



**EAST AFRICAN COMMUNITY**

**THE EAST AFRICA COMMUNITY DRAFT STANDARD OPERATING  
PROCEDURES FOR FOOD SAFETY**

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| <b>Food Controls, Inspections &amp; Approvals</b> |  |   |            |
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**STANDARD OPERATING PROCEDURES ON FOOD SAFETY**

| <b>Food Controls, Inspections &amp; Approvals</b> |  |   |            |
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## **ABBREVIATIONS**

|                |  |
|----------------|--|
| <b>SOP's</b>   | Standard Operating Procedures                    |
| <b>WTO</b>     | World Trade Organisation                         |
| <b>INFOSAN</b> | International Network of Food Safety Authorities |
| <b>IHR</b>     | International Health Regulations                 |
| <b>PCP</b>     | Preventive Control Plan                          |
| <b>CHA</b>     | Customs Handling Agent                           |
| <b>IEC</b>     | Importer Exporter Code                           |
| <b>FBO</b>     | Food Business Operator                           |
| <b>FICE</b>    | Food Import Clearance System                     |
| <b>CCT</b>     | Cold Chain Technologies                          |
| <b>BoE</b>     | Bill of Entry                                    |
| <b>NoC</b>     | No Objection Certificate                         |
| <b>NCC</b>     | Non Conformance Certificate                      |
| <b>HACCP</b>   | Hazard Analysis and Critical Control Point       |
| <b>SQA</b>     | Supplier Quality Assurance                       |

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## **I INTRODUCTION**

### **I.1 Purpose of the SOP's**

Imported food control procedures are intended to protect the health of consumers and facilitate fair practices in food trade while avoiding unjustified technical barriers to trade. In the event of a conflict with other interests, precedence is given to protecting the health of consumers.

### **I.2 SCOPE**

This document details procedures to be followed for the Control of import and export of Food, Food Ingredients, Food Additives, and Raw Materials. The controls are applied at Pre-border, Border, and In-country/Post-borders including designated premises.

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## **2 GENERAL GUIDELINES AND PRINCIPLES**

The aim of food inspection and certification systems is to ensure that foods, and their production systems, meet requirements in order to protect consumers against foodborne hazards and deceptive marketing practices and to facilitate trade on the basis of accurate product description. Competent Authorities should observe the following principles and guidelines.

### **2.1 Fitness for purpose**

Inspection and certification systems should be fully effective in achieving their designated objectives having regard to the determination of the acceptable level of protection which is required.

### **2.2 Risk assessment**

Inspection systems to ensure food safety should be designed and operated on the basis of objective risk assessment appropriate to the circumstances. Preferably the risk assessment methodology employed should be consistent with internationally accepted approaches. Risk assessment should be based on current available scientific evidence.

Inspection systems should be applied to particular commodities and processing methods in proportion to the assessed risks. In undertaking a risk assessment or in applying the principles of equivalence, importing countries should give due consideration to statements by exporting countries on a national or area basis of freedom from food-related disease.

### **2.3 Non-discrimination**

Countries should ensure that they avoid arbitrary or unjustifiable distinctions in the level of risk deemed to be appropriate in different circumstances so as to avoid discrimination or a disguised restriction on trade.

### **2.4 Efficiency**

Inspection and certification systems should have adequate means to perform their tasks. In the choice of inspection and certification systems, there should be regard to costs to consumers and to the costs in money and time to the affected food industry and government consulting with interested bodies as appropriate. Such systems should be no more restrictive of trade than is necessary in order to achieve the required level of protection.

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## 2.5 Harmonization

Member countries should use Codex standards, recommendations and guidelines (or those of other international organizations whose membership is open to all countries) whenever appropriate as elements of their inspection and certification systems. Countries should participate actively in the work of the Codex Alimentarius Commission and other relevant international bodies to promote and facilitate the development, adoption and review of Codex norms.

## 2.6 Equivalence

Countries should recognize that different inspection/certification systems may be capable of meeting the same objective, and are therefore equivalent. The obligation to demonstrate equivalence rests with the exporting country.

## 2.7 Transparency

While respecting legitimate concerns to preserve confidentiality, the principles and operations of food inspection and certification systems should be open to scrutiny by consumers and their representative organizations, and other interested parties.

Importing countries should provide information on existing requirements and proposed changes to requirements should be published and, except in the case of serious and immediate danger, an adequate time period permitted for comment. The views of exporting countries, and particularly those received from developing countries, should be taken into account in taking a final decision. A reasonable period should be allowed before a new requirement takes effect in order to permit exporting countries, and in particular developing countries, to make necessary changes to methods of production and control measures.

Importing countries should make available to the exporting countries, upon request, timely advice as to the basis of the decision they have taken regarding the compliance of foods with their relevant requirements.

Upon request by the competent authorities of the importing countries, the exporting countries should provide access to view and assess the actual working of their relevant inspection and certification systems.

## 2.8 Special and differential treatment

In the design and application of food inspection and certification systems, importing countries should take into account the capabilities of developing countries to provide the necessary safeguards.

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## 2.9 Control and inspection procedures

Importing countries should complete without undue delay any procedures necessary to assess compliance with requirements. Information requirements and any fees imposed by importing countries should be limited to what is reasonable and necessary.

## 2.10 Certification validity

Countries that certify exports of food and those importing countries which rely on export certificates should take measures to assure the validity of certification. Validation measures by exporting countries may include achieving confidence that official or officially recognized inspections systems have verified that the product or process referred to in the certificate conforms to requirements.

Measures by importing countries may include point of entry inspection systems, audit of exporting inspection systems, and ensuring that certificates themselves are authentic and accurate.

## 2.11 Principal Responsibility

### 2.11.1 Responsibilities of the Importer

Importers 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.

### 2.11.2 Responsibilities of the Competent Authority

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. if importers are meeting their responsibilities), and where there is non-compliance, undertaking enforcement actions.

The Competent Authority has responsibility for ensuring that imported food controls are designed and implemented based on international principles and guidance.

The Competent Authority will facilitate importers' ability to meet their responsibilities by providing easily accessible information on food hygiene, safety standards and other requirements (e.g. inspection processes).

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

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those of other government institutions, such as customs, plant protection, animal health and welfare.

### 2.11.3 References

The following normative references and documents are required for effective implementation of these Standard Operating Procedures:

- WTO Agreement on Application of Sanitary and Phytosanitary Measures;
- East African Community Sanitary and Phytosanitary (SPS) Protocol;
- East African Community SPS Act;
- East African Community SPS Regulations; and
- National Food Legislation.

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### 3 DEFINITIONS

- Audit** is a systematic and functionally independent examination to determine whether activities and related results comply with planned objectives.
- Certification** is the procedure by which official certification bodies or officially recognized certification 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 which may include continuous on-line inspection, auditing of quality assurance systems, and examination of finished products.
- Competent Authority** The Government Authority of the partner state having the responsibility and competence for ensuring or supervising the implementation of food safety measures, food safety certification and other standards and recommendations in the in Codex Alimentarius.
- Consignment** A quantity of food products being moved from one country to another and covered, when required, by a single health certificate (a consignment may be composed of one or more commodities or lots)
- Inspection** is the examination of food or systems for control of food, raw materials, processing, and distribution including in-process and finished product testing, in order to verify that they conform to requirements.
- Mycotoxin** Any toxic substance produced by a fungus.
- Official inspection systems and official certification systems** are systems administered by a government agency having jurisdiction empowered to perform a regulatory or enforcement function or both.
- Requirements** are the criteria set down by the competent authorities relating to trade in foodstuffs covering the protection of public health, the protection of consumers and conditions of fair trading.

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**Risk assessment** is the evaluation of the likelihood and severity of adverse effects on public health arising, for example, from the presence in foodstuffs of additives, contaminants, residues, toxins or disease-causing organisms.

**Sanitary Certificate** A certificate prepared by an authorized officer of a National Competent Authority of the exporting country, attesting to the wholesomeness of products destined for human consumption and, when necessary, giving particulars of the measures taken to prevent the spread of epizootics.

**Traceability** Codex Alimentarius Commission agreed on the following definition for traceability/ product tracing: “the ability to follow the movement of a food through specified stage(s) of production, processing and distribution.”

**Zoonoses** a group of infectious diseases naturally transmitted between animals and humans.

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## 4 FOOD SAFETY PROCEDURES

### SOP FS-001 PROCEDURE FOR IMPORTED FOOD CONTROL

#### 4.1 Imported Food Control Process

##### PRE-REQUISITES FOR IMPORTING FOOD

#### Step 1: Obtain Information on Food Imports

- 1) The Competent Authority should design and implement an imported food control system such that information is readily available to all participants:
  - a) Competent Authorities need information about the importers, and the imported food in order to develop and operate a risk based imported food programme;
  - b) importers need information about the country requirements in order to import food that meets those requirements.

#### Step 2: Profiling of Imported food, importer and exporting country

- 1) Competent Authorities shall develop and implement effective risk management options by collection and compilation of relevant data on imported food, importer and exporter countries including their associated import controls.
- 2) Competent Authorities shall undertake a systematic review and assessment of the information required, but will focus efforts on the most important information required to determine the most appropriate risk management actions.
- 3) During the review, the Competent Authorities shall identify information gaps. The Competent Authorities shall gather all information required to maintain and operate imported food controls in a systematic manner, using existing data or information already available to the Competent Authorities, or sharing information from customs or other government institutions.
- 4) Should there be significant gaps in the existing information which, although may make determination of risk management actions more difficult, the Competent Authorities will not preclude actions based on the available evidence.
- 5) The Competent Authorities shall assess the available information to identify appropriate risk management actions, and shall assess and prioritise actions to collect and assess the missing information they need.
- 6) The Competent Authorities shall then also use information on the imported food and importer profile in risk categorization.

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### a) **Importer profile**

Competent Authorities shall assess the available information about importers (e.g location and numbers) as part of their consideration of the most appropriate risk management actions.

#### i) **Residence of importers**

- (1) 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 ensuring the safety of imported food.
- (2) Non-resident importers: If importers do not reside in the country, a focus on pre-border and border controls may be more effective.

#### ii) **Proximity to borders**

- 1) Where the majority of importers are located near strategic borders (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.
- 2) 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 the Competent Authorities will consider greater use of post-border controls, as border controls may be difficult to implement.

#### iii) **Number and size of importers**

- 1) High numbers of importers: Where there are many importers, and most are small or very small, the focus shall be on identification and communication. Implementing post-border controls (e.g. licensing, assessing importers and inspecting products) may be cost prohibitive. In such cases, pre-border and border controls may be more effective.
- 2) 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.
- 3) 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.

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#### **iv) Type of storage used**

- 1) Competent Authorities shall take into account information about the size, capacity and distribution of the warehouses in establishing importer requirements.
- 2) Import permits may 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.
- 3) Where importers primarily use public warehouses for storing food, then consideration may be given to ensuring food storage warehouses are appropriately regulated, possibly within the domestic system.

#### **b) Imported Food Profile**

- i) Before food is imported, the Competent Authorities shall 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.
- ii) The Competent Authorities will develop imported food profiles beginning with assessing what information is needed, what is available and what specifics still need to be collected. This information is important in establishing risk characteristics.

#### **(I) Imported food characteristics**

- (a) **Significant or unknown/unquantifiable risk with no mitigation options:** Given significant risk, with no mitigations, the import of such foods is generally **prohibited**.
- (b) **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.
- (c) **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.
- (d) **Low risk products:** Foods deemed low risk, may have minimal controls, mostly focused on importer identification and monitoring within the country.
- (e) **Foods of animal or plant origin:**
  1. Some foods must be controlled at source (e.g. biotoxins in molluscan shellfish; aflatoxin in grains).
  2. Certain hazards must be controlled by the exporting country or importer (e.g. additives, veterinary drugs, pesticides)

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3. The animal health status of the exporting country has to be determined.

**II. Imports primarily of raw products (e.g. grains, fresh fruit and vegetables) or processed products (e.g. ready to eat and dried foods):**

1. If imported foods are processed in the importing country, the import controls may simply consist of identification and tracking the 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.
2. Where products are intended for direct sale to consumers, they may require a combination of controls. Imported food must be labelled appropriately.
3. All imported food that does not meet labelling (e.g. language, ingredients, product date codes) requirements shall be detained and upon failing to comply with the requirements within reasonable time, be returned to the country of origin.

**III. Whether imports simply supplementing domestically produced food, or imported food is 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.

**IV. 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.

**V. If processed products, whether they are 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.

**VI. Whether perishable (e.g. fresh fruit and 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.

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### c) Exporting Country's Profile

- i) The Competent Authorities seek to understand the source(s) of imported foods including the route and conditions of importation.
- ii) Where the competent authority is considering pre-border controls, it may choose to establish exporting country's profiles (e.g. processing, food safety controls).

#### (I) Knowing the source of imported food is important:

- (a) Is the food import shipped directly from a source country or is it transshipped through other countries (transshipment 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 transshipped, 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):
  - (i) 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.
  - (ii) 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.

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- (i) 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).
- (ii) 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.

## **(2) 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)?
  - (i) 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 and seasonal crops).
  - (ii) 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.

## **3) Location of imports**

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

- (c) **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?
  - i. Where there are specified ports of entry, the inspection locations may be located within the ports.

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- ii. 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.
- iii. 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.

#### **4) 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 and product inspection) as part of the decision making process.

### **Step 3: Risk Categorization**

- 1) Competent Authorities shall use the Codex Alimentarius risk analysis framework as the basis for developing risk based imported food controls.
- 2) Where countries have insufficient information for performing a full risk assessment, the scientific pillar of risk analysis, Competent Authorities shall not preclude implementation of risk based imported food control due to insufficient information for a risk assessment.
- 3) Given the difficulty in completing formal risk assessments for all imported food and hazard combinations, Competent Authorities may use risk categorization (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.
- 4) Competent Authorities may apply risk categorization process in the following scenarios:
  - a) **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.
  - b) **A consideration of other factors that can reduce or affect product risk**, such as controls implemented by the manufacturer, the exporting country or the importer,

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called control characteristics. Risks related to pesticide or veterinary drugs residues and additives would be taken into account under this step of the process.

- c) **As a result of the above 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.
- 5) Competent Authorities will use information from the imported food and importer and exporter countries' profiles to inform the risk categorization programme.

#### 4.1.1 PRE-BORDER CONTROLS

##### **Step 4: Assurance of food controls from exporting country's Competent Authority<sup>1</sup>**

- 1) Assurance from the Competent Authority in the exporting country is the most common pre-border control.
- 2) Competent Authorities of importing countries should make the following considerations for success with pre-border controls
  - a) Knowledge of importers and what they import;
  - b) Knowledge and understanding of the food control system in exporting countries; and
  - c) Effective border controls.
- 2) The Competent Authority in the exporting country shall be responsible for providing assurance that food is produced to meet the importing country's requirements. Information exchange and communication maintains confidence that controls are being properly maintained and implemented in the exporting country.
- 3) Competent Authorities in Countries shall have responsibility to provide assurances of food safety and quality to trading partners in formal arrangements between partners.
- 4) Formal agreements/ arrangements for assurance of food safety and quality may take any of the following forms:
  - a) 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;

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<sup>1</sup>Assurance of the food controls in exporting country for high-risk foods 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.

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- b) 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
  - c) 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.
- 5) In cases where 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 should form building blocks for future recognition of assurance in the controls of the exporting country.
  - 6) Countries trading need to prioritise the development of arrangements, as it requires time and resource from the exporting and the importing country. Where there is significant multi-country trade, countries may consider multilateral arrangements.

#### **Step 5: Third party verification <sup>2</sup>**

- 1) Competent Authorities may use third party service providers to inspect, audit and sample product lots, or otherwise provide information on foreign processors' food safety controls.
- 2) Competent Authorities may enter contractual agreements for third party service providers to systematically check all lots prior to shipment, as a complement (and sometimes substitute) to border controls. Third party service providers may also be used as border officials (e.g. product inspection designed to collect taxes or fees).
- 3) 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.
- 4) Where service providers are incorporated into pre-border imported food controls, accreditation is necessary, assessing the service provider against objective criteria and compliance with standards, in particular with respect to competence, independence and impartiality.

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<sup>2</sup>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.

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- 5) The Competent Authorities shall regularly assess the performance of 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.

#### **Step 6: Controls performed by importers**

- 1) Pre-border controls by importing countries may include a requirement that food importers assess their suppliers and the imported food, (e.g. implement foreign supplier verification and food safety management plans) in order to assure food safety.
- 2) Competent Authorities may require the importers to exercise controls as a primary pre-border control, or as a complement to government controls.
- 3) 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:
  - a) 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 distributors, if appropriate.
  - b) Verification can include import requirements in purchase contracts, document verification, audits, or sampling and testing.

#### **Step 7: Recognition of pre-border controls**

- 1) A mechanism of recognition can be included in arrangements with lot-by-lot certification reserved for high-risk foods.
- 2) If the imported food control programme includes pre-border controls, the importing country will need a mechanism to identify foods which have been subject to those controls when they are presented at the border.
- 3) This is generally managed through certification, provided by either the exporting country's Competent Authority or by a recognized/authorized third party.
- 4) The Competent Authority may employ several options for official certification, particularly under arrangements with exporting countries, such as:
  - a) Identification of processing plants that the exporting country certifies as meeting its requirements (often identified as plants in good regulatory standing).
  - b) Using export certificates for a specific product lot or multiple lots from a specific plant, generally reserved for high-risk foods.

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- c) 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.

#### 4.1.2 BORDER CONTROLS<sup>3</sup>

- 1) Competent Authorities may use product inspections to verify the efficacy of other controls (e.g. pre-border controls by importers, third parties or other governments).
- 2) In undertaking border controls, the Competent Authorities and their agents should have clear legal authorities for their actions.
- 3) Competent Authorities may make the following considerations for success with border controls:
  - a) Importers with significant import controls;
  - b) Presence of strong border controls; and
  - c) Inspector and laboratory capacity.
- 4) Border controls measures may include document and identity checks, inspections, sampling and analysis:
  - a) prohibiting or limiting entry for particular categories of food;
  - b) mandatory pre-notification and/or notification of imported food consignments or lots;
  - c) preclearance processes, particularly for perishable foods;
  - d) document checks to validate imports, including confirmation of product identity and validation of certification;
  - e) inspection of imported food, and condition of transport, which may include sampling and analysis of the food; and
  - f) refusal of entry or destruction of unacceptable imports.
- 1) The Competent authorities shall use the information from the importer, imported food profile and risk categorization 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.
- 2) The Competent Authority has responsibility to make readily available regulatory requirements and border control procedures to importers and exporters, as transparency

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<sup>3</sup>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.

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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.

- 3) 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.
- 4) 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).
- 5) Competent Authorities may determine admissibility of imported food at the border by going through 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).
- 6) The Competent Authorities may also carry out inspections, which may include procedures such as:
  - a) Document review of certificates and other import documentation for relevance, accuracy and validity;
  - b) 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?);
  - c) Inspecting and cross referencing the food in a shipment to validate the accuracy of the accompanying documentation, often called identity checks;
  - d) Sensory evaluation of a product;
  - e) Sampling (random) based on a sampling plan – including lab analysis; and
  - f) Mandatory lot-by-lot inspection with testing, which should be reserved for foods with the highest risk.
- 2) Competent Authorities have to ensure uniformity of inspection and decisions on imported food to enhance credibility and confidence in the imported food controls.

### **Step 8: Pre-notification or notification of imported food**

- 1) Information on every lot of imported food shall be provided to the competent authority.
- 2) In order to have efficient and effective border controls, every consignment of imported food shall be formally pre-notified or notified, that is information on the food must be

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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.

- 3) Notification shall be done, 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.
- 4) For border controls, Competent Authorities should require that accurate information is provided for each shipment, container or lot such as:
  - a) a description of the product;
  - b) the quantity;
  - c) the producer;
  - d) the country of origin, including whether the food was transshipped through a third country, or was redirected following sale while in transit;
  - e) the location where the food will be held or stored on its entry into the country;
  - f) the name, address and telephone number of the importer as declared to the border services;
  - g) 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.

## Step 9: Imported food transshipped through a third country <sup>4</sup>

### I) Transit

- a) Competent Authorities shall allow Food destined for one country to transit through another country in bond, without entering the country of transit.

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<sup>4</sup>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.

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b) The country of transit may, however, 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 may be related to animal health or plant protection requirements.

## 2) Transshipment

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 transshipment, the food will be stored under appropriate conditions, and no processing occurs.

## 3) Consolidated shipments<sup>5</sup>

- a) Details of consolidated shipments shall 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.
- b) The importer shall 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.
- c) Competent Authority of a country with many transit, transhipped or consolidated food shipments due to its location, trade patterns, market size, or importers that serve multiple countries, shall establish specific requirements for such food — such as risk management, enhanced importer requirements (e.g. foreign supplier verifications), or enhanced border inspections.
- d) In the case of transhipped or consolidated shipments, the Competent Authority of exporting country should provide assurance 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).
- e) In cases where problems 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, the consignment shall be isolated/rejected.

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<sup>5</sup>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 sufficient volume (e.g. products, types, quantity) to fill an importer's order in a third country.

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### Step 10: Document review

- 1) It is the importer's responsibility to provide the Competent Authority with clear, accurate and legible documents.
- 2) Official documents may include:
  - a) Purchase orders, including required specifications.
  - b) Bills of lading, manifests.
  - c) Packing list
  - d) Import permit, licence or other required documents that authorize importations.
  - e) Official Certificates, if required.
- 3) Only officially requested documents will be reviewed; imported food without appropriate documentation may be refused entry.
- 4) The Competent Authority shall carry out document review in a consistent step-by-step approach by assessing the completeness and validity of the official documents provided by the importer.

### Step 11: Decision to inspect or not

- 1) Upon completion of the document review, a decision on whether the lot should be inspected must be made.
- 2) Competent Authorities should base decisions to inspect on risk categorization and criteria relating to compliance of the product with importing country requirements.
- 3) The Competent Authorities shall clearly establish the criteria for when lots will be inspected.
- 4) The inspections shall be carried out by the Competent Authorities or an accredited service provider where authorized by legislation.
- 5) 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.
- 6) Imported food controls shall include requirements for product inspection:
  - a) where there is little or no history of the product or source;
  - b) if there is previously known non-compliance;
  - c) to validate the accuracy of documentation; or
  - d) to monitor the imported product according to a pre-established sampling plan.
- 7) Imported food control officials shall have full access to inspect an imported lot, which for container shipments means "destuffing", also called unloading, or turning out the container.
- 8) Containers must be destuffed or unloaded to provide officials with full access to inspect imported food lot(s).

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- 9) 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. In such cases, the admissibility decision may require a two-step process:
  - a. customs review (e.g. duty, tariffs, document review); and
  - b. food safety and quality admissibility decision with clearance being given only after both steps have been satisfactorily completed.

### Step 12: Conducting Inspection

- 1) If inspection is warranted under the importing country controls, then this decision should be communicated to the importer.
- 2) 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).
- 3) The lot may also be detained at the storage facilities until the inspection results are known.
- 4) Competent Authorities should have a written inspection and sampling plan that identifies inspection and sample requirements (e.g., numbers, tests).
- 5) 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).
- 6) 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.
- 7) 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.
- 8) 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.
- 9) Sampling should be based on acceptable international guidance (e.g., Codex, ICMFS, ISO, AOAC). In addition, internationally validated standard methods of analysis or methods validated through international protocols should be used in testing the food.
- 10) Once the inspection and sampling results are known, a decision on the food lot can be made:
  - a. If the imported food meets importing country's requirements, it can be released.

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- b. If the product does not meet the requirements and it is still under detention, then that detention should be maintained.
  - c. 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.
- 11) Results of inspection and, where used, laboratory analysis should be carefully considered in making decisions on the acceptance or rejections of lots or consignments.
- 12) Decision making rules should be clearly established and available to all importers, and include formal communication of results and opportunity for appeal.

### **Step 13: Administrative appeals**

- 1) The Competent Authority shall provide a clear and transparent process for administrative appeals including, where available, options for use or disposal of the non-compliant consignment.
- 2) The administrative appeal:
  - a) Provides importers with an opportunity to discuss the decision with officials and, possibly, to provide further information to clarify the situation.
  - b) 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.
  - c) Provides timeframes for appeals.

### **Step 14: Decisions regarding non-compliant products**

- 1) Once an imported product has been determined to be in violation of the importing country's requirements, the importer should be advised.
- 2) In addition, information on the rejected lot should be provided to the exporting country. 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).
- 3) In addition, the Competent Authority should assess whether the information should be reported under other international arrangements (e.g. International Network of Food Safety Authorities (INFOSAN), International Health Regulations (IHR)).

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- 4) 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.
- 5) With respect to the non-compliant product, there are options available, depending on the nature of the violation. Options include:
  - a) 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.
  - b) If no mitigating process is possible, the importer may seek to:
    - i) return product to supplier, particularly where the product remains the property of the exporter/supplier; or
    - ii) 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.
- 6) Where there are serious health risks, a decision to require the lot to be destroyed should be considered.
- 7) 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:
  - a) Ensuring food is destroyed to inactivate any pathogens, and render the product inedible, thus minimizing the potential for diversion or theft;
  - b) Safeguarding the workers against hazards (e.g. handling decomposing foods); and
  - c) Minimizing environmental concerns including risks posed to wildlife.
- 8) 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.<sup>6</sup>

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<sup>6</sup>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

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### Step 15: Follow up to product rejections

- 1) 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.
- 2) 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.
- 3) 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.
- 4) 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.
- 5) In such cases the importer shall also enhance controls for future import shipments from that source through increased intensity or frequency of checks, requests for information and cooperation by supplier, or on-site visits to exporting facilities.
- 6) Labelling requirements (e.g. language, common names, ingredients, sizes, descriptions or claims) are often associated with significant non-compliance for imported products. Because of the frequency of such issues, pre-import label approval may assist in reducing non-compliance.
- 7) 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

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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

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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.

#### 4.1.3 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 means of transportation 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.

#### Step I: Profiling importers

- 1) 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:
  - a) Basic identification of importers: company name, physical address, contact information (email, phone, manager), where imported food is to be stored (if different from address).
  - b) Establishing minimum importer requirements: such as meeting GIP.
  - c) Requiring import permits for high-risk foods: requirement for all importers to apply for a permit and abide by the conditions of that permit.
  - d) Limiting imports to licensed importers: no importation without a licence; establishing requirements for maintaining a licence and a process for revoking the licence.
- 2) 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.<sup>7</sup>

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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.

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- 3) 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:
  - a) collect data to design and maintain the risk based system;
  - b) educate importers about food: that it is not just “a commodity”, and identify the country requirements that must be met;
  - c) communicate on an ongoing basis with known importers (e.g. informing them of problems in an exporting country); and
  - d) create an oversight programme that can be used to verify that importers are meeting country requirements.
- 4) The importers and imported food profiles should be analyzed to determine the most appropriate controls, such as:
  - a) Requiring that importers have appropriate storage conditions and sanitation.
  - b) Requiring that documents and information on imported food are maintained and made available for review.
  - c) 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.
  - d) Licensing importers, so that only licensed importers are authorized to import food. The licence could include various conditions such as GIP, foreign buyer verification.
- 5) 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:
  - a) 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:
    - i) 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;
    - ii) enhanced frequency and intensity of imported food inspections until compliance improves; or

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- iii) suspension or revocation of an import license or permit.
- b) Reviewing importer practices for adherence to GIP such as:
  - i) procedures used to ensure exporter's ability to ensure food is in compliance with importing country'S requirements;
  - ii) 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);
  - iii) development of a risk based inspection frequency for importers, as most programmes will have limited resources to inspect importer premises and controls;
  - iv) (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.

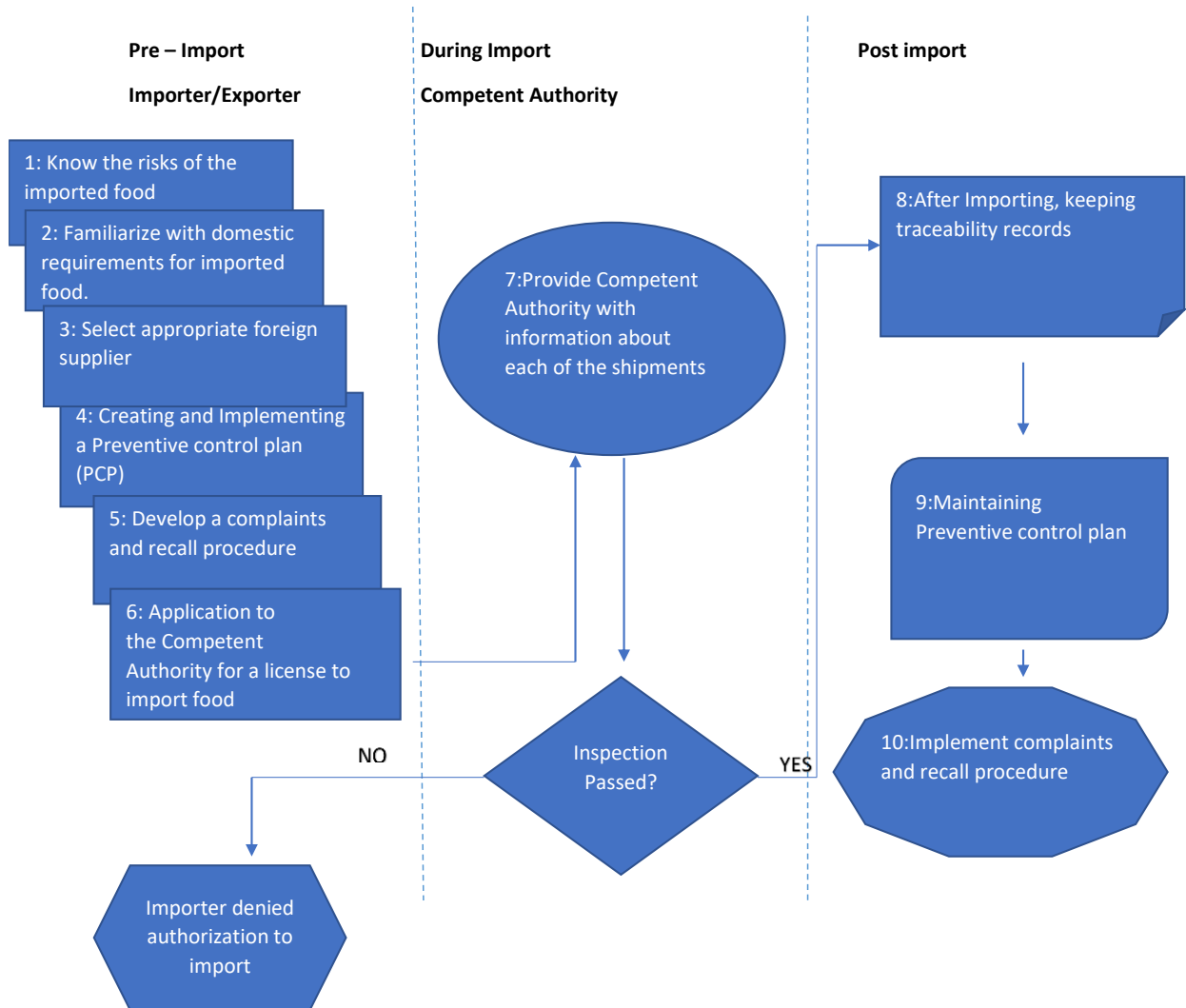
## **Step 2: In-country control of imported food**

- 1) Post-border (in-country) monitoring may include sampling products 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.
- 2) 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.
- 3) 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.
- 4) 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.
- 5) Guidance on surveillance or monitoring will be established in sampling strategies and annual sampling plans.

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## 5 SOP FS-002PROCEDURE FOR IMPORTING FOOD

### 5.1 Procedural steps for Importing Food



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Before importing food, importers should:

**Step 1: Know the risks of the food they import**

- 1) This includes knowing the following: the description of the food you import (the type of food, its common name, the quantity you intend to import, the packaging of the food) and identified hazards reasonably expected to occur with the food being imported. These hazards must be prevented from occurring, or they must be eliminated or reduced to a level that does not pose a risk to human health.
- 2) Importers shall have a general understanding of the supply chain(s) for the foods being imported.
- 3) Importers are encouraged to work with their foreign supplier to ensure they: understand the supply chain for the food being imported; understand how the foreign supplier is addressing all hazards associated with the food; know if the food will need further processing or labelling after it arriving in the importing country, so it will meet domestic requirements; can demonstrate that the food is manufactured, prepared, stored, packaged and labelled under conditions that provide at least the same level of protection as provided by the importing country.

**Step 2: Familiarize themselves with domestic requirements for importing food.**

Importers should consider the following three categories of requirements related to food imports: Food requirements;<sup>8</sup> Importer Requirements;<sup>9</sup> and Procedure Requirements.

**Step 3: Select an appropriate foreign supplier**

- 1) Importers are responsible for ensuring that their foreign suppliers are producing, preparing, storing, packaging or labelling the food before it is imported under the same conditions

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It may 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 requirements for imported food, importers are required to become familiar with any applicable requirements related to standards, grades, net quantity and labelling. In certain cases, the imported food may be subject to other regulations. Importers shall familiarize themselves with such regulations.

<sup>9</sup>Key importer requirements include (i) creating, implementing and maintaining a preventive control plan (PCP); (ii) developing recall and complaints procedures; (iii) have a license to import; (iv) ensuring that the imported food has been prepared under similar conditions as food prepared in importing country; and (v) keeping traceability records of where the imported food is sourced from and to whom it is sold to

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required in the importing country. Foreign supplier(s) needs to be aware of domestic food safety requirements and are willing and able to provide the information needed to demonstrate food safety controls are in place.

- 2) In general, for all food except meat and shellfish, Food Safety Competent Authorities do not restrict imports from certain countries or suppliers.
- 3) In the case of meat and shellfish, importers can import only from countries that have a food safety systems that are approved and recognized as providing the same level of protection as that provided by importing country.
- 4) The type of information needed from foreign suppliers will vary. It will depend on
  - a) the food being imported
  - b) the types of activities or processes the food is subject to before being imported and
  - c) whether there are existing oversight measures in place that the foreign supplier is subject to

#### **Step 4: Creating and Implementing a Preventive Control Plan (PCP)<sup>10</sup>**

- 1) The PCP is a requirement for an import license. An importer has to develop and implement it before applying for an import license and before importing food.
- 2) If the importer conducts other food-related activities other than importing (such as manufacturing, preparing, packaging or labelling food in the importing country that will be exported or sent between provinces/counties), the license and PCP may have to cover these activities as well.

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- 1) <sup>10</sup>A Preventive Control Plan (PCP) is a written document that outlines the measures and controls taken to ensure the imported food is safe and fit for human consumption and complies with food safety requirements provided under EAC SPS Protocol and Regulations. .
  - 2) Preventive controls are an internationally accepted approach to prevent or mitigate hazards associated with food products. They are based on the CODEX Alimentarius General Principles of Food Hygiene.

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### **Step 5: Develop a complaints and recall procedure**

1) Before applying for an import license, the importer must develop a complaints and recall procedure

#### **a) Complaints procedure:**

- i) Written procedures to show how the importer receives, investigates and responds to complaints will help handle them in a timely and consistent manner.
- ii) A complaint received on a product could be an important indicator of a possible issue with food safety controls applied by the foreign supplier and/or problems arising during distribution and handling of the food.

#### **b) Recall procedure**

- i) If a consumer complaint or other finding (for example, company testing) results in a recall, the importer must be prepared to quickly recall all affected product from the marketplace. If the food subject to the recall represents a risk to the health of consumers in importing country, the importer is required to notify the Competent Authority of this issue immediately.
- ii) To prepare for a potential recall, the importer is required to create a written recall procedure that:
  - (1) describes how the recall will be conducted and the name of the person who is responsible for maintaining the procedure, and
  - (2) the name of the person who is responsible for conducting the recall

### **Step 6: Application to the Competent Authority for a license to import food**

- 1) To obtain an import license, the importer needs to sign up with the Competent Authority. By signing up with the Competent Authority, the importer can create one or more business profiles based on an enrolment model of the food business.
- 2) The import license shall be valid for a period of 1 year from the effective date indicated on it. As the license approaches expiry, the importer can apply to renew the license.

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**Step 7: When it is time to import, provide the Competent Authority with information about each of the shipments**

- 1) The Competent Authority needs to be notified of all food shipments being imported.
- 2) As part of the import process referenced above, the Competent Authority may require the importer to provide certain information about all food shipments were imported prior to or at time of importation.

**Step 8: After Importing, keeping traceability records**

- 1) The importer is required to keep traceability records for all the foods imported. The documents must allow the importer to trace to his/her imported food forward to the immediate customer and back to the immediate supplier.
- 2) Tracing the imported food back to the immediate supplier means you need to keep a record of the name and address of the person or food business that sold or consigned the imported food to you (for example, the vendor). You also need to document the date the food was sold or consigned to you.
- 3) Tracing the food forward to the immediate customer means you need to keep a record of the name and address of the person to whom you transferred care, control, ownership and/or responsibility of the food after it was imported and the address of that person or food business. If you are selling your imported food at your own store; you are not required to keep a record of your customers who has purchased the imported food.
- 4) The importer's records have to be clear, readable and accessible for two years. They must also be provided to the Competent Authority upon request and must be in English. If electronic records are used, they need to be provided in a format that can be easily read by standard computer software.

**Step 9: Maintaining Preventive control plan**

- 1) Importers should consider the PCP to be a "living document," meaning that as things change in the import operation; the PCP gets updated to reflect those changes.
- 2) Your PCP should be reassessed and updated at regularly to ensure that it is current and working effectively:

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- a) The PCP should be updated when a change occurs, such as a change in your supplier or a change in food safety controls applied by your supplier.
  - b) The importer should consider a review of your PCP when a potential problem is identified, such as a complaint or a recall related to a food imported.
- 3) Importers are required to keep the documents that they receive from their suppliers that demonstrate the effectiveness of the PCP. The importers need to keep these for 2 years after the day on which it is prepared.

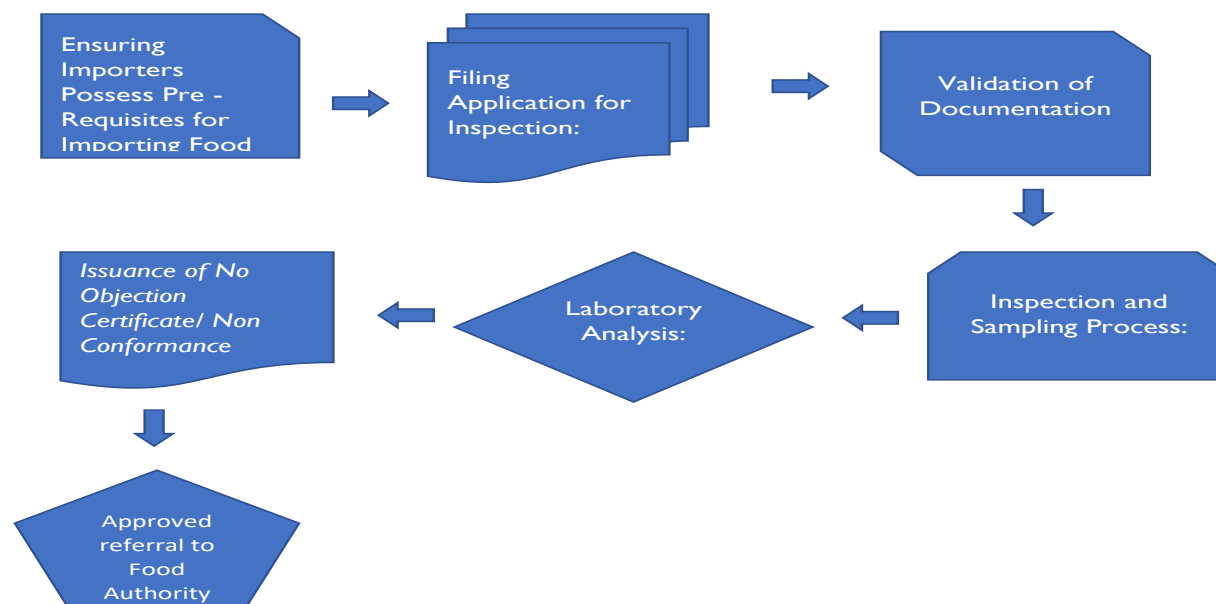
**Step 10: Implement the complaints and recall procedure as required**

- 1) Importers are required to keep a record of any complaints they receive regarding the foods imported in accordance with the procedure they developed under Step 5.
- 2) When the importers receive a complaint, they are required to keep a record of the complaints and determine whether the food in the complaint represents a risk to the health of consumers in the importing country.
- 3) Importers of food are required to implement their complaints' procedure, as needed, by taking action to follow up on a complaint and keeping a record of the details of these follow-up actions.
- 4) Importers of food are required to keep any documents related to a complaint they received and the actions taken. They need to keep these for 2 years from the date the follow-up actions were completed.
- 5) Implementation of the importer's recall procedure includes taking actions to remove the food that is subject to the recall from the marketplace and, if the food presents a risk to human health, notifying the Competent Authority immediately. Importers need to write down all details of a recall and need to keep these for 2 years after the day the recall was started.
- 6) To ensure the importer's recall plan will be effective, once every 12 months importers are required to simulate a recall using their written procedure. Importers need to write down details of the recall simulation and the results and have to keep these for 2 years from the day the recall simulation ended.

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## 5.2 SOP FS-003 PROCEDURE FOR INSPECTION AND APPROVAL OF IMPORTED FOOD

### 5.2.1 Procedural steps for Inspection



#### Step 1: Ensuring Importers Possess Pre - Requisites for Importing Food:

- 1) The Importer shall possess:
  - a) a valid Import License;
  - b) a valid Importer Exporter Code (IE code);
  - c) Product Approval (if the product proposed to be imported is non-standardised i.e. it is not in conformity with the food standards prescribed under relevant Food Safety legislation);
- 2) The Importing FBO submits an Authority Letter in favour of a Customs Handling Agent (CHA) to the Authorised officer, if he chooses to handle his imports through a CHA.

#### Step 2: Filing Application for Inspection:

- 1) The Importer shall file an application for clearance of consignment with the Department of Customs;
- 2) Upon generation of Bill of Entry and after receiving the inspection order from the Department of Customs, the Importer files for an application in the Food Import Clearance System (FICS) of the Competent Authority to obtain the 'No Objection Certificate'.
- 3) The documents required in the FICS in respect of the consignment are:

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- a) IE Code issued by the Competent Authority;
  - b) License issued under relevant legislation;
  - c) Product Approval (if required) from the Food Authority;
  - d) Bill of Entry; and
  - e) Examination Order.
- 2) Apart from the above mentioned compulsory documents in all cases, additional product specific documents are required to be attached, e.g.
- a) Import Permit;
  - b) Sanitary Import Permit;
  - c) Registration of import contracts;
  - d) Certificate of Origin containing information on Country of Origin etc. if the consignor is from a different country;
  - e) Phyto-Sanitary Certificate issued by the Plant Quarantine Department of Exporting Country in case of primary agriculture/ horticulture produce with fumigation endorsement;
  - f) Certificate of Analysis with composition (Ingredients);
  - g) Test Certificate;
  - h) End-use declaration - The Food Importer has to clearly declare the end use of the imported food product;
  - i) List of transit country, if the food consignment is trans-shipped through more than one country;
  - j) Temperature Chart / Report / Graph, if the food consignment trans-shipped under the Cold Chain Technologies (CCT) from the port of origin to the point of import;
  - k) Stuffing list, Packing List;
  - l) Commercial invoice as mentioned in the Bill of Entry (BoE);
  - m) Bill of Lading as mentioned in the Bill of Entry (BoE) for sea consignment;
  - n) Air Way Bill as mentioned in the Bill of Entry (BoE) for air consignment;
  - o) In case of aseptic package, declaration by an undertaking from the manufacturer that the representative sealed sample is from the same batch of the consignment;
  - p) In the absence of representative sample for the aseptic package, the importer should furnish an Undertaking to the effect that they do not have any objection to break open the sealed aseptic container from the consignment and collect the sample for laboratory analysis and the Food Authority is not responsible for any kind of damage to the consignment due to such drawl of sample as it is necessary for the clearance of the consignment. Similarly, if the sample quantity is insufficient to draw the duplicate sample,

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the importer shall submit declaration that —no claim shall be made for re-testing, if the primary test fails;

- q) In case of re-import in addition to the documents listed above, submit the documents filed in the customs at the time of export as well as copy of the rejection certificate with reasons for such rejection(s) issued by the Officials of importing country before its re-export thereby leading to reimport into the country;
- r) High Sea Sale Agreement;
- s) Radio Activity Certificate, if irradiation is used; and
- t) Any other report(s) / document(s) / undertaking (s)/ Affidavit(s) as directed and as specified by the Authorised Officer or by the Competent Authority from time to time.

### **Step 3: Validation of Documentation**

- 1) On presentation to officials at import controls, all documentation accompanying shipments should be subject to validation and verification in order to confirm its authenticity. This also applies to validation of certificates issued by an exporting country or third party service provider.
- 2) 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).
- 3) 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.
  - a) The Authorised Officer of the Competent Authority shall verify the documents filed by the importer and may seek clarification, if required.
  - b) Authorised Officer shall verify that import is not from the banned/ prohibited/ restricted source or food;
  - c) If the documents are found to be in order, the Authorised Officer shall ask the importer to deposit the fees as per the number of samples.

### **Step 4: Inspection and Sampling Process:**

- 1) The Authorised Officer shall inform the date and time of visual inspection of the consignment;
- 2) Importer shall acknowledge the appointment for Inspection/ sampling;

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- 3) The visual inspection of the consignment will include:
  - a) Physical condition of the consignment for visible insects and fungal infestation;
  - b) Valid remaining shelf life of the product is more than the 50% of its original shelf life at the time of import clearance;
  - c) Compliance of the Food Safety System (Packaging & Labelling) and the product specific labelling requirements;
  - d) An order to comply with rectifiable labelling defects in the Custom Bonded Warehouse; and
  - e) The Authorized Officer can re-inspect the consignment, if required, for ensuring compliance of instructions for removing the rectifiable labelling defects.
- 4) After the visual examination, labelling related compliances and after ensuring the remaining balance shelf life, the Authorized Officer shall draw two samples in the presence of Importer or his representative.
- 5) The quantity of sample to be sent to the Food Analyst shall be as per FSS Rules and the Laboratory and Sampling Analysis Regulations, 2011.
- 6) The sealed sample of imported food shall bear the following information on the Label:
  - a) Code number of the Sample;
  - b) Date and place of collection;
  - c) Quantity of Sample;
  - d) Name of food;
  - e) Name and Quantity of preservative added while drawing the Sample, if any; and
  - f) Name and signature of the sender with official seal.
- 7) One of the sealed and labelled Food Samples shall be sent to the Notified Laboratory. The second Food Sample shall be stored in appropriate conditions for re-testing, if the need arises.
- 8) In case of sealed bulk containers to maintain aseptic or hygroscopic conditions, the importer shall provide two representative Samples along with the manufacturer's undertaking.

#### **Step 5: Laboratory Analysis:**

- 1) The sample of the imported food product shall be forwarded along with Certificate of Analysis (CoA) from the country of origin of the consignment to the notified laboratory selected randomly by the Food Import Clearance System;
- 2) The samples of imported Food sent by the Authorized Officer shall be analyzed by the laboratory as per the parameters defined in the Food Safety and Standards Act and the

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Regulations thereunder and shall send its report within five days to the Authorized Officer with conclusive opinion about the product tested as conforming or non-conforming;

- 3) If the importer is not satisfied with the report of the notified laboratory, he has the option to apply for re-testing of the sample by a Referral laboratory. If so, the Authorized Officer shall send the second Sample for re-testing to the designated Referral laboratory. The Sample shall be accompanied by the Certificate of Analysis from the country of origin of the consignment and the parameters on which tests have been conducted by the Notified Laboratory. The report of analysis issued by the Referral food laboratory shall be final.

#### **Step 6: Issuance of No Objection Certificate/ Non Conformance Certificate:**

On the basis of the laboratory report for its conformance/ non-conformance as relevant legislation and the Regulations thereunder, the **No Objection Certificate (NoC)/ Non Conformance Certificate (NCC)** is issued.

#### **Step 7: Food Import Clearance for Specific Purpose**

- 1) Unless otherwise specified, the Customs authority may not refer the imported food to Food Authority for clearance, if such food is meant for:
  - a) Export as per the extant Government instructions and export rejected/ re-imported food meant for re-export;
  - b) The food articles/ ingredients/ additives which are being imported by the manufacturers/ processors for their captive use/ production of value added products for 100% exports; and/ or the consignments of food items/ ingredients/ additives imported by the firms/ companies for use of their sister concerns/ wholly owned subsidiary companies, to be used for 100% export production subject to a defined relationship agreement between the two entities in this behalf;
  - c) The importer would have to submit an Undertaking as per Annexure-3 regarding the captive/ end use of the imported product to the Customs Department at the time of filing the Bill of Entry, declaring that the imported food article is meant to be used by the importer for 100% export or re-import of food for export again as the case may be, and that no part thereof will be supplied for domestic consumption;
  - d) The above facility under sub-paras (b) and (c) above shall not be applicable in the case of trading entities, who do not import such items for their captive use in view of the problems associated with traceability of the end-use of such items.

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## 2) **Food imported by Diplomatic Missions**

The clearance of Food Imports shall be dealt in accordance with provisions of Vienna Convention on Consular Relations, 1963 (Article 50 of the Vienna Convention on Consular Relations, 1963).

## 3) **Import of Food for Quality Assurance, Research and Development**

The clearance of food import for quality assurance, research and development purposes will be subject to furnishing an Undertaking by the Food Importer that the imported food will be utilized for aforesaid purposes only and not to be utilized or released into the domestic market or used for test marketing or market research purposes.

## 4) **The food imported for the purposes of Exhibitions & Tasting**

Such shall be exempted from the normal clearance procedures of the Food Authority. The procedure for clearance of food imported for exhibition purposes shall be as under:

- a) The Exhibitor shall submit an Undertaking before the Customs Authorities stating that imported food product(s) are meant for the limited purpose of Exhibition and Tasting and not for any commercial purpose/ sale and regarding the safety of the imported food;
- b) In case the food is also proposed to be used for tasting purposes, the importing exhibitor entity shall submit a copy of the food safety certificate issued by the Food Regulatory Authority of the country of Origin;
- c) The food products, included in the list of Prohibited Items for Import or specified by the Authority from time to time will not be allowed import for exhibition purposes;
- d) All products for exhibition shall bear an additional label/ sticker stating: **“For Exhibition purpose only”** and **“Not for retail sale”**;
- e) The importing entity shall be responsible for compliance of laws and rules regarding its obligations to pay the customs or any other applicable duties and requisite state levies;
- f) The importing exhibitor shall maintain a Bill of Material:
  - i) of the items imported for exhibition;
  - ii) the items consumed for tasting purposes or destroyed; and
  - iii) the items for re-import to the country of origin at the end of the Exhibition/Fair and shall be liable to submit the same on demand by the competent authority.
- h) A placard shall be displayed at the place of exhibition of food items offered for ‘Tasting’, advising that the product may not be in compliance with the applicable food standards and regulations made thereunder;
- i) The unconsumed portion of the food products, which have been opened for tasting, shall be destroyed after the exhibition. The food product in packed containers shall be re-exported; and

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j) In case of any food received during any **Disaster/Emergency situations**, the quality/safety of imported Food shall be ascertained.

#### 5) **Import of Food for sports events**

The clearance of Food import exclusively for these purposes will be subject to furnishing an Undertaking by the Food Importer that the Food shall not be released for sale to any other person. The unused Food shall be re-exported to Exporting country after the event or it shall be destroyed. The importer shall submit the documentary proof thereof within thirty days from the last day of such event. The quantities of Food imported shall not exceed the quantities necessary for direct utilization by the persons concerned for the duration of the stay or event, whichever is earlier.

#### 6) **Provisional No Objection Certificate (NOCs)**

The consignments of fresh fruits/ perishable food items and the food which require special storage conditions (e.g. refrigerated warehousing) shall be issued Provisional NOC, without waiting for the analysis report from lab on the basis of undertakings from the Importer.

#### 7) **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.

#### 8) **Validation and verification of commercial certification**

In cases where commercial certification is used or referred to in the decision on the compliance of imported products with import requirements, sufficient checks will 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.

#### 9) **Fraudulent certificates or tampering with certificates**

a) 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:

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- i) specialized paper (e.g. fluorescent stripes etc.);
  - ii) water marks and/or embossing features; and
  - iii) barcodes or other digital references.
- b) Official signatories may also change with time.
  - c) 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.
  - d) Tampering with certificates can occur in the exporting country or during transportation to the importing country.
  - e) 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).
  - f) Importers have a responsibility to ensure imported products are accompanied by valid certificates where required.
  - g) Tampering with a certificate renders it invalid, and may render the imported food described in the certificate as ineligible for import.
  - h) Certain changes can be made to a certificate without tampering, particularly with respect to changes to ports of entry, place of loading.

#### **10) Electronic certificates**

- a) Electronic certification may 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).
- b) Where electronic certificates are used, careful consideration shall be given to ensure the system is protected against fraud, malicious damage (e.g. computer viruses) and all unauthorized entry.

#### **Step 8: Notification of failing consignments or fraudulent certification**

- 1) The certifying agency in the country of export needs to be advised of any false certificates, or certificates that have been tampered with, identified in the importing country. This information shall 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.
- 2) When notified of problems with certificates, they shall 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.

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- 3) Where the issue is non-compliant consignments, the findings shall 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.

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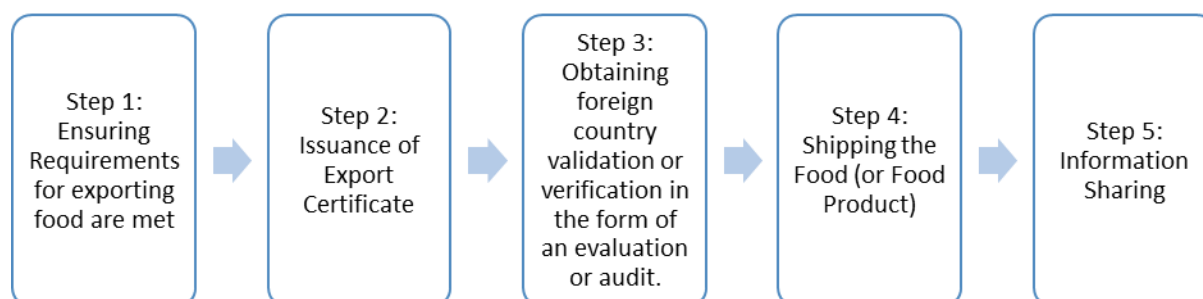
### 5.3 SOP FS-004 PROCEDURE FOR FOOD EXPORT CERTIFICATION

To export food, the Food Business Operator (FBO) will generally need:

- a compliant food product;
- preventive food safety controls in place;
- traceability procedures for their food;
- a valid export license or registration, if applicable; and
- documentation of all relevant export information.

This procedure outlines the considerations and overall process to export food which will help FBOs comply with requirements in the Acts and Regulations for food products.

#### 5.3.1 Procedural Steps



#### **Step 1. Meeting the Requirements for Exporting Food**

- I) The minimum requirements to export any food under the Competent Authority’s oversight are that the food meets domestic food control requirements (unless otherwise stated) and, if applicable, the food business holds a valid export license or registration that is in good standing with the Competent Authority.

##### **a) General requirements**

The food commodity being produced/manufactured and/or exported will determine which domestic Acts and Regulations to be complied with. These general requirements relate to licensing and registration and food safety, including inspections and traceability.

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**i) Licensing or registration**

- (1) Prior to acquiring export certificate from the Competent Authority, the establishment or product to be added to a specific list for any food or food commodities, the food business will need to be licensed or registered.
- (2) Food businesses must demonstrate that preventive controls are in place. The Competent Authority will submit requests to foreign countries or generate certificates only for companies with a valid license or registration.
- (3) Companies whose registration or license has been cancelled or suspended must not be allowed to export food as this could jeopardize the entire domestic food industry.

**ii) Preventive control plan (PCP)**

- (1) The FBO must develop a preventive control plan (PCP), which is a written document that demonstrates how hazards and risks to food products are controlled.
- (2) Exporters are required to have a PCP in place if they produce/ manufacture, prepare or label food in accordance with domestic regulations.
- (3) The FBO's PCP can incorporate additional requirements in relation to exports, or can be prepared in a separate document for measures that exceed PCP requirements.
- (4) The activities the FBO conducts in relation to the food(s) being exported will determine what the PCP covers.
- (5) A FBO who is only a licensed exporter, and who buys food from registered or licensed parties, would be responsible for documenting how the food to be exported is safe (verifying supplier is licensed/ registered and has controls, etc.) and meets the requirements of the foreign country.
- (6) The PCP documents show how the FBO maintains records and documents, and can include the certification controls, recall and any notification procedures they have in place.
- (7) A PCP covers the same content as a Quality Management Program, a Food Safety Management Enhancement Program, Hazard Analysis and Critical Control Point (HACCP) Systems or an Export Certification Control Plan, for example.
- (8) The export controls should identify all the measures taken outside those specifically for the production/ manufacturing, preparing or labelling of the food and geared to export requirements.

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### iii) Inspections and fees

The frequency of inspection varies according to the commodity and type of inspection required – some products must be prepared for export under continuous supervision of an inspector and other countries might require only pre-operational inspection weekly or daily, for example; Fees charged for the inspection, grading and/or issuance of an export certificate are listed in the Competent Authorities Fees Gazette Notices.

### iv) Food Inspection & Sampling Procedures

- (1) Inspection of all food exports shall be carried out either at the port of entry, storage facility or at packing house of the exporter prior to shipment depending on specified requirements of the importing country,
- (2) Inspection shall be by an inspector(s) of the respective Competent Authority assigned to inspect food for exports.
- (3) The sampling regime for the food exports shall be as follows:

| <b>Total No. of Packages in the consignment</b> | <b>No of packages to be sampled</b>                   |
|---|---|
| < than 10                                       | All packages  |
| 11-100  | 20 % of packages subject to a minimum of ten packages |
| 101-1000  | 5% packages subject to a minimum of 20 packages       |
| >1000   | 2 % packages subject to a minimum of 50 packages      |

5.4 Table 2.1: Sampling regime for food exports

- (4) Packages shall be sampled at random using a random table. The entire sampled packages shall be surface inspected to ensure that the packaging is right and the seals intact. The inspector will also look out for any visible pests or any suspect organism. Any suspected sample will be cut open and examined further.

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(5) The packaging shall also be inspected to verify its suitability to preserve the freshness of the product throughout the transportation period. The labelling on the packages should correctly describe the food substance(s) contained in the package.

(6) Specimens of affected packages collected during inspection for laboratory testing for pest diagnosis shall be appropriately labelled and packed

**v) Sample Forwarding /Receipt of Laboratory Testing**

(1) The sample collected/forwarded for laboratory testing shall be appropriately packed to prevent any escape of pest or contamination from environment, sealed and labelled.

(2) The testing shall be done in an accredited laboratory or any other laboratory approved by the Competent Authority for such use.

(3) On receipt at the offices of authorized agency sample details shall be entered in a sample register and stored in sample storage room until issued for laboratory testing formation including, Lot/Batch Number, Name of the Commodity, Sample size, Place of inspection, Date of inspection, Name/Signature of Inspector.

(4) The food sample storage area should be appropriately air-conditioned. The perishable samples will be held under refrigerator/cold storage room to prevent spoilage by microbial contamination.

| Lot/Batch No | Name of commodity | Sample size | Place of inspection | Date of inspection | Name of inspector | Signature of inspector |
|--------------|-------------------|-------------|---------------------|--------------------|-------------------|------------------------|
|              |                   |             |                     |                    |                   |                        |
|              |                   |             |                     |                    |                   |                        |

*Table 2.2: Sample register*

(5) The perishable samples shall be retained for 14 days hours after inspection and non-perishable commodities will be retained for a period of 180days before disposal.

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#### **vi) Laboratory Testing**

- (1) The technical expert appointed by the Competent Authority shall conduct an objective evaluation on food sample which includes chemical, physiochemical, microbial and physical methods of analysis.
- (2) The technical expert will look out for any chemical, microbiological, mycotoxins and zoonotic hazards.
- (3) The technical expert will be guided by the Laboratory handbook, Hazard Analysis Critical Control Point system HACCP, Codex standards, guidelines and recommendations on food safety or any other higher standards recommended by the importing country.
- (4) The technical expert will look out for any banned substance prescribed by either the importing country or FAO.
- (5) Results of the examination shall be entered in a laboratory work book and the particulars of the findings will be recorded in the inspection report and submitted to the authorised officer for onward forwarding to the certificate issuing authority.

#### **vii) Reporting of the Laboratory Results**

- (1) The inspector at the end of inspection shall report the results of inspection to the authorised officer giving particulars of commodity inspected, Lot Number or Marks, if any, date/time and place of inspection and number of samples drawn and the quantity along with inspection, remarks if any.
- (2) The authorised officer, immediately after the receipt of inspection/testing report shall verify with concerned laboratory expert, the identity of /food safety hazard detected and its status.
- (3) If any quarantine pest/hazardous component is detected, the consignment shall be rejected for issue of the export certificate and the exporter or his agent will be informed the action taken under intimation to Customs/port authorities concerned to prevent its export.
- (4) If no pest infestation/hazardous component is detected, the consignment shall be certified for export and the requisite export certificate issued.

#### **viii) Verification of Inspection**

- (1) The inspector at the end of inspection shall affix “Inspected” by Sanitary or phytosanitary Certificate Issuing Authority” on the packages/bags sampled.
- (2) The authorised officer shall conduct random audit checks to verify that the inspection/sampling procedures adopted by the inspector are adequate in the

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circumstances and are consistent with food sanitary requirements of importing country.

#### **ix) Preparation and Issuance of Export Health Certificates**

- (1) The export health certificates shall be prepared in the format prescribed.
- (2) The certificates issued in respect of perishable consignments will be valid for the shelf life of the product from the date of issue and shall be for the current shipment only.
- (3) The export health certificate should be verified before issue to ensure it is correct and complete and the information provided therein is adequate to meet the current sanitary requirements of the importing country.
- (4) The certificate will be issued in “Original” to the exporter and/or his authorized agent in respect of each consignment and the “Office copy” will be filed along with case folder. Under special circumstances a “certified copy” may be issued by the authorised officer that accompanies the consignment and is presented to the relevant officials upon arrival in the importing country.
- (5) All the corrections/overwriting made in the export certificates shall be clearly attested by a signature, and stamp for seal of authorised officer.
- (6) The export certificate shall bear the name of authorised officer, either typed or printed in clear capital letters and also the date indicating the day/month/year and proper signature of authorised officer as reflected in electronic database of authorised officers for issue of export certificates maintained by the Competent Authority and that the certificates will not be issued pre-dated or post-dated or issued after dispatch of the consignment.

#### **x) Rejection of Consignment/Refusal to Issue Export Certificates**

- (1) The authorized officer may reject the consignment for export/not issue Export Health Certificate if the lab results of the sample tested does not meet the Codex standards or any other sanitary standards imposed by the importing country. The authorized officer shall issue a notice of rejection of consignment for export in the format prescribed.
- (2) The authorised officer shall forward a copy of the rejection notice to the port authorities to ensure that the rejected consignment is not sneaked out of the exporting country.

#### **xi) Traceability**

FBOs must keep information on the distribution of the food exported. It is important to maintain these records.

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### **xii) Lot accountability**

- (1) FBOs should identify all the certificates issued by the Competent Authority, the food product certified by each certificate, and the status of the lots certified (in inventory or exported).
- (2) These records allow exported food products to be traceable to the first shipping destination to allow for rapid recall. For this purpose, FBOs must keep easily accessed records of the following information (as applicable per commodity) for each consignment certified by the Competent Authority:
  - (a) the country of export;
  - (b) the certificates issued;
  - (c) description of the lots:
    - (i) product description (size, grade, type);
    - (ii) the scientific and common names of the food;
  - (d) the method of production;
  - (e) the name and registration/licence number of all the establishments from which the food was sourced, and activities conducted (i.e. slaughter, processing, etc.);
  - (f) processing/packing date(s)/codes product identification marks (production code);
  - (g) processing dates;
  - (h) net weights;
  - (i) total units and unit size of each lot in the consignment;
  - (j) the storage conditions of the product;
  - (k) consignee name and address;
  - (l) consignor name and address;
  - (m) the date the consignment was exported;
  - (n) transportation information; and/or
  - (o) container and seal numbers.
- (3) Replacement certificates received from the Competent Authority must be linked to the original certificate, which the Competent Authority will cancel.

### **b) Food specific requirements**

- i) The food commodity the FBO produces/manufactures and/or exports will determine which Acts and Regulations they must comply with.
- ii) FBOs will need to comply with any program or certification body requirements beyond the domestic regulations that have been recognized by the foreign Competent Authority.

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iii) Under these programs, the Competent Authority supports these specific export requirements unique to certain foods and/or countries.

iv) Examples of food specific requirements include:

1. ractopamine in pork
2. halal meat to Muslim countries
3. Domestic Shellfish Sanitation Program
4. organic products

**c) Foreign country requirements**

- i) FBOs are responsible for ensuring that they know the requirements of countries that they export to and for adhering to those requirements.
- ii) If the food meets domestic/ in-country control requirements and that is equivalent to the foreign country requirement, the FBOs written PCP is proof of compliance.
- iii) If a country is not listed in the export database/ library, it should be assumed that there is nothing known about their requirements. For exporting to these countries, FBOs will need to work closely with their importers, and contact the National Enquiry Points or the Competent Authority's information office for assistance.
- iv) The FBO may be eligible to export a food that does not meet current domestic requirements if the FBO can prove the product will be accepted by the foreign country. Ways to demonstrate this can include:
  - (1) evidence that the container and markings comply with the requirements of the importing country
  - (2) the contract with the importer clearly stating the quality specifications of the food product
  - (3) the lot number or code of the shipment marked on the label or embossed on the container identifies the specific product
  - (4) the label on the container of the food does not misrepresent the quality, quantity, composition, character, safety, or value of the food product
  - (5) documentation of materials and incoming ingredients sources approved by the country of destination, and of any unique processes or establishment information that affect product compliance
  - (6) documentation of health and safety requirements for chemical and microbiological standards including any foreign standards that exceed national standards, or for which there is no national standard
  - (7) attestations for any animal health disease status in the area

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(8) Supplier Quality Assurance (SQA) agreements that describe the measures taken to ensure the food meets foreign country standards Foreign country requirements may change from time to time.

- v) If the FBO knows about changes in foreign country requirements they should provide this information to the Competent Authority for follow-up and verification.
- vi) Non-compliant product should never be exported as it may jeopardize a country's trade reputation. National food control systems should protect countries without food safety requirements with a minimum requirement that permits only products compliant with national regulations to be exported.

**d) Resources**

Resources to consult for ensuring FBOs meet the requirements for exporting food include:

- i) the Competent Authority export database/library
- ii) the foreign authority
- iii) the importer or specialized broker
- iv) the Competent Authority's Market Information System
- v) National Trade Commission
- vi) As part of your export documentation, keep the information you collect as evidence of your due diligence.

**e) No import requirements**

- i) If a country has no known importing requirements specific to the food product, then the FBO can take the commercial risk to export your National-compliant food. Commercial risk means that the FBO accepts that all due enquiries have been made and that there is no known impediment to entry of the product into the country concerned.
- ii) Even if the FBO assumes commercial risk, the Competent Authority can still refuse to provide a certificate if there are known issues with a type of export or a destination country.

**f) Export and eligibility lists**

- i) If a country has an eligibility list for food products being exported, and the FBO or the supplier (i.e., the food producer or cold store) need to be vetted to be included on the list, the FBO should contact their nearest Competent Authority's office to begin the process.
- ii) Approval times can be lengthy, up to **six months** in some cases.
- iii) Some countries may require all eligible establishments to be approved by the Competent Authority of exporting country or by their country and must be on a list

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before they can export the product. This will be indicated in the export requirements for each country.

## **Step 2. Obtaining Export Certification**

- 1) The certification of products is how the Competent Authority demonstrates to foreign countries that there is regulatory oversight and that the product is safe.
- 2) The Competent Authority will not issue an export certificate for your products if the food business is not licensed or registered or if the FBO does not have a PCP in place.
- 3) The process to obtain an export certificate varies depending on the commodity and the importing country. The steps can include:
  - a) applying for an export certificate from the Competent Authority
  - b) meeting the attestations and statements of the export certificate
  - c) notifying the Competent Authority of any inspection or testing required in order to be eligible to export
  - d) paying the fees for certification, inspection and sampling for your product.
- 4) The FBO must request a certificate before shipping the food products. The FBO cannot obtain an export certificate for food that has already left the exporting country.
- 5) The Competent Authority should provide on their website more information about export certificates and how to complete them.
  - a) Notification of production and shipments**

Some countries may require inspections of production and/or shipping for certain commodities. The FBO is responsible for knowing if the commodities to be exported are in this category. If so, the FBO is required to notify the Competent Authority before the commodities are produced (if applicable) and/or before they are shipped.

### **b) Certificate requests**

- i) The commodity and destination country determine the information needed to complete the certificate.
- ii) The lot accountability requirements are typical of the type of information that the Competent Authority will need when requesting a certificate.
- iii) FBOs can request a standard certificate (where applicable) for countries or products that do not have negotiated certificates or known requirements but you expose your food business to commercial risk. Records of your certificate requests and shipment details help demonstrate product compliance with foreign requirements.

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**c) Replacement certificates**

- i) If the FBO needs to request a replacement certificate or additional documentation instead of a replacement certificate, the Competent Authority needs a description of the control measures taken to capture the documentation involved.
- ii) The FBO needs to provide:
  - (1) a written explanation of why the FBO needs a replacement certificate, which may include;
    - a. an administrative error on the certificate;
    - b. the certificate is lost or damaged;
    - c. the consignee of the food product certified has changed; and/or
    - d. there is a change in the quantity of product certified.
  - (2) a description of the procedures relating to the preparation of export documentation demonstrating effort in maintaining accurate export certificate preparation, and any implemented corrective actions (if applicable); and
  - (3) the original certificate, where possible
- iii) Changes requested to a seal number, export stamp/shipping mark number, transport container number, number of cartons, weight and product description are particularly serious.
- iv) Although situation dependent, requests for supporting documentation might include a bill of lading, exporter's ship manifest, a ship schedule from the freight forwarder or processing dates, for example.
- v) For a change of destination country, the Competent Authority requires evidence the lot complied with the requirements of the new destination country during processing and storage.
- vi) It is the FBOs responsibility to provide any information acceptable to the importing country to prove the continuity of control over the lot and compliance with any other conditions required.
- vii) If the product has already been imported into the foreign country, a replacement certificate can be issued only if the consignment information, consignor and consignee on the replacement certificate are exactly the same.

**Step 3. Validation or Verification by the Foreign Country**

- I) Validation or verification is an evaluation by the foreign country, for example:
  - a) Representatives from the foreign country may come to the exporting country to audit the establishment of the FBO.

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- b) They may conduct an audit of the Competent Authority’s inspections and findings to verify that the national Food Control Safety System meets their requirements so establishments under the oversight of the Competent Authority would be considered as also meeting their standards.
  - c) The visit may be to verify that specific establishments comply with the importing country requirements. In this case, the foreign officers will be evaluating the establishment, and not how the Competent Authority inspects the establishment. The FBO may be asked to take corrective actions that are beyond the scope of the national regulatory requirements to maintain access to their market.
- 2) This step sometimes happens before the FBO is eligible to export to a foreign country. It may also be a direct result of the establishment of the FBO being on the country's eligible establishment lists.

**Step 4. Shipping Foods for Export**

- 1) Once the FBO receives the certificate from the Competent Authority, the FBO should be ready to ship your product:
  - a) The FBO should follow the dates and requirements listed on all certificates. The FBO must keep records showing that the food safety requirements for the transportation method chosen for the food were met. The FBO should also have records to demonstrate the shipping and storage temperatures met the requirements.
  - b) The FBO must control the certificates and certificate numbers, especially in relation to the use and control of stamps, stickers and seals for your shipments. Any breaks in these controls may prevent the shipment reaching its final destination. Some countries sample products to test for food safety requirements. The exported food product may be held under a "test and hold" regime. The FBO should work closely with the importer to prepare properly for such situations.

**Step 5: Consignments Held/Rejected on Arrival**

- 1) If the shipment is held due to an error on the certificate, the FBO will need to notify the Competent Authority’s office where they obtained the certificate.
- 2) The FBO will need to return the original and provide a valid reason for requesting a replacement certificate.
- 3) If the Consignment is rejected for failing to meet food safety requirements of importing country, the FBO will meet the cost of returning or destruction of the food.

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- 4) Information about rejected consignments must be shared promptly between the FBO and Competent Authority.
- 5) Corrective Actions necessary to address the problem must be implemented promptly