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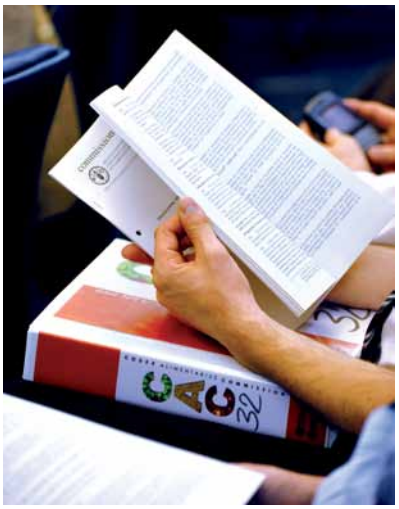

RISK BASED IMPORTED FOOD CONTROL MANUAL

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FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, ROME 2016

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PREFACE

In 2013, food products accounted for more than 80 percent of total agricultural exports. They are the third most valuable commodity group traded internationally, after fuels and non-pharmaceutical chemical products[1]. A number of countries, including many developing countries, import a significant proportion of their food supplies. Some countries rely almost entirely on food imports to ensure food security.

While developing systems of food import, countries progressively set up inspection measures in order to protect the health of their populations and ensure fair practices in trade. Over time, increasing volumes of imported foods, together with the diversification of origin and growing complexity of the technologies used for manufactured foods, have led to a need to revise the approach to food import control. Relying on a traditional approach, based on random or systematic product inspection at borders, is no longer considered effective.

Preventative approach to address priority risks, along to food chain.

The approach for food controls in general has now shifted from being mostly reactive, based on end product inspection, to being preventative and risk based, taking into account the entire food chain. For imported food, the specific challenge is that competent authorities in charge of official controls have no direct oversight over the production process of their trading partners. The development of trading relationships, increased dialogue between competent authorities of importing and exporting countries, use of certification mechanisms and improved oversight of the importers' community are some options that can help strengthen the effectiveness of imported food controls.

Updated FAO guidance on imported food controls consistent with Codex Alimentarius.

Over the last two decades, international agreements (i.e. the World Trade Organization's (WTO) agreements on Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT)) have defined a framework for control measures to protect the health of consumers and ensure fair practices in food trade. The joint FAO/World Health Organization (WHO) Codex Alimentarius Commission (CAC) sets the international standards referred to in WTO's two agreements for food safety and food standards, and has produced specific guidance for risk based official controls on imported foods, including CAC/GL 47-2003 "Guidelines for Import food control systems" and other related texts[2].

Codex standards, guidelines and recommendations provide a useful overarching framework on which countries should base their control measures as appropriate to their situation, specific challenges and resources. However, many developing and transition countries have expressed the need for additional support and guidance on the practical elaboration of these measures.

1 As reported in the World Trade Organization's International Trade Statistics 2014.

2 See www.codexalimentarius.org/committees-and-task-forces/en/?provide=committeeDetail&idList=5.

Global guidance for customized plans of action.

Upon request of member countries, FAO has developed a global guidance for risk based imported food controls. The necessity of this guidance is based on the recognition that there is no "one size fits all" solution and that each country presents a particular set of challenges and opportunities. This FAO manual aims to support competent authorities in shaping a customized plan of action, based on an analysis of their specific country situation. It provides concrete illustrations of how Codex guidelines can be implemented in different ways. While respecting the principles, guidance and objectives agreed by the CAC, different options for control measures can be selected and combined to implement a coherent set of import controls to best fit the needs of each country. Different examples, as implemented by a number of countries, are provided to show that there are often several alternatives to reach a common goal.

Particular emphasis is given to risk based programming in order to support countries in allocating available resources to target priority risks in the most appropriate manner. This takes into consideration trade and food security situation, institutional set up, legal framework, available support services etc.

Based on Codex texts, this guidance focuses on import control over **food** products. FAO recognizes that the impact of feed safety on food safety is essential. It should be noted that the majority of approaches developed in this manual for imported food control could also apply to feed.

The development of practical and widely applicable guidance was made possible by the experience gained by FAO through its many projects addressing food control issues, in particular imported food controls. More specifically, sections of this manual were tested in Gabon, India, Bangladesh and Jordan (regional approach).

This manual complements other existing FAO guidance aimed at strengthening risk based food inspection services in its member countries.

ACRONYMS

AOAC	Association of Analytical Communities
ASEAN	Association of Southeast Asian Nations
CAC	Codex Alimentarius Commission
CCFICS	Codex Committee on Food Import and Export Inspection and Certification Systems
CS/IT	Computer Systems/Information Technology
EEA	European Economic Area
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FEFO	First Expiry/First Out
FIFO	First In/First Out
GAP	Good Agricultural Practices
GATT	General Agreement on Tariffs and Trade
GHP	Good Hygienic Practices
GIP	Good Importing Practices
GMP	Good Manufacturing Practices
HACCP	Hazard Analysis Critical Control Point
ICMSF	International Commission on Microbiological Specifications for Foods
IHR	International Health Regulations
ILAC	International Laboratory Accredited Cooperation
INFOSAN	International Food Safety Authorities Network
IPPC	International Plant Protection Convention
ISO	International Organization for Standardization
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JEMRA	Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment
JMPR	Joint FAO/WHO Meeting on Pesticides Residues
MANCP	Multi Annual National Control Programme
OECD/DAC	Organisation for Economic Co-operation and Development-Development Assistance Committee
OIE	World Organization for Animal Health
QA	Quality Assurance
QC	Quality Control
RASFF	Rapid Alert System for Feed and Food
SOP	Standard Operating Procedure
SPS	Sanitary and Phytosanitary Measures (WTO Agreement)
SWOT	Strengths, Weaknesses, Opportunities and Threats
TBT	Technical Barriers to Trade (WTO Agreement)
TRACES	Trade Control and Expert System
USFDA	United States Food and Drug Administration
WHO	World Health Organization
WTO	World Trade Organization

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INTRODUCTION TO THE MANUAL

SCOPE AND OBJECTIVES OF THE MANUAL

This manual is intended to provide guidance, which countries can consult in designing imported food controls for their specific context. It can be used to develop programme and procedural directives at the regional or national level. It provides options for competent authorities with respect to designing, evaluating and managing imported food controls, consistent with the FAO and Codex Alimentarius mandates.

NOTE

Guidance pertaining to the World Organization for Animal Health (OIE) and the International Plant Protection Convention (IPPC), mandates is not within the scope of this manual. However, it does identify where competent authorities with responsibility for food safety, and other institutions responsible for animal health and welfare or plant protection, may benefit from cooperation and coordination. For detailed guidance on animal health and welfare or plant protection, it is important to consult the guidance prepared by OIE and the IPPC.

Each country will implement imported food controls within its unique situation (e.g. economic, social, legal and policy). To assist countries in addressing the challenges in doing so, this manual provides guidance on risk management options, considerations for legal and institutional frameworks, and support functions. The purpose is that countries have the tools to design and implement well designed and consistent risk based imported food controls, despite the limitations they may face in terms of capacity and resources, and make the best strategic use of what is available, while planning for improvements.

Guidance and options that countries can consider in developing imported food controls fitting their specific context.

The manual includes the following sections:

> **Section 1: Objective of Imported Food Controls.** This includes an overview of key Codex Committee on Food Import and Export Certification Systems (CCFICS) principles and guidance related to imported food controls, and an introduction to the technical and legal concepts underpinning these.

> **Section 2: Imported Food Control Framework**. This describes different risk management measures. It presents countries with a set of options for designing a coherent control "framework" or "programme" based on the country-specific situation. It provides an overview of information requirements (e.g. importer, imported food or exporting country profiles; risk categorization) that governments should take into acount while selecting the most effective risk management action(s) — whether pre-border, border or post-border/in-country — for imported food controls.

> **Section 3: Legal and Institutional Framework.** This outlines basic legal concepts that need to be taken into consideration when developing laws and regulations to implement imported food controls. It also describes different modalities to set up collaboration mechanisms among competent authorities and other institutions that have a role in imported food.

> **Section 4: Support Functions.** This provides guidance and options for competent authorities to deliver imported food controls within the legal and institutional framework outlined in Sections 2 and 3. It includes key concepts such as central management, planning and reporting, policy and programme development, science advice and laboratory services, and inspection services.

TARGET AUDIENCE

Intended for use by competent authorities to develop, maintain, implement and review their imported food controls.

This manual is intended for use by competent authorities responsible for imported food controls as a technical reference in designing, evaluating and managing those controls. It may also be useful for international agencies and experts charged with reviewing or assisting capacity development with respect to imported food controls.

This manual is not intended to be a training manual. However, it could provide a good documentary basis to construct specific national training, tailored to the specific needs of a country.

USE OF THE MANUAL

FROM CODEX ALIMENTARIUS

"Continuous Improvement means that a national food control system should possess the capability to learn through a process of review and reform utilizing mechanisms that check and evaluate whether the system is able to achieve its objectives."

CAC/GL 82-2013

Competent authorities are encouraged to consider the guidance included in this manual when developing or reviewing their imported food controls. Authorities may initiate a review of their imported food controls for various reasons, such as a crisis (e.g. food-borne illness associated with imported food), a high number of rejections of imported food, development of new regulations, industry or consumer pressure, or as part of continuous improvement. Such a review may cover all of the imported food controls (i.e. legislation, competent authorities, programme and procedures, support functions) or part of the imported food controls. When carrying out this review, it is also important to remember that an imported food control system is a subset of a national food control system, and should not only function as an efficient entity, but also integrate and interact coherently into this wider system. Countries are encouraged to refer to the "Principles and Guidelines for national food control systems" (CAC/GL 82-2013), which provides guidance on the design and operation of national food control systems.

FROM CODEX ALIMENTARIUS

"… in today's global market, much food is sourced from outside the country; hence, properly designed import and export control systems, as part of the overall national food control system, are essential."

CAC/GL 82-2013

Engaging in systematic and ongoing efforts to assess capacity of a national food control system, including imported food controls, will enhance the ability of competent authorities to plan, implement and monitor programmes and activities related to imported food controls.

FROM CODEX ALIMENTARIUS

"The national food control system should possess the capacity and capability to undergo continuous improvement and include mechanisms to evaluate whether the system is able to achieve its objective."

CAC/GL 82-2013

Imported food controls should be regularly reviewed and assessed to ensure they remain accountable and effective. This applies to countries with mature imported food controls as well as those seeking to develop or improve their controls. Using the guidance in this manual, competent authorities should be able to identify requirements for improvement, set priorities and organize their work, within the context of available resources.

FROM CODEX ALIMENTARIUS

"This should include the consistent application of a systematic framework for the identification, evaluation and, as necessary, control of food safety risks associated with existing, new or re-emerging hazards."

CAC/GL 82-2013

A systematic assessment of the appropriateness and effectiveness of a country's existing imported food controls is essential for continuous improvements.

Key areas for an assessment include:

> an assessment of the existing imported food controls in the context of international standards and guidance;

> an assessment of cooperation and coordination within and between competent authorities responsible for imported food controls, and where appropriate authorities responsible for food exports; and

> an assessment of the effectiveness of risk management actions in assuring imported food meets importing country requirements.

DEVELOPMENT OF NATIONAL CAPACITIES

Systematic review[3] of imported food controls should be tailored to the specific country situation and the rationale for the review. Systematic review ensures that any changes made to one part of the system take into account the potential impacts on other parts of the system. Programme changes that do not consider such implications can result in inadvertent problems and may negatively impact imported food controls. Reviews may focus on a part of the imported food controls, such as an inspection procedure following a particular situation (e.g. food-borne illness), or on specific import controls (e.g. legislation, policy or procedures), or all imported food controls. The approach to the review could consist of:

Systematic review of imported food controls as part of capacity development.

> a checklist (see SUPPORTING TOOLS AND GUIDANCE 1) of the current system using semi quantitative and qualitative ratings ("in place"; "partially in place"...) that provides a simple outline of the areas requiring improvements;

> an analysis of the strengths, weaknesses, opportunities and threats (SWOT) that identifies a range of options for improvements;

> more formal approaches, defining competencies and proposing a harmonised system for assessing achievement and performance (e.g. FAO/WHO Food Control System Assessment Tool, which assesses import food control as a subset of the food control system).

Whatever approach is chosen, the results of the assessment should help establish clear objectives and priorities for improving imported food controls tailored to the specific country's situation. While establishing priorities may not be an easy task, some actions (e.g. procedures to deal with food safety emergencies) are always deemed the most urgent. Areas that are co-dependent (e.g. new risk management policies and legislative authorities; inspection procedures and training requirements) should be addressed concurrently.

Using the systematic review to establish objectives and priorities for improving imported food controls.

[3] General advice on different approaches to identifying capacity development needs is provided in *Strengthening National Food Control Systems: Guidelines to assess capacity building needs (FAO; 2003).*

Once the objectives and priorities have been established, countries will have to evaluate the most cost efficient and effective risk management options for implementing their imported food controls consistent with the guidance provided by Codex Alimentarius and this manual. Assessing the costs and benefits of the options under consideration can help to inform the decision making process[4].

Implementing any proposed improvements to imported food controls will be influenced by other factors such as:

> Political support, which is of particular importance where changes to institutional responsibilities and mandates or to the legislative framework are required.

> Financial resources for increased inspectors, analysts and other operations (e.g. information management). Resources may be provided directly through increase in government funding or authority to introduce fees.

Loss of public confidence in imported food because of a recurrent problem often results in a need to implement alternative risk management actions to address the issue.

NOTE

Capacity is defined as "the ability of people, organizations and society as a whole to manage their affairs successfully. Capacity development is the process of unleashing, strengthening and maintaining of such capacity". This definition, based on the work of the Organisation for Economic Co-operation and Development (OECD/DAC), reflects the broadest consensus possible within the international development community. The FAO framework differentiates between two types of capacities: technical and functional; these operate at different dimension levels:

> individual dimension: changes in skills, behaviours and attitudes; training, knowledge sharing and networking are ways of strengthening capacities at this dimension;

> organizational dimension: taking measures to improve the overall functioning and performance of an organization. This dimension has a direct impact on how individuals within the organization develop their competencies and use their capabilities.

> enabling environment: context in which individuals and organizations put their capabilities into action, and where capacity development processes take place. It includes: political commitment and vision; policy, legal and economic frameworks; budget allocations and processes; governance and power structures; incentives and social norms.

4 Regulatory impact assessment and cost benefit tools are described in *Strengthening National Food Control Systems: Guidelines to assess capacity building needs (FAO; 2003)*.

SUPPORTING TOOLS AND GUIDANCE 1

CAPACITY BUILDING AND DEVELOPMENT ASSESSMENT CHECKLIST

Provides one tool for a systematic review of imported food controls.

Checklists should be adapted to specific country objectives and requirements.

Capacity development activities begin with a systematic review of existing capacity. One option for undertaking a systematic review is to use a checklist to assess the adequacy and appropriateness of existing controls. A checklist may be used to review all or portions of the existing imported food controls.

In deciding to use a checklist to assess its existing system, the competent authority should clearly identify its objectives, the specific areas to be included in the review and the areas to be excluded. Because each imported food control system is designed for a specific country situation, the checklist will have to be adapted to that situation. For example, where a country has little or no interest in implementing pre-border controls, there is little benefit in developing a checklist to assess pre-border actions.

The following checklist is an example of questions retrieved from the various sections of this manual that a competent authority may want to consider. The key to effective use of any checklist is to gather information and research each question, including consultation with all appropriate competent authorities, other government institutions and stakeholders.

While using the checklist tends to result in a simple response, (i.e. **Yes, No, Unknown, or NA – not applicable)** this should be supplemented by explanatory notes that provide context for the answers.

IMPORTED FOOD CONTROL FRAMEWORK

1. Imported food control has a framework that:

1.1. Is consistent with, and authorized by, the objectives established in the government's food safety and quality policy and legislation.

1.2. Has information on the imported food (profile).

1.3. Includes risk categorization.

1.4. Includes appropriate risk management activities.

1.5. Regularly reviews and adjusts food risk categories, and uses conclusions and recommendations in the periodic revision of the overall risk management policy.

2. The imported food control programme

2.1. Takes into account that importers are responsible for imported food meeting requirements, and authorities are responsible for facilitating or encouraging compliance, verifying compliance and taking action in cases of non-compliance.

2.2. Has appropriate information gathering requirements to ensure efficient and effective operations.

2.3. Has a framework for cross-agency communication and coordination on imported food matters.

2.4. Has the means to communicate with importers on food control matters (e.g. pertaining to import controls, inspection decisions, regulations, emergencies, taxes and fees).

2.5. Has developed contacts with:

2.5.1. Countries belonging to the same economic union (if appropriate).

2.5.2. Exporting countries.

2.5.3. Regional or international (INFOSAN, WHO) food safety information and alert networks to exchange information on food safety emergencies.

3. Importer and imported food profile

3.1. Identifies the importers (e.g. name, address, contact details).

3.2. Identifies the imported food (e.g. product type, source, description, time of import, volume, condition, compliance history).

3.3. Identifies the exporting country risk profile (as appropriate).

4. Risk basis of the imported food controls

4.1. The imported food control programme is based on risk:

4.1.1. Using the Codex Alimentarius risk analysis framework or a risk categorization that is science and evidence based, and results in a list of imported food targeted, in relation to specific hazards, and the identified level of risk.

4.1.2. Has appropriate risk based standards that are consistent with international requirements (Codex, FAO/WHO) or with applicable regional requirements (e.g. European Commission, Food Standards Australia New Zealand).

4.1.3. Imported food control measures (e.g. documentation, identity, inspection, sampling and analysis) is based on the risk category of the imported food.

4.1.3.1. Allows, if necessary, the possibility of strengthening or modifying the type, intensity and frequency of controls according to the exporting country risk profile and/or importer controls.

4.1.4. Risk categories are regularly reviewed and adjusted, and their conclusions and recommendations are used in the periodic revision of the overall risk management policy.

5. Import procedures

5.1. Have been prepared in consultation (e.g. with other competent authority/ies, importers).

5.2. Are not more stringent than necessary with regard to controls on domestic food products.

5.3. Are described in standard operating procedures (SOPs) or instructions as appropriate[5] that are written, published and publicly available.

5.4. Are readily available to inspectors and other officials who have been trained as to their objective and content.

5.5. Are regularly evaluated and amended following a consultative process that includes all relevant stakeholders.

6. Risk management actions

6.1. The imported food control programme has clearly identified risk management actions as appropriate to the country specific situation:

6.1.1. Pre-border Controls:

6.1.1.1. In the exporting country (e.g. assurance from exporting country's competent authority; third party verification; importer controls of foreign suppliers)

6.1.2. Border controls:

6.1.2.1. Prohibition of banned food products or ingredients (e.g. foods of animal origin that may contain carcinogenic drugs).

6.1.2.2. Mandatory pre-notification and/or notification of imported food consignments or lots.

6.1.2.3. Document/certification assessment (including validation, fraud control etc.); electronic certification (where applicable).

6.1.2.4. Inspection, sampling and testing – according the imported food risk category.

6.1.2.5. Decision making procedure on admissibility of food (e.g. allow, detain, reject or destroy) and communication procedures (e.g. importing, exporting country).

6.1.2.6. Appeal process.

6.1.2.7. Information management and archives (recording).

5 For example, import notification, review of documentation, identity and physical (inspection, sampling and testing) check, decision, information to the importer; emergency, recourses and complaints; data management etc.

6.1.3. Post-border/in-country controls:

6.1.3.1. Is there a good knowledge of importers and requirements (e.g. registration, import licences or permits)?

6.1.3.2. Is there risk based approach to assessment of importers' practices, and enhanced inspection in instances of non-compliance?

6.1.3.3. Monitoring processes (e.g. sampling and analysis of product released to market).

6.1.3.4. Process for suspension or revocation of permits/licences as needed.

7. Inspection and sampling/testing

7.1. Inspection, sampling and testing targets and frequencies are established and applied on a risk basis to both imported food products, and action performed by importers, and are:

7.1.1. Planned: dates, personnel involved, equipment, samples.

7.1.2. Implemented consistently, using documented procedures sufficiently detailed, written and published for:

7.1.2.1. Inspections;

7.1.2.2. sampling (including reports);

7.1.2.3. transportation and receipt by the laboratory;

7.1.2.4. transmission of analytical report;

7.1.2.5. final decision.

7.1.3. Inspections and sampling forms certificates and other forms pertaining to the final decision over the products.

LEGAL AND INSTITUTIONAL FRAMEWORKS

1. The legal framework

1.1. Are the imported food control laws and regulations:

1.1.1. Applicable to all imported food, at all points of entry?

1.1.2. Given clearly defined objectives (e.g. foods must meet all regulatory requirements)?

1.1.3. Consistent with national legislation, and respectful of appropriate legal hierarchy (between primary laws/regulations)?

1.1.4. Consistent with both national and subnational legislation?

1.1.5. In compliance with international agreements? Including:

1.1.1.1. Science-based risk management.

1.1.1.2. Traceability.

1.1.1.3. Non-discrimination and national treatment.

1.1.1.4. Transparency and flexibility.

1.2. Are regulations clearly written and easily accessible, and:

1.2.1. Allow the competent authority to adapt to scientific developments, new findings or change programme requirements?

1.3. Do the legal/regulatory texts applicable to imported foods define roles and responsibilities:

1.3.1. That food business operators (importers):

1.3.1.1. Have primary responsibility to ensure that imported food meets regulatory requirements?

1.3.1.2. Must meet importer obligations (e.g. GIP, foreign supplier verification, recalls, notification of import shipments, licences)?

1.3.2. Of competent authority or authorities?

1.3.2.1. Designating the institution(s) and their responsibilities.

1.3.2.2. Rules on the appointment of officers or delegation to third party service providers.

1.3.2.3. Actions required to monitor compliance (e.g. document review, inspection) and take enforcement action (e.g. seizure recall) where needed.

1.3.2.4. Requirements and, where needed, mechanisms for information exchange, collaboration among competent authorities and other institutions and with food businesses.

1.4. Does the legal/regulatory texts provide authority to:

1.4.1. Establish requirements for imported food (e.g. food safety standards, process requirements)?

1.4.2. Establish arrangements with foreign authorities, including reduced oversight on imported foods and/or certification requirements?

1.4.3. Establish admissibility requirements (e.g. prohibition on banned ingredients, mandatory notification)?

1.4.4. Gather information on importers and imported food?

1.4.5. Establish processes and procedures including:

1.4.5.1. Requirements for fees and taxes, and process for collection?

1.4.5.2. Inspection, sampling and analysis of imported food, including use of third party laboratories, and if necessary, recognition/accreditation procedures?

1.4.5.3. Decision making process, appeals and penalties and sanctions?

2. Institutional Framework

2.1. Are the competent authorities and other institutions with a role in imported food controls:

2.1.1. Authorized by legislation?

2.1.2. Do they have clear, unambiguous mandates?

2.2. Do the competent authorities have formal agreements for coordination and information sharing, where needed:

2.2.1. With all other imported food control competent authorities?

2.2.2. With other institutions (e.g. Customs, Animal Health, Plant Health, Public Health Surveillance)?

2.2.3. With private organisations (e.g. importers, third party service providers)?

2.2.4. With international organisations or mechanisms (e.g. FAO/WHO – INFOSAN)?

2.3. Is there evidence of collaboration and information exchange?

2.4. If there are supra-national (regional), multiple national or subnational competent authorities or institutions, is there:

2.4.1. An integrated framework that can facilitate collaboration and cooperation, and ensure consistent implementation at all border points?

2.4.2. Evidence of gaps or duplication?

2.4.3. Evidence of fragmentation or inconsistencies among the subnational governments or between subnational and national competent authorities?

2.5. Do imported food control competent authorities participate in the appropriate domestic or international food standard development (e.g. Codex)?

SUPPORT SERVICES

1. Management support

1.1. The imported food control competent authority(ies) should include a central management function that:

1.1.1. Provides an integration function to design, implement and manage the appropriate risk management actions.

1.1.2. Undertakes system analysis, to develop the importer profile, establishes planning and reporting procedures.

1.1.3. Has a programme planning function to assess risk management actions, with the intent of continuous improvement.

1.1.4. Has an operational delivery planning process to ensure ongoing imported food control (e.g. inspection, analysis) is delivered.

1.1.5. Ensures that the programme design is documented and that there is written programme guidance for inspectors and importers.

1.1.6. Has a management coordination and response that ensures ongoing communication between management and programme delivery personnel to respond to issues, and provide appropriate direction for emerging situations.

1.1.7. The imported food control programme should have access to ongoing science advice to establish and maintain risk based imported food controls.

1.1.7.1. Is science advice obtained from international sources (e.g. Codex, FAO) or other appropriate national sources?

1.1.7.2. Are there appropriate arrangements where science advice is provided by other national institutions to clarify roles and responsibilities, resource requirements and expectations?

1.1.7.3. Is science advice available to develop the sampling strategy and the annual sampling plans?

1.1.7.4. Are there documented annual sampling plans that set out the type and number of inspections/samples to be collected, who collects samples and where (e.g. border, importer warehouse) available for inspection staff and laboratory staff?

2. Laboratory (analytical) services

2.1. Import food programmes should have access to analytical services:

2.1.1. Domestic government laboratories; academic laboratories, private third party laboratories, international government or third party laboratories.

2.1.2. Are there appropriate arrangements where analytical services are provided by outside laboratories (i.e. laboratories external to the competent authority that clearly establish roles and responsibilities, resource requirements and expectations)?

2.1.3. Do specific communication systems/protocols exist for transmission of results from laboratories to imported food control officials?

2.1.4. Is the capacity (e.g. tests, methodology,) and confidence (e.g. quality controls (QCs) accreditation) known?

2.1.5. Are results provided in a timely manner?

2.1.6. Is a suitable infrastructure in place?

2.1.7. Are the principles of consistency, confidence and transparency taken into account for laboratories used for imported food controls?

2.1.8. To every possible extent, do laboratories used in imported food controls have adequate quality assurance (QA) or accreditation?

3. Inspection support

3.1. Import controls require government oversight to verify that imported food and importers meet regulatory requirements. Is the oversight provided by:

3.1.1. Government officials?

3.1.2. Third party service providers?

3.1.3. A combination?

4. Pre-border inspection support

4.1. Is there inspection support for pre-border controls including assessing the food safety system in an exporting country?

4.2. Are there clear eligibility requirements for the use of third party service providers to assess foreign suppliers (e.g. importer foreign suppliers verification)?

5. Border Inspection support

5.1. Who is responsible for border controls of imported food:

5.1.1. Border services?

5.1.2. Imported food control officials?

5.1.3. Importers, third party service providers?

5.2. Are there sufficient inspection services to implement the required border controls?

5.3. Is there sufficient information exchange and communication between border posts and the import food control officials, and between the importers and the imported food controls?

6. Post-border/in-country

6.1. Are there clear post-border controls (e.g. inspecting importers)?

6.2. Who is responsible for delivering the in-country controls:

6.2.1. Government officials (e.g. domestic food control officials, subnational governments)?

6.2.2. Accredited third party service providers?

7. Legal support

7.1. Is there ongoing access to legal advice:

7.1.1. To address new or amended regulations or industry/operational guidance?

7.1.2. To address non-compliance in the case of legal action or prosecutions?

7.1.3. To support officials in importer appeals or administrative sanctions?

8. Administrative support

8.1. Does administrative support include management of financial resources, procurement, establishing policies and procedures, health and safety?

9. Financial resources

9.1. Are imported food controls funded by:

- 9.1.1. Government revenue?
- 9.1.2. Fees levied on importers, whether direct or indirect?
- 9.1.3. Or a combination?

9.2. Are resources for imported food control services clearly identified, and are the planned and actual use of resources documented?

- 9.2.1. Is access to specific funding sources allowed in case of emergencies?
- 9.2.2. Are there imported food control taxes and fees (as appropriate)?
- 9.2.3. Are these authorized by legislation, including a collection process?
- 9.2.4. Are they commensurate with the service provided?
- 9.2.5. Are they published and made readily accessible to importers?
- 9.2.6. Are they regularly updated?

9.3. Are procedures for collection of fees clear and transparent to both importers and officials?

9.4. Are there regular financial audits to verify both the collection of fees and the expenditure of those fees?

9.5. Are importers required to post bonds for imported foods? If so, is there a process to:

- 9.5.1. Manage the bond?
- 9.5.2. Return the bond to the importer once the food is deemed admissible?
- 9.5.3. Use the bond to pay for re-exportation or destruction of the rejected food?
- 9.5.4. Audit and post use of bonds?

10. Location of Offices

10.1. Are offices located appropriately:

- 10.1.1. Co-located or in close proximity to the major border entry points?
- 10.1.2. Are primary offices located near the major border points?
- 10.1.3. Where one official is responsible for more than one border entry, does one office give easy access to all entry points?
- 10.1.4. Are central offices located to facilitate communication and coordination with other national organizations?

11. Laboratories

11.1. Are laboratories appropriately located so that there is effective and efficient transport of samples to them, and that the samples arrive in acceptable condition for analysis?

12. Transport

12.1. Is there adequate transport available for:

12.1.1. Inspectors to and from the inspection sites?

12.1.2. Sampling equipment and samples to the inspection site, and then to the laboratory?

12.2. Are there policies on use of transportation? And for protection of samples during transportation?

13. Procurement:

13.1. Are there procurement policies and procedures in place:

13.1.1. For capital equipment acquisition?

13.1.2. For general supplies?

13.1.3. For audit and review of procurement to ensure appropriate use of resources?

13.2. Is there adequate equipment inspecting and sampling (where necessary)?

13.3. Is equipment and material periodically maintained, renewed and available at all times?

13.4. Are uniforms or appropriate clothing,[6] including protective gear, available at all times?

13.5. Are there procedures for management and maintenance?

14. Human resources

14.1. Imported food controls require professional and administrative staff with the skills to administer and manage the risk based import controls:

14.1.1. Are there clearly identify work descriptions that outline the duties and responsibilities of a position?

14.1.2. Is there a classification system that organizes the work descriptions for the efficient management of human resources?

14.2. Are there organization charts? Are they available both for staff and for external stakeholders?

14.3. Are procedures for their nominations formal and their functions well defined?

15. Training of personnel

15.1. Are there policies in place that outline training opportunities and requirements?

15.2. Do employees understand their roles and responsibilities and have the skills and competencies required to deliver them?

15.3. Do specialists meet professional standards?

15.4. Employees should have a training plan tailored to the needs of the individual, taking into account academic background and on the job experience (within available training resources).

15.5. Are training sessions are reported on and assessed, and do they influence the activities performed?

6 i.e. specific to the inspectorate and allowing proper identification.

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SECTION 1

OBJECTIVE OF IMPORTED FOOD CONTROLS

> POLICY OBJECTIVES

> IMPORTED FOOD CONTROLS PRINCIPLES AND CONCEPTS

> DESIGN AND IMPLEMENTATION OF IMPORTED FOOD CONTROLS

POLICY OBJECTIVES

FROM CODEX ALIMENTARIUS

> "Policy setting is the process by which the goals and objectives for the national food control system are established by governments, along with the commitment to a course of action to achieve those goals and objectives. It should also include the identification and clear articulation of expected outcomes. Policy decisions guide subsequent actions, including the establishment of legislation and regulations."
>
> CAC/GL 82-2013

Governments establish policy objectives for food safety, including imported food safety, based on their national situation, including their international obligations. Countries are encouraged to develop an imported food safety policy, either as a stand-alone policy or as part of a broad based food safety policy. A country's imported food safety policy generally establishes the national objectives. Some countries may choose to refer to the principles set out in Codex Alimentarius as their national policy. Subsequently, competent authorities will develop the programme design that identifies what risk management actions are to be implemented in order to meet the national objectives.

FROM CODEX ALIMENTARIUS

> "… precedence should be given to protecting the health of consumers and ensuring fair practices in food trade over economic or other trade considerations."
>
> CAC/GL 47-2003

Protecting the health of consumers.

Facilitating fair practices in food trade.

Consistent with Codex guidance, the objectives of imported food controls are intended to protect the health of consumers and facilitate fair practices in food trade while avoiding unjustified technical barriers to trade[7]. In many countries, the objectives are included in their legislation to guide subsequent decisions on the implementation of imported food controls.

Countries recognize that effective implementation of imported food controls means targeting the highest risk products with the most appropriate risk management action(s), thereby balancing the costs of regulatory intervention (including costs to industry and consumers) and the primary objective of protecting the health and safety of consumers. The key to this balance is the application of formalised risk based approaches including risk identification, assessment and management, recommended by Codex[8], as the basis of imported food controls.

IMPORTED FOOD CONTROLS PRINCIPLES AND CONCEPTS

The information in this manual is consistent with, and elaborates on, the principles outlined in relevant Codex documents.

7 Guidelines for Food Import Control Systems (CAC/GL 47-2003).

8 Working principles for risk analysis for food safety for application by governments (CAC/GL 62-2007).

FROM CODEX ALIMENTARIUS

The "Principles for food import and export inspection and certification"(CAC/GL 20-1995) include the following principles:

- fitness for purpose,
- risk assessment,
- non-discrimination,
- efficiency,
- harmonization,
- equivalence,
- transparency,
- special and differential treatment,
- control and inspection procedures and
- certification validation.

FROM CODEX ALIMENTARIUS

The "Guidelines for Food Import Control Systems" (CAC/GL 47-2003) outline the following characteristics:

- requirements for imported food that are consistent with requirements for domestic foods
- clearly defined responsibilities of competent authority (ies)
- clearly defined and transparent legislation and operating procedures
- precedence to the protection of consumers
- provision of the importing country for recognition of the food control system applied by an exporting country's competent authority
- uniform nation-wide implementation
- implementation that ensures the levels of protection achieved are consistent with those for domestic foods

This section illustrates a number of the principles and concepts from the guidelines, however, authorities are encouraged to review the CCFIC's publications[9].

Fitness for purpose

FROM CODEX ALIMENTARIUS

"Fitness for purpose. Inspection and certification systems should be fully effective in achieving their designated objectives."

CAC/GL 20-1995

Achieving the stated policy objectives.

Risk management actions associated with imported food controls should be fully effective and fit for purpose (i.e. achieve the stated national objectives). Imported food controls can include a range of risk management actions.

Risk management actions may include border or point of entry inspections, (including documentary, identity and physical inspection), audit of exporting

9 www.codexalimentarius.org/committees-and-task-forces/en/?provide=committeeDetail&idList=5

country food safety systems, assessment of the importers' Good Importing Practices (GIP) and ensuring that official certificates themselves are authentic and accurate (e.g. by liaison with exporting food control authorities). Importing countries may:

> adjust the nature and frequency of inspections, audits, sampling and testing proportionate to the assessed imported food risk, compliance (or non-compliance) history of the imported food product, foreign supplier and/or processor, and importer;

> adjust controls in light of food-borne illness outbreaks, critical non-compliance findings (inspection or testing), international food safety alerts (e.g. from the International Food Safety Authorities Network (INFOSAN) notifications).

NOTE

INFOSAN is a global network of national food safety authorities, managed jointly by FAO and WHO, which aims to:

> Promote the rapid exchange of information during food safety related events.
> Share information on important food safety related issues of global interest.
> Promote partnerships and collaboration between countries, and between networks.
> Help countries strengthen their capacity to manage food safety emergencies.

Legal foundation and transparency

FROM CODEX ALIMENTARIUS

"Clearly defined and transparent legislation and operating procedures."

CAC/GL 47-2003

Clear legal basis and transparent requirements.

Imported food controls should have a clear legal basis, with readily available (i.e. transparent) laws, regulations, standards and other classes of operating procedures that are consistent with international food safety standards and guidelines (e.g. Codex) and, where applicable, other food related standards (e.g. OIE and IPPC).

Legislative authorities, regulations and operating procedures should be written, published and easily accessible to all interested parties (e.g. importing or exporting food businesses, exporting country(ies) competent authorities).

Further guidance on legal foundation is provided in Section 3 of this manual.

Non-discrimination

FROM CODEX ALIMENTARIUS

"Countries should ensure they avoid arbitrary or unjustified distinctions in the level of risk, so as to avoid discrimination or a disguised restriction on trade."

CAC/GL 20-1995

"As far as possible, requirements should be applied equally to domestically produced and imported food."

CAC/GL 47-2003

The competent authority should follow the principle of non-discrimination. This means, regulatory requirements for imported food should, as far as possible, be consistent with the food safety requirements established for domestically produced foods. However, assessing compliance with standards, particularly process controls (e.g. good manufacturing practices) may differ between domestic and imported food. For example, the domestic food business process controls may be reviewed during inspection, while for imported food, the assurance of process controls may be provided by the competent authority in the exporting country.

Requirements for imported foods should be consistent with requirements for domestic foods.

Using evidence (e.g. compliance history, food safety arrangements) to implement two different import controls for similar foods from two different exporting countries is not necessarily discrimination. For example, where the exporting country provides assurances of compliance, border inspection of the food may be reduced, while where there is no assurance, border inspection of a similar food may be higher.

Clearly defined roles and responsibilities

FROM CODEX ALIMENTARIUS

"Clearly defined responsibilities of competent authority or authorities."

CAC/GL 47-2003

Competent authorities

The competent authority or authorities responsible for imported food controls (whether national, subnational or regional) and other institutions (e.g. customs, agriculture, trade or health agencies) should have clear mandates and responsibilities. Where authorities use third party service providers for imported food controls, all arrangements should be consistent with CCFIC's official accreditation guidance[10].

Clear mandates for competent authorities.

Importers/food businesses' primary responsibility

FROM CODEX ALIMENTARIUS

"Food business operators have the primary role and responsibility for managing the food safety of their products and for complying with requirements relating to those aspects of food under their control."

CAC/GL82-2013

Importers have primary responsibility for imported food, and this should be clearly stipulated. This creates a duty of care. Legal requirements should clearly establish the standard of care – that is, what importers can or cannot do, such as prohibiting the importation of food that does not meet product or processing standards, or requiring the "importer" to meet requirements (e.g. GIP, mandatory import licences).

Importers have primary responsibility for the food they import.

10 Guidelines for the design, operations, assessment and accreditation of food import and export inspection and certification system (CAC/GL 26-1997).

Risk based, science based and evidence based decision making

FROM CODEX ALIMENTARIUS

"A competent authority should make decisions within a national food control system based on scientific information, evidence and/or risk analysis principles as appropriate."

CAC/GL 82-2013

Risk based imported food controls provide effective means of addressing food safety.

Imported food controls based on risk provide a more effective means for addressing food safety risks. Imported food controls should be based on an evaluation of the risks posed by the imported food itself, the risks and controls implemented by the source (e.g. exporting country; exporting food business) and the risks and controls implemented by the importer.

Recognition of foreign food safety systems

FROM CODEX ALIMENTARIUS

"Provision of the importing country for recognition of the food control system applied by an exporting country's competent authority."

CAC/GL 47-2003

Imported food controls may take into account the food control system in the exporting country.

Imported food controls may include the recognition of food safety controls in exporting countries, such as certification requirements or other forms of mutual agreements (e.g. bi- or multi-lateral agreements, memoranda of understanding, or through formal equivalence agreements).

DESIGN AND IMPLEMENTATION OF IMPORTED FOOD CONTROLS

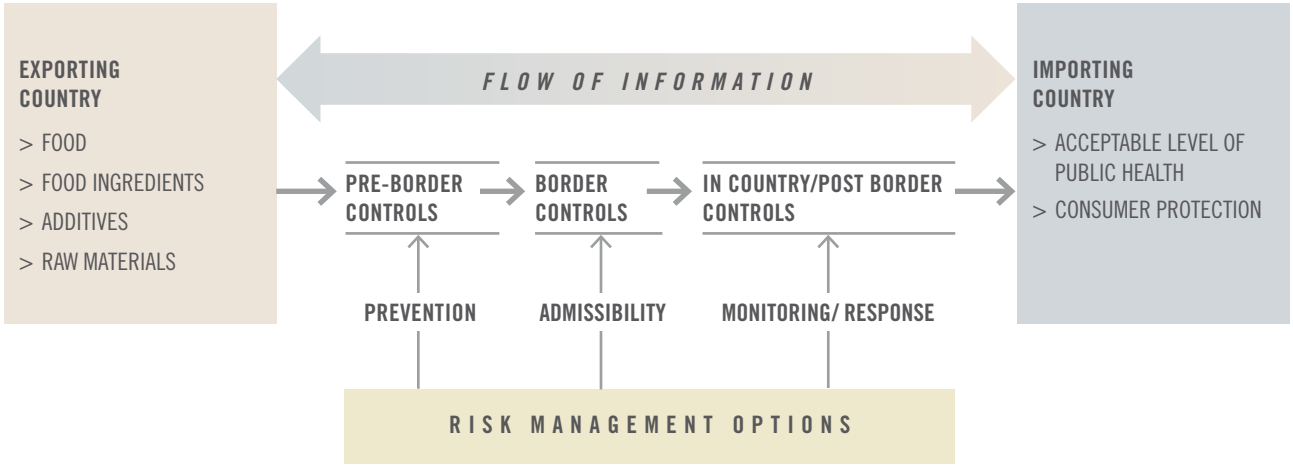
Controls are based on the optimal risk management actions, for efficiency and effectiveness, and tailored to the specific country situation.

Countries and their competent authorities have responsibility for ensuring that imported food controls are designed and implemented based on international principles and guidance. Effective imported food controls include the design of a programme framework (see Section 2) that outlines key responsibilities, information requirements and risk management options. Implementation of the framework requires the appropriate legal and institutional frameworks, (see Section 3) as well as support services (e.g. management, scientific advice, inspection services) (see Section 4). A brief introduction to the main technical and legal concepts underpinning imported food controls is provided below.

Risk based framework

Both programme design (what should be done) and programme procedures (how it should be done) should be developed based on the specificities of each country. The imported food controls, once designed and implemented, can be considered as an Imported Food Control Framework (see figure 1 below) that should be based on the optimal risk management actions for effectiveness and efficiency, whether

FIGURE 1 **ILLUSTRATION OF A SIMPLIFIED IMPORTED FOOD CONTROL FRAMEWORK**



applied pre-border, at the border or in-country. In determining the appropriate risk management actions, the competent authority will need information on importers and the imported food profile, including the exporting country profile. They will also need to assess the risk associated with imported food, taking into account the controls implemented by the competent authority in the exporting country, the exporting food business and the importer. Implementation of Imported food controls also needs ongoing communication between exporting and importing countries.

Information requirements

FROM CODEX ALIMENTARIUS

Development of an effective method of data collection across the food chain is important for situational awareness (avails itself of accurate and current information on the entire food chain), performance measurement and continuous review and system improvement.

CAC/GL 82-2013

Importer, imported food and exporting country profiles.

Designing and operating imported food controls based on risk requires the competent authority to develop a profile with respect to imported food (what is being imported, from where, when and how) and the importer, including compliance history, use (e.g. raw material, or finished products). The information from the profile is key to establishing risk based import controls, focusing on both the risk associated with the food products and any other factors that can reduce or increase risk (e.g. source processing controls, transportation controls).

Information used to implement risk based import controls.

Information provided by other competent authorities (e.g. within a country or between countries) or from international mechanisms (e.g. INFOSAN) is important as food trade is becoming more global in scope, with raw materials and final products originating from many countries.

Risk management actions

Objectives of risk reduction and increased compliance of imported food.

Although the risk management actions associated with imported food controls, including the frequency, intensity and type of inspection, may differ from domestic risk management actions, the objective remains the same — to reduce risk and increase the rate of compliance.

Risk management actions may operate pre-border, based on confidence in the controls in the exporting country or the exporting food business, at the border, or post-border (i.e. within the importing country) based on the importing competent authority assessing controls implemented by the importers.

Pre-border

FROM CODEX ALIMENTARIUS

> "Countries may wish to enter into agreements concerning food import and export inspection and certification to provide an enhanced means of assuring that exported products conform to importing country requirements"
>
> CAC/GL 34-1999

Assurance of food safety controls in exporting country.

Risk management actions implemented pre-border are primarily designed to seek assurance that controls in an exporting country result in safer food. This assurance is most often provided by the competent authority in the exporting country.

While pre-border controls can be an effective means of ensuring that imported food meets requirements, they are not always appropriate and may not be cost effective (for example in the case of small volumes or irregular trading relationships). Pre-border controls will require resources by both the exporting and importing country to implement, and should be carefully tailored to the specific country situation.

Generally, where exporting countries provide assurances of food safety, that assurance is expressed via formal arrangements based on Codex guidance. Such arrangements should include official information exchange procedures (e.g. for exchanging official certificates, and communicating details of rejected food consignments and import decisions).

Border

FROM CODEX ALIMENTARIUS

> "the nature and frequence of inspection may then be adjusted according to the demonstrated compliance to food safety requirements"
>
> CAC/GL 47-2003

Assessing compliance and addressing admissibility; adjusted based on compliance history.

Risk management actions implemented at the border are intended to assess compliance of imported food and address product admissibility. Border controls can include information on imports, document validation, product inspection and testing. The nature of the controls can be adjusted based on the demonstrated compliance with food safety requirements.

Post-border/in-country

FROM CODEX ALIMENTARIUS

"Point of control: Control of imported food by the importing country can be conducted at (…): origin where agreed upon by the exporting country; entry to the country of destination, further processing; transport and distribution, storage; and sale (retail or wholesale)."

CAC/GL 47-2003

Risk management actions supporting imported food control can also be implemented on the national territory of the importing country (i.e. post-border or in-country). This may include establishing importer controls (e.g. registration, licensing, permitting); requiring that all importers meet GIP and inspecting their compliance. Post-border controls can also include inspection and testing of product at the importer's warehouse to assess importer's controls or its surveillance and monitoring of product that has been distributed to the market place.

Effective for assessing importers are meeting their responsibilities.

Legal and institutional frameworks

FROM CODEX ALIMENTARIUS

Clearly defined and transparent legislation:
The object of legislation is to provide the basis and the authority for operating a food import control system. The legal framework allows for the establishment of the competent authority(ies) and the processes and procedures required to verify conformity of imported food against requirements.

CAC/GL 47-2003

Comprehensive, unambiguous and effective legal and institutional frameworks are essential to imported food controls. An imported food legal framework will include all legal texts (e.g. primary or secondary legislation) that establish the import control principles and objectives (e.g. ensure consumer protection, facilitate trade in foods) and define the responsibilities of competent authorities and food businesses.

Where sub-national governments enact legal requirements for imported food control on their territories, it becomes part of the legal framework. Clearly, the sub-national legal requirements should complement the national legal framework, and should not compromise or contradict it.

Includes all legislation such as primary, secondary legislation and standards impacting on the imported food controls.

Section 3 outlines considerations that countries should consider with respect to the legislative framework. This includes concepts such as consistency with domestic food legislation and compliance with international agreements, and key principles (e.g. transparency, flexibility) as well as the need for participation by stakeholders. Section 3 also provides some technical options ranging from legislative considerations for establishment of standards; authorities required for pre-border arrangements; border controls; inspections, including third party service providers; collaboration; and information sharing within the imported food controls. The section also includes information on enforcement actions and, where needed, recourse or appeals.

Consistency with international requirements, with domestic requirements, and between national and subnational legislation.

FROM CODEX ALIMENTARIUS

The system should include formal means to communicate decisions. There should be an appeal mechanism and/or opportunity for review of official decisions on consignments

CAC/GL 47-2003

Each country will establish the appropriate competent authorities to develop, implement, monitor and enforce imported food controls, such that imported food meets regulatory requirements. Successful implementation relies on competent authorities and other institutions having clearly defined objectives, mandate, powers and responsibilities, and where there are multiple competent authorities, that they have the appropriate mechanisms for cooperation and information exchange.

Each country will have a unique institutional framework.

Every country will have a unique institutional framework, tailored for its specific situation, not only for implementation of imported food controls, but also for implementation of border and customs, plant, animal health and welfare, and other appropriate requirements. In some cases, having an understanding of all institutions that have some responsibilities with respect to imported food is very useful in clarifying the situation and ensuring there is appropriate collaboration among the various institutions.

Key requirement for collaboration and cooperation between competent authorities and other institutions.

Section 3 outlines considerations with respect to imported food controls for countries with supra or regional, national or subnational competent authorities. It also outlines considerations for collaboration with other institutions (e.g. public health surveillance, custom services, standardization bodies). Where responsibilities are distributed among multiple institutions, it is important to have documented arrangements for collaboration and information sharing with respect to the imported food controls.

Support functions

Effective support functions should be servicing the import control framework and should be integrated.

Although each country will have to take into account its own specificities, there are key functions that countries should consider in the development, implementation or improvement of their imported food controls.

Support functions include central management of programme design and delivery, supported by appropriate scientific support, inspection support, and other support functions including legal, administrative, and human resources support.

Central management

Central management ensures consistency and coherence in the development and implementation of imported food controls.

Central management of imported food controls is essential for delivery of effective controls: it ensures uniformity and coherence of the approach throughout the country. Central management is responsible for determining the most appropriate risk management actions and establishing goals, objectives and priorities. In a national system, central management provides a focus for ongoing information management, administration and human resources.

Central management ensures national consistency in information management, data analysis (e.g. planning and reporting), risk based programme design and implementation and response.

Scientific support

In order to develop and implement risk based imported food controls, countries need access to scientific advice to determine the risks associated with food, identifying the standards, and developing the appropriate sampling strategy and annual sampling plans. Scientific support also means that countries have appropriate access to analytical services.

Risk based imported food controls require access to scientific advice.

Many countries will seek advice from international sources (e.g. Codex Alimentarius, FAO, WHO) to identify risks, establish food standards, and develop sampling strategies and sampling plans.

Access to analytical services is required in order to implement sampling and analysis of imported food, whether in government or private laboratories. Careful consideration as to the most cost effective options for analytical services is required, based on available capacities and level of confidence in the laboratory — which should have adequate quality assurance to ensure accuracy if results. In some cases, countries require that laboratories are accredited to provide official analytical services.

Analytical services are required to support sampling and implement analysis of imported food.

Inspection support

Inspection support is a key requirement for governments to meet their responsibilities for regulatory oversight of the compliance of importers and imported food. The oversight function can be assigned to government officials (e.g. inspectors); third party service providers (e.g. officially recognized organizations) or a combination of both. In addition, the type of inspection support should be adapted to the specific risk management actions included within the imported food controls. For example, where the importing country implements pre-border controls by seeking assurance from the exporting country, this is generally a government-to-government function; however, third party service providers may be used to undertake foreign supplier verification for importers.

Inspection support provides regulatory oversight enhancing the compliance of importers and imported food.

The key consideration is to assess what inspection support is required and the most effective means of delivering that support, taking into consideration legislative authorities, programme elements and available resources.

Other support

While scientific advice and inspection support are critical elements of implementing imported food controls, there are other elements such as legal services support, financial resources, administration and human resources. Each support area will have general considerations that will be similar to those of other food controls (e.g. domestic, export certification). However, they must all be considered in the context of the imported food controls to ensure effective implementation.

Includes legal advice, financial resources, administrative and human resources.

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SECTION 2

IMPORTED FOOD CONTROL FRAMEWORK

> **INTRODUCTION**

> **IMPORTED FOOD CONTROLS**

> **RISK MANAGEMENT ACTIONS**

> SUPPORTING TOOLS AND GUIDANCE 2.1
IMPORTED FOOD, IMPORTER AND EXPORTING COUNTRY PROFILES

> SUPPORTING TOOLS AND GUIDANCE 2.2
RISK CATEGORIZATION

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GOOD IMPORTING PRACTICES

INTRODUCTION

In designing and implementing imported food controls, a country will generally include both programme design (what should be done) and standard operational procedures (how it should be done) that ensure imported food meets the country's regulatory requirements[11].

Imported food controls should be designed, and operated based on a country specific situation.

The imported food controls, planned and implemented along the lines of what is generally called an "imported food control programme or framework", should be designed and operated based on country-specific situations, taking into account potential risks associated with imported foods (e.g. category, origin, processes, consumer use) and controls implemented by the exporting country competent authority(ies), the exporting food business or the importer.

No "one size fits all" solution, but common approaches.

As such, there is no "one size fits all" solution, no minimal specified risk management actions, as the situation in each country will be unique, not only with respect to imported food controls, but also within broader government policy (e.g. food security, international trade policy) that will have to be taken into account.

NOTE

Importing countries often consider adopting in whole or in part imported food controls that have been demonstrated to be effective in another country. While adopting a successful programme is attractive, it is unlikely to be successful unless care is taken to assess its strengths and weaknesses and to adapt the risk management actions to the country specific situation.

Nevertheless, as described in this section, there are common approaches (gathering basic information and using that information to implement risk categorization) which allow a competent authority to select and implement the most appropriate combination of risk management actions resulting in coherent, risk based imported food controls[12].

Imported food controls should be based on the optimal risk management activities for cost effectiveness and efficiency.

The Imported food control framework (see Figure 2) should be based on the optimal combination of risk management actions for effectiveness and efficiency, whether applied pre-border, at the border or in-country. In determining the appropriate combination of risk management actions, the competent authority will need information on importers and the imported food, including on the exporting country. This information can be summed up in profiles. They will also need to assess the risk associated with imported food, taking into account the controls implemented by the competent authority in the exporting country, the exporting food business and the importer. Implementation of imported food controls also needs ongoing communication between exporting and importing countries. Figure 2

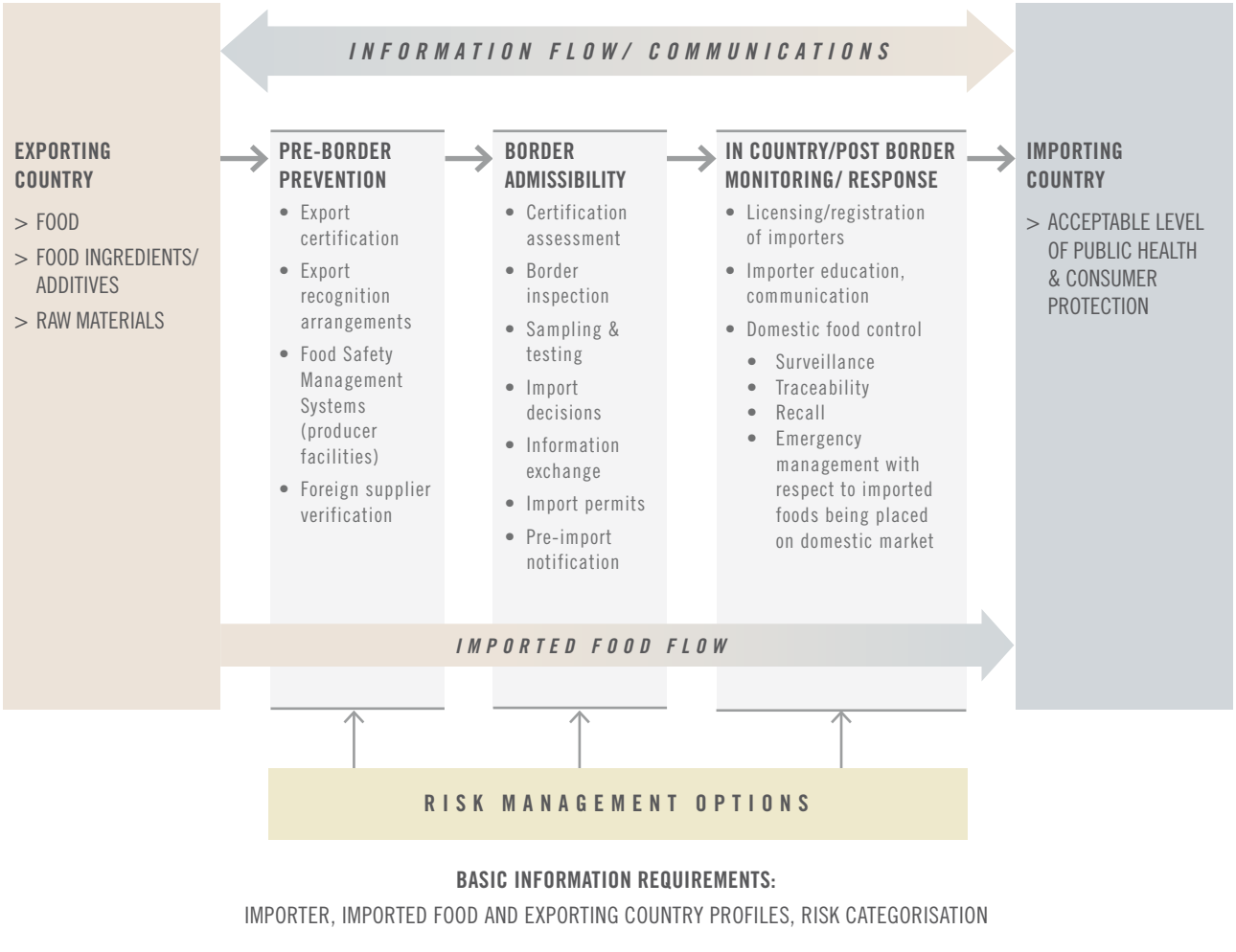
11 While food safety requirements are the primary focus of this section, as it is built around the notion of food safety risks, similar approaches can be considered for other associated requirements.

12 Imported food control means actions taken by, or on behalf of, a competent authority with respect to gathering information, risk analysis or risk characterisation, and risk management actions designed and implemented to assure the safety of imported food.

provides a visual representation outlining the full range of risk management actions that competent authorities may choose as part of their imported food[13] controls.

Further details on the elements of the imported food control framework listed in Figure 2 are outlined in this section. Countries generally select a combination of risk management actions based on the risk associated with a particular commodity and available resources that will provide assurance of acceptable level of public health and consumer protection. Clearly, not all risk management actions are required to be used for all imported foods at all times in all situations.

FIGURE 2 **IMPORTED FOOD CONTROL FRAMEWORK OUTLINING KEY COMPONENTS (E.G. PROFILES, RISK CATEGORIZATION), AND POTENTIAL RISK MANAGEMENT OPTIONS**



13 Food as used in this section generally includes food, food ingredients, food additives and raw materials, as per the definition in Codex Alimentarius.

IMPORTED FOOD CONTROLS

Development and implementation of imported food controls will require that the competent authority has sufficient information with respect to importers and imported food, particularly the potential risks associated with the food, the controls implemented in the exporting country and in the importing country (e.g. importers). This requires clear understanding of the roles and responsibilities of importers, competent authorities and other institutions.

Roles and responsibilities

Development and implementation of imported food controls should take into account the responsibilities of the importers and the competent authority(ies) having oversight of imported food safety:

Importers are responsible to ensure that imported food meets country requirements.

- Importers[14] are responsible for ensuring that imported food meets country requirements, which means they must know the food safety requirements, must communicate those requirements to foreign suppliers, and must take corrective action to prevent marketing of non compliant food.

Competent authorities are responsible for promoting or facilitating compliance, verifying compliance and, where necessary, taking enforcement action.

- Competent authority(ies) are responsible for promoting or facilitating compliance (e.g. communicating import requirements, recognizing foreign countries' food safety systems), verifying compliance (e.g. importers are meeting their responsibilities), and where there is non-compliance, undertaking enforcement actions.
  - Where there are multiple food safety competent authorities, cooperation and collaboration among them is required to reduce overlap and duplication.

The design and implementation of imported food controls should take into account these roles and responsibilities, as well as those of other government institutions, such as customs, plant protection, animal health and welfare. There is further guidance on cooperation among institutions provided in Section 3: Legal and Institutional Frameworks.

Information requirements

Implementing risk based, science based and evidence based imported food controls needs to be based on accessible information for both importers and competent authorities.

The design and implementation of an imported food control system requires that information is readily available to all participants:

- competent authorities need information about the importers, and the imported food in order to be able to develop and operate a risk based imported food programme;
- importers need information about the country requirements in order to import food that meets those requirements.

14 Countries should confirm a consistent definition of the term "importer" within their legal framework. In this manual, it is used to refer to the food business (e.g. consignee, importer of record) that is responsible for sale and distribution of the food within the importing country. It includes importation food and food ingredients for use in further processing.

An effective imported food control system will also provide information to educate importers. The competent authority can facilitate importers' ability to meet their responsibilities by providing easily accessible information on food hygiene, safety standards and other requirements (e.g. inspection processes).

Imported food, importer and exporting country profile

Knowledge and understanding of the country specific importer and imported food profile is a basic requirement. Developing and implementing effective risk management options requires collection and compilation of relevant data on imported food, importer and exporting countries including their associated import controls.

Competent authorities should undertake a systematic review and assessment of the information required, but should focus efforts on the most important information required to determine the most appropriate risk management actions.

During the review, it is normal that information gaps are identified, which emphasizes the need for ongoing collection and assessment of the missing information. It also emphasizes the need to prioritise information gathering, to make the most effective use of limited resources. However, the presence of information gaps should not preclude implementation of risk management actions based on existing evidence.

SUPPORTING TOOLS AND GUIDANCE 2.1 provides further guidance on developing imported food, importer and exporting country profiles, including how these can inform the design of effective imported food controls.

An importer, imported food and exporting country profile may include the following information:

Importer

> Who is responsible for the imported food? (E.g. importer name, consignee or owner, if not the same, and their address, responsible contact.)

> Overall history of compliance.

Imported foods

> What food is being imported? (E.g. product type, description, approximate quantities.)

> Source (e.g. country of origin and supplier; this could include a description of food control in exporting country and manufacturing plant).

> When will it be imported – seasonality (e.g. once a year, during specific seasons, all year round).

> Where (location) and mode/means of importation/transport (e.g. air, sea or land importation, including proposed points of entry).

> Conditions of shipment – is it a direct or indirect import? (E.g. shipped directly from exporting country to importing country, or shipped from exporting country via a third country to importing country; high seas sale.)

Competent authorities need information on who is importing what food from which exporting country.

Exporting country profiles provide evidence of food safety controls in source countries.

Gather only the information on profiles that can be maintained and analysed within the information system.

> Why is food being imported – are they raw ingredients to be processed and re-exported, or processed for domestic sale?

> Compliance history (e.g. product and importer compliance).

Exporting country profile

> What is the evidence of controls in the exporting country[15]?

> Competent authority(ies), roles and responsibilities? Oversight?

> Compliance history of food sourced from that country?

The imported food, importer and exporting country profile should be regularly updated over time as more information becomes available, or where new risks emerge. It is therefore important that the information is maintained in a system that facilitates the competent authority's ability to update and retrieve information quickly and efficiently both at the national level and at individual offices. Access to information at the national level allows the central management to analyse the data as part of planning, programme management and support. Access at the local level will facilitate day-to-day operation of the system, and decisions on what food, or which importer to inspect.

Countries may use computer-based systems, paper-based systems, or a combination of both to manage the information required to develop, maintain and deliver their imported food controls. The use of a paper or a combination of computer- and paper-based system is often the case where countrywide informatics systems are unavailable or unreliable. The key requirement, regardless of the information management system used, is to ensure that there is an adequate information collection and analysis system, and also an efficient information retrieval system.

EXAMPLE

An example of a comprehensive computer- or electronic-based system has been developed by the European Commission using the Trade Control and Expert System (TRACES) and the Rapid Alert System for Feed and Food (RASFF). TRACES allows the production and exchange of certificates related to animals and their products. It keeps all competent authorities informed via automatically triggered notifications. In the case of emergencies, TRACES facilitates the rapid tracing of animal and animal products, allowing rapid reactions. RASFF provides competent authorities in member states a tool to exchange information electronically, helping them to act more rapidly and in a coordinated manner in response to a health threat caused by food or feed. It provides information on border rejections for food and feed consignments that have been tested and rejected at the external borders of the European Union (EU) and the European Economic Area (EEA) when a health risk has been found. The notifications are sent to all EEA border posts in order to reinforce controls, and to ensure that the rejected product does not re-enter the EU through another border post.

15 In addition to the food safety controls, the country profile may also include the animal health status of the country and the status of plant pests as appropriate.

Risk categorization

Insufficient information for a risk assessment, does not preclude implementation of risk based imported food control.

The Codex Alimentarius risk analysis framework[16] should be the basis for developing risk based imported food controls. However, countries frequently have insufficient information for performing a full risk assessment, the scientific pillar of risk analysis. Given the difficulty in completing formal risk assessments for all imported food and hazard combinations, the starting point for developing, implementing and operating an imported food control programme will generally be risk categorization.

Risk categorization can be an acceptable alternative.

Risk categorization is an evidence-based analysis that allows a competent authority to make risk management decisions on a documented basis, using a risk based approach to imported food controls.

SUPPORTING TOOLS AND GUIDANCE 2.2 provides guidance on the development and use of risk categorization within the context of imported food controls. The information collected in the importer and imported food profile is key to the development of the risk categorization process.

Risk categorization can be described as a process that includes:

- First: a focus on risks associated with food products, called product characteristics, which generally takes into account information such as the potential for microbial growth, presence or formation of toxins, and consumer use. Product characteristics generally include the type of food processing used in production.
- Second: consideration of other factors that can reduce or affect product risk, such as controls implemented by the manufacturer, the exporting country or the importer, called control characteristics. Risks related to pesticide or veterinary drugs residues and additives would be taken into account under this step of the process.
- As a result of these two steps, a risk categorization is established. It can be considered as a function of product risk and an inverse function of controls by an exporting country, manufacturer or an importer. In using risk categorization, competent authorities can target resources toward high-risk food imports.

Information from the imported food, importer and exporting country profile should inform the risk categorization programme.

The imported food, importer and exporting country profiles, and the risk categorization are the basic evidence needed to establish the most appropriate and cost-effective risk management actions. Further information is provided below, in Risk management actions.

16 Codex Alimentarius refers to a framework for risk analysis entailing three elements: risk assessment, risk management and risk communication (ref. Codex Procedural Manual, working principles for risk analysis). Countries are generally encouraged to use information available from formal risk assessment performed by international organizations (FAO/WHO risk assessment bodies, like JECFA, JEMRA, JMPR, ad hoc expert consultation), or regional/national agencies, should it be available. Other information may be available from risk profiles prepared by national agencies.

Information exchange/communication

Communication mechanisms should be in place to exchange information about imported food, with exporting countries, other competent authorities and importers.

Information and communication about imported food products is part of developing and implementing imported food controls. In addition to information exchange with exporting countries, competent authorities may also have ongoing information exchange with other domestic competent authorities and institutions and with international organizations (e.g. FAO/WHO INFOSAN, which provide an important platform for rapidly exchanging information in cases of food safety crises, and for sharing data on routine and emerging food safety issues). This exchange of information should not only take place in situations such as rejections, or food safety emergencies[17], but also in "routine" situations. Communication mechanisms should be in place for importing countries to seek more information, for example about a product or producer, as appropriate.

Information exchange and communication is becoming more important as the food systems of countries are increasingly linked at all levels, from trade in raw materials to packaged and processed products. However, implementation of risk based imported food controls, including the mechanism for sharing information, should not impose an unnecessary burden on competent authorities in trading nations, or result in inappropriate trade restrictions.

Where food is imported from a significant number of countries, it is normal to have differences in the level and extent of collaboration and communication, in that it is generally much greater and more frequent where there is significant food trade.

Within a country, where there are multiple competent authorities (e.g. at the national and subnational level), the multidimensional nature of food safety controls will require a high level of communication and information exchange to ensure there are no gaps, and to reduce overlap and duplication.

In both international and national collaboration, establishing and maintaining key contacts (e.g. names, official titles, addresses, telephone numbers, fax numbers, emails) and written processes for the exchange of information is very important.

Where there are limited resources to maintain key contacts, competent authorities should consider using Codex contact points or INFOSAN emergency lists as contacts. Other options may include designating embassy personnel or a contact point office (i.e. not an individual) within the competent authority.

SUPPORTING TOOLS AND GUIDANCE 2.3 provides further guidance with respect to developing formal arrangements.

17 See Codex texts: Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations (CAC/GL 19-1995) and Guidelines For the Exchange of Information Between Countries on Rejections of Imported Food (CAC/GL 25-1997).

RISK MANAGEMENT ACTIONS

The importing country will not have access to information on the entire food chain of grower, processor, exporter, importer and retailer, so the regulatory controls for imported food will differ from those needed for a domestic food safety programme. The objective, however, remains the same – to reduce the risks posed by imported foods and increase the rate of compliance with importing country requirements. Regulatory oversight and risk management actions by the importing country are likely to vary, with more stringent measures applied to exports from countries with evidence of less comprehensive food safety controls.

Objectives of reducing risk and increasing compliance of imported food.

Risk management actions are often characterized (see Figure 2) as operating:

1. Pre-border, i.e. generally designed to manage risks associated with foods prior to importation, and provide oversight of imported food prior to importation, by competent authorities in the exporting country and/or by the importer.
2. Border, i.e. generally designed for programme oversight, verification that import controls are working and making admissibility decisions, exercised as the food arrives at point of entry, or another appropriate location (e.g. bonded warehouse).
3. Post-border, often called in-country controls, i.e. which generally assess importer controls or monitor imported food after it has been released to commerce. These connect the imported food controls with the domestic food controls (not covered in this manual) and provide for an integrated response should issues with imported food be identified.

Risk based imported food controls can be implemented pre-border, at the border or post-border/in-country.

In implementing risk management actions, countries should consider:

> the cost of measures as proportionate to the risk, as cost impacts the government, imported food industry, and consumers; and,

> the need to avoid using imported food controls as discriminatory or trade restrictive practices.

Risk management actions are facilitated by importers and exporting countries having access to information on import requirements (e.g. written documentation). This level of transparency and access to import requirements allows importers to provide information to their suppliers, and it facilitates access by the competent authorities in exporting countries.

Pre-border controls

The objective of pre-border controls is to seek assurance that controls in an exporting country (e.g. food production, processing and export) will result in safer food. Most importing countries will seek this assurance from a competent authority in the exporting country. However, there are other options, including requiring importers to provide assurance, or possibly working with accredited third parties.

Assurance of food controls in exporting country.

NOTE

Pre-border controls are not a "guarantee" of food safety, as no system can be considered 100 percent risk free. There are also risks associated with handling and transport "post export" that can compromise food products.

Competent authorities should use the information from the imported food, importer and exporting country profile in determining whether pre–border controls may be appropriate, and for which foods.

Assurance from exporting country competent authority

Assurance from the competent authority in the exporting country is the most common pre-border control. This assurance allows the importing country to use the food control system in the exporting country to its advantage, including reducing the level of, and resources required for, border or in-country controls.

NOTE

Considerations for success with pre-border controls
> Knowledge of importers and what they import
> Knowledge and understanding of the food control system in exporting countries.
> Effective border controls

Assurance of the food controls in exporting country for high-risk foods.

Assurance is of particular importance for high-risk foods, where the only means of controlling hazards is through regulation and oversight during primary production, harvesting and processing. The competent authority in the exporting country provides assurance that food is produced to meet the importing country requirements. Information exchange and communication maintain confidence that controls are being properly maintained and implemented in the exporting country.

EXAMPLE

For example, the EU has identified the key standards to be met by an exporting competent authority. The exporting competent authority has to demonstrate its ability to meet these standards, in order to provide assurance. The EU has established the Food and Veterinary Office, which is responsible for auditing and providing advice on the capacity of the competent authorities in the exporting country. Under such a system, importing competent authorities would generally not require import permits or licences.

Assurance expressed in formal arrangements.

Generally, countries that provide assurances of food safety and quality to trading partners express that assurance in formal arrangements between partners. Codex Alimentarius[18] has established guidance and considerations for establishing arrangements. They range from:

18 Guidelines For The Development Of Equivalence Agreements Regarding Food Import And Export Inspection And Certification Systems (CAC/GL 34-1999) and Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (CAC/GL 53-2003).

- arrangements that set out cooperative exchange of expertise and information, and that identify contacts and processes, so that competent authorities in the exporting and importing countries can communicate with each other about food safety and quality inspection results;
- arrangements that identify specific processes to reduce or eliminate the need for duplicate controls in the importing country (e.g. inspection or laboratory analysis) based on the exporting country's certification; or
- arrangements based on recognition by the importing country of the competent authorities in the exporting country and their ability to provide assurances that exported food has been produced under acceptable conditions.

It is likely that in some cases, trading partners may first seek closer collaboration and information exchange that will assist in developing bilateral and/or multilateral relations. These relations, and the mutual assistance that can arise from them, are building blocks for future recognition of assurance in the controls of the exporting country. As noted earlier, SUPPORTING TOOLS AND GUIDANCE 2.3 provides further guidance with respect to developing formal arrangements.

When should they be considered?

While an arrangement of bilateral relations between exporting and importing countries will facilitate trade and imported food controls, it will require time and resources from both the exporting and importing country. This is especially true with respect to preparing and reviewing the necessary documentation, carrying out in-country assessments or audits, and negotiation of the formal arrangement.

The following outlines some considerations for determining if it is cost-effective to invest time and resources in establishing pre-border controls. Risk categorization can be used to establish priorities for developing arrangements.

- The volume of imports from a country. In many cases it is cost prohibitive for both countries to undertake a formal agreement without having significant existing or potential trade.
- The risk categories of the food from a country. Priority should be given to high-risk foods where the hazards are best controlled in the exporting country.
- The exporting country profile, including its food control system as demonstrated by compliance history of food, existence of arrangements with other countries and available third party audits.
- The number of competent authorities in the exporting country. The existence of multiple competent authorities can make assessments more complex and difficult to complete.

Need to prioritise the development of arrangements, as it requires time and resource from exporting and importing country.

Bilateral vs. multilateral approaches

Bilateral arrangements (i.e. between an exporting and importing country) are of particular value where there is significant trade between the two. However, where there is significant regional cooperation, multilateral arrangements (i.e. between

Where there is significant multi-country trade, consider multilateral arrangements.

three or more countries) should be considered. Although they are more complex to negotiate because of the variation in food safety systems, the development of multilateral arrangements should reduce resource outputs in the long run. Once in place, partners can rely on compliance results from multiple imported food control programmes, and will be able to collaborate on assessments of exporting country systems.

Third party verification

Use of third parties to provide assurance of food compliance is becoming of increasing interest to large retailers and importers in order to fulfil their responsibilities that the food they import meets regulatory requirements. Retailers and importers have an interest in seeking assurance that imported food meets country requirements, as there can be significant costs associated with non-compliance. For example, third party service providers can inspect, audit and sample product lots, or otherwise provide information on foreign processors' food safety controls.

If third parties are being used within other imported food controls, (e.g. retailers, customs service) assess their use for food safety import controls.

Some countries have contractual agreements for third party service providers to systematically check all lots prior to shipment, as a complement (and sometimes substitute) to border controls. Others countries may use third party service providers as border officials (e.g. product inspection designed to collect taxes or fees).

In such cases, competent authorities may consider whether, and how, the use of third party service providers could also be used to deliver imported food controls as part of government controls, or as part of importer requirements.

Where service providers are incorporated into pre-border imported food controls, it is important to consider accreditation, assessing the service provider against objective criteria and compliance with standards, in particular with respect to competence, independence and impartiality. There should be regular assessment of the performance of these service providers.

In addition, the costs associated with the use of third parties need to be carefully evaluated to ensure that they are the most effective use of resources to deliver food safety.

Controls performed by importers

Importers' responsibility can include foreign supplier verification.

Pre-border controls can include a requirement that food importers assess their suppliers and the imported food, (e.g. implement foreign supplier verification; food safety management plans) in order to assure food safety.

Requiring the importers to exercise controls can be implemented as a primary pre-border control, or as a complement to government controls. Because controls will increase the cost of imported food, and may prevent some companies from importing food, the most stringent controls should be targeted at the highest risk foods. Key requirements can include:

- Importers maintaining a list of suppliers and their contact information:
  - Each supplier's company name, address, phone numbers, email address, contact person and products supplied, including consolidators and distributers, if appropriate.

- Options by which importers determine the appropriateness of a supplier such as:
  - Establishment of contracts, purchase agreements or other specification consistent with food safety requirements.
  - Requiring documented details of the supplier's food safety systems (e.g. Hazard Analysis Critical Control Point (HACCP) controls), foreign supplier verification or food safety programmes.
  - Seeking assurance that the supplier is operating legally within a foreign food safety system.
  - Verification and/or certification that the products originate from the supplier, under the stated processes, by a competent authority or other appropriate third party body.
  - Audits of foreign suppliers' premises, processes and food safety systems by a technically competent person employed by the importer.
  - Sampling and testing or increased product controls, such as sampling, laboratory testing, third party review, etc.

Verification can include import requirements in purchase contracts, document verification, audits, or sampling and testing.

Recognition of pre-border controls

If the imported food control programme includes pre-border controls as described above, the importing country will need a mechanism to identify foods which have been subject to those controls when they are presented at the border. This is generally managed through certification, provided by either the exporting country's competent authority or by a recognized/authorized third party.

There are a number of tools that can be used for official certification, particularly under arrangements with exporting countries, such as:

- Identification of processing plants that the exporting country certifies as meeting its requirements (often identified as plants in good regulatory standing).
- Using export certificates for a specific product lot or multiple lots from a specific plant, generally reserved for high-risk foods.
- Export certificates for one or multiple food lots may be paper-based or electronic. The form and format are generally negotiated between exporting and importing countries, consistent with Codex guidance.[19]

Mechanism of recognition can be included in arrangements with lot-by-lot certification reserved for high-risk foods.

Border controls

Border controls provide an importing country with the opportunity for oversight, monitoring and verification of imported food, and the controls in both the exporting and importing countries. They are fundamentally about determining product admissibility. Border controls, particularly product inspection, can be used to verify the efficacy of other controls (e.g. pre-border controls by importers, third parties

Provide an opportunity for oversight, monitoring and verification of imported food and the controls implemented by exporting country and importers.

19 Ref. CAC/GL 38-2001.

or other governments). In undertaking border controls, the competent authority and its agents should have clear legal authorities for their actions.

NOTE

> Considerations for success with border controls
> Importers with significant import controls
> Presence of strong border controls
> Inspector and laboratory capacity

Border controls measures may include:

> prohibiting or limiting entry for particular categories of food;
> mandatory pre-notification and/or notification of imported food consignments or lots;
> preclearance processes, particularly for perishable foods;
> document checks to validate imports, including confirmation of product identity and validation of certification;
> inspection of imported food, and condition of transport, which may include sampling and analysis of the food; and
> refusal of entry or destruction of unacceptable imports.

May include document and identity checks, inspections, sampling and analysis.

The competent authority should use the information from the importer, imported food profile and risk categorization (see SUPPORTING TOOLS AND GUIDANCE 2.1 and 2.2) in establishing border controls, including the level of oversight. This information will assist in determining the nature and frequency of inspection at the border or point of import control.

Regulatory requirements and border control procedures should be readily available to importers and exporters, as transparency will enhance compliance. This information should clearly identify prohibited food, requirements with respect to documentation (e.g. manifests, bills of lading, certificates) and whether pre-notification and/or notification is required for every lot of food, or for a container carrying multiple food lots.

Regardless of the documentation requirements, risk based food safety inspection, sampling, analysis and associated decisions, must be based on individual imported lots, as defined in legislation, and not on contents of shipping containers.

Admissibility based on clear decision flow from notification to final decision on admissibility of an imported food lot.

It should be noted that, for a particular food hazard where there are little or no mitigation measures available or implementable in practice, countries might choose to prohibit any importation of a suspect food. This is often the case with foods that may contain prohibited compounds (e.g. veterinary drugs).

Determining admissibility of imported food at the border involves a series of steps, which require a clear decision flow from notification of imported food at the border to a final decision. It involves recognition and decisions based on control

steps that are applied pre-border (e.g. assessment of foreign food control systems) or post-border (e.g. importer licensing). It also includes inspections, which may include procedures such as:

> Document review of certificates and other import documentation for relevance, accuracy and validity.

> Checking the general condition of the entire shipment (e.g. if the product is frozen, does the container show water stains that may indicate defrosting? Do the cartons show staining, that may indicate leaking or water damage?).

> Inspecting and cross referencing the food in a shipment to validate the accuracy of the accompanying documentation, often called identity checks.

> Sensory evaluation of a product.

> Sampling (random) based on a sampling plan – including lab analysis.

> Mandatory lot-by-lot inspection with testing, which should be reserved for foods with the highest risk.

Uniformity of inspection and decisions is important for imported food controls. Credibility of the programme may be at risk if there appear to be discrepancies in its operation between ports and/or modes of entry, inspection staff. Programme design and SOPs are important to ensure consistency. Timely decisions are also important, and operations should be developed to minimize undue delays at the point or points of entry.

Uniformity of inspection and decisions on imported food enhance credibility and confidence in the imported food controls.

However, operating procedures should also take into account the experience of imported food control officials. Where officials notice potential issues of non-compliance at time of import, they should be able to implement appropriate border risk management actions.

A description of how these approaches can be used is further described in the process set out below.

Pre-notification or notification of imported food

> In order to have efficient and effective border controls, every consignment of imported food should be formally pre-notified or notified, that is information on the food must be provided for review. Pre-notification of imports is preferable, where individual food shipments are assessed to identify high-risk lots that may be the subject of inspection, and to recommend refusal for unacceptable shipments.

Information on every lot of imported food should be provided to the competent authority.

> Notification by importer is appropriate, either on arrival or within 48 hours of importation, where food products are detained for inspection at the importer's designated storage facility, or for low risk products that are generally assessed during the in-country controls (i.e. after they have been released to commerce).

Border controls require significant information about how imported foods are reviewed by food safety officials. Efficiency of the information review is enhanced

by consistent documentation (e.g. certificates), so countries are encouraged to develop standard documentation, based as far as possible upon Codex guidance[20].

Border controls require that accurate information is provided for each shipment, container or lot such as:

Border controls require accurate information is provided on every lot of imported food.

> a description of the product;
> the quantity;
> the producer;
> the country of origin, including whether the food was transhipped through a third country, or was redirected following sale while in transit;
> the location where the food will be held or stored on its entry into the country;
> the name, address and telephone number of the importer as declared to the border services;
> the importer's licence number, where it is a mandatory requirement; and where applicable, the name, address and telephone number of the importer's agent (e.g broker) providing the notification.

Specific procedures may be required for exported food shipped from one country to another country via a third country.

Imported food transhipped through a third country

While many food shipments are produced in one country to be exported to a specific destination (importing country), this is not always the case. Countries with smaller markets may not have sufficient volume of trade to warrant direct shipments, or an importer located in one country may import food and then re-export it to neighbouring countries.

Transit

Food destined for one country may transit through another country (e.g. product destined for Russia may transit through an EU member state) in bond, thus without entering the EU. The country of transit may establish specific requirements including a transit certificate. As the food is not imported and not offered for sale in the transit country, the requirements and the certification are often related to animal health or plant protection requirements.

Transhipment

Food may be transhipped, that is: imported legally into one country, stored in that country and then shipped to, and imported into, a third country. Under transhipment, the food is stored under appropriate conditions, and no processing occurs.

Consolidated shipments

Food may be imported into one country by a consolidator, often from multiple sources, with the stated intent of re-exporting to a third country, once they have

20 Guidelines for Design, Production, Issuance and Use of Generic Official Certificates (CAC/GL 38-2001).

sufficient volume (e.g. products, types, quantity) to fill an importer's order in a third country.

Details of such shipments should be provided to import controls officials in advance of importation, outlining whether the product has simply transited through a third country, been transhipped or is part of a consolidated shipment. The importer should be able to identify the origin of the product, information on shipment (e.g. transport) and storage conditions. The importer should also be able to provide information on the procedures taken to ensure the products are in compliance with the importing country's requirements.

A country with many transit, transhipped or consolidated food shipments[21] due to its location, trade patterns, market size, or importers that serve multiple countries, should establish specific requirements for such food — such as risk management, enhanced importer requirements (e.g. foreign supplier verifications), or enhanced border inspections. In the case of transhipped or consolidated shipments, assurance from the exporting country will generally be limited to storage and transport conditions. These requirements should include what confirmation or certification is warranted from the country of origin (e.g. processing conditions). In some cases, problems can occur because the transhipped product may not have been produced specifically to meet the importing country requirements, especially when imports are distributed to a number of countries.

Document review

Once notification is received, the next step is to review the documentation (see **SUPPORTING TOOLS AND GUIDANCE 2.4**). It is the importer's responsibility to provide clear, accurate and legible documents.

Importer is responsible for providing clear, accurate and legible documents.

NOTE

Official documents may include:

> Purchase orders, including required specifications.
> Bills of lading, manifests.
> Import permit, licence or other required documents that authorize importations.
> Official Certificates, if required.

Food safety officials should review the official documentation provided by the importer, and, if that documentation is not complete, advise the importer. Imported lots without appropriate official documentation may be held pending input from the importer, or may be deemed an illegal import and refused entry.

Only officially requested documents will be reviewed; imported food without appropriate documentation may be refused entry.

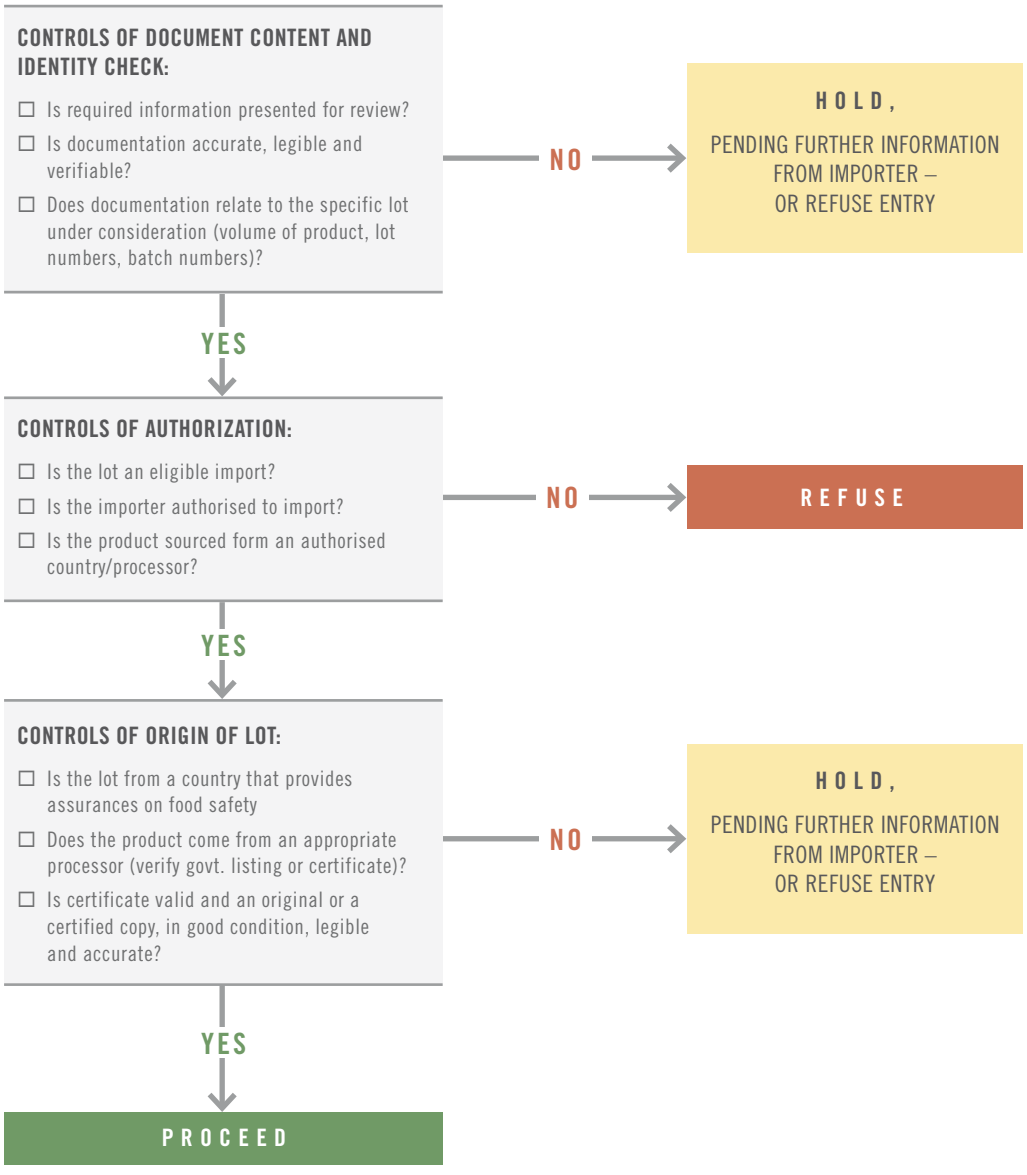
The importer should be given clear guidelines for providing any missing, relevant documentation (e.g. timelines) with statements that "ad-hoc" information will not be considered, so that a final decision on the admissibility of the lot can be made

21 Transit, transhipment or consolidated food lots are not the same as the return of rejected products. Any return of rejected product has to meet the pre-established legal requirements on returns.

in a timely fashion. This means that a lot may be rejected or refused entry (e.g. returned to exporting country) if appropriate documentation is not provided within a specified timeframe.

Figure 3 provides an example of a systematic approach to document review and lot validation. A number of key considerations and logic steps are outlined in Figure 3, starting with basic, easy to answer questions about document quality

FIGURE 3 **DOCUMENT REVIEW – SYSTEMATIC APPROACH**



and content, followed by questions that may require officials to verify official information (e.g. approved processers). Further details are provided in **SUPPORTING TOOLS AND GUIDANCE 2.4** (validation of documentation). Often the document review is completed prior to import or while the lot is still located in the port of entry. However, once further action is considered, the importer might be directed to move a lot under detention to a specified location (e.g. bonded warehouse) to undergo inspection.

Document review is a consistent step-by-step approach to assessing the completeness and validity of the official documents provided by the importer.

Decision to inspect or not

Upon completion of the document review, a decision on whether the lot should be inspected must be made. Decisions to inspect are generally based on risk categorization and criteria relating to compliance of the product with importing country requirements. Clearly establishing the criteria for when lots will be inspected and consistency in inspection delivery will reduce importers' concerns and frustration. The inspections may be carried out by the competent authority or an accredited service provider where authorized by legislation. Decisions to inspect should not be arbitrary but based on a structured decision making process and the intensity, type and frequency of inspection should be documented.

Inspection of imported food is generally based on risk categorization and compliance history.

Decisions on intensity, type and frequency of inspections should be documented as part of the imported food controls.

Generally, imported food controls include requirements for product inspection:

> where there is little or no history of the product or source;

> if there is previously known non-compliance;

> to validate the accuracy of documentation; or

> to monitor the imported product according to a pre-established sampling plan.

Another key consideration is having the appropriate location for all physical inspection. It is important that the imported food control officials have full access to inspect an imported lot, which for container shipments means "destuffing", also called unloading, or turning out the container. If destuffing cannot be accomplished at the border, then consideration should be given to establishing import warehouses, (i.e. designated sites) where inspections can take place. Physical inspection without access to the imported food can result in illegal imports being hidden within containers that are inaccessible to food inspectors and customs officials.

Containers must be destuffed or unloaded to provide officials with full access to inspect imported food lot(s).

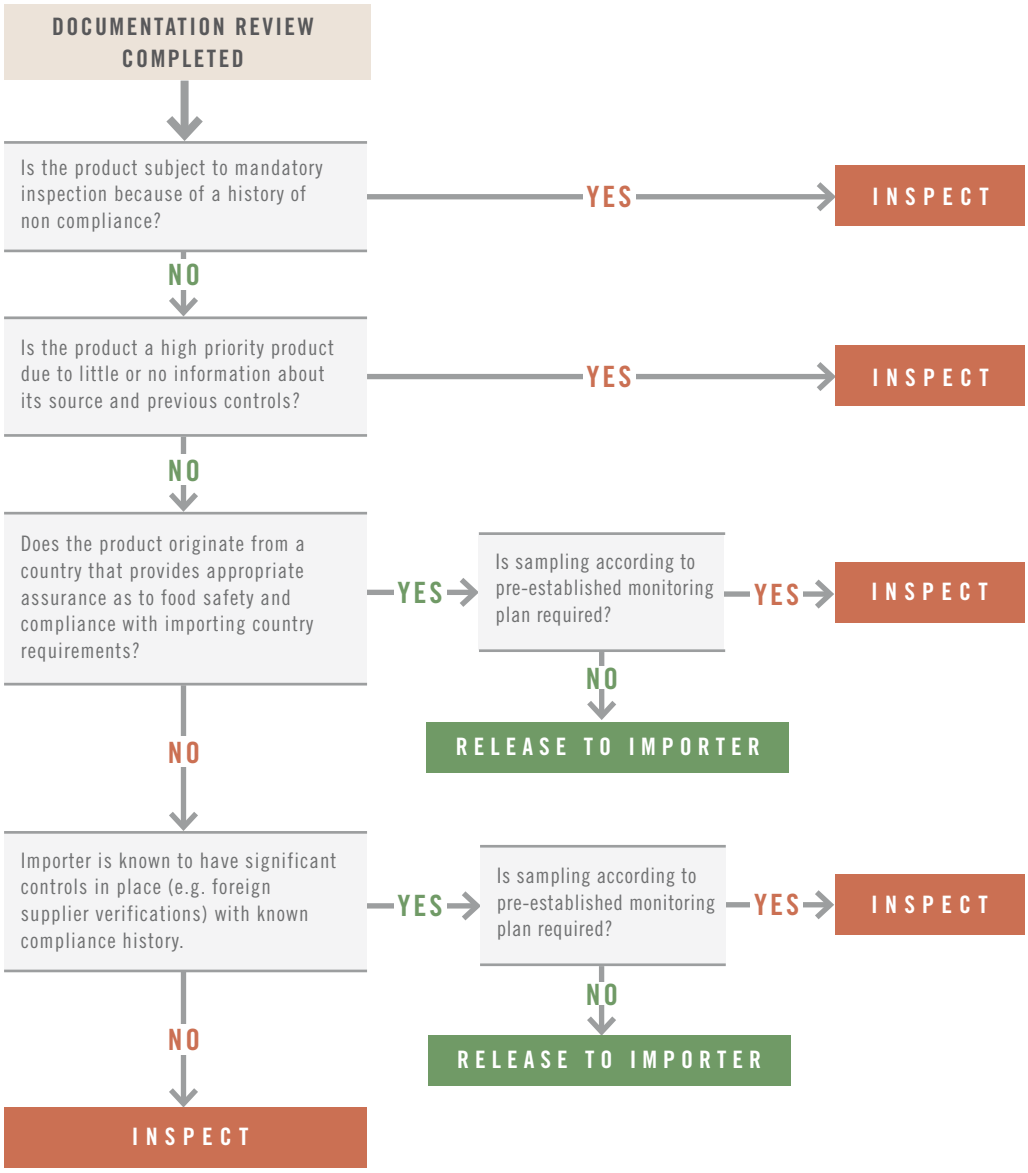
In such cases, the admissibility decision may require a two-step process:

1. customs review (e.g. duty, tariffs, document review); and
2. food safety and quality admissibility decision

with clearance being given only after both steps have been satisfactorily completed.

Figure 4 (see following page) summarizes the main steps leading to the decision to inspect or release.

FIGURE 4 DECISION TREE TO SUPPORT CHOICE OF INSPECTION



Inspection requirements

If inspection is warranted under the importing country controls, then this decision should be communicated to the importer.

> The lot may be given conditional release and moved to another facility to ensure appropriate storage conditions during the inspection processes (e.g. bonded warehouse; importer's warehouse).

> In the majority of cases, the lot will be detained at the storage facilities until the inspection results are known.

The nature and frequency of the inspection, sampling and testing of imported food should be risk based and clearly documented (e.g. an annual inspection, sampling and testing plan). The frequency of inspection and sampling may be increased for products from sources for which compliance is either unknown or there is a history of poor compliance. In some cases, every lot (i.e. 100 percent) may be subject to inspection or sampling until they are found to be compliant. Alternatively, food with poor compliance history may be held, until the importer provides evidence that the food complies with country requirements.

Competent authority should have a written inspection and sampling plan that identifies inspection and sample requirements (e.g., numbers, tests).

The competent authority should develop a written inspection and sampling plan identifying required inspection and/or analysis, numbers and procedures. There should be clear communication as to who will be responsible for sampling (e.g. government inspectors, third party service providers, importer, accredited laboratories), which tests are required and how the results are to be communicated.

Sampling should be based on acceptable international guidance (e.g., Codex, ICMFS, ISO, AOAC).

NOTE

Sampling should be based on guidance set out in Codex General guidelines on sampling (CAC/GL 50-2004) that achieves the importing country's food safety objective, or other internationally accepted sampling plan (e.g. International Commission on Microbiological Specifications for Foods (ICMFS), International Organization for Standardization (ISO), Association of Analytical Chemists (AOAC)). In addition, internationally validated standard methods of analysis or methods validated through international protocols should be used in testing the food. Codex Recommended Methods of Analysis and Sampling (CODEX STAN 234-1999) provides guidance on such methods.

Once the inspection and sampling results are known, a decision on the food lot can be made.

Decisions on admissibility should be made in a timely manner.

> If the imported food meets importing country requirements, it can be released.

> If the product does not meet the requirements and it is still under detention, then that detention should be maintained.

> If the product does not meet the requirements and the results are only known after the product has entered the country and has been distributed, then a product recall or other appropriate risk management action should be initiated, based on the risk associated with the food.

Results of inspection and, where used, laboratory analysis should be carefully considered in making decisions on the acceptance or rejections of lots or consignments. Decision making rules should be clearly established and available to all importers, and include formal communication of results and opportunity for appeal.

Administrative appeals

The competent authority should provide a clear and transparent process for administrative appeals including, where available, options for use or disposal of the non-compliant consignment. Further guidance on appeals is provided in Section 3 "Legal and Institutional Frameworks".

The competent authority should establish a clear and transparent process for administrative appeals.

The administrative appeal:

> Provides importers with an opportunity to discuss the decision with officials and, possibly, to provide further information to clarify the situation.

> Outlines criteria on what evidence the competent authority will or will not consider. For example, where the analytical results demonstrate the presence of pathogens or toxic substances, presentation of a subsequent analysis does not negate the first result, given the non–homogenous distribution of such substances.

> Provides timeframes for appeals.

Decisions regarding non compliant products

Once an imported product has been determined to be in violation of the importing country's requirements, the importer should be advised. In addition, information on the rejected lot should be provided to the exporting country[22]. Such information should be consistent with guidance provided by Codex, unless the importing and exporting countries have established specific requirements (e.g. as part of their arrangement).

In addition, the competent authority should assess whether the information should be reported under other international arrangements (e.g. INFOSAN, International Health Regulations (IHR)).

With respect to the non-compliant product, there are options available, depending on the nature of the violation. The competent authority should, in communicating with the importer, outline the conditions for storage of the lot (e.g. bonded storage) and the time limitations for a decision.

Non-compliant product decisions may include bringing the product into compliance, returning the product to the foreign supplier, re-exporting the product, or the product may be destroyed.

Options include:

1. Bringing the product into compliance if possible (e.g. where the violation is associated with labelling infractions, and can be mitigated through relabeling). Another possibility is to designate the product as animal feed, based on the risk of transmission to animals and the level of product control during storage and distribution.
2. If no mitigating process is possible, the importer may seek to:
   a. return product to supplier, particularly where the product remains the property of the exporter/supplier; or
   b. seek to re-export (where appropriate) the product. If the product is re-exported, consideration should be given to informing trading partners about the inspection decision.
3. Where there are serious health risks[23], a decision to require the lot to be destroyed should be considered.

22 Guidelines for the Exchange of Information between Countries on Rejection of Imported Food (CAC/GL25-1997).

23 Code of ethics for international trade in food (CAC/RCP 20-1979).

Returning a rejected lot to the supplier will be conditional on meeting legal requirements. For example, many countries require re-export certificates from the competent authority seeking to return a rejected meat product to the country of origin.

Where a decision is made to dispose of the food, it should proceed with minimum delay. During disposal, consideration should be given to:

> Ensuring food is destroyed to inactivate any pathogens, and render the product inedible, thus minimizing the potential for diversion or theft.

> Safeguarding the workers against hazards (e.g. handling decomposing foods).

> Minimizing environmental concerns including risks posed to wildlife.

A strategy for disposal of imported food should be prepared as part of imported food controls. Issues that need to be addressed include the options for a wide variety of food (e.g. volume, potential contamination) and to address environmental concerns during disposal. Developing a coherent strategy will require cooperation between the import food control officers and other relevant government bodies, particularly with respect to determining the method and location of disposal, and the necessary equipment and facilities. This generally requires consultation with other authorities, including national and local governments responsible for environmental protection, as appropriate. It may also require consultation with other neighbouring countries, should disposal occur near their border. Consideration should also be given to resources required, and whether the costs should be borne by the importer.

Should non-compliant products be destroyed, they should be rendered in-edible and disposal should be consistent with government policies on environmental protection and worker safety.

Follow up to product rejections

It is important that the information pertaining to non-compliance is entered into the information system of the import control programme, to inform future admissibility decisions.

On being advised of the rejection, the competent authority in the exporting country should take the appropriate corrective action to ensure compliance. This is especially important in the case of microbial or chemical contamination that can only be addressed at source.

The competent authority in the importing country may also implement enhanced controls for future lots. Where a lot fails inspection, it may result in subsequent lots from the same supplier being held for lot-by-lot analysis, or enhanced sampling and testing. It could also result in requests for information from the competent authority in the exporting country. Should the rejection of product indicate a more systematic problem, increased intensity and frequency of checks may also be extended to other suppliers from the same country/region.

The importer should also enhance controls for future import shipments from that source. These could include increased intensity or frequency of checks, requests for information and cooperation by supplier, or on-site visits to exporting facilities.

Labelling requirements (e.g. language, common names, ingredients, sizes, descriptions or claims) are often associated with significant non-compliance for

Product rejection should be included in the information management system to inform future decision on risk management.

Information should also be provided to exporting country and to the importer.

Where mislabelling is the reason for a significant number of rejections, requiring pre-approval of labels may reduce the rejections.

imported products. Because of the frequency of such issues, pre-import label approval may assist in reducing non-compliance. Pre-approval requires the exporter or importer of the food to submit the label of an imported food to the competent authority in the importing country prior to import to determine if the label meets all requirements. However, any requirement to pre-approve labels will need to be carefully managed to prevent this being a non-tariff barrier, and to minimize officials being considered as industry consultants. Consideration should be given to having a third party review the labels, or charging a fee to ensure cost recovery of the label review or to cost recovering the label review. Critical to the success of any pre-import label review is the development and publication of clear requirements.

Imported food controls may also include risk management actions taken within the importing country.

Post-border/in-country controls

Control of imported food may also include activities that take place within the importing country. For example, any control of the importer (e.g. assessment of their system to ensure the safety of imported food, the appropriateness of their warehouses, the transportation means etc.) pertains to this category. However, this can also include actual controls over specific imported food products, either still in the importer's warehouses or already placed on the domestic market.

Profiling importers

Understanding who is importing food is a key component of in-country imported food controls.

Understanding the importer's profile is the basis to understanding what control measure should be implemented, as outlined below. This ranges from basic knowledge (i.e. who is importing) to requiring permits or licences with or without conditions:

Importer profiles should be designed to gather information that can be maintained and analysed within the information management system.

1. Basic identification of importers: company name, physical address, contact information (email, phone, manager), where imported food is to be stored (if different from address).
2. Establishing minimum importer requirements: such as meeting GIP.
3. Requiring import permits for high-risk foods: requirement for all importers to apply for a permit and abide by the conditions of that permit.
4. Limiting imports to licensed importers: no importation without a licence; establishing requirements for maintaining a licence and a process for revoking the licence.

In determining which of the above control measures is most appropriate, the performance of the control system and the capacity of the importers need to be taken into consideration. Changes and improvements to the system can be made over time, as information becomes available, and as part of continual improvement to imported food controls. As improvements are introduced, importers should be provided with appropriate time to ensure their import procedures meet any new requirements.

For example, for a control system that is paper-based, with limited ability to maintain and use information, basic information on imports and importers may

be the only information collected. As the performance of the system evolves over time, (e.g. introduction of electronic files, databases) the ability to gather, maintain and use information will also evolve.

A key part of post-border controls is often gathering and maintaining a list of importers. This information is a foundational part of designing a risk based system. Once a list of importers is developed, it can be used to:

- collect data to design and maintain the risk based system;
- educate importers about food: that it is not just "a commodity", and identify the country requirements that must be met;
- communicate on an ongoing basis with known importers (e.g. informing them of problems in an exporting country);
- create an oversight programme that can be used to verify that importers are meeting country requirements.

The importers and imported food profile should be analysed to determine the most appropriate controls, such as:

- Requiring that importers have appropriate storage conditions and sanitation.
- Requiring that documents and information on imported food are maintained and made available for review.
- Requiring import permits for high-risk products, whereby importers have to apply to the competent authority when they are considering importing a high-risk food. This allows the competent authority to discuss critical issues with the importer including the hazards associated with the food, the need to store and maintain the food on arrival to maintain safety, and possibly set conditions.
- Licensing importers, so that only licensed importers are authorized to import food. The licence could include various conditions such as GIP, foreign buyer verification.

Profile should be used to determine the most appropriate importer controls within the in-country risk management actions.

Where importer requirements (e.g. licence conditions) are in place, there is also the need to assess importer compliance. The frequency and the intensity of the importer assessment will generally be based on the risk associated with the imported food and the importer's compliance. This can include:

- Reviewing compliance history of all imported food for one importer. If this review demonstrates a lack of imported food compliance, enhanced oversight may be required such as:
  - an assessment of the importer's practices to determine if import practices are appropriate, or if there is a need for more clarification or education;
  - enhanced frequency and intensity of imported food inspections until compliance improves; or
  - suspension or revocation of an import licence or permit.

> Reviewing importer practices for adherence to GIP (see SUPPORTING TOOLS AND GUIDANCE 2.5) such as:
  > procedures used to ensure exporter's ability to ensure food is in compliance with importing country requirements;
  > inspection of warehouses used for food storage, documentation review (e.g. food specifications, data on source of imports, documentation on complaints and ability to recall);
  > development of a risk based inspection frequency for importers, as most programmes will have limited resources to inspect importer premises and controls;
  > (in some instances) integration of the inspection of the warehouse as part of domestic food safety inspections, particularly where importers use public warehouses, as this may be more cost efficient.

In-country control of imported food

Post-border controls can include information gathering, importer education, inspection of importers' processes and procedures, sampling of imported food.

Post-border (in-country) monitoring can include sampling product at an importer's warehouse to assess the importer's controls. It can also include surveillance and monitoring of low-risk imported product that has been distributed to the marketplace.

Monitoring of certain foods can therefore be incorporated into controls carried out in the importing country as part of domestic food control; this allows the border activity to focus on higher risk categories, but still maintain oversight of these commodities.

In-country controls are often similar to those of domestic food controls and consideration should be given to the most effective delivering mechanism, including by other competent authorities.

Many of the components of the in-country imported food control programme are similar to those required for controls of domestically produced foods. These may include sampling and testing of imported product released to commerce; communicating with, and education of, importers, including manufacturers that use imported ingredients; inspecting or auditing importer controls; and responding to non-compliance (e.g. recalls) of imported foods.

These post-border controls can, depending on the administrative set up and institutions specific to each country, be performed by a unit which is not actually working under the imported food control services (e.g. competent authority responsible for domestic food control; subnational/local governments). It is important in these situations that communication is relevant and timely, to support appropriate risk management actions. In general, this means formal arrangements between organizations.

Guidance on surveillance or monitoring will be established in sampling strategies and annual sampling plans (see Section 4 and SUPPORTING TOOLS AND GUIDANCE 4.4 and 4.5 further below).

SUPPORTING TOOLS AND GUIDANCE 2.1

IMPORTED FOOD, IMPORTER AND EXPORTING COUNTRY PROFILES

In order to develop and operate imported food controls, the competent authority will need information on importers and imported food. This profile may also include information on food safety systems in exporting countries.

Gathering and maintaining this information will take significant time and resources. The competent authorities should carefully consider what information they need to develop, maintain and improve their imported food controls. This means that countries should start by collecting minimal information required to implement their imported food controls. Collection of more detailed information and data would then be introduced as controls improve over time, or as the system is capable of maintaining and using such information.

All information required to maintain and operate imported food controls should be gathered in a systematic manner, using existing data or information already available to the competent authority, or sharing information from customs or other government institutions. It is very likely that there will be significant gaps in the existing information which, although may make determination of risk management actions more difficult, should not preclude actions based on the available evidence.

The competent authority should assess the available information to identify appropriate risk management actions, and should assess and prioritise actions to collect and assess the missing information they need.

Information on the imported food and importer profile should also be used in risk categorization.

Implementation of risk based imported food controls requires information on imported food, importers and the exporting country's food control system.

Gaps in the information do not preclude making risk management decisions on the available data.

IMPORTER PROFILE

Competent authorities should assess the available information about importers (e.g location, numbers) as part of their consideration of the most appropriate risk management actions. Implementing imported food controls without understanding the importer's profile may result in ineffective controls and wasted resources.

Residence of importers

a. Importers located in-country: If the majority of importers are based inside the country, then implementing importer controls and requirements (i.e. **post-border controls**) can be an important tool in assuring the safety of imported food.

b. Non-resident importers: If importers do not reside in the country, a **focus on pre-border and border controls** may be more effective.

Proximity to borders

a. Importers located near strategic border crossings: Where the majority of importers are located near a border crossing (i.e. land or sea ports) then the imported food control officials can **determine whether border controls should be exercised "at" the border itself, or at the importers' location**.

b. Importers concentrated within cities and towns: Where the majority of importers are found in cities and towns throughout the country, or where there are numerous locations of importation that are widely distributed throughout the country, then greater use of **post-border controls** should be considered, as border controls may be difficult to implement.

Number and size of importers

a. High numbers of importers: Where there are many importers and most are small or very small, the **focus should be on identification and communication**. Implementing **post-border controls** (e.g. licensing, assessing importers, inspecting product) may be cost prohibitive. In such cases, **pre-border and border controls** may be more effective.

b. Very few importers: **Post-border controls** are generally more effective in managing smaller numbers of importers that are responsible for bringing in a large proportion of any particular food.

c. Combination of large and small importers: Importer controls could be a combination of post-border/in-country importer controls for importers that import large volumes of high-risk foods, with reduced requirements for smaller importers of lower risk foods.

Type of storage used

Information about the size, capacity and distribution of the warehouses should be taken into account in establishing importer requirements.

For example, import permits could be required of importers of frozen or refrigerated products, and they could be required to provide information as to location, type and capacity of freezer or refrigerated storage.

Where importers primarily use public warehouses for storing food, then consideration should be given to **ensuring food storage warehouses are appropriately regulated, possibly within the domestic system**.

IMPORTED FOOD PROFILE

Competent authorities should assess the available information about imported food (e.g. associated hazards and possibly mitigations, volume, sources) as part of their consideration of the most appropriate risk management actions. Implementing controls without understanding the imported food characteristics may result in ineffective controls and wasted resources. Development of the imported food profile should begin with assessing what information is needed, what is available and what specifics still needs to be collected. This information is important in establishing risk characteristics.

This includes assessing the hazards associated with imported foods and possible mitigation; volume of imported food; end use; and sources.

Imported food characteristics

Significant or unknown/unquantifiable risk with no mitigation options: Given significant risk, with no mitigations, the import of such foods is generally **prohibited**.

Significant risk that can be mitigated by foreign food safety control systems: Where the significant risk can be mitigated in the producing country, **pre-border controls** are often the most effective.

Medium risk that can be mitigated by foreign food control safety systems or processor/importer controls: For medium risk products, controls are often a combination of pre-border assurances, importer controls and border inspections.

Low risk products: Foods deemed low risk, may have minimal controls, mostly focused on importer identification and monitoring within the country.

Foods of animal or plant origin:

> What foods must be controlled at source (e.g. biotoxins in molluscan shellfish; aflatoxin in grains)?

> What hazards must be controlled by the exporting country or importer (e.g. additives, veterinary drugs, pesticides)?

> What is the animal health status of the exporting country?

Are the imports primarily raw product (e.g. grains, fresh fruit and vegetables) or processed products (e.g. ready to eat; dried)?

Important to assess what information is needed, what is available, and to prioritise the information collection process.

The imported food profile is important in establishing the risk characteristics as part of risk categorization.

If imported foods are processed in the importing country, the import controls may simply consist of identification and tracing product to the processor. Integration of the import controls with the domestic food control system may be the most effective means of assuring food safety.

Where products are intended for direct sale to consumers, they may require a combination of controls. Some specific country requirements, such as labelling, may require importer controls. For example, all imported food that does not meet labelling (e.g. language, ingredients) requirements should be detained at an importer specified location (e.g. warehouse) until relabeling is complete.

Is the import simply supplementing domestically produced food, or is imported food the primary source of a particular food, food product or food ingredient? The information on percentage of imported food consumed by the importing country population, particularly if it is destined as a sole source or for a vulnerable population, will assist in establishing a risk based programme.

Consider whether foods are destined for the general population or for a vulnerable group (e.g. infants, elderly, undernourished): High-risk foods for vulnerable population groups may require greater guarantees from the exporting countries.

If processed products, are they a single ingredient (e.g. frozen fish) or multiple ingredients (e.g. breaded fish); ingredients can originate from different countries with different food control systems: Controls may include certification from exporting countries that all ingredients meet importing country requirements or increased importer controls. Border controls (e.g. product inspection) may not provide sufficient assurance of food safety.

Are they perishable (e.g. fresh fruit, fish)? To prevent imports from deteriorating during an inspection process, preclearance processes under an arrangement with an exporting country or third party service provider should be considered.

EXPORTING COUNTRY PROFILE

Understanding the source of imported food and the controls exercised in the exporting country is important when considering pre-border controls.

Competent authorities should understand the source(s) of imported foods including the route and conditions of importation. Particularly where the competent authority is considering pre-border controls, it may choose to establish exporting country profiles (e.g. processing, food safety controls).

Knowing the source of imported food is important:

a. Is the food import shipped directly from a source country or is it transhipped through other countries (transhipment is frequent in the case of non-resident importers)? **Pre-border controls** based on assurances from an exporting country are more effective where the product is shipped directly from the source country. Where a large portion of food is transhipped, **border and in-country controls** are preferable.

b. What are the shipping conditions? Does the shipping container include one food type or multiple products (e.g. multiple foods or other objects for one retailer)? Pre-border and border controls are difficult to manage with multiple lots of different products in one container. In-country controls, particularly requiring importers to demonstrate the compliance of all products in a lot, are preferable.

c. Is the majority of food sourced from one country, from a few countries or from many? (Particularly the source of high-risk foods):

   > If most food originates from one county or very few countries, pre-border controls may be most effective, including seeking assurance from the exporting country. Coupling pre-border assurance with border controls should provide an effective tool for managing imported food.

   > If imported food originates from many countries, it may be cost prohibitive to establish pre-border controls for all exporting countries. A suggested approach is to establish arrangements with exporting countries based on the quantity of, and risks associated with, the imported food, coupled with control at border or in-country.

d. Understand the food safety control system in the exporting country including the legal and institutional frameworks, food safety system, the number of competent authorities, the country's history of safe food production and level of compliance of imported food from the exporting country.

   > For imports from countries with strong food safety systems, consider pre-border controls (e.g. is exporting country willing to provide assurance of food safety).

   > Where the country has a strong food safety system, but does not have export controls, consider pre-border controls by an importer

e. Determine the whole food chain, particularly for high-risk products. If foods are produced and processed in more than one country, it is necessary to work closely with the exporting country of record to understand the level of food safety controls and the strength of the food safety system along the entire manufacturing chain.

This is key to proceeding with the risk categorization (see **SUPPORTING TOOLS AND GUIDANCE 2.2**) and understanding the "control characteristics" that can be recorded.

Timing of importation

Capacities and resources need to be available both for seasonal and year-round imports.

a. Are the imports only brought in during specific periods of time? Are they seasonal (e.g. to supplement domestic supply, such as fresh fruit during northern winters, dry seasons)?

- There may be a need for increased resources during peak importing periods if food is only imported during specific periods of time (e.g. special occasion foods, seasonal crops).
- Laboratory and inspection capacity will have to be available for peak levels of imports at specific times of the year.

b. Are the imports brought in all year round? Where imports occur regularly sufficient capacity throughout the year is necessary to provide required services.

Location of imports

The ports of entry and the mode of transport for imported food need to be understood in developing imported food controls.

a. What is the percentage imported by seaport, land border or airports? Are the majority of food imports in bulk, through seaports or train/truck ports?
   - Where there are specified ports of entry, the inspection locations may be located within the ports.
   - Where ports have good infrastructure already in place (e.g. to maintain control over non-food imports) collaboration with existing organizations at the port may enhance implementation of effective border controls.
   - Where primary controls over non-food imports are in-country controls, it may not be cost-effective to develop the infrastructure at all ports of entry to establish border controls specifically for foods. In such situations, in-country importer controls may be most effective.

Compliance history

a. Identify compliance history of imported food: Are there any that have significant non-compliance, or are there categories or types of food generally associated with food-borne illnesses? These foods or categories of food warrant primary attention to evaluate why existing controls do not result in safe foods, and to improve the controls. Non-compliance should result in enhanced in-country controls to assess importers' ability to meet regulatory requirements.

b. Compliance history can also include compliance with other regulatory requirements (e.g. labelling, product inspection) as part of the decision making process.

SUPPORTING TOOLS AND GUIDANCE 2.2
RISK CATEGORIZATION

Countries are responsible for addressing thousands of hazards associated with imported foods. Competent authorities are encouraged to use existing information stemming from the updated risk assessments of international, regional or national organizations.

However, internationally available risk assessments for specific food hazards may be limited or non-existent. Countries many not have the scientific resources to develop the data necessary to support a risk assessment, as it may be prohibitively expensive. Although risk categorization is not a replacement for a full risk assessment as described in the Codex Alimentarius guidance, it is considered a practical and simpler approach that provides a systematic, consistent, evidence based and transparent approach.

The use of risk categorization, in combination with the imported food and importer profile information, can provide competent authorities with the evidence to choose the appropriate controls and risk management action or combination (i.e. targeting resources to the highest risk products).

In applying risk categorization, the competent authority can develop a consistent and appropriate level of controls whether pre-border, border or in-country (e.g. inspection type, intensity and frequency).

Risk categorization can be a useful tool to establish priorities for pre-border controls, (e.g. bilateral arrangements), the frequency of inspection of importers, or imported food.

In applying risk categorization, it is important to have a clear objective, understanding of the decision being sought, the issue or problem being resolved and the process to be used.

Risk categorization should be carried out in a consistent and transparent manner. Each competent authority will have to establish risk categories that they plan to use; the risk factors, including definitions; the procedures to be followed; the information to be used – all of which should be available to all stakeholders. The results of the categorization should be published.

In order to assist competent authorities to develop risk categorization as part of their risk based imported food controls, the following provides guidance for consideration. This guidance is based on the use of two risk categories: product characteristics and control characteristics. In implementing their own risk categorization, competent authorities will need to make a careful assessment of their own specific needs (e.g. definition, risk categories).

Based on the two risk categories noted, key risk factors associated with each category should also be developed. Key risk factors are generally high level attributes (e.g. "microbial growth" and not "*Salmonella*"; "exporting country controls" and

Risk categorization uses the information from the imported food, importer and exporting country profile to establish risk associated with imported foods.

Risk categorization is a useful tool for countries implementing risk based imported food controls.

Risk categorization requires a transparent and consistent process.

Risk categorization generally includes two categories: product characteristics and control characteristics, but competent authorities should make a careful assessment of their own specific needs.

not "specific process requirements"). The competent authority will need to validate the risk factors within their specific context and may need to be adapted to their country specific information (e.g. importer and imported food profile).

The competent authority should also establish whether they will use a points system or assign risks as high, medium and low. They should identify which criteria, information or evidence will be considered in establishing the highest risks, and which will assist in prioritising the development and implementation of imported food controls.

Generally, countries will adopt a multiple step process:

1. Work through the product characteristics in order to establish a list of high-risk foods.
2. Clearly identify the objective of the risk categorization (e.g. prioritising bilateral arrangements with exporting countries, establishing a frequency for importer inspections).
3. Work through the source characteristics related to the foods in question.
4. Develop a risk management response based on the evidence that responds to the objective

Risk category 1 – Product characteristics

Addresses risk associated with the food itself.

This category is intended to address the risks associated with the food itself, as presented to the consumer.

Foods categorized as high, medium or low risk, based on potential for causing illness or serious harm.

Food products can be categorized as posing high, medium or low risk, based on potential for causing illness or serious harm (i.e. growth or presence of microbial pathogens, biotoxins); the consumer usage (i.e. cooking); and the processes (e.g. pasteurisation, canning, fermentation, depuration). Much of the information with respect to categorising risks can be gathered from scientific papers or from Codex standards. Also consider available scientific evidence about illnesses associated with specific food products. For example, while the fact that consumers cook meat before eating may reduce risk, it is also evident that meat is associated with many food-borne illnesses. Thus while cooking may potentially reduce risk, it will not render the meat a low or medium risk.

- Risk factor 1a - potential for microbial growth generally refers to likelihood of a food containing or supporting pathogenic microbes.
  - If yes, then the food is a high-risk food
  - If no, then the food is not a high-risk food

Risk factors include potential for microbial growth, the potential of toxin formation and the end use.

- Risk factor 1b – for high-risk foods that have the potential for microbial growth, consider the end use, which generally refers to whether the high-risk food is considered ready to eat or will undergo heat treatment before eating. There are generally 3 options:
  - Raw – eaten as is (e.g. fruits, vegetables, raw milk cheeses)

- > If yes, then the food may be considered a high-risk food.
- > Processed – eaten as is (e.g. pasteurised milk; canned meats)
  - > If yes then the food may be considered a medium risk food (high-risk mitigated by processing).
- > Raw or processed – cooked before eating (e.g. fish, meat, frozen foods)
  - > If yes, then the food may be considered either a high-risk (e.g. meat) or a medium risk food (high-risk mitigated by consumer cooking).

> Risk factor 2 – potential for toxin formation (e.g. mycotoxins in grain; biotoxins in molluscan shellfish).

- > If yes, then the food is a high-risk food
- > If no, then the food is not a high-risk food

Defining classes of food

While it is fairly easy to categorize commodities such as fish, meat or produce with respect to microbial and biotoxin risks, it becomes more difficult with more complex food products that contain many ingredients and combinations of commodities. Definitions are being developed (e.g. New Zealand; FAO[24]) and will need to be considered by importing countries as they become available.

Competent authorities should publish their lists of high, medium and low risk foods.

Importing countries should establish and publish which foods are considered high or medium risk and which foods are not. The "FAO guidelines for Risk categorization of food and food establishments applicable to ASEAN Countries" provides some examples of food and food businesses categorized in risk categories.

NOTE

Risk factor 1- Possible definitions

- > High-risk foods: may contain pathogenic microorganism and/or biotoxins and will support formation of toxins or growth of pathogenic microorganisms
- > Medium risk foods: may contain pathogenic microorganisms but will not normally support growth
- > Low risk foods: are unlikely to contain pathogenic microorganisms, or biotoxins.

Risk category 2 – Control characteristics

This category is intended to consider controls exercised by the food business, the competent authority in the exporting country and the importer in determining appropriate risk management options. Where there are effective controls, risk associated with product characteristics should be mitigated. Conversely, where there are ineffective controls, product risks may be increased.

Addresses the controls implemented by the food business, the competent authority in the exporting country or the importers.

24 "FAO guideline for Risk categorization of food and food establishments applicable to ASEAN Countries" : www.fao.org/docrep/015/i2448e/i2448e00.htm

Includes risk associated with veterinary drug and pesticide residues as their presence is a result of human activity, and can be controlled by the competent authority.

Source risk may be categorized as high, medium or low risk based on the controls exercised by the exporting country, the controls exercised by the producing facility (e.g. foreign supplier verification) and controls by the importer. The information to categorize the risks can be gathered from various sources such as knowledge of the controls in the exporting country, compliance levels from product inspection or importer inspections, published reviews of foreign food safety system assessments either by importing country or other authorities, results of processor assessments by importers or other recognized third parties. Generally importing countries will choose to evaluate the exporting country food safety controls, as this is more cost-effective in that it apples to all exporting food businesses from that country. However, in some instances, (e.g. trade limited to one or two exporting food businesses), the importing risk categorization may assess a single exporting food business control.

Risk factors include classification of exporting country controls, exporting food business food safety controls or importer controls.

> Risk factor 1a – Classification of exporting country food safety controls[25] can be weighted where countries with significant controls are considered lower risk, and countries with less significant or unknown controls may be considered higher risk. Another factor to assist in classifying exporting country controls can include the volume and compliance history of the imported food. The importing country may also consider its knowledge, experience and confidence in the food safety system of the exporting country in determining weighting.
> Risk factor 1b – Classification of exporting food businesses' food safety controls can be weighted where processors with controls are considered lower risk and facilities with less significant or unknown controls may be considered higher risk. It can also be further weighted based on the volume and compliance of food based on risk.
> Risk factor 2 - Classification of importer controls can be weighted where exporting processers subject to foreign supplier verifications, (e.g. third party audits, sampling and validation) are considered lower risk, and with less significant or unknown controls by importers may be considered higher risk. It can also be further weighted based on the volume and compliance of food based on risk.

Using risk categorization

Competent authorities must establish clear objectives when applying risk categorization to establish the most appropriate risk management action.

The risk categorization framework can be used for multiple purposes, so it is essential that the intended objective is very clearly established. For example,

> if the intent is to prioritise arrangements with a foreign competent authority, the analysis would focus on all food imports from that source, the level of compliance, and not the compliance of the importers;

25 This risk factor is focused on food safety controls in the source country, however, importing countries may also implement complementary processes for assessing the risks associated with animal health or plant protection in the exporting country.

> if the objective is to assess the relative ranking of importers' controls, the focus and weighting may be assessing importers across all foods and source countries. The importers with the worst controls would have increased frequency of inspection.

The information gathered from the importer and imported food profile should form the basis of the information used in risk categorization.

The following three scenarios are intended to outline how countries may use risk categorization to identify and prioritise risk management actions. As the following scenarios are simply examples, importing countries will need to establish their own objectives for the use of risk categorization. Establishing these objectives and using risk categorization to establish risk management actions should be systematic, consistent and transparent.

Scenario 1: Pre–border controls

The objective is to determine if pre-border risk management actions is the best approach to managing imports, to establish a priority list for bilateral arrangements with exporting countries. For this scenario, the consideration would be a high-risk product (A) which is imported in significant volumes from five countries – thus all the product characteristics would be the same. This would include the following:

> Analyse importer and imported food profile, including determining the top volume imports and their source countries.

> Assess the control characteristics of the exporting country.

> Make an evidence-based decision.

Scenario 1 pertains to a determination of whether pre-border controls would be appropriate and to prioritize a list of bilateral arrangements with exporting countries.

EXAMPLE

Evidence- based priority setting

COUNTRY	VOLUME (%)	EXPORTING COUNTRY CONTROLS	PRE–BORDER CONTROLS
A	45%	Medium	Potential bilateral arrangement – priority 2
B	30%	High	Potential bilateral arrangement – priority 1
C	15%	Low – lack of controls reduces potential that importing country could have confidence in any assurance	Consider other pre-border or in-country controls (e.g. importers to provide evidence of compliance before sale; foreign suppliers' verification, product analysis)
D	5%	Medium	Potential bilateral arrangement – priority 4
E	5%	High	Potential bilateral arrangement – priority 3

Scenario 2: Border controls

Scenario 2 pertains to using risk categorisation to determine foods for priority sampling and analysis.

One border control is to implement risk based sampling. Risk categorization provides evidence-based decision making to determine products for priority sampling and analysis. In this case, the scenario uses five products (pasteurised fluid milk, baked goods (bread), oysters, flour and fresh fruit). For simplicity in this scenario, only two source countries are used. Approach would include the following:

> Analyse importer and imported food profile, including determining the volume imports and their source countries.

> Assess the product characteristics.

> Assess the control characteristics of the exporting country based on product compliance data.

> Make an evidence-based decision.

EXAMPLE

Product characteristics

PRODUCT	COUNTRY	RISK FACTOR 1	RISK FACTOR 1B	RISK FACTOR 2	PRODUCT CHARACTERISTIC SUMMARY
Pasteurised fluid milk	A	High (10)	Processed, eaten as is Medium (5)	Low (1)	16
	B	High (10)	Processed, eaten as is Medium (5)	Low (1)	16
Baked goods	A	Low (1)	Not/applicable	Low (1)	2
	B	Low (1)	Not/applicable	Low (1)	2
Oysters	A	High (10)	Raw, eaten as is High (10)	High (10)	30
	B	High (10)	Raw, eaten as is High (10)	High (10)	30
Flour	A	Low (1)	Not/applicable	Medium (5)	6
	B	Low (1)	Not/applicable	Medium (5)	6
Fresh fruit	A	High (10)	High (10)	Low (1)	21
	B	High (10)	High (10)	Low (1)	21

EXAMPLE

Combination – product and control characteristics

PRODUCT	COUNTRY	PRODUCT CHARACTERISTIC SUMMARY	SOURCE CONTROLS	VOLUME	RESIDUAL RISK
Pasteurised fluid milk	A	16	High* (1)	Low** (1)	18
	B	16	Low (10)	Low (1)	27
Baked goods	A	2	Medium (5)	High (10)	17
	B	2	High (1)	High (10)	13
Oysters	A	30	High (1)	Low (1)	32
	B	30	High (1)	Low (1)	32
Flour	A	6	Low (10)	Low (1)	17
	B	6	Medium (5)	High (10)	21
Fresh fruit	A	21	Medium (5)	Medium (5)	41
	B	21	High (1)	Low (1)	23

* High control by exporting country = good compliance (score 1); Low controls = poor compliance (score 10)
** Low volume by exporting country = lower score; high volume = higher score

Under this hypothetical scenario, the priority products for a risk based sampling programme would be: fresh fruit (country A), oysters (country A and B) and milk (country B).

Scenario 3: In-country controls

Scenario 3 pertains to using risk categorization for determining importer inspection based on volume and product risk, in association with importer and source controls.

The objective is to determine inspection priorities for importers based on the top five importers (volume and high-risk products), combined with importer and source controls. Approach would include the following:

> Analyse importer and imported food profile, including determining the volume imports and their source countries.

> Assess the control characteristics of the importer and the exporting country based on product compliance data for all imported products.

> Make an evidence-based decision.

EXAMPLE

IMPORTER	IMPORTER CONTROLS	SOURCE CONTROLS	RESIDUAL RISK/ INSPECTION PRIORITY
1	High* (1)	Low (10)	11
2	High (1)	Medium (5)	6
3	Low (10)	Low (10)	20
4	Low (10)	High (1)	11
5	Medium (5)	High (1)	6

* High control by exporting country = good compliance (score 1); Low controls = poor compliance (score 10). Inspection priority would be: Importer 3, followed by Importer 1, and third priority Importer 4.

SUPPORTING TOOLS AND GUIDANCE 2.3
RECOGNITION ARRANGEMENTS

This guidance provides further information on arrangements on pre-border controls. Where a competent authority is considering an arrangement[26] with an exporting country as part of its pre-border risk management actions, it should carefully consider the processes required. The following are some key steps that may assist competent authorities in developing and maintaining arrangements.

Key points for consideration include developing a clear objective; the benefits and costs of developing and maintaining an arrangement; the work plan and procedures; the availability of import requirements; on-site visits; and formalizing the arrangement.

1. Identify a clear objective

In developing the objective, discussions should be undertaken with the exporting country. In most instances, the arrangement will be the result of ongoing trade and existing relationships.

It is important to establish:

- whether the arrangement being sought will be based on equivalence, some other form of recognition or simply information sharing and collaboration;
- if all exported foods, or only some high-risk product(s) will be included in the arrangement, and whether this means dealing with one or more competent authorities in the exporting country;
- if the whole control system, or only a part of it (e.g. controls over meat) would be part of the arrangement; and
- if the arrangement will only include domestically produced food or also food transhipped through the exporting country from a third country. In case of the latter, careful consideration will have to be given to what assurance can be provided under the arrangement.

2. Benefits and costs

The importing country should consider quantifying the benefits and the costs of undertaking an arrangement, in that it should be the most effective instrument to ensure food safety and quality. In particular, consideration should be given to whether the countries are prepared to undertake an equivalence determination, or if another arrangement would be sufficient to meet the established objective.

26 Consistent with Guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems (CAC/GL 26-1997).

3. Work plan

The countries should collaborate on developing a work plan setting out the objectives, milestones, and timelines.

It is important to establish ongoing communication between the importing and exporting countries as they work to develop an arrangement. This is important to be able to clarify technical points and respond to requests for additional information in a timely manner.

Factors that facilitate developing an arrangement and should be taken into account in establishing a work plan include:

> Cooperation between competent authorities of the importing and exporting countries.

> The experience, knowledge and confidence the importing country has with the exporting country's food safety control system (e.g. established food trade, food compliance history).

> The similarity between the two food safety systems (e.g. legislation, programmes).

> Access to the appropriate resources such as scientific and technical capabilities.

4. Transparency and availability of requirements

Once the objectives have been clearly identified for the arrangement, the authorities should also review and ensure that its relevant requirements and control measures and the key objectives are clear, transparent and available for the exporting countries.

Development of arrangements based on clear health and safety requirements can be facilitated by the use of Codex standards, recommendations and guidelines by both parties.

Consultation with the exporting country(ies) should be initiated as a first step in the consultative process, making available the texts of its relevant control measures and identifying the objectives of these measures. Information should be exchanged on:

> legislative, regulatory, and other requirements that provide the legal basis for the food control system;

> relevant documentation that establishes the control programmes and procedures including appropriate guidance on decision criteria and action;

> facilities, equipment, transportation and communications as well as basic sanitation and water quality;

> laboratories, including information on evaluation or accreditation of laboratories; and

> organizational details of the exporting country's competent authority (e.g. inspection staff, training).

5. Implementing the work plan

Once the preliminary work of establishing the objectives and developing the work plan is complete, the work to develop the arrangement can begin. It is useful to initiate a comparison between the two systems, to identify similarities, including identical measures, and where there are differences. For those areas of difference, the exporting country will need to determine if it wants to seek a determination of equivalence, or amend its system to meet the importing country's requirements.

Experience, knowledge and confidence in the exporting country's food safety system is an important factor in developing an arrangement, because it may reduce the resources required to establish such an arrangement. Experience, knowledge and confidence include many factors (see above) but could also include:

> use of processing controls (e.g. HACCP) by industry;

> presence of export control system;

> results of audits/inspections/field examinations by the importing country, exporting country, other countries, or other officially recognized third party organizations;

> arrangements already in place between the two countries, or with other trading partners.

Areas of difference: determination of equivalence

Once the exporting country has determined that there are measures for which it will seek an equivalence determination, it should provide that information.

The importing country should specify as precisely as possible an objective of the measure, and the key basis of comparison with its own measure(s).

Based on the information provided, the exporting country should document how its measure(s) will meet the importing country requirements, as set out through meeting the key requirements for comparison.

The importing country should review the submission and be prepared to discuss it with the exporting country. It is important that these discussions are contextualized within the broader discussion, especially if there is a good compliance history for products traded between the two countries.

On-site visits

On-site visits may be beneficial in clarifying information provided by the exporting country but should be initiated with a clear scope and purpose. For example, site visits could be used to:

> Gather additional information on the exporting country's measures, in particular to exchange technical and scientific information.

> Improve knowledge and confidence in the exporting country's food control system.

> On site visits should be guided by the principles set out by Codex Alimentarius.

6. Arrangement

The exporting and importing countries should agree to develop a formal arrangement setting out their agreement. It will be important that there is a mutually acceptable understanding of the conditions established and ongoing communication, as no situation is ever static.

The arrangement could include:

- Communications – regular scheduled meetings, video or telephone calls.
- Information exchange for all new requirements, non-compliant food shipments, food emergency situations or other food safety issues.
- Certification requirements (e.g. food, food business) format and transmission.
- Periodic review to verify the continued ability of the exporting country to provide assurance.

SUPPORTING TOOLS AND GUIDANCE 2.4
VALIDATION OF DOCUMENTATION

On presentation to officials at import controls, all documentation accompanying shipments should be subject to validation and verification in order to confirm its authenticity. In order to ensure a systematic approach to assessing the validity of the documentation, countries should develop a SOP for officials to use. This also applies to validation of certificates[27] issued by an exporting country or third party service provider.

Validation of documentation should also include verification that the documents relate to the shipment (often called an identity check) in order to confirm that the documentation relates to the specific consignment as presented (volume of product, lot numbers, batch numbers).

Document requirements should be clear and consistent to facilitate compliance. Importers may on occasion provide additional documentation such as commercial certificates (e.g. laboratory analysis results), or official certificates from an exporting country that are not required by the importing competent authority.

As officials will not have a process or procedure to authenticate such documents, (e.g. sampling process used, analytical methodology and QA, chain of custody and association with imported lot) they should not be used as a basis for decision making.

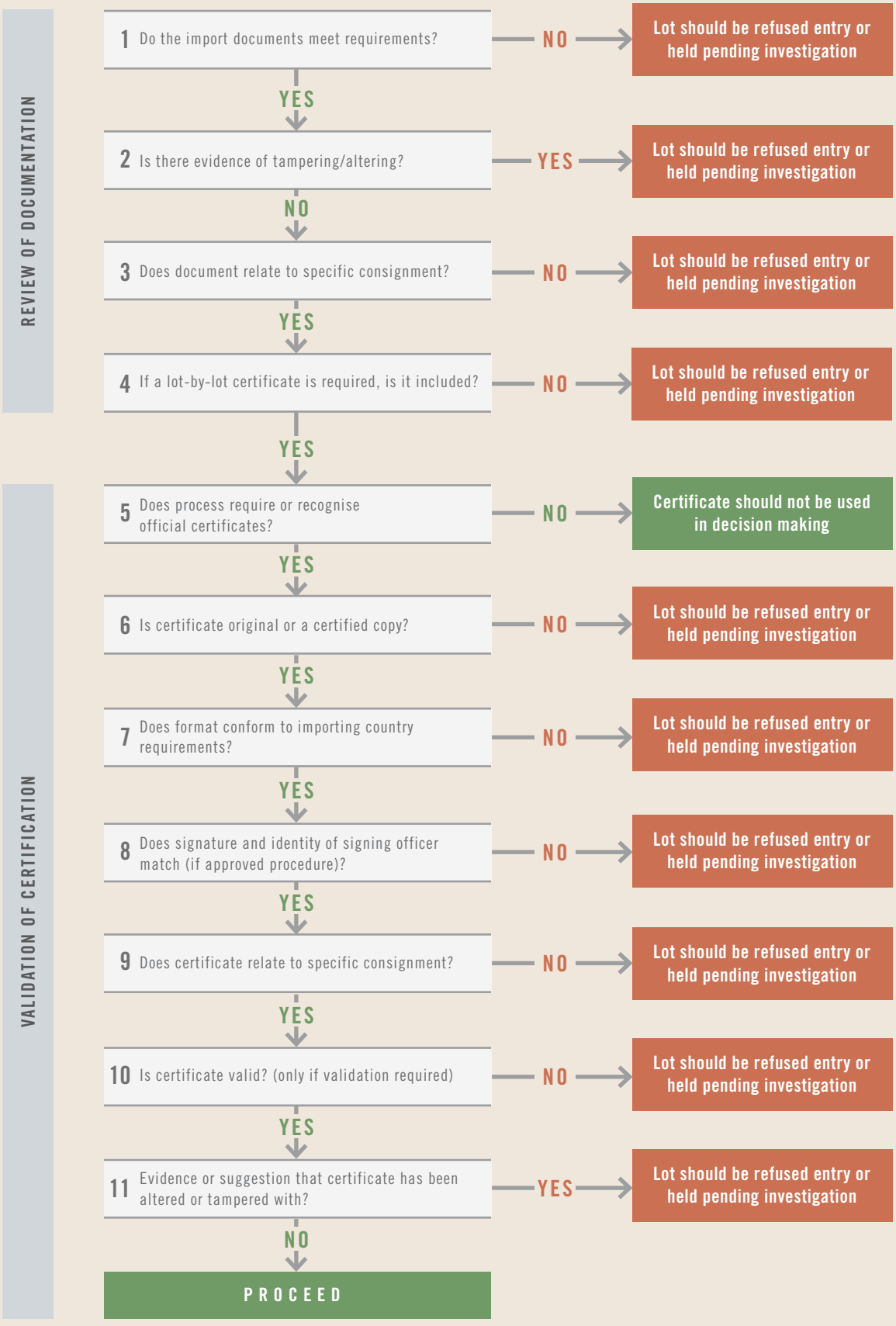
Alternatively, where such documents are considered part of the import control requirements, considerations for their use in decision making should be clearly set out and well established. They are often considered most useful within the context of an established foreign supplier verification programme as part of GIP.

The process for validation of certification is similar, and generally subsequent to, the review of other documentation. Both steps can be performed by food control staff, or the initial review of documentation can be delegated to customs officers. Figure 5 describes this process.

Documentation is subject to validation and verification to assess validity. Competent authorities should have SOPs in place for officials to follow in verifying documentation.

27 Certificates and certification should be consistent with Guidelines for design, production, issuance and use of generic official certificates (CAC/GL 38-2001).

FIGURE 5 **DOCUMENTATION AND CERTIFICATE DECISION TREE**



The following notes refer to complementary information to Figure 5, referring to the box numbers.

1. **Requirements**: all information requirements complete (e.g. original documents contain all information, and are legible in the appropriate language). Inspectors should not "chase" missing information. On determining if the information is incomplete, the importer should be requested to provide it. Should no information be forthcoming in a timely manner, the lot may be refused entry as inadmissible. Do not use documentation voluntarily provided by the importer that is not required by the import control programme.
2. **Alteration**: evidence that the documentation or the information contained in the document has been changed or altered (e.g. strikethrough, overwritten, handwritten changes). If discrepancies are found, the competent official will have to confirm details with the importer, the issuing authority or both.
3. **Food lot verification or identify checks**: validate that the documentation relates to the specific consignment presented for import (e.g. volume of product, lot numbers, common name, sizes, batch numbers).
4. **Certificates** are generally **required** where the exporting country is providing assurance that the food meets importing country requirements.
5. Verify whether the **imported food requires a certificate**, either from a competent authority or accredited third party.
6. **Original**, **certified copy** or **replacement certificates** should meet requirements (e.g. all information complete, legible, and in the appropriate language).
7. Certificate should be in the same form, format, with the required data fields negotiated by the importing country.
8. **Signatures** should be **legible** and **match** the signature of authorized officials in the exporting country.
9. Certificate should match the imported food (e.g. volume, lot numbers, batch numbers, common name, producer).
10. **Validation of the certificate**, where included in procedures: the issuing authority or the accredited third party should be contacted to verify the certificate's validity - often completed electronically.
11. **Alteration** - evidence that the documentation or the information contained in the certificate has been changed or altered (e.g. strikethrough, overwritten, handwritten changes). If discrepancies are found, the competent official will have to confirm details with the issuing authority, or third party.

Industry and commercial certification schemes

Only officially recognised documents should be used in making admissibility decisions. Industry and commercial certificates are not generally part of official import procedures, unless they are considered officially recognised.

The use of commercial certification that may be provided by importers must be set out in established procedures. Commercial certification provided by the exporter or importer at the time of import will only be useful if there is confidence in the accuracy, validity and relevance of such certification in showing compliance with importing country requirements.

Only where there are established procedures can commercial certification assist officials in making decisions about imported food. However, as in the case above, such certification should not be accepted on face value. Sufficient steps should be taken to ensure such certification is valid, and to verify that the goods being examined meet all of the requirements at the time of import.

Validation and verification of commercial certification

If the import programme uses or relies on commercial certification in the decision on the compliance of imported products with import requirements, sufficient checks need to be made to confirm the validity of the commercial certificates, and to verify that production conditions have been met. A similar process to the assessment of official certificates can be implemented. Use of well-established commercial certificates will facilitate validation.

Fraudulent certificates or tampering with certificates

Certification may also be falsified or the goods covered by the certificate may be fraudulent. In the case of paper-based certification, fraudulent certificates may be difficult to detect – hence the benefit of exchanging model certificates in establishing certification agreements with exporting country authorities, and the refusal to use "ad-hoc" certificates provided by an importer or broker. Exporting countries may also alter or enhance certificate security features over time. This may include:

> specialized paper (e.g. fluorescent stripes etc.);

> water marks and/or embossing features; and

> barcodes or other digital references.

Official signatories may also change with time. Exporting countries should ensure new signatories are transmitted to trading partners as required. Similarly, importing countries should ensure correct signatory copies are maintained at points of import.

Tampering with certificates can occur in the exporting country or during transportation to the importing country. Tampering generally occurs where a valid certificate was issued by the certifying authority, and the information on the certificate has been deliberately altered (e.g. increase in volume, altering the name of the product). Importers have a responsibility to ensure imported products are accompanied by valid certificates where required.

Tampering with a certificate renders it invalid, and may render the imported food described in the certificate as ineligible for import.

Certain changes can be made to a certificate without tampering, particularly with respect to changes to ports of entry, place of loading.

Electronic certificates

Electronic certification may also be used to provide assurance that the food meets importing country requirements. As electronic certification is generally a government to government system, it can reduce the potential for tampering with, or fraudulent use of, certificates. Where electronic certificates are used, careful consideration should be given to ensuring the system is protected against fraud, malicious damage (e.g. computer viruses) and all unauthorized entry. It should also be designed such that disruption to trade is minimal in the case of a system failure. The use and design of the systems and the certificates should be designed to minimize and prevent their fraudulent use or re-use.

Notification of failing consignments or fraudulent certification

The certifying agency in the country of export needs to be advised[28] of any false certificates, or certificates that have been tampered with, identified in the importing country. This information should indicate if there were errors with the initial certification or whether the condition of the goods had altered between the time of certification and inspection/examination on arrival. Where notified of problems with certificates, they should undertake appropriate investigation and management action to prevent recurrence. This is particularly critical in instances where food safety incidents arise from failed or fraudulent foods.

Where the issue is non-compliant consignments, the findings should be discussed with both the importer and the certifying agency in the exporting country, as they should both work with the producer/manufacturer/exporter to ensure that the same problems do not recur.

Notify the certifying body and the importer whenever imported food is rejected because of fraudulent certificates or other documentation, or evidence of tampering with certificates.

28 Guidelines for the exchange of information between countries on rejections of imported foods (CAC/GL 25 1997).

SUPPORTING TOOLS AND GUIDANCE 2.5
GOOD IMPORTING PRACTICES

Competent authorities should develop basic guidance for importers, to meet imported food requirements and basic hygiene requirements.

Countries should consider developing GIP guidance for food importers that sets out basic controls that importers should meet. The basic hygiene controls relating to storage conditions, buildings, equipment etc. included in GIP should be consistent with the Good Hygienic Practices (GHP)[29]. Requirements for importing products, maintaining documents, reception and assessment of the imported product should also be included. GIP should also include food businesses that import food ingredients solely for their own use in food processing.

GIP should cover two areas. The first should outline the importer's roles and responsibilities with respect to importation of food, while the second should outline exterior and interior building conditions, sanitary requirements and employee hygiene. The following provides some considerations that may be adapted for importing country requirements.

29 See General Principles of Food Hygiene (CAC/RCP 1-1969).

FOOD PRODUCTS, SPECIFICATIONS AND PROCEDURES

Because importers have primary responsibility for the food they import, they should source from foreign food businesses capable of meeting the importing country's regulatory requirements. They should also maintain appropriate documentation that can be made available (e.g. during an inspection, a recall) and include sufficient information to identify the product.

Importers should meet their responsibilities by sourcing from foreign food businesses that can produce food that meets the importing country requirements.

For example, importers should have written specifications that identify the minimal requirements for the type of imported food that can be provided to all foreign suppliers as part of the purchase contract. Specifications may include:

> Description of the food (e.g. meat, fish, vegetables, dairy, confectionery).

> The required standard for processing (e.g. produced under Good Manufacturing Practices (GMP), HACCP).

> Ingredients, in particular prohibited ingredients.

> Requirement for a government or third party certificate for high-risk foods.

> Storage and transport requirements. (Examples include the following: do not store with non-food items; keep refrigerated; keep frozen; store at room temperature; etc.)

> Label requirements for pre-packaged foods, including appropriate expiry date (e.g. the expiry date is sufficient for distribution, sale and consumption), language requirements.

> Statement that the food must meet "name of the importing country", Codex or other appropriate standards.

Importers should have documentation with respect to specifications provided to their suppliers.

Quality control (Importer)

As part of their responsibility, importers should also ensure they verify the imported food corresponds to the food that was ordered (QC) and that the specifications are met. This can include visual inspection of incoming lots, for example:

> Confirmation and cross reference of the information on the physical lot with the import documentation and specifications (e.g. food product, size of lot, brand, identification marks, producer).

> Confirmation that the label meets country requirements (e.g. language, codes).

> Confirmation that there are no physical signs of defects (e.g. no water damage, physical damage, leaking containers, off odours).

> If damage or defects are detected, the lot should be detained until remedial action, is determined.

Importers should have verification processes to gather information on their suppliers.

Supplier verification is also a responsibility of importers as part of ensuring the imported food meets importing country requirements such as:

> Reviewing annual inspection reports carried out by either the competent authority or a recognised third party audit, and obtained from the foreign country supplier.

> Contracting an inspection of the foreign supplier by an individual with appropriate qualifications (e.g. the importer's employee).

It may also include sampling and analysis as part of the verification procedure. Sampling and analysis allows the development of compliance history. It may include sampling a first lot from new suppliers as well as sampling of subsequent lots. Where importers do not have access to appropriate laboratory services, verification may be sought by requesting that a certificate of analysis is provided by the competent authority of the exporting country or an accredited third party.

Note: Where certificates are part of importer QA, they are not part of border admissibility procedures. Certificates should be maintained and retained by the importer and should not be provided to border officials.

Product control, storage and lot identification

Importers have a responsibility to maintain appropriate conditions for food storage and transport.

Importers also have a responsibility to maintain food while under their control (e.g. during storage). Importers should have processes to maintain product identity, and to implement a first in/first out (FIFO) or first expiry/first out (FEFO) principle so food and food ingredients are imported and sold within their established and labelled best before or expiry dates. Maintaining control may include:

> Establishing identification for all food, food ingredients.

> Establishing appropriate storage conditions (e.g. storage away from the walls, preferably on pallets or racks; separation between raw, unprocessed food and ready-to-eat foods).

> Establishing procedures for product control (i.e. tracing and tracking) that allows importers to know the location of all imported food from reception to distribution (e.g. what product, quantities, date received, storage location; date shipped, to whom and where).

> Establishing procedures for handling non-compliant food, including advising the food safety authority as well as the foreign supplier, determining what corrective action can be made or returning the lot to the suppliers. The importer should also make efforts to assess if the supplier has corrected the issue before importing further lots.

> Establishing recall procedures to enable a complete and rapid recall of any implicated lot/batch of imported food.

BUILDINGS (INSIDE AND OUT), SANITATION, UTILITIES, PERSONNEL

As with respect to food businesses that process food, importers generally require facilities in which to store the imported food. These storage facilities may be owned by the importer or by another company. In either case, facilities used for storing imported food, should meet basic requirements, such as those set out below that have been adapted from the Codex documents on Good Hygienic Practices. Some or all of these conditions may be used by competent authorities as part of GIP.

Importers must ensure that facilities used to store imported food meet basic requirements, consistent with Codex general principles of food hygiene.

A. Location

- Imported food businesses should be located in areas that are free from pollution, odours, smoke dust and other contaminants.
- Imported food businesses should be located in an area free from flooding, or where liquid waste may accumulate.
- Surrounding areas should be kept clean with no garbage accumulation or pest infestation. There should be access for liquid and solid waste removal.

B. Design and layout

- Imported food businesses should operate within a building that is designed, constructed and maintained in good repair, and which will prevent the entry of pests, dirt, debris or fumes.

C. Power

- Imported food businesses should have access to a power source capable of providing adequate power to operate the building (e.g. lights, ventilation) and food storage equipment (e.g. refrigeration, freezers).

D. Water supply

- Imported food businesses should have access to water supplies, wells, or other approved sources that are protected from contamination.

E. Layout

- Basic infrastructure appropriate to the import operations should be in place. The buildings should provide sufficient space to allow a logical flow of materials, products and personnel, and to ensure that imported food can be managed under the FIFO or FEFO principle.
  - Where food has no expiry date (e.g. bulk food) then the principle of FIFO should be used to manage food and ensure a good rotation.
  - Where food has an expiry date (e.g. pre-packaged food) then it is important to ensure no food is sold such that it will have expired before being sold to consumers or end users, and the FEFO principle should be used.

- There should be adequate separation between food storage areas and all other areas.
- There should be a provision of appropriate loading and unloading points to facilitate movement of materials, and such points should be suitably covered to provide adequate protection from pests, rain, etc.

F. Internal Structures and Fittings

- Imported food businesses should be located in buildings appropriate for food storage. This includes:
  - Walls, floors, ceilings designed to prevent the entry of pests or water (i.e. no gaps or holes that are unprotected) and built of durable material that is easy to maintain and clean.
  - Flooring should be constructed to minimize potential for contamination, to allow adequate drainage, and easy to maintain and clean (i.e. minimal cracks and crevices).
  - Ceilings and overhead fixtures should be accessible for cleaning, and should minimize the potential for dirt or condensation to fall on stored food.
  - Surfaces of walls, partitions and floors should be made of impervious materials, and walls should have a smooth surface.
  - Windows and ventilators should be easy to clean, and should prevent entry of pests.
  - Doors should have smooth non-absorbent surfaces, be easy to clean and disinfect, and designed to prevent the entry of pests.

G. Equipment

- Equipment should be located so that it permits adequate maintenance and cleaning, functions in accordance with its intended use and facilitates GHP, including monitoring, if required.
- Equipment used to cool, store or freeze food should be designed to achieve and maintain the required food temperatures as rapidly as necessary for food safety and suitability, and to be effectively maintained and allow parameters to be monitored and controlled. The monitoring and measuring devices should be periodically calibrated and records maintained. The frequency of calibration should be based on the type of equipment, criticality of the measurement, location and extent of usage.

H. Facilities environment and storage

- The imported food business should provide an appropriate environment (e.g. lighting, temperature, storage) for imported food.

I. Water supply

- Adequate potable water, or water from a source approved by the municipality or other government authority, should be supplied with appropriate facilities for its storage and distribution.
  - If bulk water is used, storage tanks or containers should protect the water from contamination (i.e. covered to prevent access by animals, birds, pests and other extraneous matter) and utensils should not contaminate the water.
  - Ice that will come into contact with food should be made from potable water and be produced, handled and stored to protect it from contamination.
  - Ice used for imported raw material should never be used for any other purpose.
- All water pipes should be made of material that is non-toxic, corrosion resistant, free from cracks, impervious and should be sealed.
- Separate non-potable water systems (e.g. fire control, steam production, refrigeration, sanitary conveniences) should be identified and should not connect with, or allow reflux into, potable water systems.

J. Drainage and waste disposal

- Imported food businesses will need to dispose of food, food packaging or cleaning material. This includes food that may have been damaged in transit or has spoiled, is past its expiry date or otherwise does not meet importing country standards.
- Drainage and waste disposal systems for imported food businesses should be appropriately designed and constructed.
- Food and packaging waste should not be allowed to accumulate in the food storage or other working (e.g. loading) areas or in the adjoining environment.
- Containers for waste, inedible or dangerous substances should be identified and suitably constructed, including covers.
- There should be adequate drainage (e.g. for melting ice) that is designed and constructed to minimize contamination of food or the water supply.

K. Cleaning facilities

- The imported food business should have adequate cleaning facilities and processes.
  - The cleaning facility should be adequate for storing cleaning utensils and supplies, and minimize the potential for food contamination. Cleaning products and other chemicals (e.g. lubricants, paints) should be clearly identified.
- Storage of cleaning materials and hazardous chemical substances should have restricted access and be available only to authorized personnel.
  - The business should have a regular cleaning process that maintains the food storage and adjacent areas.

L. Personal hygiene facilities and toilets

> The imported food business should ensure there is access to hygiene facilities for employees, either on site or available nearby, including adequate hand washing facilities with hot and cold water, adequate toilets or lavatory facilities.
  > These facilities should be appropriately located and maintained to encourage proper hygiene and minimize the potential for food contamination.

M. Ventilation

> Ventilation should be adequate to remove air-borne contamination, and control odours and humidity as needed.
  > All ventilation equipment should be clean and in good repair.

N. Lighting

> Lighting throughout the facility should be adequate to enable operations (e.g. storage, management of food products). All fixtures should be clean and protected to ensure food is not contaminated in the event of breakage.

O. Power back up

> Suitable power back up facilities (e.g. generators, invertors) should be provided to ensure uninterrupted power supply as necessary for storage and maintenance of safe food.

P. Establishment maintenance, cleaning and sanitation

> Buildings and equipment should be maintained with adequate maintenance programmes

> Cleaning and sanitation programmes as appropriate should be in place, and should cover cleaning and sanitation schedules, responsibilities, methods, equipment and cleaning and sanitizing aids, etc. to effectively control contamination of food. These should be continuously monitored for their effectiveness. It should be ensured that cleaning and sanitizing chemicals do not contaminate food.

Q. Pest control procedures

> The importer should have appropriate pest control procedures in place that include regular inspection of the premises and surrounding environment, and elimination of potential breeding grounds.

> All pest control activities should use approved products and be used according to instructions.

> All activities should be undertaken to ensure food is not contaminated.

R. Personal hygiene

- Importers should ensure that they have a health certificate for each employee.
- Importers should ensure that employees maintain a high degree of personal cleanliness and wear appropriate clean clothing.
- This includes
  - Washing hands with soap/disinfectant after use of toilets and after touching any contaminated material (including raw material, money, files, etc.) or unclean product, food contact surface, body parts and waste.
  - No spitting, smoking, eating food, and chewing gum or tobacco.

S. Transportation

- Importers should ensure that food is adequately protected during transport, including maintaining appropriate temperature, humidity, or other conditions.
- The transportation or transport containers should be designed, constructed and maintained (i.e. cleaned and disinfected) so that they do not contaminate food.
- Food and non-food should be suitably segregated during transportation to prevent contamination.

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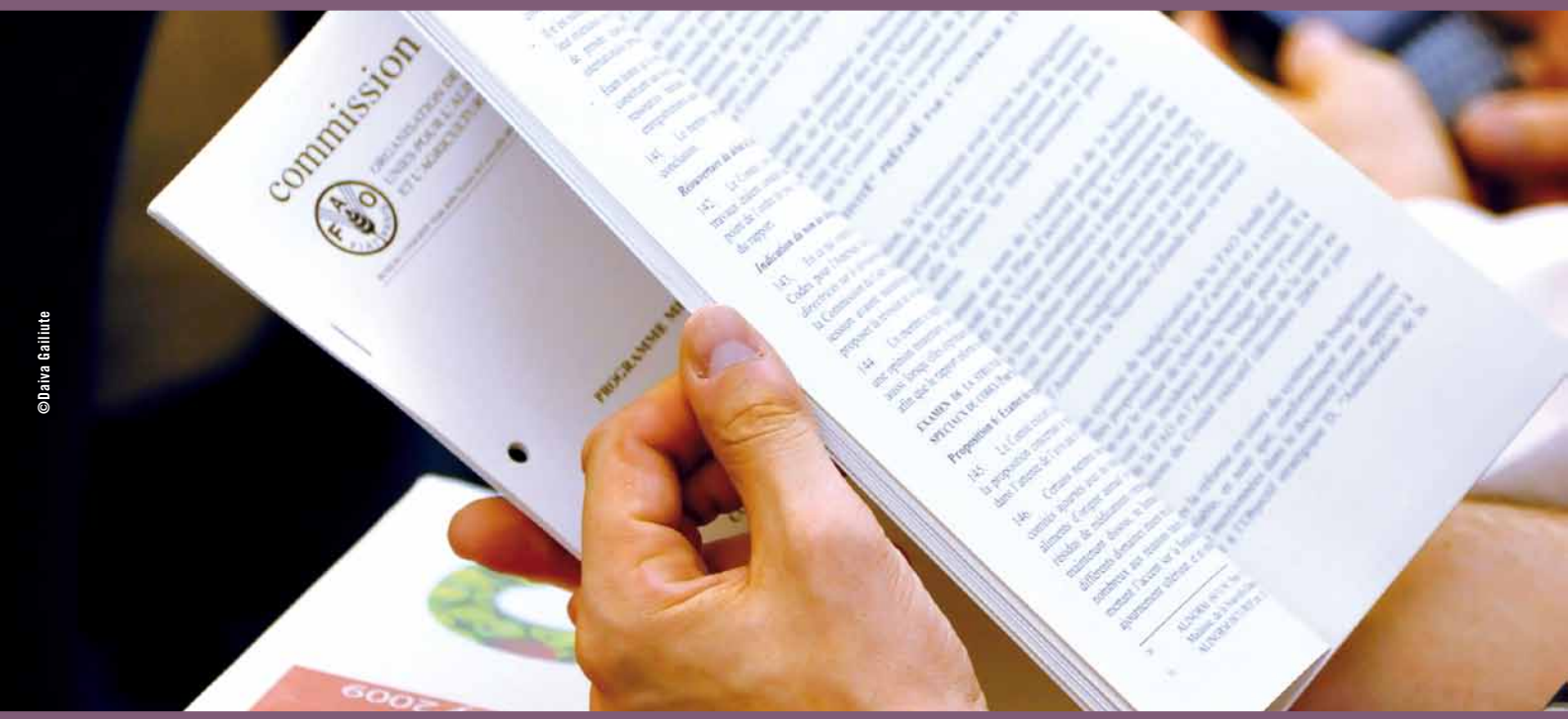

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SECTION 3

LEGAL AND INSTITUTIONAL FRAMEWORKS

> INTRODUCTION

> LEGAL FRAMEWORK FOR IMPORTED FOOD CONTROLS

> INSTITUTIONAL FRAMEWORK FOR IMPORTED FOOD CONTROL

INTRODUCTION

Risk based imported food controls are developed, implemented and maintained based on the country's specific policy and programme design (see Section 2) and support functions (see Section 4). Legislative authority (the power to implement the law), legally established requirements and obligations, and competent authorities with clearly defined mandates, roles and responsibilities are all essential for implementing risk based imported food controls.

The objective of this section is to assist countries in understanding the different options available in shaping the legal and institutional framework to support risk based imported food controls.

LEGAL FRAMEWORK FOR IMPORTED FOOD CONTROLS

Countries may choose a variety of different regulatory options to implement imported food controls. In many jurisdictions, imported food controls are integrated into broader legislation on food safety, trade of agricultural products, or commodity-based legislation.

Basic legal concepts

Consistency with national legislation

Primary legislation generally includes guidance on the key responsibilities of both competent authorities and importers.

Food safety and quality legislation refers to the body of legal provisions that regulates food safety and quality at all stages of the food production chain (e.g. governance, production, processing and sale of food). Imported food control legislation, which is a subset of food safety and quality legislation, refers to the body of legal instruments that directly or indirectly regulates imported food.

Imported food control legislation must be consistent with domestic food control legislation.

NOTE

Primary legislation includes guidance on key responsibilities of both competent authorities and food importers (i.e. it establishes the principles set out in Section 2 within a legal framework) and allows imported food controls to be administered and enforced. It generally includes provisions such as:

- Prohibitions against specific actions (e.g. import without a licence; selling unsafe/unsanitary imported food).
- Creation of offences and associated penalties.
- Import requirements and obligations for importers (e.g. primary responsibility for safe food, implementation of GIP, imported food notifications).
- Government authority and specific powers (e.g. importer inspections, product sampling and analysis, seizure and detention, establishment of fees, bilateral arrangements).
- Authority to develop and promulgate regulations that may include requirements for cost-benefit analysis, stakeholder consultation, inclusion of international standards, and review by the legislature.

Primary legislation, which is normally approved by the legislative arm of the State, is generally broad in scope (i.e. applicable to all food produced, sold or distributed in the country) and will frequently apply to imported food controls. Provisions directly related to imported food control may be a limited number of sections included in primary food control legislation.

Generally, the scope of primary legislation describes the product or products, activities, areas and responsibilities covered by this legislation. Secondary legislation cannot go beyond the scope of primary legislation.

Developing or modifying primary legislation can be cumbersome, often involving long procedures at the Parliament or Assembly of the State. However, sound primary legislation is essential for implementing imported food controls as it establishes the core obligations and responsibilities required to effect the system.[30]

Implementation of primary legislation frequently requires the development of "secondary" or "implementing" legislation (e.g. regulations, decrees, orders) pertaining to the importation of food. Secondary legislation might be linked to general food legislation or to dedicated/sector specific food products (e.g. animal products, processed products). Secondary legislation related to imported food controls might be stand-alone (i.e. only dealing with imported food controls) or included in broader trade-related or food control secondary legislation. Secondary legislation is more flexible but it is limited in scope to the areas covered under primary legislation.

Secondary legislation for imported food controls should provide detailed principles and procedures to implement all substantive provisions included in primary legislation (e.g. GIP, authorized foods and food ingredients, registration or licensing of importers, government inspections, sampling or fees).

The level of detail and the general shape of the legislation depends on the legislative tradition of the country. Some countries enact comprehensive and detailed texts of all provisions in respect to food controls . Other countries limit the contents of the primary legislation to the enabling provisions (i.e. general principles and matters subject to the rule of law, institutional framework, obligations and responsibilities) and enact more detailed secondary legislation to implement the law.

Primary legislation will also establish the institutional responsibility for imported food controls and other operations (e.g. customs) within a country. The legislation should ensure the institutional mandates of the various institutions are as clear as possible, avoiding gaps in coverage and reducing the potential for duplication to enable an efficient allocation of resources, and consistent division of roles and mandates. The legislation should also provide authority for collaboration between institutions, and allow for coordination and information exchange. More details about desired characteristics of the institutional framework are provided in the second part of this section.

All imported food legislation should be in compliance with international commitments.

30 See: faolex.fao.org and Perspectives and guidelines on food legislation, with a new model food law, Jessica Vapnek, Melvin Spreij, FAO Legislative Study, Rome 2005. www.fao.org/fileadmin/user_upload/legal/docs/ls87-e.pdf

NOTE

Primary legislation establishes Institutional responsibility.
To provide greater assurance of collaboration, primary legislation should include:

> Authority for institutions to work with other entities (e.g. subnational, national, and international levels), as appropriate.
> Clearly established mechanisms for collaboration.
> Processes to prevent duplication and minimize regulatory burden.
> Authority to enter into arrangements (e.g. collaboration, information sharing) to ensure consistency in imported food control.
> Where reporting requirements (e.g. plans and accomplishments) are included to ensure coordination, secondary legislation should outline basic reporting requirements (e.g. industry information, level of industry compliance, human and financial resource plans and expenditures).

Compliance with international agreements, standards and principles

Countries should ensure that all imported food legislation is aligned with the country's international commitments. Countries that are members of WTO would have to introduce into legislation concepts resulting from the General Agreement on Tariffs and Trade (GATT), the SPS and the TBT agreements. They should also ensure consistency with Codex Alimentarius, to enhance global recognition and acceptance, thus supporting food safety and facilitating trade.

NOTE

Incorporation by reference is the act of including a second document within another document by mentioning the title or specific sections, giving legal effect to materials published elsewhere. For example, Codex Standards may be incorporated by reference into regulations, thus making the standards a legislative requirement. Documents that are incorporated by reference should be made available to all stakeholders to ensure transparency.

The internationally recognized principles of food trade are:

> integrated approach to the food chain ("*from farm to fork*");
> science-based risk management;
> traceability;
> proportionality;
> compliance with the principles of non-discrimination and national treatment (measures applied to imported food products should be consistent with those applied to domestic products so as not to unnecessarily restrict trade); and
> primary responsibility of food business operators.

Other imported food control policy requirements should also be included in legislation (refer to Section 1 for more details).

To the greatest possible extent, internationally agreed definitions (e.g. Codex definitions) should be used for key words. This will minimize problems for legal interpretation, enhance understanding by all stakeholders, augment compliance with the international framework, and facilitate trade. In cases where there are multiple definitions of the same term and no international agreement, the terms should be defined in legislation to ensure clarity for stakeholders and trading partners.

Imported food control legislation should ensure that there are appropriate definitions to minimize confusion and ensure clarity.

NOTE

Definitions

Imprecise terminology can lead to significant confusion and misunderstanding within legislative text. Common words should be defined if their variable meanings could result in confusion. For example, law may define "sell", as sell, offer for sale, or distribute (whether or not for recompense). As the common understanding of "sell" does not include giving something away for free, defining "sale" in the law is essential. Terms that often need to be defined include:

> Importer: to indicate who is responsible for imported food. Other terms that may be used include broker, trader, and consignee.
> Import authorisations: to define what authority is required. Other terms that may be used include licence, registration, or permitting.
> Imported food (e.g. food for human consumption; ingredients; dietary supplements)
> Units of imported food (e.g. lot, consignment, line object).
> Officials employed to carry out risk management actions (e.g. inspectors, auditors, analysts); employees of accredited laboratories or other officially recognised inspection bodies.

Transparency

NOTE

Transparency in practice

Transparency is facilitated with regulations and supporting policy that are clearly written, easily accessible and where officials can be contacted for clarification where needed. Transparency should include:

> Public participation in the development of primary and secondary legislation.
> Easy availability of requirements to the public and all interested parties.
> Transparent and available decision making, that provides the process and rational for specific decisions.

To facilitate the transparency of imported food controls, the primary and secondary legislation, as well as imported food control policies and procedures should be publicly available. Legislative requirements for transparent decision making enhances the accountability of officials, ensuring maximum adherence to imported food control procedures. Where needed, the legislation should specify that the reasons for decisions (such as import permits, imported food refusal, inspections, analysis or recalls) should be clear and made available to food businesses or importers.

Transparency facilitates compliance with and understanding of the imported food controls.

Flexibility

NOTE

Delegation of authority: a tool for flexibility

Imported food control legislation may allow authorities the option of commissioning or delegating some of their statutory functions (e.g. inspections, analysis) to a public or private entity.

Delegation can be used to commission border controls, analysis or inspections, and can be a very useful tool for government with limited human resources or laboratory facilities. Primary legislation should have authority to enable commissioning or delegation, and should be implemented according to written policies and procedures.

Legal frameworks should be sufficiently precise to clarify roles, responsibilities and to establish appropriate authorities, but sufficiently flexible to enable adaptation to new situations.

Legal frameworks should be sufficiently precise to clarify roles and responsibilities, and, at the same time, sufficiently flexible to enable adaptation to scientific development or new findings, or changing programme requirements.

To this purpose, countries should consider the need for flexibility when drafting their regulatory requirements. Some countries, following their legal tradition, tend to enact very detailed and prescriptive regulations. Other countries establish minimum common rules and outcome-based requirements, leaving more flexibility for the private sector to meet those outcomes. Food regulations frequently require flexibility to allow imported food controls to be adapted as new international standards are implemented, or to address new scientific developments. Regulatory requirements detailing government actions in response to a food threat should be drafted in a manner that provides flexibility for the government to take actions based on the level of risk.

Regulations should also provide flexibility to facilitate delegation of functions to public or private entities to ease effective delivery of imported food controls.

Food businesses, stakeholders and other public participation

Importers need to understand their responsibilities for imported food and should have an active role in development of legislation.

The responsibility of the food industry is a very important principle of food safety legislation; food businesses are considered to have the primary responsibility to ensure their food meets regulatory requirements. Therefore, food businesses need to understand and implement the imported food safety requirements.

Importers are a key part of the imported food control system, and as such they should have an active role in food governance, particularly in the development of regulations pertaining to imported food controls. Countries should provide opportunities for all stakeholders to participate in regulatory processes, and should encourage their participation. This includes standard setting, as well as awareness raising, information sharing and consumer protection activities.

Technical elements

Standard setting

Legislation should provide authority for establishing food safety and quality standards. However, food standards are not specific to imported food, and they should apply to both domestic and imported foods. Where legislation provides authority to establish imported food standards, care must be taken not to duplicate the domestic standard making authority, as it could create inconsistencies and contravene international agreements (e.g. WTO).

Principle that importers are responsible for imported food should be established in legislation

Importers' responsibilities

It is important that key principles of imported food controls are established in primary legislation (e.g. food businesses, including food importers, are responsible for ensuring their food meets regulatory requirements).

Generally, this is accomplished by establishing an obligation for the food business (importer) to ensure that all imported food meets the regulatory requirements, and by establishing obligations that the food business (importer) is required to notify the specified authorities with respect to non-compliance.

Other obligations may include a responsibility to recall products that are found to be, or are suspected of being, non-compliant with regulatory requirements, and to maintain the traceability of imported foods. If these obligations are established in primary legislation, more detailed processes and procedures may be established in secondary legislation. Legislation should also include the principle pertaining to costs, such as the costs of recall should be borne by the importer.

Obligations such as notification, traceability, recalls, and foreign supplier verification should be included in legislation.

Importers' foreign supplier verification programme

Legislation may specifically require importers to assess their foreign suppliers as part of pre-border import controls. The requirement can be drafted as a prohibition (e.g. no person shall import unless they have assessed that the foreign supplier meets importing country requirements). Alternatively it can be drafted as an import requirement, either in the provisions referring to import requirements or as part of the licensing conditions (e.g. prior to being issued a licence, the importer must have a process in place to verify foreign suppliers).

Importers may have to source from countries or foreign food businesses which comply with production standard of the importing country.

Legislative requirements should include minimum requirements of a foreign supplier verification programme (e.g. level of sampling and analysis validating imported products). They should also provide importers with a range of acceptable options to meet the requirements (e.g. large importers may choose to use their own employees or agents to assess foreign suppliers; others may use third parties or an exporting government organization).

Pre-border risk management actions

Programme design may include a number of pre-border risk management actions that should be authorized by legislation.

Arrangements with foreign authorities

Legislation should authorise the competent authority to enter into arrangements with exporting country including establishing the conditions.

Recognition of foreign food safety systems requires the competent authority to have the legislative authority to enter into arrangements with foreign competent authorities and to implement conditions in the arrangement.

Generally, primary legislation will identify the authority and key elements of the agreements, while secondary legislation will outline the detailed procedures for initiating, maintaining and terminating the authorized agreements with foreign authorities[31]. Some countries may choose to include key obligations, such as information exchange, in primary legislation.

The legislation may also establish requirements for:

> Assessment of the foreign food control system, although this may be included the text of the bilateral arrangement.

> Reduced oversight for imported food produced under the controls of the competent authority in the exporting country.

> Enhanced oversight for producers not certified under the arrangement (e.g. 100 percent of lots) or prohibiting the import of high-risk foods (e.g. molluscan shellfish) with no certification.

> Certification[32] either lot-by-lot or alternative means (e.g. official list of certified processers in exporting country).

Border controls

Based on programme design, the legislation should authorize the competent authority to make admissibility decisions (see Section 2 'Border Controls') with respect to food presented for import. It should also include whether the admissibility decision will occur before the product arrives at the border (based on pre-notification); when the product arrives at the border or equivalent (e.g. bonded import warehouse); or when the product arrives at the importer's warehouse.

Legislation should authorize the competent authority to make admissibility decisions.

Legislation should authorize import requirements such as notification, document and/or identity checks, and refusal of inadmissible food.

Legislative requirements may include:

> prohibiting or limiting entry for particular categories of high-risk food or food ingredients;

> mandatory notification of imported food consignments or lots;

> preclearance processes, particularly for perishable foods;

> document checks to validate imports, including validation of certification; and

> refusing entry or disposal of inadmissible food.

31 Guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems (CAC/GL 26-1977).

32 Guidelines for design, production, issuance and use of generic official certificates (CAC/GL 38-2001).

In addition, legislative requirements should establish:

> Who is responsible for providing the information (e.g. importer, custom broker, consignee, customs services), and what information is required (see Imported food and importer profile in **SUPPORTING TOOLS AND GUIDANCE 2.1**) Documentary requirements are often established both in food legislation and within customs legislation. In the latter case, information is subsequently provided to import control officials under an arrangement.

EXAMPLE

The importer shall provide [name of the organization] written notification of each shipment of food to be imported that will include the following information: [see Section 2]

> Who is responsible for reviewing the import documentation (e.g. the customs officers, food import control officials, or both). What is the process(es) for release by customs (e.g. custom officials may release food based on custom requirements at a border point but require it to be moved to a bonded or importer warehouse, and subsequently subject it to a risk based review under the food import controls), and when this takes place.

Legislative requirements should establish responsibility for providing and reviewing documentation, decisions to inspect or sample product and to allow or reject import.

EXAMPLE

On release by customs officers, all consignments of imported food shall be held at a bonded warehouse for a decision by [name the imported food control organization].

> Who is entitled with, and the process for, rejecting and/or disposing of food that does not comply with the established requirements, and is presented for import (e.g. customs officers, imported food control officials) and who bears the cost of any associated transport, storage or disposal?

EXAMPLE

Food control officers are responsible for enforcing food control regulations established by [name the authority] and prohibiting ineligible foods from entering the country through any border point.

> Who is responsible for making inspection decisions based on programme or regulatory requirements and who is responsible for implementing the inspection or sampling and analysis (e.g. customs services, imported food control officials, or a third party service provider). It may also specify conditions about the lot or consignment pending the results of the inspection or analysis.

Authority for Inspections and controls

Another key element of imported food control legislation are the provisions addressing the government's responsibility for monitoring compliance and taking enforcement action where needed. Based on programme design, governmental institutions may carry out all inspections and controls, or designate one or more

The legislation should include the competent authorities' responsibilities for monitoring compliance and taking enforcement action.

private organizations to undertake the oversight of imported food, within legislative authorities.

EXAMPLE

An inspector may, at any reasonable time, enter any place where any imported food, subject to this law or regulation, can be found, and inspect, examine and take samples, examine and make copies of any documentation, records or parts thereof that are relevant to the imported food, and seize and detain as necessary, where the requirements of this law and regulations have been contravened.

The authority and powers required to carry out inspection functions should be established in primary law, particularly those authorities which may compromise fundamental rights, such as the authority to enter into premises, take samples, confiscate items or restrict business activity. Given that such powers could potentially affect or limit constitutional rights and freedoms of their citizens, they are generally discussed and passed by a legislative body.

The legislation will generally establish:

> The competent authority(ies) by designating the name(s) of the organization responsible for oversight inspections, and rules on the appointment of inspectors.

> Actions the authority may undertake to monitor compliance (e.g. document review, product and premise inspection, sampling analysis) and enforcement measures (e.g. seizure, recall, revocation of licences, administrative penalties, prosecution, injunctions).

> The possibility for the competent authority to delegate or commission these activities to another entity or to a third party service provider.

> Penalties for contravening the law (e.g. establishment of maximum fines or prison sentences after prosecution).

Specific authorities related to the declaration and management of food safety emergencies are generally provided in legislation, as greater authority may be needed to control, manage and report on the issue (e.g. ability to make an emergency prohibition on importing food). Legislation should identify who can declare the start and finish of an emergency and approve emergency measures. Legislation should expedite decision making in emergency situations as well as appropriate risk communication and transparency. These measures should be proportionate to the risk, time-limited, and be removed once the emergency is over.

Delegated import control

Where imported food controls include the delegation of specific public functions to other public or private entities, provisions enabling delegation will be included in primary legislation, with further details of the delegation addressed in secondary legislation.

NOTE

Delegation in practice

Legislative authorities and requirements should include eligibility, activities that can and cannot be delegated, mandate and reporting duties of persons or entities selected for delegation, and monitoring and inspection of delegated activities.

Delegation should be limited to those functions that do not involve the exercise of public sovereign duties, for example the signature of official documents should not be delegated.

Role of third party service providers

Service providers may assume a public function (by means of delegation) or be recognized as certifiers of product compliance with national requirements, product or process standards. Legislative requirements may set out the roles (e.g. sampling, analysis, inspection), responsibilities, accountability and reporting requirements of third party service providers, as well as minimum requirements for service providers to be authorized (e.g. accreditation). It should also outline how the recognition will be removed, should the service provider fail to meet established standards. Alternatively, requirements may be incorporated by reference to an external standard (e.g. ISO; domestic accreditation standards).

Where imported food controls include third party certification, legislation has to provide guidance on how certification will be undertaken, and how this can be used by the competent authority (e.g. potential for reduced oversight where product is certified by a third party).

The use of third party service providers within imported food controls must be authorized by legislation, that should also establish requirements, such as accreditation of third party service providers.

Post-border/in-country controls

There should be legislative authority for all in-country imported food controls, and in particular, all importer requirements. Importer controls may include requirements for registration, acquiring import permits, or having an import licence in addition to establishing associated conditions. These conditions may be drafted either as a prohibition or as requirements (all importers must have a licence). Associated requirements might include mandatory fees, mandatory implementation of GIP (see Section 2, SUPPORTING TOOLS AND GUIDANCE 2.5) or foreign supplier verification. They could also include mandatory requirements with respect to validation, and verification that imported food meets all regulatory requirements, record keeping, and traceability.

Legislation should include authority for all in-country imported food controls such as importer licences or GIP.

EXAMPLE

No person shall import food without:

> being registered
> holding an import permit or
> holding an import licence.

Imported food importer and exporting country profiles

Knowledge of imported food and importers is critical in implementing risk based imported food controls. Officials will require legal authority to gather information, or require food businesses to provide information in order to build and maintain imported food and importer profiles (see Section 2). For example, legislation could authorize officials to set up and maintain a registry of importers and/or imported food.

Legislation should provide authority for official to access and review the importers' documentation.

Legislation should establish the authority for imported food control officials to access (e.g. may inspect) importers' documents (e.g. books, invoices, written procedures, computers) during product or premise inspection. Legislation should also specify the documents and information that importers have to make accessible, when, and in what form. While primary legislation should establish the food business obligation to maintain and report information, more detailed information on record keeping requirements is generally established in implementing regulation, including:

> what information, documents and records must be maintained;

> who is responsible for maintaining documents;

> where they must be maintained and for how long.

Collaboration among institutions

Where multiple institutions are involved in imported food controls (e.g. multiple national institutions, national, subnational governments) coordination among these institutions is important. Legislation should include mechanisms to ensure communication and collaboration between and among institutions to minimize duplication, avoid overlaps and gaps, and provide for effective and efficient controls.

Legislation should include authority and mechanisms to facilitate cooperation and information exchange among competent authorities and other institutions with responsibility for imported food.

Legislation should include authority for sharing information, whether that information is gathered by a government institution or submitted to the government by a food business. For example, countries that have established customs services as a single window for all importers will require legislative authority for those customs services to share information with imported food control officials. Where food businesses are required to provide information, legislation should also specify that officials protect private information from public distribution.

Fees

Fees (also see Section 4) imposed within imported food controls must be authorized by legislation. The authority to approve, modify and collect fees is generally included in the law. The actual fees (e.g. amount) might be set in secondary legislation and include a mechanism to facilitate their revision and update. In establishing fees, it is important that the amount is proportionate to the service provided (e.g. importers pay for the cost of a specific import control activity) and the law clearly stipulates how any fees will be established and collected (i.e. procedures), including potential exceptions.

Legislation should authorize all fees associated with the imported food controls.

NOTE

Legislation may establish fees as follows:
> A fee for a service (e.g., importer licence fee is X$)
> An hourly inspection cost (e.g., inspections – X$ per hour) or the full cost of an inspection (e.g. X$ per importer inspection for GIP)
> A fee for kilogram weight imported, generally a very small amount (e.g. X cents per kilogram).

Where importers are required to engage and pay for third party service providers, the government has a responsibility to ensure that the fee for service is appropriate.

NOTE

Where there is limited third party capacity, fees may be set in legislation, commensurate with the cost of the activity or service. In some cases, third party service providers may be required to provide the government with evidence of costing.

Sampling and analysis

Legislation should clearly establish authority for product sampling and analysis, including who is responsible for taking and analysing samples.

Legislation provides authority to officials for product sampling and analysis. This includes establishing authority to designate and use official laboratories or, where appropriate, recognize third party laboratories, which may be either domestic or in an exporting country.

Legislation may authorize third party laboratories to undertake sampling and analysis for monitoring purposes. However, sampling and analysis for enforcement action is generally restricted to government officials. As described in 'The role of third party service providers' above, legislative authority should establish designation and accreditation requirements for laboratories, and the processes and procedures to remove such designation and/or accreditation.

Enforcement

Legislation should clearly establish controls such as licence withdrawal, seizure and detention, with respect to non-compliant importers or imported food.

Legislation should clearly establish the authorities required to implement control over non-compliant importers or imported food, particularly when the powers granted may compromise importers' fundamental rights. These include the power to suspend or revoke import authorizations, to refuse entry of food, to seize and detain non-compliant product, to destroy non-compliant food, to levy administrative fines or penalties, to prosecute importers and seek court imposed penalties, and to request court injunctions against importers. More detailed legislative requirements for mandatory recalls, public notifications or seizures are generally established in regulations.

Where there are specific legal requirements pertaining to sampling (e.g. chain of custody) or analysis (e.g. official procedures) for enforcement actions and prosecutions, these requirements are generally specified in regulations. This may include incorporation by reference of analytical methodology or specific requirements for sampling procedures.

Recourse or Appeals

Because regulatory decisions and enforcement actions within imported food controls may impact importer's rights and freedoms, the legislation should incorporate appeal mechanisms and/or opportunities for review of official decisions on consignments.

The authority to establish an appeal process is normally included in primary legislation, and can be further detailed in separate food safety or general administrative procedures. Appeal processes and procedures must be seen to be fair and transparent, and support the credibility of the programme. Depending on the national legal system, administrative appeal processes might be a necessary step prior to initiating a legal appeal through the Courts. Legislation may provide for first stage administrative appeals, which can include:

1. An informal appeal where a food business communicates, either verbally or in writing, to seek clarification of actions taken by officials. In such cases, the officials should document their response to the food business.

EXAMPLE

Under the **Fish Inspection Act (Canada)** "… the importer may, within 60 days after that suspension or revocation, request in writing the President of the Agency to determine whether the licence should be reinstated." The procedures for reviewing the licence revocation are set out in policy.

2. Formal appeals normally start with a request for reconsideration to the authority that made the decision (e.g. a food business may contest an alleged incorrect application of a procedure). In such cases, the appeal would be reviewed by senior officials, possibly including a representative nominated by the food business.
3. Legislation might also open the possibility to use alternative dispute resolution mechanisms. In this case, specific food safety legislation, commodity legislation or general legal procedures legislation may set up a mechanism for the establishment of an independent board to hear complaints or appeals. Such legislation would include:
   - Establishing the board (e.g. qualifications, conditions of the appointment).
   - Powers of the board (e.g. establishing procedures, examining evidence, witnesses, production and inspection of documents).
   - Authority to impose penalties (e.g. fines).
   - Legal effects of the decisions of the board.

EXAMPLE

The **Canada Agricultural Products Act** establishes a Board of Arbitration to hear complaints relating to regulatory failures for imported products. The procdures followed by the Board are established in regulation.

INSTITUTIONAL FRAMEWORK FOR IMPORTED FOOD CONTROL

Food safety and QCs performed over imported food products provide assurance that these meet all regulatory requirements of the importing country. Depending on countries' institutional framework for imported food controls, there might be one or more competent authority involved. Although many variations exist, coordination and effective sharing of information between all institutions that have responsibilities for imported food controls is critical for effective implementation.

In addition, during the import process of food products there are other controls performed (e.g. animal health and welfare, plant health, as appropriate, and customs tariffs and duties). Although they are of a different technical nature from the ones considered in the scope of this manual, all these activities require some coordination and information sharing in order to maximize efficiency and minimize disruption and additional costs to food businesses, as the additional costs generated are inevitably charged to the final consumer.

Coordination and information sharing

Imported food controls are most effectively implemented where the competent authoritiy(ies) (imported food safety and quality) and institutions' (e.g. animal health, customs services) mandates (e.g. objectives, powers and responsibilities) are clearly established in legislation; and they coordinate their operations and share information. This includes both government and private organizations where applicable (e.g. importers, third party services providers).

While these appear fairly basic, they can be very challenging to implement. Countries should consider the following general recommendations:

> Unambiguous mandates in primary legislation, without contradictions between different texts (e.g. between mandate descriptions in food safety or sectoral legislation and mandate descriptions outlining responsibilities of a ministry).

> Clear procedures to identify any existing or emerging gaps or overlaps, to implement appropriate collaborative processes to minimize duplication (e.g. if both animal health and food safety require the same information, one organization should collect and share it).

> Appropriate use of coordination mechanisms, such as memoranda of understanding for collaboration, or clear agreements for delegation of authority.

> To the greatest possible extent, one national, common imported food control programme (based on risk).

The multiple institutions involved in the importation of food must have clearly established roles and responsibilities including coordination of operations and information sharing.

Institutional framework

This section outlines some common variations for institutions involved in imported food controls. However, it is not intended to be exhaustive, and each country will need to assess its own unique situation and organize its institutions appropriately.

In general, there may be several institutions involved in imported food controls, and regulatory and implementing powers might be distributed at the supra-national level, the national level, or a combination of national and local levels.

Supra-national or regional institutions

Where there is significant multi country trade within a region, countries may consider developing a supra-national or regional approach to imported food control, to enhance consistency in controls and facilitate trade.

Where there is significant trade integration and either a trade agreement or a food safety agreement among countries in a particular region, governments may consider managing imported food controls (or parts thereof) on a supra-national or regional basis. For example, the EU has established a community framework for official controls applied by the competent authorities of member states.

Implementing supra-national import controls, or adopting a common framework or approach, can improve the efficiency and effectiveness of border controls, allowing more resources to be assigned to imported food safety, and facilitating trade among countries. It can also enhance ongoing communications between the import control services, enhancing consistency in the application of imported food controls.

Supra-national import controls also strengthen the negotiation position with exporting countries, and can improve the standard and safety of exported and imported food.

The establishment of formal arrangements (See Section 2, SUPPORTING TOOLS AND GUIDANCE 2.3) among countries or appropriate institutions will be a key requirement for any successful implementation.

National institutions

In most countries, imported food controls are national in scope, in that the controls apply to all imported foods, all parts of the county, all ports of entry and all districts. A single national import control programme administered and delivered by the designated competent authority(ies) ensures consistent imported food controls across the country.

The responsibilities assigned to the imported food control competent authority(ies) are often consistent with those established for domestic food controls (i.e. if domestic food controls are commodity based, so are imported food controls).

A single competent authority provides a greater focus on food safety, ensuring imported and domestic food meet the same standard, and consistent implementation of food safety programmes.

Single food control competent authority

Many countries have chosen to consolidate imported and domestic food safety by having only one competent authority responsible for controls on imported and domestic food.

NOTE

It should be noted that although there are many references to countries having "one" organization performing controls over food, the concept of "one" is somewhat inaccurate, as a country will have other border controls managing the flow of people and products (e.g. immigration control, customs).

Keeping the focus on food safety ensures:

> That both imported and domestic foods meet the same standards.

> Consistent implementation of food safety programmes.

> More effective application of risk based programming and use of resources and expertise (e.g. laboratories and infrastructure).

Generally the mandate of this single competent authority covers food safety and quality, but there are many variations.

Multiple competent authorities system

Another frequent approach is having multiple competent authorities responsible for food safety and quality, whose legal mandates include responsibility for food safety in different stages of the food production chain. In these jurisdictions, more than one competent authority may have a role in imported food control.

The division of responsibilities for imported food control can also be based on different regulatory objectives (health, trade, agriculture) established by a national government or by division of responsibilities between national and subnational governments. In these situations, the multiple competent authorities share legal mandates to monitor compliance with food safety and quality requirements.

Where multiple competent authorities are involved, it is important to find administrative ways to minimize duplication (e.g. importers required to obtain licences or permits from multiple institutions such as the Ministry of Agriculture, the Ministry of Health, the Ministry of Trade, Chamber of Commerce; importers being inspected by multiple institutions) and to maximize collaboration and information exchange (e.g. one licence issued by customs services on behalf of all relevant institutions), following a clear process whereby potential food safety issues are not overlooked because of other concerns (e.g. fiscal, commercial).

Countries that establish multiple competent authorities should ensure collaboration and cooperation to ensure consistency across commodities and minimize duplication.

Some countries may have commodity-based imported food control competent authorities. For example there may be one institution dealing with imported fish, another dealing with imported meat, and a third dealing with all other food imports. Frequently, where commodity based import controls are in place, the competent authority dealing with imports is also responsible for both domestic production and export requirements of the same commodity. Such national competent authority(ies) generally facilitate consistent programme design and cost effective delivery within the specific commodity, however, similar risks may be addressed differently between the commodity institutions.

In multiple competent authorities systems, overlapping mandates can result in duplication (e.g. two agencies inspecting the same importer), and increased administration costs (e.g. human resources, training, procurement). To prevent this duplication, all competent authorities should work to develop an integrated framework that can facilitate collaboration and coordination, without necessarily restructuring and reorganizing. This integrated framework will facilitate information exchange about importers and imported food, can be used to ensure consistent risk

management approaches across commodities, and minimize duplication. Formal arrangements (See Section 2, SUPPORTING TOOLS AND GUIDANCE 2.3) between all competent authorities are generally a key requirement for any successful implementation.

Many countries with states, provinces or districts will have both national and subnational competent authorities.

National/subnational governments

Where countries have a division of powers between national and subnational governments, it is very likely that there will be multiple competent authorities involved in imported food controls. In most of these situations, the primary control of imported food (i.e. pre-border and border functions) is the responsibility of the national government.

EXAMPLE

> The United States Food and Drug Administration (USFDA) is responsible for imported food and food in interstate commerce; the 50 US state governments have responsibility for food in commerce within their state.

> Canada Food Inspection Agency is responsible for imports, exports and interprovincial trade of food; while the 13 provincial and territorial governments are responsible for food, including imported food sold within the province or territory.

Formal and transparent reporting requirements will contribute to consistent and effective implementation.

Subnational governments generally assume responsibility for in-country controls within their territory. In some cases, however, subnational governments may be delegated the responsibility for implementing border controls and reporting results to the national government. In such instances, it is important to develop and maintain arrangements between the two levels of government to establish roles and responsibilities, ensure collaboration and minimize duplication.

Because subnational governments are generally responsible for all food sold within their territories, they can be more effective and efficient implementing "in-country" controls. This can include monitoring (e.g. sampling and analysis of imported food at importers' premises or on the domestic market) or inspection (e.g. GIP). Subnational governments can also integrate the "in-country" approach into their public education activities and industry capacity building. However, without a national framework, delivery of in-country controls can result in fragmented implementation (e.g. different approaches and levels of controls) based on differences in the capacity and the efficiency of the subnational governments.

Coordination and information exchange between national and subnational governments is very important because of the number of competent authorities that may be involved. Successful implementation will require coordination and information exchange between the national and subnational government competent authorities and among subnational competent authorities. Clearly established roles and responsibilities, and coordinating mechanisms will be needed to ensure effective delivery of the imported food controls and reporting between the two levels of government. Formal and transparent reporting requirements will also contribute to consistent and effective implementation.

EXAMPLE

Coordination and information exchange: EU member countries should prepare and report on their multi annual national control programmes (MANCPs), where coordination and reporting mechanisms are clearly explained, in support of well targeted control programmes, with specific objectives, detailing which controls should be operated by which competent authority, and on what. Import controls are part of these MANCPs, along with domestic controls.

Other institutions [33]

In addition to food safety and QCs, a country may have other institutions with responsibility for imported food. All these institutions should ensure that there is ongoing communication and, where appropriate, collaboration and task-sharing to improve effectiveness and efficiency of programme delivery.

Customs services

Customs generally have a mandate related to the protection of the country from external threats (e.g. smuggling of illegal products) and collection of revenues from legally imported products. As customs services will generally have an office at all border crossings, they have significant authority to collect information about importers and imported products, including food. Customs services are an important partner for imported food safety as a source of information on developing the importer and imported food profiles (see Section 2) as part of food safety planning. Customs services can also:

> Prevent the admission of illegal foods,

> Gather information on importers through a single window (minimize duplication).

Customs services are an important partner for all competent authorities implementing imported food controls.

Codex contact point

Countries may establish the Codex Contact point in various institutions (e.g. the food safety control body, the agricultural ministry or the standardisation body). Notwithstanding the institution appointed as the contact point, imported food control officials should work with the body in respect to input/participation in the CCFICS.

Public health surveillance

Imported food safety control institutions should collaborate on an ongoing basis with authorities responsible for Public Health Surveillance within the country, particularly with respect to sharing information about food-borne illnesses.

Collaboration and information sharing on domestic and international instances of food borne illnesses.

33 Non food safety and quality controls.

Institutions responsible for plant health, animal health and other international arrangements

Imported food safety control institutions should collaborate with institutions responsible for implementing other international arrangements (e.g. IPPC,OIE, the Convention on International Trade in Endangered Species of Wild Flora and Fauna[34], Illegal, Unreported and Unregulated Fishing[35]), or institutions responsible for plant or animal quarantine.

Other institutions implementing international arrangements can be sources of information to improve the effectiveness and efficiency of information gathering.

This collaboration can include:

> Consistent and common information sharing mechanisms and procedures for importers of animals, plants and their products, to improve efficiency and reduce duplication.

> Information exchange on the situation in foreign countries with respect to the use of chemicals or disease outbreaks that might lead to prohibiting or restricting food imports.

> Validation that imported fish was caught legally, with appropriate food safety oversight during processing.

Primary production institutions

The institutions responsible for primary production (including agriculture, livestock and fisheries) generally provide market support to producers (e.g. farmers, fishermen) that may include support and recommendations for improving primary production and, in some cases, export certification (e.g. for IPPC or OIE purposes).

Where primary production institutions have overlapping mandates (in particular for export certification) collaboration and information exchange with the competent authority can improve efficiency.

Imported food control competent authorities should assess the benefits of collaboration and information exchange with institutions responsible for supporting primary production industries.

Standardization, conformity assessment and accreditation

Some countries have established standardisation bodies that have legal responsibility for developing product (e.g. electrical) and process (e.g. accreditation) standards that may be included in regulation (e.g. incorporation by reference). These institutions may also have responsibility for establishing and implementing standards for domestic and imported food.

Some industry associations (e.g. British Retail Consortium) have established private standards, including conformity assessments and certification to ensure that imported food meets regulatory requirements (e.g. foreign food suppler verification). Implementation of standards by food businesses should be taken into account in implementing risk management actions (see Section 2).

34 www.cites.org

35 Most countries have agreements in place to prevent the import of illegal, unreported and unregulated fishing practices managed as part of fishing quotas.

Standardization bodies or an industry association may also establish requirements for conformity assessments, including process for assessing and recognizing organizations capable of undertaking conformity assessments. In such instances, there may be an opportunity for collaboration and information exchange with the institutions responsible for imported food control. The imported food controls may also take industry standards into account in risk categorization, particularly for foreign food supplier verification.

Coordinating activities between imported food controls and recognized conformity assessment bodies can increase efficiency and minimize duplication. This will generally require arrangements between the imported food control and standardization organizations to establish roles, responsibilities and information sharing. In other cases, the imported food control incorporates such assessment bodies to deliver import controls (see Section 4).

Coordination of activities and information exchange between the competent authority and recognised conformity assessment bodies can increase efficiency and reduce duplication.

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SECTION 4

IMPORTED FOOD CONTROLS – SUPPORT FUNCTIONS

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INTRODUCTION

The objective of this section is to assist competent authorities in understanding the key functions required to support an imported food control programme, and key considerations in developing and implementing them. As outlined in Section 2 (Imported food control framework) and Section 3 (Legal and institutional frameworks) countries must understand there is no "one size fits all" template approach. Each country will present a specific situation, not only with respect imported food controls (e.g. legislation, competent authority(ies)) but also within broader government institutions (e.g. customs services, animal health, domestic food control). However, there are key functions of imported food controls that countries should take into consideration in developing, implementing or improving imported food controls, which may be part of a broader food control programme.

Imported food controls need appropriate management of program design and delivery and inspection, scientific, legal, administrative and human resource support functions.

As noted in Section 2, imported food controls should be structured as a programme, including central management of programme design and delivery; and appropriate inspection, scientific, legal services, administrative, and human resources support functions. It is the integration of all the support functions that will ensure imported food controls are effective in achieving the government's objectives. This means a focus on activities that will achieve the greatest food safety outcome.

Figure 6 outlines the key components of imported food control support functions.

FIGURE 6 **KEY COMPONENTS OF IMPORTED FOOD CONTROL SUPPORT FUNCTIONS**

MANAGEMENT SUPPORT FUNCTIONS

CENTRAL MANAGEMENT
- System analysis, planning and reporting
- Risk based programme design and maintenance
- Programme management, coordination and response

TECHNICAL SUPPORT FUNCTIONS

SCIENTIFIC SUPPORT
- Scientific advice
- Analytical services

INSPECTION SUPPORT
- Pre-border
- Border
- Post-border

OTHER SUPPORT FUNCTIONS

LEGAL SERVICES SUPPORT

ADMINISTRATIVE SUPPORT
- Financial
- Location
- Transport
- Procurement
- Other polices and procedures

HUMAN RESOURCES

Most countries will have some or all of the support functions outlined in Figure 6 in place, in some form or another. Building a comprehensive system will take time, thus it is important to build on what already exists, assess the existing components in a systematic manner to identify the gaps, and follow this with the development of a multi year plan for improving the imported food control support functions.

NOTE

Imported food controls are rarely the sole responsibility of an institution or competent authority, but are mostly delivered by institutions with other food safety responsibilities (e.g. import-export controls, or domestic food safety controls). Some support functions (e.g. scientific advice, analytical resources) are generally shared between domestic and import control programmes.

CENTRAL MANAGEMENT

Central management provides a critical integration function for imported food controls. Central management designs, implements and manages the appropriate mix of risk management actions based on the legal authority and within the legal and institutional framework established by the government. Central management is responsible for establishing goals and objectives for the imported food control programme, including design and redesign, stakeholder engagement and national or international arrangements[36].

Central management designs, implements and manages the appropriate mix of risk management actions.

Generally central management is responsible for establishing priorities for imported food controls, for identifying the scientific advice required, and coordinating the appropriate government oversight (e.g. inspection, sampling and analysis requirements). In addition, they are responsible for ongoing information management, administration and human resources. The central management activities needed to carry out their responsibilities can be described as:

> Information gathering, systems analysis, planning.

> Risk based programme design and maintenance.

> Programme management, coordination and response.

Information gathering, system analysis and planning

Central management must be able to gather information (e.g. develop an importer and imported food profile), and then undertake a systematic data analysis. The results of that analysis will feed into the ongoing planning and implementation processes. Where countries already have some data gathering and planning processes in place, the guidance in this section should be used to make improvements in design and implementation.

Gathering and analysing information informs the planning and implementation processes.

36 Codex Alimentarius: Principles and guidelines for national food control systems (CAC/GL 82-2013).

Most countries will begin with basic information gathering processes, often paper-based, or partially paper-based. Paper-based systems can form the core of information gathering processes about an imported food and importers for many years, especially in countries with limited infrastructure or limited resources to develop informatics programmes. Where a paper-based system is used, the focus should be on gathering and analysing the key import information (e.g. identity of importers, top 10 imported foods) rather than attempting to gather all information for an imported food, importer and exporting country profile. It is important to only gather the type and amount of information that can be effectively and efficiently analysed. Where too much information is gathered, it will take time to analyse and may delay the implementation of risk based imported food controls.

Information gathering should not exceed central management's capacity to undertake systematic analysis.

The competent authority should ensure that improvements in its information management system correspond to increased information gathering about imported food and importers. Ensuring an appropriate information management system, whether paper-based, or partially or fully computer-based, is important so that officials have ready access to the information.

The information gathered about importers and imported food should be systematically analysed within an annual planning cycle that makes the analysis available for decision making by senior management. The information analysis should assess:

> Specified information pertaining to imported food, importer and exporting country profiles.

> Science advice on hazards associated with foods, sampling and testing results.

> Results of inspection activities (e.g. audits of exporting countries, inspections of importers, border controls).

> The required legal, financial, administrative and human resources support needed to deliver the imported food controls.

Planning

Once the information analysis is complete, the results should direct priorities for imported food controls planning processes, which can be described as:

Information and the results of its analysis establish priorities for programme and operational delivery planning.

1. Programme planning.
2. Operational delivery planning.

NOTE

Inspectors (government or non government)

Resources, including the number of available inspectors, are generally considered a limiting factor in imported food controls. Planning and prioritisation is key to the effective use of the existing inspectors in delivering a risk based imported food control programme. Governments are generally reluctant to provide increased resources for imported food controls without a detailed assessment of current resources, the gap between current and required resources to deliver the programme, and the expected results (e.g. greater food safety) from providing more resources.

Programme planning

Programme planning refers to activities undertaken to assess the risk management actions of an imported food control programme with the intent of improving the programme, or to implement new risk management actions.

Programme planning is generally a multi year process, as changes to imported food controls require significant information gathering and analyses of all functions and activities across the organization (e.g. programme support, inspection support, science support). It also includes significant information gathering and situational analysis from many stakeholders including academia, stakeholders, and other government partners.

Proposed changes should be assessed for implications on results (e.g. food safety outcomes); costs (e.g. for importers, public and imported food controls); and delivery (e.g. laboratories, inspection services). The intent is to avoid unintended negative impacts while efficiently and effectively improving food safety and quality. An example of a multi year programme planning function can be found in **SUPPORTING TOOLS AND GUIDANCE 4.1**.

EXAMPLE

If seeking assurance from trading partners will be undertaken, including introduction of imported food certification with associated changes for border inspection and importers, then prioritising development of international arrangements is a programme priority. This requires analysis of the importer and imported food profile, inspection, science, administrative support and human resources to assess support requirements for the implementation and management of international arrangements.

EXAMPLE

Reviewing the number of inspectors required for imported food control is a very common programme planning function. This means analysing the number of importers, the volume of imports requiring inspection and/or sampling, and the location of imports. In addition, careful examination of existing inspection capacity and where they are located, whether they are government or non-government inspection resources, also needs to be undertaken. Assessing the estimated time for each task performed by an inspector, the number of tasks required to be performed, and ranking the tasks by risk will allow an approximation of the number of inspectors required to deliver the programme. This information can be used to re-assign inspectors to the highest risk activities, to support requests for increased resources from governments or to support programme changes (e.g. using third party or non-government inspectors).

Where partial programme changes are being considered, the assessment may be undertaken in phases, especially if central management has limited resources for either the assessment or for subsequent implementation. Recognizing the capacity for assessment or implementation, and working within that capacity, will enhance the success of any proposed changes, allowing central management to focus on key priorities.

Should a complete design or redesign be undertaken (i.e. an assessment of all risk management activities) the result is generally new imported food controls.

This will require a complete assessment of all existing imported food controls and what risk management activities will be changing (e.g. adding new activities, dropping some activities, changing delivery or regulatory requirements). It should also include an implementation plan for making the proposed changes. Consideration should be given to the involvement of an outside entity (e.g. an expert committee of external stakeholders, or an audit and evaluation team) that could lead such design or redesign processes, in collaboration with responsible authorities. Having an external lead may facilitate consultations and transparency, and enhance stakeholder support for the proposed changes.

EXAMPLE

For example, where pre-border import controls are being implemented as a new programme element, the process would include full assessment of the importer and imported food profiles, assessment of risk categorization, assessment of organization capacity (e.g. government oversight) with full engagement with trading partners, stakeholders and government officials. There would be consultation over months, if not years, to develop detailed programme guidance for importers and officials, ensure appropriate publication and distribution, and finally implementation.

Operational delivery planning

Operational delivery planning establishes the ongoing activities of inspections, importer licensing, sampling and analysis, where changes are generally based on evidence from previous years.

Operational delivery planning refers to ongoing activities including scientific advice, sampling plans, importer licensing, inspection and coordination. In most imported food control programmes, the majority of programme activities remain consistent from year to year, with some changes where required to improve the programme or respond to changing circumstances. Changes result from assessment of the evidence from the previous year's activities (e.g. if delivered as designed; whether results indicated food safety objectives were met). Operational planning generally reprioritises inspection and analytical resources to the highest risk, thus ensuring effective and efficient delivery.

Operational planning is an integral function of the import control programme, and most countries will have some form of operational planning in place. Operational planning is generally based on a predetermined information gathering/reporting, analysis and planning cycle over 18 or 24 months, structured around the annual financial year. An example of annual planning can be found in SUPPORTING TOOLS AND GUIDANCE 4.1.

Programme design and maintenance

The competent authority is required to provide readily available documented guidance on standards and process for external and internal audience.

Risk management actions are combined to form the country specific imported food controls.

Programme design and maintenance is responsible for ensuring there is readily available information for both external (e.g. industry, consumers) and internal (e.g. inspectors, analysts) audiences. The information will have to be documented, such as importer guidance documents or SOPs for inspectors.

Importer guidance

Importer guidance documents should be detailed enough for all importers to understand the basic requirements for the importation of food. They should also provide policy statements outlining the objective of each requirement. In addition, they should provide points of contacts (e.g. name and address of responsible officials, email addresses) for obtaining further information.

Four examples of importer guidance documents are set out in **SUPPORTING TOOLS AND GUIDANCE 4.2**.

Guidance can include importer guidance and SOPs for officials.

EXAMPLE

Where an imported food control programme requires that the importer is licensed or registered, or to apply for an import permit:

> There must be guidance for importers on obtaining the required authorisation.

Inspection delivery guidance

Inspection personnel guidance is generally developed as SOPs that include detailed information and procedures. Detailed SOPs enhance the consistency of programme delivery. There should be one or more SOP for every risk management action included as part of the imported food controls. An example of a SOP is set out in **SUPPORTING TOOLS AND GUIDANCE 4.3**.

Programme management and response

Imported food control programmes require a programme management and response function because it is impossible to provide guidance to importers and programme delivery personnel for every possible situation.

Programme management and response provides operational guidance and ensures ongoing collaboration between inspection, delivery and laboratories to respond to issues and provide direction.

EXAMPLE

There needs to be ongoing communication between programme management and the laboratories undertaking food analyses. This will enable laboratories to understand and meet the import programme requirements (e.g. new testing requirements), thus enhancing planning and preparations (e.g. testing protocols, maintenance schedules, staff requirements, and equipment investments).

Programme management and response is an operational function between central management and programme delivery personnel to respond to issues, manage collaboration and provide direction on emerging situations at the national and international level.

Programme management requires ongoing communication and collaboration with international trading partners, particularly with respect to maintaining bilateral or multilateral arrangements. It is also important to ensure ongoing communication and collaboration with national partners to ensure smooth operations with customs services and domestic organizations. Ongoing collaboration ensures that there are no gaps, will minimize duplication and enhance consistent approaches.

Programme management responds to emerging issues and non-compliance to enhance consistency at the national level.

The programme management functions are also responsible for responding to issues of non-compliance where action needs to be taken on a national basis. The establishment of a national coordination and response centre within the programme management function allows for coordinated response. It also allows consistent programme guidance for importers and delivery personnel where new or unusual situations are identified. The programme management functions are also responsible for monitoring results and reprioritising inspection activities within a planning cycle, thus ensuring consistency. Programme management is responsible for annual reporting of the results of the imported food programme delivery.

NOTE

In order to maintain a consistent and coherent national programme, individual inspectors must not be authorized to make programme changes or alter programme management decisions.

SCIENTIFIC SUPPORT

Competent authorities will need access to science advice and analytical support.

The imported food control programme will require scientific support in order to establish and maintain risk based import controls. Generally, scientific support can be divided into two types:

> scientific advice, including the development of sampling strategies and annual sampling plans; and

> analytical support.

Scientific advice

Scientific advice is important in risk assessment or risk categorization, as well as in the development of sampling strategies and annual sampling plans.

The central management function will need access to scientific advice to develop, implement and maintain risk based import controls.

Scientific advice may be sought from international sources, other national or sub-national government institutions, or from academia. This includes using international sources such as Codex Alimentarius, and the joint FAO/WHO risk assessments (e.g. Joint Expert Committee on Food Additives (JECFA), Joint Meeting on Pest Residues (JMPR), and Joint Expert Meetings on Microbiological Risk Assessment (JEMRA)). Some countries establish a national, independent organization to provide risk assessment or scientific advice to risk managers (e.g. Food Safety Commission of Japan). In other cases, governments have created regional partnerships that provide scientific advice to multiple governments (e.g. Food Safety Authority of Australia and New Zealand, the European Food Safety Agency). Regional (supra-national) partnerships allow regional countries to pool resources for developing and providing scientific advice.

Where scientific advice is provided by another institution, the relationship with the competent authority should be formalised through a documented process or arrangement. This is important to establish the roles and responsibilities of each institution, the resources provided by them, and expectations and outputs. The

competent authority receiving the advice will need to ensure that programme officials have the scientific knowledge and capacity to understand and implement the scientific advice.

Sampling strategy and annual sampling plans

Science advice is needed to develop and maintain a sampling strategy and annual sampling plans.

Sampling strategies and annual sampling plans provide guidance for inspection personnel, but also for industry and other government stakeholders. Sampling strategy and annual sampling plans are generally based on the premise that all imported food is subject to inspection with the objective to:

> verify that effective controls have been implemented by importers in providing reasonable assurance that imported food consistently meets country requirements; and

> verify the effectiveness of the import control programme (e.g. determine if the programme is being implemented effectively or if there are porous borders).

Sampling strategy and annual sampling plans provide guidance to officials and external stakeholders.

Sampling strategy

Programme management is generally responsible for documenting the sampling strategy as part of programme planning. Once approved, the strategy is the basis for developing the annual sampling plans.

Sampling strategy identifies principles and concepts within a framework that informs the development of annual sampling plans.

SUPPORTING TOOLS AND GUIDANCE 4.4 provides two examples of sampling strategies. Although they have the same objective – to assess the compliance of imported food and importers with regulatory requirements – they have different underlying philosophies. The first considers all imported food as good order, i.e. assumes it meets import requirements. The second is based on classifying foods as either high-risk or surveillance foods.

Annual sampling plans

Annual sampling plans are generally developed as part of planning operational delivery, as they consolidate into one document all planned sampling activities and analyses. Sampling plans identify the numbers of samples to collect, give direction on the types of products to sample, and also give direction for the required analysis. They are developed and maintained based on regular reviews of sample results, coupled with information from the imported food, importer and exporting country profile, risk categorization information and other pertinent information (e.g. information from trading partners or INFOSAN).

Sampling plans consolidate into one document all planned sampling activities and analyses, including the numbers of samples to collect and the types of foods to be sampled.

Annual sampling plans generally set out the type and number of inspections (including labelling reviews) and analysis/tests to be conducted. They also establish whether sampling should be carried out as part of border (admissibility) controls or as part of in-country controls. Sampling and testing should be used as simply one tool within the risk based imported food controls, within the capacity of available laboratory resources and their analytical ability.

Responsibility for sampling and analysis

Sampling and analysis may be the responsibility of government officials, the importer or a combination of both.

In developing sampling plans and guidance documents, careful consideration must be given to the responsibility for both sampling and analysis. There are various options available for imported food control programmes that include:

> all sampling and analysis will be carried out by government personnel; or

> all sampling and analysis are the responsibility of an importer; or

> sampling and analysis are the responsibility of both government and importers, in other words the programme uses a combination of both.

Capacity of the laboratory and government officials must be considered to ensure decisions can be made in a timely manner.

In the first option, the competent authority must take into account the capacity of laboratories and government personnel so that results are obtained, and decisions on the imported food taken in a timely manner.

NOTE

As part of their oversight, government officials may take random samples to validate importer procedures, ensuring that importers do not fraudulently sample from lots or consignments predetermined to be in compliance.

In the second option, the imported food control programme may require importers to employ third party service providers, either recognized or accredited bodies. These service providers may be required to sample lots at a predetermined rate, submit the samples for analysis and provide the government with the analytical results. In such instances, the programme is building on the principle that importers are responsible for importing food that meets regulatory requirements. Where non-compliance is identified, government officials may be responsible for compliance sampling and any follow up action.

The third option can be any combination, such as requiring the importers to pay for the sampling, with government personnel responsible for carrying out the sampling and analysis.

Assigning responsibility for sampling and analysis is a programme decision and must not be changed by inspectors.

Assigning responsibility for sampling and analysis is a programme decision, within legislative authorities. It is important not to allow individuals to change the sampling decisions (i.e. if the government is responsible for sampling, individual inspectors must not be allowed to alter the programme and allow the importer to provide samples, as there will be no programme checks and balances in place to ensure the integrity of the samples).

Where importers are responsible for sampling and analysis, there must be sufficient capacity to meet these requirements.

While requiring that importers either pay for sampling and analysis or actually undertake and bear the cost of sampling and analysis makes financial sense for many imported food control programmes, it requires careful consideration before implementing. First, such action must be authorized by the import food safety laws and regulations, with sufficient rules and controls clearly established. If importers are to undertake the sampling and analysis, they must have access to sufficient third party service providers to undertake sampling; sufficient private laboratories to undertake the analysis; and sufficient oversight of the process by government

officials to eliminate, to the highest possible extent, any conflicts of interest or fraudulent practices by either the importer or the service provider.

Imported food controls may also provide for the option of the exporting country to become the third party service provider. In such instances, the exporting country may provide the importer with evidence of adequate monitoring, sampling and analysis, based on the imported food control programme's confidence in the exporting country's inspection and laboratory services.

Laboratories

The imported food control programme will also need access to analytical services as part of the scientific support function. Analytical services are necessary within import controls to assess compliance with regulatory requirements and monitor programme delivery (e.g. assess microbial pathogens, contaminants).

Competent authorities require access to analytical services to assess compliance with regulatory requirements.

Delivering all analytical services is very costly for governments, and thus the import food control programme should carefully consider the full range of options for accessing analytical services. As noted above, options include both the use of government laboratories, third party laboratories or a combination. There are advantages or disadvantages with respect to these options.

There are generally no dedicated imported food control laboratories. These analytical services are most often shared with other food control programmes (domestic controls, export certification etc.). However, this integration also means that decisions on accessing analytical services (e.g. government or third party) will generally be undertaken for all food safety controls, not simply imported food controls.

Assessment of analytical capacity should include government, academic and other third party national or international laboratories.

Determining the best option also requires an understanding of the legislative authorities governing sampling and analysis. In some instances, the law requires government testing to be carried out in government laboratories. In other instances, there is no requirement that the government is responsible for testing. Where the imported food control programme has options, then a full assessment of existing analytical capacity is required:

- domestic food control government laboratories, national and subnational governments;
- university, college and other academic institutional laboratories;
- private third party laboratories; and
- international government or third party laboratories (particularly regional trading partners).

Knowing the available capacities (e.g. tests and methodology) and the level of confidence in each laboratory (e.g. QCs, assurance or accreditation) is necessary. Any laboratory providing analytical support for import controls must be able to provide results in a timely and appropriate manner, and to fully support the analytical result in the case of any appeal.

Where the imported food control programme has access to government laboratories, there is greater control over personnel, supplies, methods, and QA. This generally provides officials with a significant level of confidence in the delivery of services. However, this requires that government laboratories have sufficient resources.

Where the imported food control programme depends on other public institutions (e.g. other national government ministries or sub-national governments) for analytical services, it will have less control over the operation of the laboratories, but still have a high level of confidence in the laboratory results if there are appropriate QA systems. In addition, the import control programme will only be responsible for some of the laboratory resources, proportional to the analytical services provided. Where the imported food control programme contracts for laboratory services with other institutions, formal agreements should be developed and maintained to outline roles, responsibilities, service standards, resourcing etc. Formalising the arrangements, along with ongoing communications, is critical to ensuring appropriate service delivery.

Where the imported food control programme contracts with academic or private third party laboratories, it must carefully consider what oversight of those laboratories is required in order to have confidence in the results. Some key principles should be considered with respect to all laboratories accessed by the imported food control programme.

> **Consistency**
To the highest possible extent, all laboratories should be held to the same standard and evaluated against the same criteria so that the results they produce are valid, accurate and reproducible.

Key principles for all laboratories used by the competent authority include consistency, confidence and transparency.

> **Confidence**
Through the use of objective, verifiable criteria, the competence of laboratories will be assessed. Confidence in laboratory results used for decision-making is essential to maintain their credibility in the view of industry, the public and other countries.

> **Transparency**
Laboratories and those who use laboratory testing services must be made aware of the standards and requirements that have to be met, and how conformity is assessed. Assessment is based on objective criteria and the outcome of the assessment is communicated to the laboratory being assessed.

The process for assessing the competency of laboratories and the results of that assessment should be communicated to industry, the public and other countries, periodically and openly.

Laboratory QA and accreditation

Laboratories used by imported food control programmes to make regulatory decisions about imported food should have adequate QA systems in place, to ensure the accuracy of their sampling and testing procedures. This applies to

both government and third party laboratories. These laboratories must be able to demonstrate that there is a Laboratory QA programme[37] in place. QA encompasses a range of activities that enables laboratories to achieve and maintain high levels of accuracy and proficiency despite changes in test methods and the volume of specimens tested. A good QA system should include:

> established laboratory SOPs for each step of the laboratory testing process (e.g. sample intake, instrument performance validation);

> clear administrative requirements, such as mandatory recordkeeping, data evaluation and internal audits;

> pre-defined corrective actions should deficiencies be found, including responsibility for implementing corrective actions.

Laboratories used within the imported food programme should have adequate QA in order to ensure the accuracy of their results.

NOTE

In some countries, QA systems are still in the process of being implemented in food control laboratories. At a minimum, the imported food control programme must have some oversight, either directly or indirectly, of all laboratories undertaking analysis for the programme. When using third party service providers, the imported food control programme should publish a list of laboratories that it recognizes as having the capacity and ability to deliver sampling and analysis.

NOTE

International standards – laboratories

Many countries have adopted ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories* as a basic standard for the acceptability of laboratories carrying out testing, as it provides an internationally accepted basis for the evaluation of laboratory competence. In addition to the ISO/IEC 17025 Standard, other criteria may also be used to cover specific testing requirements. These could include participation in programmes from selected external sources (e.g. participation in AOAC Proficiency Testing programme for pesticide residues in fruits and vegetables), along with elaborations or interpretations on the requirements in ISO/IEC 17025 in the context of the specific imported food controls.

Some countries also require that all laboratories participating in imported food controls, whether government or third party, are accredited. An accredited laboratory should have established SOPs that are routinely followed and have quality management systems in place for identifying and correcting deviations from those procedures. In order to have confidence in laboratory accreditation, the accrediting organization should be a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement, (i.e. operating in accordance with the ISO standard ISO/IEC 17011, 'General requirements for accreditation bodies accrediting conformity assessment bodies', or equivalent).

Alternatively, laboratories may need to be accredited to international standards.

37 OECD Series on principles of good laboratory practice and compliance monitoring Env/Jm/Mono(99)20.

Accreditation generally has two components: an assessment of the laboratory's general operations, and a specific assessment that the laboratory is competent to perform a specific test method(s) within the scope of its accreditation. The accreditation body will conduct periodic audits of the laboratory to ensure it is performing to standards. Such audits may include technical staff from the import control programme by arrangement between the accreditation body and the government. There should also be arrangements for the accrediting body or accredited laboratory to provide the imported food programme with the results of the audits, particularly if the accreditation is withdrawn or suspended.

INSPECTION SUPPORT

A key principle of imported food control is the responsibility for government oversight to verify that imported food and importers meet regulatory requirements (see Section 3). Government oversight is built into the programme design and can occur pre-border, at the border or post-border. The imported food control programme must carefully consider options for implementing government oversight. The generally recognized options are oversight by government officials, either import control officials or other government officials, by third party service providers or a combination of both.

Careful consideration is required to determine the most effective option for inspection support, as part of the government oversight of imported food.

Pre-border

Oversight in the context of pre-border controls is generally intended to assess the capacity of an exporting country or its industry to produce food that meets the importing country requirements.

Assessing exporting government controls

In general, inspection support for the assessment of foreign food safety systems is provided by government officials.

Assessing the food safety system in an exporting country is generally a government-to-government function. The assessment should be based on Codex Alimentarius Standards, in particular the "Principles And Guidelines For The Conduct Of Assessments Of Foreign Official Inspection And Certification Systems"[38]. Assessments are generally carried out by government officials, but may be supplemented by non-governmental technical experts.

Assessing foreign suppliers

Importers will generally use third party service providers to assess foreign suppliers, although some importers will use technically competent employees.

A third-party auditor can be a foreign government, foreign cooperative, or other third-party, and must meet standards for legal authority, competency and capacity, impartiality/objectivity, QA, and records procedures. The imported food control

38 Guidelines For The Design, Operation, Assessment And Accreditation Of Food Import And Export Inspection And Certification Systems (CAC/GL 26-1997).

programme should establish eligibility requirements (e.g. international standards or equivalent) for third party service providers and either assess those third parties against the requirements, or work with other national accreditation bodies, who will do so.

Border

Most countries have some border controls in place, particularly with respect to customs and border protection. Generally, customs are responsible for managing the border, that is making decisions on the products and persons prohibited from entering the country and those which can be admitted under particular conditions (e.g. payment of tariffs or fees, passport controls and visas). As a result, customs services generally have officials stationed at all formal border points, and some form of oversight on the entire border and other points of entry (e.g. airports).

The imported food control programme will need to work with customs services in order to implement its oversight at the border points. There are a number of options and considerations to take into account when choosing who should deliver these services.

Government officials

Consideration may be given to employing either customs services officials or imported food control officials to implement border controls.

Inspection support for in-country controls may be provided by the competent authority or by other government officials at the national or subnational level.

Imported food control officials

The customs services may simply refer all documents pertaining to imported food to designated imported food control officials, for review. This allows importers to have a single and efficient entry point into the government. It also ensures that the imported food control programme receives information on all legal imports. Illegal food imports may be addressed through spot checks and border blitzes carried out by customs officials.

Where documentation is referred to the imported food control officials by customs services, the document review requirements can occur as a preclearance or on arrival of the lot at the border. Imported food control officials will have the training and scientific knowledge to undertake the risk decisions required by the imported food control programme.

Having the imported food control officials review documentation will facilitate identification of consignments or lots of imported food that require inspection and sampling (see SUPPORTING TOOLS AND GUIDANCE 4.5). Appropriate arrangements can be made by officials (e.g. relocation of a lot, destuffing and full inspection) as needed.

Customs services

The use of customs officials to implement risk management actions at the border (e.g. importer documentation, certification from foreign government) is another option, which has the advantage of reducing potential for duplication of official controls such

as review of documentation for admissibility (and provides for a single entry point) and streamlining costs. Under such an arrangement, there will be full government oversight of all food consignments, at all ports. However, customs officials generally consider revenue collection, anti smuggling and anti terrorist activities as being a higher priority than food safety. In addition, customs personnel won't usually have sufficient specific knowledge to make the risk decisions required for managing the imported food controls. If customs officials are used to implement selected imported food controls, there should be a formal arrangement with competent authorities for food control, with clearly identified priorities and procedures (see Section 2), specifying which control activities they can undertake (e.g. review of certification and identity checks, but not physical inspection and sampling).

Non-government approach

Where there are importers with a good compliance history (i.e. imported food products have consistently met regulatory requirements), then the imported food control programme may consider reducing official border controls, while keeping the requirement to receive information on what food is imported from where, by whom and when. In such cases, the importer, under a formal arrangement with the imported food control programme, is responsible for inspecting, sampling and testing imported products, according to established specifications, or for ensuring inspection, sampling and testing is carried out by an accredited or recognized third party provider. The importer is also responsible for providing the results of the inspection, sampling and testing to the imported food control programme.

Where third party inspection support, is considered for pre-border or in-country controls, the competent authority will have to establish eligibility requirements and ensure that third parties meet those standards.

As with third party service providers in pre-border controls, the government will have to set eligibility requirements and either assess those third parties against these requirements, or work with other national accreditation bodies who will do so. The third party service provider must meet standards for legal authority, competency and capacity, impartiality/objectivity, QA, and records procedures (see Section 3).

Post-border/in-country

In-country controls generally consist of authorizing and inspecting importers, including sampling of imported food at the importers' warehouse. Monitoring of imported food available for sale on the domestic market is generally integrated into the domestic food control programme.

Government officials

Inspection of importers to ensure they are respecting GIP and meeting regulatory requirements, including sampling and analysis of food at import warehouses, is generally the responsibility of the imported food control officials. This has several advantages, as the information gathered from pre-border and border risk management actions can be used to prioritise importer inspections, thus targeting them at the highest risk, and information about the importers can inform pre-border and border activities.

However, where there are other levels of government, or other national government competent authorities responsible for in-country/domestic food control, it can also lead to duplication and ineffective use of resources, as monitoring of imported food on the domestic market may be subject to duplicate sampling and analysis. Where there are multiple authorities, it is important that arrangements are made to ensure coordination and communication (see Section 3).

Non government approach

An alternative approach is to require the importer to be assessed against the regulatory requirements (e.g. GIP in SUPPORTING TOOLS AND GUIDANCE 2.5) by a third party service provider. The service provider or the importer would be required to provide the results of the assessment to the imported food control programme. In such situations, the imported food control must carefully consider the availability of the third party service providers, their numbers, competence and reliability. The government will have to set eligibility requirements and either assess those third parties against the requirements, or work with other national accreditation bodies who will do so. The third party service provider must meet standards for legal authority, competency and capacity, impartiality/objectivity, QA, and records procedures (see Section 3).

OTHER SUPPORT FUNCTIONS

Legal services support

Development and management of imported food controls requires access to legal services. Legal advice will be required for many activities, including:

> development and implementation of imported food control laws and regulations;

> development and implementation of industry and operational guidance, particularly ensuring consistency with legal authorities;

> advice on legal authorities or constraints where programme management has to address new/unusual situations;

> advice on non-compliance follow up/legal actions/enforcement actions;

> supporting the import control programme during enforcement actions (e.g. appeals by importers/businesses, licence suspensions or revocations, court cases).

Imported food controls require access to legal advice for development of legislation, industry and operational guidance.

Legal advice is generally sought with respect to regulatory and enforcement actions, delegation of authorities and identification of officials.

Access to legal advice will ensure import control activities are consistent with legal authorities and requirements. It is important that the personnel providing legal advice have the training, knowledge and understanding of the appropriate legal system (e.g. common law, civil code).

Regulatory/Enforcement

While monitoring and surveillance activities may be undertaken by third party service providers, regulatory and enforcement actions are generally undertaken by government officials. All regulatory/enforcement action must be authorized by legislation (see Section 3) and as the objective is to ensure compliance, there should be guidance for importers to use such legislative actions that could include:

> suspension or revocation of importer licences or import permits;

> recall of non-compliant imported foods from the market;

> destruction of seized products;

> seizure; and

> prosecution.

In undertaking regulatory and enforcement actions, officials must ensure they are following appropriate procedures within their delegated authorities. In many instances, officials will seek legal advice as part of the decision making process for taking enforcement actions.

Delegation of authorities

Regulatory decisions and enforcement actions need to be consistent and legally defensible, and reflect the authority of imported food control officials. Thus the imported food control programme will need a policy on the delegation of authorities under the legislation. This policy generally sets out the level of responsibility assigned to particular officials or a level of official. For example, junior officials may be assigned authority to inspect documents and sample imported foods. However, more senior officials will be responsible for authorizing formal arrangements with trading partners. Having a policy that establishes delegation of legal authorities will also facilitate training officials to understand their legal duties and responsibilities.

Credentials

Identification for imported food control programme officials is essential for the programme. Means of identification may include official cards or badges. Policy and procedures should outline who should carry identification, what information should be on the identification (e.g. name, official number, legislative authority). It is also important that the process for authorizing these documents is established. Ensuring that only authorized officials have official identification reduces the potential for identity theft, and also reduces the potential for people to misrepresent themselves as officials as a means of personal gain.

Administrative Support

Ensuring that the imported food controls function smoothly and effectively requires implementation of administrative services. Administration covers a wide range of service from managing financial resources (e.g. fees); health and safety requirements; procurement (e.g. laboratory supplies, office supplies); purchase and maintenance of capital resources (e.g. offices, vehicles); and establishing policies and procedures to ensure consistency across the imported food control programme.

Financial resources

Financial resources are essential to provide infrastructure, equipment and personnel needed to effectively operate imported food controls. Implementation of effective risk management activities will ensure countries get the most results out of limited resources.

Resources may be provided by the government, through fees levied on importers or through a combination of both.

As food safety is considered a "public good", financial resources for implementing import controls are generally provided by governments. However, as importers are generally private companies working for profit (i.e. private good), import controls are often funded by a combination of government resources, supplemented by import fees.

Where importers provide resources, these generally take two forms: requiring importers to pay a third party for services (e.g. inspection, laboratory analysis); or paying import fees for government delivered services.

Where the importer is required to pay fees or pay for third party service, the fee schedule should be established by the central agency in consultation with stakeholders, and easily available to importers, exporters and other interested parties (e.g. published on websites). A regular review cycle for all fees should be included as part of the planning cycle. Where fees are paid to third parties, they should be commensurate with service levels.

Types of Fees

Where importers are required to be licensed or authorized prior to imports, fees are often associated with the issuance of any licence or permit. Different approaches can be used to establish fees:

> Import fees can be applied as a flat charge (e.g. according to weight or volume of import) or based on fee for service (e.g. fee for document review, product inspection, laboratory analysis). Where the fee for service is established, particularly if it includes hourly or time-based fees, it is important that inspectors are not pressured to complete their work.

> Total charges will usually be higher for imported foods that pose high risks, due to the increased regulatory intervention required (e.g. document assessment, inspection, sampling / testing, audit).

> Fees can be structured to take compliance history into account, thus influencing importers. By establishing higher fees for sampling and inspection following non-

compliance, an importer with a poor compliance history will pay higher fees. By establishing lower fees for importers with QA programmes, an importer with a good compliance history will pay lower fees.

> Countries may also consider increasing service fees for bad performance (e.g. repeated test failures) thus increasing the costs for poorly performing imports and importers. In this way, the use of import control fees is leveraged to ensure importers are responsible for managing the risks and costs associated with food imports.

> Lower-risk imported foods may be associated with lower costs, as import control requirements and interventions should not be extensive for these foods.

Collection of fees

Legislation governing import fees should establish the collection process. Fees may be collected by customs, and subsequently provided to the imported food control programme to fund import services. In such instances, there should be formal arrangements in place with respect to fee collection and transfer of resources between organizations. It is important to include audit provisions within the arrangement.

Fees should generally be collected centrally, with clear and transparent procedures and regular financial audits.

Alternatively the imported food control programme may collect the import fees directly. In such instances, fees should be collected at the central level, as far as possible. There should be clear and transparent procedures, available to both importers and officials, on the collection of all import fees. In addition, there should be regular financial audits to verify both income and expenditure.

Based on the legislative authority, fees may be applied at different points in the import pathway (e.g. licensing, consignment arrival, document review, inspection activities, sampling, testing). In general, fees should not be collected directly by inspectors, but through a central cashier or other secure financial arrangement, and, where possible, payment should be handled electronically to minimize potential for bribery or corruption.

Bonded imports

Countries may include requirements for importers to post a bond or provide a guarantee for their imported foods. In some cases, this is a condition of import, with bond money (usually a percentage of the declared cost of consignment) being returned to the importer when the imported food has met its import requirements and is released. Where the product does not meet regulatory requirements, the bond money is used to pay for re-exportation or destruction. This approach underlines the importers' responsibilities for assuring their products meet regulatory requirements.

The location of offices and laboratories should allow for efficient transport of inspectors and samples, and enhance communication.

Location of offices/laboratories

The imported food control programme should carefully consider the location of both its offices and laboratories, with particular consideration of imported food trade patterns and volumes. As a general approach, frontline officials may be co-located with border points to facilitate communication and collaboration with

customs officials. However, there are many other considerations to take into account, including the number of border points and modes of entry for imported food.

Office location should allow for efficient transport of both inspectors and samples, and should facilitate communication both with importers and other government officials. For example, if most of the food enters via ship, then locating the primary offices at seaports may be appropriate. However, if most food is transported to major cities for inspection at importer or other designated warehouses, then locating offices and laboratories near the inspection points may be more appropriate. In some instances, there is a need to restrict import points to allow for effective imported food controls, especially in countries with extensive borders. Countries may also choose to establish designated ports of entry for high-risk foods where the appropriate infrastructure is available.

Central offices (e.g. national headquarters) are often located in national capitals. This facilitates communication and coordination with other national organizations and national government bodies.

As noted earlier, laboratories are an essential part of an imported food control programme, but are also a significant expense to establish, maintain and operate. Careful consideration of the number and location of laboratories is important to ensure effective and efficient use of resources. Some considerations include the number and types of samples, the requirements for transport (e.g. refrigeration), the method and cost of transport (e.g. by car, by aeroplane), the types of analysis and equipment required. The ideal scenario (i.e. samples arrive at designated laboratories in two hours or less) is impossible in many countries, often because of geography or limited infrastructure. In such instances, samples should be packed and transported in order to maintain appropriate conditions (e.g. cold chain) so that on arrival the laboratory will be able to undertake meaningful analysis.

Transport

The imported food control programme will require adequate transportation for officials and samples. It is difficult if not impossible to transport sampling equipment (e.g. coolers, ice packs) to the inspection site and return samples to the laboratory, if the only transport is by foot. Storage and transport of samples needs to be clearly described and arranged otherwise results of analyses may not to be accurate (e.g. frozen or refrigerated samples should arrive at the laboratory at the appropriate temperature) and the analytical results will be meaningless.

Transport to and from sampling sites can include rental cars, use of official or personnel vehicles, motorcycles, public transport, or a combination of these. Considerations include the distance to be travelled both to and from the inspection site, the availability of the mode of transport and costs.

In some instances, (e.g. for pre-border assessments) travel by aeroplane may be required for officials, and in some instances for samples.

It is important that the imported food control programme establishes clear policies and procedures for the use of particular types of transport, outlining what transport should be used, and under what conditions. For example, if an official

vehicle is available, that should be the primary transport rather than a private vehicle. If public transport is used, then procedures must be established to ensure protection of the samples.

Procurement

The imported food control programme will need to purchase a wide range of equipment and supplies over time as part of its operations. These may include capital purchases (e.g. cars, laboratory equipment, buildings) or general supplies (e.g. office supplies, laboratory reagents). In making procurement decisions, the programme should take key government requirements into account (e.g. consideration of international providers under free trade policies).

The competent authority should ensure that it has appropriate administrative policies in place to ensure consistency.

Purchases may be made by many people (e.g. administration staff, inspectors, policy analysts, laboratory analysts) and it is important to have a procurement policy and procedures to guide purchases. The imported food control programme may choose to follow other established government procurement policy and procedures to enhance consistency and reduce duplication or, where appropriate, develop their own requirements.

Procurement policy and procedures should outline who is responsible for authorizing the purchase. For example, for capital acquisitions (e.g. laboratory equipment, cars), senior management may have to authorize the purchase, while authority for buying laboratory supplies may be delegated to less senior personnel. Policy should also outline the checks and balances which ensure the purchases are required by the programme for efficient and effective operation, that the goods received meet the purchase orders, and that the costs were commensurate with the purchased goods. These checks and balances are important to minimize the potential for bribery and fraud.

Policies and procedures

The imported food control programme will require a number of administrative policies and procedures to provide guidance on key activities. These documents are different from the technical guidance provided by the programme (e.g. sampling procedures) but are important in ensuring personnel actions are consistent across the programme. Policies should be developed, for example, with respect to travel, occupational health and safety, and hiring personnel. There should also be policies and procedures for hiring contractors or third party service providers.

Human resources /personnel

Implementation of imported food controls requires professional and administrative staff.

Implementation of imported food controls requires professional and administrative staff. The risk based programming and support functions should be the starting point for determining the skills required to administer, manage and implement the controls. The imported food control programme may choose to follow other established government human resource policy and procedures to enhance consistency and reduce duplication or, where appropriate, develop their own requirements (see SUPPORTING TOOLS AND GUIDANCE 4.6 for an example of job descriptions).

Organizational charts should be readily accessible and all roles and responsibilities, qualities, skills and capacities (i.e. work descriptions) should be clear and available to both internal and external stakeholders, and should include:

> clearly identified powers and duties (detailed in job descriptions);

> clearly identified titles (e.g. inspector, national manager) that designate the responsibilities of officers and the management hierarchy.

Personnel Descriptions

A job description describes the duties and responsibilities of a position. It also establishes the relationship with other positions in the organization. Such descriptions are generally based on occupational groups, wherein roles that perform similar types of work and require similar types of skills are grouped (classified).

Classification

A classification system is also needed to organize the job descriptions. Classification facilitates establishment of minimum and consistent education and training requirements, both for hiring and for advancing through the organization.

NOTE

Classification: the creation and maintenance of sound organizational structures provides the framework for the efficient management of human resources.

Training

Policies should outline the training and learning opportunities and requirements for employees. Employees should be expected to have a common understanding of their role within the imported food control programme; managers should have the necessary knowledge to exercise their delegated authorities; specialists in finance, human resources, internal audit, procurement, material management, real property, information management etc. should meet professional standards; employees at all levels should acquire and maintain the knowledge, skills and competencies related to their level and functions.

Employees should have a training plan to ensure they can adequately perform their current work and prepare for future work assignments. Training should be based on individual needs, taking into account academic background and applicable experience. It is important to develop individual learning plans in consultation with management. Training should assist employees in increasing their knowledge, understanding, skills and abilities, thus preparing them to do their jobs more effectively, and to assume greater responsibilities.

While encouraging employees to undertake ongoing training, it must also be understood that the training policy must operate within the confines of a budget, which will never be large enough to provide for all desired training. Imported food control training should be integrated into multi year and operational planning processes. Some guidance on training can be found in SUPPORTING TOOLS AND GUIDANCE 4.7.

SUPPORTING TOOLS AND GUIDANCE 4.1
PLANNING

All imported food controls require a planning function. This includes programme planning (i.e. to assess and update the suite of risk management activities) and operational planning (i.e. to establish operation priorities for delivering risk management activities). Many countries will have developed and implemented a planning and reporting process for existing import activities. For such countries, the following will provide guidance on improving their processes.

PROGRAMME PLANNING: MULTI-YEAR PLANNING PROCESS

Programme planning in this tool provides a description of a multi-year evidence based planning process with stakeholder participation that is designed to improve imported food control.

When developing or improving import programming, such as implementing new risk management activities (as set out in Section 2) the process will generally take several years. The planning process will need to gather and analyse the evidence, engage stakeholders, and document and provide guidance on the proposed changes, all of which takes time.

Thus the following is a description of a planning process that is evidence based, includes stakeholder participation and improves imported food controls over time.

Year 1

In system analysis and programme design, generally the first year is dedicated to the analysis phase. This includes reviewing existing data, assessing implementation, identifying critical gaps, beginning to develop the required documentation and engaging and consulting stakeholders.

The outcome should be a document that lists key risk management actions to be implemented over time (e.g. pre-border arrangements with named countries; border processes and procedures; post-border importer controls). This document should also identify what controls currently exist, identify the critical gaps that need to be addressed and give a timeframe for addressing them.

Year 2

Development phase: generally the second year is the development of programme documents that will establish requirements for both external stakeholders (i.e. importers) and for the delivery organizations (e.g. inspectors, laboratories, third party service providers). These programme documents outline the processes to address previously identified gaps.

The outcome should be clear programme documentation with established procedures for priority risk management activities. All personnel involved in implementation should have had sufficient training for delivery and, where

appropriate, pilot implementation should have been undertaken. Preliminary discussions with key organizations (e.g. trading partners, domestic partners) should have been undertaken to advance collaboration and arrangements. The documentation should also include a process for addressing the gaps identified in Year 1.

Year 3

Implementation phase – generally the third year is the beginning of programme implementation. This should include significant outreach and education for importers and key trading partners. Operational plans should be in place to ensure that programme activities are delivered as designed, and that results are reported as required. The reported results provide information on implementation and whether more training and education is needed, and can contribute to further programme delivery improvements in subsequent years.

There should be clear written enforcement strategies and procedures should non-compliance be found. National programme coordination should be in place to ensure consistency.

Year 4 and subsequent years

Re-assessment and redesign: this is the ongoing phase of programme implementation. It should include assessment of programme delivery in previous years, and answer the following questions:

> Were activities delivered as intended?

> Was the desired outcome achieved?

There should be ongoing delivery of the programme and reporting of importer and imported food compliance.

ANNUAL PLANNING (OPERATIONAL)

Operational planning in this tool outlines the concurrent activities that should take place throughout the annual cycle at the national, central management, and the delivery levels.

Import control programmes require planning and reporting processes for effective resource allocation and targeting. Planning and reporting processes are needed to assess the effectiveness of the programme in meeting regulatory requirements.

The following is intended to assist countries in making improvements to their operational planning processes. Generally, operational planning is a cyclical process, based on the competent authority's fiscal year. Figure 7 provides a visual representation of a typical planning process that occurs on a cyclical basis, generally over an 18-24 month cycle.

Operational planning will occur at two levels:

1. National planning by the central management functions intended to assess national programme results, prioritise risk management actions and establish new goals and activities.
2. Delivery planning by the operational level (inspection delivery, laboratories) to clearly identify what actions will be completed, when, and by whom.

In the 1st quarter of the fiscal year (Months 1-3)

> Operational level will be finalising reports, data analysis from last fiscal year and implementing risk management (i.e. inspection, sampling for this fiscal year).

> Central management will be providing direction, responding to questions on the current fiscal year plan (Month 1) and initiating preliminary analysis of previous fiscal year data.

In the 2nd quarter (Months 4-6)

> Operational level will provide reports for previous quarter and continue implementation of current year activities.

> Central management will review previous fiscal year results, identify any in-year reprioritisation, and areas for further analysis for next year's priorities.

In the 3rd quarter (Months 7-9)

> Operational level will provide reports for previous quarter, incorporating in-year reprioritisations, and continue implementation of current year's activities.

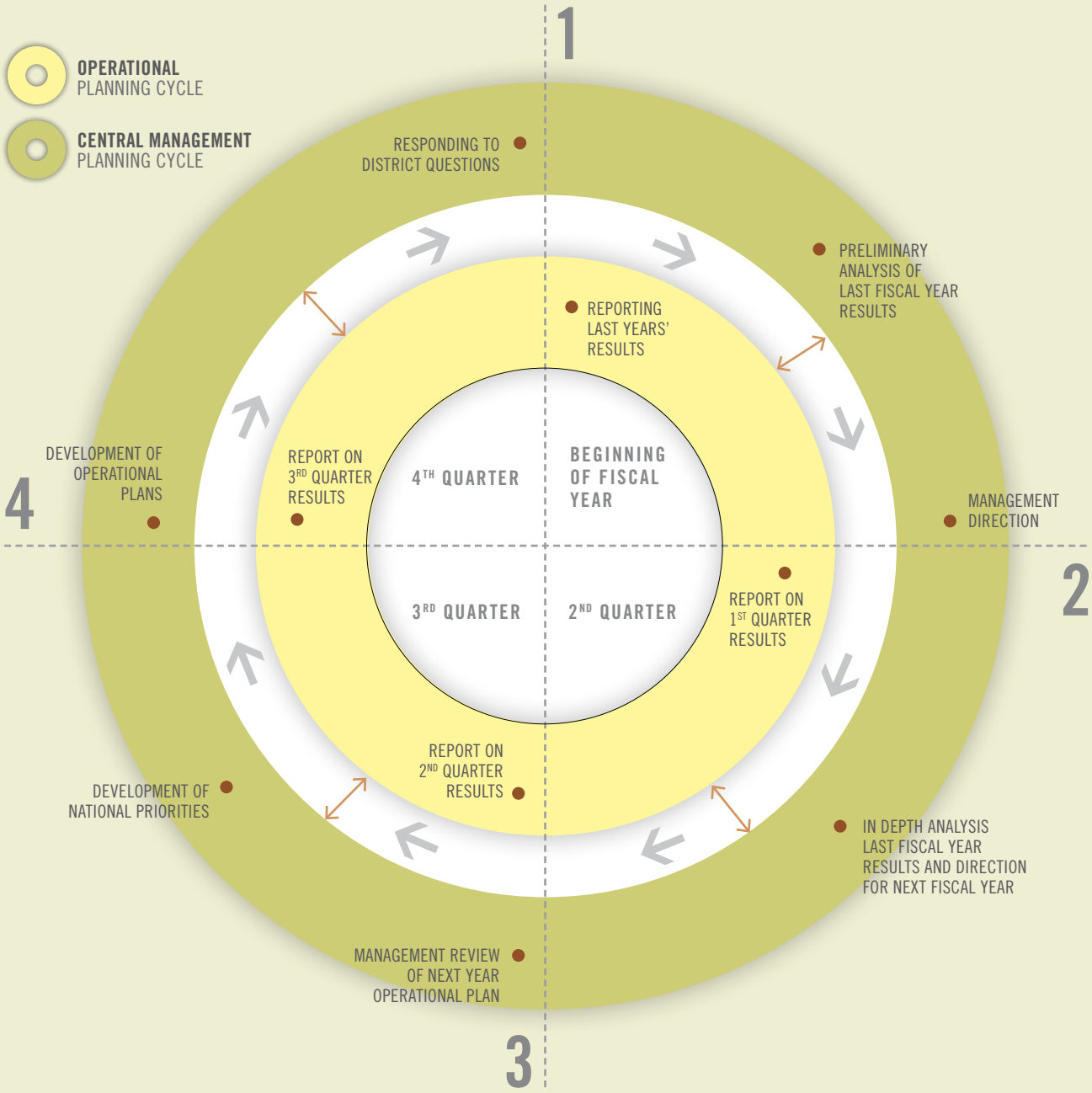
> Central management will begin developing annual sampling plans and inspection numbers for next fiscal year, for approval. These sampling plans should outline what analysis should be undertaken; how many analyses should be undertaken; and who should deliver that service. Inspection plans should outline which sectors, goods and business should be inspected, what samples should be taken, and which controls should be carried out on which facilities.

In the 4th quarter (Months 10-12)

> Operational level will review next fiscal year's sampling plans and inspection priorities, and begin the process of developing detailed implementation plans (e.g. monthly delivery plans for inspections, samples) while continuing to deliver this fiscal year's activities.

> Central management will finalise guidance documentation, work with delivery organizations to clarify directions, and respond to questions.

FIGURE 7 **OPERATIONAL PLANNING CYCLE**



SUPPORTING TOOLS AND GUIDANCE 4.2
PROGRAMME DESIGN – IMPORTER ADVICE AND INFORMATION

Importer guidance will need to be developed for all imported food regulatory requirements.

The importer advice and information should provide the policy statement, the basic requirements and the general information that an importer will require to comply with the policy statement. The following are **examples** of simple guidance provided to importers on the basis of possible policy statements.

EXAMPLE

> New Zealand's Guide to importing food: www.foodsafety.govt.nz/industry/importing/guide/
> Australia – Food testing: Information for importers. www.daff.gov.au/biosecurity/import/food/information-importers
> Food Standards Agency, UK: Guidance for importers: www.food.gov.uk/business-industry/imports

LICENSING

Policy statement

All importers are required to have an annual import licence that is non transferable.

To apply for an import licence, submit a complete application package to the [insert name of the organization] office.

By applying for a licence you agree that you will meet the import licence and regulatory requirements and that the imported food meets all the applicable regulatory requirements.

A complete application import licence package must include the following:

> Completed application form including the process for meeting GIP (see Section 2).
> Fee (if any).

The [name of organization] will review the application package and additional information to ensure it meets all the requirements prior to issuing the licence.

Providing false information or failure to meet the applicable regulatory requirements may lead to a suspension or revocation of the import licence.

The [name of organization] may refuse to issue a licence if you are unable to demonstrate that you are willing or able to comply with the regulatory requirements, including the payment of fees.

SOURCING PRODUCT

Policy statement
The importer must have a process in place to make sure that the imported food meets the applicable regulatory requirements.

This means understanding the risk(s) associated with the product(s) that you import and ensuring that they meet applicable regulatory requirements.

It is important to source product only from suppliers that can provide assurances that the product meets regulatory requirements. If the supplier is not the producer of the product, they must be able to provide you with the name and address of the producer, and you must be able to verify and confirm the accuracy of this information. The supplier or producer of the product must be able to provide accurate product information regarding the food, food ingredients, and the processing method.

IMPORT PRODUCT NOTIFICATION, CONTROL, STORAGE, AND IDENTIFICATION

Policy statement
All importers must report their import shipment to the customs and customs services and the [name of organization] by submitting paper documentation or through an electronic data interchange.

NOTE

Generally, customs services require notification at import or prior to import for assessment of tariffs or collection of duties. The imported food control programme must determine if notification is to be prior to import, at the time of import or within a specified period of time after import.

You are also required to notify the [name of organization] of all food imports using the specified form. You must accurately complete the notification with all required information that includes:

> Importer name, licence number and contact person.
> Contact Email, Telephone Number, and Fax Number.
> Importer Tracking number (if used) coordinates invoices with notifications.
> Customs Services Transaction Number – this verifies the legality of the imported product.
> Expected Date or Date of Arrival - date the shipment is due to arrive or, if shipment has already arrived, the date it cleared customs.
> Customs Entry Point.

- Warehouse Name and Address - name (for public warehouses) and address of the warehouse where the shipment must be held for inspection.
- Foreign Producer - name, address, and country of the producer.
- Product Description (the name of the product as identified on the label (retail or master carton)) and including for each lot:
  - Brand Name (if applicable).
  - Storage Conditions and Shelf Life (room temperature, frozen or refrigerated).
  - End Use: Retail, Food Service, For further processing.
  - No. of cases - the number of shipping cartons/cases and Units per case - the number of individual units packed in each shipping carton and unit weight.
- Certificate Number - Enter the certificate number for a lot when a recognized certificate has been issued by the competent authority.
- Attestation - name, signature, and date of person acknowledging that the information declared on the form is accurate, and that all reasonable steps have been taken to ensure that the products meet regulatory requirements.

PRODUCT CONTROL AND INSPECTION PROCESS

Policy statement

The importer must hold the imported product at the storage location declared on the import notification until they are notified of the inspection decision.

Imported food that has been approved for entry by the customs services can be moved to the storage location identified on the import notification. You must ensure that imported products in your control are stored in such a way to maintain product quality, and prevent contamination of your product. This includes proper temperature control during transportation and storage. Importers should maintain records pertaining to storage, including date in/date out, temperature, other environmental conditions.

All records pertaining to storage must be maintained for a period of three years minimum.

SUPPORTING TOOLS AND GUIDANCE 4.3
DEVELOPING STANDARD OPERATING PROCEDURES

It is important for countries to develop standardized procedures to enhance consistency and to enhance confidence in the implementation of the imported food controls. While this tool describes the theoretical development of a SOP, SUPPORTING TOOLS AND GUIDANCE 2.4 illustrates what a imported food control SOP flow chart might look like.

In general, a procedure is a written document or instruction that outlines requirements for the various processes that an inspector or other official may perform as part of the programme. Written procedures are very important to the efficient operation of an organization, ensuring that basic procedures are followed consistently, allowing staff to focus on more complex or problematic areas. Written procedures can eliminate the variation that often occurs when individuals approach a task without guidance. Although this document will use the term procedures, other terms such as protocols, instructions, worksheets, and laboratory operating procedures may also be used.

Development of SOPs enhances consistency and confidence in the imported food controls. SOPs provide written instructions to be performed as part of imported food controls.

Procedures need to be part of the ongoing implementation of imported food controls. Current versions need to be readily accessible for reference in the work areas of those individuals actually performing the activity, either in hard copy or electronic format.

Procedures can also be used as a part of a personnel training programme, since they should outline important work instructions.

Development of a procedure

It is important that the import control programme is supplemented by more detailed procedures that will guide and assist staff. Determining the priority of developing and writing procedures can be integrated into the planning process.

Knowledgeable people should write procedures. These individuals are essentially subject-matter experts who actually perform the work or use the process in collaboration with quality management. Procedures should be written in a concise, step-by-step, easy-to-read format. The information presented should be unambiguous and not overly complicated. Information should be conveyed clearly and explicitly to remove any doubt as to what is required. Also, the use of a flow chart to illustrate the process being described is often very helpful.

Procedures implemented frequently, and by many people, require more detailed information to ensure consistency. SOPs should provide sufficient detail so that officials with limited experience can successfully follow the steps.

The level of detail provided in procedures may differ based on whether the process is critical (e.g. requires more detail), the frequency of that procedure being used, the number of people who will use the procedure, and availability of training. Generally, the more frequently a procedure is used and the more people use it, the more details are required to maintain consistency and coherence. A good rule is that a procedure should include sufficient detail so that someone with limited experience of the procedure can successfully follow and understand the steps.

Many SOPs use checklists and flow charts to ensure that steps are followed in order, and can also be used to document completed actions. In such cases it is important to remember that the checklist is not the entire procedure but simply a subset of the procedure. The checklist should be referenced in the appropriate part of the written procedure and appended or attached to the final document.

Review and approval

Once developed, the procedure should be reviewed and validated by another individual with similar expertise or experience. This will allow improvements and changes to be made before the document is approved for distribution. It can also be helpful to field test a draft procedure before it is finalized.

Once finalized, the procedure should be approved by the appropriate management and made readily available to staff.

Updates

Procedures must remain current to be useful and to ensure they achieve their objectives. Therefore, it is important that there is a regular schedule of review to assess whether procedures remain relevant, need updating or should be completely rewritten. To minimize work, where possible only specific sections of the procedure should be modified to reflect process changes. This will require noting the change date/revision number for that section in the document control area.

Control of procedures

It is important that there is a master list of all procedures, with pertinent details (e.g. number, title, version, date of issuance, author, status, organization).

The programme should establish a numbering system to identify their procedures and should establish a document control procedure. Generally, document control procedures include requirements that each page of the procedures have control notation. Document control notation is often located in the upper right-hand corner of each page.

EXAMPLE

Control notation
Short Title/ID #
Rev. #:
Date:
Page 1 of

Should electronic formats be used to maintain procedural documents, electronic access can be limited to a read-only format, thereby protecting against unauthorized changes made to the document

Format

Procedures are normally developed specifically for and by each institution. It must be said that there is no one "correct" format, and thus documentation will vary with each organization. A generalized format is discussed below.

Title page
The first page or cover page of each procedure should contain the following information:

> a title that clearly identifies the activity or procedure, an identification (ID) number;
> date of issue and/or revision;
> the name of the applicable organization to which it applies;
> the names/signatures of the authors;
> the names/signatures of approving officers;
> date of approval.

Table of Contents
A Table of Contents may be needed for quick reference, especially if the SOP is long, for locating information and to denote changes or revisions made only to certain sections of a SOP.

Purpose or objective
Briefly describe the purpose or objective of the work or process. This can also include the scope to indicate what is covered and when the procedure should be used.

Authority
Briefly describe the legislative or regulatory authorities pertinent to this procedure. This could include identifying qualifications such as certification or training experience. It might also identify the particular position or positions responsible for the activity described.

Definitions
Define any specialized or unusual terms or acronyms.

Guidance sections
Before describing the procedures, it is important to note fundamental requirements or cautions. This section could include personnel qualifications, equipment needs and safety considerations.

Procedures
As noted above, procedures need to be clearly worded and should clearly describe each step in order. Use of diagrams and flow charts can help illustrate the process.

Quality assurance
Finally, describe appropriate QA and QC activities for that procedure, and list any cited or significant references.

Annex
Attach any appropriate information. Where other procedures or other shorter documents are referenced, it is appropriate to cite the reference and attach a copy. For longer documents, it would be inappropriate to attach the document, and the information should be included in the reference section.

SUPPORTING TOOLS AND GUIDANCE 4.4
EXAMPLES OF SAMPLING STRATEGIES

This section illustrates the underlying "philosophy" behind different sampling strategies. This in turn informs the development of annual sampling plans.

Sampling strategies provide the framework and fundamental principles for developing annual sampling plans. They should be documented and available to importers and officials.

MONITORING AND COMPLIANCE SAMPLING STRATEGY

This is based on the principle that importers have taken the appropriate steps for product sourcing and have obtained assurances that the imported foods are of "good order" (i.e. that they will meet regulatory requirements). Each year, the competent authority will develop a sampling plan based on this strategy that identifies the foods to be sampled, what analysis will be carried out, when to sample, where to sample, and actions in the case of a non-compliant result. Under this plan, sampling is undertaken as part of comprehensive regulatory control measures that include assessment of importers' activities.

The individual results of sampled lots are assessed against regulatory standards and the cumulative data is reviewed on a periodic basis, usually quarterly, in order to determine trends and identify any developing issues and the appropriate response.

Under this strategy, sampling is broken down as:

> Monitoring sampling: product inspection coverage of good order product at a pre-specified "normal" sampling frequency (e.g. 5 percent of imported lots); this also includes options for relaxed or reduced sampling, based on confidence in the originating country (e.g. under a bilateral arrangement).

> Compliance sampling: as a result of non-compliant products being identified, subsequent shipments or lots from the same producer are sampled at a higher frequency or "tightened" inspection, generally 100 percent of lots/consignments from that producer until a set number of lots, (e.g. five) have been analysed and found acceptable. Imported lots sampled under tightened/compliance sampling should be held until results are known.

> Directed sampling is targeted towards suspected problems suggested in the monitoring programme or other environmental scanning, and is intended to verify suspected food safety issues that may have been identified through environmental scanning, information from INFOSAN or other international partners, or through trends identified in the monitoring sampling. It is based on available evidence and generally directed at targeted populations (e.g. specific imported products, importers, commodities or foods originating from geographical areas).

Where non-compliance is identified, the sampling plan outlines guidance for addressing the non-compliance. This generally includes both response to the specific lot (e.g. re-condition, re-export, destroy), and requirements for sampling future import lots (i.e. the rules for moving from a normal sampling to compliance sampling

at a tightened frequency). It also generally includes assessing the importer's GIP, verifying that they result in importation of food that meets regulatory requirements. As part of programme management, there must also be operational procedures for moving from a tightened inspection frequency back to a normal frequency.

CATEGORIZATION SAMPLING STRATEGY

This is based on imported food consignments or lots categorized into two categories: a "high-risk food" or a "surveillance food". The competent authority will develop a sampling plan with two parts, one for high-risk foods, and one for surveillance foods.

High-risk foods may be inspected and tested at a rate of 100 percent against a published list of potential hazards – including microorganisms and contaminants. Once a set number of consecutive consignments from same producer (e.g. five) have passed inspection, the inspection rate may be reduced (e.g. to 25 percent), and further reduced (e.g. to 5 percent) after another set number of consecutive consignments or lots passes inspection (e.g. ten).

High-risk foods are generally "held", that is they are not released for sale until results are known. Consignments that do not meet regulatory standards cannot be sold. All food from these consignments must be brought into compliance, re-exported or destroyed. Where any consignment fails, all future consignments or lots from that producer for that risk food will be sampled and analysed at 100 percent testing.

Surveillance foods (i.e. all non high-risk foods) are considered to pose a low risk to human health and safety. These should be subject to a lower frequency for random sampling and evaluation (e.g. 5 percent). The sampling should be a random selection across all importers, foreign producers regardless of the country of origin. Consignments or lots of surveillance foods may be analysed for regulatory requirements (e.g. pesticides or antibiotics above accepted levels, microbiological contaminants, natural toxicants, metal contaminants and food additives).

As surveillance foods are considered to be low risk, they are generally not held pending results. This means that most foods are distributed for sale before test results have been received. However, where the consignment or lot fails inspection, a recall of that product lot may be required.

NOTE

In both types of sampling plans, the numbers, such as percentage for normal sampling, the set number of lots to move from tightened to normal, are generally negotiated as part of programme design. This requires taking into account imported food profile and compliance history, as well as inspector and analytical capacity, in order to establish appropriate levels.

Similar to high-risk foods, if a lot of surveillance food fails inspection, subsequent lots from that producer should be sampled at 100 percent until a set number of consecutive lots (e.g. five) passes inspection. Following the appropriate number of consecutive passes, the inspection rate returns to 5 percent.

The plan should also require an evaluation of the importer's practices subsequent to any product non-compliance to ensure they meet regulatory requirements.

SUPPORTING TOOLS AND GUIDANCE 4.5
INSPECTION AND SAMPLING – PROCEDURAL GUIDANCE

SUPPORTING TOOLS AND GUIDANCE 4.4 describes the concepts regarding sampling strategy and annual sampling plans (e.g. numbers of samples, type of inspection or analysis). This section provides some information and guidance that should be considered in the development of a SOP on sampling, although it does not include all the detailed requirements to be included in a SOP.

The inspector will require access to the entire lot for inspection and sampling, which requires "destuffing/unloading" containers. During the inspection or sample collection, there should be no interference or pressure for the inspector to hurry the procedures, nor should any person try to prevent access to the entire lot. Inspectors should note and report any interference encountered because it may compromise the results of the inspection or sample/analysis.

An imported lot may be inspected to verify physical condition, labelling, or verify the food products are consistent with the documentation whether samples are taken or not.

> During inspection or sampling, the inspection procedures noted below should be followed.

> During sampling, the appropriate sampling procedures should be followed to ensure that sample integrity is maintained from the time of collection until the sample is delivered to the laboratory.

INSPECTION PROCEDURES

Inspectors should have access to, and follow, inspection procedures. They should consult the procedures prior to undertaking lot inspections.

The key steps in the procedures should include:

> Process for identifying which lots will be physically inspected, and include verifying the location (e.g. held by customs at the border, held at a bonded warehouse or at the importer's warehouse) and conditions for the inspection.

> Systematic procedure for confirmation and cross-reference of the information on the physical lot with the information provided as part of the import documentation (e.g. the food product, the size of the lot, the identification marks (lot number, codes) and any other information required).

> Process for verifying the physical condition of lot (e.g. leaking containers, water damage, physical damage) and, if found, specific guidance on what, if any, remedial actions can be taken by the importer (e.g. culling, reworking, disposal).

- Procedures for label inspections (e.g. language of label, codes, approved common name, authorized ingredients).
- Procedures for documenting the inspections, including all reporting requirements
- Decisions on the lot, (e.g. release if compliant; detain if non-compliant) and requirements for any follow up for non-compliant lots.

SAMPLING PROCEDURES

The sampling strategy and plan will provide direction for inspectors and should be consulted before inspection and sampling of the lot. (E.g. bacteriological, organoleptic, composition, chemical, physical.) It should also provide guidance on sampling procedures, including sample identification that will link results to an import consignment. When sampling, it is important to maintain the integrity and continuity of the sample associated with the lot (from the time the sample is drawn to the completion of the inspection).

The sampling procedure should describe what information will be documented on the sample report, prior to samples being withdrawn:

- As maintaining integrity and continuity is important, the procedure should identify what information on the lot is required (e.g. customs entry number; location sampled; size of lot, and amount available when sampled; lot size; and identification number, production code).
- Because sampling can be undertaken by government or non-government personnel, the identity of the sample collecting entity (e.g. government official, accredited laboratory or sampling service) and individual must be included.
- The procedures should identify all the required information about the sample (e.g. sample collection date; sample collection method; sample preparation techniques; sample size;) and should include any observations by the sample collector about the condition of the lot, containers or other conditions that could affect the sample's integrity.
- The procedure should also include guidance for situations where the condition of the lot can be determined through inspection and should not be sampled (e.g. frozen product has thawed, physical damage renders the product inedible).

The sampling procedure should also establish the information about the sample itself.

- Identification of the analysis being requested:
  - microbiological (e.g. bacteriological, commercial sterility, viral);
  - chemical (e.g. additives, composition, drug residues, contaminants, toxins);
  - container/package integrity;
  - sensory, net content and package integrity.

- Provide guidance on the number of sample units required. It may be that more that one analysis will be undertaken and samples will have to be taken to perform all of the required analyses.
- Provide guidance on selection of sample units (i.e. random selection or representative samples) and physical sampling.
  - When sampling a large lot of food containers, which may be packed in large cartons, the sampling collector will require assistance from the industry representative to physically move the cartons from the lot to an appropriate location.
  - When sampling smaller lots that are readily accessible, the sampling collector should determine if assistance is necessary.
- Sampling storage and transport information including temperature (e.g. refrigeration, freezing), transport time (e.g. maximum time), and reception procedures (e.g. documentation requirements for laboratory).
- Laboratory reception (e.g. log in requirements, validation of sample conditions, validation of information requirements).
- Communication of results following analysis.
- Report of the analytical results. (Note: follow up of non-compliant lots is included in the inspection protocol.)
- Chain of custody linking the sample to the import consignment (e.g. all persons involved, and their roles in collecting and delivering the sample to the lab, and subsequent analysis and reporting).

SUPPORTING TOOLS AND GUIDANCE 4.6
JOB DESCRIPTIONS AND PERSONNEL CATEGORIES

The management and delivery of imported food controls will need a variety of skills and training in a number of areas.

SCIENTIFIC SUPPORT

Laboratory analysts (e.g. biologists/chemists)

Laboratory analysts may be used to conduct tests or perform research in a laboratory environment, or work to develop product standards. Activities may include:

> Performing analyses and scientific assessments for diagnostic and testing purposes.

> Providing advice on the establishment of legislative and regulatory standards.

> Participation in negotiation with national and international governments or international standard setting bodies.

Laboratory technicians

Laboratory technicians are generally supervised by laboratory analysts, and provide analyses in specific fields (e.g. chemistry, microbiology, toxicology).

Laboratory managers

Managers are generally responsible for the delivery of analytical service. Key activities may include:

> Planning and reporting of analytical activities.

> Coordinating work with other organizations (e.g. oversight of third party providers, private laboratories).

EXAMPLE

Examples of educational requirements

Laboratory analysts:

> University degree in Chemistry, Food Microbiology, Virology or other relevant discipline

Laboratory technicians:

> College Diploma (technical specialisation) in Chemistry, Food Microbiology, Virology or other relevant discipline

INSPECTION SUPPORT

Inspectors

Inspectors are responsible for delivering the imported food control programme, including all of the risk-based activities (e.g. document inspection, product inspection, importer assessment). Veterinarian inspectors, a subset of inspectors, may be used within the imported food control programme with a specialty in imported products of animal origin.

EXAMPLE

Examples of educational requirements

Inspectors:

> High school graduation with appropriate training in technical disciplines; or
> College diploma (technical specialisation); or
> University degree, such as food science, veterinary medicine, environmental health.

Inspection managers

Inspection managers are generally responsible for the delivery of inspection support activities. Key activities may include:

> Planning and reporting of imported food control activities, including coordinating work with other organizations.
> Resolving issues (e.g. response to regulated parties, consumer and trade complaints and regulatory infractions).

CENTRAL MANAGEMENT SUPPORT

Policy officer

Policy officers play a role in policy studies and projects, analysing issues and monitoring trends.

Planning officer

Planning officers are responsible for managing the national planning and reporting functions. They work closely with Inspection and Laboratory Managers in developing annual inspection and sampling plans and annual reports.

Programme officer

Programme officers work at the national level managing programme delivery and response. They are generally responsible for international negotiations with trading partners, managing international audits and ensuring consistency across all functions.

Statisticians

Statisticians support both programme and science support functions.

ADMINISTRATIVE SUPPORT

Administration/clerical

Administrative and clerical positions support and assist all of the professional and management activities for science, inspection, administration, finance and Human Resources managers. Types of administrative services positions may include clerical positions (e.g. filing, mail, supplies) and administration assistance (e.g. scheduling, coordination, meetings) for managers, directors.

Computer Systems/Information Technology (CS/IT)

CS/IT professionals plan, deliver, and maintain the information technology infrastructure services that underpin planning and reporting functions.

Financial analysts

Financial analysts work with financial planning, strategy, analysis, forecasting and reporting, financial management, and management control systems.

Human Resources support

Human Resources professionals work in staffing, classification, compensation, staff and labour relations, learning and development, policy, systems or human resources strategies, planning.

SUPPORTING TOOLS AND GUIDANCE 4.7
TRAINING

Imported foods controls require that both inspectors and other officials understand the basics of imported food (e.g. hazards, risks), the conditions of imports and the imported food programme itself.

Officials, particularly inspectors, laboratory and programme officials, should have:

> a technical background that allows them to understand food safety risks;

> administrative training, allowing them to understand the laws and standards that apply to imported foods, their legal powers and duties, and basic technical and operational procedures (see Sections 2 and 3);

> a training in occupational health and safety.

The imported food control programme training curricula may be divided into modules which build from basic knowledge (e.g. inspection, document assessment) to more specialized forms of activities (e.g. sampling methods and techniques). Training curricula, programmes and modules can also be officially accredited. This is particularly useful where multiple organizations are involved in delivering imported food controls. It will enhance consistency across all organizations. Understanding of the training course material should be formally assessed through both written and practical examinations.

Many organizations include "on the job" training, as it is particularly effective for entrenching key knowledge and competencies. Where trainee inspectors or other officials are undergoing on the job training, they will require appropriate supervision and their performance should be formally assessed. This approach allows trainees to advance once they have demonstrated mastery of the subject material.

Performance should also be monitored and the results should be included in performance management, to identify if further training is required.

An introductory imported food module should cover the following subjects:

> Introduction to food safety: key food hazards and risks.

> Basic food hygiene and food production practices (GHP, Good Agricultural Practices (GAP), GMP etc.).

> Food imports: the country context (by risk, composition, country).

> Background on the imported food control programme: history, organizations.

> Imported food control legislation, including roles and responsibilities of government organizations and other key stakeholders, standards and requirements.

- Risk management activities (pre-border, border and post-border) including an introduction to workflow (e.g. documentation inspection; visual inspection; labelling inspection; sampling and laboratory analysis) and inspection decisions (e.g. options for non-compliant imported foods (re-conditioning, destruction and re-export)).
- Import control information management: reporting, systems and operation.

GLOSSARY

For the purpose of this manual, the specific meaning and use of recurring expressions is provided below:

AUTHORITY: the legislative or regulatory authority for a competent authority or an official to implement a specified risk management action.

CERTIFICATION: the procedure by which official certification bodies and officially recognized bodies provide written or equivalent assurance that foods, or food control systems, conform to requirements. Certification of food may be, as appropriate, based on a range of inspection activities, including continuous on-line inspection, auditing of QA systems and examination of finished products. The certification procedures may be paper-based or electronic certificates.

COMPETENT AUTHORITY(IES): government agencies or institutions responsible for imported food control (covering food safety and quality as defined in legislation).

CONTROLS OR IMPORTED FOOD CONTROLS: actions taken by, or on behalf of, a competent authority with respect to gathering information and managing risks to assure the compliance of imported food. Implementation of controls means the full suite of risk management actions used to assure imported food meets importing country requirements. Pre-border, border and in-country are the locations where these controls are implemented.

DESTUFFING: removing all items from a shipping container, also called unloading or turning out the container.

DUTY OF CARE: the legal obligation imposed on an individual. In the case of imported food controls, establishing that importers have the primary responsibility to ensure that imported food is safe, creates a duty of care.

IMPORTER: the food business (e.g. consignee, importer of record) that is responsible for sale and distribution of the food within the importing country. It includes importation food and food ingredients for use in further processing.

INSTITUTIONS: government agencies or institutions (e.g. animal health and welfare) that have responsibility for food, other than food safety and quality.

NOTIFICATION: information on imported food being provided to the competent authority as the food arrives in the importing country, or within 48 hours of its arrival.

PRECLEARANCE: a government-mandated process that relies on product verification information (e.g. sampling procedure details, analytical results) to be provided to the importing country prior to the lot arriving at the border. The imported food controls specify what information is required and who is responsible for providing it (i.e. exporting country, an independent recognized third party or the importer). The decision on accepting the lot is made by the competent authority before the lot is shipped, thus minimizing deterioration of a perishable product. However, laboratory results outside of a pre-established process should not be used as part of the decision process as it is impossible to validate that information.

PRE-NOTIFICATION: the information on imported food being provided to the competent authority prior to the food arriving in the importing country.

STANDARD OF CARE: the action(s) that a reasonable person should take to meet their duty of care. Generally, the standard of care is the legally established requirement that importers have to meet, such as prohibiting the importation of food that does not meet product or processing standards, or requiring that importers implement GIP, or that importers have mandatory import licences or permits.

SUPRA-NATIONAL OR REGIONAL GOVERNMENT: an organization having power or influence that transcends national boundaries or governments.

RISK ASSESSMENT: a scientifically based process consisting of the following steps: (i) hazard identification; (ii) hazard characterization; (iii) exposure assessment; and (iv) risk characterization.

TRANSHIPMENT: where some or all food imported into a country, that is not subject to further processing and has been stored under appropriate conditions, is exported to a third country.

TRANSIT: the food destined for one country may have to "transit" or travel through another country (e.g. products destined for Russia, may transit through an EU member state) although it is never imported nor offered for sale in the transit country. The country of transit may establish specific requirements, often pertaining to animal health or plant protection, and may require a transit certificate.

NOW In Season
Vine ripened
Tomatoes
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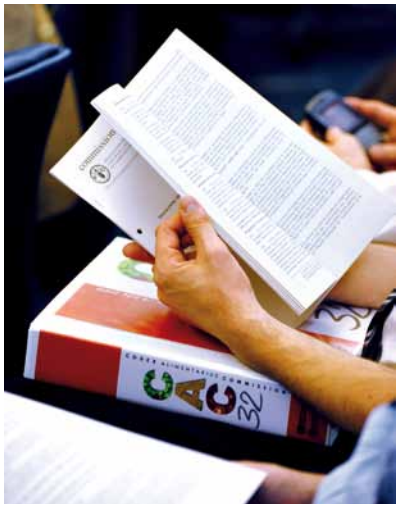
kg
19.20
IMPORTED PRODUCE



RISK BASED IMPORTED FOOD CONTROL MANUAL

This FAO manual on Risk based imported food control aims to support competent authorities in improving the effectiveness of the control measures they are overseeing, based on an analysis of their specific country situation. It discusses the different types of approach to managing risks related to imported food, and provides concrete illustrations of how Codex guidelines can be implemented in different ways. While respecting the principles, guidance and objectives agreed by the Codex Alimentarius Commission, different options for control measures can be selected and combined to implement a coherent set of import controls to best fit the needs of each country. Different examples, as implemented by a number of countries, are provided to show that there are often several options to reach a common goal. It also provides insights on the legal and institutional frameworks, as well as on the necessary support services to effectively implement risk based food controls.

FOOD SAFETY AND QUALITY UNIT

FOOD SAFETY OFFICE

AGRICULTURE AND CONSUMER PROTECTION DEPARTMENT

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