, taking 1000-2000 samples per year (SAG, 2011b).²

The Ministry of Finance, through customs, is in charge of checking documentation for all imports upon arrival to the border (Chilean Government, 1982).

The National Fisheries Service (Servicio Nacional de Pesca, SERNAPESCA) oversees the seafood exports. The agency is part of the Ministry of the Economy (Ministerio de Economía). SERNAPESCA regulates the export of both fresh and canned/processed seafood. Chile imports very little seafood and the safety of these products, either domestically or on import, is addressed by the Ministry of Health. (ACHIPIA, 2011)

The Chilean Agency for Food Quality and Safety (ACHIPIA) (Agencia Chilena para la Calidad e Inocuidad Alimentaria, ACHIPIA) is a presidential advisory committee created in 2005 to help coordinate food policy, and provide a modern system for food safety as well as a foundation for export market access. ACHIPIA brings together and coordinates the roles of the following Ministries:

- Agriculture
- Economy
- Foreign Affairs
- Health

(ACHIPIA, 2011 and DIRECON, 2011)

¹ This program also involves growers signing up, being audited, and having products tests prior to exportation (SAG, 2011b).
² The laboratories are private, but under SAG control.
The Ministry of Foreign Affairs, Office of the General Directorate of International Economic Affairs (Dirección General de Relaciones Económicas Internacionales, DIRECON) implement and coordinate government policy on International Economic Relations, to promote an adequate inclusion of Chile in the world, through negotiation and administration of international economic agreements, promotion of exports of domestic goods and services, foreign collaboration entities that promote foreign investment in Chile and support for Chilean investment abroad.

DIRECON, working in partnership with Chilean food and feed authorities, coordinates contacts with foreign governments for the Chilean government (ACHIPIA, 2011) and manages WTO SPS notifications. Each of the Chilean agencies, however, is responsible for developing the science and justification for WTO SPS notifications (USDA, 2010).

Most ministries are divided into regional constituencies called Regional Ministry Secretariats (Secretarías Regionales Ministeriales or SEREMIs). There is one SEREMI per region, and each SEREMI performs the duties of its ministry in the assigned region. The SEREMI offices are considered to be part of their ministry, and the head of each SEREMI (the “intendent”) is appointed by the president (EGOBS, 2011). There is no regional difference among the norms (standards) of the SEREMIs of different regions. Every SEREMI must follow the national policy and regulations, but they have some autonomy in terms of how they execute them. (ACHIPIA, 2011)

The Ministry of Health relies on its SEREMIs to perform its duties. For example, the SEREMIs of Health approve or reject imported goods within Chile for their respective regions (Chilean Government, 2011). SAG (the Ministry of Agriculture) uses regional offices to perform their duties; these offices are coordinated by SAG headquarters (SAG, 2011j).

The Ministries of Health, Foreign Affairs, Agriculture, and Economy serve on the Chilean National Committee for Codex Alimentarius (CNC). The 2011 Codex leadership for Chile is shared between DIRECON and ACHIPIA as a transitional step; the latter will be taking over leadership of Codex in the future. The CNC intends to adopt Codex international standards into Chilean food regulations. The current CNC president is from the Ministry of Foreign affairs, (DIRECON). (Ministry of Health, 2011)

The National Metrology Network (Red Nacional de Metrología RNM) was created, in part, to help Chile comply with CODEX standards. The RNM operates under the Ministry of the Economy and is in charge of ensuring that all the food regulations utilized within Chile are transparent and acceptable to other countries (ACHIPIA, 2011a). The laboratories of the RNM are those of the Custodial Laboratories of National Patrons (Laboratorios Custodios de Patrones Nacionales (LCPN)). The LCPN laboratories are all government owned, but all RNM resources are controlled and administered by INN (see below), which is privately owned (ACHIPIA, 2011a).

The National Institute of Normalization (Instituto Nacional de Normalización, INN) is a privately owned institution created by COREO (SAG, 2011j). The INN is in charge of accrediting laboratories for inspections (ACHIPIA, 2011a). The Institute of Public Health of Chile (Instituto de Salud Pública), through the “Control” (Fiscalización) subdepartment of the Department of National Control (Departamento de Control Nacional), is in charge of laboratory quality assurance control, including verifying that the good practices for the manufacturing industry (recommended by the WHO) are in place (ISPCH, 2011e). The INN is also in charge of administering the resources of the RNM (INN 2011).
The Institute of Public Health of Chile (Instituto de Salud Pública de Chile, ISPCH) acts as a countrywide reference laboratory, collaborates in the development of food safety programs, and it coordinates interactions between the RNM and the network of national public health laboratories (IPSCH, 2011a).

1.2 Agencies Responsible For Animal Feed and/or Pet Foods

Imports of animal feed and veterinary drugs are regulated, sampled, and tested by SAG (SAG, 2011; ACHIPIA, 2011).

1.3 Food Importation Process Steps and the Government Units That Oversee Each Step

All importers must submit documentation to SAG prior to the good entering the country and the documentation must be approved by SAG officials. Upon arrival, goods carry their respective documentation, for example, sanitary, microbiological, and composition certificates, among others as appropriate. (SAG, 2011j) At the border, SAG is responsible for checking that products meet quarantine regulations/standards on all agricultural products before they can enter the country, and Customs verifies import documentation. If no issues are detected, the foods are granted entry to Chile, and sent to an authorized storage facility, where the Ministry of Health, which is responsible for food safety concerns, determines which foods require examination, sampling and testing, and/or release. The steps are as follows:

- If the food is an “agricultural product” subject to quarantine restrictions, such as food products of animal origin or fresh produce, then SAG Service Inspectors will check the shipment before it goes through Customs. The SAG SEREMI has three days before it must decide on the disposition of the import. If the SEREMI does nothing over the three days, the product is allowed to go to its destination by default. In almost all cases, however, the SEREMI makes its decision within the allotted time. For highly perishable products, the SEREMI can speed up the approval process, if appropriate. (Ministry of Health, 2011)

- The importing party for any food product, whether classified as an agricultural product or not, must request a Certificate of Customs Destination (Certificado de Destinación Aduanera) from the Ministry of Health (Ministry of Health, 2011b). The certificate requires information on the party that is importing the goods, region in which the goods are currently stored, information on the place where the items will be stored once they have passed Customs review (the storage locations has to be one that is authorized to store the type of good that is being imported), and information on the carrier company and route that the food will follow from the point in which it leaves the customs storage location and goes to the importer’s destination³. The document also requires a signature stating that the goods will not be used until they are authorized through a certificate by the Ministry of Health, and acknowledging that

³ The certificate can be found at: http://www.asrm.cl/Archivos/Servicios/SOLICITUD_CERTIFICADO_DESTINACION_ADUANERA.pdf
once they have been released, the party submitting the certificate is responsible for the goods. (Ministry of Health, 2011c)

- Once the Certificate of Customs Destination is approved, the product is allowed to enter the country, and the importer is responsible for making sure that the goods are moved to the storage place that was specified in the certificate. The importer is entrusted not to use or dispose of the product in any way until the SEREMI of Health of the region where the storage place is located approves it. The importer is subject to severe sanctions if he does not comply in keeping the shipment intact until receiving official release. (Ministry of Health, 2011b)

- The importer must submit a request for a release for use and consumption of the product from the Ministry of Health. The SEREMI may choose to release the product or hold it for inspections depending on the country of origin and risk classification of the product. Again the SEREMI of Health has up to three days to make a decision (though determinations can be made very quickly). (Ministry of Health, 2011b)

- The degree of product scrutiny at the border and in the storage facility depends on the inherent risk of the imported product and the producer’s or importer’s food safety record with regard to that product. Foods are classified as high, medium, or low risk. Foods with high water content are more likely to be classified as high risk, whereas dry goods tend to be low risk. Products that are tested cannot leave storage until results are available. In the case of microbiological testing, the delay might take two weeks. (Ministry of Health, 2011b)

1.4 Assistance, Cooperation or Contributions from Other Government Bodies (National or Local) in the Imported Food and Feed Process

Customs requires the importer to present a Certificate of Customs Destination issued by the SEREMI of Health of the pertinent region. Without that certificate, Customs is not allowed to release the goods to their designated storage location. Customs agents receive training in how to deal with imports from different countries (Chilean Government, 2011a)

The Institute of Public Health and the Health Services in representation of the SEREMI of Health, as well as SAG, are allowed to inspect goods as they see fit prior to their release. While inspections are permissible, the official inspection of all non-agricultural products occurs after the products are in an authorized storage location. (Chilean Government, 1982)

See also Sections 1.1 and 1.3
1.5 Laws and Regulations that Provide Authority for the Oversight of the Safety of Imported Foods and Animal Feed, and the Policies and Procedures that Guide Import Officials

Law 977 applies to all “edible items” in Chile and discusses guidelines for food safety\(^4\) (Ministry of Health, 2011a).

Law No. 97-1996 establishes the pertinent authorities in the food importation process (Ministry of Health, 1996).

Law 725 of 1968 gives the government power to regulate food safety.

Law No 18.164\(^5\) delegates responsibility on different parts of the process to various government entities. (See Section 1.1)

**Legal framework** (as described by the Institute of Public Health):

The Sanitary Code (Código Sanitario) of 1968 provides the authority to the SEREMIs of Health to regulate imports. It contains general principles, regulations regarding additives, frozen foods, irradiation, labeling, publicity, establishment requirements, among other requirements. The type and rigor of controls are based on risk and history of compliance, it also gives the SEREMIs the authority to inspect and design SOPs for sampling, do analytical testing and review documentation. (Ministry of Health, 2011)

*Article 5 of law 707 (1999) (Ley 7070 de 1999):* The Institute of Public Health, as part of its duty as a reference laboratory must normalize the analytical techniques and procedures of food and water. The Institute must also perform a yearly evaluation to determine the accuracy of each laboratory’s techniques, procedures and results. The results of the evaluation must be submitted to the Health Service of each respective establishment to make any corrections necessary to the laboratory. (Ministry of Health, 1999)

1.6 Handling of Products Transshipped Through a Third Country as Compared to Directly Imported Products

There are no specific procedures for dealing with transshipments, but Chile’s inspection program is aware of the problems that transshipment can present.

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\(^4\) The most recent update of law 977 can be found in: [http://www.redsalud.gov.cl/portal/url/page/minsalcl/g_proteccion/g_alimentos/reglamento_sanitario_alimentos.html](http://www.redsalud.gov.cl/portal/url/page/minsalcl/g_proteccion/g_alimentos/reglamento_sanitario_alimentos.html)

\(^5\) Law No 18.164 establishes custom rules and modifies relevant legislation on the subject (Establece normas de carácter aduanero y modifica la legislación pertinente). The text can be found in: [http://seremi5.redsalud.gov.cl/url/item/93b074222d12e6fee04001011f011872.pdf](http://seremi5.redsalud.gov.cl/url/item/93b074222d12e6fee04001011f011872.pdf)
Shipments that are transshipped through Chile (i.e. goods whose final destination is not Chile) can obtain a permit allowing their goods to be transported to storage areas, but transshipped products may not to be consumed in the country. (Ministry of Health, 2011)

2 INSPECTION PROGRAMS

2.1 Mechanisms to Prioritize Food/Feed Import Surveillance Activities, such as Product Sampling and Testing, Inspections at the Border, and Facility Inspections of the Exporting Country

When the SEREMI of Health receives the application for the authorization of use and consumption of imported products, they decide whether to screen the items according to their risk classification system (Ministry of Health, 2011b).

The decision by the SEREMI whether to sample or test food (feeds do not fall under the Ministry of Health’s jurisdiction) in the storage facility depends on the inherent risk of the imported product and the producer’s or importer’s food safety record with regard to that product. (See Section 1.3)

Foods are classified as high, medium, or low risk. Foods with high water content are more likely to be classified as high risk, whereas dry goods tend to be low risk. Examples of foods in each category include:

- High: animal origin products, milk, high-protein content foods, sauces
- Medium: canned goods, noodles
- Low: Cereals, coffee, dried goods.

Labeling may also be checked and must be in accord with the new labeling laws. There is no preapproval of labels, so if a product is mislabeled, The Ministry of Health may allow the problem to be corrected with stick-on labels. (Ministry of Health, 2011)

2.2 Special Screening Requirements and Trading Partner Requirements where Disease or an Outbreak has Occurred

Decree No.20 was created as a result of the BSE outbreak. The decree is a set of guidelines that enforce special screening for foods that are considered at risk due to special circumstances. (Ministry of Health, 2009)

For phytosanitary products, Chile’s Agriculture and Cattle Services can limit the number of authorized locations for production, packaging, and treatment of products. The decision to enact this policy depends on factors such as disease outbreaks or the exporting country’s risk level. The establishments authorized to export to Chile are selected through publically available information and data received from the exporting country’s competent authority. (SAG, 2011g)
2.3 Percentage of Imported Food Shipments Examined and the Relationship between Risk-Ranking of Foods and Volume of Imported Foods Examined

Imports undergo three levels of evaluation:

- Documentation review
- Physical inspection
- Sampling/Testing

All shipments are checked for documentation. The riskier products may be subjected to further scrutiny. The risk assessment is primarily based on the record of compliance of both the importing company and the producer and the inherent risk of the imported item. (Ministry of Health, 2011)

Many imports are transported by train and truck. Every truck receives a visual inspection (Ministry of Health, 2011).

Chilean officials noted that, while FDA estimates that less than one percent of US imports are physically inspected, a substantially higher percentage of imports are inspected in Chile. Documentation is checked for all imports.

2.4 Types of Review, Examination and/or Testing of Imported Products Performed by Food Safety Inspectors

The Chilean government expects all imports to abide by the standards set forth for labels within Chile. Law 977, under the “labeling” section, which specifies expectations on units, aspects of the goods that must be mentioned (e.g. fat content), and the chemicals that, if used, must be noted. The Certificate of Customs Destination will not be approved unless the item is properly labeled; however, a transport approval can be granted to allow the importer to bring the product to the labeling facility. There are also requirements regarding the origin of the good (country and address) and all labels must be in Spanish, and if they are not, a translated label must be placed on the container. The labeling system is different for food categories such as dried foods, substitute foods, foods with added nutrients, etc. There are also labeling requirements for food packaging categories. (Law 977 pp. 25-37)

Twenty-one laboratories in the Ministry of Health network perform the testing of food samples. There are two other special laboratories (e.g., Red Tide\(^6\)). Of the 55,000 samples taken in the annual market survey, 30 percent are tested for chemical contaminants such as pesticide residues, additives, and veterinary drugs, and seventy percent for microbiological pathogens. (Ministry of Health, 2011)

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\(^6\) Red Tide is an algal bloom, usually caused by dinoflagellates or diatoms that can cause color (often red-brown) changes in the water; the algae may release toxins and cause seafood in the area to be hazardous to consumers.
2.5 Frequency of Documentation and Labeling Checks as Compared to Analytical Examinations

All documentation is checked, and no products can enter Chile unless the Certificate of Customs Destination is approved.

2.6 Types of Examination and Testing Processes Used for Ensuring Animal Feed and Feed Ingredient Safety

Imports of animal feed are regulated, sampled, and tested by SAG. SAG is currently (mid-2011) in the middle of a 3-year program during which they are reassessing their approaches to testing of animal feed. (SAG, 2011)

Chile is assessing testing protocols for a range of potential feed hazards, including dioxins, bovine spongiform encephalopathy (BSE), chemical and microbiological contamination, mycotoxins, and heavy metals. The Ministry of Health also participates in some testing for BSE and coordinates BSE control efforts with SAG.

Basic feeds are more likely to have been produced domestically and are not necessarily tested, such as feed produced on farms for their own or local use. There are no statistics for the amount of animal feed tested. (SAG, 2011b)

2.7 The Dependence of Examination and Testing Requirements on Conditions (such as the Presence of BSE or Other Zoonotic Diseases) in the Exporting Country

The examination and testing requirements are changed depending on conditions in the exporting country. For example, when the BSE outbreak occurred, Chile followed WHO recommendations on precautions for bovine imports by designing new screening processes to be followed. These processes assessed risk based on the likelihood of infestation in the country of origin and the sensitivity of the product. (Ministry of Health, 2009) (See Section 2.2)

2.8 Inspections of Food or Animal Feed Manufacturers or Shippers in Other Countries (including Selection Criteria and Frequency)

Chile does not regularly send inspectors to other countries (SAG, 2011b).

2.9 Notification System(s) to Directly Notify Foreign Governments When Foods or Animal Feed Manufactured in their Countries are Found to be Unsafe; and to Notify the Public When Imported Products do not Meet Safety Standards

If food shipments are contaminated, they are either destroyed or returned to the country of origin. There is no indication of official notification to the country’s government. (Ministry of Health, 2011b)
3 AUDITS AND CERTIFICATION

3.1 Assessing and Measuring the Effectiveness of the Food/Feed Safety Import Program (e.g., Self Audits of the Program, Public Health Outcomes, Surveillance Sampling Results, Number/Rates of Refusals, Periodic Program Evaluations)

There are no audits on the program per se, but The National Food Safety Policy was developed to provide continuous improvements of the food safety system, and ACHPIA exists to provide oversight over the program. (ACHPIA, 2011)

3.2 Extent of Reliance on Trading Partners’ Food Safety Programs to Ensure That Imported Foods or Animal Feed are Safe

The Ministry of Health does not have agreements with other countries on food safety, nor does it have good importer practice regulations. Importers are aware, however, that their suppliers need to comply with Chilean food safety requirements. If their products are found with violations, the importer must have the next 3-5 shipments tested by an official laboratory and must pay a fee for that service. This rate of testing is also required the first time a new product (new product/exporter/company) is brought into Chile. When there is a food safety infraction, the SEREMI of Health also has the option of assessing penalties based on the seriousness of the infraction. The legal department within the SEREMI determines penalties for domestic and imported food products. (Ministry of Health, 2011)

3.3 Requirements for Food and/or Animal Feed Export Certificates Issued by the Exporting Country’s Competent Authority, and Types of Inspection or Testing for Each

For agricultural goods, Chile requires the importer to submit a phytosanitary certificate in addition to the Certificate of Customs Destination. The phytosanitary certificate is issued by the National Phytosanitary Protection Agency. Both of these certificates can be submitted prior to the product’s arrival. (SAG, 2011)

Chile does not take into consideration the certificates or food safety practices of other countries as part of their import regulations system (ACHIPIA, 2009).

3.4 Use of ISO, Global Gap or Other Assurance Systems and Confidence in the Assurance System(s) Utilized

The INN performs the accreditation of testing laboratories. Each Agency has its own accreditation system. SAG laboratories are certified to ISO 17025, and the Ministry of Health is in the process of obtaining their ISO 17025 certification for its laboratories. (Ministry of Health, 2011)

Each private laboratory participating in the national program (the laboratory network that is used to scrutinize all food items, that is, imports and exports) must undergo annual quality control tests.
SAG laboratories sometimes do backup tests; confirming the test results of other, often private, laboratories. Occasionally, for certain unusual tests, samples are sent to the UK for testing. (Ministry of Health, 2011)

3.5 The Nature and Frequency of Foreign Food Safety Systems Audits Performed

Chile does not regularly conduct audits of foreign food safety systems or of foreign facilities. (Ministry of Health, 2011)

3.6 Equivalence Agreements Requiring Periodic Audits/Reevaluations of Exporting Countries’ Food Safety Programs

Chile does not have equivalency agreements with other countries concerning food safety (Ministry of Health, 2011).

3.7 The Utilization of Third-Parties (Within the Exporting or Importing Country) to Carry out Inspections and/or Product Certification (Nature and Extent of Programs) and Methods for Verifying the Adequacy and Reliability of the Third Party Work

Chile uses several private laboratories to test the food items when samples are collected (ISPCH, 2011b). There is no indication that Chile uses third parties for inspections or product certifications.

In some situations, Chile relies on the government of the exporting country to specify food facilities that can meet Chile’s standards. Government third parties may be used in this process. (SAG, 2011h)

3.8 Arrangements with other Governments Relating to Imported Foods or Animal Feed (such as Memoranda of Understanding, Mutual Recognition Agreements, etc.)

Beyond WTO agreement obligations and Free Trade Agreements, no arrangements are in place with other governments concerning food safety and animal feed.

The Ministry of Foreign Affairs (DIRECON) has the authority to negotiate agreements with other countries and currently has 21 agreements covering 91 percent of the world population. These are economic agreements, primarily focused on export development. (DIRECON, 2011)

3.9 Registration or Licensing of Firms That Import and/or Export Foods or Animal Feed to the Country or for Firms That Import Foods or Animal Feed

It is unclear whether Chile requires registration or licensing of importers. It appears that SAG or the Ministry of Health may require authorization or registration of Chilean facilities that desire to export (e.g., dairy facilities).
3.10 Use of Sampling Surveys of Imported Foods/Feed (as Opposed to Targeting Specific Products/Producers for Inspections and/or Testing) to Gather Information and Identify Trends and Potential Areas of Difficulty

Chile has an annual survey of the entire food market (including imports) with certain areas of emphasis each year. The survey is performed by twenty-one laboratories under the Ministry of Health’s network. The laboratories collect around 55,000 samples and test 70 percent of them for microbiological organisms and 30 percent for other chemical contaminants. (Ministry of Health, 2011)

3.11 “Good Practices” Programs for Foods/Feed Importers

There is no official guidance regarding good importer practices, according to the Ministry of Health (Ministry of Health, 2011)

3.12 Description of Import Program User Fees and Cost Recovery System

The cost of sampling and analysis must be paid by the importer in the User Services Office (Oficina de Atención a Usuarios) of the respective SEREMI of Health within 72 hours from the time in which the sample was taken. Along with the payment, the importer must bring along the reference number for the sample and the documents provided by the SEREMI personnel at the time of inspection. (Ministry of Health, 2011a)

There are also charges made to exporters, mainly for inspection services and issuance of a certificate (SAG, 2011b).

The funds received through fees for testing go into the government’s general fund. Thus, Chile has made no calculations regarding the cost recovery for the import program. (SAG, 2011b)

3.13 Incentives to Increase Industry Involvement in Ensuring That Imported Foods Meet Safety Standards

According to the Ministry of Health, incentives to comply with food safety standards include: avoiding fees, penalties, and increased product scrutiny (Ministry of Health, 2011).

3.14 Obstacles to Industry Participation in Ensuring That Imported Foods Meet Safety Standards

Obstacles to industry participation in ensuring the safety standards of imported food were not identified in this study.
4 LABORATORY SUPPORT

4.1 The Role of Laboratories in Supporting the Imported Food and Feed Programs and Description of Laboratory Capabilities

The Ministry of Health has laboratories scattered all over the country that are in charge of inspecting and analyzing samples of food that will be consumed in Chile. The Ministry of Health relies on its regional SEREMIs to perform inspections and collect samples, when appropriate.

Similarly, SAG has its own laboratories at the federal and regional levels (ACHIPIA, 2011a). These laboratories sometimes perform back-up tests to confirm the findings of other, usually private, laboratories. Nine of the SAG laboratories perform analysis of veterinary drugs and 11 perform pesticide analysis. (SAG, 2011b)

SERNAPESCA has developed a network of public (i.e. state owned) and private laboratories (currently 40). The network is in charge of seafood inspections and sampling. (ACHIPIA, 2011a)

Institutions in public and private sectors play a role in certifying laboratories. For example, the Institute of Public Health, a publically owned entity, ensures that all Ministry of Health laboratories are performing the same measurements in addition to training and advising staff in these laboratories (ACHIPIA, 2011a). Similarly, the INN, a privately owned entity, certifies both public and private laboratories on ISO 17025 standards (Ministry of Health, 2011).

Chile’s laboratories are capable of identifying 180 analytes. The range of inspections and tests performed by laboratories depends on the facility’s type of accreditation. Examples of the types of analyses performed include the analysis of residues and microbiological organisms in seafood products (including fish protein) and the analysis of pesticides and fertilizers (ACHIPIA, 2011a). It is not uncommon for samples from one laboratory to be submitted to another due to the variation in laboratory capabilities. Occasionally, certain cumbersome tests that are not possible in Chilean laboratories require samples to be sent to the UK for testing. (SAG, 2011b; Ministry of Health, 2011)

4.2 Participation of Non-government Laboratories (Including Industry and Academic Laboratories) in the Food Import Control Program

There are approximately 120 laboratories that are accredited to perform food safety testing in Chile. Most of these laboratories are private and university-owned. (ISPCH, 2011b)

4.3 Methods for Laboratories to Achieve Quality Assurance (such as Voluntary or Mandatory Accreditation)

Each ministry has its own accreditation system, and is responsible for ensuring its reliability. For example, while SAG laboratories are ISO 17025 accredited, the Ministry of Health laboratories are not yet certified under this standard. (Ministry of Health, 2011)
All laboratories that inspect/test food on behalf of any of the government institutions must be accredited by the National Institute of Normalization (INN)\(^7\) (ACHIPIA, 2011a). When the INN evaluates a laboratory for accreditation, the decision is based on whether the practices of the laboratory are in alignment with the international requirements and criteria (INN, 2011). While the accreditation is performed by the INN, recognizing a laboratory as a Public Health laboratory under the Sanitary Code (See Section 1.5) requires the additional approval of the respective SEREMI of Health, which is obtained through the Institute of Public Health. (ISPCH, 2011f)

Laboratories in Chile are accredited for distinct procedures, depending on their specialty. Thus, food analysis is performed through a network where different aspects of food are analyzed in different laboratories. This network is coordinated by the Institute of Public Health. (ISPCH, 2011c)

The INN also oversees the RNM, an institution created for quality assurance and traceability of laboratory testing. (ACHIPIA, 2011a) (See Section 1.1)

Private laboratories can be accredited voluntarily. This allows them to gain international recognition and validity in the eyes of national and international institutions. (ACHIPIA, 2011a)

All laboratories undergo quality assurance audits conducted by SAG. All certified private laboratories are audited by SAG on a yearly basis. (SAG, 2011b)

5 **ENFORCEMENT AT BORDER**

5.1 **Approach to Visual Inspections and Analysis of Imported Foods (e.g. Risk-Assessment and Prioritization Schemes, Documentation Review, Sample Collection)**

Once foods move to the storage facility, the Ministry of Health has control of the product. The importer must submit a request for a release for use and consumption of the product to the Ministry of Health. The SEREMI may choose to release the product or hold it for inspections depending on the country of origin and the risk classification of the product. The degree of product scrutiny depends on the inherent risk of the imported product and the producer’s or importer’s food safety record with regard to that product. Foods that are high risk are more likely to be tested. Foods with high water content are more likely to be classified as high risk, whereas dry goods tend to be low risk. Products that are tested cannot leave storage until results are available. In the case of microbiological testing, the delay might take two weeks. (Ministry of Health, 2011b)

5.2 **The Process that Occurs When an Imported Food is Found to be Contaminated or does not Meet Standards**

When a product does not meet Chilean standards, the SEREMI of Health issues a Rejection Resolution (Resolución de Rechazo). The Rejection Resolution contains details regarding the

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\(^7\) The INN also oversees the activities of the RNM, an institution created for quality assurance and traceability of laboratory testing. (ACHIPIA, 2011a) (See Section 1.1)
cause of rejection and also highlights relevant information about the product such as its contents and place of production. Once the resolution is issued, the importer has ten business days to select the following product options: re-exportation (i.e. return to country of origin), destruction, or a different end use\textsuperscript{8} (such as down-grading the product to be used as animal feed). If the importer chooses to destroy the good, it must be done under the supervision of the SEREMI of Health, and the cost is incurred by the importer. (Ministry of Health, 2011b)

5.2.1 The Procedure and Outcome for Imported Foods that are Refused Entry (Including Efforts to Prevent them from Mistakenly Entering Domestic Commerce)

If shipments are contaminated, they are destroyed, returned to the country of origin, or used for a different purpose than originally intended (Ministry of Health, 2011b).

According to Article 105 of Law 977 of 1996, good that are contaminated are required to be:

- Under the custody of the owner (in this case the importer), but the use of the good for any purpose is forbidden.
- Stored in a large physical space.
- Properly and clearly labeled with symbols that indicate that their use is forbidden.

These products may be used for purposes other than those originally intended (e.g. industrial use, or animal feed) as long as they are authorized for that use by the proper authority. Otherwise, the good must be destroyed under the supervision of the SEREMI of Health, who will also decide the means of destruction and location. (Ministry of Health, 1996)

5.2.2 Entry of Detained Products Based on Further Testing or Reconditioning of the Product

Imported products may be reconditioned. If an imported product is initially rejected, the importer is allowed appeal the decision by submitting a written request to the SEREMI of Health. If the appeal is approved, the good is re-inspected in a more rigorous manner (taking twice the number of samples that were taken initially), and if it passes this inspection, it may be cleared for distribution. If the product was rejected under article 105 of Law 977 (See Section 5.2.2), then there is no possibility for appeal. (Ministry of Health, 2011b)

5.2.3 Process for Identifying and Tracking Producers or Countries that have Repeated Violations

The direct responsibility for product traceability rests with the importer (Ministry of Health, 2011).

\textsuperscript{8} A permit that allows for that use from the relevant institution must be presented with this option (Ministry of Health, 2011b).
5.3 Program for Investigating and Responding to Intentional Contamination of Foods

Chile does not have a program to respond to the intentional contamination of food products. Intentional contamination is treated as a criminal act and forwarded to the Justice Department. (Ministry of Health, 2011)

6 FOOD RELATED ILLNESS OUTBREAKS

6.1 System for Tracking Imported Foods once they are Cleared at the Point of Entry

All importers must fill out a Certificate of Customs Destination for the product to be released from Customs. The certificate requires information on: the party that is importing the goods; the region in which the goods are currently stored; the place where the items will be stored once they have passed Customs review (the storage locations has to be one that is authorized to store the type of good that is being imported); and the carrier company and route that the food will follow from the point in which it leaves the customs storage location and goes to the importer’s destination.

6.2 Systems for Identifying Foodborne Illness Outbreaks

The regional SEREMIs of Health manage and identify foodborne illness outbreaks. (ACHIPIA, 2011)

6.2.1 Procedure for Tracking Illnesses back to the Food Source when a Foodborne Illness Outbreak Occurs

ACHIPIA is making improvements on Chile’s information systems and communications regarding foodborne illness outbreaks. (ACHIPIA, 2011)

6.3 How Consumers Notify the Government and/or Importers of Food Problems

Chile uses consumer complaints as part of the risk assessment of imported products (Ministry of Health, 2011b).

7 EXPORT PROGRAMS

7.1 Programs for Ensuring Safety Requirements of Export Destination Countries

SAG expends tremendous resources to assure that their products meet the exporting country’s food safety requirements. As a result, Chile has very few product refusals.

The National Certification of Agricultural Organic Products is one of Chile’s quality assurance programs. It provides a seal to come with each product that includes the producer’s identification

9 The certificate can be found at: http://www.asrm.cl/Archivos/Servicios/SOLICITUD_CERTIFICADO_DESTINACION_ADUANERA.pdf
number, the region that the good is coming from, the certifying agent and the seal number for exported lots. The program applies to imports, exports and domestic production.

Individual programs for exported products have been developed to verify that producers are adhering to requirements of the countries to which the products are destined for exports. The programs requirements vary with the product. For example, SAG has a program for raspberry growers and for pesticide residues in vegetables intended for export under the GAPS program (Good Agricultural Practices). Products are not cleared for export unless SAG has audited the producers for quality assurance; thus, potential exporters must sign up for the programs.

(ACHIPIA, 2011)

7.1.1 Use of Export Certificates to Provide Assurances to the Importing Country

All producers who want to export food from Chile need an export certificate. This is usually obtained through SAG, except when the product is seafood (in which case SERNAPESCA issues them).

The process for obtaining an export certificate differs depending on the type of product (e.g., meat and poultry, dairy, fruit and vegetables, organic products, wine). Upon rigorous evaluation of the production facilities and the hygiene standards, SAG usually audits the specific shipment before issuance of the certificate. The private sector pays fees for these export services.

There are special certificates for some of the bigger Chilean industries. For example, Chile maintains a list of vineyards and specific wine vessels because there is an official certificate for exporting wine.

(SAG, 2011b)

7.1.2 Providing to the Import Country Lists of Establishments that Meet the Importing Countries’ Food Safety Requirements

Listing(s) of establishments that meet specific requirements of an importing country were not identified. Generally, the procedures mentioned in sections 7.1 and 7.1.1 assure that the exporting country’s requirements will be satisfied. The names of the individual producers are provided in some cases, under specific programs.

7.1.3 Authorized Third Party Issuance of Export Certificates

SAG or SERNAPESCA issue export certificates for foods, rather than third parties (SAG, 2011b).
8  WORLD TRADE ORGANIZATION (WTO) OBLIGATIONS

8.1  Methods for Ensuring Consistency between Domestic and Imported Food Safety Requirements

The Ministry of Health is responsible for protecting and regulating the safety of foods for Chilean consumers, and the same standards are applied to foods of domestic or import origin (Ministry of Health, 2011).

8.2  Methods of Documenting the Scientific Justification for Import Practices with regard to Article 5 of the SPS Agreement, which Requires that Measures are based on an Assessment of Risk, as Appropriate to the Circumstance

Every agency is responsible for justifying its own regulations and procedures under the terms of the WTO SPS/TBT Agreement. DIRECON may assist the agencies in complying with international trade obligations. (Ministry of Health, 2011)

8.3  Involvement in Article 4 of the WTO SPS Agreement Regarding Equivalence Determination

The individual ministries are responsible for evaluating equivalence. For example, the Ministry of Agriculture and SERNAPESCA have engaged in equivalence evaluations, but to date, the Ministry of Health has not. (Ministry of Health, 2011) Agreements reached with foreign governments are managed by DIRECON.

8.4  Process for Recognizing a Foreign Country’s Food Safety System as having Adequate Regulatory Oversight

Information on this topic was not identified.
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OVERVIEW OF INTERVIEW AND FOOD AND FEED SAFETY SYSTEM

As a Member State of the European Union (EU), Ireland’s Food and Feed Import Control System operates within the broader import guidelines and regulations of the EU. Key safety components of the EU food and feed import control system include:

- Imported foods of animal origin and certain foods of non-animal origin arriving directly in Ireland can only come from other countries that have been approved under the EU system;
- EU businesses are required to notify authorities about food safety issues;
- EU businesses are required to be able to trace their products “one step forward and one step back”;
- An EU Rapid Alert notification system is in place to communicate import-related information between agency officials and Member States; and
- All of these above components are followed up by market surveillance and consumer report-type issue indicators.

(Ellard, 2011)

The Food Safety Authority of Ireland (FSAI) is the competent authority with overall responsibility for the enforcement of food legislation in Ireland. FSAI’s responsibility for the enforcement of food legislation is managed through contractual arrangements (service contracts) between the FSAI and the competent official agencies involved in the enforcement of food legislation. Agencies with primary responsibilities regarding import controls include: The Department of Agriculture, Food and the Marine (DAFMM), which has primary responsibility for products of animal origin and animal feed; The Health Service Executive (HSE), which oversees import controls for products of non-animal origin, and Sea-Fisheries Protection Authority (SFPS), which oversees imported fish and fisheries products (DAFM and FSAI, 2011a).

Import control activities in Ireland are risk-based, and the surveillance of imported goods depends on the product’s categorization as being: 1) foods or feed of non-animal origin that is not subject to increased controls, 2) foods or feed of non-animal origin that is subject to increased controls, and 3) foods or feed of animal origin.¹ Imported foods of non-animal origin that are not subject to increased official controls or emergency measures are free to enter Ireland without restriction. Prior notification is required by DAFM for all imported feeds of non-animal origin. These products are required to meet EU standards, such as those pertaining to labeling,

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¹ Products of non-animal origin subject to increased controls are products that present an increased risk to human health. These products as well as their associated increased import controls are listed in Appendix I of EC regulation no. 669/2009 (EC, 2009).
additives, flavoring, pesticides, and contaminants (FSAI, 2011i). Foods and feed of non-animal original requiring increased import controls and foods and feed of animal origin face additional import requirements.

Foods of non-animal original requiring increased import controls and foods of animal origin require importers to provide prior notification to DAFM or HSE (depending on the content of the product) before product importation occurs. Foods and feed of non-animal original requiring increased import controls must enter Ireland through designated points of entry (DPEs) where they undergo inspection by HSE environmental health officers (food) or DAFM Feedingstuffs inspectorate (feed) in accordance with the increased controls designated in Annex I of Regulation (EC) No. 669/2009 (EC, 2009) before they are able to attain Customs clearance. Foods and feed of animal origin are also required to enter Ireland through specified locations known as Border Inspection Posts (BIPs). At BIPs, products of animal origin are subject to inspection by DAFM inspectors. All products arriving at DPEs or BIPs also undergo a documentary check (DAFM and FSAI, 2011; Ellard, 2011).

After imported products have cleared Customs and are in the marketplace, emerging product issues may be identified by consumers, annual agency monitoring plans (e.g. chemical, microbiological), the Health Protection Surveillance Centre (HPSC), or information passed through the Rapid Alert System for Food and Feed (RASFF). Should a foodborne illness outbreak be suspected, FSAI works closely with the official agencies, such as DAFM and HSE as well as the Health Protection Surveillance Centre (HPSC) to investigate the issue (FSAI, 2009). Information is communicated to other agencies and Member States via RASFF. For foodborne illness outbreaks spanning beyond Ireland and potentially impacting other EU Member States, FSAI informs the European Centre of Disease Prevention and Control (ECDC) through the Early Warning Response System—a computer database that deals with communicable diseases.

There are approximately 60 laboratories involved in food safety monitoring, analysis, and research in Ireland that may operate directly under the control of government departments, HSE, local authorities, non-departmental public bodies, institutes of higher education others, or national agencies (FVO, 2010). There is also a private laboratory sector with nearly 40 departmentally (government) approved laboratories that offer routine food safety analytical laboratory services to industry (FVO, 2010). All laboratories involved in the official controls of imported food and feed in Ireland are accredited to ISO 17025 by the Irish National Accreditation Board (INAB) (FSAI, 2011n).

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2 Foods of non-animal origin that are subject to increased controls are listed in Annex I of EC regulation no. 669/2009 (EC, 2009).
3 RASFF involves all Member States, the European Community, and the European Food Safety Authority, as well as the non-EU countries of Iceland, Liechtenstein, and Norway. The exchange of information allows participating states to immediately ascertain whether they are also affected by a problem. Authorities can order withdrawals/recalls and this information is shared via RASFF (FSAI, 2011).
1 ROLES AND FUNCTIONS OF AGENCIES RESPONSIBLE FOR IMPORTS OF HUMAN FOODS AND ANIMAL FEED

1.1 Governmental Ministries and Subunits (Including National/Regional/Local, as Appropriate) With Responsibility for Assuring the Safety of Imported Food

Food Safety Authority of Ireland (FSAI)

The Food Safety Authority of Ireland (FSAI) has “overall responsibility for the enforcement of food legislation in Ireland” (DAFM and FSAI, 2011a). Established through the FSAI Act 1998, FSAI is responsible for ensuring that food produced, distributed or marketed in Ireland meets particular specified food safety and hygiene standards. Reporting to the Minister for Health, FSAI’s responsibility extends from the farm gate to the final consumer (DAFM and FSAI, 2011; FSAI Website, 2011a). FSAI employs approximately 77 FTEs (FVO, 2010).

Structurally, FSAI operates through a board and Chief Executive Officer. A Consultative Council and Scientific Committees form another structural tier of the Authority. The Scientific Committee is an advisory body composed of scientists from a range of disciplines working in a voluntary capacity.

- The Food Safety Consultative Council comprises representatives of consumers and industry who consider food safety issues and provide input to the agenda of the FSAI.

Divisions within FSAI include the following:

- The Food Science and Standards Division provides a scientific base to support enforcement and compliance activities.
- The Service Contracts Division manages the relationships between FSAI and the competent authorities involved in food safety controls.
- The Audit and Compliance Division – audits the work of the official agencies, manages food incidents and provides training programmes

(DAFM and FSAI, 2011a).

FSAI manages the responsibility for surveillance, inspection and enforcement of EU and national food law through service contracts with official agencies (See Figure 1). The service contracts are in force for a minimum of 3 years. FSAI has service contracts with the following agencies:

- Sea Fisheries Protection Authority (SFPA),
- Department of Agriculture Food and the Marine (DAFMM),
- Health Service Executive (HSE),
- Marine Institute,
- 27 County Councils,
- 4 City Councils, and
- National Standards Authority of Ireland.

**Figure 1: Entities Involved with Food and Feed Safety in Ireland**

*The Department of Health and Children is now titled the Department of Health.

Entities represented in Figure 1 not holding service contracts with FSAI have a Memorandum of Understanding with the Authority (DAFM and FSAI, 2011a).

FSAI is also responsible for carrying out risk assessment to underpin risk management decisions and actions as well as providing scientific and technical support to competent authorities through publications and training programs (DAFM and FSAI, 2011a).

**Department of Agriculture Fisheries and Food (DAFM)**

DAFM oversees the safety of feed, animal welfare as well as animal and plant health (DAFM and FSAI, 2011a). DAFM is the competent authority for policy development, negotiation (EU level), and implementation of EU rules in national law as well as official controls in the following areas:

- Primary production of food of animal origin,
- Slaughtering, cutting, preparation and processing of foods of animal origin, up to, but not including, retail level,
Sea Fisheries Protection Authority (SFPA)

The SFPA was established on January 1, 2007 under the Sea-Fisheries and Maritime Jurisdiction Act (2006) to enforce national and EU Regulations on sea-fisheries conservation and seafood safety. SFPA is responsible for the implementation and enforcement of national and EU legislation on the health conditions for fish, live bivalve shellfish, and fishery products at all stages; from primary production and processing by fishing vessels through to processing at approved land-based processing centers, with the exclusion of retail (FVO, 2010).

The SFPA deploys an inspectorate comprised of Sea Fisheries Protection Officers who work closely with other government agencies, such as the Irish Naval Service, the FSAI and the Marine Institute, in the implementation of fisheries control and seafood safety programs. A specialized Food Safety Unit was established in SFPA headquarters in 2007 to support and coordinate food safety regulation activities of the SFPA. The Unit has a lead role in the management of contract arrangements between the SFPA and the Food Safety Authority of Ireland. For operational purposes, the SFPA has divided the country into three regions, each under the control of a Regional Sea Fisheries Control Manager (FVO, 2010).

The Marine Institute

“The Marine Institute is responsible for marine research as well as technological development and innovation. It provides analytical and technical services to SFPA. It carries out analyses to ensure compliance with legislative requirements with respect to general food law, official controls, food hygiene, contaminants, residues, microbiological criteria and marine biotoxins and is the National Reference Laboratory for certain parameters” (FVO, 2010).

Health Service Executive (HSE)

HSE implements controls such as verifications, inspections, audits, sampling and analysis, and monitoring and surveillance to help ensure that legislative requirements pertaining to food safety are met (DAFM and FSAI, 2011a). HSE is responsible for import controls on most products of non-animal origin and is contracted by the FSAI to provide the following food control services:

- **Environmental Health Service**, covers inspection of food businesses, including food sampling, to ensure compliance with food law and the management of food alerts and outbreaks.

- **Food Safety Laboratory Service**, is a network of laboratories comprising three Public Analyst Laboratories and seven Official Food Microbiological Laboratories.
responsible respectively for the chemical and microbiological testing of foodstuffs. The Public Analyst Laboratories are the National Reference Laboratory for certain chemical parameters.

- Public Health Medical Service, participates in multi-disciplinary teams investigating, managing and controlling outbreaks of foodborne illnesses. The PHMS links closely with the EHS and FSLS during these investigations.

(DAFM and FSAI, 2011a)

HSE is divided into four geographical regions; each region containing between seven and nine environmental health sections for a national total of 32 HSE sections. Each section is supervised by a Principal Environmental Health Officer (FVO, 2010).

**Customs Division of the Revenue Commissioners (Customs)**

Customs carries out controls on imports and exports. It has a memorandum of understanding with FSAI in relation to imports of food of non-animal origin and a service contract with DAFM in relation to imports of products of animal origin as well as products of non-animal origin that are subject to increased controls (DAFM and FSAI, 2011a).

### 1.2 Agencies Responsible For Animal Feed and/or Pet Foods

The Animal Feedingstuffs Control Group (AFCG) within DAFM currently oversees imported animal feed and pet foods (DAFM and FSAI, 2011). Approximately 20 percent of Ireland’s animal feed is imported to augment animal rations (DAFM and FSAI, 2011). All feed importers must register as feed business operators with DAFM and provide them with notice of importation at least five days before the consignment reaches the country. The advanced import notification submitted by the feed importer contains the following information:

- Importer name,
- Feed material name,
- Quantity,
- Country of origin,
- Port of loading,
- Port(s) of entry,
- Holding store(s),

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4 Oversight of animal feed and pet foods may be transferred to FSAI as legislative changes take place in accordance with DAFF changing to the newly titled Department of Agriculture, Food and the Marine (DAFM) (DAFF and FSAI, 2011).
After arriving in Ireland, the Customs carries out a document check on all feed imports. Feed products appearing in Annex 1 of EC regulation No. 669/2009 are subject to increased levels of control (such as an increased level of physical check), and the Annex provides product-specific information regarding potential product hazards and the frequency of checks required for these products (EC, 2009). Any feed products that may be of concern or have an unknown product status are referred by Customs to DAFM for investigation before the product may be imported (DAFM, 2011c).

1.3 Food Importation Process Steps and the Government Units That Oversee Each Step

Foods imported into Ireland are separated into the categories of: 1) foods of non-animal origin and 2) foods of animal origin. As the name implies, foods of non-animal origin (e.g. fruits and vegetables) are not derived from, and do not contain, animal products. The process for importing foods varies depending on how the product is categorized in terms of its content, and this section begins by describing the process for importing products of non-animal origin, followed by the import process for products of animal origin.

Products of Non-Animal Origin

The Health Service Executive (HSE) is under service contract to FSAI to oversee the importation of foods of non-animal origin. Foods of non-animal origin are classified as: 1) foods that do not require increased official import controls, and 2) foods that require increased official import controls. Imported foods of non-animal origin that require increased controls are those foods that have been deemed, at the EU level, to pose an increased risk to human health. Annex I of Regulation (EC) No. 669/2009 provides a list of non-animal origin products requiring increased controls, the potential hazard presented by that product, and the types and frequency of increased controls applicable to that food (EC, 2009).

For foods arriving in Ireland from outside of the EU, importers are required to register with the Health Service Executive (HSE) before the imported food arrives at Ireland’s border. Importers also submit import declarations to Customs which include product information such as Customs nomenclature codes (CN). Customs scans the collected product information in order to compare it with a list of CNs provided to them by FSAI for food products which are subject to increased levels of import controls or emergency measures.

Imported foods of non-animal origin that are not subject to increased official controls or emergency measures are free to enter Ireland (and the EU) without restriction. These products are required to meet EU standards, such as those pertaining to labeling, additives, flavoring,
pesticides, and contaminants (FSAI, 2011i). Further, these products are not required to enter Ireland through a designated point of entry (DPE) or a Border Inspection Posts (BIPs).

Foods of non-animal origin requiring increased import controls must enter Ireland through designated points of entry (DPEs). Importers of these products must complete a Common Entry Document (CED) and submit it to HSE at least one working day before the arrival of the consignment (EC, 2009). When Customs’ information indicates CN codes for products of non-animal origin requiring increased controls, Customs contacts the relevant Environmental Health Officer or HSE who will examine the product (FSAI, 2011).

All products arriving at the DPE are subject to a document check. Identity and physical checks are performed on a product-specific basis as listed in Annex I of EC regulation no. 669/2009 (EC, 2009). When the checks have been carried out, the Environmental Health Officer completes, signs, and stamps Part II of the CED and makes a copy of the signed and stamped document for their records. Consignments can only be released when a completed CED or its electronic equivalent is presented to the Customs authorities (FSAI, 2011b).

“When Customs are advised of products subject to emergency measures they apply a Red or Orange routing to imports of the food bearing customs tariff numbers (CN codes) from the affected countries. Red routed entries will trigger a physical check on the goods and Orange routed goods will trigger a documentary check and possibly a physical check. When suspect products of non-animal origin or foods subject to EU emergency measures are found, Customs arrange to suspend release of the product concerned from customs control for up to a maximum of three working days and immediately notify the HSE or FSAI” (DAFM and FSAI, 2011a).

**Products of Animal Origin**

Under service contracts with FSAI, The Department of Agriculture, Fisheries and the Food (DAFM) is responsible for enforcing legislation dealing with imports of animal products, and SFPA enforces legislation pertaining to fish and fishery products. Products of animal origin undergo a similar process to products of non-animal origin requiring increased official controls, yet there are some process variations. For purposes of this report, we primarily focus on those animal products that fall under the purview of FDA in the U.S., such as seafood, dairy, and shell eggs.

Products of animal origin must come from both a country and an establishment that appear on EU-approved lists. Importers of animal origin products must register with the DAFM or the

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5 Foods of non-animal origin that are subject to increased controls are listed in Annex I of EC regulation no. 669/2009 (EC, 2009).

6 “In exceptional circumstances where there is reason to authorize the onward transportation of a consignment before receiving results of product checks or sampling, arrangements will be made by the competent authority to ensure that the consignment remains under its continuous control and cannot be tampered with. The competent authority will also need to make arrangements with Revenue’s Customs Service to ensure that any such movement will not interfere with customs controls and that any potential duties payable are secured. A certified copy of the original CED must be issued to accompany the consignment.” (FSAI, 2011d)
SFPA as appropriate for the animal product being imported and provide 24 hours advance notification to DAFM or the SFPA that the products will be arriving at a BIP.⁷

When arriving at a BIP, products of animal origin must pass through veterinary controls in order for the consignment to be released to Customs. As animal origin products pass through veterinary controls at BIPs, three types of checks are carried out:

- **Documentary**: A documentary check is carried out on all consignments. Products of animal origin must be accompanied by a common veterinary entry document (CVED) a health certificate.

- **Identity**: A visual, identity check is carried out on all consignments to verify that the identity of the goods corresponds fully with the veterinary documents supplied.

- **Physical**: A physical check is carried out on a percentage of consignments on the basis of the type of animal or animal product and the country of origin to ensure it does not pose a threat to public and animal health. Animal origin products must be appropriately wrapped and labeled with a health mark. EU legislation also specifies a minimum number of physical checks to be carried out for each product group (e.g., meat, fish, or dairy) by each member state. A physical inspection may also involve taking samples for laboratory tests.

(EC, 2009)

When all tests and checks are satisfactory, the consignment’s Common Veterinary Entry Document (CVED) is completed, and the product is placed on the market. Foods failing to comply with the control checks may be detained for further examination, returned to the exporting country, or destroyed. Once the shipment has met the required conditions it is released for free circulation within Ireland or the broader EU (FSAI, 2011b).

### 1.4 Assistance, Cooperation or Contributions from Other Government Bodies (National or Local) in the Imported Food and Feed Process

In addition to FSAI and DAFM, Customs and Health Service Executives (HSE) are integral to the imported food and processes (See Sections 1.2 and 1.3 above).

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⁷ Dublin is the designated port of entry for Ireland, and BIP locations for Ireland include:
- BIP Dublin Airport: Collinstown, County. Dublin
- BIP Dublin Port: Eirfreeze, Bond Rd, Dublin Port, Dublin 3
- BIP Shannon Airport: County. Clare

BIPs are staffed with three to ten DAFF personnel staff at each post during normal port operations schedule (DAFF and FSAI, 2011).
1.5 Laws and Regulations that Provide Authority for the Oversight of the Safety of Imported Foods and Animal Feed, and the Policies and Procedures that Guide Import Officials

As a Member State of the European Union, many of the regulations underlying the import controls on food and feed are those stemming from the European Commission (EC). Ireland has adopted these regulations through statutory instruments which reference the EC regulations. Below, the overarching regulations for the safety of imported foods and feed into Ireland are listed in relation to EC regulations.8

**Regulation (EC) No 178/2002** “establishes the common basis for food law in Member States.” The objective of the regulation is to provide consumer protection while taking into account the “protection of animal health and welfare, plant health and the environment.” The regulation established the European Food Safety Authority (EFSA) and laid down the procedures for matters of food safety. Some key food safety provisions included in the regulation are:

- **Traceability:** Food Business Operators must be able to determine who supplied them with their product as well as to whom they have supplied their product.
- **Risk Analysis:** The three components of risk assessment, risk management, and risk communication, in terms of food safety, are established.
- **The Precautionary Principle:** When there is uncertainty regarding food safety, precautionary risk management efforts will be taken.
- **Establishes the Rapid Alert System or Food and Feed (RASFF)**

(FAI, 2011g)

Regulation (EC) No 178/2002 is transposed into Irish legislation through two statutory instruments (S.I):

- S.I. No. 432 of 2009 “as it relates to the work of the Department of Agriculture, Fisheries and Food, Local Authorities and the Sea Fisheries Protection Authority.”
- S.I. No. 747 of 2007 “as it relates to food and the work carried out by environmental health officers of the Health Service Executive (HSE).”

(FAI, 2011g)

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8 This list is intended to reflect overarching import control regulation and does not include: 1) all product-specific statutes and regulations, and 2) foods falling outside the jurisdiction of those foods regulated by the FDA in the U.S. (foods other than seafood, dairy and shell eggs, fruits and vegetables, processed foods, dietary supplements including vitamins and minerals, and foods for special dietary uses). Legislation specific to particular foods can be accessed at: [http://www.fsai.ie/legislation/food_legislation.html](http://www.fsai.ie/legislation/food_legislation.html).
Regulation (EC) No 882/2004 “requires that Member States organize official controls to enforce food law and monitor and verify that the relevant requirements thereof are fulfilled by business operators at all stages of production, processing and distribution.” The regulation aims at 1) “preventing, eliminating or reducing to acceptable levels risks to humans and animals, either directly or through the environment; and 2) guaranteeing fair practices in food trade and protecting consumer interests, including food labeling and other forms of consumer information” (FSAI, 2011m).


Regulation (EC) No 669/2009 regards the increased level of official controls on imports of certain feed and food of non-animal origin. The regulation:

- Requires food business operators or their representatives to give prior notification of the arrival of imported consignments.
- Specifies a list of products requiring increased official controls as well as that product’s hazard and frequency for documentary, identity, and physical checks.
- Discusses products requiring a country entry document (CED) and provides CED format.

(EC, 2009)


Council Regulation No. 315/93EEC defines contaminants, provides for maximum contaminant levels to be provided, and lays down procedures for dealing with contaminants (FSAI, 2011c).


Ireland Statutory Instrument 432 (2009) requires food and feed importer registration, prior import notification, and provides statutory authority for DAFM, SPFA, and Local Authorities to oversee components of the import control process (FSAI, 2011d ).

2 INSPECTION PROGRAMS

2.1 Mechanisms to Prioritize Food/Feed Import Surveillance Activities, such as Product Sampling and Testing, Inspections at the Border, and Facility Inspections of the Exporting Country

Import control activities in Ireland are risk-based, and the surveillance of imported goods depends on the product’s categorization as being: 1) foods or feed of non-animal origin not subject to increased controls, 2) foods or feed of non-animal origin that are subject to increased controls, and 2) foods or feed of animal origin. HSE oversees import controls and surveillance activities surrounding foods of non-animal origin products, and DAFM oversees import controls and surveillance activities for foods of animal origin (DAFM and FSAI, 2011a).

Foods of non-animal origin that are not listed in EC No. 669/2009 as presenting possible increased risk to human health are considered to be low risk (EC, 2009). These foods are subject to random checks and are not required to enter Ireland through DPEs or BIPs (Ellard, 2011).

All food of non-animal origin that is subject to increased controls undergoes document checks upon arrival in Ireland. Identity and physical checks are performed on a product-specific basis and frequency listed in Annex I of EC regulation no. 669/2009 (EC, 2009).

Foods of animal origin are inspected at BIPs “in accordance with an annual inspection program or in line with the frequencies established in documented procedures. The criteria for determining the frequency of inspections include:

- The outcome of previous inspections,
- Compliance history,
- Nature of risk to public health in terms of type of product produced,
- Effective food safety management systems, and
- Self-monitoring programmes operated by the food business operator.

(DAFM and FSAI, 2011a)

The FSAI is responsible for the organization of surveillance activities required by EU coordinated control plans. FSAI participates in EU working group meetings to decide on the topics for these plans and advising the relevant competent authorities (DAFM and HSE) of the sampling and analytical requirements. FSAI also compiles sample and test data; sending verification-related reports to the Commission (DAFM and FSAI, 2011a).

Also see Section 3.10 for DAFM and HSE annual sampling and monitoring programs.


2.2 Special Screening Requirements and Trading Partner Requirements where Disease or an Outbreak has Occurred

Special screening requirements for foods of non-animal origin that require increased import controls are indicated EC 669/2009 Annex I (EC, 2009) (See Section 2.1 above). In recent years, increased import controls have been implemented in response to food safety concerns pertaining to products from a range of non-EU countries (DAFM and FSAI, 2011). In urgent cases, the European Commission can also take safeguard measures on its own initiative, pending confirmation by the Member States (DAFM and FSAI, 2011).

2.3 Percentage of Imported Food Shipments Examined and the Relationship between Risk-Ranking of Foods and Volume of Imported Foods Examined

In Ireland, the foods presenting the highest potential risk to human health are examined more frequently than foods considered to relatively safe, or posing low risk. Animal products such as meat, milk, fish, and honey, as well as live animals, are deemed to present the highest level of risks to consumers because they can transmit serious human and animal diseases. Identity and physical checks are determined by EU regulations (EC, 2004; EC, 2009).

Products of non-animal origin undergo random surveillance, unless they have been specified as requiring increased controls due to prior product history or being listed in Appendix I of EC Regulation 669/2009 (EC, 2009). Appendix I of EC Regulation 669/2009 specifies products of non-animal origin, which, based on associated product hazards, undergo more frequent product checks (EC, 2009).

Per EU directive, DAFM and FSAI conduct a 100 percent documentary review of imported products. Roughly 50 percent of products undergo visual review, and only about 10 percent are sampled routinely (DAFM and FSAI, 2011). FSAI has three levels of import control based on EU regulations, which specify the level of import inspection:

- Regulation [EC] 882/2004 – Routine controls
- Regulation [EC] 669/2009 – Temporary additional controls for all countries

(FSAI, 2011n)

2.4 Types of Review, Examination and/or Testing of Imported Products Performed by Food Safety Inspectors

When a consignment arrives at a BIP or DPE, three potential types of checks, documentary, identity and/or physical, are carried out by DAFM and HSE officials (See Section 1.3).
2.5 Frequency of Documentation and Labeling Checks as Compared to Analytical Examinations

Document checks are performed on all imported foods, whereas roughly 50 percent of products undergo visual review, and only about 10 percent are sampled routinely (DAFM and FSAI, 2011).

2.6 Types of Examination and Testing Processes Used for Ensuring Animal Feed and Feed Ingredient Safety

Customs performs documentary review for all feeds. DAFM Physical exam rates by DAFM are 100 percent for non-EU feed, 15 percent for EU unprocessed feed, and 25 percent for EU processed feed (DAFM and FSAI, 2011).

“The FSAI are responsible for the enforcement of controls on contaminants in food. Feedingstuff Division staff draws samples of some bulk food grains on behalf of FSAI and has them tested for mycotoxins (specifically aflatoxin and ochratoxin A). This satisfies FSAI’s requirements for controls to check out compliance with maximum levels laid down in Regulation 466/2001 for these contaminants in food. Meetings are held on an ad hoc basis between the FSAI and DAFM to address issues as they arise” (DAFM, 2011).

“All feed materials put into circulation [are also] subject to random checks to ensure that the correct descriptive name and the appropriate labeling particulars accompany each batch. The inspecting officer [completes] a report in respect of each inspection carried out at such premises. The analysis programme [focuses] in particular on the statutory labeling requirements as laid down in the annex to Regulation 767/2009 and will be based on a risk assessment” (DAFM, 2011).

2.7 The Dependence of Examination and Testing Requirements on Conditions (such as the Presence of BSE or Other Zoonotic Diseases) in the Exporting Country

Conditions of exporting countries are assessed by the Food and Veterinary Office (FVO) of the European Commission rather than Irish officials. Conditions in exporting countries that may potentially increase the risk of exported products may be accounted for through increased import controls for products of non-animal origin listed in Appendix I of Regulation EC 669/2009 (EC, 2009). Products of animal origin are only allowed to enter Ireland and the EU if they are on an EU list of countries and establishments that have been verified by the FVO has meeting EU standards, and these products undergo additional review as they enter Ireland through BIPs (Ellard, 2011). DAFM may also require increased product testing or exclude “specified risk material” from entering Ireland when particular health concerns arise, as is the case with BSE (DAFM, 2011a).
2.8 **Inspections of Food or Animal Feed Manufacturers or Shippers in Other Countries (including Selection Criteria and Frequency)**

Foodstuffs of animal origin may only be sourced from premises in recognized countries that have been approved by the EU. Inspections of these establishments are carried out by the Food and Veterinary Office (FVO) of the EU to ensure that only establishments that meet standards equivalent to those operating within the EU are approved (FSAI, 2011i).

2.9 **Notification System(s) to Directly Notify Foreign Governments When Foods or Animal Feed Manufactured in their Countries are Found to be Unsafe; and to Notify the Public When Imported Products do not Meet Safety Standards**

Problems with imports are normally brought to light by inspections at BIPs or from inspection or testing carried out during the course of market surveillance by Member States, business or consumer groups, or media reports (FSAI, 2011d). When an issue with imported food or feed arises, businesses are required to inform the authorities of any problems and, where necessary, inform consumers (FSAI, 2011d). Ireland is able to notify foreign governments of relevant issues through the EU’s electronic Rapid Alert System for Food and Feed (RASFF) which is managed by DG- SANCO in Brussels (FSAI, 2011o).

RASFF involves all Member States, the European Community, and the European Food Safety Authority, as well as the non-EU countries of Iceland, Liechtenstein, and Norway. The exchange of information allows participating states to immediately ascertain whether they are also affected by a problem. Authorities can order withdrawals/recalls and this information is shared via RASFF (EUROPA, 2011).

Each Member State has a contact person who is authorized to send and receive notifications to RASFF. FSAI is the national contact point for Ireland. Notifications are, then, considered at the Member State level (FSAI) for follow-up, consumer, or industry notification. When an incident occurs off-hours, the 24-hour call center notifies an FSAI contact person, who in turn, determines action (DAFM and FSAI, 2011).

EU countries use a template to ensure that critical product information, such as identification, hazard, and traceability information, is reported to RASFF. Once the information is received through RASFF, other EU countries verify if the product is of concern to them, and, if so, they are able to trace it using the information available in the notification. Affected countries report back to the RASFF on what they have found and what measures they have taken to address the product issue. In case of products produced in the EU, the country of origin also reports to RASFF the outcome of its investigations into the origin and distribution of the product and the cause of the problem identified. This allows other EU countries to take rapid action if required (GAO, 2008; FSAI, 2011o).

The RASFF portal database also provides notifications to consumers. Consumers can access an online database that allows them to see information relating to RASFF notifications within 24 hours after information is transmitted to the RASFF network. Ireland also provides recall data online and notifies consumers through the VWA site (EUROPA, 2011).
3 **AUDITS AND CERTIFICATION**

3.1 **Assessing and Measuring the Effectiveness of the Food/Feed Safety Import Program** (e.g., Self Audits of the Program, Public Health Outcomes, Surveillance Sampling Results, Number/Rates of Refusals, Periodic Program Evaluations)

Each competent authority is required, under the terms of its service contract with the FSAI, to carry out official controls, such as audits, in accordance with documented procedures as required by Regulation (EC) No. 882/2004 (FVO, 2010; EC, 2004). The larger official agencies, such as DAFM and HSE, have internal audit systems in place. The FSAI carries out audits for the competent authorities which do not have systems for internal audit, such as SFPA (FVO, 2010).

Internal audits are carried out in accordance with documented procedures and, to the extent possible, by personnel independent of the function being audited. FSAI carries out the following three categories of audits under its annual audit program:

- **Targeted Audits** determine compliance with a specific piece of EU or national legislation, including Regulation (EC) No. 882/2004. These audits are typically carried out in food business operations. Following the audit, the operator is issued with a report with details of any non-compliance identified. The competent authority supervising the food business is responsible for ensuring that appropriate corrective action is put in place for each non-compliance;

- **Service Contract Audits** are designed to ensure that the competent authorities adhere to the terms and conditions set out in their contract;

- **Closeout Audits** provide follow-up to recommendations made in FVO reports to check that the necessary corrective action has been taken.

DAFM has an independent internal audit unit, the agricultural inspectorate audit unit (AIAU), to ensure that the implementation of official controls by the various DAFM services (Agricultural Inspectorate, Veterinary Public Health Inspectorate, Animal Health, Animal Welfare and the Veterinary Laboratory Service) meet the requirements of EU legislation (FVO, 2007; DAFM and FSAI, 2011a). DAFM audits are recorded, and when necessary, a plan for corrective action is formulated with division management to address relevant issues. The audits are also subject to independent review by an independent audit monitoring body composed of experts from outside DAFM (DAFM and FSAI, 2011a).

The DAFM Feed Control Plan “is formally reviewed on a quarterly basis”, and “an annual audit is carried out in conjunction with the NRL (Animal Protein) at the designated laboratory in relation to microscopic testing.” “The principle findings from the annual inspection programme are included in the annual reports of the MANCP submitted to EU Commission...and the outcome of certain controls is communicated bi-laterally to the relevant Commission services” (DAFM, 2011).
3.2 Criteria Used for Program Evaluation and/or Assessment of the Food/Feed Safety Import Program, and the Frequency of Food/Feed Safety Import Program Assessment

The internal audit systems of FSAI, DAFM, “is focused on the requirements of the standards ISO9001:2000 or ISO 17025 and are currently being expanded to take account of the requirements of Regulation (EC) No. 882/2004” (DAFM and FSAI, 2011a). The general scope of audits under Regulation (EC) No. 882/2004 is to include “measures concerning the protection of the health and safety of humans, animals or plants, as well as measures designed to adapt or update certain non-essential provisions of a basic instrument” (EEC, 1999 as referred to by EC, 2004). “In general, the service contracts between the FSAI and the competent authority include requirements in relation to documented procedures and/or a quality management system” (DAFM and FSAI, 2011a).


Measures assessed by DAFM during audits include:

- Impartiality, quality and consistency of controls,
- Conflict of interest considerations for staff,
- Laboratory capacity,
- Availability of suitably qualified and experienced staff,
- Adequacy of facilities and equipment,
- Adequacy of legal powers,
- Level of cooperation between food and feed business operators and staff performing official controls,
- Availability of documented procedures, and
- Records maintenance.

(DAFM and FSAI, 2011a)

3.3 Extent of Reliance on Trading Partners’ Food Safety Programs to Ensure That Imported Foods or Animal Feed are Safe

Ireland relies on trading partners’ food safety systems to help ensure the safety of food and animal feed, as the importer has the primary responsibility for the safety of imported food. The extent to which Ireland relies on trading partners’ food safety systems depends on the risk
categorization of the imported product and whether that food product is classified as being of animal or non-animal origin (See Section 2).

3.4 Use of Additional Measures (e.g., Audits of Producers, Exporters and Shippers) to Verify the Safety of Trading Partners’ Food and Animal Feed

FVO conducts audits of equivalence agreement partners to verify systems standards. The FVO also audits the work of the Member States on a regular basis. EU’s FVO assesses the performance of the Member States’ competent authorities, countries aspiring to join the EU (referred to as candidate countries), and non-EU countries intending to export to the EU (referred to as non-EU countries), to verify the effectiveness of national control systems for meeting EU standards in the areas of food safety, animal health and welfare, and plant health. Feed suppliers, for example, must apply HACCP principles, register with their national competent authorities to help ensure traceability, and comply with specific microbiological criteria, such as for levels of *Salmonella*, molds, and yeast. The FVO conducted its most recent audit/review of FSAI in 2011 (FSAI and DAFM, 2011).

3.5 Requirements for Food and/or Animal Feed Export Certificates Issued by the Exporting Country’s Competent Authority, and Types of Inspection or Testing for Each

Export certificates issued by the exporting country’s competent authority are not required for food and feed products imported into Ireland. However, foods of non-animal origin that are subject to increased import controls (as listed in EC 669/2009) require a common entry document (CED), and foods of animal origin require a common veterinary entry document (CVED). Country entry documents may require official assurances from the exporting country to be included, such as a health certificate for products for products of animal origin (EC, 2009; EC, 2006a).

3.6 Use of ISO, Global Gap or Other Assurance Systems and Confidence in the Assurance System(s) Utilized

All FSAI and DAFM are ISO accredited per ISO 17025. While laboratory and testing data is required to support importation of certain products, FSAI and DAFM must confirm these results using their own laboratories before approving shipment release/entry (DAFM and FSAI, 2011).

3.7 The Nature and Frequency of Foreign Food Safety Systems Audits Performed

All establishments producing food of animal origin have to be approved and meet EU standards in order for their products to be imported into Ireland and other Member States. The countries in which the establishments are located must have control systems which offer the same food safety guarantees as those within the EU. Regular audits are carried out by FVO to ensure the standards are maintained. (FSAI, 2011).
3.8 Equivalence Agreements Requiring Periodic Audits/Reevaluations of Exporting Countries’ Food Safety Programs

For Ireland and other Member States, equivalency agreements take place at the EU level. Food products of animal origin imported from non-EU countries must meet standards at least equivalent to those of the EU for food quality and hygiene.

Among the requirements for approving the export of products of animal origin are the following:

- A country’s formal submission of a written application to export to the EU;
- The EU’s verification of the exporting country’s animal and public health system, such as its legislation, control systems, disease surveillance measures, and laboratory facilities;
- The country’s submission and approval of a monitoring plan for residues of banned or restricted substances in the EU, including veterinary medicines and growth-promoting hormones; and
- The country’s provision of sanitary certification that the products to be exported to the EU meet import requirements.

Inspectors from the EU’s Food and Veterinary Office normally visit non-EU countries to verify compliance with these conditions (GAO, 2008).

3.9 The Utilization of Third-Parties (Within the Exporting or Importing Country) to Carry out Inspections and/or Product Certification (Nature and Extent of Programs) and Methods for Verifying the Adequacy and Reliability of the Third Party Work

All inspections are carried out by government officials. Further, competent authorities of non-EU countries are the only bodies entitled to officially declare that establishments fully comply with EU legislation requirements (DAFM and FSAI, 2011).

3.10 Arrangements with other Governments Relating to Imported Foods or Animal Feed (such as Memoranda of Understanding, Mutual Recognition Agreements, etc.)

Arrangements such as Memoranda of Understanding pertaining to food and feed imports are not made between Ireland and other countries, but rather on behalf of Member States through EU agreements.

3.11 Registration or Licensing of Firms That Import and/or Export Foods or Animal Feed to the Country or for Firms That Import Foods or Animal Feed

Importers of foods of non-animal origin are required to be registered with HSE, and importers of feed and animal origin products are required to be registered with DAFM prior to importing
products (Ellard, 2011). Exporters of non-animal origin products to Ireland are not required to be registered.

3.12 Use of Sampling Surveys of Imported Foods/Feed (as Opposed to Targeting Specific Products/Producers for Inspections and/or Testing) to Gather Information and Identify Trends and Potential Areas of Difficulty

DAFM and HSE implement monitoring surveys in addition to their targeted enforcement efforts at DPEs and BIPs. Monitoring surveys capture both domestic and imported products. DAFM performs random sampling on domestic products, and HSE performs annual chemical and microbiological surveys in addition to product-specific studies on emerging food issues (Ellard, 2011).

“The FSAI coordinates a national microbiological surveillance program in conjunction with the Environmental Health Service and Official Food Microbiological Laboratories in the HSE. This involves selecting three topics on an annual basis. The FSAI prepares a sampling protocol, prepares a questionnaire to collect information at the time of sampling, compiles the sample and test data and produces a report on the findings of these surveys” (DAFM and FSAI, 2011a).

DAFM implements national monitoring programs for residues of pesticides, veterinary medicines, and environmental contaminants. According to the FSAI 2009 Annual Report, “In 2009, 1,324 samples of imported and domestically produced food were analyzed for pesticide levels. Where a sample exceeds the maximum permitted residue limit, a dietary intake risk assessment is immediately carried out to assess if the acceptable daily intake or the acute reference dose has been exceeded. The level of risk is calculated based on consumption data for both adults and children. When a maximum residue limit of a pesticide is exceeded, the relevant food commodity [is] targeted for testing in the next year’s sampling plan. Depending on the case, action could also involve withdrawal of food from the market, issuing an alert through the Rapid Alert System for Food and Feed and prosecution” (FSAI, 2009).

DAFM also has a feedingstuffs annual inspection programme (FAIP) which includes “inspection, sampling, and analysis activities in relation to all levels of the feed chain.” In particular, the program covers the following broad areas:

- General food law,
- Feed hygiene,
- The circulation and use of feed materials,
- The marketing of compound feed,
- Additives for use in animal nutrition,
- Undesirable substances in animal feed,
- Feedingstuffs for particular nutritional purposes,
• Certain protein products used in animal nutrition,
• GMO in feed,
• Medicated feedingstuffs, and
• Animal health (as it relates to animal feed).

(DAFM, 2011)

3.13 “Good Practices” Programs for Foods/Feed Importers

FSAI and DAFM food and feed safety programs promote good manufacturing practices. Good practices programs for importers were not discussed during the site visit or located in publically available information (DAFM and FSAI, 2011).

3.14 Description of Import Program User Fees and Cost Recovery System

DAFM collect fees for import inspections (DAFM and FSAI, 2011; EC, 2004). Specific information on the fee system was not uncovered during discussions with country officials due to time constraints or through publically available information.

3.15 Incentives to Increase Industry Involvement in Ensuring That Imported Foods Meet Safety Standards

In order to communicate the need for compliance with food safety legislation, and to promote best food safety practices, the FSAI has in place various effective systems for engaging with the food industry. There are four industry fora, namely the:

• Artisan food producers,
• Forum retail forum,
• Food services forum, and
• Molluscan shellfish safety committee.

These industry fora meet periodically and serve as a platform to progress issues relating to food safety and hygiene in specific industry sectors (MANCP, 2009).

3.16 Obstacles to Industry Participation in Ensuring That Imported Foods Meet Safety Standards

There is no indication of obstacles to industry participation in ensuring the safety of imported food and feed (Ellard, 2011a).
4 LABORATORY SUPPORT

4.1 The Role of Laboratories in Supporting the Imported Food and Feed Programs and Description of Laboratory Capabilities

There are approximately 60 laboratories involved in food safety monitoring, analysis and research in Ireland. These laboratories may operate directly under the control of government departments, Health Service Executive, local authorities, non-departmental public bodies, institutes of higher education, or national agencies. There is also a private laboratory sector with nearly 40 departmentally (government) approved laboratories that offer routine food safety analytical laboratory services to industry (FVO, 2010).

FSAI and DAFM maintain comprehensive laboratory operations to meet testing and standardization requirements of Ireland’s food and feed safety system. When such expertise or technology is not available within FSAI or DAFM, services may be provided through cooperative agreements with international experts such as RIKILT (DAFM and FSAI, 2011).

Safefood, a North-South body responsible for promoting food safety in Ireland, aims to increase coordination and interaction between food safety laboratories in Ireland by:

- Developing a strategy for cooperation and linkages between laboratories,
- Developing a reporting system for rapid access to laboratory results,
- Sharing knowledge and experience on methodologies of testing and surveillance,
- Setting priorities for laboratory network development,
- Advising on developing linkages and on the means to be employed,
- Establishing and promoting appropriate information technology solutions, and
- Monitoring effectiveness of the linked laboratories system, including advising on its continuing development.

(Safefood, 2011)

To that end, Safefood has set up a number of support programs that encourage and initiate inter-laboratory co-operation such as information sharing and technology transfer. Safefood, 2011)

The Pesticide Control Laboratory (PRCD) is dedicated to analyses samples of food for pesticide residues. It is accredited to ISO 17025 and is designated as a national research laboratory for pesticides residues in: food of non-animal origin; food of animal origin; cereals; and single analytical methods. The samples, taken by PRCD at wholesale and retail level covering both imported and domestic produce, are brought by the sampling officer to the laboratory. Samples are routinely analyzed for some 332 pesticides including their metabolites. If the residue level
found is higher than the maximum allowed and the residue is considered a risk to the consumer and the rapid alert process is followed (FVO, 2007).

Laboratory sampling and analysis volumes from 2009 are indicated in Table 1.

**Table 1: 2009 Sampling and Analysis**

<table>
<thead>
<tr>
<th>Type of Sampling/Analysis</th>
<th>Number of Samples Taken</th>
<th>Party Responsible for Taking Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical</td>
<td>10,792</td>
<td>Environmental Health Officers</td>
</tr>
<tr>
<td>Microbiological</td>
<td>14,262</td>
<td>Environmental Health Officers</td>
</tr>
<tr>
<td>Fish and fishery products</td>
<td>5,100</td>
<td>SFPA</td>
</tr>
<tr>
<td>Imports</td>
<td>1,189 (animal origin)</td>
<td>DAFM</td>
</tr>
<tr>
<td></td>
<td>7,773 (non-animal origin)</td>
<td>HSE</td>
</tr>
</tbody>
</table>

Source: MANCP, 2009

4.2 **Participation of Non-government Laboratories (Including Industry and Academic Laboratories) in the Food Import Control Program**

Non-government laboratories may supply required testing data for foods and feed of non-animal origin requiring increased import controls under EC 669/2009. However, FSAI must confirm data through government laboratory tests before releasing the shipment (DAFM and FSAI, 2011).

4.3 **Methods for Laboratories to Achieve Quality Assurance (such as Voluntary or Mandatory Accreditation)**

Laboratories are ISO 17025 accredited. Accreditation audits are conducted and granted by the Irish National Accreditation Board (INAB) (FSAI, 2011n).

5 **ENFORCEMENT AT BORDER**

5.1 **Approach to Visual Inspections and Analysis of Imported Foods (e.g. Risk-Assessment and Prioritization Schemes, Documentation Review, Sample Collection)**

The inspection and testing of imported foods and feed in Ireland is risk-based and is specified by EU regulations and procedures (also see Section 2).

5.2 **The Process that Occurs When an Imported Food is Found to be Contaminated or does not Meet Standards**

If the imported shipment is found to be contaminated while in the entry review process, it is held while a determination is made as to whether the product should be destroyed or exported back to the country of origin. The authority inspecting the product, such as HSE or DAFM, notifies the import agent in question and seeks to have import information corrected or additional data supplied (DAFM and FSAI, 2011). Contaminated shipments identified after products are on the market may be recalled, as initiated by DAFM, HSE, or FSAI. Relevant information pertaining to the contaminated food is also entered into the TRACES or RASFF systems (DAFM and FSAI, 2011).
5.2.1 Procedures for Refusing Imported Foods Based on a Finding that they do not Comply with Requirements

If an imported food or feed is refused for not complying with food safety standards before it enters Ireland, then the product is subject to withdrawal. If the product is within Ireland at the time of refusal, a recall is undertaken. Product traceability requirements enable the importer to recall the violative imported product in question (DAFM and FSAI, 2011).

5.2.2 The Procedure and Outcome for Imported Foods that are Refused Entry (Including Efforts to Prevent them from Mistakenly Entering Domestic Commerce)

If a consignment does not comply with EU requirements, it may be rejected. In these cases, EU officials inquire with the owner of the consignment and the country of dispatch, where appropriate, about whether to destroy the product, to use it for purposes other than the human food chain, or to export it. Food or feed business operators or their representatives are responsible for the consignment and are liable for any costs incurred by the competent authorities during this process. In addition, if consignments are not in compliance, all other border inspection posts are notified through the RASFF (GAO, 2008). Also see Section 2.7.

5.2.3 Entry of Detained Products Based on Further Testing or Reconditioning of the Product

Products can be detained awaiting CED/CVED data, re-labeling, and other remedy before release at the border. Products not meeting specified product standards may be reconditioned for food or feed purposes other than those originally intended as specified by EC regulation 882/2004 (EC, 2004).

5.2.4 Process for Identifying and Tracking Producers or Countries that have Repeated Violations

There are several sources of information that may be used to help identify and track producers or countries with repeated food or feed import violations. First, importer information is recorded as importers are required to register with DAFM or HSE before importing their products. Importers of products with increased controls and those of animal origin are also required to submit product information through CEDs/CVEDs. CVEDs are entered into the EU TRACES system, which allows information on animal origin products to be shared among Member States and can be used to notify border inspection posts of non-compliant consignments (EUROPA, 2011a).

Imported products presenting repeated health and safety risks may be incorporated into the listing of products requiring increased import controls presented in EC 669/2009 Annex I (EC, 2009) (See Section 2.1 above).

5.3 Program for Investigating and Responding to Intentional Contamination of Foods

Intentional contamination is an extremely rare occurrence in Ireland, and as such, officials stated that intentional contamination did not appear to be a significant enough risk to warrant or
outweigh current risk priorities for animal-origin/non-animal origin foods and feeds (DAFM and FSAI, 2011).

6 FOOD RELATED ILLNESS OUTBREAKS

6.1 System for Tracking Imported Foods once they are Cleared at the Point of Entry

Irish importers are required to be able to trace their products one step forward (to whom they supplied their product) and one step back (who supplied the product to them) under Regulation (EC) No 178/2002. The operator must be able to document the names and addresses of the suppliers and customers, as well as the nature of the product and date of delivery. The operators are also encouraged to keep information on the volume and quantity of a product; the batch number, if there is one; and a more detailed description of the product, such as whether it is raw or processed (FSAI, 2011g).

6.2 Systems for Identifying Foodborne Illness Outbreaks

When an outbreak of foodborne disease is suspected, FSAI works closely with the official agencies and the Health Protection Surveillance Centre (HPSC) within HSE. HPSC is the Irish body responsible for collating and reporting on cases of infectious disease (FSAI, 2009).

For foodborne illness outbreaks spanning beyond Ireland and potentially impacting other EU Member States, FSAI informs the European Centre of Disease Prevention and Control (ECDC) through the Early Warning Response System—a computer database that deals with communicable diseases. ECDC assesses risk at the EU level to confirm a threat and then: 1) works with other entities to ensure a coordinated approach to investigation and control; 2) cooperates closely with other EU agencies, particularly EFSA; 3) ensures proper communication with the EU and the public; and (4) assists the Member States involved (FSAI, 2011h).

There are also networks of EU reference laboratories linking national reference laboratories for each of the major foodborne pathogens. These networks provide support to Member States’ competent authorities in analyzing suspect food and exchanging information on the molecular typing of isolates (samples). The epidemiological investigation of foodborne outbreaks is an important tool for identifying the major causes of foodborne infections in humans. It is a major source of information used when deciding on priorities for the control of foodborne infections in the EU (FSAI, 2011h).

6.3 Procedure for Tracking Illnesses back to the Food Source when a Foodborne Illness Outbreak Occurs

Foodborne illness investigations are carried out by HPSC. Investigations are a combination of laboratory work, micro fingerprinting of bugs in people and food and animals, interviews, case control and cohort studies using systems like Epinfo, legwork, and detective work in food businesses. In the case of an outbreak or a suspected outbreak, a multi disciplinary team is called together and follows a standard protocol. As there were a number of regional protocols in place, Ireland has recently drafted a national protocol (Ellard, 2011a).
6.4 How Consumers Notify the Government and/or Importers of Food Problems

The FSAI website contains information for consumers on how to submit a complaint concerning food issues. The “Make a Complaint” webpage provides consumers with three options for voicing any concerns that they might have: 1) talk to the manager at the establishment where the concern occurred, 2) contact the local HSE environmental officer via the contact numbers provided, and 3) notify FSAI of food problems by filling out the online consumer complaint form on the FSAI website (FSAI, 2011a).

7 EXPORT PROGRAMS

7.1 Programs for Ensuring Safety Requirements of Export Destination Countries

7.1.1 Use of Export Certificates to Provide Assurances to the Importing Country

Export certificates for foods of non-animal origin are issued by HSE Environmental Health Officers when countries outside of the EU request such certification. In order to obtain an export certificate from HSE, producers must: “

- Be registered/approved by the Environmental Health Service (EHS) of the HSE and have been inspected within the last 12 months and found to comply with EU food law,
- Analyzed by independent laboratory within 12 months of export for measures appropriate to that product,
- Ensure that labels meet EU requirements, and
- In cases where the exported product originated outside of the EU, submit a letter from the competent authority of the non EU country where the good was produced, stating that it meets EU standards.”

The exporter can then fill out an application for export certification and submit it to HSE for approval (HSE and FSAI, 2011).

Exports of fish or fishery product from Ireland to a non-Member State of the EU may require a Catch Certificate Validated by the SFPA if the product will be re-imported to Ireland or if the country of import makes such a request (SFPA, 2011). Information to be provided for the certificate includes:

- Scientific species name,
- Eight digit product code, and
- Estimated landed weight of the consignment.
After the catch certificate is prepared, it is sent to the local port office where an SPFA officer may review it for validation (SFPA, 2011).

Animal origin products such as eggs and egg products, milk and milk products, and honey require export licenses (DAFM, 2011b). Further information pertaining to export certification and licensing was not located in publically available information.

7.1.2 Authorized Third Party Issuance of Export Certificates

Export certificates are not issued by third parties.

8 WORLD TRADE ORGANIZATION (WTO) OBLIGATIONS

8.1 Methods for Ensuring Consistency between Domestic and Imported Food Safety Requirements

“As a member of the World Trade Organization, EU Member States have an obligation to harmonize their food safety measures with international standards, guidelines and recommendations adopted by the Codex Alimentarius Commission documenting the scientific justification for import practices with regard to Article 5 of the SPS Agreement” (EC, 2006).

8.2 Methods of Documenting the Scientific Justification for Import Practices with regard to Article 5 of the SPS Agreement, which Requires that Measures are based on an Assessment of Risk, as Appropriate to the Circumstance

The scientific justification for Ireland’s risk-based import practices as they relate to the SPS Agreement are documented in EC No. 178/2002 (FSAI, 2011g).

8.3 Involvement in Article 4 of the WTO SPS Agreement Regarding Equivalence Determination

Equivalency determinations for Ireland and other Member States are made at the EU-level by The Directorate General Health and Consumers (DG-Sanco) (Ellard, 2011a). Within the EU, Member State food systems are recognized as equivalent (FSAI, 2011g).

8.4 Process for Recognizing a Foreign Country’s Food Safety System as having Adequate Regulatory Oversight

EC Regulation No. 178/2002 indicates that the adequacy of a foreign country’s food safety system is based on its comparability to the food safety system and standards of the EU, stating, “food and feed imported into the Community for placing on the market within the Community shall comply with the relevant requirements of food law or conditions recognised by the Community to be at least equivalent thereto or, where a specific agreement exists between the Community and the exporting country, with requirements contained” (FSAI, 2011g).
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ISRAEL

FOOD AND FEED IMPORT PRACTICES

APPENDIX E
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OVERVIEW OF INTERVIEW AND FOOD AND FEED SAFETY SYSTEM

The key components of the import system in Israel for food and feed that similar to the food and feed regulated by FDA are as follows:

Ministry of Health (MOH):

- The MOH supervises food in Israel, primarily, via the Food Control Service, with other Departments of the Ministry addressing specific aspects of food supply.
- The Food Control Service is one among several departments in the Public Health Services of the MOH. The Food Control Service includes a Headquarters Unit and seven District Units.

Ministry of Agriculture (MOAG):

- MOAG is the competent authority for imported animal feed.
- Two departments handle food safety—Veterinary Services and Animal Health (VSAH) and Plant Protection and Inspection Services (PPIS).

The main elements of the import system in Israel for food and feed are as follows. Customs authorities are the first to receive and last to approve the consignment. Customs authorities release the consignment after confirming the consignment’s checklist of papers from all relevant competent authorities.

The first condition for the importation and release of food into Israel is receipt of a Certificate of Registration as a Food Importer from the National Food Service. Goods cannot be released from customs without first obtaining a Prior Authorization for importation of food and approval for release from the MOH’s quarantine station.

- The Veterinary Unit responsibilities include the inspection of imported fish and fish products and also ready to eat meat products into Israel.
- The Imports Department supervises imported foods (with the exception of fish, meat, and their products), with the goal of ensuring the safety, quality, and authenticity of food. Food that arrives in Israel is checked at the point of entry in accordance with the conditions that appear on the prior approval.

Imported products are divided into “sensitive” and “regular” products. Food supplements, infant formulas and foods for special dietary use, dairy products, low acid canned food and baby foods are categorized as “sensitive food” groups, and all other foods are considered “regular foods.”

At the Border Inspection Point (BIP):

- Documents are verified and samples taken for laboratory examination.
- Veterinarians sample 100 percent of the fish and fish product shipments.
- Based on laboratory data, a permit can be issued for national distribution or the cargo can be rejected. If the data does not match with approved limit legislation, the shipment can be detained.
A Municipal Veterinary Inspection Point approves or rejects shipments of fish and meat. Every shipment of food of animal origin must have a veterinary certificate and each shipment is inspected for a veterinary certificate, refrigerated car license, temperature verification, and labeling verification.

Importers of animal feeds containing material of animal origin must have an import license. Each consignment with a veterinary certificate is submitted to the official VSAH veterinarian at each port. Certificates must be received from the exporting country, and are required for all animal feed of animal origin.

All imports of plant material (including produce, dried fruits, and nuts) and animal feed made from plant material must have an import license from the PPIS, and they must undergo a pest risk assessment (PRA) before the import license application can be approved. The quarantine inspector checks the shipment and the accompanying certificates at the port of entry. In addition, the inspector sends a sample of the shipment to the PPIS laboratory for further examination. In case of missing certificates or unsuccessful test result, the shipment will be held at the port for further assessment.

1 ROLES AND FUNCTIONS OF AGENCIES RESPONSIBLE FOR IMPORTS OF HUMAN FOODS AND ANIMAL FEED

1.1 Governmental Ministries and Subunits (Including National/Regional/Local, as Appropriate) With Responsibility for Assuring the Safety of Imported Food

Ministry of Health

The Ministry of Health (MOH) supervises food in Israel, primarily, via the Food Control Service (FCS), with other Departments of the Ministry addressing specific aspects of the food supply.

Among the departments of the Public Health Services of the MOH, the FCS serves as the primary department for the supervision of food in Israel. Other departments in the Public Health Services include: Environmental Health, Epidemiology, Nutrition, Education and Health Promotion, Laboratories, Mother and Child Development, and Occupational Health.

The FCS includes a Headquarters Unit and seven District Units. District Health Units are responsible for inspection of food imports at ports and border crossings.

The FCS consists of the following units: Management, Veterinary, Food Quality, Proper Manufacturing Conditions, Food Import, Food Additives, Risk Assessment and Food Contamination, Border Transfer and Transfer with the Palestinian Authority.

- The Veterinary Unit responsibilities include the inspection of imported fish, fish products, and meat (ready to eat) products into Israel.
- The Imports Department supervises imported foods (with the exception of fish, meat, and their products), with the goal of ensuring the safety, quality, and authenticity of food. Food that arrives in Israel is checked at the point of entry in accordance with the
conditions that appear on the prior approval and requirements list. The Unit acts as an advisory body and information source for all points of entry.

- The Risk Assessment and Food Contamination Unit works to prevent and minimize existing and predicted risks from food contamination by applying principles of risk assessment, developing appropriate legislation, and inspection tools. The unit performs risk assessments for food and toxicological assessments of chemical substances in food, develops methods for health risk assessment, and addresses ways to deal with (MOH, 2011a)

**Ministry of Agriculture**

The Ministry of Agriculture (MOAG) is the competent authority for imported animal feed. Within MOAG, two departments handle food safety—Veterinary Services and Animal Health (VSAH) and Plant Protection and Inspection Services (PPIS).

VSAH responsibilities include controlling the import and export of animals and animal products, national surveillance of residues in foods of animal origin, and the food safety of animal products. Within VSAH, veterinary officers in the Department of Import Export are responsible for the veterinary control at borders. (VSAH, 2011)

PPIS is responsible for feed safety enforcement. It provides inspection services for exported fresh agricultural products and is recognized by USDA National Organic Program as an equivalent agency.

Within PPIS, Quarantine Services specifies the phytosanitary requirements for importation of fruits and vegetables imported into Israel, and carries out phytosanitary control on all consignments of plants and plant products imported into Israel. PPIS Quarantine Inspectors are deployed in all cargo import terminals and passengers’ arrival terminals in order to ensure that any imported plant material is in conformity with the Israeli import regulations. (MOAG, 2011a)

VSAH has the responsibility for the safety of raw products (e.g., raw milk, raw meat). After products have been processed, responsibility shifts to the MOH. (Interview, 2011)

**1.2 Agencies Responsible For Animal Feed and/or Pet Foods**

The majority of grains for animal feed are imported into Israel. MOAG PPIS is responsible for the quality and safety of animal feed, as well as the supervision of its importation. PPIS is authorized to issue permits for manufacturing and trading in animal feed. Its jurisdiction includes carrying out regular inspection and supervision of animal feed products. PPIS laboratories conduct tests for contaminants, food additives and nutritional values of fodder products, plants by-products and grains. (MOAG, 2011a)

Animal feed are divided into eight categories, with specific requirements for each group:

- Major grains
- Minor grains
- Plant Products and By-products
Currently, MOAG is formulating legal proceedings for a new Animal Feed law. The new law will resolve all aspects necessary to control and monitor the safety and quality of animal feed all along the production and marketing chain. (MOH, 2011a)

1.3 Food Importation Process Steps and the Government Units That Oversee Each Step

Customs authorities are the first to receive, and last to approve, the consignment. Customs authorities release the consignment after confirming the consignment’s checklist of papers from all relevant competent authorities. (Interview, 2011)

MOH, FCS

The first condition for the importation and release of food into Israel is receipt of a Certificate of Registration as a Food Importer from the National Food Service. Goods cannot be released from customs without first obtaining a Prior Authorization for importation of food and approval for release from the MOH’s quarantine station. (MOH, 2011)

Imported products are divided into “sensitive” and “regular” products, and this categorization can undergo ad hoc changes. Food supplements, infant formulas and foods for special dietary use, dairy products, low acid canned food, baby foods and others are categorized as “sensitive” food groups, and all other foods are considered “regular foods.” A food is classified as a “sensitive food” following a risk assessment with regard to microbiology, animal source, and whether the food is intended for a particular consumer group. (MOH, 2011a)

Food is registered with the MOH, prior to sale within Israel. The registration process typically takes up to 4-6 weeks. To import regular food products, a preliminary application for authorization to import non-sensitive food products is required. To release products the following are required:

- A preliminary application for authorization to import food products
- A border station release application
  - The following certificates are required for the purpose of releasing the food products from the border station:
    - Original/copied official importer certificate
    - Original/copied food certificate
    - Shipment invoice
    - Gate pass certificate
• After sampling, the shipment can be released for storage in the importer’s warehouse, under the conditions that: 1) the importer has a proper warehouse fitted for the storage of the particular food type, and 2) submittal of a bank guarantee and an obligation by the importer not to sell of the imported product until the approval by the Import Division at the Food and Nutrition Services. Public Health Laboratories are requested to forward the test results to the Manager of the Import Division with the MOH. (USDA, 2010)

In order to get a license for the import of food supplements to Israel, the following documentation is required, in accordance with the Food Supplements Regulation (1997):

- Confirmation submitted by an approved authority that the production plant is under inspection.
- Free Sale Certificate, submitted by an approved authority.
- A Confirmation that the manufacturer is producing under Good Manufacturing Practice (GMP). Confirmation will be accepted only if submitted by an approved competent authority, or by an independent body, certified by International accreditation Forum (IAF).
- Content - A certificate from the manufacturer listing the content of the container, including botanical names of the plants.
- Analysis results - A document from an authorized laboratory, signed by the test executer, detailing the analysis results. In addition, microbiological tests should be executed for the following products: food additives made of vegetative raw materials (leaves, dried plants and powders), plant extracts, and food additives that include microorganisms.
- Original label of the product.
- Stability of the product - test results of the shelf life of the product, or an announcement made by the manufacturer that the claimed shelf life was determined on the basis of stability tests.

**Baby Food Formula**

As of 2004, each batch of imported infant formula is tested. In December 2009, MOH published guidance for the handing of food compositions for babies (FCB) and food directed for complete nutrition. As a result of a sampling model, the number of tests has been reduced from 100 percent to 33 percent. (Interview, 2011)

**Labeling Requirements for Food**

Specific labeling regulations apply to some commodities, and special packaging requirements apply to fruit, plants, and meat. All imports into Israel must have a label indicating the country of origin, the name and address of the producer, the name and address of the Israeli importer, the name of the food, producer country (if food is not to be used in the manufacturing of food in
Israel), and the weight and volume in metric units. Hebrew must be used on all labels. Other languages may be added, provided the printed letters are no large than those in Hebrew, and the information is identical in content to the Hebrew. Nutritional labeling is required on all packaged foods. Any food marked with the word “kosher” shall also be marked with the name and location of the person certifying the kashrut or the registered mark in Israel of the organization certifying the kashrut. (USDA, 2010)

**FCS (MOH) Importer Registration**

The importer must fill out an application that he is a qualified importer, and he declares that he or someone on his behalf has a warehouse for the purpose of storage. An importer of “regular products” must fill out the Importer Statement certificate. Following the completion of the importer certificate, an official importer certificate from the Israeli Food Control Services will be issued. (USDA, 2010)

**Import Documentation**

The Israeli Customs Services prefer that exporters use their own commercial invoice forms containing all required information including: name and address of supplier, general nature of the goods, country of origin of the goods, name and address of the customer in Israel, name of agent in Israel, terms, rate of exchange (if applicable), Israel import license number (if applicable), shipping information, and a full description of all goods in the shipment including shipping marks, quantity or measure, composition of goods (by percentage if mixed), H.S. tariff heading number, gross weight of each package, net weight of each package, total weight of shipment, price per unit as sold, and total value of shipment.

The commercial invoice must be signed by the manufacturer, consignor, owner, or authorized agent. United States exporters should also double-check whether other documentation, including bill of lading and packing list, is required.

**Approved Exporter**

Exporters may apply for a blanket Certificate of Origin (CO), or “approved exporter” status. An “approved exporter” must present an invoice which substitutes for the CO and contains an “approved exporter” number as well as a declaration that the goods comply with the origin requirements. Certification and notarization are not necessary. A manufacturer or exporter who wishes to become an “approved exporter” should complete a declaratory form and present it to the Export Department, Israel Customs Services. Israel Customs will then check whether the manufacturer or exporter complies with the criteria and grant approval for “approved exporter” status. The approved exporter will be given an identity number to be stamped on all invoices. The approval is valid for six months, after which the exporter will receive an automatic extension from Israeli Customs. Exporters who do not receive an automatic extension from Israel Customs must terminate use of the approval. (USDA, 2010)

**Fish and Fish Products**

There is a three step process to import fish and fish products:
The permit is unique to Israel and issued by Food Control Services Veterinary Department (FCSVD). The importer must register with FCSVD, sign a declaration indicating they are familiar with all regulations/guidelines and are able to implement a recall if necessary, and contract with a FCSVD certified cold storage facility.

In order to import fish and fish products from a certain producer/establishment, two conditions have to be fulfilled:

- HACCP system in place;
- The producer/establishment has successfully passed an audit done by an external regulating body (e.g., differing from the country of origin which manufactures the product, including by Israel) which disseminates the information, results and conclusions of the audit in a transparent and accessible way (e.g., internet).

A sample label must be provided showing the scientific and commercial name.

Ultimately, the Annual permit consists of:

- An unique number, which changes annually
- The importer’s name, address and telephone
- The product definition (fish name and form of processing)
- The form of distribution (e.g., wholesale, raw material)
- The form of packaging (e.g., IWP, IVP, block)
- The country of manufacture and manufacturer’s name
- A list of specific accompanying laboratory examinations, which is dependent upon the type of product and the origin of the fish. For example, tuna would require laboratory tests for mercury.
- Aquaculture – veterinary drug residues
  - Norway – government declaration #
  - China - lab tests
  - A list of specific laboratory test to be done for every container. e.g., TVBN is only tested for frozen raw fish, organoleptic examination

Border Inspection Point (BIP)

At the BIP, documents are verified and samples are taken for laboratory examination. If the original laboratories were private laboratories, proof of national accreditation must be provided. Veterinarians sample 100 percent of the fish and fish product shipments.

Based on laboratory data, a permit can be issued for national distribution or the cargo can be rejected. If the data does not match with approved limit guidelines, the shipment can be detained, and a decision is made to:

- Re-sample (at importer’s cost, using the national lab)
- Re-export (importer must provide declaration from the country accepting the shipment)
- Recondition (i.e. shorten the shelf life)
- Destroy the shipment
- Municipal Veterinary Inspection Point
  - A Municipal Veterinary Inspection Point approval or rejection of the shipment is determined. Every shipment with fish and meat must have a veterinary certificate, and is inspected for a veterinary certificate, a refrigerated car license, temperature verification, and labeling verification.

As lot numbers can vary due to repackaging, the importer is requested to use a unique number developed by Israel.

(Interview, 2011)

**MOAG, VSAH**

Importers must have an import license for animal feed containing animal products and by-products that supplies the details of the manufacturing plant and a plant certification form. The certification form must be received from a competent authority from the importer’s country.

Each consignment with a veterinary certificate is submitted to the official veterinarian at each port. The importer must know the Israeli competent authorities and their requirements for importation.

Certificates must be received from the exporting country and are required for all animal feed with an animal origin. Consignments with animal feed arrive with laboratory test information (e.g., bacteriological, salmonella, official veterinary certificate) and are then tested for aflatoxin. Each consignment must undergo microbiological testing and is checked for residues (e.g. drugs, heavy metals, pesticides)

(Interview, 2011)

VSAH publish regulations regarding the importation of specific fish species (USDA, 2010).

**MOAG, PPIS**

PPIS requires all plant material not listed in the Import Regulations to have an import license and approval from the PPIS. If a good does not qualify as a PPIS licensed import, the good must undergo a pest risk assessment (PRA) before a decision is made to approve the import license application and particular restrictions. If the application for the import license is denied, a denial letter will be sent, specifying the reasons for the decision. The license includes the import terms for the specific product, additional importation terms, and requirements for additional statements. The statements appear in the health certificate accompanying the shipment from the country of origin.

The following certificates are required prior to releasing a shipment of animal feed from the border station:

- “Request to import feed for animals and its products” (PPIS certificate);
- Import Data: grain kind, name of the ship, country of origin, name of the importer and name of the producer;
The shipment must be accompanied by Quality and Health certificates which were issued by authorized foreign laboratories. The certificates must contain the following:

- Quality Requirements: Including label indicating the name of the product, percentage of wetness, net weight of the product, whole grains percentage, foreign material percentage;
- Health Requirements: According to the National Maximum Residue Limits, which, when appropriate, are based on Codex Alimentarius limits.
- The health certificate includes the following data: level of pesticides, fungicides, steaming material, heavy metals, and radio activate radiation;

- Certificate of origin;
- Importer Statement if the feed for animals is containing genetically modified organisms;
- Importer statement that he or someone on his behalf has a warehouse for the purpose of storage.

The quarantine inspector checks the shipment and the accompanied certificates at the port of entrance, and tests for aflatoxins. In addition, the inspector sends a sample of the shipment to the PPIS laboratory for further examination. The shipment is released after the inspector finishes the first tests. In case of missing certificates or unsuccessful test result, the shipment will be held back at the port for further assessment.

(USDA, 2010)

To import feedstuff, a yearly permit for the production and marketing and trading feedstuff, granted by the PPIS, is required. Importers wishing to import a feedstuff shipment must receive a certificate for feeds and their products from the Department of Feeds Quality in the PPIS, in accordance with the Free Import Order. The Department of Feeds Quality in PPIS needs to receive an application form for “Special Certificate in accordance with Free Import Order”, together with a valid Permit for Feed Production, Marketing and Trade.

Importation of complete or supplemental animal feed mixture depends on a special permit, issued by the Foreign Trade Department in the Ministry of Agriculture. In order to obtain such a permit, a valid Permit for Feed Production, Marketing and Trade is required, as well as a permit from the Veterinary Services in the MOAG.

(PPIS, 2011)

1.4 Assistance, Cooperation or Contributions from Other Government Bodies (National or Local) in the Imported Food and Feed Process

Upon a consignment’s entry to borders and ports, Customs authorities are the first and last to approve the consignment after confirming the checklist of papers received from all relevant competent authorities (Interview, 2011).
1.5 Laws and Regulations that Provide Authority for the Oversight of the Safety of Imported Foods and Animal Feed, and the Policies and Procedures that Guide Import Officials


- Inspection of Products and Services Act (1964) provides for feed quality control, and the Order of Supervision on Consumer Goods & Services (1971) includes provisions for animal feed production and commerce.
- The Plant Protection Law – Plant Protection Regulations (Plant Import) regulates plant material imported, including fresh produce (fruit, vegetables, cut flowers, etc.), and references pesticides.
- The Control of Goods and Services Order (Production of Feedstuff and trading in them) (1971) regulates the production of feedstuffs, their marketing and trading. According to this Order, every commercial deal in feeds must to be preceded by a permit granted by the General Director of the PPIS. The Order gives authority to the Department of Feeds Quality for the testing the products, registration and issuing permits. (PPIS, 2011)

The primary legislation providing authority to Veterinary Services and Animal Health is the Animal Disease Ordinance, which has specific regulations for import/export of products of animal origin.

The primary legislation providing authority to the Food Control Service is: Public Health Ordinance and its regulations (for example Public Health Regulation (Food) (Food Additives) 1997 and its amendments), Control and Commodities Services Law, Business License Law, Standards Law (160 standards include final products), Consumer Protection Order, and the Free Import Order.

- The Standards Law sets Israeli standards for food products, dealing with quality, composition, labeling, wrapping, weight, and safety aspects. the standards are divided into specific product and/or group of products and general standards that apply to all kinds of the food, for example IS 1145( Labeling of repackaged food)
- The Free Import Order is the source of the MOH enforcement authority. It also identifies competent authorities and their associated products. (Interview, 2011)

1.6 Handling of Products Transshipped Through a Third Country as Compared to Directly Imported Products

As a part of the preliminary documentation, the importer must send the dossier for the product from the original manufacturer in the foreign country. Documentation should be addressed to the
The food inspector at the port checks and verifies that the documentation and laboratory analysis are compliant. (Interview, 2011)

A 2001 amendment to the Free Trade Agreement between Israel and Canada (1996), allows for the transshipment of goods through the United States, under certain conditions. “It also allows for minor processing in the United States without losing the original status. In particular, processing should not increase the transaction value of the goods by more than ten percent.” (Pareto Engineering LTD., 2010)

2 INSPECTION PROGRAMS

2.1 Mechanisms to Prioritize Food/Feed Import Surveillance Activities, such as Product Sampling and Testing, Inspections at the Border, and Facility Inspections of the Exporting Country

As stated in Section 1.3 above, imported products are divided into “sensitive” and “regular” products.

2.2 Special Screening Requirements and Trading Partner Requirements where Disease or an Outbreak has Occurred

Based upon a decision in the 1980s by the former Minister of Agriculture, no animal feed of mammalian origin entered Israel. Food of mammalian origin is permitted if it is already processed into pet food, but raw materials are not permitted. Israel tries to be similar to OIE in the restriction of imported animal feed. (Interview, 2011)

Imports of bone-in beef from countries where there is a danger of transmitting Foot and Mouth Disease (FMD) or Bovine Spongiform Encephaly (BSE) are not permitted (USDA, 2010).

“In March 2010, the Israeli Veterinary Services published new draft BSE regulations related to all bovine products, including beef meat, feeder cattle, pet food, and blood serums” (USTR, 2011).

2.3 Percentage of Imported Food Shipments Examined and the Relationship between Risk-Ranking of Foods and Volume of Imported Foods Examined

MOAG has testing frequencies for mycotoxins and heavy metals (e.g. aflatoxins, fumonisins, cadmium, lead) in imported grains for animal feed (MOAG, 2011). The percentage of imported food shipments sampled depends upon the risks of production. MOH veterinarians sample 100 percent of shipments containing fish and fish products. The sampling plan for fish and fish products depends on the sample size; that is the total weight of the product, the number of packages and physical check during sampling. In principle, every container is checked, frozen fish and ready to eat products undergo laboratory tests, and fresh fish are sampled at the border. (Interview, 2011)

“Regular” foods are certified by import department (five percent of applications of all regular foods are inspected daily), and three percent of shipments are inspected by quarantine station. All other shipments of regular food are approved for release. In addition, the National Food Service
initiates sampling of different types of foods depending on previous information, country of origin and group of products. (MOH, 2011)

2.4 Types of Review, Examination and/or Testing of Imported Products Performed by Food Safety Inspectors

2.5 Frequency of Documentation and Labeling Checks as Compared to Analytical Examinations

At Border Inspection Points, MOH inspectors verify documents and samples are taken for laboratory examination. Municipal Veterinary Inspection Points approve or reject the shipment. Every shipment with food of fish and meat products must have a veterinary certificate and is inspected for:

- Veterinary certificate
- Refrigerated car license
- Temperature verification
- Labeling verification

When the shipment arrives at the port, the importer or its representative submits to the quarantine station a request for release. The quarantine station's office checks and enters the particulars of the request into the system. The file includes the following documents:

- Prior Authorization/Certification for importation of food, with all its attachments;
- Certificates of Analysis for each batch in the shipment, including specific information on the product, and the information will be cross-checked with the Prior Authorization that the importer received from the import department;
- For a "sensitive food" a sample of the product from the shipment (the sample will be taken from the shipment and submitted to the supervisor for inspection);
- Supplier's invoice;
- Packing list;
- Bill of lading;
- Gate pass;
- Payment-of-fee slip.
- Lab analysis related to product in the shipment

At the end of processing in the office, the requested file is forwarded to the inspector at the station for inspection. Checking of the requested file by the inspector at the quarantine station includes the following stages:

- Professional inspection of the documents/requirements
- Sampling of the product for laboratory inspection in Israel in accordance with the directives of the National Food Service. Further sampling as-per prior authorization remarks.
  - The inspector compares the analyses accompanying the shipment with the Prior Authorization, relating to each batch separately; in the event that the findings do not meet the requirements, the inspector consults, as necessary, with the import department.
  - The inspector compares the labeling of the product that arrived with the Prior Authorization that was given for the product.
  - The inspector physically and visually inspects the shipment in the container. If he chooses to do so and if there is a reason to do so.
  - The inspector takes a sample and sends an item from each batch separately for laboratory inspection for example heavy metals, pesticide residue, microbiology, micro- and macro-nutrients and mycotoxins, if there is a remark in the prior authorization.
  - The shipment is kept in the port's warehouses or is released to the importer's warehouse until the laboratory results are received. Release to the importer's warehouse is conditioned on the consent of the import department, and requires both a bank guarantee and a letter of undertaking from the importer that the goods will not be marketed until the results are received.
  - The inspector incorporates the laboratory-inspection findings in the file that is sent to the import department for inspection, in case of some products like infant formulas and foods intended for special medical purposes or in the case that there is no legislation concerning the special product. In the other case the port inspector checks the laboratory findings by himself according to the relevant legislation.
  - The inspections findings are checked against the criteria described in the relevant Israeli legislation.
  - Every release from the quarantine station to the importer's warehouse prior to marketing of the goods is contingent on the consent of the import department. In the event that additional sampling from the importer's warehouse is needed, it will be carried out by an inspector from the District Health Office in whose jurisdiction the warehouse is located or by quarantine inspector in the case that the goods are still in port.
  - In the event that the findings comply with the requirements, the quarantine inspector sends notice to the importer, indicating that the findings of the inspection conducted in Israel are in order.
  - In the event that the findings are not in order, the quarantine inspector sends two notices, one to the import department and the other to the importer, indicating that the inspection's findings are not in order and attaching instructions on the actions that must be taken. The instructions are based, in part, on consultation and the opinion of other professionals in the professional departments at the National Food Service headquarters and other professionals as required. Possible requirements range from additional sampling and confirmatory laboratory analysis to returning of the shipment to the country of origin or its destruction.
MOAG PPIS inspectors increasingly check safety, rather than quality. Their checks include:

- Check documents
- Check safety (contaminants)
- Test for aflatoxins;
- Take samples for laboratory examination

(PPIS, 2011a)

PPIS “quarantine inspectors are stationed at all entrance ports into Israel, harbours, airports and land terminals, checking each imported shipment for the health of included plant material. The purpose of this inspection is to verify compliance with all the pre-determined importation terms. The inspection includes checking all the documentation, visual examination, and if needed – sampling for laboratory analysis.” (PPIS, 2011a)

2.6 Types of Examination and Testing Processes Used for Ensuring Animal Feed and Feed Ingredient Safety

MOAG inspectors use the same processes described in Question 2.4 on animal feed. (Interview, 2011)

2.7 Inspections of Food or Animal Feed Manufacturers or Shippers in Other Countries (including Selection Criteria and Frequency)

MOH relies upon a similar body within the foreign country for the inspection of foreign facilities. (Interview, 2011)

Fresh and frozen meat and poultry products must be accompanied by an FSIS inspection certificate. The veterinary or phytosanitary requirements of the Israeli authorities are indicated on the import permit which must be obtained prior to contracting for the goods. Application for an import permit must be made by a resident of Israel. (USDA, 2010)

2.8 Notification System(s) to Directly Notify Foreign Governments When Foods or Animal Feed Manufactured in their Countries are Found to be Unsafe; and to Notify the Public When Imported Products do not Meet Safety Standards

The FDA and MOH have agreements to allow an exchange of information. Israel uses the European Union Rapid Alert System for Food and Feed (RASFF) rapid alert system to exchange information. (Interview, 2011)
3 AUDITS AND CERTIFICATION

3.1 Assessing and Measuring the Effectiveness of the Food/Feed Safety Import Program (e.g., Self Audits of the Program, Public Health Outcomes, Surveillance Sampling Results, Number/Rates of Refusals, Periodic Program Evaluations)

Working procedures are updated following the review of a problem. Based on the result of some surveys or external auditors (e.g. EU, US), changes may be made. A check is done every year to ensure previous decisions are still relevant. (Interview, 2011)

3.2 Extent of Reliance on Trading Partners’ Food Safety Programs to Ensure That Imported Foods or Animal Feed are Safe

See information provided in Section 2.6.

In addition to the Israeli MOH risk assessment, the following institutions’ food risk assessments are taken into account with adjustment to local exposures and needs:

- The European Communities/EFSA
- USDA (FSIS)
- FDA
- Health Canada
- ANZFA – Australia and New Zealand Food Authority/ FSANZ Food Standards Australia New Zealand
- Japan – Department of Food Safety, Ministry of Health
- WHO/FAO CODEX ALIMENTARIUS Expert Committees

(Interview, 2011)

3.3 Requirements for Food and/or Animal Feed Export Certificates Issued by the Exporting Country’s Competent Authority, and Types of Inspection or Testing for Each

Information on this topic was not gleaned from publically available information or country interviews.

3.4 Use of ISO, Global Gap or Other Assurance Systems and Confidence in the Assurance System(s) Utilized

The Unit for Proper Manufacturing Conditions within the MOH works to advance the implementation of quality and safety systems in food plants, by means of standards of Good Manufacturing Practices (GMP). Standards include requirements of quality systems such as ISO 9001, ISO 22,000 and process evaluation according to HACCP. (MOH, 2011a)
In accordance with the belief that the best way to achieve the objectives of the service is via education, the unit concentrates much of its effort on bringing the supervision provided by inspectors of the Ministry into accordance with these new methods. (MOH, 2011a)

“Israel has not officially adopted ISO-9000 standards, although there is a growing preference for ISO-9000 standards among Israeli importers. This is especially important in the case of ingredients and raw materials destined for the production of export products.” (USDA, 2010)

3.5 The Nature and Frequency of Foreign Food Safety Systems Audits Performed

Information on this topic was not gleaned from publically available information or country interviews.

3.6 Equivalence Agreements Requiring Periodic Audits/Reevaluations of Exporting Countries’ Food Safety Programs

Information on this topic was not gleaned from publically available information or country interviews.

3.7 The Utilization of Third-Parties (Within the Exporting or Importing Country) to Carry out Inspections and/or Product Certification (Nature and Extent of Programs) and Methods for Verifying the Adequacy and Reliability of the Third Party Work

Information on this topic was not gleaned from publically available information or country interviews.

3.8 Arrangements with other Governments Relating to Imported Foods or Animal Feed (such as Memoranda of Understanding, Mutual Recognition Agreements, etc.)

There is a gap between the idea and implementation of mutual recognition of inspections. The Ministry of Trade may have agreements but MOH does not for food safety. (Interview, 2011)

Israel has memoranda and trade agreements with a range of other countries that relate to food; however, the agreements do not necessarily focus on importation (e.g. technology transfer).

Examples of memoranda relating to food include:

- Israel/Germany/Ghana MOU (2010) is intended to strengthen Ghana’s agricultural sector focusing on citrus production, including technology transfer of agro-technologies.
- Israel/Germany MOU (2010) regarding development cooperation, with emphasis on water and agriculture.
- Israel and Sri Lanka (2011) focusing on issues of harvesting technology; dairy products; water management; and the cultivation of potatoes.
Israel also has a number of Free Trade Agreements (e.g. U.S., Canada, EU, Jordan, Mercosur) intended to reduce tariffs and increase the flow of certain imported food products. (MOITAL, 2011)

3.9 Registration or Licensing of Firms That Import and/or Export Foods or Animal Feed to the Country or for Firms That Import Foods or Animal Feed

As stated in Section 1.3, the first condition for the importation and release of food into Israel is receipt of a Certificate of Registration as a Food Importer from the MOH. To obtain the certificate, the importer must submit a request for registration to the MOH. This request must precede the submission of any request for prior authorization for importing a food. The registration process typically takes up to 4-6 weeks.

3.10 Use of Sampling Surveys of Imported Foods/Feed (as Opposed to Targeting Specific Products/Producers for Inspections and/or Testing) to Gather Information and Identify Trends and Potential Areas of Difficulty

The Food Quality Unit and risk assessment units of the FCS MOH prepares and collects data from surveys and operations with regard to food safety and quality, performed by the District Units. (MOH, 2011a)

Information for data collection is prepared as a part of a survey. Upon completion, it is connected to assurance. (Interview, 2011)

When food is sampled for background information, the portion not held goes to market. The importer has the option to transfer the held portion to a warehouse owned by the importer. Holding times vary based on the test result times. For example, fruits/vegetable microbiological testing takes 48-72 hours, pesticide testing takes 48 hours, and infant formula testing could be months. (Interview, 2011)

3.11 “Good Practices” Programs for Foods/Feed Importers

A “Good Practices” program does not exist as guidelines; it is similar to a checklist of requirements built into import procedures to be used by MOH employees or importers. It is only available in Hebrew, and has not been translated. MOH is currently discussing Good Importer Practices similar to those used in Canada. (Interview, 2011)

3.12 Description of Import Program User Fees and Cost Recovery System

PPIS charges for the import permit and VSAH charges for sampling animal feed (Interview, 2011).

3.13 Incentives to Increase Industry Involvement in Ensuring That Imported Foods Meet Safety Standards

Encouragement of the applying food safety systems by the establishment.
3.14 Obstacles to Industry Participation in Ensuring That Imported Foods Meet Safety Standards

Information on this topic was not gleaned from publically available information or country interviews.

4 LABORATORY SUPPORT

4.1 The Role of Laboratories in Supporting the Imported Food and Feed Programs and Description of Laboratory Capabilities

Government laboratories must be certified by national agency authorities (Interview, 2011).

Public Health Services

“Israel has four food testing laboratories (in Tel-Aviv, Haifa, Beer-Sheba and Jerusalem) that are part of the Public Health Services. All four are recognized by the MOH, authorized for testing food according to Israeli standards by the Supervisor of Standardization in the Ministry of Commerce and Industry and accredited by the Israeli Authority for Laboratory Accreditation according to the international standard ISO-17025. All four laboratories perform microbiological examinations, whereas different labs specialize in different chemical examinations (according to different abilities in personnel training and in available analytical equipment). Food testing is carried out primarily for the purpose of assisting the MOH (National Food Services) in its role of supervising food quality. The laboratory receives routine food-supervision samples, samples from surveys, samples of imported food and samples that are send as part of the investigation of public complaints and suspected food poisonings. Therefore, the laboratories are required to develop (or adapt) a wide range of new methods, including some that are rare and not performed elsewhere in Israel.”(Haleva, 2005)

PPIS Feed Quality Inspection Laboratory

PPIS Feed Quality Inspection Laboratory checks feed and feed products for their quality: grains, feed mixtures, vegetal by-products, animal by-products, vitamins and nutritional additives. The laboratory also tests feeds for contaminants such as mycotoxin, heavy metals and pesticide residues. Official methods of AOAC (Association of official Analytical Chemists) are used to analyze feeds for:

- Nutritional composition
- Heavy metals content
- Mycotoxin content
- Vitamin content in nutritional additives
- Coccidiostats content in nutritional additives

The PPIS laboratory pest identification service accepts insect specimens for identification from importers and exporters, as well as check samples of biotic material (insects and acarides) for cleanliness and identity.
Agricultural Research Organization (ARO)

As the research arm of the MOAG, ARO is responsible for most of the agricultural research conducted in Israel. Its research infrastructure supports both basic and applied research. The Food Quality and Safety subunit of the Postharvest and Food Sciences Institute research topics include:

- Antimicrobial peptides produced by food-grade bacteria and their use in the preservation of perishable food products
- Preventing adverse effect of microorganisms in food
- Improvement of food products quality (fruits and vegetables)
- Replacement of chemical additives by natural products (food pigments and antioxidants)
- Modified-atmosphere storage of foods
- Chemistry and biochemistry of lipid oxidation
- Technology for poultry and fish products
- Fumigation of stored food and feed products
- Microflora and mycotoxin-producing fungi occurring in stored grain and animal feed

(ARO, 2011)

4.2 Participation of Non-government Laboratories (Including Industry and Academic Laboratories) in the Food Import Control Program

Private laboratories must be certified by national agency authorities and recognized by MOH. (Interview, 2011)

4.3 Methods for Laboratories to Achieve Quality Assurance (such as Voluntary or Mandatory Accreditation)

Biological laboratories

The PPIS Recognition Unit provides recognition for plant health diagnostic laboratories testing for diseases caused by fungi, bacteria, mycoplasm, viruses and viroids. The Recognition Certificate attests to the laboratory fulfilling the requirements of the Plant Protection and Inspection Services (PPIS) regarding plant and seed health diagnostic laboratories. These requirements include an obligation to accept additional specific requirements, should they arise at any point in the future. PPIS reserves the right to inspect the laboratory working procedures at any time, to reject the methods used for a particular test, and/or to cancel the Laboratory Recognition.

Analytical laboratories
The PPIS also certify external laboratories performing pesticide analyses in fresh agricultural produce. The purpose of certification is to create a pool of analytical laboratories operating in internationally accepted methods, whose results are recognized by the MOAG. A certification prerequisite (as of March 2003) is an ISO 17025 certification granted by the Israel Laboratory Accreditation Authority, at the MOITAL. The certification process is an examination of external laboratories carried out according to the required order of operations and the professional requirements of the PPIS. A laboratory requesting recognition of its analyses should implement the PPIS requirements in its procedures. The certification process includes periodic audits at the laboratory, which focus on a thorough review of its quality system and evaluation of its professional competence. The Pesticide Residue Laboratory of the PPIS is carrying out, additionally, regular comparative analyses with other certified laboratories. (PPIS, 2011)

5 ENFORCEMENT AT BORDER

5.1 Approach to Visual Inspections and Analysis of Imported Foods (e.g. Risk-Assessment and Prioritization Schemes, Documentation Review, Sample Collection)

The percentage imported foods sampled depends upon the risks of production.

5.2 The Process that Occurs When an Imported Food is Found to be Contaminated or does not Meet Standards

If a shipment is found to be in violation, it is subject to exportation, destruction, or reconditioning.

If an inspector decides to test, the importer can choose the laboratory, provided it is certified. If additional testing is necessary, the importer must use the national laboratory.

If all test results are not compliant, the options are to: 1) destroy the product; 2) send it back to the originating country with a declaration that the country will accept it; 3) recondition the product (depending on the test results). The decision is made at the Headquarters level, not the Border Inspection Point.

(Interview, 2011)

5.2.1 Procedures for Refusing Imported Foods Based on a Finding that they do not Comply with Requirements

An importer with repeated products in violation is viewed as an unreliable importer. The license certificate has the importer, product, produce, and country of origin. Through the license, problems with a type of food, producer, or importer can be detected. For a non-reliable importer, MOH can revisit the import application. If the application is refused, the food is put into detention or a bonded warehouse to prevent sale to the public. Although the producer cannot be banned, each shipment can be rejected at the border, or the import license could be cancelled. (Interview, 2011)
5.2.2 The Procedure and Outcome for Imported Foods that are Refused Entry (Including Efforts to Prevent them from Mistakenly Entering Domestic Commerce)

If the product needs sampled and or tested, the shipment is kept in the port's warehouses or is released to the importer's warehouse until the laboratory results are received. Release to the importer's warehouse is conditioned on the consent of the import department, and requires both a bank guarantee and a letter of undertaking from the importer that the goods will not be marketed until the results are received.

(Interview, 2011)

5.2.3 Entry of Detained Products Based on Further Testing or Reconditioning of the Product

There is a model of re-testing while the shipment is in a warehouse. If the shipment fails the re-testing, it is then subject to exportation, destruction, or reconditioning.

Destruction of a shipment takes place in front of a MOH representative. (Interview, 2011)

5.2.4 Process for Identifying and Tracking Producers or Countries that have Repeated Violations

If there are repeat violations, a ban is possible. If repeat violations are an issue, the import license can be revoked.

For fish, five shipments must go through bonded cold storage before removal from the repeat violators list.

(Interview, 2011)

5.3 Program for Investigating and Responding to Intentional Contamination of Foods

In general, it is difficult to determine whether an incident is an accident or intentional as well as the magnitude of the incident. If the issue is food safety or security, then MOH has the primary responsibility/authority in addressing the incident. If the issue is food terrorism, then the primary authority is the Ministry of Defense. (Interview, 2011)

Among the duties of the Risk Assessment and Food Contamination Unit of the MOH is to “address ways to deal with intentional poisoning of food.” (MOH, 2011a)

6 FOOD RELATED ILLNESS OUTBREAKS

6.1 System for Tracking Imported Foods once they are Cleared at the Point of Entry

The MOH system is a combination of prevention, rapid detection, and response. During the response to a food-borne outbreak, the FCS and other departments in the Public Health Service lead the investigation. The FCS investigates “suspect” food, while the other departments investigate areas according to their specialty. Every division in each district makes its own investigation and consequently reports it to the upper levels. The ability to track foods varies based upon the food; fish have a lot number that can be tracked, and a lot number was recently added to meat.
Until recently, the ports did not have a computerized system and only used hard copies of documentation. However, Customs currently has a computerized system.

MOH has promised to develop a tracking system to centralize knowledge by the end of 2011. Two pilot modes are currently underway to develop a system to connect Customs, MOH, MOAG, and the laboratories. Imported food is a small part of the larger system being developed.

(Interview, 2011)

6.2 Systems for Identifying Foodborne Illness Outbreaks

Foodborne illness outbreaks are detected through complaints to district health authorities or hospitals. The Epidemiological Services Section of district health authorities investigates the outbreak. The districts then report to an epidemiological center, which is in communication with a contact within MOH. A consumer complaint triggers an investigation but not necessarily an epidemiological investigation. If there is more than one complaint, then MOH will consider a recall. There are new procedures that state compliance of two reports to be an outbreak.

The traceability of food epidemiology depends upon the circumstances. For example, if it is possible to review uneaten production samples, the traceability is easier. Milk production has good traceability, but a product that commonly is combined with other products, such as bread, is not necessarily easy to identify as the problem source.

6.3 How Consumers Notify the Government and/or Importers of Food Problems

District Health Units collect and respond to complaints from the public regarding food as well as legal enforcement in response to citizen complaints. (MOH, 2011a)

7 EXPORT PROGRAMS

7.1 Programs for Ensuring Safety Requirements of Export Destination Countries

PPIS certifies exports of fresh agricultural produce from Israel to other countries (MOAG, 2011).

7.1.1 Use of Export Certificates to Provide Assurances to the Importing Country

MOAG/VSAH: If another country asks for a permit, the domestic plant must comply with MOH requirements for a valid user license, business license from local jurisdiction, public veterinary inspector, and requirements of the importing country. A paper system is currently used for certificates. Papers are sent to the plants, and then inspected by veterinarians rather than officers. The last certification is at the port prior to disembarkation. A certificate is issued for each dairy and fish exported product after asking the exporter for the importer’s requirements. Only treated products are permitted to be exported; the export of raw materials is not allowed. (Interview, 2011)

An interested party wishing to export fresh agricultural produce is required to present the produce to a PPIS Inspector to be examined and its compliance with quality standard confirmed. PPIS allow exporting operators (e.g., growers, packing houses, exporters) to carry out self-
inspection of produce intended for export. Certification for self-inspection enables exportation through the “Green Lane.” Through the “Green Lane,” the exporting party will be able to inspect its own produce from different aspects of quality, safety and health, in accordance with procedures previously approved by the PPIS. Self inspection is performed during the whole production process, from harvest through actual export, and not just at the end of the process. The system shifts the responsibility for quality to the producers themselves, with the aim to improve produce quality. The “Green Lane” is intended for every operator owning packing facilities for agricultural produce. Certification for self-inspection is granted to a specific produce, packed at a specific packing house. (PPIS, 2011)

7.1.2 Providing to the Import Country Lists of Establishments that Meet the Importing Countries’ Food Safety Requirements.

As each situation depends upon the country that is importing the good, there is no comprehensive list of establishments that meet the importing countries’ food safety requirements. For processed food and fish, there is no authorized list. However, a list does exist for meat. (Interview, 2011)

8 WORLD TRADE ORGANIZATION (WTO) OBLIGATIONS

8.1 Methods for Ensuring Consistency between Domestic and Imported Food Safety Requirements

To ensure consistency between domestic and imported food safety requirements, the same legislation applies to products of domestic and foreign origin. The standard of the end product is the same regardless of origin. Supervision or control differs based on product origin (for example, labeling may be different) There is also a different manner of inspection, but the tests are the same. (Interview, 2011)

8.2 Methods of Documenting the Scientific Justification for Import Practices with regard to Article 5 of the SPS Agreement, which Requires that Measures are based on an Assessment of Risk, as Appropriate to the Circumstance

Israel is unable to participate within the “vertical” standardization Codex committees; however, they can participate within the “horizontal” standardization committees (e.g. pesticide MRLs, food labeling, hygiene). As a result of the Codex committees, Israel works Codex standards into domestic agreements, and Israeli legislation is increasingly harmonized with Codex standards. When there are gaps in the legislation, Codex is the reference. (Interview, 2011)

8.3 Involvement in Article 4 of the WTO SPS Agreement Regarding Equivalence Determination

Information on this topic was not gleaned from publically available information or country interviews.
8.4 Process for Recognizing a Foreign Country’s Food Safety System as having Adequate Regulatory Oversight

Information on this topic was not gleaned from publically available information or country interviews.
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JAPAN

FOOD AND FEED IMPORT PRACTICES

APPENDIX F

* In October 2012, Japan provided corrections to Appendix F. The corrections have been incorporated into this version.
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OVERVIEW OF FOOD SAFETY SYSTEM

Japan has two primary authorities for ensuring the safety of imported food and feed. The Ministry of Health, Labour and Welfare (MHLW) oversees the safety of imported food for human consumption and has divisions which handle all facets of importing food; from standard-setting to the inspection of imported foods. The Ministry of Agriculture, Forestry and Fisheries (MAFF) oversees the safety of imported feed and pet food, and MAFF relies on the Food and Agriculture Inspection Center (FAMIC) to monitor feed for contaminants and other unwanted substances.

MHLW reviews imported products and makes a determination about their possible entry into Japan before Customs officials are involved in the import process. Importers are required to submit a "Notification Form for Importation of Foods" to a MHLW quarantine station for the product that they wish to import, along with supporting product documentation such as information on ingredients and manufacturing and health certificates (where required). At the border, food sanitation inspectors at the quarantine station review product documentation and determine whether or not the good requires inspection. When the food sanitation inspector is satisfied that the imported food meets all statutory requirements, the importer is granted a certificate of notification, and the product can, then, clear Customs.

The inspection and monitoring of imported foods and feed in Japan is risk-based. For feed, FAMIC uses the toxicity, extent, and estimation of hazards as criteria for prioritizing risk. For Food, MHLW develops an annual plan of monitoring requirements for imported foods which is based on relevant information such as regulatory requirements, usage of certain chemicals, and cases of detection of agricultural chemicals in other countries. MHLW then uses three types of inspections to target food with varying levels of risk: 1) Inspection order system, which requires the foods presenting the highest levels of risk to be inspected every time they enter Japan; 2) monitoring inspections, which are implemented every year for the purpose of monitoring safety conditions of various foods based on the provision of Article 28 of the Food Sanitation Act and to reinforce inspections; and 3) other inspections, which include inspections for the foods being imported to Japan for the first time, items that are not in compliance with the Food Sanitation Law, and inspections to examine the food and related items that have experienced an accident during transportation (MHLW, 2011d).

When food or feed does not meet Japan's statutory requirements during quarantine at the border, the product may be destroyed or re-exported. MAFF also requires unused or unsold feed related to the questionable lot to be recalled. Once the imported product has cleared Customs, the imported food or feed is under the jurisdiction of the local prefectures, and MHLW will coordinate with them to recall necessary products. MHLW lists violators of safety standards (names and products) on the MHLW website for up to a period of one year for serious violations (MHLW, 2011c).

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1 As noted in the methodology section of the report, Japanese food and feed officials not able to be interviewed due to unforeseen country circumstances. This appendix is a culmination of publically available background research and supplementary information provided by MHLW and MAFF officials.
1 ROLES AND FUNCTIONS OF AGENCIES RESPONSIBLE FOR IMPORTS OF HUMAN FOODS

1.1 Governmental Ministries And Subunits (Including National/Regional/Local, As Appropriate) With Responsibility For Assuring The Safety Of Imported Food

Ministry of Health, Labour and Welfare (MHLW)
MHLW oversees the safety of imported food in Japan. Within MHLW, The Department of Food Safety, under the Pharmaceutical and Food Safety Bureau, has primary responsibility for the administration of food safety. The Department of Food Safety divides the various duties and responsibilities for the safety of imported food among the following divisions and their respective offices:

- **Policy Planning and Communication Division:** performs general coordination of food safety activities as well as risk communication. Offices within this division include:
  - Office of International Food Safety: performs coordination of international affairs under the jurisdiction of the Department
  - Office of Port Health Administration: handles quarantine business and the inspection of imported food

- **Standards and Evaluation Division:** develops specifications and standards for food, food additives, pesticide residues, and animal drug residues. Offices within this division include:
  - Office of Health Policy on Newly Developed Food: oversees dietary supplements and safety assessments of genetically modified foods

- **Inspection and Safety Division:** oversees food inspection, health risk management such as measures for food poisoning, safety measures for meat, dissemination and promotion of the HACCP approach, Good Laboratory Practice (GLP), and measures for environmental contaminants. Offices within this division include:
  - Office of Import Food Safety: provides assurance of import food safety
  - Office of Foodborne Disease Surveillance: manages domestic foodborne disease surveillance

(MHLW, 2011)

*Food Safety Commission*
"The Food Safety Commission is an organization that undertakes risk assessment, and is independent from risk management organizations such as the Ministry of Agriculture, Forestry and Fisheries, the Ministry of Health, Labour and Welfare, and the Consumer Affairs Agency." The Commission's primary goals can be summarized into three main tasks:

- Conducting risk assessment on food in a scientific, independent, and fair manner, and making recommendations to relevant ministries based upon the results from the risk assessment.
- Implementing risk communication among stakeholders such as consumers and food-related business operators.
**Responding to food-borne accidents and emergencies**

(Food Safety Commission, 2011)

*Ministry of Agriculture, Forestry and Fisheries (MAFF)* is in charge of ensuring safety of domestically produced foods by reducing the levels of contaminants and microorganisms causing foodborne illness by process control throughout food chain. For this purpose, MAFF establishes priority lists of chemical and microbial hazards and conducts surveillance and monitoring of these hazards in foods and feeds, both domestically produced and imported. Based on the results of surveillance and monitoring, MAFF estimates potential health risk for the Japanese. If the risk from a hazard in domestically produced foods is not negligible, MAFF develops a code of practice for prevention and/or reduction of contamination by that hazard for use by farmers and/or food business operators. If the risk from a hazard in imported foods is not negligible, this information is transmitted to the Ministry of Health, Labour and Welfare of Japan and the embassy(ies) of relevant country(ies). (MAFF, 2011)

MAFF is responsible for reducing the food safety risk arising from use of feeds, veterinary drugs, pesticides and fertilizers, and is promoting the use of good agricultural practices, and supporting food business operators introducing prerequisite program of Hazard Analysis and Critical Control Point (HACCP) and HACCP itself. (MAFF, 2011)

**Prefectural and Municipal Governments**

Local governments have the following responsibilities with regard to food safety:

- Formulate inspection and guidance plan for food hygiene.
- Establish standard for business facilities by business type.
- Establish standards for management/operation of business facilities.
- License businesses.
- Inspect food related businesses and distributed foods and give guidance.
- Revoke business licenses, and prohibit and suspend business operations.

These activities are executed through health centers of local governments under the jurisdiction concerned (MHLW, 2011). (MHLW, 2011e)

**1.2 Agencies Responsible For Animal Feed And/Or Pet Foods**

*Ministry of Agriculture, Forestry and Fisheries (MAFF)* oversees the importation and safety of animal feed under the Feed Safety Law. MAFF oversees the implementation of the Feed Safety Law. Duties of MAFF pertaining to animal feed include:

- Establishing specifications and standards relating to feed product safety.
- Testing and labeling of feed products.
- Prevention of the distribution of feed products containing toxic substances.
Ensuring the manufacture, distribution, etc. of appropriate feed products at manufacturing, sales, and other facilities (notification of manufacturers and importers, obtaining reports, spot inspection, sampling of feed products, etc.).

(MAFF, 2008)

With regard to pet foods, MAFF and the Ministry of the Environment (MoE) oversee the importation and safety under the Law for Ensuring the Safety of Pet Food (Pet Food Safety Law). Duties of MAFF pertaining to pet foods include:

- Establishing specifications and standards relating to pet foods safety.
- Prevention of the distribution of pet foods containing toxic substances.
- Ensuring the manufacture, distribution, etc. of appropriate pet foods at manufacturing, sales, and other facilities (notification of manufacturers and importers, obtaining reports, spot inspection, sampling of pet foods, etc.).

Food and Agriculture Inspection Center (FAMIC) performs a monitoring of feed for detection of contamination and other undesirable sources and also collects information from importers on factors that may affect the quality of imported feed products. FAMIC also disseminates feed-related information. (Takagi, 2011)

MAFF has provided guidelines for importers, manufacturers, and shippers of feed (MAFF, 2008). Importer responsibilities with regard to imported animal feed include:

- Importers and manufacturers are to register their email addresses with FAMIC so they can receive information from FAMIC.
- Establishing feed product specifications that ensure the safety of the feed products based on regulation as well as guidance from FAMIC and MAFF.
- Confirming safety of imported feed products by methods such as signing verification agreements and conducting foreign on-site inspections when necessary
- Establishing procedures for quality control, complaint handling, product recall, education and training
- Implementing Procedures
  - Perform quality control measures such as required sampling and reporting of violative testing results to FAMIC. Testing records must be maintained for two years.
  - Investigate product complaints and maintain a record of complaint handling for two years.
  - Investigate cause of product recall, address source of recall, and maintain a record of recall-related actions taken. The facts of the recall with the results of the investigation need to be reported to MAFF through FAMIC. Recall records must be maintained for two years.
  - Provide education and training to employees with responsibility for the safety of imported feed and maintain records of these trainings for two years.
1.3 Food Importation Process Steps And The Government Units That Oversee Each Step

The steps in the importation process for food are as follows:

- Importers may consult with the inspection section of the quarantine station prior to importing products
- Preparation of documentation for import notification, including: information on ingredients and manufacturing, health certificates (where required), and results of self-testing (where required)
- Cargo arrives at Japanese border
- Importers submit an "Notification Form for Importation of Foods" to a MHWL quarantine station for the product that they wish to import.
  - "The import notification form can be submitted starting 7 days before the estimated date of cargo's arrival. Except for the cargo that needs an inspection, a copy of certificate of notification is issued immediately, either before the arrival of cargo or after the cargo is unloaded to the bonded area" (MHLW, 2011g).
  - "If a certain food or related item is planned to be imported repeatedly, an import plan can be submitted at the time of the first import. When the plan is found satisfactory, the submission of import notification is exempted for a certain period." (MHLW, 2011g).
- Food sanitation inspectors at the quarantine station perform a document examination to determine whether or not an inspection is required. The examination considers information such as country of export, imported items, manufacturer, place of manufacture, ingredients and materials, methods of manufacturing and use of additives.
  - If the inspection is not necessary, a certificate of notification is granted to the importer, and the importer can clear Customs
  - If inspection is deemed necessary, products inspection may take two forms:
    - Monitoring, or administrative, inspections are performed at the quarantine station, and
    - Ordered Inspections are sent to a designated inspection laboratory
      - Products passing inspection are granted a certificate of notification and are able to clear Customs
      - Products failing inspection are destroyed or re-exported

(MHLW, 2011f)
1.4 Assistance, Cooperation Or Contributions From Other Government Bodies (National Or Local) In The Imported Food And Feed Process

Customs officials do not permit importation of illegal foods based on the Customs Act (MHLW). See Section 1.1 for other entities involved in the imported food and feed process.

1.5 Laws And Regulations That Provide Authority For The Oversight Of The Safety Of Imported Foods And Animal Feed, And The Policies And Procedures That Guide Import Officials

*Food Sanitation Act,* also commonly referred to as "the Act", is intended to help "ensure the safety of imported foods and related products". The law requires measures for risk management such as requiring importers to submit import notifications to MHLW each time they wish to import a product. (MHLW, 2011)

*Food Safety Basic Act (2003)*, helps ensure food safety by requiring "necessary measures appropriate at each step of the food supply process both in Japan and overseas". The Food Safety Basic Law is responsible for the risk assessment (MHLW, 2011)

*The Imported Foods Monitoring and Guidance Plan" is a plan for the implementation of monitoring and guidance conducted by the national government with respect to imported foods". Based on Article 4 of the Food and Safety Basic Act (2003), the plan is prepared in order approach the sanitation of imported goods at three stages: 1) in the exporting country, 2) at the time of importation, and 3) at the time of domestic distribution. These plans are updated annually. (MHLW, 2010a)

*Law Concerning Safety Assurance and Quality Improvement of Feed (Feed Safety Law) (1953)* is intended to contribute to public health and stable livestock production by ensuring safety and improving quality of feed. The law requires measures for risk management such as prohibition of importing feed products which do not meet the standards or specifications. (MAFF, 2008)

*Law for Ensuring the Safety of Food (Pet Food Safety Law) (2008)*, is intended to ensure the safety of pet food and thus to protect the health of pets and contribute to animal welfare.

1.6 Handling Of Products Transshipped Through A Third Country As Compared To Directly Imported Products

The Food Sanitation Act does not have any specific handling regulation for transshipped products, except for meat and organs of livestock and poultry. A certificate issued by a government that conducts slaughter inspections shall be attached to the products (MHLW).

With regard to feed products, there is no difference between the handling of transshipped products and that of directly imported products. FAMIC receives the importation plan from importers and schedules for sampling. Sampling of imported feed products is made without distinguishing between transshipped products and directly imported products. (MAFF, 2011)
2 INSPECTION PROGRAMS

2.1 Mechanisms To Prioritize Food/Feed Import Surveillance Activities Such As Product Sampling And Testing, Inspections At The Border, And Facility Inspections Of The Exporting Country

When imported foods arrive at Japan's border, the food sanitation inspector uses the information reported in the Notification Form to validate whether:

- The imported food complies with the manufacturing standards regulated under the Food Sanitation Act.
- The use of additives complies with the standards.
- The product contains a poisonous or hazardous substance
- The manufacturer or country of export has a record of sanitation problems in the past.

The inspector will make a judgment as to whether the products should undergo inspection based on this information. (MHLW, 2011a)

MHLW determines the number of imported foods subject to monitoring inspection as well items to be monitored and inspected. When establishing these monitoring plans, MHLW considers" the conditions of regulations on agricultural chemicals, status of their use, and cases of detection of agricultural chemicals in other countries." Schedule 1 of the Imported Food Monitoring and Guidance Plan details MHLW's annual monitoring requirements. (MHLW, 2011c)

Quarantine stations establish an annual monitoring program "based on the number of foods subject to monitoring inspection assigned by the MHLW and systematically implement inspection on the assigned number of specimens". "The quarantine stations also inspect imported foods based on the import-notification document when they are imported for the first time, when an accident occurs during transportation, or in other necessary occasions, in addition to the inspection they conduct based on the monitoring plan." (MHLW, 2011c)

Introduced in 2006, The Positive List System established a uniform MRL limit of 0.01 ppm for foods without previously established MRL limits and provides a list of MHLW exempt substances (MHLW, Positive List, 2006).The Positive List System generally prohibits the sale of food products containing amounts of residual agricultural chemicals that exceed the amount determined as not causing health damage. "Agricultural chemicals include pesticides, feed additives and veterinary drugs". (MHLW, 2011c)

When MHLW "deems it necessary in order to prevent any harm to food sanitation", the MHLW shall issue an inspection order which requires importers having foods with a high possibility of violating the Act to have those products inspected each time that the food is imported. Inspection orders can be exempted where:

- "The exporting country has taken preventive measures, such as investigation of causes, issuance of new regulations corresponding to the results of investigation and
enhancement of the condition of control of agricultural chemicals, etc. and inspection system, and the measures have been determined to be effective through bilateral discussions, on-site inspections or inspections at the time of importation"

- "There have been no violations during two years since the issuance date of inspection order or the number of the imported foods inspected under the order is more than 300 lots during one year since the issuance date of inspection order and no violation occurs. These actions temporarily cancel the inspection order.
  - The rate of inspection for goods under a temporarily canceled inspection order remains at a higher proportion of the imported foods for a period of time necessary to obtain a certain statistical reliability that no violations are occurring

(MHLW, 2011c)

**Feed**

"FAMIC conducts systematic surveillance and monitoring inspections for toxic substances in feed products, including actions undertaken in accordance with the Annual Plan for the Surveillance and Monitoring of Toxic Substances Related to Food Safety as established by the Ministry of Agriculture, Forestry and Fisheries" (MAFF, 2008). The criteria for the risk prioritization of feed products are as follows:

- Toxicity of hazards
- Extent of occurrence of hazards
- Estimation of intake of hazards

In addition to the above criteria, the following are considered to decide the hazards to be subjected to the surveillance and monitoring.

- Existence of standards or guidelines on the maximum residue limits established by MAFF
- Interest of stakeholders
- International concerns (e.g. standards are established/discussed by international organizations)

### 2.2 Special Screening Requirements And Trading Partner Requirements Where Disease Or An Outbreak Has Occurred

In the case of BSE, management and regulation of feed, introduction of traceability, and testing risk cattle have occurred. The BSE test is carried out by slaughtering inspectors, who own veterinarian's licenses and civil servants in slaughterhouses of prefectural and city governments based on "Legislation for slaughterhouses" and "Special Measures Law on Bovine Spongiform Encephalopathy". (Food Safety Commission, 2004)

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2 Further TSE testing information can be found under ESE test methods at: http://www.mhlw.go.jp/english/topics/foodsafety/bse/index.html
In order to export feed materials such as animal-derived protein/oil/fat, once banned due to BSE risk, the government of the exporting country also has to exchange "Animal Health Requirements" with MAFF including taking risk management measures equivalent to the measures taken in Japan. In addition, MAFF prescribes requirements for importers of these feed materials and the importers must be certified by MAFF prior to importing. (FAMIC, 2011b)

Emergency measures based on information on related problems from overseas include: 

- The MHLW collects information on food-safety problems from the governments of the exporting countries in cooperation with related ministries
- MHLW publishes major cases on its website
- When MHLW finds that foods violating the Act may be imported into Japan, it shall check the status of their importation into Japan.
- If violative foods are being or actually have been imported, the MHLW shall ask the quarantine stations and/or prefectures concerned to investigate their distribution and inventories in Japan
- Based on the investigation of quarantine stations and concerned prefectures, importers may be instructed to inspect and, potentially, recall the items in question.
- The MHLW also instructs the quarantine stations to reinforce inspection of those foods and publish the progress of countermeasures."

(MHLW, 2011c)

2.3 Percentage Of Imported Food Shipments Examined And The Relationship Between Risk-Ranking Of Foods And Volume Of Imported Foods Examined

"Imported foods are inspected by 31 quarantine stations placed across Japan under the central government" (MHLW, 2011). "Inspection Results of the Imported Foods Monitoring and Guidance Plan for FY 2010, published in December 2011, provided preliminary figures of approximately 1,000,000 cases of notification of imports and some 12 million tons in imported volume between April and September 2011. Out of these cases, approximately 119,000 of them, or 11.4% of the overall number of notifications, were inspected. Among the inspected cases, 619 were identified as violations." (MHLW, 2011b)

At the border, the food sanitation inspector determines whether or not a food should be inspected by using the information reported in the Notification Form to validate whether:

- The imported food complies with the manufacturing standards regulated under the Food Sanitation Act.
- The use of additives complies with the standards.
The product contains a poisonous or hazardous substance.

The manufacturer or country of export has a record of sanitation problems in the past. (MHLW, 2011a)

Monitoring inspections are also implemented every fiscal year for the purpose of monitoring safety conditions of food, and these inspections may be used to target imported foods that are potentially problematic. "When the MHLW receives information on the recall of a food or harm to health by a food in a producing country, or when such a food is found to violate the Act during monitoring inspection, the MHLW conducts monitoring inspection on a higher proportion of imported foods concerned and for more inspection items for a certain period of time so that inspection will identify violations with a certain statistical reliability. When no similar violation is identified for one year or in more than 60 cases of inspections conducted after the monitoring inspections are reinforced, the inspection system will return to normal." (MHLW, 2011c; MHLW, 2011d)

2.4 Types Of Review, Examination And/Or Testing Of Imported Products Performed By Food Sanitation Inspectors

The Import Notification documentation is checked for all imported products entering Japan in order to determine if inspection and product testing is necessary. MHLW uses three types of inspection with regard to imported food: 1) Inspection order system, 2) monitoring inspections, and 3) other inspections.

Inspection orders require importers having imported foods with a high possibility of violating the Food Sanitation Act to have their products inspected each time that the goods are imported, based on the provision of Article 2. "The items that are subject to this system are designated in the cabinet order, and detail of each item is specified every year" (MHLW, 2011c; MHLW, 2011d). Schedule 1 and Schedule 2 in the Imported Food Monitoring and Guidance Plan lists required tests and testing frequencies for imported foods. Depending on the category of food (e.g. meat versus fruit), testing is completed for the following:

- Antibacterial substances
- Residual agricultural chemicals
- Additives
- Standards for constituents
- Radiation irradiation
- Mycotoxins

(MHLW, 2011c)

Monitoring inspections are systematically implemented every fiscal year for the purpose of monitoring safety conditions of various foods based on the provision of Article 28 of the Food Sanitation Act and to reinforce inspections at the time when violations of the Act occur.
Monitoring to reinforce inspections occurs when “the MHLW receives information on the recall of a food or harm to health by a food in a producing country or the like, or when such a food is found to violate the Act during monitoring inspection”. Under these circumstances, the MHLW "shall continuously conduct monitoring inspection on a higher proportion of imported foods concerned and for more inspection items for a certain period of time so that inspection will identify violations with a certain statistical reliability. When no similar case of violation is identified for one year (or in more than 60 cases) of inspections conducted after the monitoring inspections are reinforced, the inspection system will return to normal." (MHLW, 2011c; MHLW, 2011d)

Other inspections are described as "inspections for the food and related items that are imported first time to Japan, inspections to examine the items that are not in compliance with the Food Sanitation Act, and inspections to examine the food and related items that have experienced an accident during transportation." Also, in some occasions of a first-time import or regular import, the MHLW quarantine station requires the importers to conduct an inspection of the cargo on some necessary items, based on the idea that importers also have the obligation to secure the food sanitation and safety." (MHLW, 2011d)

2.5 Types Of Examination And Testing Processes Used For Ensuring Animal Feed And Feed Ingredient Safety

Examination and testing of imported feed varies from that used for imported food. The Import Notification documentation is requested only when importing the feed products designated by the Minister of MAFF as which may not conform to the specifications or standards. For other feed products, animal-derived protein/oil/fat needs to be confirmed by MAFF that the production process of the products are completely separated from that of other animal-derived protein/oil/fat. Importers are requested to submit the applications for confirmation to FAMIC prior to their first importation. (MAFF, 2011)

"FAMIC conducts systematic surveillance and monitoring inspections every year for toxic substances in feed products, including actions undertaken in accordance with the Annual Plan for the Surveillance and Monitoring of Toxic Substances Related to Food Safety as established by the Ministry of Agriculture, Forestry and Fisheries" (MAFF, 2008).

The surveillance of feed products is conducted for dioxins, mycotoxins (fumonisins), bacteria (Salmonella, Escherichia coli 0157:H7), nitrates, etc. and the monitoring is planned for heavy metals (cadmium, mercury, lead and arsenic), mycotoxins (aflatoxin, zearalenone and deoxynivalenole), pesticides, antimicrobials, unapproved GM events and animal-derived protein. The samples are taken when FAMIC conducts periodical on-site inspections at feed manufacturers and importers. (MAFF, 2011)

2.6 Inspections Of Food Or Animal Feed Manufacturers Or Shippers In Other Countries (Including Selection Criteria And Frequency)

MHLW encourages importers to voluntarily conduct safety control in exporting countries and urges exporting countries to actively gather information on safety measures. MHLW directs importers to verify that their imported products' manufacturing practices comply with a HACCP-
type program and are in accordance with the laws and regulations of the country in which the product is made. (MHLW, 2011c; MHLW, 2008)

MHLW has previously conducted on-site visits on safety controls in exporting countries with relation to bovine spongiform encephalopathy, and the 2011 Imported Food Monitoring and Guidance Plan lists on-site inspections to "promote safety measures during the production process in exporting countries" (MHLW, 2011c).

"For foods that are subject to inspection orders at the time of importation, as well as those with a high possibility of violating the Act, the MHLW shall ask the governments of the exporting countries to investigate the causes of such violations and to take corrective actions based on the results of such investigations, through bilateral discussions and other means. In addition, the MHLW shall promote such measures as safety control in the production stages, the enhancement of monitoring systems and the introduction of pre-export inspections in the exporting countries. [In these cases], MHLW shall dispatch experts to the exporting countries of the relevant imported foods in order to verify the safety measures in the exporting countries." (MHLW, 2011c)

2.7 Notification System(S) To Directly Notify Foreign Governments When Foods Or Animal Feed Manufactured In Their Countries Are Found To Be Unsafe; And To Notify The Public When Imported Products Do Not Meet Safety Standards

If unsafe food is confirmed, the MHLW will notify the country of origin's embassy in Japan and provide relevant information. For serious cases, MHLW will notify to the International Food Safety Authorities Network (INFOSAN). (MHLW, 2011h)

When animal feed manufactured in overseas countries is found to be unsafe, MAFF provides the information to the relevant government directly or through its embassy. The information is also provided to the media through press releases, web-sites of MAFF and also requests prefectural governments to post the information on their web-sites. (MAFF, 2011)

3 AUDITS AND CERTIFICATION

3.1 Assessing And Measuring The Effectiveness Of The Food/Feed Safety Import Program (E.G., Self Audits Of The Program, Public Health Outcomes, Surveillance Sampling Results, Number/Rates Of Refusals, Periodic Program Evaluations)

The imported foods monitoring program under the Food Sanitation Act is modified in accordance with imported conditions at the half point of each fiscal year in Japan. The monitoring program is designed every fiscal year based on the evaluation of the program of the previous year, such as the amount of import refusal cases and their contents. (MHLW, 2011h)

FAMIC’s performance, which includes the monitoring survey for contaminated feed, is evaluated annually by the Evaluation Committees of the MAFF and Ministry of Internal Affairs and Communications (MIC). The results of surveillance and monitoring are published on the web-site of FAMIC and used for assessment of the current status of imported feed. (FAMIC, 2011)
3.2 Extent Of Reliance On Trading Partners' Food Safety Programs To Ensure That Imported Foods Or Animal Feed Are Safe

"Article 8 of the Food Safety Basic Act stipulates that food business operators, including importers, must recognize their own responsibility for securing the safety of food and calls for taking appropriate measures at each stage of the food supply process with the necessary measures to insure food safety. Also, Article 3, paragraph 1 of the Act stipulates that it is the responsibility of food business operators, including importers, to acquire the necessary knowledge and technology, to ensure the safety of raw materials and to implement voluntary checks for the purpose of ensuring the safety of imported foods at their own discretion." (MHLW, 2011c)

MHLW guidance for exporting countries also states that "the standard of establishments, facilities and equipment of the manufactory [should be] at least equal to the standards concerning establishments, facilities and equipment stipulated in related Japanese laws and ordinances, etc. (MHLW, 2008).

With regard to animal feed, importers will confirm safety of imported feed, for example, by making contracts with overseas manufacturers on the compliance with the specifications and, as necessary, by visiting overseas manufacturing plants and other facilities to assess the conditions under which feed products are manufactured, and record their findings.

3.3 Requirements For Food And/Or Animal Feed Export Certificates Issued By The Exporting Country's Competent Authority, And Types Of Inspection Or Testing For Each

Article 9 of the Food Sanitation Act and Schedule 2 of the Imported Food Monitoring and Guidance Plan (2011) lists livestock and seafood products as requiring certification (MHLW, 2011c).

As for the importation of animal-derived protein, the "Animal Health Certificate" is required, certifying that the risk management measures taken by the manufacturer is equivalent to those taken in Japan (MAFF, 2011).

3.4 Use Of ISO, Global Gap Or Other Assurance Systems And Confidence In The Assurance System(S) Utilized

The Food Sanitation Act does not provided assurance systems. In principle, certification by a foreign government is prioritized. The use of other assurance systems may be considered depending on bi-lateral consultations. (MHLW, 2011h)

3.5 Foreign Food Safety Systems Audits

MHLW have been examining the food sanitation control systems of exporting countries by conducting foreign audits since 2009 for the purpose of enhancement of an inspection system at the border (MHLW, 2011h).
3.6  **Equivalence Agreements Requiring Periodic Audits/Reevaluations Of Exporting Countries' Food Safety Programs**

MHLW has been requiring an equivalent inspection program of exporting countries to accept health certification of meat/poultry products between exporting countries (MHLW, 2011h).

3.7  **The Utilization Of Third-Parties (Within The Exporting Or Importing Country) To Carry Out Inspections And/Or Product Certification (Nature And Extent Of Programs) And Methods For Verifying The Adequacy And Reliability Of The**

MHLW accepts an analytical report of official laboratories (including third bodies) registered by a government of an exporting country as reference on document examination at Quarantine Station (MHLW, 2011h).

3.8  **Arrangements With Other Governments Relating To Imported Foods Or Animal Feed (Such As Memoranda Of Understanding, Mutual Recognition Agreements, Etc.)**

"Memorandum on Japan-China Food Safety Promotion Initiative" was signed by the ministers in charge from the both Japan and China. Both countries reached an agreement on action plan of FY 2010 and agreed that they will promote exchange and cooperation in safety of the foods that are imported and exported between the both countries (MHLW, 2011c). In addition, the "Memorandum concerning enforcement of Japan's pesticide maximum residue levels" was signed between MHLW and the relevant authorities of the United States in FY2009, and "The molluscan shellfish memorandum of understanding " was signed between MHLW and Food and Drug Administration (FDA) in FY1962 (MHLW, 2011h).

In order to export feed materials such as animal-derived protein! oil/ fat, the government of the exporting country needs to provide to MAFF "Animal Health Requirements" including the scientific proof that risk management measures taken are equivalent to those taken in Japan. (FAMIC, 2011b)

3.9  **Registration Or Licensing Of Firms That Import And/Or Export Foods Or Animal Feed To Your Country Or For Firms That Import Foods Or Animal Feed**

The registration and/or licensing of import firms for foods of human consumption are not required under the Food Sanitation Act (MHLW, 2011h).

Importers of animal feed need to submit notifications to MAFF, two weeks prior to the importation, on their names, addresses, types of feed product, dates to start importation, and ingredients of the feed products. The registration or licensing of firms that export animal feed to Japan is not required under the Feed Safety Law but the importers will confirm the safety of the imported feed products. (MAFF, 2011)

On the other hand, overseas manufacturers producing specific feed products subject to testing and labeling after importation into Japan under the Feed Safety Law may apply for registration by MAFF if they wish to conduct testing and labeling by themselves. Specific feed products include antibiotics to be used as feed additives. In this case, FAMIC makes on-site visit to the
testing facilities of the manufacturer to determine whether the quality management system is appropriate for registration. (MAFF, 2011)

3.10 Use Of Sampling Surveys Of Imported Foods/Feed (As Opposed To Targeting Specific Products/Producers For Inspections And/Or Testing) To Gather Information And Identify Trends And Potential Areas Of Difficulty

Monitoring inspections are systematically implemented every fiscal year for the purpose of monitoring safety conditions of various foods based on the provision of Article 28 of the Food Sanitation Act and to reinforce inspections at the time when violations of the Act occur (MHLW, 2011c; MHLW, 2011d).

MHLW has also performed a "survey on the system in exporting countries with respect to food safety, and conducted consultations and surveys on individual issues with exporting countries in order to prompt exporting countries to take appropriate safety measures on foods imported to Japan." (MHLW, 2011c)

The results of surveillance conducted by FAMIC are used for assessment of the current status of imported feed and for establishment of standards on undesirable substances (MAFF).

3.11 "Good Practices" Programs For Foods/Feed Importers

The MHLW and quarantine station provide advisory guidance on good importing practices and standards for exporters. Technical support is provided to exporting countries so "as to contribute to the strengthening of monitoring systems, including improvement of testing techniques for residual agricultural chemicals". The quarantine stations also hold seminars to provide pre-import guidance in order to promote voluntary safety control, which is the duty of importers as the food business operators." (MHLW, 2011c)

Guidelines for Preventing the Contamination of Feed Products with Undesirable Substances (MAFF, 2008) include good practices for importers. MAFF provides guidance on examples of specifications and documented procedures for the quality control of imported feed products to be established by each importer. In addition, importers are provided with the results of the surveillance and monitoring conducted by FAMIC and other information on undesirable substances in feed products. FAMIC also annually holds seminars on the Guidelines for the interested parties to promote voluntary safety control by importers and manufacturers.

3.12 Description Of Import Program User Fees And Cost Recovery System

Importers are responsible for inspection fees related to inspection orders (MHLW, 2011d).
3.13 Incentives To Increase Industry Involvement In Ensuring That Imported Foods Meet Safety Standards

To promote voluntary inspection before importation, "when a cargo is inspected by an official inspection organization in the exporting country prior to the export, and a report of the result from the inspection is attached to the cargo, the inspection at the quarantine station for the cargo may be exempted (inspection items whose results are subject to change during transportation (bacteria, mycotoxin, etc.) are excluded)." (MHLW, 2011g)

Importers can also seek advanced approval of their food products, whereby "when the imported food is confirmed to be compliance with the Food Sanitation Act, the items and the manufacturers may be registered. Inspection at the upcoming import is exempted for these items for a certain period of time and the certificate of notification is issued immediately after the submission of import notification." (MHLW, 2011g)

3.14 Obstacles To Industry Participation In Ensuring That Imported Foods Meet Safety Standards

MHLW directed Japanese importers showing high violation rates to make improvements in food sanitation control. In this process, MHLW confirmed some obstacles to industry participation, including:

- In-sufficient food sanitation control based on low level maintenance of the public order
- In-sufficient placing for High performance food analysis equipment in foreign laboratories (ex: LC/MS)
- Difficulty of control for agricultural chemicals based on high illiterate rate at exporting country (impossible to read a user manual and to make a report of using).

(MHLW, 2011h)

4 LABORATORY SUPPORT

4.1 The Role Of Laboratories In Supporting The Imported Food And Feed Programs And Description Of Laboratory Capabilities

"Monitoring for chemical residues is conducted by MHLW quarantine offices (for imported crops) and local government laboratories (for both imported and domestically produced crops)" (USDA, 2009). The registered conformity assessment laboratories to MHLW also supports an official and non-official inspection (MHLW, 2011h).

"MHLW has certified certain U.S. laboratories as eligible to test foods and beverages for compliance with Japan's Food Sanitation Act for export to Japan. U.S. products will not need to be tested upon arrival to Japan if an analytical certificate from a laboratory approved by MHLW accompanies the shipment." (USDA, 2009)
4.1.1 Participation of Non-Government Laboratories (including industry and academic laboratories) in Food Import Control Program

Under the Food Sanitation Act chapter VIII, the non-government laboratories are registered as a "registered conformity assessment laboratory" if they satisfy requirements for registration (MHLW, 2011h).

4.1.2 Laboratory Quality Assurance

Registered conformity assessment bodies under the Food Sanitation Act control quality assurance of analytical results by introducing Good Laboratory Practice (GLP) (MHLW, 2011h).

5 ENFORCEMENT AT BORDER

5.1 Approach To Visual Inspections And Analysis Of Imported Foods (E.G. Risk-Assessment And Prioritization Schemes, Documentation Review, Sample Collection)

See Section 2.1

5.2 The Process That Occurs When An Imported Food Is Found To Be Contaminated Or Does Not Meet Standards

"If the MHLW specifically determines that foods manufactured in a specific country or area, or by a specific manufacturer, should no longer be imported in order to prevent possible harm to food-sanitation conditions in Japan, it shall ban the importation of such foods by issuing a comprehensive order for an import ban under Article 8 or Article 17 of the Act." (MHLW, 2011c)

"When a violation of the Act has been identified, the MHLW and quarantine stations shall give instructions on discarding relevant foods or other measures as well as measures to prevent recurrence of such violations including publishing examples of violations and providing guidance to importers." (MHLW, 2011c)

Once imported goods have cleared Customs "prefectures and cities and specially designated wards that operate public health centers shall monitor and give guidance on imported foods". If any violation of the Act is identified, the MHLW, the quarantine station and the prefectures, shall cooperate with each other to take appropriate measures to ensure that the importer concerned properly recalls the food as soon as possible. To facilitate instructions on recall from the prefecture(s), the quarantine station immediately reports the lot numbers, name and address of the importer as well as other information on the violating food to the MHLW. [It is responsibility] of the prefecture having jurisdiction over the location of the importer to ensure that recall by the importer and other necessary measures are appropriately taken."

"The MHLW shall, under the Consumer Safety Act (Act No. 50 of 2009), strive to share information with the Cabinet Office."

(MHLW, 2011c)
Repeat Violators

When an importer repeatedly violates imported foods standards, the importer:

- Must "investigate the causes of the violation and immediately report the results to the quarantine station. If the causes of the violation are still not identified after three months have passed since the discovery of the violation, the importer shall report the progress of the investigation to the quarantine station."
- Must confirm that corrective action has been taken when planning to import the same food again.
- May be required to carry out field investigations in the exporting country.
- Carries out inspections for each item that did not previously comply with the Act and report the corrective action to the quarantine station.
- Quarantine stations will strengthen monitoring inspections of foods imported by importers who have violated the Act for more than about 5 percent of all cases of importation in accordance with the details of violation and will verify measures to prevent recurrence by the concerned importers.

"The MHLW may order a prohibition or suspension of business with respect to importers who commit repeated violations or food importers who have caused harm or posed risks to public health by violating the Act, in order to make them improve the causes of the violation, prevent recurrence and take other required sanitary measures." (MHLW, 2011c)

Recall

Importers are responsible for establishing and maintaining a recall system for their imported products which includes measures of contacting the appropriate administrative officials and removing the product in an appropriate and timely matter (MHLW, 2008).

According to the Imported Food Monitoring and Guidance Plan (2011) the MHLW and quarantine stations are also to provide the general public with information on ensuring the safety of imported foods via the MHLW website or other means (MHLW, 2011c).

Feed

When imported feed is found to be contaminated or does not meet the related standards, MAFF "requests that importers, manufacturers, and distributors suspend shipments of and recall unused/unsold products from the same lot and that users refrain from using [the product]" (Takagi, 2011). Should a food emergency occur that stems from a contaminated feed, MAFF establishes a task force that will investigate the situation; communicates and coordinates with the Food Safety Commission and other relevant government Agencies (MHLW); and collects and disseminates information (Takagi, 2011). MAFF will dispatch FAMIC employees to perform inspections and sampling of concerned products as necessary (MAFF, 2008).
5.2.1 Procedures for Refusing Imported Foods Based on a Finding that they do not Comply with Requirements

See Section 5.2

5.2.2 The Procedure and Outcome for Imported Foods that are Refused Entry (Including Efforts to Prevent them from Mistakenly Entering Domestic Commerce)

Foods that are refused entry are re-exported or destroyed (MHLW, 2011f).

5.2.3 Entry of Detained Products Based on Further Testing or Reconditioning of the Product

The Imported Food Monitoring and Guidance Plan (2011) states that "additional guidelines shall be given depending on the types of imported foods that the importers handle and the relevant exporting countries.” (MHLW, 2011c)

5.2.4 Process for Identifying and Tracking Producers or Countries that have Repeated Violations

The method or process of identifying repeat violators was not located, however, it is evident through other import measures that repeat violators are, in fact, tracked (See Section 5.2)

The MHLW also maintains a list of importers who have repeated violations. The MHLW lists the names of importers who have violated the Act or any actions taken under the Act, as well as the names of the violating imported foods on the MHLW website. Names remain on the website for one year "for the purpose of disclosing information to the public regarding any potential harm from the viewpoint of food sanitation". If the violation is not very serious and the importer remedies it immediately, importers are excluded from the list. "In addition to the listing of the names of violating importers, measures taken against food violations, such as disposal or recall and corrective actions and causes of the violations shall also be published as soon as the information is available.” (MHLW, 2011c)

5.3 Program For Investigating And Responding To Intentional Contamination Of Foods

"The quarantine stations may indict if it considers that any crime is committed, for example, submission of a false import notification document and illegal importation of foods violating the Act and or foods with a high possibility of suspicion, as well as make a publication of such indictments." (MHLW, 2011c)

6 FOOD RELATED ILLNESS OUTBREAKS

6.1 System For Tracking Imported Foods Once They Are Cleared At The Point Of Entry

Article 3 of the Food Sanitation Law states: “A food business operator shall endeavor to make a record of any necessary information such as the name of the person who has sold food for sale or the raw materials thereof to said food business operator and retain such record within the
limit necessary for preventing food sanitation hazards resulting from food for sale, etc.”

"Guidelines concerning preparation and retention of records by food business operators states that (Notice No. 0829001 of the Department of Food Safety dated August 29, 2003) the quarantine stations shall instruct importers to properly prepare and retain records of the importation, sales and other details for the imported foods in order to allow the quarantine stations to check and identify the conditions of import and distribution of those foods at all times." (MHLW, 2011c)

6.2 Systems For Identifying Foodborne Illness Outbreaks

MHLW gathers information pertaining to foodborne illness outbreaks from all local governments on a daily basis. Article 58 of the Food Sanitation Act stipulates mandatory reports of every incident of foodborne illness from local governments to the MHLW. (MHLW, 2011h)

6.3 How Consumers Notify The Government And/Or Importers Of Food Problems

The consumer's food problem is received by a local government health-center, and the health-center is in charge of investigation for that notified problem. MHLW receives information pertaining to food problems from a Consumer Agency. (MHLW, 2011h)

7 EXPORT PROGRAMS

7.1 Programs For Ensuring Safety Requirements Of Export Destination Countries

The Food Sanitation Act does not prescribe a program for ensuring the safety requirements of exporting countries. Individual guidelines for food export, however, are established by the MHLW based on bilateral discussion, if they are needed. Guidelines prescribe the role of central governments, local governments, food business operators and laboratories with regards to safety requirements of exported foods and export certificate. (MHLW, 2011h)

When an importing country requires a corrective action(s) to be taken on agricultural/fishery products including foods exported from Japan due to violation to their regulations, MAFF will inform the exporter or manufacturer, as appropriate, to observe the regulations of the importing country concerned and provide guidance on how to implement corrective actions. (MAFF, 2011)

When regulations of an importing country is revised or amended, which may have significant impact on the export of agricultural/fishery products from Japan, MAFF will disseminate such information to exporters and manufacturers concerned. (MAFF, 2011)

MAFF financially and technically supports farmers and manufactures in implementing process control systems such as GAP and HACCP. (MAFF, 2011)
7.1.1 Use of Export Certificates to Provide Assurances to the Importing Country

MHLW and MAFF, in collaboration with each other, established a system under which they issue export certificates upon request by importing countries on specific commodities. The certificate issuing body can be central governments, local governments or non-governmental third parties (MHLW, 2011h, MAFF, 2011).

Such system has been established by MHLW and/or MAFF for the following:

- Meat and meat products to the USA, Canada and other 9 countries.
- Fishery products to Brazil, China, EU, Malaysia, Nigeria, Republic of Korea, Russia, Ukraine and Vietnam;
- Bivalve mollusks to New Zealand; and
- Meat and shrimp, and products thereof to Malaysia.

(MAFF, 2011)

In response to the request from importing countries in the aftermath of the failure of Fukushima Daiichi Nuclear Power Plant, export certificates have been issued specifying that the foods being exported have been tested for radionuclides and comply with the provisional regulatory levels to:

- Brazil, EU, French Polynesia, Iceland, Lichtenstein, Malaysia, Norway, Republic of Korea, Switzerland, Singapore and Thailand.

(MAFF, 2011)

7.1.2 Providing to the Import Country Lists of Establishments that Meet the Importing Countries' Food Safety Requirements.

The MHLW establishes and maintains the list of establishments if importing countries require registration of exporting establishments (MHLW, 2011h).

Upon request from importing countries, establishments meeting their requirements are registered in Japan. So far, a list of registered establishments includes those for:

- Fishery products to Brazil, China, EU, Republic of Korea, Russia, USA and Vietnam.

(MAFF, 2011)

7.1.3 Authorized Third Party Issuance of Export Certificates

Upon request from importing countries, those third parties designated by MHLW or MAFF, specializing in food sanitation, food analysis or public health, issue export certificates for specific commodities (MAFF, 2011; MHLW, 2011h).

Export certificates have been issued for:
- Fishery products to Australia, Brazil, China (multiple third parties), Nigeria, Russia and Ukraine.
  (MAFF, 2011)

8 WORLD TRADE ORGANIZATION (WTO) OBLIGATIONS

8.1 Methods For Ensuring Consistency Between Domestic And Imported Food Safety Requirements

The Food Sanitation Act is applied equally to domestic and foreign foods in accordance with the WTO rule (MHLW, 2011h).

Maximum levels for contaminants and maximum residue limits for pesticides in feeds are established scientifically on a basis of surveillance data and are applicable equally to both domestically produced and imported feeds (MAFF, 2011).

8.2 Methods Of Documenting The Scientific Justification For Import Practices With Regard To Article 5 Of The SPS Agreement, Which Requires That Measures Are Based On An Assessment Of Risk, As Appropriate To The Circumstance

[Japan's] "approach is to scientifically assess risks (expressed as the probability and degree of adverse health effects) and develop necessary measures based on the risk assessment. The risk analysis consists of three components:

- Risk assessment-assess risk scientifically;
- Risk management-implement necessary measures based on risk assessment; and
- Risk communication-exchange information and opinions among related people representing the people including public, government, and academia."
  (MHLW, 2011c)

As for feed, measures are also considered and established following the framework of risk analysis. For example, maximum levels for contaminants and maximum residue limits for pesticides are established on a basis of surveillance data.

8.3 Involvement In Article 4 Of The WTO SPS Agreement Regarding Equivalence Determination

MHLW accepts health certificates for meat and meat products issued by the competent authorities of 21 countries after recognition that their inspection program is equivalent to domestic program (MHLW).

8.4 Process For Recognizing A Foreign Country's Food Safety System As Having Adequate Regulatory Oversight

MHLW recognizes the food safety systems of foreign governments based on bilateral meetings held with the relevant and responsible parties of those foreign governments (MHLW, 2011h).
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OVERVIEW OF INTERVIEW AND FOOD AND FEED SAFETY SYSTEM

There are two federal agencies primarily responsible for the safety of imported food and animal feed in Mexico: 1) SENASICA, the agency within SAGARPA (under the Ministry of Agriculture) is responsible for animal and plant health as well as sanitary regulation of primary production and processing of agricultural, aquacultural and fishery foods 2) COFEPRIS, the public health agency within SALUD (under the Ministry of Health) which serves as the national food safety regulatory agency. SENASICA and COFEPRIS, in combination with Customs, non-governmental third parties, and state authorities with responsibility for health risks, comprise the major food and feed safety system organizations of Mexico.

Foods imported into Mexico are categorized according to their composition as falling under the jurisdiction of SENASICA or COFEPRIS. Each agency has its own methods for analyzing and addressing food safety issues within the broader Mexican food safety system, although there are also overlapping agency efforts such as those dealing with foodborne illness outbreaks. COFEPRIS, including cooperative state authorities, and SENASICA also manage import equivalency and export certification issues.

With the exception of equivalence agreements for foods of animal origin, Mexico’s food safety system does not focus on imported foods, but rather treats domestic and imported foods equally. The system focuses on NOMS, or standards in establishing and maintaining good producer practices, in order to meet national, export, and international standards. Producer practices are targeted through mandatory and random inspection, a testing and enforcement regime for non-animal foods and feeds, and a third party-government cooperative effort for foods of animal origin.

Mexico primarily relies on the product assurance of its trading partners. Customs provides the main check of imported goods as it reviews documentation attesting to product-specific hygiene requirements at the border. Neither COFEPRIS nor SENASICA staff border posts but rely on Customs to hold, re-export or destroy violative products should they be found.

SENASICA and COFEPRIS conduct and target their surveillance, inspection, and enforcement activities according to risk-based strategies established within norms (laws, federal regulations, guidelines and others) that identify hazardous foods and feeds as well as acceptable product contaminant levels. Animal-origin foods and feeds, including seafood and shellfish, are products, which have the greatest degree of preventive control measures as well as equivalence and/or certification programs. The degree of preventive controls and product enforcement depends on the levels of risk determined for the product or product category. Neither agency has ranked intentional contamination of food or feed as a significant risk warranting regulation or risk management.

When food and feed related issues occur, such as contamination, mislabeling, or foodborne illness outbreaks, prompt enforcement action is taken, product tracebacks are completed, and if necessary the investigation may lead to the product’s country of origin for remedy. COFEPRIS serves as the public risk communicator for all foods and feeds, whereas each agency has
established communication networks within Mexico and internationally to its respective industry and competent authority counterparts.

1 ROLES AND FUNCTIONS OF AGENCIES RESPONSIBLE FOR IMPORTS OF HUMAN FOODS AND ANIMAL FEED

1.1 Governmental Ministries And Subunits (Including National/Regional/Local, As Appropriate) With Responsibility For Assuring The Safety Of Imported Food

Secretariat of Health (Secretaría de Salud, SALUD). Federal Commission for the Protection against Sanitary Risks (Comisión Federal Para La Protección Contra Riesgos Sanitarios, COFEPRIS) is the subunit of the Mexican Secretariat of Health (SALUD) that oversees and produces federal regulations that are designed to protect human health (SALUD, 2003). COFEPRIS has 62 people working in the product safety- foods, cosmetics, perfumes and other imported products program. The agency serves as the national food safety regulatory agency, where it establishes rules and regulations to improve food safety. COFEPRIS implements and enforces these measures through its inspection and testing surveillance program as well as with its state partners.

Secretariat of Agriculture, Cattle, Rural Development and Food (Secretaría De Agricultura, Ganadería, Desarrollo Rural, Pesca Y Alimentación, SAGARPA). The National service of food hygiene, safety and quality (Servicio Nacional De Sanidad Inocuidad Y Calidad Agroalimentaria, SENASICA) is part of SAGARPA. SENASICA is the agency with oversight for imported feed and food of plant and animal origin. The agency works in collaboration with other secretariats of the federal and state government, congress, and other private groups that are concerned with agricultural, water and cattle goods to develop regulations. SENASICA’s responsibilities include:

- Ensuring the sanitation of local agricultural, water, aquaculture, fishery and cattle goods
- Overseeing organic food production and regulating pesticides for agricultural goods
- Passing regulations that lower the risk of food and animal feed contamination
- Through basic guidelines for food safety, facilitating national and international trade of vegetable and animal goods.

(SAGARPA 2010)

SENASICA also builds guidelines and publishes manuals to reiterate agricultural, water (including fishery) and cattle good safety practices. Most of these are based on the system of contamination risk reduction (sistema de reducción de riesgos de contaminación). (Mexico, 2011)

Directorates within SENASICA include:

- The General Directorate of Vegetable Sanitation (DGSV, Dirección General de Sanidad Vegetal) which has responsibility for regulating the entry of certain product codes and classifications (all of which relate to food).
SENASICA also has committees for the following areas:

- Plant Health
- Animal Health
- Food Safety
- Inspection process for ports of entry

(SENASICA, 2011)

General Directorate of Agricultural, Aquacultural and Fishery food safety (Dirección General de Inocuidad Agroalimentaria, Acuícola y Pesquera, DGIAAP). The DGIAAP has the authority to implement and develop norms regarding the “System of Contamination Risk Reduction” (Sistema de Reducción de Riesgos de Contaminación) as well as the basis for equivalency and other international agreements. (Mexico, 2011)

Customs. Customs is the primary check of goods coming into Mexico; reviewing paperwork from importers which attests to the quality of products under that country’s competent authority. COFEPRIS and SENASICA also rely on Customs to hold, re-export or destroy if and when violative products are found. (COFEPRIS, 2011)

Secretariat of Economy (Secretaría de Economía, ECONOMIA). Mexico’s Secretariat of the Economy (ECONOMIA) through its subunit, The Federal Consumer Protection Agency (PROFECO) is in charge of ensuring the quality of goods sold in Mexico that are for personal use. Thus, all regulations that relate to human health and food safety developed by federal agencies in their respective jurisdictions must go through ECONOMIA for publication. The regulations are referred to as NOMs (Norma Oficial Mexicana, Official Mexican Norm) (ECONOMIA, 2011). The Mexican Bureau of Standards (DGN, Dirección General de Normas) is the subunit of ECONOMIA that processes and publishes NOMs.

States. Mexican states each have their own authorities for health risk. Through cooperative agreements, COFEPRIS delegates certain food safety authorities and responsibilities to each state. These signed agreements between the States and COFEPRIS explicitly define the duties of each party regarding health risks. SAGARPA, the secretariat under which SENASICA functions, also coordinates with state government officials and other supporting bodies to support the proper functioning of food safety and sanitation programs. There is, however, no participation of state government in the federal level with SENASICA. (COFEPRIS, 2011; SENASICA, 2011)

1.2 Agencies Responsible For Animal Feed And/Or Pet Foods

SENASICA is responsible for overseeing imported animal feed (SAGARPA, 2010). Until 2009, the SENASICA surveillance program only focused on sampling products used for human
consumption, but they are now also considering some plants and plant-based animal feeds (SENASICA, 2011).

1.3 Food Importation Process Steps And The Government Units That Oversee Each Step

Products intended for import are categorized as falling under the jurisdiction on SENASICA or COFEPRIS. COFEPRIS and SENASICA both have distinct, yet closely related, responsibilities for imported food and feed products. COFEPRIS oversees imported food for humans and focuses on public health issues. SENASICA focuses on plant and animal imports, including animal feed. Imported foods fall under the jurisdiction of COFEPRIS or SENASICA depending on the composition of the product and its end use. Below, the steps in the import processes for each of these agencies are described.

COFEPRIS

Import Procedures/Process for foods falling under the jurisdiction of COFEPRIS include:

- Importer submits application to import product via mail/fax.
  - The application attests to the safety of the product/meets Mexican hygiene or other standards
- The products listed in the application (by tariff number) indicate whether importers will fall under the jurisdiction of COFEPRIS or SENASICA
- Importers having products that fall under the jurisdiction of COFEPRIS are registered with COFEPRIS
  - The sanitary history of each producer is also maintained in this registry
- The importer must submit a request for an import permit
  - Permits may be awarded by COFEPRIS as well as 12 states within Mexico that have agreements regarding import permits with COFEPRIS
- The permit application informs COFEPRIS of the company’s history (e.g. product compliance), and this allows the agency to then refer the product to one of the following types of sampling:
  - Sample and release: where the product sample is taken, and the product is released before testing results are known
  - Sample and hold: where products are held during analysis so that they may be seized if they do not comply with regulations
  - Sampling without restriction
- Importers are required to hire a customs expert or agent to aid them in the import process. The agent is supposed to help the importer with the proper documentation based on the sector requirements for the imported good. (Mexico Federal Government, 2011d).
- When the product arrives at the border, Customs checks the products, along with any associated documentation such as import permits. Customs is the primary check of
goods coming into Mexico; checking paperwork from countries of origin which attests to the quality of products under that country’s competent authority.

(COFEPRIS, 2011)

**SENASICA**

SENASICA’s import program began as a voluntary program and pieces of it are becoming mandatory, as the market allows (e.g. equivalence for animal origin foods and feeds). The general guidelines for the Operation and Certification of the *Systems of Contamination Risk Reduction* (Sistema de Reducción de Riesgos de Contaminación), a forthcoming regulation, are intended to make some of the voluntary components of the import program mandatory. Details about this new regulation are forthcoming.

(SENASICA, 2011 and Mexico, 2011)

1.4 Assistance, Cooperation Or Contributions From Other Government Bodies (National Or Local) In The Imported Food And Feed Process

At the national level, Customs and ECONOMIA as well as a number of states work with COFEPRIS in the imported food and feed process (See Section 1.3).

1.5 Laws And Regulations That Provide Authority For The Oversight Of The Safety Of Imported Foods And Animal Feed, And The Policies And Procedures That Guide Import Officials

*The Law on Federal Agencies and Their Duties (Ley orgánica de la administración pública federal)*

- Makes the Secretariat of Agriculture responsible for elaborating federal norms that ensure animal and vegetable safety; organizing and encouraging investigations on various food items; establishing institutes for experimentation and laboratories that allow for testing; proposing policies in regard to international food trade (SFP, 2011a).

- Gives the Secretariat of Health (SALUD) the power to oversee food imports when they relate to human health. Makes SALUD responsible for ensuring that the food imports are managed in a hygienic manner when they relate to human health and overseeing the General Health Law (Ley General de salud) (SFP, 2011b). A decree by Secretariat of Health delegates these responsibilities to its subunit, COFEPRIS (SALUD, 2011a).

- It delegates the Secretariat of the Economy, ECONOMIA, with the task of coming up with general policies for international commerce, studying and establishing restrictions on imported and exported items (including food items) in cooperation with the relevant agencies (SFP, 2011).

*The Federal Law of Metrology and Normalization* “gives authority to the competent Mexican ministries and agencies to establish regulations relating to the protection of human, animal and
plant health, and the environment. This law establishes the requirements for products, services, processes, raw materials, labeling, testing, packaging, facilities, and safety and hygiene, among others. In addition, it lays out the administrative procedures by which the regulations are developed and disseminated". (USDA, 2010)

*General Health Law* allows the Mexican Secretariat of Health (SALUD) to issue regulations related to the promotion and protection of human health. This includes the ability to authorize imports based on health risks. SALUD is also allowed to randomly sample and inspect imported products. These tasks, as mentioned previously, have been delegated to COFEPRIS (by this law and by the decree previously mentioned). (Federal Government, 2010)

*The System of Contamination Risk Reduction (Sistema de reducción de riesgos SRRC)* is a forthcoming set of guidelines regarding ways to maintain sanitary conditions and food safety. The guidelines will make voluntary aspects of the food safety program mandatory, and will be supported by federal legislation regarding food safety, like the Federal Law of Vegetable Sanitation, the Federal Law of Animal Health and the General Law of Fishery and Aquaculture. (Mexico, 2011)

*The Federal Law on Animal Health* gives the Secretariat of Agriculture (SAGARPA) the authority to pass regulations that lower the risk of food and animal feed contamination, and create guidelines that aid national and international trade of goods derived from animals (Federal Government, 2007). The enforcement of this law involves aspects of good practices (including SRRC) and traceability matters (Mexico, 2011).

*The Federal Law on Vegetable and Plant Health (Ley Federal the Sanidad Vegetal)* gives SAGARPA de authority to require Phytosanitary Certificates for imports as they see fit based on risk and to develop specific requirements for different plant product imports (Federal Government, 2007a). The rule includes national regulations in the matter of food safety (including SRRC) among what are considered good agricultural practices (Mexico, 2011)

### 1.6 Handling Of Products Transshipped Through A Third Country As Compared To Directly Imported Products

The importer requesting a waiver must supply all relevant information concerning the food and its country of origin for COFEPRIS review. For animal origin equivalence and export certification agreements, only approved/registered producers may export to Mexico.

### 2 INSPECTION PROGRAMS

#### 2.1 Mechanisms To Prioritize Food/Feed Import Surveillance Activities Such As Product Sampling And Testing, Inspections At The Border, And Facility Inspections Of The Exporting Country

At the national level, imported foods are classified according to product categories which have associated potential hazards (e.g. chemical, microbiological). Each category of imported products has a NOM specifying product risk levels and the procedures required to ensure the safety of the product when imported (SAGARPA, 1995). An analytical framework has been
established for the different classifications of food groups, and national laboratories establish the allowed contaminant levels according to regulation (COFEPRIS, 2011).

COFEPRIS conducts random inspections and as well as surveillance sampling and testing. Imported products identified as hazardous within federal regulations are termed high risk and receive the most scrutiny in terms of inspections and sampling. Annual sampling covers standard products, and remains relatively similar from year to year. New foods may be added to the sampling plan as product issues/concerns arise. (COFEPRIS, 2011)

SENASICA performs contaminant and residue monitoring for animal, agriculture and aquaculture products. Both domestic and imported products are monitored, and imported products are not specifically targeted. (SENASICA, 2011)

2.2 Special Screening Requirements And Trading Partner Requirements Where Disease Or An Outbreak Has Occurred

NOM-006-FITO-1995 gives SAGARPA the duty of creating an “Official Emergency Norm” in case of a change in the conditions of a country (i.e. outbreak or disease). A NOM of this sort might forbid imports from the country or cancel a phytosanitary requirement. Under such circumstances SAGARPA is allowed to enforce the new regulation even before it has been published, to avoid any kind of exposure (SAGARPA, 1995). Emergency NOMs are legal for a maximum of 6 months, after which they stop being applicable. (SAGARPA, 2011c)

SENASICA previously dealt with BSE risk by:

- Regulating the slaughter of animals
- Avoiding the use of meat meals
- Sampling cattle producers

SENASICA stated that no BSE has been found to date in Mexico. (SENASICA, 2011)

2.3 Percentage Of Imported Food Shipments Examined And The Relationship Between Risk-Ranking Of Foods And Volume Of Imported Foods Examined

Documentation for all imported products is reviewed by Customs when goods arrive at the Mexican border. While the overall percentage of imported goods sampled or tested is unknown, Mexican officials provided the following statistics:

- Approximately 90,000 imported products, foods, and other consumer products such as perfume, under the jurisdiction of COFEPRIS are received by the Commission
- Approximately 20,000 imported products under the jurisdiction of COFEPRIS are sampled at the state level
- Sampling volumes for products under the jurisdiction of SENASICA include:
  - Agricultural goods-700 samples
  - Shrimp- 300 samples
– Honey - 300 samples
– Organic Goods - 30 samples

COFEPRIS samples foods according to an analytical framework for the different risk classifications of food groups. Permissible contaminant levels for the classified food groups have been established by National laboratories according to regulation. It is not evident how SENASICA prioritizes the sampling of its imported goods. (COFEPRIS, 2011)

2.4 Types Of Review, Examination And/Or Testing Of Imported Products Performed By Food Safety Inspectors

Documentation attesting to the quality and content of imported goods is reviewed by Customs when foods arrive at the Mexican border. Sampling and testing of imported goods is also performed by SENASICA and COFEPRIS (See also Section 2.3). (COFEPRIS, 2011; SENASICA, 2011)

Documentation is reviewed by Customs for all imported food while the frequency of analytical examinations is much lower (See Section 2.3 for sampling volumes).

2.5 Types Of Examination And Testing Processes Used For Ensuring Animal Feed And Feed Ingredient Safety

Types of testing and examination for animal feed and feed ingredients were not made evident through interviews or public information.

2.6 The dependence of examination and testing requirements on conditions (such as the presence of BSE or other zoonotic diseases) in the exporting country

COFEPRIS and SENASICA officials adjust their monitoring plans to emerging risk or health issues, including those resulting from country-specific conditions. (COFEPRIS, 2011; SENASICA, 2011)

2.7 Inspections Of Food Or Animal Feed Manufacturers Or Shippers In Other Countries (Including Selection Criteria And Frequency)

As of now, there have been four official inspections at the origin of products. These inspections included 19 American enterprises in vegetable production. (Mexico, 2011)

2.8 Notification System(S) To Directly Notify Foreign Governments When Foods Or Animal Feed Manufactured In Their Countries Are Found To Be Unsafe; And To Notify The Public When Imported Products Do Not Meet Safety Standards

COFEPRIS manages a national alert system, Rapid Alert, which is used to communicate issues pertaining to foodborne illness or contamination. COFEPRIS uses the Rapid Alert system to notify government officials and industry as well as the public and media. (COFEPRIS, 2011)
3 AUDITS AND CERTIFICATION

3.1 Assessing And Measuring The Effectiveness Of The Food/Feed Safety Import Program (E.G., Self Audits Of The Program, Public Health Outcomes, Surveillance Sampling Results, Number/Rates Of Refusals, Periodic Program Evaluations)

SENASICA has an external audit process as well as internal agency audits. The process of granting a certificate is done by specialists that are hired outside of SENASICA; however, SENASICA performs federal audits in which they inspect certified companies to oversee the work of the third-party agencies (Mexico 2011). Examples of SENASICA’s annual programmatic audits include Food Safety (2010) and Aquaculture (2009) programs. The Follow-up Commission to tracks SENASICA’s use of agency resources as well as for program evaluations that focus on different programs (e.g. food safety or agriculture) from year to year. (SENSICA, 2011)

3.2 Extent Of Reliance On Trading Partners’ Food Safety Programs To Ensure That Imported Foods Or Animal Feed Are Safe

SENASICA and COFEPRIS stated that equivalence and export certification affords benefits due to a reduction in risk that occurs before foods enter Mexico. Mexico is increasingly moving toward adding additional emphasis and reliance on the food safety programs of trading partners to ensure that imported foods and feed are safe. Documentation attesting to the quality and content of imported goods is reviewed by Customs when products enter the country. (COFEPRIS, 2011; SENASICA, 2011) See also Section 2.6.

3.3 Requirements For Food And/Or Animal Feed Export Certificates Issued By The Exporting Country’s Competent Authority, And Types Of Inspection Or Testing For Each

COFEPRIS operates three certificate programs for Mexican foods exported to the U.S. and EU (U.S. bivalve mollusks, EU fishery products, and red tide (HABs)). In the case of foods of animal origin, a health certificate is required as part of the documentation attesting to the quality and content of imported products that are reviewed by Customs.

Information on specific products requiring certification for importation into Mexico was not obtained through interviews, however, an example of Mexican certification requirements for U.S. imports found in publicly available information includes:

- Sanitary and Phytosanitary Certificates. To obtain this, an export certificate would be emitted by the pertinent food authority in the exporting country. (This applies to both food and feed)
- Free sale certificate. This certificate is emitted by any entity that is authorized to attest that a good is being sold freely in the exporting country.

(USDA, 2010)
3.4 Use Of ISO, Global Gap Or Other Assurance Systems And Confidence In The Assurance System(S) Utilized

COFEPRIS and SENASICA laboratories are accredited to the ISO 17025 standard. Third party laboratories must also be accredited under the same ISO standard (in addition to approval by the Secretariat of Health) (Mexico, 2011). COFEPRIS officials stated that third party laboratory data is valid to support enforcement, certification and or equivalence agreements. (COFEPRIS, 2011; SENASICA, 2011)

3.5 The Nature And Frequency Of Foreign Food Safety Systems Audits Performed

SENASICA did not include audits as part of its equivalence agreements, and COFEPRIS currently does not audit foreign food safety systems (COFEPRIS, 2011; SENASICA, 2011).

3.6 Equivalence Agreements Requiring Periodic Audits/Reevaluations Of Exporting Countries’ Food Safety Programs

Mexico does not currently have systems-based equivalence agreements with any other countries, but officials are developing a system for mutual recognition of systems between Mexico and countries such as the US, Canada, and countries in the EU (Mexico, 2011). Mexico does, however, have several equivalence measures with other countries based on certain products. For example, SENASICA has equivalence with USDA FSIS and other governments for the trade of meat and poultry. (SENASICA, 2011)

3.7 The Utilization Of Third-Parties (Within The Exporting Or Importing Country) To Carry Out Inspections And/Or Product Certification (Nature And Extent Of Programs) And Methods For Verifying The Adequacy And Reliability Of The Third Party Work

SENASICA utilizes auxiliary third party groups as information conduits for emergencies, news, and the implementation of new measures such as the system of contamination risk reduction. Their focus is mostly on best practices and preventive controls at point of production; promotion of food/feedstuffs. Their efforts also include:

- Re-evaluating the contaminant levels set by SENASICA
- Providing certification to producers
- Developing professional guidance for the Secretary of Agriculture as consultants.
- Performing audits to ensure implementation of Agency standards and policies
- Technical assistance and skill building as well as promotion of the requirements for risk reductions

(SENASICA, 2011)

Methods for verifying the adequacy and reliability of third party work were not gleaned from public information or interviews.
COFEPRIS does not employ third parties to carry out inspections or product certification (COFEPRIS, 2011).

3.8 Arrangements With Other Governments Relating To Imported Foods Or Animal Feed (Such As Memoranda Of Understanding, Mutual Recognition Agreements, Etc)

Currently, there is a Memorandum of Understanding between the United States and Mexico regarding cantaloupe melon. (Mexico, 2011)

3.9 Registration Or Licensing Of Firms That Import And/Or Export Foods Or Animal Feed To Your Country Or For Firms That Import Foods Or Animal Feed

Importers of goods under the jurisdiction of COFEPRIS are registered with the agency, as they must apply for an import permit for these products. The import application attests that the product meets Mexican hygiene or other standards and may include certification from competent authorities of the exporting country. (COFEPRIS, 2011)

3.10 Use Of Sampling Surveys Of Imported Foods/Feed (As Opposed To Targeting Specific Products/Producers For Inspections And/Or Testing) To Gather Information And Identify Trends And Potential Areas Of Difficulty

COFEPRIS conducts annual surveillance sampling and testing. Sampling strategy covers a list of risk products and remains relatively similar from year to year. New foods may be added to the sampling plan as product issues and concerns arise. SENASICA performs a similar contaminant and residue monitoring for animal and aquaculture products. (COFEPRIS, 2011; SENASICA, 2011)

3.11 “Good Practices” Programs For Foods/Feed Importers

SENASICA is trying to establish good practices with producers by working with them on voluntary food safety processes and criteria (SENASICA, 2011). COFEPRIS does not currently have a “good practices” program for food importers (COFEPRIS, 2011).

3.12 Description Of Import Program User Fees And Cost Recovery System

Information pertaining to user fees and cost recovery found in publically available information and discussed during site visits was limited. Known user fees include those charged to producers by COFEPRIS for export certification (COFEPRIS, 2011).

3.13 Incentives To Increase Industry Involvement In Ensuring That Imported Foods Meet Safety Standards

Incentives to increase industry involvement in ensuring imported food safety standards were not uncovered through publically available information or country interviews. SENASICA, for example, provides industry incentives through free training and work with auxiliary third parties (e.g. trade associations and producer groups), however, these programs are geared toward local food production rather than imports. (Mexico, 2011; SENASICA, 2011)
3.14 Obstacles To Industry Participation In Ensuring That Imported Foods Meet Safety Standards

Obstacles to industry participation were not found in publicly available information or noted during discussion with country officials.

4 LABORATORY SUPPORT

4.1 The Role Of Laboratories In Supporting The Imported Food And Feed Programs And Description Of Laboratory Capabilities

COFEPRIS and SENASICA both have their own laboratory resources, and all labs, including third party, are accredited using the ISO 17025 standard.

COFEPRIS

COFEPRIS utilizes the following types of laboratories for research and analysis:

- Federal-COFEPRIS
- State
- University/research center
- Third party

Analytical laboratories are accredited by EMA in Mexico. Officials commented that certain third party laboratories contribute increased efficiency and advanced technological capabilities that offer certain benefits to industry. In addition to accreditation, third party laboratories are audited for national laboratory norms so that they can be utilized as an extension of the federal authorities.

State laboratories perform sanitary surveillance, sampling/testing, and research activities. State laboratories are equipped for microbiological and chemical testing, but not all labs share the same range of tests or physical testing capabilities. Some states utilize regional laboratories, or submit tests to a reference laboratory.

(COFEPRIS, 2011)

SENASICA

SENASICA conducts laboratory testing at producer, auxiliary, and federal levels. Laboratory samples may be analyzed in SENASICA-approved laboratories accredited by EMA and audited by SENASICA or performed in the national center under the CENAPA lab network. CENAPA is the network of “reference laboratories” that SENASICA delegates for quality assurance in food health and hygiene matters. (SAGARPA, 2011)

Private, accredited labs do not receive federal funding. For example, EMA (a private Mexican accreditation authority) charges private labs for accreditation services. (SENASICA, 2011)
5  ENFORCEMENT AT BORDER

5.1 Approach To Visual Inspections And Analysis Of Imported Foods (E.G. Risk-Assessment And Prioritization Schemes, Documentation Review, Sample Collection)

All imported foods undergo a documentation review by Customs when they arrive at the Mexican border. Sampling occurs after products enter Mexico in accordance to agency sampling plans (See response 2.3).

Public information also indicates that SAGARPA is in charge of risk assessment. Several products have already been analyzed and have an established “risk level” along with a coinciding set of phytosanitary requirements that must be met in order to import the product. These requirements are provided through product-specific NOMs. Products not falling under any of the current NOMs are subject to a “risk of plagues analysis” (análisis the riesgo de plagas). The analysis has three steps:

- Look at the product information provided by the importer and use previously collected products information that may be relevant as a resource.
- Evaluate the risk: levels of phytosanitary risk and protection from plagues are established on a product-specific basis,
- Manage the risk: Specific regulations are established to minimize the phytosanitary risk of the product.

(See also Section 2)

5.2 The Process That Occurs When An Imported Food Is Found To Be Contaminated Or Does Not Meet Standards

COFEPRIS and SENASICA rely on Customs to hold, re-export or destroy if and when violative products are found. Once in Mexico, SENASICA is responsible for food/feed at the point of production, COFEPRIS is responsible for food at the point of sales, and states oversee food safety and health risks using COFEPRIS regulations and policy under their own authority against health risks.

If SENASICA finds a product to be contaminated, the following steps are taken:

- The producer receives a specific plan to address the issue
- SENASICA implements its procedure for sanitary alert
- SENASICA communicates food safety concerns warranting public awareness to COFEPRIS, and COFEPRIS communicates these concerns to the public when appropriate.

(COFEPRIS, 2011; SENASICA, 2011)
5.2.1 **Procedures for Refusing Imported Foods Based on a Finding that they do not Comply with Requirements**

When a product does not fall under a NOM, and the analysis of risk is performed, SAGARPA and/or COFEPRIS can deny the entry of the product based on the information provided. The agency responsible for denying the product must provide a response to the interested party explaining the reason for refusal. The same procedure applies if the product is denied entry without an analysis of risk. (SAGARPA, 1995)

5.2.2 **The Procedure and Outcome for Imported Foods that are Refused Entry (Including Efforts to Prevent them from Mistakenly Entering Domestic Commerce)**

COFEPRIS and SENASICA rely on Customs to hold, re-export or destroy if and when violative products are found (COFEPRIS, 2011).

5.2.3 **Entry of Detained Products Based on Further Testing or Reconditioning of the Product**

It is not clear whether food products may be allowed entry after further testing or reconditioning.

5.2.4 **Process for Identifying and Tracking Producers or Countries that have Repeated Violations**

COFEPRIS does not have a list of producers but maintains the sanitary history of producers in its importer registry (COFEPRIS, 2011).

5.2.5 **Detailed Description of Enforcement Scheme for Refused Foods**

A detailed enforcement scheme for refused foods was not indicated in interviews or publically available information.

5.3 **Program For Investigating And Responding To Intentional Contamination Of Foods**

Although COFEPRIS officials acknowledge the possible production of fraudulent goods, they stated that intentional contamination is not of significant risk to warrant or outweigh current food safety risks and priorities. No program pertaining to the intentional contamination of food currently exists. (COFEPRIS, 2011)

6 **FOOD RELATED ILLNESS OUTBREAKS**

6.1 **System For Tracking Imported Foods Once They Are Cleared At The Point Of Entry**

COFEPRIS and SENASICA require food and feed producers to have records showing food shipment and receipt one step forward and one step back (COFEPRIS, 2011; SENASICA, 2011).
6.2 Systems For Identifying Foodborne Illness Outbreaks

When an outbreak occurs within a single state, the incident is dealt with by that state’s public health authorities. COFEPRIS provides follow-up for these outbreaks to make sure that this outbreak is controlled by the state. If the outbreak or contamination is more widespread (e.g. involving multiple states), COFEPRIS asserts oversight and control of the incident. (COFEPRIS, 2011)

COFEPRIS notifies SENASICA if the product in question falls under their jurisdiction. COFEPRIS also notifies colleagues in public health and may conduct public awareness communication regarding the issue. (COFEPRIS, 2011)

SENASICA may:

- Notify the producer and applicable state of the issue
- Inspect the producer of the product involved in the outbreak to help ensure safety of the product
- Inform the producer of what they must do to correct the problem
- Issue a report via research center and/or third party specialists that assesses whether or not the producer implemented the steps required by SENASICA to fix the problem

(SENASICA, 2011)

6.3 Procedure for Tracking illnesses back to the food source when a foodborne illness outbreak occurs

COFEPRIS and SENESICA rely on industry records to follow the suspect food one step forward and one step back. (COFEPRIS, 2011; SENASICA, 2011)

6.4 How Consumers Notify The Government And/Or Importers Of Food Problems

Consumers can find contact information for food-related issues as well as file complaints online via the COFEPRIS and SENASICA websites. Consumers can also contact their state food safety officials (COFEPRIS, 2011).

7 EXPORT PROGRAMS

7.1 Programs For Ensuring Safety Requirements Of Export Destination Countries

COFEPRIS and SENASICA provide certification attesting to plant or animal health for exported goods (COFEPRIS, 2011; SENASICA, 2011).

7.1.1 Use of Export Certificates to Provide Assurances to the Importing Country

COFEPRIS provides export certification for the following products:

- EU fishery products
- U.S. Bivalve mollusks
- Red Tide (HABs)

Eight states, through COFEPRIS administrative authority, can also issue export certificates. (COFEPRIS, 2011)

Currently SENASICA, in compliance with Federal legislation, emits a recognition of risk reduction systems for agricultural and cattle products (Mexico, 2011). SENASICA may also provide export certification attesting to plant or animal health for exported goods (SENASICA, 2011).

7.1.2 Providing to the Import Country Lists of Establishments that Meet the Importing Countries’ Food Safety Requirements.

List of establishments are not provided to importing countries (COFEPRIS, 2011).

7.1.3 Authorized Third Party Issuance of Export Certificates

Eight states are authorized by COFEPRIS to issue export certificates, however, details about the state entities issuing the certificates are not known (COFEPRIS, 2011).

8 WORLD TRADE ORGANIZATION (WTO) OBLIGATIONS

8.1 Methods For Ensuring Consistency Between Domestic And Imported Food Safety Requirements

COFEPRIS officials noted that Mexico applies sanitary measures and regulations equally for domestic and imported products (COFEPRIS, 2011).

8.2 Methods Of Documenting The Scientific Justification For Import Practices With Regard To Article 5 Of The SPS Agreement, Which Requires That Measures Are Based On An Assessment Of Risk, As Appropriate To The Circumstance

Details on this topic were not identified through interviews. Public information indicates that import restrictions are few and may be imposed when prior contamination history, based on laboratory testing, has not been remedied. COFEPRIS officials stated that this policy is consistent with SPS agreement (COFEPRIS, 2011).

8.3 Involvement In Article 4 Of The WTO SPS Agreement Regarding Equivalence Determination

SENASICA is required by law to recognize equivalence in other countries and also certify Mexican producers as being equivalent to the standards of these foreign countries. Equivalence measures with other countries are product-dependent rather than system equivalent. (SENASICA, 2011)
8.4 Process For Recognizing A Foreign Country’s Food Safety System As Having Adequate Regulatory Oversight

Information on this topic was not identified in public information or gleaned from discussions with country officials.
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OVERVIEW OF INTERVIEW AND FOOD AND FEED SAFETY SYSTEM

An interview with Netherlands food safety authority officials was conducted in Zwijndrecht on June 14, 2011, along with on-site visits to border inspection posts in Rotterdam.

The Netherlands food safety authority is called the VWA (Voedsel en Waren Autoriteit/Food and Consumer Products Safety Authority). As a member of the EU, the VWA is guided by EU regulations and policy to establish food and feed safety programs, including (but not primarily focused on) imported food and feed. For the most part, EU regulations focus on strict preventive controls for food and feed of animal origin, including seafood and shellfish, and to a lesser extent controls for non-animal origin food and feed since they are considered lower risk. Preventive controls used include HACCP, equivalence agreements, a surveillance and monitoring program, including random and mandatory inspection and testing, and export certification as outlined in national control plans.

VWA has, within its adherence to EU regulations, forged a unique streamlined and efficient food and consumer products oversight operation through its politically-driven merger of numerous food, feed and other consumer product organizations and personnel into a single agency. This merger will be completed in 2012. Further, through the development and enhancement of its VGC (veterinaire grens control/veterinary border control) interactive data system (initially built to support products of animal-origin but now expanded to cover all products), VWA has improved port operations significantly with a transparent and interactive process called the “one-window shopping operation”.

VWA, like all EU members, works directly with import agents who submit CVED/CED documentation for all imported food and feed shipments. Each EU member can designate the number of ports of entry/border inspections points for all food and feed shipments for their country. Further, corresponding to normal port operations coverage on a 24-hour basis is not required. For example, the VWA only provides staffing 5 days a week from 7 am to 10 pm in the port of Rotterdam.

The CED/CVED data are sent to the VGC system by customs agents, except for the hard copy original health certificate. The hard copy is scanned and linked to the electronic file. Dedicated, trained, and experienced customs officials perform the primary review of all CVED/CED submissions. After checking data compliance and document completeness, customs officials record the documentary check as satisfactory in the VGC system. Customs officials are working under responsibility of an official veterinarian of the VWA during performance of documentary checks. In case of an omission, documents are handed over to a VWA official veterinarian for review and release or further action. The VGC system is transparent and interactive in that it is accessible at every VWA-location and messages are sent automatically to import agents to apprise them of progress or data needed to satisfy the requirements.

The Netherlands requires VWA and third-party (including private and university) laboratories to be accredited per ISO 17025. While accredited third-party laboratories supply data in support of imported food requirements, VWA must confirm these test results through their own testing
before deciding on the shipment’s status. VWA noted that this approach is not EU-wide (e.g., Belgium uses only third party labs for all testing).

Within the EU, each member is subject to Food and Veterinary Office (FVO) audits and reviews of its National Control plan performance and adherence to EU regulations. Further, the Netherlands is continually reviewing and pilot-testing innovations to improve its operations and performance. To this end, the VWA has established an informal network of approximately 8 to 10 EU port government officials to share best practices and improve communications for emerging issues. For example, when a port recognizes that a “bad actor” is port shopping, an alert is issued so all network ports are aware and take appropriate measures. This work-around the EU RASFF (Rapid Alert System for Food and Feed) system was developed because RASFF has not been sufficiently responsive to such information sharing needs.

EU risk management and policy have for the most part focused on animal-origin products as higher risk and warranting stricter controls. Thus non-animal-origin products import procedures remain consistent with CED submission but have fewer requirements. Additionally, the EU and the Netherlands have determined that intentional contamination of foods and feeds is not a significant enough risk to warrant specific import or domestic controls.

The Dutch system, within EU regulations, establishes equivalence and export certificates with competent authorities to further enhance its preventive controls plans. By working with these competent authorities, the burden is reduced to interacting with a select number of competent authorities rather than the multitude of exporters and food producers worldwide. When a problem occurs with an imported shipment, VWA works with a custom agent(s) and or competent authority only to seek a remedy. VWA has also used TRACES (Trade Control and Expert System), a single electronic database for monitoring the movement of animals and certain products of animal origin within the EU and from countries outside the EU, successfully to locate shipments/foods for recall.

Finally, VWA serves as a full partner to customs in the Netherlands port operations to ensure the safety of imported consumer products and offers an efficient and effective review system for importer agents and other competent authority trading partners.

1 ROLES AND FUNCTIONS OF AGENCIES RESPONSIBLE FOR IMPORTS OF HUMAN FOODS AND ANIMAL FEED

1.1 Governmental Ministries and Subunits (Including National/Regional/Local, as Appropriate) With Responsibility for Assuring the Safety of Imported Food

European Commission (EC)

Directorate General for Health and Consumers (DG-SANCO). The Netherlands is subject to the food safety legislation of the EU. The development and implementation of EU Food Safety Legislation is the responsibility of the Brussels-based Directorate General for Health and Consumers (DG-SANCO).
European Food Safety Authority (EFSA). In 2002, the EU created a new independent food safety institution, the European Food Safety Authority (EFSA). EFSA is responsible for providing independent scientific advice on all matters related to food and animal feed safety. They coordinate activities with regards to risk communication and evaluation and advise the EC with respect to food safety.

Food and Veterinary Office (FVO). The Food and Veterinary Office (FVO) of the EU has oversight responsibilities with regards to EU regulations and inspects activities of the competent authority for food safety in the Netherlands. In turn, the competent authority allows their experts to help FVO inspection in other member states and developing countries. The Netherlands has been inspected recently. In November 2009, import/transit controls and border inspection posts were inspected. In October/November 2009, controls on feed legislation were inspected. Import controls on food/feed legislation of non-animal origin were last inspected in May of 2006 (FVO, 2011). The last FVO inspection on veterinary import took place in March 2011 (VWA, 2011p).

European Center for Disease Control (ECDC). The mission of the European Center for Disease Control (ECDC) is to identify, assess, and communicate current and emerging threats to human health posed by infectious diseases. ECDC works in partnership with competent bodies in EU member countries. These competent bodies include institutions and scientific bodies that provide independent scientific and legal advice or capacity for action in the field of prevention and control of human disease. The competent bodies designated to this role in the Netherlands are the (ECDC, 2011):

- The Ministerie van Volksgezondheid, Welzijn, en Sport or in English, the Ministry of Health, Welfare, and Sport.
- Rijksinstituut voor Volksgezondheid en Milieu or in English, National Institute for Health and the Public Environment.

The Netherlands

Ministerie van Landbouw, Natuur, en Voedselkwaliteit (LNV). The Ministerie van Landbouw, Natuur en Volksgezondheid (LNV) translates to the Ministry of Agriculture, Nature, and Food Quality in English. In 2010, this Ministry was combined with the Ministry of Economic Affairs into the Ministry of Economic Affairs, Agriculture, and Innovation (In Dutch, Ministerie van Economische Zaken, Landbouw en Innovatie (EL&I)). It will take roughly two years for this merger to come to completion. This Ministry is responsible for policy setting and implementation and management of food safety legislation, including those of food imports and exports, through bodies such as the VWA (described below). (EC, 2007).

Ministerie van Volksgezondheid, Welzijn, en Sport (VWS). The Ministerie van Volksgezondheid, Welzijn en Sport (VWS), or in English, the Ministry of Public Health, Welfare and Sports, is responsible for the protection of consumer health. It also drafts food safety legislation together with the EL&I and VWA. It provides most of the VWA budget. (EC, 2007).
Ministerie van Financiën (MF). The Ministerie van Financiën (Ministry of Finance) Customs territory is divided into 9 regions with a national office in Rotterdam (since 2010). Customs officers are authorized to act as VWA personnel as part of their duties with respect to document control. (EC, 2007). This is based on an agreement between the Ministry of Finance and the Ministry of EL&I (VWA, 2011p).

Voedsel en Waren Autoriteit (VWA). The competent authority for food safety in the Netherlands is called the Voedsel en Waren Autoriteit (VWA) or, in English, the Food and Consumer Product Safety Authority. The VWA is a government agency commissioned by the VWS and EL&I. It is under administrative responsibility of the EL&I but performs executive functions for both ministries. The three main responsibilities of the VWA are supervision, risk assessment, and risk communication. It also provides incident and crisis management.

The VWA controls imports in four sections:

- Live animals
- Food products of animal origin (including meat, fish, wild and animal feed)
- Food products of non-animal origin (including vegetables, dried fruit, spices, nuts and seeds, and animal feed of plant-origin)
- Consumer products (including toys, Christmas lights, and electrical apparatus)

The VWA ensures compliance with relevant legislation and regulations. (EC, 2007).

Locations

The VWA is headquartered in Utrecht with four other offices in Zwijndrecht, Zwolle, Wageningen and Eindhoven. Support points are found in 10 other cities across the Netherlands. Utrecht currently manages the program for export certification. The import inspection units are located in Rotterdam Port, Amsterdam Port and Amsterdam Airport. Surveillance preparation and evaluation on import is located in Zwijndrecht in the province of South Holland and covers food imports and non-food product safety. The office in Wageningen covers feed and food safety. (EC, 2007; VWA, 2011p). They also have a laboratory in Wageningen.

The Division of Product Safety and Import/Export oversees safety requirements of the Commodities Act (“Warenwet”), Environmental Management Act (“Wet Milieubeheer”) and Crop Protection Products and Biocides Act (“Wet Gewasbeschermingsmiddelen en biociden aan consumentenproducten”). Thus this office also oversees the abidance with the law of imports animal feed, food, veterinary products, live animals and consumer products. Two divisions are involved, the Division Product Safety and Import/Export (PRIMEX) and the Management Division. Within PRIMEX Division, the Department of Surveillance Preparation and Evaluation, Team Import is responsible for training, development of guidance, and instructions. The technical administration of the Management Division is responsible for the daily planning of the inspection teams (EC, 2007). The import operations include roughly 100 FTEs, of which 85 are dedicated to products of animal origin (and 35 of the 85 FTEs are veterinarians). Another 10
FTEs are dedicated to products of non-animal origin, 10 FTEs cover legislation and planning, and 2 FTEs manage the VGC system (see below for a description) (VWA, 2011; VWA, 2011p).

Each division drafts annual inspection plans/protocols and provides research capabilities. Each also has enforcement, research and monitoring departments. Communication within the VWA is facilitated by ISI Intranet applications which contain lists of food establishments, data on inspection activities, inspection plans and protocols, and recommendations on sampling procedures. It also acts as a portal for disseminating new legislation (EC, 2007). VWA annual plans are drawn up on the basis of EL&I and VWS budgets and are available on the ISI Intranet. These are intended to support the National Control Plan.

**Fusion with PD and AID**

In 2012, the new VWA will fuse with the Plant Protection Service (Plantenziektendienst or PD) and the General Inspection Service (De Algemene Inspectiedienst or AID). The new name of the agency will be the Food and Consumer Product Safety Authority. This agency will be responsible for all foods and feeds and consumer items like irons, baby cribs, etc. This decision to merge responsibility for all foods and feeds is based on a 2007-2008 political decision (VWA, 2011). The Netherlands has worked to bring their national food safety laws in line with EU and is working on consolidating agencies to reduce overlap, improve coordination, and respond to public concern about dioxin contamination of animal feed, BSE, and other animal diseases and to bring food safety laws in line with EU requirements.

The operations of VWA at BIPs (including organizational charts) are laid out in the publicly available VWA handbook on this topic (VWA, 2011f). It is not clear, however, whether this will be the future organization when the merger is finalized in 2012. Other VWA handbooks that detail operations are available as well.

**Bureau Risicobeoordeling en onderzoeksprogrammering (BuRO)**

The Bureau Risicobeoordeling en onderzoeksprogrammering (BuRO), or in English, the Office of Risk Assessment and Research, is an advisory board of the EFSA and is part of the VWA. It provides advice to the EL&I and VWS about food and product safety, as well animal health and welfare.

**Participation in International Organizations**

The VWA also participates in the OIE (World Organization for Animal Health), Codex Alimentarius, WHO, and the FAO. Other network contacts are Prosafe (Product Safety Forum of Europe), FLEP (Food Law Enforcement Practitioners Forum) en coordination with European Food Authorities. They participate together in international projects and exchange colleagues (VWA, 2011d).

**Rijksinstituut voor Volksgezondheid en Milieu (RIVM)**. The Rijksinstituut voor Volksgezondheid en Milieu (RIVM), or in English, the National Institute for Public Health and the Environment, assists the VWA in developing food safety policy and conducts formal risk assessments.
(processed and ready-to-eat foods) for VWA (commissioned through VWA’s office of Risk Assessment), as well as a number of other inspection services and Dutch ministries (EC, 2007). It is unclear how much the RIVM contributes to policy and risk assessments associated with imports.

RIKILT Instituut voor Voedselveiligheid. The RIKILT Instituut voor Voedselveiligheid, or the Dutch Institute for Food Safety, is part of the University of Wageningen. They are a private research institute performing statutory tasks for the government and are primarily funded by the Ministry of Agriculture (EC, 2007). RIKILT is also a national reference laboratory (NRL), which is responsible for assuring the quality and reliability of the laboratories which carry out the official controls in a country within the framework of EU food and animal feed regulations. The task of an NRL is coordinating the activities of the national laboratories, standardizing analytical methods, developing new methods, and organizing comparative tests between laboratories. They also conduct risk analysis for feed and food quality (at the farm level). RIKILT monitors the safety and quality of food in the Netherlands and carries out high quality research on detection, identification, and functionality of substances in food. They investigate samples and are available 24 hours a day in case of a crisis. The Central Veterinary Institute (CVI) also assists this organization (RIKILT, 2011). It is unclear how much the RIKILT is involved with food imports.

Public and Private Boards/Bodies. The Netherlands also has semi-autonomous public/private bodies responsible for food safety. The Centraal Orgaan voor Kwaliteitsaangelegenheden in de Zuivel (COKZ), or in English, the Central Body for Dairy Quality, provides export certificates. Product boards exist for livestock meat and eggs, fish and fish products, animal feed, dairy produce, and horticulture (EC, 2007). Product boards are authorized by the government to formulate statutory rules for particular sectors (EC, 2007). The Dutch Fish Product Board has been designated as a Competent Authority to assist the VWA in carrying out tasks (EC, 2007). Also, the Raad voor Accreditatie (RvA), or the Dutch Accreditation Council, accredits laboratories (EC, 2007). It is unclear, however, how much involvement these organizations (other than COKZ) have with regards to food imports. Traderoute Asia is a website developed by the VWA and other agencies to help safely import from Asia. It is not clear, however, how prevalent its use is.

1.2 Agencies Responsible For Animal Feed and/or Pet Foods

The VWA has the responsibility for animal feed and pet foods, along with support from the other agencies listed above. The Industry Division of VWA has the responsibility for animal feed but coordinates with support of the other agencies listed above.

According to a 2009 FVO inspection report, significant changes in the organization of official controls on imported feed (and products of non-animal origin) are expected in 2010 as a consequence of the implementation of EC 669/2009. According to VWA, only feed covered by the regulation would be subject to a prior notification while for other imported feed, a national list of high risk products could be drawn up. The modality and intensity of controls to be implemented on such feed was still being discussed at the time of the FVO inspection, in particular because of the possible financial implications for VWA (EC, 2009a). In 2010, VWA is expected to start implementing checks on ship manifests by means of a computerized system.
allowing queries to be run based on key words. However, these arrangements would only concern consignments of feed subject to EC 669/2009. (EC, 2009a)

1.3 Food Importation Process Steps and the Government Units That Oversee Each Step

As noted previously, the management of import controls is the responsibility of the Division of Product Safety and Import/Export of the VWA. The Netherlands has some of the largest ports in Europe. Rotterdam is the largest port and expanding and Schiphol is the third largest in the EU (VWA, 2011). The basis of all imports is the EU’s CVED (Common Veterinary Entry Document) and CED (Common Entry Document) and the Netherlands VGC system (VWA, 2011). CVEDs and CEDs are sent by the person responsible for the load (also called a customs agent) on behalf of the importer (VWA, 2011). Pre-arrival information in the form a manifest, while very helpful to start the pre-notification (CED/CVED) process for customs agents and VWA, it largely general in nature and only when CED/CVED specifics are known can an assessment be made (VWA, 2011).

The VGC system, unique to the VWA/Netherlands, is an automated integrated data system that includes electronic entry of the CVED/CED, the health certificate (the original has to be scanned), and automatic electronic updates to and from customs agents/government/veterinarians. The VGC is an interactive and open system. Customs agents and VWA staff can check registration of exporters without having to exit the VGC system to check another database. Staff can go to the VWA website, go to registered facilities/exporters and CVED/CEDs numbers can be verified with the database. Both customs agents and the public have access to view shipments in process. Only VWA and Customs in relevant ports have access to the VGC system by a log in under a personal account. Based on digital messages from the VGC system, custom agents can view consignments in their own system. The VGC is a two-way messaging system. When Part 1 of the CVED/CED is complete, a message is automatically sent to the agent. If a problem is found during Phase 1 (customs) or Phase 2 (VWA review) of the process, the system notifies the agent. The veterinarian and the customs agent can discuss “re-export”, where a product may be changed to pet food or something other than human food. VGC is real-time, so all data is current and cached on daily and weekly basis (VWA, 2011; VWA, 2011p).

For animal-based products, the EU still requires an original health certificate, so the process is not entirely automated. Custom agents, who are private individuals representing importers, must deliver by mail, in person, or courier the original health certificate to one of the 7 Border Inspection Posts (BIPs) within the Netherlands. The VWA then scans the original health certificate to merge into the VGC data system but the original must remain part of the official record (VWA, 2011).

By 2012, the new VWA will emerge, finalizing the fusion of previously disparate groups. This will also mean that non-veterinary foods and feeds will have adopted the VGC system to work with the CED and other operations (VWA, 2011). The module for food is already implemented in the VGC system since 2010. The import processes, separated by whether the food and animal feed is from non-animal origin or animal origin, is detailed further below.
Types of checks on food and feed of animal origin

As noted above, imports of veterinary (animal) products come in via BIPs (Jeuring, 2010). SIPs (subinspectionposts, the establishments where identity and physical checks are performed, usually coldstores) are also used and lie within the BIP (VWA, 2011p). BIPs and SIPs must fulfill requirements concerning equipment, infrastructure, and facilities in accordance with Decision EC/2001/812 and Directive EC/97/78 (VWA, 2011).

There are seven BIPs:

- Amsterdam (Schiphol airport)
- Amsterdam (harbor)
- Eemshaven (harbor)
- Harlingen (harbor)
- Maastricht (airport in Beek)
- Rotterdam (harbor)
- Vlissingen (harbor)

The border controls are based on guarantees by veterinary authorities in the country of origin (VWA, 2011). There are 1 to 4 inspection centers at each post. Checks have to be carried out at these entry points (VWA, 2011). If a shipment is destined for a third country, and does not fulfill public health requirements, it can be stored at an approved free warehouse for nonconforming consignments.

To send CVED’s electronically to the VGC system, customs agents need permission from the competent authority (VWA). The VGC-system is a part of the CLIENT-program (Controle op Landbouwgoederen by Import en Export naar een Nieuwe Toekomst or Control on Agricultural Products with Imports and Exports for a New Future), which was initiated by the Ministry of LNV. (VWA, 2011p)

The pre-arrival process is started when shipping lines send the manifest to customs as the summary declaration (mandatory, based on customs legislation). The pre-notification for veterinary shipments starts when the customs agent fill in Part I (details of the consignment) of a document called a Gemeenschappelijk Veterinair Document van Binnenkomst (GVDB) in Dutch, or a Common Veterinary Entry Document (CVED) in English, at least before arrival (Jeuring, 2010; VWA, 2011p). The CVED is laid down in the annex of Regulation (EC) 136/2004. This CVED part I is sent as an electronic message from the company system of the agent. In return, the VGC system sends a consent number (GDB number) and the number of the container(s) to be checked at the BIP (VWA, 2011; VWA, 2011p). Messages about reduced checks (discussed below) are also included if applicable (VWA, 2011). Upon receipt of this number, the importer sends the health certificate to customs, for documentary check. (VWA,
The competent authority in the Netherlands (VWA) fills in part II of the CVED after completion of the documentary, identity, and physical checks. When the results of the checks are satisfactory, the official veterinarian makes a decision on the shipment. The completed CVED is printed from the VGC system and is signed and stamped by the veterinarian (VWA, 2011). In case of a laboratory check, detention of the consignment, or rejection, the system can print standard forms (VWA, 2011). A competent authority along the route or at the destination verifies the information by filling in part III (monitoring), only when channeling procedures are applicable. All the competent authorities can see all the information in the European system TRACES because all CVED’s are entered in this system (VWA, 2011). Once completed and the product is granted access to the EU by completing part II, the document will continue travel with the shipment (Jeuring, 2010).

Every shipment with product of animal origin requires documentary checks (“document controle” or D-control) and identity checks (“overeenstemmings controle” or O-control). Seafood and shellfish shipments are considered products of animal origin (VWA, 2011). The documentary check is done by customs and includes checking Part I of the CVED (if the veterinary certificate is an original and fully completed, if it meets EU requirements, if it is signed by a veterinary authority and if it comes from an authorized country and approved establishment). The identity check is when the shipment is checked to make sure it agrees with the information on the veterinary document, including the container number, country of origin, product description, and codes and numbers on the shipment and of the producers. Specific requirements regarding labeling might also be applicable (VWA, 2011). This is done for all shipments by the VWA for import in the EU as well as those that go on in transit to other (third) countries (non-conforming consignments). The physical check (“materiaal controle” or M-control) might include opening of packages, organoleptic control, temperature control if refrigerated or frozen, and laboratory sampling. Physical checks are based on EU risk assessment. The VWA veterinary doctor will make a final decision based on the results of the control. Once permitted, the product is available to the entire EU. Physical checks are only performed for shipments that are destined for the EU (VWA, 2011).

When all tests and checks are satisfactory, the consignment is issued a CVED and is placed on the EU market. If a consignment does not comply with EU requirements, it may be rejected. In these cases, EU officials negotiate with the customs agent of the consignment and the country of dispatch about whether to destroy the product, to retreat it for uses other than the human food chain, or to return it. Product can be temporarily detained in an inspection center or at a container terminal within the BIP (under customs supervision) and can be released in case of rectification. Food or feed business operators or their representatives are responsible for the consignment and are liable for any costs incurred by the competent authorities to destroy or redispacth it. (VWA, 2011)

Through the VGC system, the customs agent is kept up to date as to the controls are being completed on a shipment. Electronic exchange occurs through “Digipoort”, the electronic mailbox of the government. Software can be purchased or a third party can be used to connect to Digipoort. The messages are sent in the form of EDIFACT, as described in the Message Implementation Guide (MIG) of the VWA. VWA is working on possibilities for receiving certificates in XML format (in cooperation with third countries involved) (VWA, 2011).
notifications (CVED part I) can still be used but parties are charged for the time to convert these to electronic forms. (VWA, 2011a)

There exists a decision tree for which products of animal origin need to be checked at the BIP. This is especially applicable on composite products. All products, subject to veterinary checks at the EU border are laid down in Decision 2007/275/EC, based on CN-codes (VWA, 2011p).

Based on Decision 94/360/EC reduced checks can be applied on specific products from specific third countries. Some countries, such as New Zealand and Canada, are also subject to highly reduced checks when the EU has set up agreements with them (VWA, 2011h).

Importers can learn more about requirements by utilizing a public online information database called Import Veterinair Online (IVO). IVO provides information on what exactly will be required for D-, O-, and M-control after entering information about the product and country of origin. It also informs the importer why the product cannot be imported. It is kept up to date daily by the VWA import team of the Department Surveillance Preparation and Evaluation and has reduced the number of questions about imports. IVO also simplifies the documentary check and makes import information easy to access (VWA, 2011).

The VWA charges fees for the controls at the BIP, as do the inspection centers. Fees depend on the time of day that the inspection is done as well as the weight and the type of product. Additional inspections are charged on a 15 minute basis, in addition to a flat fee (VWA, 2011).

**Types of checks on food and feed of non-animal origin**

Foods of non-animal origin generally do not require a health certificate, but like foods of animal origin, they must comply with all relevant EU legislation such as that covering labeling, additives, flavoring, pesticides, and contaminants. An importer first has to request a registration number using a PDF registration form that has to be sent in. Once received, a pre-notification of shipment can be submitted electronically via the CLIENT import system. This is only obligatory for consignments of food and feed (not of animal origin) considered to be of high risk according to EU legislation (EC669/2009). If animal-based food or feed is also submitted, this step can be omitted and the electronic request as described above for animal-derived products can be used to do preliminary reporting of the non-animal food and feed items as well.

The pre-arrival information is provided electronically to the VWA so they can determine what additional checks they will do based on feedback from their automated system. Consignors can create a certificate for export to the EU by filling in part I of the CED. The competent authority at the place of origin validates or rejects part II. Each stage triggers a notification to all those involved.

Designated non-animal products are subject to documentary checks (done by customs), identity checks (done randomly on a portion of products that require document control, done by VWA) and material checks (sampling done by VWA on products designated by EU according to EC669/2009, and special EC decisions, such as EC 504/2006, as well as the Netherlands
National Control Plan, based on risk). The VWA analyzes samples in their own laboratories (VWA, 2011).

Products of non-animal origin under EC669/2009 come into designated ports of entry (DPE). There are 21 DPEs in the Netherland. These DPEs voluntarily designate themselves as control locations but have to conform to Article 4 of EC 669/2009.

For products not on under EC 669/2009, the frequency of identity and physical checks of products is based on the National Control Plan (EC 884/2004, Article 15.1), which are derived on the basis of:

- The risks associated with different types of feed and food;
- The history of compliance with the requirements for the product concerned of the third country and establishment of origin and of the feed or food business operators importing and exporting the product.
- The controls that the feed or food business operator importing the product has carried out;
- The guarantees that the competent authority of the third country of origin has given (EC 882/2004)

1.4 Assistance, Cooperation or Contributions from Other Government Bodies (National or Local) in the Imported Food and Feed Process

At the BIPs and DPEs, the VWA works together with Dutch customs that carry out documentary checks on imports. Customs agents cross-check the pre-arrival manifest and the CED/CVED. VWA conducts identity and physical checks independently. The VWA, however, is responsible for the entire procedure. (VWA, 2011)

The philosophy behind the partnership with Dutch customs is that the interaction with importers should be seamless (customs is specialized in dealing with documents, clearances and border formalities). VWA operation hours match those of the port customs that usually work weekdays from 8 am to 6 pm to conduct documentary reviews. At BIPs, there are 2 shifts of personnel covering 7 am to 10 pm. If importers were to extend operation hours, then the VWA would also extend their hours of to support port operations (VWA, 2011).

It was noted during the interview with VWA, that VWA and Dutch customs take great pride in the operation of Rotterdam port. VWA partners with Rotterdam port operators to conduct high quality business. VWA is receptive and flexible in its oversight/management operations and is willing to extend hours and redirect staff as needed. Further, VWA is always looking for ways to improve operations within EU regulations/mandates. In Rotterdam, customs and VWA are in the same office space. Customs are dedicated to document checks and then register the results in the VGC system. Customs does not charge VWA for their services. They have been trained by VWA for over 15 years and are considered experts in the field and equivalent to VWA experts/reviewers, albeit without veterinary degrees. This partnership allows VWA to maintain
highly efficient and effective operations despite a growing number of imported food and feed. (VWA, 2011). VWA Import division has put itself under ISO 17020 (as an accredited Inspection Service) and has been approved since 2005 (VWA, 2011p).

The VGC is an automated border control system that notifies VWA of incoming shipments. As described above, the process for this system is that the sender sends in a pre-notification (CVED part I). The sender then gets an identification number (CVED number) by a message to send the health certificate along with the results of the sampling and analysis in the country of origin, if required, to customs. Once the health certificate is received, the customs agent can check it off if it conforms, and see if other checks are necessary or if the product can be provided entry, with acceptance sent back through the automated system to the importer. If identity checks are necessary, that is completed before physical examination. The systems are slightly different depending on if the product is animal-based or not, as described earlier. The percent of product to be checked is available automatically in the automated system and is based on EU regulations and the National Control Plan. If a product does not conform then it is taken into custody.

1.5 Laws and Regulations that Provide Authority for the Oversight of the Safety of Imported Foods and Animal Feed, and the Policies and Procedures that Guide Import Officials

EU legislation is made up of Directives, Decisions and Regulations which must be translated into the 23 official languages in use in the EU-27. Directives define the result that must be achieved but leave to each Member State the choice of form and methods to transpose the directive into national laws (usually within 2-3 years after adoption) (USDA-FAS, 2009).

The European Commission (EC) is the administrative, implementing, and enforcement body of the EU. They test the performance of member states’ control capacities through audits and inspections. According to EU sources, the primary law laying out the regulatory framework for food safety in the EU is the General Food Law of 2002. Subsequent legislation merged, harmonized, and simplified detailed and complex hygiene requirements previously contained in 17 directives covering the hygiene of foodstuffs and the production and marketing of products of animal origin (GAO, 2008).

EU relevant rules for products of animal origin are (may not be exhaustive) (GAO, 2008):

- EC 136/2004, laying down procedures for veterinary checks at community border inspection posts on products imported from third countries (includes copy of the CVED, or Common Veterinary Entry Document).
- EC 882/2004, on official import controls performed to ensure the verification of compliance with feed and food law.
- EC 852/2004, covers general rules for food business operators on the hygiene of all foodstuffs

EC 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

EC 178/2002, the general food law.

EC 2002/99, covers general animal health rules and the introduction from non-EU countries products of animal origin intended for human consumption. Aim is to prevent spread of animal diseases.

EC 97/78, covers the principles governing the organization of veterinary checks on products of animal origin entering the EU from third countries.

EU relevant rules for non-animal products are (this list does not include specific rule, such as EC 289/2008 on GMO rice from the U.S. or EC 388/2008 on sunflower oil from the Ukraine, and may not be exhaustive) (VWA, 2011j):

- EC 433/2011, the most recent amendment to EC 669/2009.
- EC 1152/2009, describes which products have to be reported with a CED outside the borders of an EU country (covers aflatoxin contamination).
- EC 669/2009, lists products requiring additional controls, including those that have to be checked outside the borders (also includes a copy of the required CED).
- EC 882/2004, on official import controls performed to ensure the verification of compliance with feed and food law.
- EC 178/2002, the general food law.

EU relevant rule for animal feed is (may not be exhaustive) EC 183/2005, the EC feed hygiene regulation.

What and how products are controlled is determined by the National Control Plan (EC 882/2004, Article 15.1.), which is based on risk. The EU uses known or new risks to develop a list of products that that require additional controls (EC 882/2004, Article 15.5 and EC 669/2009). Sometimes specific regulations are developed too if greater control is required for some products (aflatoxins).

The EC regulations are executed in the Dutch “Warenwet” (Commodities law) and “Kaderwet dierenvoeders” (Animal feed law). There are many components to these laws, with many revisions over time that are complicated to track.

Work at BIPs, specifically, is covered by the following Dutch laws (VWA, 2011f):
In their regulations, the EC also emphasizes the importance of being able to trace food “one step forward and one step back” to quickly track any questionable food products. Each food and feed business operator must be able to identify its suppliers and which businesses it supplied. Specifically, the operator must be able to document the names and addresses of the suppliers and customers, as well as the nature of the product and date of delivery. The operators are also encouraged to keep information on the volume and quantity of a product; the batch number, if there is one; and a more detailed description of the product, such as whether it is raw or processed. Food and feed business operators must also have systems and procedures that allow them to provide this information to the competent authorities on demand. There exists a farm to table approach. Producers have primary responsibility with government bodies providing oversight. Exporters in trading partner countries are not required to fulfill the EU’s traceability requirement, except in circumstances where there are special bilateral agreements for certain sensitive sectors or where there are specific EU requirements, such as in the veterinary sector. However, these traceability requirements pertain to EU importers, who should be able to identify their direct supplier in the non-EU country. (GAO, 2008).

According to EU sources, the EU’s traceability system proved useful during an incident that took place in 2004. During standard random monitoring of dioxin levels in milk at a Dutch farm, the national competent authorities found a high level of dioxin. EU sources noted that the competent authorities immediately barred the farm from trade and began tracing the product through the food chain. They found that the source of contamination was clay, used in food processing to separate higher-quality potatoes from lower-quality ones. The dioxin-tainted clay had contaminated potato peels used for feeding dairy animals. The EU’s electronic Rapid Alert System for Food and Feed was used to trigger an exchange of information among national authorities about the problem. According to EU sources, the authorities quickly established that the clay had also been supplied to several food-processing companies located in Belgium, France, Germany, and the Netherlands. The authorities rapidly identified these businesses and barred from trade over 200 farms that had received the potentially contaminated potato peels. EU sources noted that because of the traceability system, the contaminated products never reached consumers (GAO, 2008).

In addition, to ensure the traceability of animals across the EU, the EU established the Trade Control and Expert System (TRACES) (GAO, 2008)
1.6 Handling of Products Transshipped Through a Third Country as Compared to Directly Imported Products

For animal origin foods and feeds, all exporters must be registered. So regardless of shipment or transshipment, this information remains accurate. For non-animal origin foods and feeds, the CED requires country of origin information and custom agents are required to attest to CED validity.

2 Inspection Programs

2.1 Mechanisms to Prioritize Food/Feed Import Surveillance Activities, such as Product Sampling and Testing, Inspections at the Border, and Facility Inspections of the Exporting Country

According to the EU, focus has shifted from regular, but random, sampling to paying attention to the sources of greatest risk. If the risk of a given food product is not known or quantified, the EU applies what it refers to as the “precautionary principle.” If there are reasonable grounds for suspecting a problem, the commission acts to limit the risk. The EU asserts that it does not necessarily need to wait for proof that there really is a risk. The EU has described risks for food and animal feed. Importers bear the cost of disposing or reinspecting non-compliant food products (GAO, 2008).

The way in which products become high risk products on the EC level under EC669/2009 is described in that Regulation. The Netherlands also uses a risk-based inspection system to create the National Control Plan that is based on the degree of risk posed by particular food types. Every year the VWA gives customs a list of products (of non-animal origin) which might pose a risk. Customs reports when these products are at the entry port and the VWA has three days to come to inspect them. This list is based upon notifications from the Rapid Alerts System for Food and Feed (RASFF), reports received from the FVO, quantities of the products introduced to the EU, reports received from countries outside the EU (third countries), communication between member states, European Commission (EC), and the European Food Safety Authority (EFSA), scientific assessment, and other relevant info (Vera, date unknown).

The vast majority of raw materials and foodstuffs come from abroad. This calls for particular attention to the way inspection of incoming flows is carried out (in addition to the flows out of the Netherlands). The selection criteria are based on risk analysis, experience and knowledge with respect to places of origin with high/medium-risk microbiological or chemical conditions. This approach permits a balanced assessment of whether or not to organize an inspection as well as the frequency and location of such inspections. The VWA will test and report on many of these regulatory measures with regard to practicability and enforceability. When prioritizing these issues, consideration will be given to the risk profile to be drafted and the available means of enforcement. Important aspects in this respect are (VWA, 2004):

- Type of product, country of origin and producer.
- Whether the production or supply chain is particularly vulnerable to illegal trade.
- Expansion of the EU and the internal market.
2.2 Special Screening Requirements and Trading Partner Requirements where Disease or an Outbreak has Occurred

Safeguard measures are in place (e.g., heavy metals fishery products in Indonesia, radiological contamination of products from Japan) and a monitoring plan for Sudan dyes and mycotoxins. Also EC 609 Annex I and/or emergency authority are utilized to this effect.

2.3 Percentage of Imported Food Shipments Examined and the Relationship between Risk-Ranking of Foods and Volume of Imported Foods Examined

Any products with a CED or CVED are subject to 100% documentary control. The information on the certificate is compared to what is in the shipment.

When and what controls are done are described in the EU regulations. The percentage of food physically examined is determined by three sources, the National Control Plan (based on Article 15.1), the list specified by the EU (based on Article 15.5) and specific EU regulations (VWA, 2011e).

Annex 1 of EC 669/2009 lists the feed and food of non-animal origin that is subject to an increased level of control at the DPE. The identity and physical check rates are determined by the EU regulations and vary between 5 to 50% of a shipment (VWA, 2011e). Checks of consignments include hazards such aflatoxin, heavy metals, Sudan dyes, and pesticide residues. Once a decision to open a container is made, the process takes a minimum of 4 to 5 hours to complete (VWA, 2011).

Surveillance sampling is conducted according to the National Control Plan and is executed at the border or while in transit in Netherlands commerce (VWA, 2011). There has been pressure recently to cut budgets and this could affect surveillance activities. The VWA, however, understands the benefits of surveillance sampling and will try to retain the service as best they can. It is challenging as there is a mandate from the government to reduce staff by 20 percent in 5 years, while imports of food and feed are expected to double over the same time period.

There are reduced frequency checks on some products of animal origin from certain countries. Depending on the product and place of origin, only 1%, 20% or 50% of the product has to be physically checked. (VWA, 2011h). For products of animal origin, the identity and physical checks also depend on the type of product and the country of origin. The following physical check rates apply: 20% for meat, meat products and fishery products; 50% for dairy products, poultry and game meat; 2% for shipments from New Zealand; and 10% on shipments from Canada (VWA, 2011p).
The annual plan for feed for 2009 requires that bulk feed is subject to 1% identity check and physical checks. For feed in bags or containers, 10% identity checks and 1% physical checks are foreseen (EC, 2009a).

VWA is considering a trusted exporter program to reduce the percentage of inspection that need to be conducted. Cargill is one of the firms being considered. It has not been considered how EU regulation would affect what can be done in this regard. The VWA and other similar organizations are trying to move to a risk-based inspection system to the degree allowed within EU regulation due to budgetary and other resources losses. It is also considered a more efficient and effective way to run operations. Of the number of consignments received annually, only 2 percent have problems requiring follow up (VWA, 2011).

2.4 Types of Review, Examination and/or Testing of Imported Products Performed by Food Safety Inspectors

Documentation and labeling is checked and some products are sampled. See discussions above. During the interview, VWA also discussed border security in the context of the nuclear disaster in Fukushima, Japan. Containers themselves coming from that region contained small amounts of radiation and ports had to clean them before recycling into further shipping use (depositing the cleaning waste at a radioactive waste site). This is an example of the extra effort that the VWA and customs assume to maintain the high quality of services at the Rotterdam port. The cleaning of radioactive containers could have been problematic for the workers due anxiety/physical health issues but it was handled in a way that it was never an issue (VWA, 2011).

2.5 Frequency of Documentation and Labeling Checks as Compared to Analytical Examinations

See response to 2.4 above.

2.6 Types of Examination and Testing Processes Used for Ensuring Animal Feed and Feed Ingredient Safety

To measure aflatoxin presence, the laboratory uses the latest Immuno Affinity Column method (sample preparation). Analysis used HPLC with post-column derivatization (cobra cell) (EC, 2006).

2.7 The Dependence of Examination and Testing Requirements on Conditions (such as the Presence of BSE or Other Zoonotic Diseases) in the Exporting Country

EC 183 requires feed exporters to be registered and approved/recognized by the competent authority.
2.8 Inspections of Food or Animal Feed Manufacturers or Shippers in Other Countries (including Selection Criteria and Frequency)

Food imports of animal origin from a third (non-EU) country are only permitted if the country is “recognized”. Foodstuffs of animal origin may only be sourced from premises in recognized countries that have been approved and must carry an EU approved health mark/identification mark. Inspections of these establishments are carried out by the Food and Veterinary Office (FVO) of the EU to ensure that only establishments that meet standards equivalent to those operating within the EU are approved. Countries and establishments permitted to import into the EU, and the products concerned are listed on the Commission’s Website. (GAO, 2008)

2.9 Notification System(s) to Directly Notify Foreign Governments When Foods or Animal Feed Manufactured in their Countries are Found to be Unsafe; and to Notify the Public When Imported Products do not Meet Safety Standards

The Netherlands participates in the RASFF (Rapid Alert System for Food and Feed) of the EU, an electronic notification system managed by DG- SANCO in Brussels. The EC notifies third countries if product has been exported to that country or the product originating from the country is the subject of the notification. RASFF involves all member states, the European Community, and the European Food Safety Authority, as well as the non-EU countries of Iceland, Liechtenstein, and Norway. Each participating country has a rapid alert system contact point to collect information on national notifications and enter them into the database. The exchange of information allows participating states to immediately ascertain whether they are also affected by a problem. (EC, 2010)

A template exists that EU countries use to provide all relevant and useful information such as identification of the product, hazards found, measures taken and traceability information of the product. Once the information is received through the system, other EU countries will verify if they are concerned. If the product is on their market they will be able to trace it using the information they find in the notification. They will report back to the RASFF on what they have found and what measures they have taken. In case of products produced in EU, the country of origin will also report to RASFF the outcome of its investigations into the origin and distribution of the product and the cause of the problem identified. This allows other EU countries to take rapid action if required. (EC, 2010)

The publication of notifications through the RASFF portal database makes consumers aware as well. Consumers can get access to an online database allowing them to see information relating to RASFF notifications the latest 24 hours after their transmission in the RASFF network. The Netherlands also has recall data available online and notifies consumers through the VWA site.

Foodborne illness is also reported. The investigating country informs the ECDC through the Early Warning Response System—a computer database that deals with communicable diseases. ECDC assesses risk at the EU level to confirm a threat and then (1) works with other entities to ensure a coordinated approach to investigation and control; (2) cooperates closely with other EU agencies, particularly EFSA; (3) ensures proper communication with the EU and the public; and (4) assists the member states involved. (GAO, 2008)
Data from all foodborne illness outbreaks are reported to EFSA and published annually. Cross-border outbreaks are not reported separately. In case of a foodborne illness outbreak, EU countries must carry out epidemiological investigations. EFSA also provides guidance on what information should be reported in case of a foodborne illness outbreak. (GAO, 2008)

ECDC manages a computerized database—Enter-net—an international surveillance network for human gastrointestinal infections. It involves all 27 EU countries, as well as Australia, Canada, Japan, South Africa, Switzerland, and Norway. Network participants include the microbiologists in charge of each country’s national reference laboratory. (Safefood, 2011)

3 AUDITS AND CERTIFICATION

3.1 Assessing and Measuring the Effectiveness of the Food/Feed Safety Import Program (e.g., Self Audits of the Program, Public Health Outcomes, Surveillance Sampling Results, Number/Rates of Refusals, Periodic Program Evaluations)

According to EU regulations, competent authorities carry out internal audits or may have external audits carried out, and must take appropriate measures in the light of their results. Audits are subject to independent scrutiny and have to be carried out in a transparent manner. The EU’s Food and Veterinary Office has conducted numerous reviews of aspects of all EU countries’ food safety systems and identified areas needing improvement (EC 882/2004).

The internal audit unit of the VWA (Centrale Interne Audit Eenheid) carries out internal audits of the import/transit control system focused on different aspects of the system and BIPs, and report the results to the Inspector-General. Additionally, an annual audit by the Dutch Accreditation authority takes place. There is also an internal audit department within the VWA who carry out audits as foreseen under Art. 4 of Regulation (EC) No 882/2004 using both internal and external expertise (EC, 2009b).

On a weekly basis 10% up to maximum of 10 consignments in the BIPs are examined by the veterinarian in charge of the BIP to check compliance with requirements. The team leader for BIP Rotterdam port, in addition to these checks, chooses ten targeted CVEDs monthly to examine problematic areas to verify compliance (EC, 2009b). Customs also carry out their own review of the documentary checks carried out by them by checking up to 10 CVEDs per month in each of the Customs offices involved in documentary checks (EC, 2009b).

The VWA Audit Department plans to carry out an audit in 2010 in order to check the implementation of regulation EC 822/2004. At the beginning of May 2010 a new Audit Department was established in the VWA. There are 12 auditors within the Audit Department and in addition to this, each Division have 1-3 auditors. The follow up activities are performed by the Business Control Division within the VWA. The independent Audit Committee review all audit reports and the annual audit plan. The annual audit plan is adopted by the VWA Executive Board (EC, 2007).

The audit manual and auditor's charter are under review and are expected to be harmonized and finalized in the second half of 2010. The audit cycle and long term scope of audits still have to be
determined. In relation to control bodies/authorities (e.g. KDS, COKZ) the Audit Department reports do not always reflect compliance with Regulation (EC) No 882/2004 requirements (EC, 2007).

The EU’s FVO assesses the performance of the member states’ competent authorities, countries aspiring to join the EU (referred to as candidate countries), and non-EU countries intending to export to the EU (referred to as third countries), to verify the effectiveness of national control systems for meeting EU standards in the areas of food safety, animal health and welfare, and plant health. Feed suppliers, for example, must apply HACCP principles, register with their national competent authorities to help ensure traceability, and comply with specific microbiological criteria, such as for levels of Salmonella, molds, and yeast. The competent authorities in each country approve certain feed operators (i.e., those manufacturing and/or selling certain feed additives) by visiting the facility before they start up any activity to ensure that the operators meet EU standards, and once the operator is approved, the competent authority provides oversight and imposes penalties for noncompliance. In turn, FVO inspects the competent authorities’ oversight and provides recommendations when there are shortcomings. As for imported feed, importers must ensure that the feed meets EU standards (GAO, 2008).

3.2 Criteria Used for Program Evaluation and/or Assessment of the Food/Feed Safety Import Program, and the Frequency of Food/Feed Safety Import Program Assessment

See response to 3.1 above.

3.3 Extent of Reliance on Trading Partners’ Food Safety Programs to Ensure That Imported Foods or Animal Feed are Safe

The EU maintains a list of non-EU countries for which it has recognized the capacity of the competent authorities, as well as its animal and public health system but does not appear to maintain such a list for food of non-animal origin.

Commission experts may carry out official controls in third countries in order to verify, on the basis of the information referred to in Article 47(1), the compliance or equivalence of third country legislation and systems with Community feed and food law and Community animal health legislation. The Commission may appoint experts from EU countries to assist its own experts.

3.4 Use of Additional Measures (e.g., Audits of Producers, Exporters and Shippers) to Verify the Safety of Trading Partners’ Food and Animal Feed

No information is publically available nor was it obtained during the interview.
3.5 Requirements for Food and/or Animal Feed Export Certificates Issued by the Exporting Country’s Competent Authority, and Types of Inspection or Testing for Each

Japan is required to declare for human food and animal feed when the products were harvested or processed en where they came from (Regulation EU 297/2011). If they came from the area of Fukushima, the declaration has to be accompanied by a laboratory analysis of radioactivity (VWA, 2011c). The EC has required this and is on top of existing requirements for products imported from Japan. Since March 17, the Netherlands (as required by EC) also tests random samples of food and animal feed (and ingredients for). Frequency depends on where the food comes from in Japan. They are already taking 10 to 20% samples of food and animal feed coming from Japan and nothing has been found (VWA, 2011).

CVEDs are required for products of animal origin. These need to be signed and provided by the Veterinary authority in the country of origin. CEDs are required for some products of non-animal origin.

3.6 Use of ISO, Global Gap or Other Assurance Systems and Confidence in the Assurance System(s) Utilized

Laboratories are accredited to ISO 17025 standards by the RVA, the Dutch Accreditation Council for laboratories. According to RIKILT, 90% of the methods used for analyses on feed have been validated and accredited according to EN ISO/IEC 17025. While third party laboratories are accredited and submit required data to support imported consumer products meet standards, VWA must confirm these test results in their own labs in order to determine release/rejection of the shipment (VWA, 2011).

3.7 The Nature and Frequency of Foreign Food Safety Systems Audits Performed

The Netherlands may serve as a member of FVO expert team that conducts such audits on behalf of all EU states as discussed earlier.

3.8 Equivalence Agreements Requiring Periodic Audits/Reevaluations of Exporting Countries’ Food Safety Programs

Reduced physical check agreements exist for some categories (fish, dairy, meat, honey, poultry, gelatin, eggs, and mollusks) and some countries. The FVO determines the frequency of audits. (VWA, 2011h)

3.9 The Utilization of Third-Parties (Within the Exporting or Importing Country) to Carry out Inspections and/or Product Certification (Nature and Extent of Programs) and Methods for Verifying the Adequacy and Reliability of the Third Party Work

EU regulations specify that EU members must have sufficient resources to undertake their food and feed safety responsibilities. No third party contribution was noted in the Netherlands. The
competent authorities of third countries are the only bodies entitled to officially declare that establishments fully comply with EU legislation requirements. (VWA, 2011)

3.10 Arrangements with other Governments Relating to Imported Foods or Animal Feed (such as Memoranda of Understanding, Mutual Recognition Agreements, etc.)

These are the reduced physical check agreements as described above.

3.11 Registration or Licensing of Firms That Import and/or Export Foods or Animal Feed to the Country or for Firms That Import Foods or Animal Feed

Inspectors from the EU’s FVO normally visit non-EU countries to verify compliance with these conditions. If compliance is satisfactory, the EU may approve countries and establishments for export to the EU. In addition, non-EU countries must certify and approve business establishments wishing to export to the EU, noting that they meet the relevant EU requirements. The EU maintains lists of these establishments online for all the major categories of animal products (e.g., beef, dairy, fish, or poultry), and compliance is verified during follow-up inspections.

3.12 Use of Sampling Surveys of Imported Foods/Feed (as Opposed to Targeting Specific Products/Producers for Inspections and/or Testing) to Gather Information and Identify Trends and Potential Areas of Difficulty

There is a division of VWA called “Surveillance and Monitoring” that works together with RIKILT. This surveillance effort is part of the National Control Plan to monitor and test products for compliance, regardless of country of origin (VWA, 2011).

3.13 “Good Practices” Programs for Foods/Feed Importers

VWA provides technical and program assistance via a helpdesk to assist importers/customs agents (VWA, 2011).

3.14 Description of Import Program User Fees and Cost Recovery System

VWA charges fees for inspections and border operations to oversee EC/EU regulations compliance. However, costs for the National Control Plan are covered by Government. Therefore these food protection efforts in tight budgetary times might be impacted by budget cuts (VWA, 2011).

3.15 Incentives to Increase Industry Involvement in Ensuring That Imported Foods Meet Safety Standards

VWA provides full time employees to operate a help desk for importers and customs agents. VWA and customs strive to provide importers, customs agents with a “one-window operation” offering streamlined, efficient oversight while providing consumer protection. (VWA, 2011)
3.16 Obstacles to Industry Participation in Ensuring That Imported Foods Meet Safety Standards

No information is publically available nor was it obtained during the interview.

4 LABORATORY SUPPORT

4.1 The Role of Laboratories in Supporting the Imported Food and Feed Programs and Description of Laboratory Capabilities

The VWA conducts enforcement and monitoring testing in its own laboratories. There are 5 designated laboratories, all accredited to ISO 17025, for surveillance and/or for cause sampling. For cause sampling is picked up at the port by VWA and transported in VWA vehicles. Labs are accredited in specific analyses/analytes (VWA, 2011).

The RIKILT Instituut voor Voedselveiligheid is a national and EU reference laboratory (the role of which is to make sure that the laboratories in the country are qualified). EU countries are required to arrange for the designation of one or more national reference laboratories. A country may designate a laboratory situated in another Member State or European Free Trade Association (EFTA) and a single laboratory may be the national reference laboratory for more than one Member State.

According to the VWA Handbook for BIPs, the RIKILT is consulted when required tests are beyond the skill of the VWA laboratories, along with the RIVM, CVI, and RIVO, as described below. The RIKILT is a reference laboratory for pesticides and veterinary residues, feedstuffs, and GMO analysis. In addition, when requested by the VWA to do so, RIKILT investigates possible cases of fraud (within the framework of the EU subsidy schemes) or the illegal use of prohibited substances (pesticides, animal drugs etc.). Based on the results of such forensic analyses, the Public Prosecutor’s Office can initiate criminal proceedings. They also participate in international committees, for example within the framework of the EU, the EFSA, Codex Alimentarius and the World Health Organization (VWA, 2011f).

The RIVM (National Institute for Public Health and Environment) is a government research institute that conducts research on public health. It houses several of the Dutch national reference laboratories and EU community reference laboratories on Salmonella and residues (GAO, 2008). RIVM is responsible for conducting risk analysis for food (fork), while RIKILT is generally responsible for assessing food and feed quality (farm). The RIVM also supports the VWA by taking measures to combat food borne infections.

The Central Veterinary Institute (CVI) is also at the University of Wageningen and is the national reference laboratory for animal products. The Nederland Instituut voor Visserij Onderzoek (RIVO), or the Dutch Institute for Fisheries Research in English, in Ijmuiden also conducts laboratory tests on fishery products (VWA, 2011f).
4.2 Participation of Non-government Laboratories (Including Industry and Academic Laboratories) in the Food Import Control Program

VWA does not use third-party laboratories (EU leaves this up to each country; e.g., Belgium does use private labs). When third-party laboratory data is required to meet a standard or requirement e.g. EC 669 Annex I, it is insufficient without a confirming VWA lab result to release/reject shipment. Thus third-party lab data only assists industry but not the government (VWA, 2011).

4.3 Methods for Laboratories to Achieve Quality Assurance (such as Voluntary or Mandatory Accreditation)

Laboratories are accredited by the RVA (Raad voor Accreditatie) or in English, the Dutch Accreditation Council. They are compliant with ISO 17025.

5 Enforcement at Border

5.1 Approach to Visual Inspections and Analysis of Imported Foods (e.g. Risk-Assessment and Prioritization Schemes, Documentation Review, Sample Collection)

As mentioned earlier in describing import review, all products are reviewed by Customs. Customs conducts the documentary control, i.e., the verification of required documents and/or certificates. The border inspection (customs) performs the review of extra documents required for certain high risk non-veterinary products. Omissions are reported to the VWA. The VWA performs the identity check and physical inspection/lab testing. This can include sampling. The check is performed by import teams. If the material is not conforming to requirements, intervention is possible. Otherwise it will be rejected. For high-risk products, additional documents might be required (certificate of analysis, etc) and samples. Laboratory analysis can also be included. The quality control methods are described in the VWA Quality Handbook and are mostly based on EU directives. Reduced controls are required for some products of some countries.

5.2 The Process that Occurs When an Imported Food is Found to be Contaminated or does not Meet Standards

5.2.1 Procedures for Refusing Imported Foods Based on a Finding that they do not Comply with Requirements

If a consignment does not comply with EU requirements, it may be rejected. In these cases, EU officials negotiate with the owner of the consignment and the country of dispatch, where appropriate, about whether to destroy the product, to retreat it for uses other than the human food chain, or to redispacth it. Food or feed business operators or their representatives are responsible for the consignment and are liable for any costs incurred by the competent authorities to destroy or redispacth it (GAO, 2008). There is a 3 day window for disposition of product for products not of animal origin. Fifteen days (maximum) are allowed for sampling and testing. Shipments may also transit unless specified for hold (VWA, 2011).
5.2.2 The Procedure and Outcome for Imported Foods that are Refused Entry (Including Efforts to Prevent them from Mistakenly Entering Domestic Commerce)

See above under 5.2.1.

5.2.3 Entry of Detained Products Based on Further Testing or Reconditioning of the Product

Products can be detained awaiting CED/CVED data, re-labeling, and other remedy before release.

5.2.4 Process for Identifying and Tracking Producers or Countries that have Repeated Violations

If consignments are not in compliance, all other border inspection posts are notified through the TRACES system. All CVED’s are entered in TRACES by EU Member States. In case of certain reasons of rejection, a notification is done through the Rapid Alert System for Food and Feed, as described earlier. At the VWA, it was noted that RASFF often has too much data in each report, which in turn obscures the important information that should be acted upon. (VWA, 2011; VWA, 2011p)

In another venue, The VWA and Rotterdam Port established an informal, independent system- a port-to-port network (outside formal EU and port channels). They meet twice a year and have an informal network informing each other of problems and shipments of concern. When a port reported an exporter whose products were continually rejected but had not been seen for a while, all other ports were alerted (including VWA operations) to implement a 100 percent review and check in real time. This was not done through RASFF but through this informal network. The EU has asked and received approval to attend these meetings. (VWA, 2011)

5.2.5 Detailed Description of Enforcement Scheme for Refused Foods

See response to 5.2.4 above.

5.3 Program for Investigating and Responding to Intentional Contamination of Foods

In the interview, the Netherlands officials expressed that intentional contamination is not of significant risk to outweigh current risk priorities. Therefore, the Netherlands currently does not have a specific program to address intentional contamination. They do acknowledge that some fraudulent products and/or mis-labeling do occur and is found during regular identity and or physical checks (VWA, 2011).
6 FOOD RELATED ILLNESS OUTBREAKS

6.1 System for Tracking Imported Foods once they are Cleared at the Point of Entry

The TRACES (Trade Control and Expert System) is a risk management tool for animal and public health. It is a single electronic database that monitors movement of animals and certain product of animal origin within the EU and from third countries. The Netherlands is working on completing the interface between VGC (Veterinary Border Control System) and TRACES. The EU is sponsoring the effort (VWA, 2011).

All producers are required to be able to trace unsafe products. They have to keep manual or electronic records to enable tracking, they have to have documented tracking procedures, and they must be able to trace one step forward and back from their operation (VWA, 2011).

VWA requires that firms be ready to show VWA how their systems work at any given moment. A firm must be able to show who has received their product and from whom they have received their product (VWA, 2011i).

According to the VWA website, documentation needs to be kept for 5 years at least. If the product has an expiration date longer than 5 years, then it must be kept for that many years plus 6 months. This does not excuse a firm from being held responsible if problems arise after the expiration date. If the expiration date is less than 3 months, then documentation needs to be kept for at least 6 months (VWA, 2011i).

This is also required for those producing animal feed. The tracing system is required from primary production through the retailer. Internal tracing is not required but can improve management and scope of a potential retail crisis (VWA, 2011i).

6.2 Systems for Identifying Foodborne Illness Outbreaks

When a possible new danger or incident is identified, the VWA publicizes its assessment within 24 hours. This assessment is based on the information available at the time. One way in which the VWA makes its assessment public and accessible is via its website (VWA, 2004).

See above discussions about RASFF and ECDC epidemiological investigations, if conducted.

6.3 Procedure for Tracking Illnesses back to the Food Source when a Foodborne Illness Outbreak Occurs

No information is publically available nor was it obtained during the interview.

6.4 How Consumers Notify the Government and/or Importers of Food Problems

Consumers can call reports of food problems in at number 0800-0488 (warenklachtlijn) of the VWA or it can be reported online in electronic format (VWA, 2011k).
7 EXPORT PROGRAMS

7.1 Programs for Ensuring Safety Requirements of Export Destination Countries

7.1.1 Use of Export Certificates to Provide Assurances to the Importing Country

The CLIENT export programme, which is not a part of the VGC (the VGC system is only used for import controls at the EU border), is used for electronic communication for border controls. Voluntary export certificates (called “export declarations” or export verklaringen) are available for non-animal food products and “export certificates” are required for animal products, animal feed, and possibly vegetables and fruit. Export declarations and certificates are provided by shipment, except for free sale certificates, which are provided by product. Export certificates for animal feed come from the division “Certificering op Afstand” (CoA) and do not require an inspection of the exporting facility (VWA, 2011j). The Netherlands also provides free sale certificates for animal feed. This type of certificate is bound to the product not the shipment and excludes shipment to Norway, Liechtenstein, and Iceland (VWA, 2011m).

The export declaration for non-animal food products includes information such as unique identification, name and address of processing plant, exporter name, date, name and address of receiving party, name of product, quantity, mode of transport, nature of packaging, what firm can be held responsible for (e.g., method of production, human consumption, etc). Voluntary export declarations have to be requested by the firm and can vary in detail. The VWA inspects roughly 1% of shipments that require an export declaration (VWA, 2011n).

With respect to the export certificates for products of animal origin and animal feed, there are EU certificates for export within the EU (except for eggs, fish, meat and meat products, which just require binding certificates based on agreements between the government of the Netherlands and the receiving foreign government) and certificates based on other specific requests from a country as provided by the requesting exporting firm. Some countries have an agreement with the Netherlands on what information should be included. In some cases, there are no requirements from the exporting country or the Netherlands. The VWA advises using a standard health declaration (not certain whether this is the same as an export declaration) in that instance. Data included on the export certificate includes the name of product, product code or other identification information, number and weight, nature of packaging, name and address of processing plant, exporter name, name and address of receiving party, mode of transport, laboratory results, declaration of safety, and signature. Export certificates for products of animal origin are paper for now, but in the future will be received electronically by receiving countries through the CLIENT Export system. Currently, requests are submitted electronically already for some foods, like dairy and meat (VWA, 2011o).

A copy of the export certificate for products of animal origin is available on the VWA website (VWA, 2011b).
7.1.2 Providing to the Import Country Lists of Establishments that Meet the Importing Countries’ Food Safety Requirements.

For bilateral agreements where such data is required, it is usually available on the VWA website (VWA, 2011).

7.1.3 Authorized Third Party Issuance of Export Certificates

Only an official VWA veterinarian can sign the health certificate and that the certificate requires authorization of the VWA with an official VWA stamp. Dairy export certificates are provided by COKZ. COKZ is accredited by the VWA to issue export certificates (VWA, 2011). COKZ manages a control program that, if passed, results in the issuance of a health certificate declaring the product suitable for human consumption. The organization also issues certificates of analysis based on laboratory test results that countries might require and veterinary certificates. A VWA-employed veterinarian is present on-site to sign the health certificate (COKZ, 2011).

8 WORLD TRADE ORGANIZATION (WTO) OBLIGATIONS

8.1 Methods for Ensuring Consistency between Domestic and Imported Food Safety Requirements

No information is publically available nor was it obtained during the interview regarding WTO.

8.2 Methods of Documenting the Scientific Justification for Import Practices with regard to Article 5 of the SPS Agreement, which Requires that Measures are based on an Assessment of Risk, as Appropriate to the Circumstance

No information is publically available nor was it obtained during the interview regarding WTO.

8.3 Involvement in Article 4 of the WTO SPS Agreement Regarding Equivalence Determination

No information is publically available nor was it obtained during the interview regarding WTO.

8.4 Process for Recognizing a Foreign Country’s Food Safety System as having Adequate Regulatory Oversight

No information is publically available nor was it obtained during the interview regarding WTO.
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FOOD AND FEED IMPORT PRACTICES
APPENDIX I
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OVERVIEW OF INTERVIEW AND FOOD AND FEED SAFETY SYSTEM

Food Standards Australia New Zealand (FSANZ) serves as the food standards setting body for both New Zealand and Australia, but serves no role in New Zealand public health promotion nor public health protection. The New Zealand government agency primarily responsible for implementing and enforcing the standards set forth by FSANZ is the Ministry of Agriculture and Forestry (MAF). MAF now incorporates the agency formerly known as the New Zealand Food Safety Authority – the merger occurred 1 July 2010. MAF sets policy, standards, criteria, and procedures for monitoring and enforcing the safety of domestic and imported foods for human consumption under The Food Act 1981. MAF governs the importation of animal feeds and pet foods under the provisions of the Biosecurity Act 1993 and the Agricultural Compounds and Veterinary Medicines Act 1997 the Importation of Processed Animal Feeds of Plant Origin into New Zealand Standard (2010) and Import Health Standard for Shelf Stable Pet Foods Containing Animal Products 2007.

The integrated MAF is responsible for animal and plant health, animal feeds, and food safety. Primary responsibility for public health rests with New Zealand’s Ministry of Health, but MAF also has outcomes linked to public health protection.

New food safety legislation, replacing The Food Act 1981, is anticipated for 2012. The new legislation is part of an overall streamlining of MAF functions and Local Authority responsibilities and for strengthening the risk and science based approach to food safety management. MAF is also working closely with Customs and stakeholders on Trade Single Windows to streamline border clearance process and to realize a single-window gateway for food business operators, importers and trading partners while ensuring animal, plant and public health protection and facilitating trade (See Section O).

Under current legislation (The Food Act 1981), MAF’s imported foods program requires importers to be listed. MAF uses Customs product tariff codes in close cooperation with Customs to target foods that present an increased level of risk and warrants further review by MAF. Foods presenting an increased food safety risk are identified as “prescribed foods” under the 1981 Food Act, and currently fall within the product categories of meat, dairy, seafoods, nuts and spices.

Prescribed food shipments are referred by Customs to the MAF Central Clearing House (CCH). Importers having products referred to CCH are required to obtain a single use permit, showing the product meets applicable standards before it can be released for sale. An administrative arrangement enables a few significant volume importers to run a multiple release permit system. CCH collaborates with 12 District Health Boards and their Public Health units, who carry out verification, inspection, sampling and arrange for testing on imported and domestic foods as required.

Private laboratories are employed by both government and private sectors. Laboratories approved by MAF and accredited by International Accreditation New Zealand (IANZ) are valid.

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1 MAF will primarily be referred to throughout the remainder of the document as NZFSA no longer exists despite the fact that programmatic and legislative integration is still occurring.
for supporting food safety monitoring and enforcement. These laboratories provide service to domestic, export industries and also for food imports (prescribed foods).

MAF Verification (Animal and Food Products) (VAFP) verifies that food safety programs and risk management programs are adhered to at premises where meat, seafood and other foods are processed. VAFP serves as the verifier on behalf of the competent authority for equivalence, export certificates\(^2\) and other mutual recognition agreements for foods with the exception of certificates for plant and organic products issued by MAF. The agency may employ third party entities, under international standards, to provide product verification.

New Zealand has conducted few audits of foreign food manufacturers or processors. New Zealand, as a rule, will recognize comparable country-wide plans that have already been instituted to meet EU and/or US standards.

THE NEW SYSTEM FOR FOOD IMPORTS

New Zealand is in the process of transitioning away from its current imported food safety system and structure to a new system based on the new food legislation that is expected to be in place in the year 2012. The new imported food program is consistent with WTO requirements and is:

- Responsive and flexible
- Risk management targeted
- Intelligence-led
- Science and risk-based
- Looks at possible import interventions throughout various points of the import process chain

The new food act and related system does not change the current imported animal feed law and regulations.

COMPONENTS OF THE NEW SYSTEM

The new system will feature six main components: 1) Categorization of foods as to their level of regulatory interest; 2) Creation of a new data capture and IT system to manage a single window (multi-agency) import framework and to better target resources; 3) Clear roles and responsibilities (duties and obligations) for all parties involved in the import process; 4) A verification system; 5) Risk management strategies and options (standards and guidance) to ensure the ‘appropriate level of protection’ and safety of imported foods at any point along the import continuum that spans pre-border to post-border; and 6) Some extent of integration of the domestic and import regime. These components are designed to help New Zealand facilitate trade while minimizing food safety risks. (MAF, 2011)

\(^2\) Animal product exporters requiring official assurances under the *Animal Products Act 1999* must be registered with MAF.
**O.1.1 Categorization of Foods as to their Level of Regulatory Interest**

Categorization under the proposed system is a two stage process:

1. Conduct a science based risk/hazard assessment of foods, which categorizes products according to risk
   - Based on the science based assessment, foods / food groups will broadly be categorized as high or low risk or “products needing more information”. Products requiring further information to enable risk categorization are referred to as ‘scanning list foods’ and are monitored to assist in gathering information, enabling risk categorization.

2. Generate a risk profile, which considers the source of food and associated food safety controls in addition to international standards.
   - Risk profiling considers the food safety risks associated with the source of the food such as the comparability or equivalence of a foreign country’s food safety system, emerging food issues, compliance history, and outbreaks.
   - Profiling has the potential to elevate a low risk food, determined from the science-based assessment, to high regulatory interest.
   - All foods determined as high risk foods, from the science based assessment, are automatically considered high regulatory interest.
   - Information gathered upon risk profiling inputs into development of appropriate risk management options. Thus, risk management options are appropriate to the level of regulatory interest and source of food.

In summary, information gathered from application of the risk categorization process (stage 1 and 2), will generate a range of risk management control options appropriate to the level of risk of an imported food. These include Mutual Recognition Agreements (MRAs), equivalence agreements, and/or controls at points along the import chain that spans from pre-border to post-border. (MAF, 2011)

**O.1.2 Data Capture and IT mechanisms**

Currently Customs runs an IT system at the border, and the import information in this system is shared with MAF Biosecurity and Quarantine groups. MAF food safety information is currently run from a stand-alone system. Under the new system (currently under design), certain functionality will be combined into a new IT system in keeping with the future vision of a Joint Border Management System. The development and implementation of the new IT system is expected to occur in two phases:

- Phase 1 (2012): A single trade windows interface will be operational that will allow traders to submit once at a single entry point to fulfill import, export, and transit related regulatory requirements, including registration.
- Phase 2 (2015-2020): The development and implementation of risk and intelligence systems will occur and be added onto the IT component developed in Phase 1.
Tariff codes will still be used as a primary product filter for imported goods, although MAF is investigating the introduction of additional filtering and targeting mechanisms. The new technology solution will not necessitate change regarding the responsibility for clearing imported products of interest.

**O.1.3 Clear Roles and Responsibilities**

Roles and responsibilities for each party involved in the imported food process (MAF, importers, customs brokers and exporters) will be clarified. MAF will not be assuming accountability for imported foods, but rather, they will manage the framework of operation, oversee, and enforce the system of expectations.

The new food bill broadly defines the term “importer” to cover everyone in the import process, a definition aligned with that of Customs. There will be general obligations under the new regulation that will apply to all importers as well as additional requirements for all importers of products of high regulatory interest.

The “registered importer” is the party who will assume responsibility for the imported food. There will be specific requirements under the new legislation that will apply to all registered importers. MAF, unlike current system operations, will enforce registered importer responsibilities.

Initially determining whether importer obligations are being met will be gauged from monitoring surveys and verification outcomes. Importer direction will be provided through the regulation as well as guidance documents and rules for high regulatory interest foods.

(MAF, 2011)

**O.1.4 Verification**

The new system is under design, but is likely to remove the reliance on sampling, testing, and release at border to more reliance on recognition of overseas standards and systems. All imported foods, not just those categorized as high regulatory interest, may require some form of verification or be subject to monitoring under the new system. The focus is to improve the level of due diligence and acceptance of responsibility by the importer and therefore demonstrable reductions in risk to consumers. Key points relating to the verification of imported foods under the new system include:

- The level of intervention with imported products will decrease as the level of regulatory interest associated with the food decreases. The level of regulatory interest considers the food / hazard combination and risk profile of food source.
- Verification of the importer will determine the level of compliance against notified duties and obligations and any criteria further specified for the importer.
- MAF is moving toward centralization of information collection (e.g. results of verification) to enhance decision making capability.
Duties and obligations for importers may include the requirement for all registered importers to communicate known issues to NZ authorities as they arise and to take corrective action.

Domestic and imported food verification activities will become integrated where feasible.

(MAF, 2011)

**O.1.5 Monitoring Review and Intelligence**

The intention, under the new system, is to move away from the reactive-type monitoring system that is currently in place to an effective monitoring and review programme which assesses the ongoing adequacy and appropriateness of the imported food programme.

Monitoring activities are reflective of the type of information required. For example, surveys may be undertaken post-border.

An intelligence gathering process details clear responsibilities to perform and capture emerging issues and food safety incidents that aligns with other MAF intelligence gathering approaches. This process provides for MAF responses to align with international standards, methodologies and practices or where different are justifiable.

(MAF, 2011)

1 ROLES AND FUNCTIONS OF AGENCIES RESPONSIBLE FOR IMPORTS OF HUMAN FOODS AND ANIMAL FEED

1.1 Governmental Ministries and Subunits (Including National/Regional/Local, as Appropriate) With Responsibility for Assuring the Safety of Imported Food

*Ministry of Agriculture and Forestry (MAF)*

Below the subunits and duties of MAF are outlined.

- Biosecurity New Zealand was the division of MAF charged with leadership of the New Zealand biosecurity system. Biosecurity New Zealand has now been fully incorporated into MAF with functionality remaining. It encompasses facilitating international trade, protecting the health of New Zealanders and ensuring the welfare of our environment, flora and fauna, marine life and Maori resources.

- Verification (Cargo and Passenger) (VC&P) Directorates “[was] responsible for ensuring that MAF’s biosecurity requirements for imported foods and animal feed and ACVM Act requirements for animal feeds and pet foods are met. MAF VC&P monitors all imports for biosecurity risk material, and where appropriate confirms that Import Health Standards have been complied with. It also monitors animal feeds and pet foods to confirm appropriate ACVM authorization. The majority of MAF VC&P’s food-related work is for non-‘prescribed’ foods such as fresh fruit and vegetables,
but some foods (such as processed meats and cheeses) that are prescribed under the 1981 Food Act require additional clearances by Food Officers employed by District Health Boards and directed from the Central Clearing House.”

- MAF’s Import Export Standards Directorate sets “policies, criteria and procedures to monitor the safety of imported food for human consumption”

- The Central Clearing House (CCH) is the part of MAF that carries out the imports operational procedures. They “facilitate the inspection and clearance of imported prescribed foods”\(^3\).

- Verification (Animal and Food Products) (VAFP) “verifies that risk management programmes\(^4\) are adhered to at premises where meat, seafood and other animal products are primary processed. It employs veterinarians to inspect animals, ensure animal welfare protocols are followed and provides export certification to the products.” The VAFP:
  - “provides verification and related services to export sectors as a mandatory prerequisite for gaining access to overseas markets
  - Fulfills overseas market requirement for Government involvement as the “competent authority”. As a result, more than 75 percent of the work undertaken by the VAFP relates to the export meat sector.
  - “Provides verification or related services (for example evaluation) to industry operators in a particular sector”
  - Implements regulatory programmes (for example, residue monitoring programmes)
  - Contributes to emergency management procedures (MAF, 2008a)

- The Approvals and Agricultural Compounds and Veterinary Medicines Directorate within MAF “implements the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 which regulates the importation, manufacture, sale and use of agricultural compounds. Agricultural compounds are veterinary medicines, agricultural chemicals, fertilizers, oral nutritional compounds (animal feed and pet food) and vertebrate toxic agents (control of vertebrate pests such as rodents, possums, rabbits).”

*New Zealand Customs Service (Customs)* “protects [the] community by enforcing controls and requirements and by assessing the risk of what crosses [the] borders.” Customs uses a commodity coding system to identify and describe goods entitled, the “New Zealand Customs Service Working Tariff document. New Zealand Customs conducts formalities at the point of entry into New Zealand by screening out items harmful to New Zealand’s interest and enforcing the prohibition on the importation of some goods.” (MAF, 2010)

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\(^3\) Prescribed foods are foods that present a risk to consumers and are monitored for specific hazards (MAF, Import Clearance Procedure, 2010).

\(^4\) Risk management programmes are HACCP programmes mandated under the Animal Products Act 1999.
The Ministry of Health “is the Government’s principal agent and advisor on public health. It is responsible for ensuring that surveillance and disease investigations identify significant public-health issues, including food-borne illness. It must also ensure that all relevant information on foodborne illness is passed to MAF.” (MAF, 2004)

District Health Boards (DHBs) and their Public Health Units (PHUs). “Regional public health services are delivered by 12 district health board-owned public health units (PHUs)” (Ministry of Health, 2011). “Food and Health Protection Officers employed by the various public health services are responsible for the inspection and sampling of high-risk imported foods under the coordination of CCH. Only designated Food or Health Protection Officers may carry out sampling of ‘prescribed’ food. These officers are employees of DHBs and are subject to direction from the Director-General of Health. Officers do not report directly to NZSFA, nor does MAF currently have formal contracts with the public health units of DHBs to provide these services. However, MAF is responsible for assessing their performance. (MAF, 2004)

Territorial Authorities (local governments) “are not directly involved in the imported foods regime, but are involved in ensuring the safety of domestic food. Their Environmental Health Officers are officers under the Food Act and register commercial food premises under the Food Hygiene Regulations 1974. Some local authorities also investigate food-borne illness under agreements with their local public-health services. Food complaints are investigated by Territorial Authorities, but those involving public-health risk such as metal or glass contamination are usually referred to the public health service for investigation.” (MAF, 2004)

Food Standards Australia New Zealand (FSANZ) “is the statutory authority that develops Food Standards for composition, labelling and contaminants, including microbiological limits, that apply to all foods produced in or imported for sale into Australia and New Zealand. Food Standards Australia New Zealand has no direct role in food-safety promotion and public-health protection in New Zealand, but it does have these roles in Australia.” (MAF, 2004)

Commerce Commission oversees the implementation of the Fair Trading Act 1986 which “encourages competition and protects consumers from misleading and deceptive conduct and unfair trading practices. The Fair Trading Act applies to all aspects of the promotion and sale of goods and services.” (MAF, 2010)

Environmental Protection Authority (EPA) “makes decisions on applications to introduce hazardous substances (HS) or new organisms (NO) including genetically modified organisms (GMO’s).” It has also set group standards for animal feeds and pet foods in regard to avoidance on potential hazardous substances

International Accreditation New Zealand (IANZ) “is the national authority for the accreditation of testing and calibration laboratories, inspection bodies and radiology services. We promote the development and maintenance of good practice in testing and inspection and maintain a registration scheme for organisations that comply with that practice.” (IANZ, 2011)
Private laboratories “are employed by both the government and the private sector. Only tests by laboratories approved by MAF are valid for food-safety purposes, and at present MAF recognizes only laboratories that are accredited by International Accreditation New Zealand (IANZ) for the relevant test. (MAF, 2004)\(^5\)

Private sector quality control consultants. “Food companies can employ private consultants to monitor the quality of their products. These are voluntary arrangements, and there is no register of such consultants.” (MAF, 2004)

Institute of Environmental Science and Research Limited (ESR) serves as primary scientific advisors to the Ministry of Health and MAF and “ensures that comprehensive reporting on the incidence of enteric diseases likely to be of foodborne origin can be provided.” ESR has a central role in outbreak surveillance which includes regular analysis of surveillance data to detect emergent problems, helping to prevent disease outbreaks in New Zealand and reducing their impact (ESR, 2010).

1.2 Agencies Responsible For Animal Feed and/or Pet Foods

Animal feed and pet food are regulated under the Biosecurity Act 1993, the Agricultural Compounds and Veterinary Medicines Act (ACVM) 1997, and the Hazardous Substances and New Organisms Act (HSNO) 1996. The first two statutes are administered by MAF, while the HSNO Act is administered by the Environmental Protection Authority (EPA). See Section 1.5 for Regulation details.

1.3 Food Importation Process Steps and the Government Units That Oversee Each Step

Customs

In order to import goods into New Zealand, importers must first obtain Customs clearance. All customs clearances are required to be filed electronically, and importers must register with Customs in order to lodge electronic entries. In order to become a registered user, the importer must complete a registration application, and provide evidence of their identity and ability to use the Customs Computerised Entry Processing System. (Customs, 2011)

If the importer’s application is approved, “applicants are issued a Customs declarant code and a unique user identifier (UUI). The UUI is used in the same way as a Personal Identification Number (PIN). Considered to be the importer’s electronic signature, “a registered user may only have one current declarant code and one current UUI. The entries that can be submitted via this site are a legal declaration under the Customs and Excise Act 1996.” (Customs, 2011)

When an importer lodges an electronic entry in the Computerised Entry Processing System in order to gain clearance for importing a product, that product gets coded by the Customs commodity coding system (based on the product’s tariff code). The code assigned to the product

will eventually be used to help determine which products need further review by MAF before being cleared for sale.

**Biosecurity Clearance**

Imported food products must first receive biosecurity clearance from MAF Verification (Cargo) Biosecurity Inspectors before the food falls under the jurisdiction of the MAF Central Clearing House. MAF Verification (Cargo) is mainly focused on preventing the introduction of harmful pests and diseases for the plants and animals of New Zealand. Accordingly, biosecurity clearance mainly focuses on imported products containing substances of plant or animal origin.  

**Food clearance**

Before importing food into New Zealand, importers must be listed with MAF. During the import process, food commodities fall under the jurisdiction of MAF Central Clearing House once they have obtained biosecurity clearance. According to the import diagram provided by MAF (see beginning of section), remaining steps in the import process include:

- Determination of high-risk foods or *prescribed foods* (See also Section 2.1 and 2.2).
  - As mentioned in this section under *Customs*, when importers apply for customs clearance, there is a tariff code associated with their products that has an associated risk level. “If the tariff code entered is for food that is of interest to MAF, the importer will be referred to [Central Clearing House] (CCH) to apply for a ‘MAF single use permit’.” (MAF, 2010)
  - “Where a government to government pre-clearance arrangement exists, or MAF recognises specific overseas manufacturers, then approved assurances/certification may be accepted with imports of a prescribed food under that specific arrangement. The purpose of pre-clearance is to “Assess and recognise controls in place overseas to ensure that food meets or is equivalent to New Zealand standards for domestic food””. (MAF, 2010)
  - “If the food is not of interest to MAF, it will undergo the normal clearance process of Customs and MAF Verification (Cargo) without reference to MAF Central Clearing House. However in some circumstances either of these agencies may involve MAF if they have a concern with the food item being imported.” (MAF, 2010)

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6 In order to obtain biosecurity clearance, importers can determine commodity-specific requirements for goods to be imported by referring to the Import Health Standards (IHSs) issued under Section 22(1) of the Biosecurity Act 1993 (available via an online search tool).

7 Three types of [pre-clearance] arrangements with overseas/commercial entities will be considered by MAF, those: 1) meeting New Zealand Standards; 2) applying measures equivalent to New Zealand Standards; and 3) complying with a food control system that MAF has determined as equivalent to New Zealand Standards. (MAF, 2008d).
For all food imports whether referred to MAF or not, the importer must have documentation showing:

- How the food product has been produced and managed in a manner that enables the food to be safe for human consumption
- Description of the product’s passage including documenting the product flow (including the port of entry, the carrier, and if applicable the import broker)
- Supplier list and relevant supplier information
- Purchase records (the quantity, the product code, the date and the buyer) are available for all products.

(MAF, 2008b)

- Determination of testing and sampling of prescribed foods.
  - Sampling and testing of prescribed foods is determined by published Imported Food Requirements (IFR) that are commodity specific.
  - If sampling/testing is not required, the importer needs to meet appropriate documentation criteria, and the product is able to be sold. Food cannot be sold until this documentation is cleared.
  - Food requiring sample/testing is issued a Conditional Release Sampling Permit
- Satisfactory sampling and testing results must be achieved by importer holding a Conditional Release Sampling Permit
- Food Act Officer must clear the product, acknowledging that it meets the applicable standards.
- MAF single use permit is issued
- Food may be sold

(MAF, 2010)

**Importation of animal feed and pet food**

Importers of animal feed and pet food are not required to be listed with MAF. The MAF Verification (Cargo) Biosecurity Inspectors are also appointed as ACVM officers with the power to clear goods appropriately authorized under the ACVM Act. To facilitate clearance of these goods the Approvals and ACVM Group of MAF issues Class Determination Outcome Letters. The class determination service provides advice regarding the regulatory status of an agricultural compound. If the advice in the outcome letter says that the substance is an agricultural compound that fits into one of the registration exempt categories (such as animal feed and pet food) listed in the ACVM Regulations the importer can then submit the letter to have the consignment released at the border.

It should be noted from the above, that the MAF Verification (Cargo) Biosecurity Inspectors undertake a dual role of clearing the animal feed/pet food for both Biosecurity IHS and ACVM requirements.
1.4 Assistance, Cooperation or Contributions from Other Government Bodies (National or Local) in the Imported Food and Feed Process

Multiple entities participate in the food and feed import process, although it appears as though fewer entities participate in the importing of animal feed than of food for human consumption. See Section 1.1

1.5 Laws and Regulations that Provide Authority for the Oversight of the Safety of Imported Foods and Animal Feed, and the Policies and Procedures that Guide Import Officials

**Food**

*The Food Act 1981* is administered by the Ministry of Agriculture and Forestry and prohibits the sale of “food that is unsafe, unfit for human consumption, or contaminated. It also allows the Minister of Food Safety to set standards and requires importers to satisfy a Food Act Officer that the food they are importing complies with the Food Act, relevant Regulations and applicable Standards.” (MAF, 2011h)

*The Health Act 1956* “provides for surveillance and disease investigation activities, including identifying problems with foodborne illness” (MAF, 2004)

*Customs and Excise Act 1996* “provides that it is unlawful to import any food where the sale of that food in New Zealand would be an offence against the Food Act”. (MAF, 2011h)

*Trans-Tasman Mutual Recognition Act 1997 (TTMRA)* states that food produced in New Zealand or imported into New Zealand that meets New Zealand’s legal requirements, may also be sold in Australia and vice versa. There are some exceptions. For example, some prescribed (high-risk) foods listed in either country require certification or testing before being permitted entry. These exemptions are being reduced such that there will be minimal Trans Tasman trade barriers. (MAF, 2011h)

*Food (Fees and Charges) Regulations 1997* sets out fees and charges associated with imported food (MAF, 2011h).

*Food Hygiene Regulations 1974* sets food handling requirements including registration of food premises (MAF, 2011h).

*Australia New Zealand Food Standards Code* specifies joint food standards. These include composition and labeling requirements for food for sale in New Zealand and Australia.

*Food (Importer Listing) Standard 2008* requires importers to list certain details with MAF (MAF, 2011h).
Food (Importer General Requirements) Standard 2008 covers what is expected in sourcing, storage, transportation of imported food, and record keeping requirements (MAF, 2011h).


Food (Imported Milk and Milk Products) Standard 2009 sets out requirements for all milk and milk products imported into New Zealand for sale (MAF, 2011h).

Food (Supplemented Food) Standard 2010 regulates food type dietary supplements (MAF, 2011h).

**Animal Feed**

The Importation of Processed Animal Feeds of Plant Origin into New Zealand Standard (2010) “describes the phytosanitary requirements for the importation of processed animal feeds of plant origin for pet food and stock feed from all countries” (MAF, 2010b).

Import Health Standard for Shelf Stable Pet Foods Containing Animal Products 2007 describes the import requirements for shelf stable pet foods containing plant or animal products (MAF, 2007).

The Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 requires all agricultural compounds to be registered under the Act unless they are exempt from registration with the main mechanism being via regulations made under section 75. The ACVM Regulations (2001), which were promulgated under section 75 of the ACVM Act, exempt oral nutritional compounds (ONCs) from registration (these Regulations list all the categories of agricultural compounds that are exempt from registration subject to compliance with certain conditions). The Regulations define an ONC as a substance ingested by an animal as feed, or a nutritional preparation intended for oral administration to an animal to achieve a nutritional benefit. This includes products such as animal feeds, premixes, pet food, nutritional supplements, including cattle licks and vitamin and mineral supplements and oral electrolyte replacers to support performance. It also includes products used to provide special or routine nutritional requirements (MAF, 2011n). Schedule 4 of the ACVM Regulations 2001 specifies the conditions ONCs must meet before they can be imported, manufactured and sold in New Zealand. One key requirement is that the product must be fit for the purpose intended.\(^8\)

\(^8\) The ACVM Regulations are being amended and are expected to be promulgated later in 2011.
The Agricultural Compounds and Veterinary Medicines Regulations 2001, exempting animal feeds and pet foods from registration, but imposing conditions for minimum labeling, and fit for purpose requirements.

The Biosecurity Act 1993 requires animal feed and pet food to meet the requirements of relevant Import Health Standards (IHSs) before they can be imported into the country. The IHSs state the measures that must be undertaken in the exporting country, during transit and during importation so that the imported animal feed and pet food do not pose a biosecurity threat to New Zealand. These standards are issued under section 22(1) of the Biosecurity Act. The IHSs are available via an online search tool.

Hazardous Substances and New Organisms Act (HSNO) 1996. The purpose of the HSNO Act is to protect the environment, and health and safety of communities by preventing or managing adverse effects of hazardous substances and new organisms. The Act requires animal feed and pet food to include specific statements on the product label if they contain hazardous substances at concentrations exceeding certain limits. The labeling requirements with respect to hazardous substances are included in the Animal Nutritional and Animal Care Products Group Standard 2006, available online at EPA’s website. Additional HSNO approval is required if the imported animal feed and pet food contain probiotics that are new to New Zealand. This group standard is complementary and informs the minimum requirements in the ACVM Regulations.

1.6 Handling of Products Transshipped Through a Third Country as Compared to Directly Imported Products

Goods arriving at New Zealand are either cleared by New Zealand Customs for entry, or transit to point of destination without entering clearing the New Zealand border.

2 INSPECTION PROGRAMS

2.1 Mechanisms to Prioritize Food/Feed Import Surveillance Activities, such as Product Sampling and Testing, Inspections at the Border, and Facility Inspections of the Exporting Country

MAF retains the legislative capability to target any imported food and may intervene at the border or post border for the purposes of e.g.

- Collecting information on emerging issues
- Responding to emerging issues and events
- To inform standards development and the food categorization process
- To conform conformance with New Zealand standards (e.g. prescribed foods)

MAF prioritizes clearance/surveillance activities around whether or not a food product is considered to be a “prescribed food”. Prescribed foods are foods that present risks to consumers and are monitored for specific hazards and are targeted at the border using tariff code(s), (See Determination of Risk below) (MAF, 2010).
Prescribed foods must not be imported into New Zealand unless the importer of those prescribed foods has satisfied a Food Act Officer (FAO) that the food complies with the Food Act, relevant regulations and applicable food standards.

**Determination of Risk and Prescribed Foods**

MAF’s determination of food safety risks, and therefore conclusion on whether a food is a ‘prescribed food’, is currently undertaken by assessing food/hazard combinations. The resulting risk profiles “provide contextual and background information relevant to a food/hazard combination so that risk managers can make decisions and, if necessary, take further action”. The Risk profiles made available on the MAF website were prepared by the Institute of Environmental Science and Research Limited (ESR) and cover food and feed products.

The MAF Science Group is involved in an ongoing process to determine a single metric for ranking risk that “can be applied to both chemical and microbiological hazards and is applicable to the varied risk ranking needs of the MAF.”

Risk ranking criteria include:

- Public health (incidence of illness apportioned to the food of interest);
- Severity (morbidity, mortality);
- Uncertainty about the risk (quality of data);

(MAF, 2011)

### 2.2 Special Screening Requirements and Trading Partner Requirements where Disease or an Outbreak hasOccurred

MAF has specific Imported Food Requirements (IFR) for prescribed foods which may require product verification in the form of documentation or sampling.

In addition to the testing of imported ‘prescribed’ foods, MAF also has monitoring programs (planned and time bound information gathering activities) in place which include “sample and testing of imported foods and feeds for known hazards, including microbiological pathogens and chemical residues” for the purpose of information gathering (MAF, 2011). Currently, MAF conducts the following monitoring programs for imported foods:

**Food Residue Surveillance Programme (FRSP)**

“MAF conducts a Food Residues Surveillance Programme (FRSP) annually to assess the effectiveness of current controls of chemical residues on imported and locally-produced foods. The FRSP focuses on between four and eight different food/residue combinations each

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10 For specific IFRs, see: [http://www.foodsafety.govt.nz/elibrary/industry/Imported_Food-Changes_Have.pdf](http://www.foodsafety.govt.nz/elibrary/industry/Imported_Food-Changes_Have.pdf)
year. MAF prioritises the list of food/residue combinations every year against the following criteria:

- Available information about use and residues of agricultural compounds
- Dietary intake-related factors (such as residue levels in specific foods)
- Availability of cost-effective laboratory analyses for the residues of interest
- Integrity in the food supply chain”

(MAF, 2011d)

**New Zealand Total Diet Study (NZTDS)**

The NZTDS “Assesses the public’s exposure to a range of residues and elements (e.g., iodine) through analyzing foods ‘as consumed’” (MAF, 2011d).

**Annual Imported Food Monitoring Programme**

In 2008, MAF began an annual programme of surveys of imported foods for selected hazards. Foods and hazards are selected according to set criteria. Samples are taken at the most appropriate point in the supply chain. This may be at the border, post-clearance or at retail level. The types of monitoring activities included in the Annual Imported Food Monitoring Programme are:

- Surveys:
  - Hazards in foods, e.g. microbiological or chemical residue testing
  - To inform standards review
  - To fill an information gap
  - Importers, behaviours and practices across the imports chain and associated factors.
- Audits including sampling and testing of products e.g. Audit of importers to verify compliance with applicable standards

(MAF, 2011q; MAF, 2011m)

Verification surveys are carried out on compliance to the minimum requirements for animal feeds and pet foods, and where compliance is inadequate or where confidence of compliance is low specific verification programs are imposed.

**2.3 Percentage of Imported Food Shipments Examined and the Relationship between Risk-Ranking of Foods and Volume of Imported Foods Examined**

**Pre-Clearance Shipments**

“Where a government to government pre-clearance arrangement exists, or MAF recognises specific overseas manufacturers, then approved assurances /certification may be accepted with imports of a prescribed food under that specific arrangement.
The standard inspection rate used to verify certification under a specific arrangement may be:

- 1 in every 20 where imports of that food type under a specific certification arrangement are more frequent than 20 in a six-month period; or

- 1 inspection every 6 months where imports of that food type under a specific pre-clearance arrangement are less than 20 in a six-month period.”

(MAF, 2010)

**Prescribed Foods**

“The sampling frequency of a specific prescribed food is based on the sampling and testing history developed by each importer for that prescribed food. As a compliance history is developed, the frequency of sampling and inspection is reduced if the consignment is found to be acceptable. This reduction is governed by the “Switching Rule”, which follows the steps below:

- Sampling initially starts out at the **tightened level** (where 100 percent or every import of that specific food is sampled and tested) until 5 consecutive compliant imports have been cleared;

- Sampling is then lowered to the **normal level** (where percent or 1 in 5 imports of that specific food is sampled and tested), until another 5 consecutive compliant imports have been cleared;

- Sampling is then lowered to the **reduced level** (where 10 percent or 1 in 10 imports of that specific food is sampled and tested). The sampling frequency will not adhere strictly to every 5th or 10th import but will be random. The end result will remain at the same required % overall i.e., 20 in 100 or 10 in 100.

- The frequency of sampling returns to the tightened level when a non-compliance with the IFR has been determined by a FAO. Non-compliance may include failed test result, importer refusal to test prescribed food or product fails inspection.

- CCH selects the frequency of sampling that is to apply to an imported food at any particular time using the “Switching Rule” for the specific prescribed food.”

(MAF, 2009)

**Non-Prescribed Foods**

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11 See Section 2.1 regarding the determination of prescribed foods.
MAF retains the legislative capability to target and intervene at border or post border for any imported food. The percentage of non-prescribed imported foods that are inspected is very minor. “Under the Food Act, imported foods that are listed as ‘prescribed’ (high-risk) foods may routinely be stopped and intervention is cost recovered. Foods that are not on the ‘prescribed’ foods list go directly to further manufacture or to distribution and retail unless MAF intervenes for other reasons, however these activities are not cost recovered. There are currently no routine proactive border or post-border controls or checks of these imported foods unless: 1) they become part of food production in New Zealand, 2) complaint is made about them, or 3) an overseas country raises concerns, or MAF has reason to intervene.” (MAF, 2004)

2.4 Types of Review, Examination and/or Testing of Imported Products Performed by Food Safety Inspectors

Documentation for prescribed foods via single use permits and importer food requirements is checked (See Sections 2.2 and 2.3).

Sampling occurs for prescribed foods (See Section 2.3)

Residue and Microbiological testing is also performed (See Section 2.2)

2.5 Frequency of Documentation and Labeling Checks as Compared to Analytical Examinations

Documentation accompanying consignments may be subject to review by Customs and MAF for any consignment. Documentation is routinely checked by MAF for prescribed foods and for foods subject to emerging issue and event response (e.g. melamine) or other intervention purposes. Imported Food Requirements (IFRs) may further specify minimum documentation verification rates. Labeling checks for imported food are not routinely conducted at the border, except in the case of clearance of prescribed foods. Labeling compliance is managed at the domestic retail level at which point products for sale must meet FSANZ minimum requirements.

2.6 Types of Examination and Testing Processes Used for Ensuring Animal Feed and Feed Ingredient Safety

The ACVM Regulations require animal feeds and pet foods sold for use in New Zealand to be fit for the purpose of feeding to the species, type, and class of animal for which the product is intended. The responsibility for ensuring this lies with the importer/manufacturer.

2.7 The Dependence of Examination and Testing Requirements on Conditions (such as the Presence of BSE or Other Zoonotic Diseases) in the Exporting Country

MAF published Imported Food Requirements may cover conditions in exporting countries.
Meat or other food product of a bovine animal, and any food product derived from or containing the meat or products of a bovine animal is considered a prescribed food for the presence of bovine spongiform encephalopathy (BSE).

2.8 **Inspections of Food or Animal Feed Manufacturers or Shippers in Other Countries (including Selection Criteria and Frequency)**

New Zealand does not routinely inspect food or feed manufacturers and shippers in other countries.

New Zealand does however perform sporadic audits of foreign producers and competent authority infrastructure where necessary to facilitate conclusions on import preclearance arrangements (See Section 3.2). New Zealand may also take into account published findings of the EU Food and Veterinary Office and other country audits.

The imported food system, generally, places the burden of product safety on the importer. For example, “Under the Food (Importer General Requirements) Standard 2008, importers must be able to provide evidence that imported food has been produced and managed in a way that results in food that is safe for human consumption. The type and amount of evidence that importers request from suppliers should be appropriate for the level of risk posed by a particular food.” (MAF, 2008c)

Overseas animal feed and pet food manufacturers are not audited. Under the ACVM Regulations 2001, all parties including importers are obliged to meet the minimum fit for purpose obligation. Verification surveys are carried out on compliance to the minimum requirements for animal feeds and pet foods, and where compliance is inadequate or where confidence of compliance is low specific verification programs are imposed.

2.9 **Notification system(s) to directly notify foreign governments when foods or animal feed manufactured in their countries are found to be unsafe; and to notify the public when imported products do not meet safety standards**

MAF publishes alerts and advisories on foods that are considered to be a significant food safety risk and that may have, or could be imported into New Zealand. MAF also publishes information to consumers on significant food safety risks that may be present on the domestic market. Imports of food that fail verification import testing and accompanied by agreed government certification are reported to the exporting competent authority.

It is the responsibility of the importer to create and implement a food recall procedure. MAF provides guidance for the development of recall procedures via their website (e.g. reference guide, sample press release, news advertisement template). (MAF, 2011k)

“The decision to recall a food is based on there being a risk assessment including:

- Identification of a hazard that makes a food unsafe and,
- Likelihood of affecting public health.
“When a food safety problem is identified in a product that has been distributed beyond the manufacturer, the manufacturer must advise or warn consumers/industry by way of a trade level or consumer level recall notice”, which are the two levels of product recall.

- Recall is a removal of unsafe or unsuitable food from the distribution chain and extends to food sold to consumers and therefore requires effective communication with consumers.
- Withdrawal (also known as Trade Recall) is the removal of an unsafe or unsuitable foodstuff from the distribution chain but does not extend to food sold to the consumer.”  

(MAF, 2005a)

According to the MAF Recall Quick Reference Guide, “When a recall is initiated, actions in recalling the food need to be coordinated with MAF. A Food Act Officer at the local Public Health Unit\textsuperscript{12}, MAF verifier or contracted third party agency (as appropriate) should be notified as soon as a recall is likely. MAF will provide support and technical advice via the Officer coordinating the recall.” (MAF, 2005)

The ACVM Act contains recall provisions and prohibition notices that can be issued in regard to import, manufacture, sale or use of animal feeds and pet foods. There is no existing procedure for notifying foreign governments about animal feeds and pet foods found to be unsafe.

MAF will communicate directly with trading partners through NZ Embassies, High Commissions and Consulates if a foreign food or feed safety issue or concern is identified.

3 AUDITS AND CERTIFICATION

3.1 Assessing and Measuring the Effectiveness of the Food/Feed Safety Import Program (e.g., Self Audits of the Program, Public Health Outcomes, Surveillance Sampling Results, Number/Rates of Refusals, Periodic Program Evaluations)

MAF does not routinely audit the effectiveness of the imported food program. Programmatic audits of importer activities and clearance agency (CCH) compliance with expectations have been completed over the last 2 years. Findings are being used to inform the development of the future imported food program.

MAF Verification (Animal and Food Products) is also subject to assessments by the accreditation body, International Accreditation New Zealand (IANZ), and by the MAF Compliance & Enforcement Group (MAF, 2008a).

3.2 Extent of Reliance on Trading Partners’ Food Safety Programs to Ensure That Imported Foods or Animal Feed are Safe

\textsuperscript{12} The MAF recall site states that during a recall, MAF monitors the situation, but it is handled by the Public Health Units. See: http://www.foodsmart.govt.nz/food-safety/recalls/questions-answers/
“Under the Food (Importer General Requirements) Standard 2008 part 2, 6 (b) (i) importers must be able to provide evidence that imported food has been produced and managed in a way that results in food that is safe for human consumption. The type and amount of evidence that importers request from suppliers should be appropriate for the level of risk posed by a particular food” (MAF, 2008c). New Zealand officials acknowledged that while importers are currently listed and required to meet import standards, MAF has not fully enforced nor verified these requirements in current system (MAF, 2011).

The preclearance arrangement framework provides MAF with the ability to recognize exporting country programs against New Zealand’s regulatory environment. Types of preclearance arrangements include mutual recognition and equivalence agreements.

New Zealand has performed sporadic audits of foreign producers and competent authority infrastructure where necessary to facilitate conclusions on preclearance arrangements (See Section 3.5).

MAF will also recognize comparable country-wide plans that have already been instituted to meet, for example, U.S. or EU standards under pre clearance arrangement. Many exporting countries rather than submitting programs for recognition of equivalence will simply put forward US and EU-based export plans, so foreign authorities are relied upon for verification and audit processes. (MAF, 2011)

3.3 Requirements for Food and/or animal feed export certificates issued by the exporting country’s competent authority, and types of inspection or testing for each

Current certification arrangements for prescribed food imports are historical and based on the type of product and whether certification has been agreed with the exporting country competent authority. MAF is currently reviewing the approach in anticipation of the new food legislation in 2012 with greater emphasis being placed on encouraging recognition of competent authority certification.

MAF’s current framework provides for the facilitation of competent authority certification for any food listed as prescribed. Certification provides for recognition of food safety controls applied by the exporting country or testing any inspection procedures that ensure the associated product hazard is addressed13 (See table below. Note that the Hazards are for particular products within each of the general categories):

Table 1: Prescribed Foods and Potential Hazards

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Examples of Hazards that Certification Must Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meat</td>
<td>▪ Bovine Spongiform Encephalopathy (BSE) agent</td>
</tr>
<tr>
<td></td>
<td>▪ Salmonella</td>
</tr>
<tr>
<td>Seafood</td>
<td>▪ Histamine</td>
</tr>
<tr>
<td></td>
<td>▪ pathogenic bacteria</td>
</tr>
</tbody>
</table>

13 For list of prescribed foods and their specific requirements, see: [http://foodsafety.govt.nz/industry/importing/nzfsa-clearance/](http://foodsafety.govt.nz/industry/importing/nzfsa-clearance/)
### 3.4 Use of ISO, Global Gap or Other Assurance Systems and Confidence in the Assurance System(s) Utilized

MAF Verification (Animal and Food Products) maintains accreditation to ISO 17020 – the international standard for inspection bodies (MAF, 2008a)

### 3.5 The Nature and Frequency of Foreign Food Safety Systems Audits Performed

New Zealand does not routinely audit foreign food safety systems. New Zealand does however perform sporadic audits of foreign food safety systems where necessary to facilitate conclusions on import preclearance arrangements (See Section 3.2), or to maintain confidence in the exporting system. New Zealand may also take into account published findings of the EU Food and Veterinary Office and other country audits.

### 3.6 Equivalence Agreements Requiring Periodic Audits/Reevaluations of Exporting Countries’ Food Safety Programs

As stated in the MAF Equivalency Policy (2010), “If an equivalence determination is granted, [the two countries will] develop a process for ongoing maintenance and review of the relevant control systems.”

### 3.7 The Utilization of Third- Parties (Within the Exporting or Importing Country) to Carry out Inspections and/or Product Certification (Nature and Extent of Programs) and Methods for Verifying the Adequacy and Reliability of the Third Party Work

New Zealand does currently recognize third party inspection and certification, but does not routinely audit third-parties. MAF is currently reviewing the approach in anticipation of the new food legislation in 2012.

Private laboratories “are employed by both government and the private sector. Only tests by laboratories approved by MAF are valid for food-safety purposes, and at present MAF recognizes only laboratories that are accredited by International Accreditation New Zealand (IANZ) for the relevant test.”

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14 The Import Policy Background Paper can be found at: [http://www.foodsafety.govt.nz/elibrary/industry/Nzfssa_Policy-Concept_Allows.pdf](http://www.foodsafety.govt.nz/elibrary/industry/Nzfssa_Policy-Concept_Allows.pdf)

the quality of their products. These are voluntary arrangements, and there is no register of such consultants.” (MAF, 2004)

Export certificates pertaining to animal and dairy products are issued by certifiers in MAF Verification (Animal and Food Products). MAF Verification (Animal and Food Products) “provides verification and certification services to approximately 700 food processing companies (e.g. meat, seafood and game); the majority of whose products are exported worldwide (MAF, 2011f; MAF, 2011o). Export assurances and certificates pertaining to plant and organic products are also issued by MAF (MAF, 2011b).

According to Food Importer Standards Guidance (2008) “Importers may need to produce a certificate of analysis (CoA) detailing testing results of the specific batch of product. CoAs should only be accepted from laboratories accredited to ISO 17025, which is an international standard for testing laboratories. (MAF, 2008)

3.8 Arrangements with other Governments Relating to Imported Foods or Animal Feed (such as Memoranda of Understanding, Mutual Recognition Agreements, etc.)

“The agreements and arrangements with Australia (which began with the Closer Economic Relations Trade Agreement in the early 1980’s, saw the Joint Food Standard Agreement signed in 1995 and later the Trans Tasman Mutual Recognition Agreement of the late 1990’s). The TTMRA is the most comprehensive trade agreement example for New Zealand, in that food animal feeds and pet foods that can be legally sold in one country can be sold in the other without any additional measures applying. The New Zealand - European Union Agreement, signed in 1996, at its highest level recognises the equivalence of the food control systems and sets out a process for determining equivalence of specific commodity / measures as well. New Zealand and the United States of America have also reached agreements focused at the specific commodity /control measures level largely in relation to microbiological monitoring. In recent years, New Zealand has also entered into a number of free trade agreements (FTAs) that include a specific SPS chapter. Examples include the Trans-Pacific Strategic Economic Partnership Agreement (‘P4’) between Brunei Darussalam, Chile, New Zealand and Singapore signed in 2005; the New Zealand - China FTA signed in 2008; the New Zealand - Malaysia FTA signed in 2009; and the ASEAN - Australia and New Zealand Free Trade Area Agreement signed in 2010 and the New Zealand - Hong Kong, China Closer Economic Partnership Agreement also signed in 2010.” (MAF, 2010a)

“New Zealand applies principles of transparency in all cases where food safety equivalence is applied– both when New Zealand seeks recognition from another country, and when another country seeks recognition from New Zealand” (MAF, 2010a).

3.9 Registration or Licensing of Firms That Import and/or Export Foods or Animal Feed to the Country or for Firms That Import Foods or Animal Feed

The Food (Importer Listing) Standard 2008 requires importers of food to list certain details with MAF (MAF, 2011h).
Firms that import food and feed into New Zealand must also be registered with Customs (See Section 1.3). It is the importer’s responsibility to provide the necessary registration and documentation information. Information pertaining to the licensing and registration of firms exporting food and feed to New Zealand was not located. Documentation may include certificates or licensing that was performed by the exporting country’s competent authority (See Sections 3.2, 3.3, and 3.7).

“For imports in excess of NZ$1,000, a supplier code is required as part of the import entry preparation.” An application for a supplier code must be submitted to Customs along with documentation that provides evidence of the supplier’s name and country. (Customs, 2011a)

Exporters of animal products require registration (See Section 7.1).

3.10 Use Sampling Surveys of Imported Foods/Feed (as Opposed to Targeting Specific Products/Producers for Inspections and/or Testing) to Gather Information and Identify Trends and Potential Areas of Difficulty

Surveys of imported food and feed are performed. (See Section 2.2)

3.11 “Good Practices” Programs for Foods/Feed Importers

MAF provides importer guidance documents, such as *Food Importer Standards Guidance* (2008) and *Import Clearance Procedures* (2010), which outline importer requirements. MAF is currently reviewing the approach in anticipation of the new food legislation in 2012 which will provide for strengthened duties, obligations and verification of importer compliance. This will include the development of improved tools and guidance material to support ‘good practices’ by importers.

3.12 Description of Import Program User Fees and Cost Recovery System

The imported food program is funded by the Government of New Zealand, however, some user fees are assessed to importers for services such as permit processing and sampling of prescribed goods (MAF, 2011c; MAF, 2011)16.

MAF is currently reviewing the approach in anticipation of the new food legislation in 2012

3.13 Incentives to Increase Industry Involvement in Ensuring That Imported Foods Meet Safety Standards

MAF Verification (Animal and Food Products) (VAFP) assists “industry operators to increase their understanding of risk-based management practices by: “

16 For further fee information, see: [http://www.foodsafety.govt.nz/industry/importing/fees-and-charges/](http://www.foodsafety.govt.nz/industry/importing/fees-and-charges/)
MAF is currently reviewing the approach in anticipation of the new food legislation in 2012

3.14 Obstacles to Industry Participation in Ensuring That Imported Foods Meet Safety Standards

The main obstacle to ensuring imported foods meet safety standards is the current lack of importer understanding and acceptance of responsibilities. MAF is currently reviewing the approach in anticipation of the new food legislation in 2012. Registration enforcement and verification of importer activities will strengthen compliance levels and understanding.

4 LABORATORY SUPPORT

4.1 The Role of Laboratories in Supporting the Imported Food and Feed Programs and Description of Laboratory Capabilities

Laboratories generally undertake testing of prescribed foods when required for import clearance as well as foods being sampled through the import monitoring programs (See Section 2.2). Samples can only be tested by laboratories listed by MAF for that specific purpose and MAF only lists laboratories that are accredited by International Accreditation New Zealand (IANZ)\(^{18}\) to do the relevant test (MAF, Sampling and testing Protocol, 2009). There is no specific MAF approval process for laboratories performing tests on imported food, although MAF administratively recognizes the same laboratories that provide for export certification testing.

4.2 Participation of Non-government Laboratories (Including Industry and Academic Laboratories) in the Food Import Control Program

Private laboratories are employed by both government and the private sector. Only tests by laboratories approved by MAF are valid for food-safety purposes, and, at present, MAF only recognizes laboratories that are accredited by International Accreditation New Zealand (IANZ) to the international standard ISO/IEC 17025 – General Requirements for the Competence of Testing and Calibration Laboratories.

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\(^{17}\) “To preserve its independent status, MAF Verification (Animal and Food Products) does not, however, participate in activities that relate to final decision making by operators, or that would involve giving instructions or providing solutions to resolve non-compliance issues relating to a specific risk-based management plan” (MAF, 2008a).

\(^{18}\) IANZ itself complies with ISO/IEC 17011, it meets the requirements of the Asia Pacific Laboratory Accreditation Cooperation (APLAC), and of the European cooperation for Accreditation (EA). It was a foundation member of the International Laboratory Testing Cooperation (ILAC).
4.3 Methods for Laboratories to Achieve Quality Assurance (such as Voluntary or Mandatory Accreditation)

“IANZ-approved laboratories will select the most appropriate test method. The IANZ-approved laboratory must be accredited to perform that test. Importers should check that the laboratory is accredited to perform the required test before submitting the samples for testing.” (MAF, 2004)

5 ENFORCEMENT AT BORDER

5.1 Approach to Visual Inspections and Analysis of Imported Foods (e.g. Risk-Assessment and Prioritization Schemes, Documentation Review, Sample Collection)

See Sections 1.1, 2.1, 2.2, and 2.3.

5.2 The Process that Occurs When an Imported Food is Found to be Contaminated or does not Meet Standards

“The guidance criteria for rejection of a lot are set in each specific imported food requirement (IFR). The Food Act Officer (FAO) may reject the prescribed food for other reasons if not satisfied that the product complies with the Food Act. When lots fail the import criteria, they:

- Should be rejected
- Should not be re-tested.
- Will be detained by the FAO under the provisions of the Food Act. The importer will be given five working days to provide written advice to MAF as to what they intend to do with the failed lots and their intentions for the remaining lots in the consignment. Failure to notify MAF within 14 working days of the detention may result in seizure and destruction of the consignment in accordance with the Food Act.
- Are prohibited imports and must be disposed of in a manner approved by MAF. Detention and seizure costs for failed product will be borne by the importer.”

(MAF, 2009)

5.2.1 Procedures for Refusing Imported Foods Based on a Finding that they do not Comply with Requirements

See Section 5.2

5.2.2 The Procedure and Outcome for Imported Foods that are Refused Entry (Including Efforts to Prevent them from Mistakenly Entering Domestic Commerce))

“When clearance cannot be given because the importer has not satisfied a FAO that the food complies with the Food Act, all determinations on disposition of non-complying consignments should be made in full consultation with MAF. This will facilitate appropriate corrective action and communication with relevant entities.
Dependent on the nature of the non-compliance, options would include:

- Re-processing providing the nature of the non-compliance can be suitably addressed by an appropriate intervention step,
- Re-export back to country of origin where country of origin confirmation of acceptance has been received,
- Re-export to a 3rd country where 3rd country confirmation of acceptance has been received,
- Denaturing or destruction of the consignment to prevent distribution or use”

(MAF, 2009)

5.2.3 *Entry of Detained Products Based on Further Testing or Reconditioning of the Product*

See Section 5.2.2

5.2.4 *Process for Identifying and Tracking Producers or Countries that have Repeated Violations*

The current approach focuses on prescribed foods. Repetitive failures in meeting clearance requirements are notified to the exporting country, or competent authority in the case of agreed certification.

MAF is currently reviewing the approach in anticipation of the new food legislation in 2012. This will include strengthening duties and obligations of importers round their responsibility for taking corrective action with suppliers to minimize repetitive non compliance. Develop of IT systems under Trade Single Widows (TSW) will also improve MAF’s ability to track and respond to repetitive non compliance.

5.3 *Program for investigating and responding to intentional contamination of foods*

The Strategic Review of Regulatory Arrangements (2004) notes that additional funding was provided for Customs as well as intelligence activities in order to help combat bioterrorism and the intentional tampering of food products. The review team in the report recommended “a substantial strengthening of recall and traceability systems as a key element of any response to bioterrorism and sabotage”. (MAF, 2004)

The forthcoming imported food program (See Overview) will address the intentional contamination of food through intelligence efforts.

See also Sections 2.9 (Recall), 5.2 (Meeting standards), section 6.2 (Outbreaks)

6 **FOOD RELATED ILLNESS OUTBREAKS**
6.1 System for Tracking Imported Foods once they are Cleared at the Point of Entry

The following importer requirements are used to help track imported food:

- Importers are given a unique identifier when they register with customs, and they are also required to be listed with MAF.
- Food (Importer General Requirements) Standard (2008) requires importers to maintain records that include “supplier contact details and details of products supplied for all suppliers and a supplier list kept in a form that makes the information readily available for tracking and recall purposes”. These records may be maintained in paper or electronic formats (MAF, 2011).
- Labeling requirements include listing the food supplier (MAF, 2011)

6.2 Systems for Identifying Foodborne Illness Outbreaks

The Ministry of Health and MAF share responsibilities for foodborne illness outcomes at a high level (MAF, 2011). State and territorial public health services generally “manage disease outbreaks independently, and rarely require the support or assistance of agencies such as the Ministry of Health, ESR and other public health services.” (ESR, 2002)

ESR is responsible for Notifiable Disease Surveillance and for Outbreak Surveillance (food borne illness may fit into both).

“The Institute of Environmental Science and Research Limited (ESR) has a central role in outbreak surveillance which includes regular analysis of surveillance data to detect emergent problems, helping to prevent disease outbreaks in New Zealand and reducing their impact.

This work includes the following:

- ESR operates an outbreak surveillance system on behalf of the Ministry of Health. This system collates data on all outbreaks reported by New Zealand public health units. This data is a resource for all agencies seeking to understand the pattern of disease outbreaks in New Zealand, both locally and nationally, in order to develop strategies for disease outbreak prevention.
- On request, ESR provides public health unit staff with advice on outbreak detection and investigation.
- ESR has the capability to contribute to and to coordinate the investigation of disease outbreaks of national importance, particularly those involving more than one health district.
- ESR has also produced the Disease Outbreak Manual as a guide to management of disease outbreaks in New Zealand.” (ESR, 2011a)

“The Population and Environmental Health group in ESR is funded by the Ministry of Health to provide assistance with the epidemiologic investigation of outbreaks. Under this arrangement,
previously called the epidemiologic consultancy, ESR may provide advice on some or all of the following areas:

- Clarification of the aims of the investigation
- Relevant literature and related research
- Developing the study design, including reviewing draft questionnaires
- Conduct of the investigation
- Statistical analysis of results
- Preparation of the outbreak report” (ESR, 2002)


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6.3 Procedure for Tracking Illnesses back to the Food Source when a Foodborne Illness Outbreak Occurs

On request, ESR provides public health unit staff with advice on outbreak detection and investigation. ESR has the capability to contribute to and to coordinate the investigation of disease outbreaks of national importance, particularly those involving more than one health district (See Section 6.2). (ESR, 2011a)

ESR EpiSurv collates notifiable disease information on a real-time basis from the Public Health Services (PHS) in New Zealand. Key data fields collected include case demographics, clinical features and risk factors. EpiSurv also incorporates an outbreak functionality that enables cases to be linked via a common cause (ESR, 2011b). MAF is notified of emerging issues through both

19 Table information taken from (ESR Disease Outbreak Manual, 2002)
the Ministry of Health (under a MoU) and ESR (including via weekly Public Health Aberrant Infectious Disease Event newsletters).

### 6.4 How Consumers Notify the Government and/or Importers of Food Problems

MAF has a consumer advice help line and specific industry direct contact line. In addition consumers may lodge ‘food complaints’ directly via MAF website (MAF, 2011i).

### 7 EXPORT PROGRAMS

#### 7.1 Programs for Ensuring Safety Requirements of Export Destination Countries

MAF’s export certification systems (refer to paragraph 44 for a listing) are similar in their overall approach – they rely on eligibility/verification and support of certification based on validation of overseas market access requirements. However, the detail differs in the electronic and manual platforms used, the data element structures and formats, the underpinning eligibility/verification systems, and even the output formats and transmissibility. A single export consignment may be required to have up to four different types of MAF certificate (e.g. health, organic and quota), all of which currently have to be processed separately.

MAF export certification includes:

- Ad hoc statements
- Animal products (E-cert), includes IUU (illegal, unregulated and unreported) catch certificate for the EU
- Certificates of free sale
- Country product registration certificates
- Dairy products (E-cert) – in the process of merging into animal products E-cert
- Dairy quota management
- Germplasm
- Live animals
- Milk product E-cert
- Organic products
- Plant and forestry products (phyto-sanitary E-cert referred to as ePhyto)
- Plant grade certificates
- Plant agrichemical assurances
- Seed varietal certification
- Wine

The output of MAF certification is for international government-to-government assurances (paper or electronic) relating to production, process and product compliance. Therefore, MAF certification relies upon the validation of whole of production, process and storage chain eligibility and verification information and not just the supply of information by the exporter at the point of export.

Aside from equivalency determinations (See Section 8.3) and export certification (Section 7.1.1), MAF also requires exporters of certain goods to be registered.
Exporter Registration for animal products
“The basic position is that no person may export from New Zealand any animal products intended for human or animal consumption or any other animal material and products that are subject to market access requirements needing an official assurance, unless they are registered as an exporter.” This basic position is modified by the Animal Products (Exemptions and Inclusions) Order 2000 as follows: “
* Inclusion
  - Exporters of glands or bile of any animals, animal blood or blood products, and deer velvet or deer velvet products must be registered as exporters whether or not the material or products are intended for human or animal consumption.

* Exemptions
  - No exporter of dairy produce only is required to be registered under the Animal Products Act, and exporter duties will not apply (see section 50 of the Animal Products Act). Note that this does not prevent the issuing of an official assurance under the Animal Products Act in respect of any product that is or contains both animal product and dairy produce.

  - Exporters of fish caught in the EEZ but not landed in New Zealand will not need to be registered.

  - Also the following consignments are exempted from coverage of Part 5 of the Animal Products Act so exporters of such consignments do not need to be registered:
    - Multi-ingredient foods and other prepared foods which, despite containing 1 or more ingredients that are animal material or products, do not consist principally of animal material or products (for example, biscuits, cakes, bread, soups, sauces, snack goods, pastries, confectionery, and also prepared meals that do not consist principally of meat):
    
    - Food for the consumption on any vessel or aircraft of passengers, crew, and animals during transit by sea or air from New Zealand, being meals in a ready-to-eat state or other food for human or animal consumption (for example, airline meals, ships’ stores, and feed for animals being transported).”

(New Zealand, 2010)

7.1.1 Use of Export Certificates to Provide Assurances to the Importing Country

Where New Zealand does not have equivalency or mutual recognition agreements with a country regarding a product, MAF will provide assurances that the product meets the importing country’s standards (MAF, 2011). Export certificates may be obtained for the following categories of food products: animal, plant, organic, and wine. Exporters may obtain electronic certification for animal and plant (for phytosanitary certification) products via MAF’s electronic certification system, E-Cert. The primary purpose of E-Cert is to “track the market eligibility and product
status from the time of production until export (verification) and approve and print sanitary
export certificates (certification).” (MAF, 2011a)

There are different E-Cert Systems. The systems applicable to this study are the Animal Products
E-cert used for exported animal products excluding dairy products (i.e. meat, seafood, game,
poultry, eggs, pet food, bee products, hides, wool and skins) and Dairy E-cert used for exported
dairy products. (MAF, 2011a)

“The content of the export certificates are supported by the verification regime which manages or
controls the advice about the product compliance with importing country requirements. An
approved export certificate is available to the appropriate border agency of the importing country
(electronically or in paper form). Animal certificates are “supported by an extensive collection of
approved electronic internal transfer documents that track the product movements within New
Zealand. These are called eligibility documents or eligibility declarations.” (MAF, 2011a)

MAF audits New Zealand food exporters and also review export certificate applications (MAF,
2011; MAF, 2011a).

7.1.2 Providing to the Import Country Lists of Establishments that Meet the Importing
Countries’ Food Safety Requirements.

“Certain countries require exported animal products to be from an approved premises/operator.
This requirement is specified in the Overseas Market Access Requirements that relate to
particular countries.

Country lists are updated routinely. Individual premises/operators that apply for listing or
modification to their listing will continue to receive letters of listing confirmation.” (MAF,
2011p)

7.1.3 Authorized Third Party Issuance of Export Certificates

Principle 8 of the Market Access and Official Assurances Principles states, “Third parties will be
used at the verification step in the provision of official assurances wherever possible and their
roles will be clearly defined.”

must meet internationally recognised standards that cover competencies, conflict of interest and
quality systems. Government will define appropriate secondary SUPPLEMENTARY criteria to the
international standards.”

(MAF, 2008a)

8 WORLD TRADE ORGANIZATION (WTO) OBLIGATIONS

8.1 Methods for Ensuring Consistency between Domestic and Imported Food Safety
Requirements
MAF notifies changes to domestic and imported food safety requirements through the WTO process.

MAF is currently reviewing the approach for ensuring consistency in anticipation of the new food legislation in 2012. The new approach will further strengthen the current review process for proposed requirements on imported food relative to outcomes required for the same products produced in New Zealand. In undertaking this review MAF’s overarching objective is the management of imported food safety and suitability, while at the same time ensuring trade is facilitated to the maximum extent possible. Where requirements are required to manage risks for imported foods, a range of risk management options will be made available including open invitation for exporting parties to apply for recognition of programmes.

8.2 Methods of Documenting the Scientific Justification for Import Practices with regard to Article 5 of the SPS Agreement, which Requires that Measures are based on an Assessment of Risk, as Appropriate to the Circumstance

MAF notifies changes to domestic imported food safety requirements through the WTO process. MAF facilitates public consultation on proposed changes and provides access to supporting information on risk assessment and selected risk management options. MAF also takes a proactive stance with major trading partners to assess the impact of proposed measures on current exports and to proactively work through with the trading partner on solutions.

The Market Access and Official Assurances Principles have been approved by the SPS Forum, which is comprised of senior representatives from MAF. Principal 2 states, “Government will endeavour to ensure that importing country official requirements are commensurate with risk and aligned with the principles espoused in the WTO SPS Agreement.” (MAF, 2008a).

8.3 Involvement in Article 4 of the WTO SPS Agreement Regarding Equivalence Determination

“In October 2001 the WTO Committee on Sanitary and Phytosanitary Measure (SPS Committee) adopted a Decision on the Implementation of Article 4: Equivalence of the SPS Agreement (G/SPS/19). New Zealand participated in the discussions of the SPS Committee in the development of this decision. In doing so, New Zealand placed particular emphasis on the importance of the work being undertaken in the international standard setting bodies – Codex and OIE – in developing standards, guidelines and procedures that would support the implementation of the concept of equivalence.” (MAF, 2010a)

New Zealand was also the lead country with the US, Australia, and Canada in development of the Codex guidance document on equivalence, Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification.

“When New Zealand seeks to develop an equivalence arrangement, the steps usually involved can be summarized as follows:
8.4 Process for Recognizing a Foreign Country’s Food Safety System as having Adequate Regulatory Oversight

Pre-clearance arrangements confirm that export of interest is derived from a regulated environment in the exporting country which manages hazards and meets New Zealand’s requirements. The competent authority of an exporting country can apply to MAF for determination of an equivalency assessment and pre-clearance arrangement. The application must be submitted as one of the three types of arrangement considered by MAF:

- Overseas country / commercial entity applies measures equivalent to New Zealand Standards
- Overseas country / commercial entity comply with a food control system that NZFSA has determined as equivalent to New Zealand Standards (USA / EU).

- Overseas country / commercial entity meets New Zealand Standards.

MAF assessment may be through desk top assessment alone or be supplemented by exporting country visits. MAF’s preferred approach is to reply on desk top assessment and recognition followed by performance based verification during clearance. Most application received by MAF for ‘equivalence’ are through recognition of the exporting country applying existing EU or US programmes.

Following recognition of equivalence and preclearance arrangement, MAF will require that the competent authority of the exporting country to provide assurances, through certification, as to the compliance or equivalence with New Zealand food safety requirements.

MAF may undertake audits to review the arrangements. However, confidence could also be based on assessment of these systems by other competent authorities.
SOURCES CITED

The Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.


International Accreditation New Zealand. 2011. About IANZ.


-2011q Annual Imported Food Monitoring Programme.  

-2010. Import Clearance Procedure.  


-2008c. Sourcing from a Regulated Environment.  


SOUTH AFRICA
FOOD AND FEED IMPORT PRACTICES
APPENDIX J
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The Department of Health (DOH) is responsible for the import, manufacture, sale, and export of mainly processed products; development of food safety regulations; nutritional labeling; and is the contact point for Codex, INFOSAN, and RASFF. Although the control of exports have been added to their mandate in 2007 through the amendment of Act 54 of 1972, no regulations have been published in this regard to date, and the role of the health sector is limited to the issuance of health certificates by provincial or municipal health departments in the event of requests received on an ad hoc bases from prospective exporters of foodstuffs and where the products concerned are not dealt with by the Department of Agriculture, Forestry and Fisheries (DAFF), or the National Regulator for Compulsory Specifications (NRCS) under their legislation, and in the event of an importing country requiring a health certificate. The Department of Agriculture Forests and Fisheries (DAFF) regulates safety and quality of agriculture and animal products, as well as agricultural input products such as pesticides, animal food and feed, etc. Within DAFF, responsibilities are divided among over 12 divisions, including the Agricultural Inputs Control, Plant Health, Inspection Services, Animal Health, Food Safety and Quality Assurance, and International Trade.

Department of Trade and Industry (DTI)/National Regulator for Compulsory Specifications (NRCS) is responsible for Certain Compulsory Food Regulations enacted by the Parliament of the Republic of South Africa to administer various Compulsory Specifications to protect the safety and well being of consumers utilizing various consumer products and utensils. They are responsible for the compulsory specifications that set minimum safety standards for certain fish products.

The nine Provincial Departments of Health have Environmental/Port Health sections. Their role includes monitoring and co-ordination of food control at the provincial level and the District and Metropolitan Municipality level. They are responsible for coordinating activities within the province; providing support to the metro and district municipalities rendering Municipal Health Services (MHS); rendering Port Health Services, which includes the control of imported foodstuffs; and setting protocols and strategies for health within the province.

All persons who import goods into South Africa must register as an importer with Customs. Importers importing commercial goods into South Africa, and exporters exporting commercial consignments from South Africa, must register with the South African Revenue Service (SARS). All goods entering South Africa in the normal course of trade must be declared on the prescribed bill of entry. If errors are detected by Customs - whether duties were payable or not - the Act provides for penalties of up to three times the value of the goods, in addition to the forfeiture of the goods.
1 ROLES AND FUNCTIONS OF AGENCIES RESPONSIBLE FOR IMPORTS OF HUMAN FOODS AND ANIMAL FEED

1.1 Governmental Ministries and Subunits (Including National/Regional/Local, as Appropriate) With Responsibility for Assuring the Safety of Imported Food

Department of Health (DOH)

The DOH is responsible for the import, manufacture, sale, and export of mainly processed products; development of food safety regulations; nutritional labeling; and is the contact point for Codex, INFOSAN, and RASFF. Although the control of exports have been added to their mandate in 2007 through the amendment of Act 54 of 1972, no regulations have been published in this regard to date and the role of the health sector is limited to the issuance of health certificates by provincial or municipal health departments in the event of requests received on an ad hoc bases from prospective exporters of foodstuffs and where the products concerned are not dealt with by DAFF, or the NRCS under their legislation, and in the event of an importing country requiring a health certificate.

Although the Director General of the DOH is responsible for the control of imported foodstuff covered by Act 54 of 1972, it is delegated to the provinces through the National Health Act, Act 61 of 2003. Within the organizational structure, the Directorate: Food Control coordinates with Provincial Health Departments responsible for rendering Port Health Services on all imported foodstuffs related matters. (Interview, 2011)

The Directorate: Food Control is responsible for the Foodstuffs, Cosmetics and Disinfectant Act, Act 54 of 1972. “The Directorate: Food Control ensures an optimal non-personal preventative primary health care service in respect of the safety of food for the South African community based on basic needs and the right to make informed choices without being misled by means of scientifically founded legislation, auditing and information actions.” (DOH, 2011a)

The main functions of the Directorate: Food Control include the administration, compiling and publication of legislation relating to food safety; food labeling; regulatory nutrition and related matters; as well as advising stakeholders on the contents, application and interpretation; initiate, coordinate and evaluate general and specific food monitoring programs; and manage food safety alerts. The Directorate audits and supports provinces and local authorities with food law enforcement and related matters. (DOH, 2011a)

They evaluate risk assessments related to agricultural chemicals and food produced by means of biotechnology, on/at the request of the Department of Agriculture, Forestry and Fisheries, as well as of contaminants, additives, maximum residues etc., based, inter alia, on assessments conducted by JECFA and JMPR of the FAO/WHO. They inform, educate and communicate food safety and related matters to stakeholders such as industry, consumers and other departments, and act as the national contact point for the Joint
Where applicable, the Directorate liaises and coordinates with other Departments such as the Department of Agriculture, Forestry and Fisheries or the National Regulator for Compulsory Specifications, as well as other stakeholders such as industry and consumer representative bodies. (DOH, 2011a)

For the purposes of its regulatory activities, the Directorate is advised by the Food Legislative Advisory Group (FLAG). FLAG is a non-statutory body is composed of representatives of academic and research institutions, the food industry, consumer and professional organizations, other government departments and provincial health authorities. The Director: Food Control is the chairperson. (DOH, 2011a)

**Department of Agriculture, Forestry & Fisheries (DAFF)**

DAFF regulates safety and quality of agriculture and animal products, as well as agricultural input products such as pesticides, animal food and feed, etc. Within DAFF, responsibilities are divided among over 12 divisions, including the Agricultural Inputs Control, Plant Health, Inspection Services, Animal Health, Food Safety and Quality Assurance, and International Trade.

The Directorate: Agricultural Inputs Control is responsible for animal feed safety. In terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947), all animal feed and feed raw materials, except maize and unbroken grains, must be registered before it can be sold into the South African market or used in animal feed production.

The Agricultural Pests Act, 1983 (Act No. 36 of 1983) mandates the Directorate: Plant Health to regulate plants, plant products and other regulated articles when imported into South Africa in respect of pests (including diseases) that are not yet present in South Africa, or present but under official control.

The Directorate: Inspection Service (IS) is a technical inspection Directorate which does inspection with regard to plant health, quality assurance, genetic resources, liquor products and animal health.

In terms of the Animal Diseases Act, 1984 (Act No. 35 of 1984), all animals and animal products require a veterinary import permit to be imported into South Africa. The veterinary import permit stipulates the import requirements for the animal or animal product according to the OIE Terrestrial Animal Health Code, to prevent risk to South Africa due to animal diseases. Within the Directorate: Animal Health, the Import Export Policy Unit is responsible for the import requirements, with the following functions:

- Control risk assessment and risk management
- Provide National Animal Health contact point with regard to national and international notification systems for notification and interception of Animal Health non-compliance and dispute settlements; International Animal Health information system; WTO-SPS and OIE Animal Health responsibilities and obligations.
- Manage and maintain a database of import and export approved facilities and quantities imported and exported.
- Audit the enforcement of policy for the establishment and management of import and export approved facilities.
- Audit the policy for import and export risk assessment.
- Issue import permits.

The Directorate: Food Safety and Quality Assurance standardizes quality norms for agricultural and related products by establishing the criteria for such norms and distributing the information to all interested parties. The aim of the regulations administered by the Directorate is to provide the consumer with products of consistent quality through the correct application of quality standards.

The Directorate: International Trade represents DAFF at international forums and negotiations to promote the interest of the agricultural sector, and ensures the operation of permits, quotas and schemes to facilitate trade in terms of trade agreements and other international commitments. They issue import permits in terms of trade agreements signed between South African and trading partners. (DAFF, 2011c)

**Department of Trade and Industry (DTI)/National Regulator for Compulsory Specifications (NRCS)**

Certain Compulsory Food Regulations are administered by the NRCS, a public entity reporting to the Minister of Trade and Industry and enacted by the Parliament of the Republic of South Africa to administer various Compulsory Specifications to protect the safety and well being of consumers utilizing various consumer products and utensils.

These specifications were formerly administered by the Regulatory Division of the South African Bureau of Standards in terms of the Standards Act of 1993. The National Regulator for Compulsory Specifications Act (Act 5 of 2008) was promulgated in July 2008, and took effect on September 1, 2008. The Act transferred the Regulatory Division of the South African Bureau of Standards (SABS) and all regulatory functions of the SABS to a new statutory Department of Trade and Industry (DTI) institution - the National Regulator for Compulsory Specifications (NCRS). However, the writing and the enforcement of standards is divided to comply with WTO TBT and SPS agreements. NRCS is mandated to advise the Minister of Trade and Industries on matters relating to compulsory specifications, development and enforcement of compulsory specifications and other relevant regulations on the Minister’s behalf. NRCS leads the Codex delegation of South Africa to the Codex Committee on Fish and Fishery Products and represents
South Africa as part of the delegations to the Codex Alimentarius Commision Sessions and the CCFICS meetings.

Among the five functional NRCS Divisions is the Perishable Products, Food and Associated Industries (FAI) Division, established in 1945. In 1947, FAI was requested to draft its first standard for canned fish, which became compulsory in 1953. FAI is responsible for the implementation and administration of Compulsory Specifications and Technical Regulations for six types of commodities, as well as meeting the obligation to protect the health and safety of the public and the environment and promote fair trade.

The six products for which FAI is responsible for the compulsory specifications that set minimum safety standards are:

- Frozen fish and fishery products;
- Frozen rock lobster and frozen lobster products;
- Frozen shrimps (prawns), langoustines and crabs;
- Smoked snoek;
- Canned fish and fishery products
- Canned meat

FAI inspectors are authorized to carry out inspections in terms of the Foodstuffs, Cosmetics and Disinfectants Act (Act 54 of 1972). All imports of foodstuffs falling under the jurisdiction of the NRCS are detained by the Port Health Officers, for inspection and testing by the NRCS in terms of the requirements of the relevant compulsory specifications and those requirements of the regulations falling under the Foodstuffs, Cosmetics and Disinfectants Act. FAI is ISO/IEC 17020 accredited and approved by South African National Accreditation System (SANAS) for inspection bodies.

FAI works with DAFF, as the SPS reference point, DTI, WTO, the TBT reference point (SABS) DOH, at national, provincial and local levels, and Department of Finance (Customs and Excise).

**Provincial Departments of Health**

‘Food Control’, as included in the definition of “Municipal Health Services” in the National Health Act, 2003 (Act 61 of 2003), refers to the law enforcement and food safety promotion activities rendered by district and metropolitan municipalities.

The nine Provincial Departments of Health have Environmental/Port Health sections. Their role includes food control at the provincial level, referred to as Environmental/Port Health Services. They are responsible for coordinating activities within the province; providing support to the metro and district municipalities rendering Municipal Health Services (MHS); rendering Port Health Services, which includes the control of imported foodstuffs covered in terms of Act 54 of 1972 and regulations published under the Act; and setting protocols and strategies for health within the province. (DOH, 2004b)
Environmental Health Practitioners (EHPs) and/or Port Health Officers (PHOs) respond to inspect imported foodstuff consignments for Port Health Services. PHOs inspect imported food, grant extended health detentions or releases, examine imports, and take samples for bacteriological/chemical/histological/physical analyses. PHOs enforce the Foodstuffs, Cosmetics and Disinfectants Act no. 54 of 1972. Port Health can ask a municipal colleague (EHP) to do an inspection for extended detention. Products on store shelves are the responsibility of the District or Metro Municipality. Approximately 2,100 EHPs are employed, which is approximately 50-60% of the country’s needs, based on the prescribed population/EHP ratio. (Interview, 2011)

Local authorities (metro and district municipalities) are responsible for, health promotion; inter-sectoral collaboration; community participation; and the rendering of health services to communities, including maintenance of its area in a hygienic condition, investigating complaints, enforcement of relevant legislation, and identification and control of health hazards.

Local authorities “have no direct function related to the control of imported foodstuffs and their activities in this regard generally focuses on monitoring and law enforcement of such products offered for sale within their areas of jurisdiction, especially regarding foodstuffs brought into the country illegally and without clearance by the Port Health Services rendered by the Provinces.”

1.2 Agencies Responsible For Animal Feed and/or Pet Foods

DAFF regulates the importation of animal feed. Importers of farm feed must register the product in terms of Act 36 of 1947, ensure that the product’s information, composition, and labeling meet the Act’s regulation. Animal feed imports that are not accompanied by a registration certificate or an import permit issued under Act 36 of 1947 by the Registrar or by a designated official are not allowed into the country.

Production facilities in the country of origin must be approved. The importer must be in possession of a South African veterinary import permit before any animal product departs from the country of origin. The veterinary import permit must include the V-number given to products which are registered according to Act 36 of 1947. A Veterinary Health Certificate, which is in compliance with the conditions stipulated by the South African Veterinary Import Permit, must be obtained from the veterinary authorities in the country of origin before the product is shipped. The original veterinary import permit and the original veterinary health certificate must be presented to the veterinary officer responsible for import control at the port of entry.

All animals and animal products must be inspected at the port of entry, which will be stipulated on the veterinary import permit. When applying to register the product, if the manufacturer is outside of South Africa, proof of compliance by the manufacturer with local authorities or legislation in the country of origin must be supplied.

(Interview, 2011)
1.3 Food Importation Process Steps and the Government Units That Oversee Each Step

When a consignment reaches a point of entry, Customs reviews a restricted and prohibited goods list to ensure the consignment is permissible, and then refers the consignment to the respective agency for inspection. Following the review of the respective agency, imports are only released when both customs and the respective agency agree to clear the consignment. (Interview, 2011)

DOH Import Procedure

All food consignments are subject to random checking and sampling at all points of entry in South Africa to ensure food items imported into the country are safe and comply with the prescribed standards and regulations.

All foodstuffs covered under Act 54 of 1972 are detained for inspection by the Port Health Officer, except when they are intended for consumption by diplomatic and consular representatives or for own use. Those foodstuffs falling within the jurisdiction of the NRCS are referred to the NRCS for inspection and only released on completion of inspection and approval by the NRCS.

To assist Port Health Officers employed by the nine provinces, as well as to promote the standardization of the functions and procedures performed by them within the various ports of entry related to the control of imported foodstuffs in terms of Act 54 of 1972, a Standard Operating Procedures (SOPS) for Port Health was developed by DOH.

The ports of entry where imported foodstuffs are permitted by Customs to enter South Africa are indicated on the following map:
The following flowchart outlines the procedure generally applied by the Port Health Services rendered by the Provinces for importing food into South Africa covered under Act 54 of 1972. (DOH, nd)
PORT HEALTH SERVICES PROCEDURE FOR IMPORTING FOODSTUFFS INTO SOUTH AFRICA

Importer files “Bill of Entry” (B.o.E) or electronic documents with S.A. Customs

S.A. Customs notifies Port Health Officer (PHO) in accordance with Prohibitive List document (refers importer to PHO)

FULL CONTAINER LOADS (F.C.L.)

Importer provides copies of B.o.E or Customs Notification (C.N), R.918 cert & completed Guarantee (GW22/6) to PHO

PHO issues “Extended Health Detention” (E.H.D) by stamping (C.N.) / B.o.E.

Importer removes consignment to its premises under prescribed conditions

Own location: PHO inspect/sample foodstuffs at importer’s premises

Other locations: PHO notifies EHO in other location of consignment (fax copy of relevant docs.) For inspection/sampling

PHO/EHO releases consignment by stamping B.o.E / C.N., or issue Order (GW22/3) for rejection (destruction or re-export) or corrective action

PHO/EHO sends samples to departmental laboratory in Cape Town/Pretoria (chemical) or NHLS (microbiological)

LESSEE CONTAINER LOADS (LCL) / BREAK BULK

PHO inspects/samples foodstuffs at harbor shed/ container depot

PHO releases consignment by stamping B.o.E / C.N., or issue Order (GW22/3) for rejection (destruction or re-export) or corrective action

EHO informs PHO of final outcome, PHO informs S.A. Customs accordingly
The Regulations Relating to the Powers and Duties of Inspectors and Analysts conducting Inspections and Analyses on Foodstuffs and at Food Premises (R328 of 20 April 2007), published under Act 54 of 1972, make provision for metropolitan and district municipalities to detain, sample and, if necessary, seize, condemn and dispose of in their areas of jurisdiction, foodstuffs that have been examined and deemed to be unsafe for human consumption.

**South African Revenue Service Importer Procedure**

All persons who import goods into South Africa shall register as an importer with Customs. Importers importing commercial goods into South Africa, and exporters exporting commercial consignments from South Africa, must register with SARS. SARS processing time is 60 business days. However, non-commercial consignments are excluded from registration, provided that they are limited to three importations per year.

All goods entering South Africa in the normal course of trade must be declared on the prescribed bill of entry. These bills of entry and related documents must normally be retained for five years. If errors are detected by Customs - whether duties were payable or not - the Act provides for penalties of up to three times the value of the goods, in addition to the forfeiture of the goods.

Goods must be declared to Customs within seven days from the date on which such goods are deemed to have been imported in terms of the Customs and Excise Act. In the case of containerized cargo, this period is 21 days, while break bulk cargo must be declared in 28 days.

Imports from outside the Southern African Customs Unions (SACU), which includes Botswana, Lesotho, Namibia, South Africa and Swaziland, must be declared on a (DA 500 referenced to SAD) DA 500 - Bill of Entry. For the movement of goods between South Africa and the other members of the Southern African Customs Union, importers must complete a CCA1 (CCA1 - Reconciled with SAD)- Declaration of Goods Removed within the Southern African Common Customs Area.

Three methods of making import declaration:

- **Manual entry** - The prescribed bill of entry is submitted along with supporting documentation in manual form to the Customs office at the place of entry. The bill of entry will then be captured by Customs onto the Customs Automated Processing of Entries (CAPE) system.

- **Computer disk** - The prescribed bill of entry together with an electronic supply on computer disk is submitted to the Customs office. The entry will then be captured by Customs on the CAPE system. This is done by using the computer disk to directly transfer the information contained thereon to the CAPE system. Parties using this facility make use of a program specifically written to capture the detail onto the computer disk. This process is quicker than the manual processing of bills of entry.
• Electronic Data Interchange (EDI) - EDI is the electronic communication of structured business data between the computer systems of trading partners, for automated processing of bills of entry and is the simplest and quickest process in which import declarations are submitted to Customs electronically.

Customs utilizes risk profiling to interrogate import bills of entry lodged. This may result in the import shipment being detained pending the production of additional documentation to verify the classification or a call for the physical examination of the goods. Goods found to be in order will be released as entered. Import control permits/certificates will be requested, where applicable.

(SARS, 2011)

**NRCS Importer Procedure**

Products regulated by the NRCS (e.g. fish, canned meat products, frozen shrimp etc) are required to be detained by Port Health Officials for inspection by the NRCS. Fish and fish products require import permits issued through the Minister of Trade and Industry. Customs refers importers to Port Health and NRCS. Port Health will also detain consignments for NRCS. Importers may also notify NRCS directly of an incoming consignment to improve the importation process. (Interview, 2011)

**DAFF Importer Procedure**

Before importing into South Africa, an importer should:

- Find out the phytosanitary import conditions that apply to the commodity to be imported by consulting the Agricultural Pests Act (Act 36 of 1983) or the National Plant Protection Organisation of South Africa (NPPOZA) within DAFF.
- Apply for an import permit from the DAFF if the commodity to be imported is not exempted from an import permit in terms of the Act 36 of 1983. If the commodity to be imported is exempted from an import permit, ensure compliance with phytosanitary measures for such exemption.
- When applying for an import permit, submit the completed application form together with proof of payment.
- Forward a copy of the import permit to the exporter or supplier in the exporting country to ensure that the consignment to be exported meets the phytosanitary import requirements of South Africa.
- Ensure that the exporter or supplier presents the commodity to be imported to the National Plant Protection Organization (NPPO) of the exporting country for phytosanitary inspection and certification where necessary in terms of the permit and/or exemption requirements.
- If a phytosanitary certificate is required, inform the exporter or supplier to send the original phytosanitary certificate with the consignment to South Africa.
In the case of animals and animal products, the original veterinary import permit and veterinary health certificate are required. The veterinary health certificate must be endorsed by the veterinary authority of the country of origin to confirm that the consignment complies with the import requirements, which are made in accordance with the OIE Terrestrial Animal Health Code.

All imports of fresh fruits and vegetables, nuts and spices are detained at the port of entry for inspection by the Directorate of South African Agricultural Food, Quarantine and Inspection Services (SAAFQIS) of the Department of Agriculture. SAAFQIS inspects for pests under the Agricultural Pests Act (Act 36 of 1983). Before DAFF can issue an import permit for fresh fruits and vegetables, a Pest Risk Analysis (PRA) based on scientific data must be conducted and specific conditions set according to the phytosanitary risks involved.

When imported commodities arrive at the port of entry in South Africa, a declaration must be made with SARS. Customs then sends the consignment to detention for DAFF to inspect at the port of entry or elsewhere. DAFF requires an import permit; phytosanitary certificate, veterinary health certificate, or any compliance certificate; a declaration at the port of entry; and inspection or testing. Following DAFF inspection, the consignment is referred to other departments, as necessary. (Interview, 2011)

If the consignment meets the import requirements, it will be released by the DAFF inspector(s). If the consignment does not meet the import requirements, risk management measures will be recommended and the consignment may then either be treated and released, sent back to the country of origin or destroyed. Once the consignment has been released by the DAFF inspector(s), the importer or their agent must take the import documents to SARS for final release. In the case of animals or animal products which do not comply with the import requirements, the consignment is either refused entry into South Africa and returned to the country of origin or destroyed, or the consignment is treated, according to the product, to negate the potential risk of introduction of animal disease.

DAFF import protocols for specific commodities include:

- Phytosanitary Requirements for the Export of Apple Fruit from the United States of America, Pacific Northwest States of Washington, Idaho and Oregon (PNW) to South Africa
- Phytosanitary Requirements for the Export of Apple Fruit from China to South Africa as agreed between the Department of Agriculture of the Republic of South Africa and the General Administration of Quality Supervision, Inspection and Quarantine of the People’s Republic of China
- Phytosanitary Requirements for the Export of Pear Fruit from China to South Africa as Agreed between the Department of Agriculture of the Republic of South Africa and the General Administration of Quality Supervision, Inspection and Quarantine of the People’s Republic of China

12
Irradiated foodstuffs

In South Africa, there are facilities in Cape Town, Durban, and Kempton Park, (near Johannesburg), that irradiate food and commodities such as medical devices. The foodstuffs most frequently irradiated in South Africa are spices for food safety purposes, followed by honey and fresh garlic for pest control purposes.

Phytosanitary requirements are laid down by the Directorate: Plant Health of DAFF for specific commodities, such as honey and fresh garlic, as well as other fresh vegetables and fruit. The importer must produce a permit signed by DAFF before DOH may proceed with processing of the application. This procedure ensures that the irradiation of food for Phytosanitary purposes will only be allowed after consultation between DOH & DAFF.

All irradiated foodstuffs must be correctly labeled in terms of Act 54 of 1972. Documentary evidence is required for food irradiated elsewhere and to be imported into South Africa. The importer must produce an authentic certificate with the following information: name of the foodstuffs; name and address of the owner; name of irradiation facility and address in the country of irradiation; date of irradiation; absorbed dose; and verification of a governmental authority of exportation of foodstuffs.

(DOH, 2004a)

1.4 Assistance, Cooperation or Contributions from Other Government Bodies (National or Local) in the Imported Food and Feed Process

DOH

Food import control is conducted by the Port Health Services rendered by the provincial health departments in terms of the provisions of the National Health Act, with oversight regarding the control of imported foodstuffs provided by DOH in terms of the provisions of Act 54 of 1972. Consignments of foodstuffs are detained by Customs for the Port Health Officer to inspect and/or sample for compliance to the provisions of Act 54 of 1972, before granting permission for its release. South Africa has 8 metropolitan municipalities, 44 district municipalities, 229 local municipalities, 9 provinces. The fifty-two municipalities consisting of the metros and districts are responsible for enforcement of food legislation within their areas of jurisdiction as part of the rendering of Municipal Health Services.

A private organization, Consumer Goods Council, similar to the Grocery Manufacturers Association in the United States, can be asked to have their members take certain actions. (Interview, 2011)

DAFF

DAFF carries out its own inspections but may on occasion appoint assignees to undertake inspections at the point of sale, manufacture, packing or export to ensure that the set
standards and requirements are maintained and that the benefits of classification, grading and marking reach the consumer. Currently appointed assignees are:

- The Perishable Products Export Control Board (PPECB): for all agricultural products intended for export
- South African Meat Industry Company: for meat carcasses intended for sale on the local market
- PROKON: for potatoes intended for sale on the local market

**NRCS**

If there is a reoccurring problem, the industry association can be contacted, and the industry then comes together to address the general issue. In general, industry is used to convey information or used to have a regulatory presence overseas, if needed. (Interview, 2011)

### 1.5 Laws and Regulations that Provide Authority for the Oversight of the Safety of Imported Foods and Animal Feed, and the Policies and Procedures that Guide Import Officials

*Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972 (Act 54 of 1972)*

The purpose of Act 54 of 1972 is to control the sale, manufacture, importation and exportation of foodstuffs, cosmetics, disinfectants; and to provide matters connected herewith. The Act is supplemented by a comprehensive set of Regulations published by DOH setting the minimum standards and requirements to which all foodstuffs should comply, including labeling and advertising. The philosophy is reactive, and places the onus on the manufacturer/seller and importer to comply. Enforcement of the Act is delegated to provincial and local health authorities. (Interview, 2011)

Act 54 of 1972 assures the prevention of misleading consumers, and is also prohibitive, in that nothing present can be detrimental to health, even if it is not specified.

The Act does not provide for the issuance of food import permits by health authorities, and only requires specifically HACCP certification in terms of the relevant regulations for listed sectors/handling enterprises, which is also applicable to imported foodstuffs. The Act is supplemented by regulations published by DOH for various products including food-grade salt, sweeteners in foodstuffs, microbiological standards for foodstuffs, and labeling and advertising of foodstuffs, etc.

Any pre-packaged foodstuff imported into or consigned to any place in South Africa must bear a label carrying the particulars specifically required by the Act or its regulations. (ITC, 2010)

The Act also makes provision for persons employed as Customs and Excise Control officers by SARS and as law enforcement officers by the South African Police (SAPS) to act as inspectors and to carry out the powers, duties and functions of an inspector with respect to the control of imported foodstuffs. (DOH, nd. b)
Food is detained by Customs and Excise for clearance by Port Health and may be inspected, sampled and analyzed. Entry into the country can be denied if the food is not in compliance with the requirements of the Act. (DOH, 2011a)

Regulation No. R.1600 of 1983 of this Act specifies that foodstuffs that have been irradiated may not be sold unless the Minister of Health or the Director-General of Health has approved the sale of such irradiated foodstuff in writing. This authority has been delegated to the Director: Food Control of the Department of Health. The Minister of Health is responsible for the promulgation of regulations that govern food irradiation. The national DOH administers such regulations, while authorized local authorities are responsible for enforcing the regulations in their areas of jurisdiction.

HACCP system (hazard analysis and critical control point) system that identifies, evaluates and controls hazards which are significant for food safety. “HACCP certification” means the issuing of documentary evidence by a certifying body accredited for the purpose by an internationally recognized accreditation authority. DOH published regulations in terms of Act 54 of 1972 related to the mandatory implementation of HACCP by specific categories of food sectors and/or food handling enterprises within the food industry in South Africa. Such a requirement has been in place since November 10, 2010 for peanut sorters/graders and peanut butter manufacturers. (Interview, 2011)

Act 15 of 1973 requires the licensing of irradiation facilities, training experience and qualification of the operators and prescribes the requirements for radiological safety. A register of all irradiation facilities is maintained by the Department of Health’s Directorate: Radiation Control in Bellville. The Directorate: Radiation Control of the national Department of Health is responsible for the licensing and various other safety aspects in terms of the Act. (DOH, 2004a)

Health Act 63 of 1977 (Act 63 of 1977)
Act 63 of 1977 has been repealed with the hygiene provisions now included in Act 54 of 1972, including, for example, prohibition of the importation of any article of food which is not clean, sound and free from decay or any infection or contamination; seizure and disposal of any unhygienic foodstuffs. (Interview, 2011)

Act 28 of 1974 provides for the approval by the DOH of the source of food for consumption at ports, airports, on vessels and on aircraft, as well as for the inspection of such premises and the sampling of food by local authorities. The provincial health departments currently approve premises on behalf of the DOH. PHOs required to oversee hygiene and food safety on airplanes and ships, and oversee appropriate waste disposal. Currently, the International Health Regulations Food Safety Expert appointment is the Director, Directorate: Food Control. The new WHO International Health Regulations are
currently in the process of being enacted and which will replace this Act. (Interview, 2011)

Act 119 of 1990, amended in 1998, although reactive, provides for the control over the sale of certain imported agricultural products. Criteria for quality norms for agricultural and related products include: quality, packaging, marking and labeling, as well as the chemical composition and microbiological contaminants of the products. The norms are validated by publication in the Government Gazette, and are based on the specific needs of the South African market and are usually harmonized with international standards. (Agricultural Product Standards Act, 1990)

Through Act 119 of 1990, DAFF: Agricultural Products Inspection Services (APIS) has a legislative mandate. The Act is supplemented by regulations for numerous products. (Interview, 2011)

Fertilizers, Farm Fees, Agricultural Remedies and Stock Remedies Act 36 of 1947 (Act 36 of 1947)
Act 36 of 1947 provides for the appointment of a Registrar of Fertilizers, Farm Fees and Agricultural Remedies; for the registration of fertilizers, farm fees, agricultural remedies, stock remedies, sterilizing plants and pest control operators; to regulate or prohibit the importation, sale, acquisition, disposal or use of fertilizers, farm fees, agricultural remedies and stock remedies; to provide for the designation of technical advisers and analysts; and to provide for related matters. Through the Act, DAFF: Directorate Feeds, Stock Remedies, Pesticides and Fertilizers has a legislative mandate. (Interview, 2011)

Act 36 of 1983 and its subordinate legislation provides for measures by which agricultural pests may be prevented and combated and for related matters. (DAFF, 2011a) Regulation R. 111 of 27 January 1984, and its amendments, regulate the importation of plants, plant products and other regulated articles by import permit. Government Notices R. 1013 of 26 May 1989, and its amendments, determines the requirements for importation of controlled goods without a permit. As stated in Section 1.1, Act No. 36 of 1983 mandates DAFF/APIS to regulate plants, plant products and other regulated articles when imported into South Africa in respect of pests (including diseases) that are not yet present in South Africa, or present but under official control. (Interview, 2011)

The Act 35 of 1984 provides for the control of animal diseases and parasites, for measures to promote animal health, and for related matters. Through the Act, DAFF/APIS and DAFF/Directorate Animal Health have legislative mandates. (Interview, 2011)

Act 15 of 1997 provides for measures to promote the responsible development, production, use and application of genetically modified organisms; to ensure that all activities involving the use of genetically modified organisms (including importation, production, release and distribution) shall be carried out in such a way as to limit possible harmful consequences to the environment; to give attention to the prevention of accidents and the effective management of waste; to establish common measures for the evaluation and reduction of the potential risks arising out of activities involving the use of genetically modified organisms; to lay down the necessary requirements and criteria for risk assessments; to establish a council for genetically modified organisms; to ensure that genetically modified organisms are appropriate and do not present a hazard to the environment; and to establish appropriate procedures for the notification of specific activities involving the use of genetically modified organisms; and to provide for related matters. The Act applies to both human and animal food. Through Act 15 of 1997, DAFF/APIS has a legislative mandate. (Interview, 2011)

National Regulator for Compulsory Specifications Act (Act 5 of 2008)
Act 5 of 2008 establishes the NRCS as the administrator of compulsory specifications. FAI enforces compulsory specifications that set minimum safety standards for:

- The manufacture, production, processing and treatment of canned fish, canned marine molluscs and canned crustaceans (Compulsory Specification, 2004);
- Frozen fish, frozen marine mollusks and frozen products derived therefrom (Compulsory Specification, 2003);
- The manufacture, production, processing and treatment of canned meat products (Compulsory Specification, 2004);
- Frozen rock lobster and frozen lobster products derived therefrom (Compulsory Specification, 2003);
- Smoked snoek (Compulsory Specification, 1974);
- Frozen shrimps (prawns), langoustines and crabs. (Compulsory Specification, 1987)
- A compulsory specification for live abalone has been introduced, but not yet promulgated.

(NRCS, 2011b)

Import and Export Control Act of 1963
Through this Act, the Minister of Trade and Industry may control the import of certain goods, including fish and fish products into South Africa.

1.6 Handling of Products Transshipped Through a Third Country as Compared to Directly Imported Products

Transshipping through South Africa is characterized as a consignment-in transit which passes through the country without being imported, and without being exposed in that
country to contamination or infestation by pests. The consignment may not be split up, combined with other consignments, nor have its packaging changed. When the consignment is exposed to infestation or contamination by pests, the NPPO should issue a phytosanitary certificate. When the consignment is split up, combined with other consignment or repackaged, the NPPO should issue a phytosanitary certificate for re-export.

DOH labeling regulations, effective March 1, 2012, will require the country of origin or processing, for example, “product of” or “processed in.” As transshipping is also a trade issue, there are DTI regulations which also require the country of origin.

If a product does not meet DAFF requirements, it can be stopped, or a non-manipulation certificate can be issued. In pet foods, a health certificate may need to be provided if the ingredients are sourced from other countries.

Act 54 of 1972 provides the following for articles imported in transit: The Minister may, at the request of the government or administration of a state or territory which is not part of the Republic, by notice in the Gazette apply any provision of this Act to any foodstuffs, cosmetics or disinfectants which arrive at or are imported through an import harbor or other place in the Republic and which are addressed to or intended for transmission to such State or territory, and may at any time withdraw or amend such notice by notice in the Gazette.

Although no formal requests have been received thus far from any of the land-bound neighboring countries of South Africa, e.g. Lesotho, Swaziland, Botswana and Zimbabwe, Port Health authorities will inspect foodstuffs which are unpacked at points of entry (lesser container loads/break bulk consignments), as well as grant an extended guarantee and notify the colleagues of the relevant neighboring country of full container loads on route to their countries.

(Interview, 2011)

2 INSPECTION PROGRAMS

2.1 Mechanisms to Prioritize Food/Feed Import Surveillance Activities, such as Product Sampling and Testing, Inspections at the Border, and Facility Inspections of the Exporting Country

DOH


The Port Health components of the Provinces must develop a system of identifying high-risk importers and/or foodstuffs. Detailed Standard Operating Procedures (SOPs) have been developed to assist Public Health Services in dealing with imported foodstuffs.
DOH utilizes a risk-based system for sampling and inspections. A list of food categories have been created with high/medium/low risk and the associated frequencies for inspection. In addition, the reputation of the importer, foodstuff risk, past performance, country of origin, if the foodstuff is processed or has undergone heat treatment, incidents at the time depending on the media or INFOSAN (e.g. melamine, honey) all factor in the risk level. Nuts are checked for aflatoxin, and some foodstuffs are required to stay under detention until the analysis results are available.

**DAFF**

DAFF uses a risk-based system for sampling and inspections. Risk analysis components include both policy, that is the risk assessment, and operation, that is the audits or inspections. Foodstuff risk, past performance, country of origin, incidents at the time depending on the media or INFOSAN, and the frequency of importation all factor in the level of risk assigned to a product.

Per DAFF, for animals and animal products, a risk evaluation is done for countries from which South Africa has not imported previously. This risk evaluation is taken into consideration when determining whether South Africa will import animals and animal products from the country under review, and also be used when determining what risk mitigation measures will be applied. The veterinary health certificate is then negotiated with the exporting country according to the determined risk mitigation measures. Consignments may only be imported once this process has been completed.

**NRCS**

NRCS uses a risk-based system. For example, inspectors are in canneries frequently. Low acid canned foods and ready-to-eat foods are considered to be a higher risk. The risk level is also dependent on the species or products (e.g. sharks and mercury level).

*(Interview, 2011)*

### 2.2 Special Screening Requirements and Trading Partner Requirements where Disease or an Outbreak has Occurred

Corn from the United States is not authorized entry into South Africa, as the United States has approved genetically modified maize events that are not approved in South Africa.

As required by the Consumer Protection Act, from October 1, 2011, food producers, importers and packagers will be required to choose one of three mandatory labels for genetically modified foods and marketing materials. Where the genetically modified content is at least 5%, the food will be labeled as “containing GMOs.” Where the food is produced directly from GMO sources, there will be no need for testing, and food must be labeled as “produced using genetic modification.” Industry may also choose “may contain GMOs” labels in circumstances where they are able to argue that it is scientifically impractical and not feasible to test food for genetically modified content.
2.3 Percentage of Imported Food Shipments Examined and the Relationship between Risk-Ranking of Foods and Volume of Imported Foods Examined

**DOH**

“South African port health authorities consider themselves fortunate if they can check 10% of imports…” (USAID, 2009)

Information is not available within DOH, currently provinces keep records of their own activities in this regard. The percentages of food examination may depend on product category, as well as availability of human and other resources provided by the provincial governments. For example, some agricultural products regulations specify inspection frequencies. Imported foodstuffs are inspected at random for possible hazardous or toxic substances at all entry ports.

**DAFF**

Relevant imported products that are inspected for pests include animal products, plant products, and farm feeds. Inspection Services takes samples occasionally. If further analysis is needed, it is referred to others.

Every consignment is inspected; however, not necessarily at the individual unit level. As the health certificate applies to a particular product type, individual unit inspection is not necessary.

**NRCS**

Consignments may be composed of a variety of products. Using a prescribed inspection method, every consignment falling under a NRCS Compulsory Specification is inspected and tested. All canned meat and canned fish, and approximately 90 percent of frozen fish is inspected. Almost all are sampled, except with certain fishery commodities from Thailand, where a reduced sampling procedure is in place, in terms of a Technical Cooperation Agreement between the Thai Department of Fisheries (DOF) and the NRCS.

(Interview, 2011)

2.4 Types of Review, Examination and/or Testing of Imported Products Performed by Food Safety Inspectors

2.5 Frequency of Documentation and Labeling Checks as Compared to Analytical Examinations

**DOH**

The inspection regulation has provisions for inspection and procedures provided.

(Interview, 2011)

**DAFF**
Samples taken during DAFF inspection may be sent for analysis. Routine analysis of various agricultural products helps to determine the composition, microbiological contamination and pesticide residue levels in food products. Chemical residue analyses and the detection of harmful organisms are of particular importance for products marketed internationally. (DAFF, 2011d)

Specific Requirements for inspections include checking that documents are complete, consistent, valid and not fraudulent; verification of consignment identity and integrity; and visual examination for pests, diseases or other non conformities. The nature of the inspection findings determines the type of decisions to be adopted. These decisions include certifications, passed for export or rejections. (Maelane, 2010)

The application of inspection include the assumptions that the pests or diseases of concern, or the signs or symptoms they cause are visually detectable; inspection is operationally possible; and some probability of pests and diseases being undetected is recognized.

DAFF requires the following for inspectors:

- Veterinarians - BVMCh degree; in-house training, authorization
- Scientists - Pathologists, Entomologists, etc.; BSc Degree; and in-house training
- Technicians - 3 year National Qualification (diploma/degree) in Agriculture or other scientific fields; in-house training
- Auxiliary Officers - Grade 12; in-house training

(Holtzhausen, 2010)

NRCS

NRCS requires the following for inspectors: BSc Food Science, BTech degree or National Diploma in Food Technology; in-house training; and possession of Inspectors Certificate.

2.6 Types of Examination and Testing Processes Used for Ensuring Animal Feed and Feed Ingredient Safety

2.7 The Dependence of Examination and Testing Requirements on Conditions (such as the Presence of BSE or Other Zoonotic Diseases) in the Exporting Country

DAFF requires importers to state on the health certificate if the animal feed comes from a country with BSE. Importers must also have the proper health certificate, which relates to time/temperature/processing in a GMP facility. Only imports from controlled risk countries are permitted. Animal feed must come from a dedicated plant to ensure there is no possibility for cross-contamination. There have been issues with agreements from the
European Union, as they expire after a given time. If the agreements are not in place, the consignment is rejected. (Interview, 2011)

2.8 Inspections of Food or Animal Feed Manufacturers or Shippers in Other Countries (including Selection Criteria and Frequency)

DOH

The provisions of Act 54 of 1972 do not make provision for, and neither does DOH have sufficient resources to inspect food manufacturers or shippers in other countries or the food control systems in other countries.

DAFF

DAFF limits inspections to imports, exports, and local distribution. No foreign inspections are performed. Inspection Services inspects for food safety and quality assurance using food import and export standards at 15 of 22 import locations.

NRCS

NRCS has the ability to inspect foreign establishments. If the results of the inspection are unsatisfactory, it can create sanctions on the facility, and even possibly the country. (Interview, 2011)

2.9 Notification System(s) to Directly Notify Foreign Governments When Foods or Animal Feed Manufactured in their Countries are Found to be Unsafe; and to Notify the Public When Imported Products do not Meet Safety Standards

The Directorate: Food Control within DOH is registered as the National Contact Points for the WHO INFOSAN Emergency and the European Union RASFF, and both networks are available to inform foreign governments when foodstuffs manufactured or produced in South Africa are found to be unsafe and exported to the relevant countries. Similarly, DOH are notified through the secure websites of both INFOSAN and RASFF in the event of unsafe foodstuffs being imported into the country, where applicable. Regarding animal feed, although DOH has no responsibility in terms of the provisions of Act 54 of 1972, both INFOSAN and RASFF are utilized for the same purpose in cases where the feed might have a food safety implication. (Interview, 2011)

Policy Guidelines on National Food Safety Alerts and Official Product Recalls

A national food safety alert could be instituted by DOH, Directorate: Food Control could institute a national food safety alert by issuing an official notice to the provincial and municipal health authorities informing them of the foodstuff(s) posing a risk to human health and what steps to take to ensure the safety of consumers. Alternatively, DOH, Directorate: Food Control could issue a media release, through DOH’s Communication
Unit, intended to inform the public of the situation in question and stating what measures should be taken by consumers to protect their health.

There are three mechanisms by which a food product recall can be initiated:

- A recall can be undertaken voluntarily at any time by a food business (e.g., a manufacturer, distributor, wholesalers, etc), and it is then referred to as a voluntary recall.
- A food control authority, in the interest of public health, can request any food business to initiate and undertake a food product recall.
- The national health authority can institute a National Food Safety Alert as described in these guidelines. These National Food Safety Alerts are official notices currently referred to as “detention notifications” which are normally issued by DOH when a need arises for the EHPs employed by the metropolitan and district municipalities to remove a product from the shelf. The notification triggers the procedure/actions provided for in the Regulations Relating to the Powers and Duties of Inspectors and Analysts conducting Inspections and Analyses on Foodstuffs and at Food Premises (R328 of 20 April 2007), published under Act 54 of 1972, namely to detain, sample and, if necessary, seize, condemn and dispose of foodstuffs that have been examined and deemed to be unsafe for human consumption.

Steps in instituting a national food safety alert or official food product recall include identifying a need for the food product recall, determining the level of a food product recall, convening a food product recall committee, notification, and post recall reporting/documentation.

In terms of indentifying a need for the food product recall, necessary information is obtained and thoroughly analyzed before a decision is made to initiate a national food safety alert and an official food product recall. The decision to initiate a national food safety alert or an official food product recall should be made after consultation between the relevant food business (industry), the food control authority issuing the instruction and the Department of Health (if it is not the authority issuing the instruction) and it should be in the interest of public health. Food businesses can voluntarily initiate food safety alerts and food product recalls at any time as part of their responsibility towards ensuring consumer safety. However, all Class I and Class II food product recalls should be reported to the Directorate: Food Control for record-keeping purposes.

It is also during the process mentioned above that a food product recall should be classified either as a class I or class II recall. It is recognized that there are essentially three types of food product recalls:

- Class I recall, involving a health hazard situation where there is a reasonable probability that eating the food will cause health problems or death.
- Class II recall, involving a potential health hazard situation where there is a remote probability of adverse health consequences from eating the food.
- Class III recall, involving a situation where eating the food will not cause adverse health consequences.

A Food Product Recall Committee is formed only when a need for a national food safety alert and/or an official food product recall has been identified; it is not a standing committee. Such a Committee should be convened and chaired by the food control authority that is directly responsible for the affected food product (e.g. NRCS for canned fish). In addition, it is up to that control authority to decide which other food control authorities should be represented on that Committee and what their roles will be during the incident. It is recommended that the affected food business be represented on the Committee. Those chosen to serve on the Committee can be informed in any manner, depending on the urgency of the matter. Requests for participation in the Committee as well as a list of all the participants should be documented. Any decline to serve on the Committee should also be documented. In addition, DOH introduced the Food Safety Alert Response Team (FSART), which is intended to be convened on short notice to deal with specific food safety alerts requiring a speedy response, consisting of the relevant authorities, e.g. DOH, DAFF, NRCS and industry representative bodies and/or affected business(es), consumer bodies, etc.

It is suggested that the following are key role players on any Food Product Recall Committee: DOH Directorate: Food Control; Environmental Health Services of the Provincial Health Department in whose province the problem was first identified; Environmental Health Services at the Local Authority in whose area of jurisdiction the problem was first identified; the affected food business(es).

The following are suggested as role players that should be represented on the Food Product Recall Committee as necessary: NRCS, in situations where the product being recalled falls under its control; The Directorate: Disease Prevention and Control of DOH and its provincial counterparts, in situations where the food product has been implicated in outbreaks of foodborne illness; DTI, where consumer bodies may become involved; relevant laboratory services, in situations where laboratory tests were conducted; relevant Directorates of the DAFF, depending on the product concerned.

For a voluntary recall, notification mechanisms will depend on the level of the recall. During a trade/industry recall, notification should be to the distribution network/distribution chain and trade customers. The notification should detail methods for stopping distribution and sale of the product, for storing the recovered product safely and for isolating and disposing of the product. Food businesses should maintain current contact lists of suppliers, distributors, wholesalers, retailers and customers. During a trade/industry recall it may not be necessary to notify the public. However, there may be cases where consumers/customers may be advised to return the food to the place of purchase, such as retail premises. The food business conducting the trade/industry recall should inform the businesses receiving returned goods on how they should dispose of that product. If the affected food business chooses to dispose of the affected product, this
should be done in collaboration with the relevant food control authority and the necessary
documentation, referring to the disposal of the product, should be acquired by the food
business from the control authority as proof that the product was disposed of in the
proper manner.

During an official food product recall, public notification may be necessary if the product
in question is offered for sale to the consumer. The recall committee takes a unanimous
decision on how the notification is to be conducted and which Department or component
will be responsible for drafting the content thereof and ensure its release. The main factor
affecting the notification mechanism is the classification of the recall (i.e class I or II) and
how hazardous is the product that is being recalled. These may include the use of one or
more of the following: official media releases, paid advertisements, the internet, in-store
announcements. According to the Codex Alimentarius Commission it is also necessary to
notify the exporting country of the recall, if the implicated product was imported into
South Africa, and the importing country, if the implicated product was exported from
South Africa. Notifications should be conducted as indicated in these Codex guidelines:

- The Codex Guidelines for the Exchange of Information Between Countries on
  Rejections of Imported Food would be relevant in situations where South
  Africa imports a food product from a particular country and finds that that
  product poses a health risk and initiates a recall, which may result in
  subsequent consignments of foodstuffs from the importing country being
  rejected.

- The Codex Guidelines for the Exchange of Information in Food Control
  Emergency Situations would be relevant in situations where South Africa
  exports a certain product to a particular country and thereafter discovers that
  the exported product is unfit for human consumption and must be recalled
  from the importing country.

Post recall reporting/documentation will be used to develop a database of Class I and II
recalls that were initiated from within South Africa at any given time. Information in this
database will include quarterly reports of Class I and II food product recalls, the types of
food products that were recalled and the reasons the food products were recalled, the
levels of the recalls and, where possible, the amount of food product recalled. Post-recall
reporting also helps in assessing the effectiveness of the recall. The effectiveness of a
recall is assessed on the basis of the amount of product received in proportion to the
amount of product that originally left the food business. Post-recall reporting also
includes investigating the reason for the recall so that action can be taken to prevent a
recurrence of the problem. A post-recall report can also be used by industry, following a
voluntary recall, as a means to notify the Directorate: Food Control of the recall.

(Interview, 2011)
3 AUDITS AND CERTIFICATION

3.1 Assessing and Measuring the Effectiveness of the Food/Feed Safety Import Program (e.g., Self Audits of the Program, Public Health Outcomes, Surveillance Sampling Results, Number/Rates of Refusals, Periodic Program Evaluations)

NRCS

NRCS is audited by SANAS. Within NRCS, every task has a documented procedure.

The NRCS quality management system requires two internal audits annually, with any necessary corrective actions within a prescribed period of time. SANAS does an annual audit of NRCS, where they review the self audit, and then do their own audit to ensure the accreditation. There is also an internal annual review of the quality management system. Inspectors are trained to ISO9011 certification. (Interview, 2011)

3.2 Extent of Reliance on Trading Partners’ Food Safety Programs to Ensure That Imported Foods or Animal Feed are Safe

DOH

DOH does not require certification, except for HACCP for peanut butter and peanuts sorters and graders. There are no prior arrangements for importers.

NRCS

NRCS relies on technical support from the Department of Fisheries of Thailand and the National Standards Institution of Nambia, as competent authorities in terms of Technical Cooperative Agreements. Shortly it will also be with Mozambique, Morocco and India. NRCS will review certificates for biotoxins from other countries.  

(Interview, 2011)

3.3 Use of Additional Measures (e.g., Audits of Producers, Exporters and Shippers) to Verify the Safety of Trading Partners’ Food and Animal Feed

Due to the reactive nature of Act 54 of 1972, no provisions are currently made for DOH to introduce such measures. DOH employs a system of “horizon scanning” which involves assessing various information sources, e.g. media, internet, etc., of food safety challenges/incidents/outbreaks and assessing the likelihood of those issues to affect South Africa. (Interview, 2011)
3.4 Requirements for Food and/or Animal Feed Export Certificates Issued by the Exporting Country’s Competent Authority, and Types of Inspection or Testing for Each

Due to the reactive nature of Act 54 of 1972, no provisions are currently made for DOH to introduce such measures. HACCP is mandatory for peanut butter and peanut graders and sorters. Anyone importing such products will need to produce HACCP certification from the exporting country. (Interview, 2011)

3.5 Use of ISO, Global Gap or Other Assurance Systems and Confidence in the Assurance System(s) Utilized

DOH

DOH does not require laboratory analysis certificates for its two laboratories. Neither laboratory is accredited; however, the Cape Town laboratory is anticipated to achieve accreditation by 2012. (Interview, 2011)

NRCS

NRCS relies upon assurance systems for the laboratories. All laboratories must be accredited to ISO 17025. Microbiological standards are prescribed in Compulsory Standards. (Interview, 2011)

3.6 The Nature and Frequency of Foreign Food Safety Systems Audits Performed

NRCS

NRCS visits foreign countries and foreign processing plants with the presence of the regulatory authority of the country. Priority is given to places or sites deemed questionable, otherwise one to two foreign visits, or ad hoc when a problem arises. There is an agreement with DAFF regarding shellfish monitoring audits on an annual basis.

DAFF

DAFF foreign audits are not specific to animal feed; they are done for meat safety. It is not routine, but for a new market, new product, or to re-open the market. European Union audit is also accepted.

( Interview, 2011)

3.7 Equivalence Agreements Requiring Periodic Audits/Reevaluations of Exporting Countries’ Food Safety Programs

DOH

27
There is no legislative basis for it, and it is difficult to institutionalize.

**NRCS**

Equivalence agreements are not product specific. Approximately one in five is sampled for products from Thailand. Any MOUs or MRAs would be with DTI, which would be administratively difficult. As a result, NRCS has Technical Cooperative Agreements with Thailand, and several other Southern African countries, but no MRA to date with other countries.

3.8 **The Utilization of Third-Parties (Within the Exporting or Importing Country) to Carry out Inspections and/or Product Certification (Nature and Extent of Programs) and Methods for Verifying the Adequacy and Reliability of the Third Party Work**

**DOH**

Only within the context of HACCP for peanut sorters and graders and peanut butter manufacturers.

**DAFF**

There is a model for using third parties, but it has not been successful. They are trying to use an accredited body for a function. Laboratories are only utilized for results, they are not given capacity for decision-making.

**NRCS**

Similar to DAFF, laboratories are only utilized for results, they are not given capacity for decision-making.

3.9 **Arrangements with other governments relating to imported foods or animal feed (such as memoranda of understanding, mutual recognition agreements, etc)**

**NRCS**

NRCS, FAI issues health guarantees as a competent authority for the European Union and also to Asia in terms of an agreement with DOH.

Technical Cooperative Agreements have been made with: Mauritius, Mozambique, Namibia, Brazil, Australia, Tristan da Cunha, Papua New Guinea, and Thailand. In Mozambique, all products must have a health guarantee. In Namibia, FAI assists in the training of NSI inspectors. Previously, until 2005, NRCS was the Competent Inspection Body, on behalf of the Namibian Competent Authority. With Thailand, there is a reduced inspection agreement, provided there is a health guarantee from the competent authority.
This ensures the emphasis is on the department within Thailand, but South Africa will inspect facilities in Thailand. (Interview, 2011)

3.10 Registration of Licensing of Firms That Import and/or Export Foods or Animal Feed to the Country or for Firms That Import Foods or Animal Feed

DOH

Foreign firm registration or license is not required for any commodities.

DAFF

DAFF expect countries to have lists, but defaults if the company is European Union approved.

NRCS

Foreign firm registration or license is not required for any commodities, except in the case of Thailand. Firms must apply to Department of Fisheries in Thailand for approval to export to South Africa. This will also take place for Mozambique in the near future. (Interview, 2011)

3.11 Use of Sampling Surveys of Imported Foods/Feed (as Opposed to Targeting Specific Products/Producers for Inspections and/or Testing) to Gather Information and Identify Trends and Potential Areas of Difficulty

DOH

DOH currently does not have sufficient laboratory support to do sampling for information or data gathering. Sampling is done for compliance monitoring purposes. For local products, DOH does have specific sampling plans, focusing on the manufacturing level. During the coming year, DOH will have four sampling plans, salt, preservatives, colorants and aflatoxin. The sampling runs are scheduled so laboratories can cope over a period of time, and a maximum number of samples are determined.

NRCS

NRCS collects samples of fish and fishery products for pesticides and PCBs testing on local fish, and occasionally from imported products for information or data gathering. (Interview, 2011)

3.12 “Good Practices” Programs for Foods/Feed Importers

NRCS

29
A “Good Practices” program is in place with governments and guidance to processes, as well. Pre-import samples are allowed so the importers can have an indication of what to expect. NRCS meets one time a year with industry to review good practices. (Interview, 2011)

3.13 Description of Import Program User Fees and Cost Recovery System

DOH

DOH does not have a system for cost recovery. If a sample’s results are disputed, the importer pays to send the sample to an alternative laboratory.

DAFF

DAFF has a hybrid system due to the travel to extended detention.

NRCS

Industry pays a levy to NRCS based on the amount of product brought into South Africa. Similar fees are applicable to local producers. In addition, if a sample’s results are contested, the importer pays for the re-testing, and may pay for the inspector’s expenses in certain instances.

(IInterview, 2011)

3.14 Incentives to Increase Industry Involvement in Ensuring That Imported Foods Meet Safety Standards

Under certain circumstances, Port Health will allow for a reduction in the frequency of inspections, based on the record/history of specific importers. Discounts are not available, and DOH is not in the position to offer formal incentives in terms of their current legislation. (Interview, 2011)

3.15 Obstacles to Industry Participation in Ensuring That Imported Foods Meet Safety Standards

See inputs applicable to DOH as provided under Section 3.2.1. As it is a reactive situation, there are no specific deterrents other than monitoring for compliance. The importer loses money when the shipment is detained and/or rejected, so the onus is on the importer to meet safety standards. DOH does not allow advance samples, a copy of the label, or certificates issued by other countries prior to the arrival of consignments at ports of entry. (Interview, 2011)
4 LABORATORY SUPPORT

4.1 The Role of Laboratories in Supporting the Imported Food and Feed Programs and Description of Laboratory Capabilities

**DOH**

The Sub-Directorate: Forensic Chemistry Laboratories (FCLs) provide scientific support for actions taken in terms of Act 54 of 1972. They are divided into the following sections:

- Toxicology section (Pretoria, Johannesburg and Cape Town)
- Blood alcohol section (Pretoria, Johannesburg and Cape Town)
- Food section (Pretoria and Cape Town)

Regarding the food section, the FCL performs the chemical analysis of food. Chemical analysis entails the identification of potentially harmful chemical substances, for example, prohibited food colorants. The NHLS performs the microbiological analysis of food. This entails the identification of potentially harmful bacteria, viruses and fungi.

(Auditor-General South Africa, 2009)

FCL functions include: analysis of food samples to control compliance; participation in annual food sampling runs to assess specific problem areas; participation in food analysis proficiency scheme; education of Environmental Health Officers in aspects of Act 54 of 1972; participation in food control meetings by providing statistics of food analysis, assisting in identifying problem products and commenting on food legislation; and analysis of food samples for pesticides and other agricultural chemical residues, to ensure compliance with local regulations. (DOH, 2011b)

When sampling, in terms of the provisions of Act 54 of 1972, a representative sample is not required. The inspector takes one sample, and divides it into three: one goes to the owner, one goes to DOH laboratory, and one sample is used if the owner/DOH results are contradictory and a court says it should go to a third laboratory. It is not prescribed that both the owner and DOH laboratories use the same method for analysis. The owner’s sample is typically not analyzed until receiving the DOH laboratory result. The owner can contact the DOH laboratory to receive information regarding methods and sensitivity levels, but it is not a frequent occurrence. If a magistrate has the third sample analyzed, the government witness and owner will look for laboratories previously unused for testing.

**DAFF**

DAFF APHFS has two laboratories that perform analysis on agricultural products. In addition, they may use the Agriculture Research Council or other laboratories, but they must be accredited. (Interview, 2011)
**NRCS**

NRCS FAI does not have its own laboratories. However, they only use accredited laboratories or those that meet certain minimum requirements before use. NRCS does have service level agreements with accredited laboratories, both state or private. (Interview, 2011)

4.2 Participation of Non-government Laboratories (Including Industry and Academic Laboratories) in the Food Import Control Program

**DOH**

DOH has two laboratories which need strengthening, but in general does not use private laboratories. At the DOH Cape Town and Pretoria locations, there is no research component; they do ad hoc work e.g. sampling instituted as a result of for example, media reports, similar to sampling runs. Any research is not aimed at improving methods, but rather they may purchase methods or ask for outside help for methods.

NHLS, a semi-government organization created through legislation, but self sufficient, does microbiological analysis and testing for compliance monitoring by provinces and municipalities, as well as during the investigation of incidents of food borne diseases, and is accredited.

**DAFF**

DAFF utilizes two private laboratories, with a focus on MRLs.

**NRCS**

NRCS utilizes laboratories that were previously for SABS, Council for Scientific and Industrial Research (CSIR) laboratories, and private laboratories. CSIR is a semi-government, public entity, linked to government, which charges for services.

**Private Laboratories**

CGC is, among others, an international company operating in South Africa and the South African Grain Laboratory Services was established by the grain industry to support their members.

Pathology laboratories can also test samples; one such laboratory is in Cape Town to analyze nutrition content, and Swift Laboratories do microbiological testing. Samples are taken by municipalities, not at the national level. The national level liaises with the chemical forensic laboratories and coordinates the sampling runs (four this year, previously mentioned). Municipalities can contract with private laboratories at their own cost. In the Western Cape there are two to three municipalities with contracts for microbiological tests with Swift Laboratories. Free State also has a contract for
laboratory services. Some private laboratories refer to their own methods and adopt ISO methods.

(Interview, 2011)

4.3 Methods for Laboratories to Achieve Quality Assurance (such as Voluntary or Mandatory Accreditation)

Regulatory Authorities do not specify compliance with the OECD Principles of Good Laboratory Practice for studies submitted for regulatory purposes. The organizations or facilities entering the SANAS Good Laboratory Practice (GLP) Compliance Monitoring Programme have done so to meet international client demands. DAFF through the Minister has officially recognized SANAS as the authority for the regulatory scope covered by the DAFF. In addition to GLP Compliance Monitoring, this scope is given as Pesticides and Agricultural Medical Products (Good Clinical Practice for Veterinary, GCPV) and Good Manufacturing Practice (GMP). A Memorandum of Agreement between DAFF and SANAS detailing this arrangement is in the final stages of approval. SANAS is finalizing an Agreement with DOH similar to that with DAFF. (SANAS, 2008)

NRCS does have six SANAS accredited facilities for the inspection of fish and fishery products in: Port Elizabeth, West Coast, Western Cape, Hermanus, Pretoria and Durban. The NRCS, as an official inspection body, only makes use of SANAS accredited laboratories using accredited methods for testing purposes.

FCL-Cape Town does have a SANAS Chemistry accreditation.

5 Enforcement at Border

5.1 Approach to Visual Inspections and Analysis of Imported Foods (e.g. Risk-Assessment and Prioritization Schemes, Documentation Review, Sample Collection)

See response for Section 1.3 for information regarding the methods for choosing to inspect imported foods.

5.2 The process that Occurs When an Imported Food is Found to be Contaminated or does not Meet Standards

DOH

In terms of Act 54 of 1972, the Director-General of DOH has the following authority, delegated to the Director: Food Control, to deal with consignments of imported foodstuffs which is found to be not in compliance with the provisions of the Act, or the relevant regulations published under it: An Order be issued by means of the completion of form GW 22/3, that provides for an imported foodstuff to be: (a) confiscated and
destroyed; (b) returned to port of shipment or place of origin; (c) may be imported on certain conditions; or (d) shall be dealt with in a specific manner.

If there is a non-compliance of imported food occurring, not in respect of the label, options for corrective action to be taken by an importer could be considered. The PHO would liaise with the DOH Directorate: Food Control on what options that are available to the importer, which are communicated in writing by means of the Order form GW22/3. If the average MRL is above the standard level for samples, blending would most likely not be allowed, as there is a risk of the MRL being too high. If the average is below standard levels, blending is allowed.

DAFF

If a consignment is found to be contaminated or does not meet standards, it can be returned to the country of origin, treated in an approved manner, or destroyed.

NRCS

If a consignment is non-compliant, NRCS may stop its sale, seize the consignment, or prosecute. Non-conforming products can be embargoed with a Directive to be re-worked or re-labeled, or may be directed by the Board to destroy the consignment due to the unsafe nature. If the issue in a non-conforming consignment is not clearly food safety, it may also be returned to country of origin.

(Interview, 2011)

5.2.1 Procedures for Refusing Imported Foods Based on a Finding that they do not Comply with Requirements

See Section 5.2 for information.

5.2.2 The Procedure and Outcome for Imported Foods that are Refused Entry (Including Efforts to Prevent them from Mistakenly Entering Domestic Commerce)

DOH

Importers have options regarding reconditioning of the foodstuff, as the consignment may still be okay for animals, not humans. Importers can receive Port Health approval to deliver the consignment to an animal feed place, or arrange with the EHP in a municipality to be dumped at a municipal dump. Port Health asks the EHP of the relevant municipality to ensure or check that it is buried. The PHO confirms with the animal feed facility that the consignment was received. There is an element of uncertainty, but it is verification. A switch where the consignment mistakenly enters human food chain has not being recorded to date.
5.2.3 Entry of Detained Products Based on Further Testing or Reconditioning of the Product

See Section 5.2 for information.

5.2.4 Process for Identifying and Tracking Producers or Countries that have Repeated Violations

DOH

There is no formal system for detaining or listing a particular country if there are repeated problems with shipments. For particular countries, DOH has a higher level of alertness, and requests the PHO to be more vigilant.

DAFF

DAFF currently has an embargo for poultry from China.

5.3 Program for Investigating and Responding to Intentional Contamination of Foods

DOH

Intentional contamination would be dealt within the framework of the Food Safety Alert System, as was the case in the Melamine issue. As melamine had no determined health safety level, initially DOH said it was not allowed, then started a regulation to have a non-zero level. To develop a level or response, DOH looked to the international community. INFOSAN was helpful for identifying the goods to inspect and the health safety levels. Ultimately, WHO did the risk assessment and provided recommended health safety limits.

DOH distinguishes between people trying to benefit from the contamination and food terrorism, but there is no specific system in place as there are not enough resources and South Africa has not been targeted.

Food defense was coupled with the security section during the Soccer World Cup event hosted in South Africa in 2010. One central food preparation area was located in Cape Town, and the food was transported up to 2000 kilometers to the game sites. Due to concerns regarding the security during the transportation portion, the Confederations Cup was treated as a precursor, and sniffer dogs were used for inspecting trucks at each game site. As sniffer dogs were determined not good hygiene for the food trucks, the DOH drafted a SOP that included EHP and police present prior to loading to check the truck, EHP checks during the loading, then the truck is sealed with a police seal (with number). The seal information was communicated to the search park at the destination, where the truck and seal were verified by security park police and then accompanied to the stadium. To create awareness on food defense, DOH and the World Health Organization also sent a notice to all catering people to be vigilant, and a separate notice was sent to all manufacturers.
6 FOOD RELATED ILLNESS OUTBREAKS

6.1 System for Tracking Imported Foods once they are Cleared at the Point of Entry

There is no system for tracking food, other than through the information included as labeling requirements. Imported foodstuffs would be made available for retail or further processing, anywhere in the country. The labeling requirements, effective March 2012, have been strengthened to mandate the declaration of a country of origin and batch number.

Using the name of the importer, DOH can follow up with the list of the importer’s clients. RASFF has occasionally notified third party countries that have received exported products. Through the municipality, EHPs are requested to go to the importer and remove the product. EHP liaises to make sure the product is removed or the client list has a recall. The EHPs try to follow up to see everything is returned to the importer.

Customs does have a subscription-based database system of what is imported.

6.2 Systems for Identifying Foodborne Illness Outbreaks

6.2.1 Procedure for Tracking Illnesses Back to the Food Source when a Foodborne Illness Outbreak Occurs

DOH

Within DOH, a multi-sectorial team looks at the epidemiology, while EHPs do the food poisoning investigation and/or traceback of the food. Food poisoning is not necessarily commodity-specific. The major causes of food poisoning are catering issues such as time and temperature, and cross contamination. (Interview, 2011)

Section 23 (a)(ix) of The National Health Act (Act 61 of 2003) ensures that “the National Health Council advises the Minister on ‘epidemiological surveillance and monitoring of national and provincial trends with regard to major diseases and risk factors for diseases.’” (DOH, 2007)

The Directorate: Communicable Disease Control has established a National Outbreak Response Team. Each Province and District is also required to have in place, outbreak response teams that are responsible for identification of outbreak or potential outbreak. It is the responsibility of the provincial communicable disease control coordinator to inform the national communicable disease coordinator of any outbreaks at local level. The national communicable disease coordinator then informs all the stakeholders responsible
for various outbreaks at national level, e.g. Food Control and Environmental Health Directorates in case of food poisoning.

Through media and formal communication, the National Outbreak Response Team notifies other provinces of any reported outbreak in a province in order for the other provinces to be on the alert.

The National Outbreak Response Team draft the technical inputs for media release, which are submitted to the Cluster: Communication for publication. If the outbreak prevails for a longer period daily media releases may be necessary. The communication Cluster is the only unit authorized to speak to the media. There are instances that the Communication section can request the technical staff to communicate directly to the media.

(DOH, 2004b)

**NRCS**

NRCS cooperates with DOH and/or provincial health services during food illness outbreaks. (Interview, 2011)

### 6.3 How Consumers Notify the Government and/or Importers of Food Problems

**DOH**

DOH Directorate: Food Control does not operate a consumer help line for notification of food problems. However, if the public were to call the general DOH health help line, the call would be logged and sent to the food section.

Directorate: Food Control is not on the clinical side, but part of a team of responders to Food Poisoning Outbreaks. The CDC is responsible for following up regarding any illness. There is a National Outbreak Response Team (NORT), on which Directorate: Food Control has a staff member, and a Provincial Response Team. The NORT links with all nine provinces, and there is a direct link to the ports. If there is an incident in the province, they notify NORT and respond themselves. If they need technical help, they would ask NORT.

If food borne disease is an issue, perhaps detention is needed. DOH may ask EHPs to detain the product in domestic commerce. The next step would be to seize, condemn, destroy.

NICD has field epidemiologists, who deployed during the World Cup. Seven or eight incidents were reported around food, and they could follow up and track the issue.

(Interview, 2011)
7 EXPORT PROGRAMS

7.1 Programs for Ensuring Safety Requirements of Export Destination Countries

DOH Health Certification

DOH Directorate: Food Control developed a guideline document based on official documents previously issued by the DOH, as well as on the decisions of the Codex Committee on Import and Export Inspection and Certification Systems (CCFICS). The guideline document indicates that health authorities should ensure that they are capable to assist prospective exporters regarding the health certification of consignments of foodstuffs destined for export. The responsibility to ensure that a health certificate contains the correct and true information is that of the certifying officer and the competent health authority involved.

Types of health certification include Voluntary and Official Certification and Compliance Certification, comprising product related compositional and/or labeling requirements, facility related structural and/or hygiene requirements, contamination related requirements, food Treatment related requirements, and safety Management systems related requirements.

Health certificates, unless specified otherwise by the importing country, include the following information:

- Technical information: details of the consignment; details of the exporter and, if required, the consignee in the importing country; details regarding the mode and time of transport and product destination; the identity of, and details on, the competent health authority involved; and unique identification number of the certificate.
- Statement of origin
- Health attestation

(DOH, 1999)

DAFF

DAFF Directorate: Plant Production, Health and Quality Control oversees certification related to SPS requirements of those foodstuffs covered by the regulations published in terms of Act 119 of 1990, as well as for the quality of the foodstuffs in question for which regulations related to export standards have been promulgated. The Directorate also appoint assignees to deal with the certification of certain products destined for export, such as the Perishable Products Export Control Board (PPECB).

Through the authority detailed in the Perishable Products Export Control Act, 1983 (Act No. 9 of 1983), the PPECB controls all perishable exports from South Africa. The
PPECB currently acts as an independent service provider of quality certification and cold chain management services for producers and exporters of perishable food products. (PPECB, 2011)

The PPECB, at the beginning of 2002, was the first South African-based service provider accredited to deliver GLOBALGAP certification under ISO 65 guidelines. It was also the first South African Control Board accredited to ISO 17021 to grant HACCP certification services. It achieved ISO 17025 for mycotoxin analytical laboratory services, and is a certification body accredited by SANAS to perform GLOBALGAP, HACCP, BRC, LEAF and TNC audits. (Diergaardt, 2010; Julius, 2009)

Regarding phytosanitary compliance of exports of fresh fruit and vegetables with the relevant import conditions of trading partners, among other regulated articles, in terms of South Africa’s signatory membership of the International Plant Protection Convention (IPPC), the NPPO of South Africa, comprising DAFF Directorate Plant Health and Directorate Inspection Services, establishes export programs in cooperation with the NPPOs of importing countries.

Businesses in South Africa that produce, process or handle food products of plant origin that are regulated under the Agricultural Product Standards Act, 1990 (Act 119 of 1990) and are destined for export must meet the food safety requirements of the relevant South African standards, including product quality standards and the Food Hygiene and Food Safety system under the Act 119 of 1990, SOPs for Maximum Residue Limits (MRLs) and Export Certificates. To be exported to a specific market, products must meet the requirements of the phytosanitary agreements established by the NPPOs of the importing country and special market protocols agreed with the DAFF Directorate Plant Health, which serves as the policy component and contact point of the South African NPPO. (DAFF, 2007)

At a minimum, a unique certificate number is printed on the certificate, as well as a period of validity as determined by the competent authority. (DAFF, 2008)

The standard operating procedure currently applies to paper certificates (DAFF, 2008).

However, Project EDiN (EDI Project), a PPECB initiative, hopes to “deliver integrated, efficient, safe, reliable and cost effective way to exchange exports information by creating a fully integrated Electronic Export Certification System. The project is divided into 5 high level phases, Phase 1 the initiation phase, Phase 2 the Analysis phase, Phase 3 the Development phase, Phase 4 the Implementation phase and Phase 5 the project closeout phase. … Critical steps that are currently in progress and are part of the next phases of Project EDiN include but are not limited to the pilot of the Electronic Export Certification systems as well as the eventually appointment of the supplier via the tender process, the supplier will then develop and implement the complete system.” (PPECB, 2011a)

**NRCS**
The NRCS is the competent authority officially authorized to certify consignments of the foodstuffs it regulates (e.g. canned fish, frozen fish and marine molluscs and crustaceans, frozen prawns etc.) and as such is also recognized by the importing country for this purpose.

**7.1.1 Use of Export Certificates to Provide Assurances to the Importing Country**

**DOH**

DOH (through the local authorities) issues export certificates, when requested/required by the exporting country, i.e. on an ad hoc basis.

**NRCS**

NRCS checks for cholera for certifications for other countries at request. NRCS also issues certifications for fish products, as the European Union requires health guarantees. The health certification is on security paper, with seven different features, but will eventually be in an electronic format. In addition, there is a requirement by the producer to ensure it meets specifications. NRCS is nominated in DOH guidelines for the certification of some processed foods. Certifications are given shipment by shipment, especially for exports to the European Union, where they require “verification.”

(Interview, 2011)

**7.1.2 Providing to the Import Country Lists of Establishments that Meet the Importing Countries’ Food Safety Requirements.**

**DOH**

A list of commodities approved for export is not in place. (Interview, 2011)

**DAFF**

A list of commodities approved for export is in place, but it depends upon the importing country. (Interview, 2011)

The Food Safety Forum decided to regard food business operators (FBOs) with “a commercial certification relevant to the official food safety system as a low risk, and to not audit these FBO’s under the official system until further consideration by the Technical Work Group (TWG). This decision was based on the fact that commercial certificates address the majority of the food safety risks, while FBO’s with no system in place are probably more likely to pose a food safety risk to consumers.”

Commercial certificates that are acceptable under the official food safety system that would thus qualify the FBO for provisional exemption from official food safety audits:

- Eurepgap
- Tesco Natures Choice
- HACCP (with a GMP basis / SABS 049 hygiene requirements)
- British Retailer Consortium (BRC)
- HACCP (with a GMP basis / SANS 10049 hygiene requirements, Prerequisite requirements for HACCP)
- IFS
- ISO 22000:2005
- AIB HACCP
- Pick & Pay GAP standard
- Pick & Pay Produce handling std.

Although these commercial certificates are regarded as acceptable, an FBO could still be audited if any risks are detected with the product or the certification or for any other purposes. (DAFF, 2008a)

NRCS

NRCS does have a list of commodities approved for export to the European Union. (Interview, 2011)

7.1.3 Authorized Third Party Issuance of Export Certificates

Information on this topic was not identified in public information or gleaned from country discussions.

8 WORLD TRADE ORGANIZATION (WTO) OBLIGATIONS

8.1 Methods for Ensuring Consistency between Domestic and Imported Food Safety Requirements

There are three national contact points: DAFF is the SPS contact, SABS is the TBT contact, and DOH is the Codex contact.

DOH

Within DOH, there are no separate requirements for imported versus domestically produced products.

To ensure legislation is harmonized, DOH seeks to be in line with Codex when the legislation is created. DOH is active in the horizontal committees of Codex. To publish new legislation in food additives, DOH refers to Codex standards within the legislation, so there is not a need to change the legislation if the standard changes. In some cases, South Africa is more strict than Codex; for example, regarding aflatoxins in maize,
because the South African population consumes a large amount of maize. Regulations say South Africa does not have one HACCP system, it is the Codex HACCP system.

Whenever a draft regulation is published, notification is sent to WTO SPS and TBT, and labeling items go to both.

(Interview, 2011)

8.2 Methods of Documenting the Scientific Justification for Import Practices with regard to Article 5 of the SPS Agreement, which Requires that Measures are based on an Assessment of Risk, as Appropriate to the Circumstance

DOH does not have a risk assessment component, so they depend upon JECFA/Codex. If it is a MRL, DAFF is where the product should be registered. The toxicological evaluation then goes through DAFF. DOH has a retired colleague perform toxicological reports, which then goes to the Veterinary Control Committee for peer review; once they are approved DOH sends them to DAFF.

Following a company proposal for certain MRLs, DOH uses FAO software to check the proposed MRLs. If the MRLs are high, based on the software, they ask for a lower MRL, and provide evidence from the software calculations. Once DAFF agrees to an MRL, they then ask DOH to amend the MRLs in the regulations.

(Interview, 2011)

The methods of documenting the scientific justification are a process that is still developing within DAFF. There is a recognized need for increased research and development capacity in order to gain “relevant and up to date scientific data for effective implementation of SPS requirements.” The lack of capacity has led to a domino effect, resulting in a lack of technical justification for phytosanitary requirements. (Theyse, 2010)

This reflects the South African phytosanitary regulatory system, rather than as a general cautionary observation, Directorate Plant Health strives to ensure that its phytosanitary import conditions are based on accepted principles of Pest Risk Analysis (PRA) and technical justification. Quarantine pest lists are currently being extracted and consolidated from individual import permit conditions. National surveillance is currently conducted for quarantine fruit flies. (Interview, 2011)

8.3 Involvement in Article 4 of the WTO SPS Agreement Regarding Equivalence Determination

DOH is not involved in equivalence determinations with another country. DOH does not have the specific expertise necessary, and there has not been a request. As previously reference, NRCS has signed the Technical Cooperative Agreement with Thailand. (Interview, 2011)
8.4 Process for Recognizing a Foreign Country’s Food Safety System as having Adequate Regulatory Oversight

DOH does not have a formal process to recognize another country’s food safety system, and the capacity and resources are not available. (Interview, 2011)
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