CHAPTER V

IMPORT REGULATIONS

INDIA

Import Policy and Regulations

Every importer shall comply with the provisions of the Foreign Trade (Development and Regulation) Act, 1992, the Rules and Orders made there under, the provisions of Foreign Trade Policy and the terms and conditions of any License/certificate/permission/Authorization granted to him, as well as provisions of any other law for the time being in force. All imported goods shall also be subject to domestic Laws, Rules, Orders, Regulations, technical specifications, environmental and safety norms as applicable to domestically produced goods.

Interpretation of any provision contained in this policy shall be referred to the Director General of Foreign Trade.

Foreign Trade (Development and Regulation) Act, 1992

FTDR Act is to provide for the development and regulation of foreign trade by facilitating imports into, and augmenting exports from India and for matters connected therewith or incidental thereto.

The FTDR elaborates the following:-

1. **Power of Central Government to make Orders and Announce Export and Import Policy:** The Central Government may by Order published in the Official Gazette, make provision for the development and regulation of foreign trade by facilitating imports and increasing exports, continuance of existing orders and formulating export-import policy.

2. **Importer-Exporter Code Number:** No person shall make any import or export except under an Importer-Exporter Code Number granted by the

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1 Section 3,4,5 & 6 of the Foreign Trade (Development and Regulation) Act,1992.
Director General or the officer authorised by the Director General in this behalf, in accordance with the procedure specified in this behalf by the Director General.²

3. **Search, Seizure, Penalty and Confiscation:** The Central Government may authorize any person for the purposes of exercising such powers with respect to entering such premises and searching, inspecting and seizing of such goods, documents, things and conveyances, subject to such requirements and conditions, as may be prescribed³.

4. **Appeal and Revision:** Any person aggrieved by any decision or order made by the Adjudicating Authority under this Act may prefer an appeal⁴.

5. **Miscellaneous⁵**

**Prevention of Food Adulteration Act (PFA) of 1954 with the PFA Rules of 1955:**

The law to protect India against impure, unsafe, and fraudulently-labeled foods is the Prevention of Food Adulteration Act (PFA) of 1954 with the PFA Rules of 1955, as amended from time to time. PFA standards and regulations apply equally to domestic and imported products. The PFA covers various aspects of food processing and distribution, such as food color, preservatives, pesticide residues, packaging and labeling, and regulation of sales.

All imported products must adhere to the rules as specified in the regulation, including the labeling and marking requirements.

Other standards applicable for Imported food products:

1) The Standards of Weights and Measures Act, 1976, and the Standards of Weights and Measures (Packaged Commodities) Rule, 1977 Importers of packaged food products must adhere to the act, including labeling the product. The name and address of the importer, the net quantity, date of manufacture, best-before date, and maximum sales price must be included on the label.

² Section 7 to 9 of Foreign Trade (Development and Regulation) Act, 1992.
³ Section 10 of the Foreign Trade (Development and Regulation) Act, 1992.
⁵ Section 17 to 20 of the Foreign Trade (Development and Regulation) Act, 1992.
2) The Fruit Products Order, 1955 and amendments there under. Processed fruit and vegetable products imported into the country must meet the FPO standards.

3) Meat Food Products Order, 1973: This order is equally applicable to domestic processors and importers of meat products.

4) Livestock Importation Act, 1898: Under the Livestock Importation Act, 1898, the government established procedures for the importation of livestock and related products to India, which are implemented by the Department of Animal Husbandry and Dairying, Ministry of Agriculture.

5) Milk and Milk Products Order, 1992: Standards specified in the order also apply to imported products.

6) Plant Quarantine (Regulation of Import into India) Order, 2003: Under the Destructive Insects and Pests Act, 1914, the Government formulated the Plant Quarantine (Regulation of Import into India) Order, 2003. It was published with “…The purpose of prohibiting and regulating the imports into India of agricultural articles…” The implementing agency is the Directorate of Plant Protection, Quarantine, and Storage, under the Department of Agriculture and Co-operation, Ministry of Agriculture.

**Import Procedure**

1) **Filing of Application:**

Every application for an Import/Export license/certificate/Authorisation/permission or any other purpose should be complete in all respects as required under the relevant provisions of the Policy/Procedures.

An incomplete application is liable to be rejected giving specific reason for rejection. However in case of manual applications, the applicant would furnish a soft copy of the application in MS word format.
2) **Documentation:**

Importers must furnish an import declaration in the prescribed Bill of Entry format, disclosing the value of the imported goods. This must be accompanied by any import licenses and phyto-sanitary certificates (in case of agricultural commodities), along with documentation such as sales invoices and freight and insurance certificates.

All consignments are required to be inspected prior to clearance. The clearance of imported food products at the port of entry requires a certification from the port health authority that the product conforms to the standards and regulations of the PFA.

The custom clearance period may last between one day and one month, depending on the product and experience of the importer. In case of a dispute or rejection of the consignment, the importer can file an appeal at the Customs office at the port of entry.

3) **Application for Import and Export of Restricted Items:**

An application for grant of license/certificate/ permission for import or export of items mentioned as restricted in ITC (HS) may be made in the form and to the regional authorities specified under the relevant chapters of this handbook.

4) **Profile of Importer/ Exporter:**

Each importer/exporter shall be required to file importer/exporter profile once with the Regional Authority in Part 1 of ‘Aayaat Niryaat Form’.

5) **Countries of Imports / Exports:**

Unless otherwise specifically provided, import/ export will be valid from/to any country.

The above provisions shall, however, be subject to all conditionality, or requirement of license/ Authorization, or permission, as may be required.
6) Application for Grant of IEC Number

An application for grant of IEC (Importer - Exporter code) number shall be made by the Registered/Head Office of the applicant to the Regional Authority under whose jurisdiction, the Registered office in case of company and Head office in case of others, falls in the ‘Aayaat Niryaat Form’ and shall be accompanied by documents prescribed therein.

Customs Clearance Procedure for food items

Board Circular No.58/2001–Cus dated 25.10.2001 which provides detailed guidelines for examination and testing of food item prior to its testing and clearance by Customs officers under the provisions of Prevention of Food Adulteration Act, 1954 (PFA Act, 1954).

Recently the procedure of clearance of food articles has been revisited by the Board, and following modified procedure has been prescribed vide Circular No.3/2011-Customs (From F.No.450/115/2009-Cus.IV):

a) All consignments of high risk food items, as listed in DGFT Policy Circular No. 37(RE-2003)/2002-2007 dated 14.06.2004 (as may be modified from time to time), shall be referred to Authorised Representative of FSSAI or PHOs, as the case may be, for testing and clearance shall be allowed only after receipt of the test report as per the instructions contained in the Customs Circular No. 58/2001–Cus, dated 25.10.2001.

b) All consignments of perishable items like fruits, vegetables, meat, fish, cheese, etc., will continue to be handled in terms of the guidelines contained in Para 2.3 of the Board’s Circular No.58/2001-Customs dated 25.10.2001.

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7 http://www.cbec.gov.in/customs/cs-circulars/cs-circulars31/circ03-2k11-cus.htm
c) In respect of food items not covered under (a) and (b) above, the following procedure would be adopted in addition to the general checks prescribed under Para 2.1 of the Circular No. 58/2001–Cus, dated 25.10.2001:

(i) Samples would be drawn from the first five consecutive consignments of each food item, imported by a particular importer and referred to Authorised Representative of FSSAI or PHOs, as the case may be, for testing to ascertain the quality and health safety standards of the consignments.

(ii) In the event of the samples conforming to the prescribed standards, the Customs would switch to a system of checking 5% - 20% of the consignments of these food items on a random basis, for checking conformity to the prescribed standards. The selection of food items for random checking and testing would be done by the Customs taking into consideration factors like the nature of the food products, its source of origin as well as track record of the importers as well as information received from FSSAI from time to time.

Authorised Officers of FSSAI will ascertain that for the imported pre-packaged good items, the language and other major requirements of the label like mention of best before date, nutrition information etc. should comply the labeling provisions under PFA Rules, failing which sample may not be drawn from such consignment for testing.

It is also clarified that Risk Management System (RMS) module for import consignments of edible / food items, presently does not provide for random sampling as it is one of its CCR (Compulsory Customs Requirements) targets. Accordingly, Risk Management System (RMS) shall take necessary steps to modify the RMS module to conform to the new requirements. Till such time, this modification is carried out, Customs shall take appropriate decision to waive the CCR requirements in respect of food items not covered under Para 7 (a) and 7 (b) above and to the extent mentioned under Para 7 (c) above. In terms of Circular
No.43/2005-Cus dated 24th November, 2005 such a course of action shall, however, be taken only with the prior approval of the jurisdictional Commissioner of Customs or an officer authorized by him for this purpose, who shall not be below the rank of Addl./Joint Commissioner of Customs, and after recording the reasons for the same. A brief remark on the reasons and the particulars of Commissioner/ADC/JC authorization should be made by the officer examining the goods in the departmental comments in the EDI system.

Further, as per Para 13 of Chapter I A (General Notes Regarding Import Policy) of the ITC (HS) Classification of Export and Import items, import of all such edible/ food products, domestic sale and manufacture which are governed by PFA Act, 1954 shall also be subject to the condition that at the time of importation, the products are having a valid shelf life of not less than 60% of the original shelf life. Shelf life of the product is to be calculated based on the declaration given on the label of the product, regarding its date of manufacture and the due date for expiry. Therefore, Customs shall ensure that this condition is complied with before allowing clearance of such consignments.

It is clarified that at certain ports / airports / ICDs / CFSs where Port Health Officers (PHO) under PFA, 1954 or Authorised officers under FSS Act, 2006 are not available, the samples will be drawn by Customs and the same may be got tested from the nearest Central Food Laboratory or a laboratory authorized for such testing by DGHS or FSSAI.

Risk Management Division (RMD) shall develop an application software that incorporates the stipulation of testing of imported foodstuff and alerts the Customs officer to the effect the number of past shipments already tested and found fit warrants future shipments need not ordinarily be tested. This should apply regardless of port of import so long as the importer, supplier and item of import do not change. In other words, if such a shipment is imported say, at Mumbai and the previous 5 shipments imported at, say, Delhi have passed the test, then the next shipment at Mumbai need not be tested. A suitable data base
would also be prepared at each Custom House to indicate the compliance history of importers.

In *The Commissioner of Customs (Import) v. Amrit Banaspati Co. Ltd*[^8] goods were confiscated by Customs on the ground of being sub-standard and not as per standards prescribed under Prevention of Food Adulteration Act and Rules. Authorities were directed to reprocess impugned goods and if found fit for human consumption on reprocessing, same be allowed clearance for home consumption. Appeal was filed against this order. The question arose whether Tribunal was justified in setting aside the order of adjudication. It was held that, “in the absence of any express bar under the Customs Act or the 1954 Act, the Tribunal in an appropriate case is entitled to allow redemption of the confiscated goods subject to reprocessing.” In the present case, since the imported goods were found to be sub-standard, the Tribunal ought to have upheld the confiscation and allowed redemption of the confiscated goods for reprocessing subject to payment of fine and penalty and subject to the reprocessed goods conforming to the prescribed standards. Therefore, the appeal was partly allowed.

**EUROPEAN UNION**

**Import Policy and Regulations**

Member States are responsible for carrying out inspections on a regular basis and in cases where non-compliance is suspected. Products can be checked at import or at all further marketing. In case of non-compliance, the EU hygiene directive (Com. Reg. 93/43 EEC) allows the Commission to suspend imports from third countries or introduce special conditions for products from the third country concerned, applicable on the entire EU territory.

Specific detailed inspection requirements exist for animal products. Inspections are done under supervision of a veterinarian at a limited list of ports and border

[^8]: 2007 (116) ECC 186, Also see *Marico Limited v. Agro Tech Foods Ltd.*, MIPR 2010(2) 14
inspection posts. Fresh fruits and vegetables are subject to phytosanitary controls and are checked for compliance with EU-harmonized marketing standards.

Product samples have to comply with the food regulations applicable in the EU. Exemptions exist for meat products, for which a waiver may be obtained⁹.

Generally there is no EU requirement to register imported foods except for the introduction of novel foods. The person/company introducing a novel food has to submit a request to the authorities in the Member States where the product will be marketed and a copy of this has to be sent to the Commission's Health and Consumer Protection Directorate. Importers of organic products are required to notify the competent regulatory authority of the State of their activity. The introduction of foodstuffs with particular nutritional uses needs to be notified to the Member State where the food is sold. Exporters of vitamin enriched foods or nutritional supplements are especially advised to check for the existence of specific member State registration or notification requirements¹⁰.

Import Procedure

Certification and Documentation Requirements:

AGRIM Certificates-

The EU requires import licenses (AGRIM certificates) for most agricultural products for which it provides market support, including grains, milk, meat, olive oil, most fruits and vegetables, wine and sugar. In order to obtain a license, an application form must be submitted and security fee must be paid to the issuing Member State. Licenses vary in validity with most expiring three months after the month of issuance. The license is applied for by the importer¹¹.

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⁹ Section VI, USDA GAIN Report No. IT 8023, 22nd September (2008).
¹⁰ Ibid.
Health Certificates-

Plant Products
Phytosanitary certificates issued by APHIS have to accompany plant, fruit, vegetables and nut shipments to the EU.

Animal Products
The European Community is in the process of harmonizing legislation on imports of animal products. This is a three-stage process that starts with the recognition of a country to export a certain animal product. The U.S. is recognized by the EU for nearly all animal products. In a second stage, lists of EU approved establishments are drawn up in recognized countries. Various U.S. agencies, including FSIS, APHIS, AMS, and FDA are involved in the listing process. Establishments are subject to EU inspections prior to listing and/or to occasional EU audits after listing12.

Processed Foods
All animal products imported into the EU need animal or public health certification. For processed foods containing animal product, the situation is more complicated because there is no legislation specifying the percentage of dairy, egg, red meat or poultry meat that a foodstuff must contain to necessitate certification. However, the specific EU legislation applicable to the animal product in question contains certain provisions on certification.

Red meat & poultry meat: Products containing any amount of red meat or poultry meat must be certified.

Egg products & dairy: Certification of products containing egg products or dairy products depends on the composition of the product in relation to the definitions in the relevant13.

12 Ibid.
13 Ibid.
Obligations of importers:

Food business operators importing products of animal origin must ensure that the products:

1. Come from a country or a part of a country that appears on a Community list,
2. Where applicable, come from an establishment that appears on a list,
3. Where applicable, carry a health or identification mark,
4. Where applicable, are accompanied by a certificate issued by the representative of the competent authority of the third country,
5. Are made available for control in a border inspection post,

Obligations of competent authorities in third countries:

EU food law requires that the competent authority of the exporting country offers guarantees compliances or equivalence with EU requirements:

1. There control services comply with the operational criteria laid down law, in particular in Regulation (EC) No 882/2004.
2. The establishments that are authorized to export to the EU comply and Continue to with the EC requirements and that the list of such establishments is kept up-to-date communicated to the Commission.
3. The certification requirements are satisfied15.

Animal health requirements:

Food of animal origin from third countries must comply with requirements that prevent the ion of animal diseases into the EU. These requirements lay down the

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14 Guidance Document on certain key questions related to import requirements and the new rules on food hygiene and on official food controls by European Commission Health & Consumer protection Directorate-General, Brussels, 20, 5\textsuperscript{th} January (2006 ).
15 Ibid.
animal health rules governing the production, processing, distribution and introduction of products animal origin for human consumption.\textsuperscript{16}

Process for importing food Products of Animal Origin into the European Union:\textsuperscript{17}

- The Competent Authority in the dispatching country contacts the European Commission to request approval
- The Commission visits the country and establishments to check hygiene standards are equivalent to those in the EU
- Approval is proposed, accepted or rejected. Updated list of approved countries are published in the Official Journal of the European Community and notified to member states
- A commission decision is drawn up giving the format for health certification and a list of approved establishments
- The Competent Authority in country of dispatch issues and stamps the health certificate as per the Commission decision
- Products of animal origin must be imported into the EU through Border Inspection Post (BIP)
- The importer must notify the BIP of the arrival of consignment - 24 hours by sea – 06 hours by air
- The official veterinary surgeon or Official fish inspector (for fishery products) carry out a document, identity, physical check
- If the consignment fails the checks then it must be either re-exported or destroyed
- If the checks are satisfactory, a Common Veterinary Entry Document is issued for that consignment of goods. It can then be imported into EU

\textsuperscript{16} Ibid.
\textsuperscript{17} www.globfish.org/filedownload.php?fileld=408 -
UNITED KINGDOM

There are a number of important considerations before importing food. It is the responsibility of the importer to ensure that products imported into the UK, or any other European Union (EU) country, are safe and legal. Failure to comply with UK and EU hygiene and safety rules could cause delay in shipments, increase costs and require action to be taken by enforcement authorities.

All food imported into the UK must comply with the food hygiene requirements of Commission Regulation (EC) 852/2004, and there are additional measures for imports of food of animal origin under Commission Regulation (EC) 853/2004.\(^\text{18}\)

**Importing food from inside European Union**

Food coming into the UK from other European Union (EU) Member States is not officially an import. It is subject to free movement of trade between EU countries and not subject to routine checks at UK ports.

This is because all Member States are operating to the same food safety controls. The European Commission, through the Food and Veterinary Office (FVO), checks that there are sufficient controls across the Member States. This is achieved through a series of inspection visits\(^\text{19}\).

**Importing food from outside European Union**

All food imports of products of animal origin, such as meat and dairy products, from countries outside the EU must enter the UK through designated Border Inspection Posts. These are operated by local port health authorities and food enforcement officers from local authorities.

The identity and documentation (such as veterinary health certificates) of all these products are checked. Some products will also be checked physically. This might include looking, smelling or tasting the food, testing temperatures, checking

\(^{18}\) [http://www.food.gov.uk/foodindustry/imports/beforeimporting/]

\(^{19}\) [http://www.food.gov.uk/foodindustry/imports/importsadvice/inside_eu_imports]
wrapping and labeling, or laboratory testing. These controls are the same throughout the EU.

Food that isn't of animal origin from countries outside the EU must also comply with UK law in relation to food safety and standards. Port health authorities and local food authorities have powers to check food products when they come into the UK20.

**Government Organizations involved in import:**

**Food Standards Agency (FSA)**

FSA is an independent Government Department responsible for enforcement support, advice and audit of enforcement activity with respect to local authority food safety and standards controls including some imported products of animal origin (POAO) and food not of animal origin (non-POAO)21.

**Defra, Executive Agencies and devolved agriculture departments**

Defra is responsible for implementation of import control legislation and communication with the European Commission on import control matters. Defra focuses on the animal health aspects of imported food and feeds, and the FSA and Defra work closely on import issues, as there are many areas with relevance for both public and animal health.22

**Her Majesty's Revenue and Customs (HMRC)**

HMRC operate a number of Customs teams at ports of entry. Since 11 April 2003, HMRC have had powers to undertake anti-smuggling controls on non-European Union country imports of POAO within Customs approved areas at seaports, airports and international rail terminals and Enhanced Remote Transit Sheds23.

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21 [http://www.food.gov.uk/foodindustry/imports/enforceauthorities/roles](http://www.food.gov.uk/foodindustry/imports/enforceauthorities/roles)

22 Ibid.

23 Ibid.

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**Food and Veterinary Office of the European Commission (FVO)**

All European Union Central Competent Authorities and Competent Authorities (Defra and the FSA in the UK) are subject to oversight through the FVO and, together with Border Inspection Posts, are subject to regular audits and inspections.

**Local authorities and Port Health Authorities**

Local authorities and Port Health Authorities (PHAs) are responsible for food safety and standards checks on imported food at ports of entry, including products of animal origin (POAO) presented at some types of Border Inspection Posts (BIPs).

**Local Authorities Co-ordinators of Regulatory Services (LACORS)**

LACORS is the local government central body that co-ordinates the enforcement activities of environmental health and trading standards services, including food enforcement24.

**Association of Port Health Authorities (APHA)**

APHA has the primary objective of preventing the introduction into the country of dangerous epidemic, contagious and infectious diseases and ensuring the wholesomeness of imported food. Membership of the Association is open to any local authority or other body with a port, airport, land frontier or customs clearance depot in its district25.

**Maritime Coastguard Agency (MCA) (also known as MCGA)**

MCA is responsible for enforcement of safety and standards on vessels. They carry out a wide range of functions with the overall aims of preventing loss of life, continuously improving maritime safety and protecting the marine environment.

Medicines and Healthcare Products Regulatory Agency (MHRA)

MHRA is the UK Governmental executive that controls and licenses medicines for human use.

SITPRO (formerly 'The Simpler Trade Procedures Board') and Business Link

SITPRO is dedicated to encouraging and helping business trade more effectively and to simplify the international trading process. Its focus is the procedures and documentation associated with international trade.\(^{26}\)

AUSTRALIA

Import Policy and Regulation

There are two set of requirements that imported food must meet to ensure successful importation:

Quarantine requirements:-

All food imported into Australia must comply with Australia’s quarantine laws in the Quarantine Act, 1908.

ICON is AQIS’s quarantine import conditions database. ICON can be used to determine if a commodity intended for import to Australia requires a quarantine permit and/or treatment, or if there are any other quarantine conditions.\(^{27}\)

Food Safety requirements:-

Once all quarantine requirements have been addressed, food must also comply with Australia’s imported food laws in the Imported Food Control Act, 1992. The applicable standards for food under the Imported Food Control Act 1992 are set down in the Australia New Zealand Food Standards Code. All food requirements

\(^{26}\) Ibid.
must meet the requirements of the Australia New Zealand Food Standards Code in its entirety, ensuring imported food complies with Australia’s requirements is the responsibility of the importer. Food Standards Australia New Zealand published User Guides that assist importers to understand the requirements of the Australia New Zealand Food Standards Code. Labeling is where most imported food fails to meet requirements. Commercial importers of food such as fresh fruit and vegetables or food containing milk, egg, meat or other animal products will need to obtain an import permit prior to importing the food.

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Import Procedure

Application for Food Control Certificate

Agency decision on food to be inspected and/or analysed or not

A statement to the effect that the food is required to be inspected and/or analyzed shall appear on the certificate

A statement to the effect that the food is not required to be inspected and/or analyzed shall appear on the certificate

Food to be analyzed: Food required to be analyzed under the Scheme may be subjected to microbiological, chemical or physical analysis, or any other kind of analysis, or any other kind of analysis, necessary to determine whether :-

a) It poses a risk to human health
b) It complies with the Food Standards Code

Inspection or Inspection and analysis failed

Failing food:
1. To be treated as per the advice
2. To be destroyed
3. To be re-exported

Holding Orders

Inspection and/or analysis passed

Accept the food
Imported Food Inspection Scheme

Under the Imported Food Inspection scheme, foods are classified according to the potential risk to human health based on the nature of food and historical inspection data. These categories are:-

1. **Risk Category food**

   These are foods that have been deemed to represent the highest potential risk to human health as categorised by FSANZ. All consignments of risk food lodged with Customs are referred to IF operations. The intensity of inspection applied to these foods depends on the compliance history of overseas producers (manufacturers or packers).

   Producers whose food products consistently comply with Australian requirements will be inspected at a less intensive rate than those with a low compliance rate. All producers will have their food inspected at the initial rate of 100% of consignments. Usually after five consecutive consignments have passed inspection the food will be inspected at a less intense rate of one in four consignments on a random basis. Twenty passes must be achieved before the rate reduces to one in twenty on a random basis, providing imports continue to pass inspection and the food continues to be imported at a steady rate\(^{31}\).

   Risk category foods are listed in section 14.

2. **Active Surveillance Category Food**

   Certain classes of food are classified for active surveillance by FSANZ in order to gather more information about them. Though their previous inspection history, foods in this category have been identified as requiring a more intensive inspection regime to determine if the food should be categorised as Risk or return to the Random surveillance level.

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Food in this group is selected for inspection at a rate of approximately 10 per cent by country-of-origin.

For example, if chocolate was classified for active surveillance, 10 per cent of chocolate consignments from Argentina, 10 per cent of chocolate consignments from Austria, 10 per cent of chocolate consignments from Denmark, and so on, would be referred to AQIS for IF clearance\(^{32}\).

3. Random Surveillance Category

All other food not in the Risk or Active Surveillance Category is Random Surveillance Category food. Food in this category is referred to AQIS by Customs at the rate of 5 per cent of all shipments by tariff classification for inspection\(^{33}\).

**Holding Orders:**

When an imported food is found not to comply with Australian standards, AQIS officers can apply a Holding Order. A Holding Order is a legal mechanism under the Act which ensures that future comparable consignments of a failed food are referred to AQIS to ensure the reason that the food failed has been rectified.

Holding Orders are only placed on foods in the active and random surveillance categories. The normal rate of inspection for active surveillance and random surveillance foods is:

- **active surveillance**—10 per cent that is randomly selected
- **random surveillance**—5 per cent that is randomly selected.

Food subject to a Holding Order will be inspected at a rate of 100% to enable AQIS to monitor future consignments and confirm that action has been taken by the manufacturer or importer to ensure the food now complies with Australian standards.

\(^{32}\) *Ibid.*

\(^{33}\) *Ibid. at 4.*
Generally a Holding Order will remain in force until the food subject to the Holding Order demonstrates continued compliance with Australian standards. This is usually when five consecutive consignments comply with Australian Standards.\(^{34}\)

**USA**

**Import Policy and Regulations**

The Food and Drug Administration (FDA) mission is to enforce the Federal Food, Drug, and Cosmetic (FD&C) Act and other laws which are designed to protect consumers' health, safety, and pocketbook. These laws apply equally to domestic and imported products.

With the exception of most meat and poultry, all food, drugs, biologics, cosmetics, medical devices, and electronic products that emit radiation, as defined in the FD&C and related Acts, are subject to examination by FDA when they are being imported or offered for import into the United States. Most meat and poultry products are regulated by the U.S. Department of Agriculture.

All imported products are required to meet the same standards as domestic goods. Imported foods must be pure, wholesome, safe to eat, and produced under sanitary conditions; drugs and devices must be safe and effective; cosmetics must be safe and made from approved ingredients; radiation-emitting devices must meet established standards; and all products must contain informative and truthful labeling in English.

As defined in the FD&C Act the term adulteration has to do with the content of a product (such as the addition of a substance which makes a product inferior, impure, not genuine, etc.) while misbranding includes statements on labels or labeling that are false or misleading.\(^{35}\)


\(^{35}\) [http://www.fda.gov/ForIndustry/ImportProgram/ImportAlerts/default.htm](http://www.fda.gov/ForIndustry/ImportProgram/ImportAlerts/default.htm)
PRIOR NOTICE OF IMPORTED FOODS

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) directs the Food and Drug Administration (FDA), as the food regulatory agency of the Department of Health and Human Services, to take additional steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply and other food-related emergencies.

To carry out certain provisions of the Bioterrorism Act, FDA has established new regulations requiring that:

- Food facilities are registered with FDA, and
- FDA be given advance notice on shipments of imported food.

The Act requires that FDA receive prior notice before food is imported or offered for import into the United States. Advance notice of import shipments allows FDA, with the support of the Bureau of Customs and Border Protection (CBP), to target import inspections more effectively and help protect that nation's food supply against terrorist acts and other public health emergencies.

Import Procedure:

1. Importer or agent files entry documents with U.S. Customs Service within five working days of the date of arrival of a shipment at a port of entry.
2. FDA is notified of an entry of a regulated food through:
   - Duplicate copies of Customs Entry Documents (CF 3461, CF 3461 ALT, CF 7501 or alternative),
   - Copy of commercial invoice, and,
   - Surety to cover potential duties, taxes and penalties.

[36 http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/PriorNoticeofImportedFoods/default.htm]
3. FDA reviews Importer's Entry Documents to determine if a physical examination, wharf examination, sample examination should be made.

4. A) Decision is made not to collect a sample. FDA sends a "May Proceed Notice" to U.S. Customs and the importer of record. The shipment is released as far as FDA is concerned.
   
   B) Decision is made to collect a sample based on:
   
   - Nature of the product,
   - FDA priorities, and,
   - Past history of the commodity.

FDA sends a "Notice of Sampling" to U.S. Customs and the importer of record. The shipment must be held intact pending further notice. A sample will be collected from the shipment. The importer of record may move the shipment from the dock to another port or warehouse (contact U.S. Customs for details)\textsuperscript{37}.

5. FDA obtains a physical sample. The sample is sent to an FDA District Laboratory for analysis.

6. A) FDA analysis finds the sample to be in compliance with requirements. FDA sends a Release Notice to U.S. Customs and the importer of record.

   B) FDA analysis determines that the sample "appears to be in violation of the FD&C Act and other related Acts." FDA sends U.S. Customs and the importer of record a Notice of Detention and Hearing which:
   
   - Specifies the nature of the violation, and,
   - Gives the importer of record 10 working days to introduce testimony as to the admissibility of the shipment\textsuperscript{38}.

\textsuperscript{37} http://www.foodsafety.gov/~lrd/import.html & www.importexportcustoms.com
\textsuperscript{38} Ibid.
The hearing is the importer's only opportunity to present a defense of the importation and/or to present evidence as to how the shipment may be made eligible for entry.

7. A) Consignee, true owner, importer of record, or a designated representative responds to the Notice of Detention and Hearing. The response permits the introduction of testimony, either orally or written, as to the admissibility of the shipment.

B) Consignee, true owner, importer of record, or a designated representative neither responds to the Notice of Detention and Hearing nor requests an extension of the hearing period.

8. A) FDA conducts a hearing concerning the admissibility of the product. The hearing is an opportunity to present relevant matters and is confined to the submission of pertinent evidence.

B) FDA issues a Notice of Refusal of Admission to the importer of record. This is the same person or firm who was sent a Notice of Sampling. All recipients of the Notice of Sampling and the Notice of Detention and Hearing are sent a copy of the Notice of Refusal.

9. A) Importer of record presents evidence indicating that the product is in compliance. Certified analytical results of samples, examined by a reliable laboratory and which are within the published guidelines for levels of contaminants and defects in food for human use, may be presented.

B) Importer of record submits an Application for Authorization to Recondition or to Perform Other Action (FDA Form FD 766). The form requests permission to try to bring a food that is adulterated or misbranded into compliance by relabeling or other action, or by converting to a non-food use. A detailed method to bring the food into compliance must be given.
C) FDA receives verification of the exportation or destruction of the shipment from U.S. Customs. The exportation or destruction of the merchandise listed on the Notice of Refusal of Admission is carried out under the direction of U.S. Customs39.

10. A) FDA collects follow-up sample to determine compliance with guidelines.

B) FDA evaluates the reconditioning procedure proposed by the importer. A bond is required for payment of liquidated damages.

11. A) FDA finds that the sample is "in compliance." A Release Notice with the statement "Originally Detained and Now Released" is sent to U.S. Customs and the importer.

B) FDA finds that the sample is not in compliance. The importer may either submit an Application for Authorization to Recondition or to Perform Other Action (see 9B), or, FDA will issue a Notice of Refusal of Admission (see 8B).

C) FDA approves importer's reconditioning procedures. The approved application contains the statement "Merchandise Should Be Held Intact Pending the Receipt of FDA's Release Notice.

D) FDA disapproves applicant's reconditioning procedure if past experience shows that the proposed method will not succeed. A second and final request will not be considered unless it contains meaningful changes in the reconditioning operation to ensure a reasonable chance of success. The applicant is informed on FDA Form FD 766 40.

12. Importer completes all reconditioning procedures and advises FDA that the goods are ready for inspection/sample collection.

39 Ibid.
40 Ibid.
13. FDA conducts follow-up inspection/sample collection to determine compliance with the terms of the reconditioning authorization.

14. A) FDA analysis finds that the sample is in compliance. A Release Notice is sent to the importer and to U.S. Customs. The charges for FDA supervision are assessed on FDA Form FD 790. Copies are sent to U.S. Customs which is responsible for obtaining total payment including any expenses incurred by their personnel.

   B) FDA analysis finds that the sample is still not in compliance. Charges for FDA supervision are assessed on FDA Form FD 790. Copies are sent to U.S. Customs which is responsible for obtaining total payment including expenses incurred by their personnel.\textsuperscript{41}

MALAYSIA

Import Policy and Regulations

Import of food items in Malaysia is regulated under Food Act 1983. Subject to the provisions of sub-sections (2) and (3), the importation of any food, which does not comply, with the provisions of this Act or any regulation made hereunder is prohibited. FoSIM, Food safety Information System of Malaysia (Under Ministry of Health) is a web-based information system, which establishes food import surveillance system. The system having interfaced with Customs Information System allows importers/agents and authorised officers at the entry point to manage food importation activities electronically\textsuperscript{42}.

Import Procedure

All importers/agents must register with Ministry of Health for an identification number and password. Importers and agents may log into FoSIM to give prior

\textsuperscript{41} \textit{Ibid.}

notification of import or to enquire possible examination level of a particular food item to be imported. Upon declaration using Customs Declaration form to Customs, importers/agents should log into FoSIM to generate import notification. The import notification will be transmitted online to the respective authorised officers for necessary action to be taken, guided by the recommended examination level and the final decision will be transmitted electronically to Customs and importers/agents.

The examination level of goods is determined based on the information from the Master Database, Transaction database or Knowledge database. Following are the examination levels:

**EXAMINATION LEVELS**

<table>
<thead>
<tr>
<th>Level</th>
<th>Examination Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUTO CLEARANCE (LEVEL 1)</td>
<td>Food automatically released without inspection</td>
</tr>
<tr>
<td>DOCUMENT EXAMINATION (LEVEL 2)</td>
<td>Food released after satisfactory document inspection</td>
</tr>
<tr>
<td>MONITORING EXAMINATION (LEVEL 3)</td>
<td>Food released after inspection and samples may be taken for analysis</td>
</tr>
<tr>
<td>SURVEILLANCE EXAMINATION (LEVEL 4)</td>
<td>Food released after inspection with samples taken for analysis</td>
</tr>
<tr>
<td>HOLD, TEST &amp; RELEASE (LEVEL 5)</td>
<td>Food detained pending results of sample analysis</td>
</tr>
<tr>
<td>AUTO REJECTION (LEVEL 6)</td>
<td>Food automatically rejected</td>
</tr>
</tbody>
</table>

43 www.mift.org.my/Export%20control%20on%20food%20product.ppt
Where food, which is sought to be imported into Malaysia, is processed food in a finished form and if sold in Malaysia constitutes an offence relating to labeling, the food may be imported into Malaysia for the purpose of re-labeling it so that it complies with the provisions of the Food Act relating to labeling.

Where food, which is sought to be imported into Malaysia, is raw or semi-processed food and if sold in Malaysia constitutes an offence, the food may be imported into Malaysia for the purpose of reprocessing or reconditioning it so that it complies with the provisions of the Food Act.

<sup>44</sup> www.mifi.org.my/Malaysian%20Perspective%20in%20Food%20Import%20Control.ppt
Where such food is imported into Malaysia for the purposes of re-labeling, reprocessing or reconditioning it and the food is not relabeled, reprocessed or reconditioned within three months of the importation, the food shall be exported by the importer within a period of two months or such other period as the Minister may determine and, where it is not so exported, it shall be forfeited and disposed of as the Minister may direct.45

JAPAN

Import Policy and Regulations

Food import in Japan is regulated under Food Sanitation Law and Food Safety Basic Law. Food Importers or others must first notify the Minister of Health, Labour and Welfare on each occasion. The notification form is to be filed with a food import inspection office of the Quarantine Stations. The Quarantine Stations carefully import, and when necessary take samples for testing in order to ensure food sanitation.

Import Procedure

Procedure for the importation is done through the Food Automated Import Notification and Inspection Network System (FAINS) by which notification for the importation can be made on-line or by floppy disk from terminals of an importer and by promoting interface with the Nippon Automated Cargo Clearance System (NACCS)46.

i. Pre-certification System of foods manufactured in foreign countries, those which conform with specifications and standards in advance under the Food Sanitation Law are registered with the Ministry of Health, Labour and Welfare. In the case of notifying registered foods, a certificate of notification for

importing foods, etc. is issued immediately after inspection\textsuperscript{47}.

ii. Planned Import System: If specially selected foods, (foods subject to planned importation) are to be repeatedly imported, a one-year or three-year import plan is attached to Import Notification of Foods, at the initial importation. As a result of an examination, if it is judged to have no problems, through this system notification at every importation may be omitted from the following time (limited to within the relevant period)\textsuperscript{48}.

iii. Item Registration System: When the same foods are continuously imported, matters to be mentioned concerning foods, etc. to be imported are registered. If there are no problems in the mentioned matters, through this system matters mentioned and registered at the time of notification for import may be processed through a registration number for one year following.

iv. Minor errors on a notification for import: Minor errors such as typing mistakes related to mentioned matters on Import Notification of Foods, etc. are disregarded.

v. Continuous Import System: When the same foods are repeatedly imported, if inspection results for the same foods conducted within a certain period are attached, through this system inspection at the time of importation within the effective period concerning the inspection items may be omitted.

vi. System of Foreign Official Laboratories: In the case of obtaining an inspection at the time of importation by foreign official laboratories (testing organization listed on a list of foods, is issued before the arrival of the cargo or immediately after its arrival).

vii. Electronic Transmission of an Inspection Certificate: Although it is prohibited to import meat to Japan unless an inspection certificate issued by the governmental organization in the exporting country is attached, if matters to be mentioned on an inspection certificate are transmitted to the computer of the

\textsuperscript{47} Ibid.
\textsuperscript{48} Ibid.
quarantine office from the governmental organization of the exporting country and are recorded in a file provided by the said computer, this does not apply\textsuperscript{49}.

**Flowchart of Import notification system\textsuperscript{50}**

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Customhouse broker ← Importer ← Arrival of cargo ← Counseling at an imported food counseling room
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- Acceptance of food import notification
  - Import Certification of Foods, etc.
  - Sanitation certificate
  - Self-inspection results, etc.

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Documentary examination
```

- Inspection unnecessary
- Administrative inspection (monitoring inspection)
- Administrative inspection (other than monitoring inspection)
- Order inspection

```
Customs clearance
```

- Passed
- Rejected

- Re-shipment or disposal

**Other Product Specific requirements**

1. **Requirements for Meat and Meat Products:**

   a) Import quarantine certificate:

   If the product is complying & appropriate inspection certificate is attached, implement the inspection of the items to be imported & issues an import quarantine certificate after the items are found to be free of any causative agent

\textsuperscript{49} Ibid.
\textsuperscript{50} Ibid.
that may spread infectious disease affecting domestic animal.

b) Health certificate requirement:

Meat or meat product shall be exported with a health certificate from a govt. agency of the exporting country, stating that there is no possibility of spreading any causative agent of infectious diseases affecting domestic animals.

c) Application:

An application for import inspection & an inspection certificate issued by an appropriate govt. agency of the exporting country shall be submitted to the Animal quarantine station51.

2. Requirements for Fruits and Vegetables:

a) Plants which do not fall under import prohibition shall be subject to procedures for the prevention of plant epidemics.

b) The inspection certificate issued by an appropriate government agency of the exporting country must be attached at the Quarantine site.

c) After inspection, an import quarantine certificate will be issued when it is established that there is no possibility of infestation by noxious insects in the specified quarantine items52.

3. Microbiological requirements:

a. Listeria contamination of natural cheese has recently become a problem. Therefore, natural soft and semi-soft cheese types imported from all countries are subject to inspection53.

b. The specification for frozen foods shall be applied for frozen fillets of fish and stripped shellfish for sashimi, which stipulates the number of bacillus

52 Id. at 35.
53 Id. at 27.
per specimen of 1 gram as 100,000 or less and colon bacillus as negative.54.

c. Processed marine products frozen after heat processing (frozen foods processed after heating) shall have 3,000,000 or fewer bacilli per 1 (one) gram of Specimen and Escherichia- Coli (E-coli) must be negative.55.

THAILAND

Import Policy and Regulations

Import of Food in Thailand is regulated under the Food Act B.E 2522. The Thai food and Drug Administration controls import of food under the Pre- Marketing Control activities. A license is required for the import of food into Thailand. A licensed importer may import various kinds of Food providing that the concerned agencies approve them. The concerned agencies are:56:

1) DA.
2) Department of Livestock Development.
3) Department of Agriculture.

The designated storage or warehouse has to be inspected and approved before a license is issued.57.

Role of Customs

Imported goods may not legally enter into Thailand until the shipment has arrived at specified port of entry and delivery of the merchandise has been authorized by the Thai Customs Department. This is normally accomplished by filing the appropriate documents, either by the importer or by its agent. The Customs

________________________________________________________________________

54 Id. at 22.
55 Ibid.
56 www.fda.moph.go.th/eng/food/details/foodControl
57 Ibid.
Department does not notify the importer of the arrival of a shipment. The carrier of the goods usually makes notification.

The importer should make their own arrangements to be sure that they or their agent will be informed of the arrival of shipment immediately so that the entry can be filed and delays in obtaining the goods are avoided.\(^{58}\)

**Customs Clearance of Prepackaged Foodstuffs**

Prepackaged foodstuff will need additional inspection by related authorities before proceeding to regular customs formalities. In addition to the FDA, other concerned officers such as animal quarantine officers, plant quarantine officers, and fisheries department officers, are stationed at the port of entry to determine whether certain imported foodstuffs meet the requirements set by their agencies. In such cases, certain certificates i.e. health certificate or phytosanitary certificate, may be required.\(^{59}\)

**Product Specific Requirements**

The Food Act classifies foods into three main categories:

1. Specially controlled Foods
2. Standardized Foods
3. Other Foods

1) Specially controlled foods are strictly controlled. Before importing such foods, product registration is must. An analysis of the product as well as details of the process and ingredients is required for the registration process. The products also have to meet the standards specified in the Ministerial notifications.

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\(^{59}\) Id. at 27.
2) For standard foods the application for such permission is not required, but they must be produced up to the prescribed quality or standard\textsuperscript{60}.

3) Other foods

i. Specific Import Control on Unprocessed Meat and Meat Carcasses

Instead of the Thai FDA, the Department of Livestock Development (DLD), Ministry of Agriculture and Cooperatives directly monitors the importation of meat.

Requirements for importing unprocessed meat and meat carcasses are as follows:

a. An import permit from the DLD is required for these products, frozen or chilled.

b. Prior to importation, an application for a permit should be made at the Animal Quarantine Station at the port of entry to which the products will be shipped, whether by air or by sea.

c. Also, a health certificate is needed.

d. Upon entry, the animal quarantine division prior to release by Thai Customs must inspect the products\textsuperscript{61}.

ii. Specific Import Control of Seafood

Imports of seafood, frozen or chilled, are under the supervision of Thai FDA. Basically, an import permit (normally granted shipment by shipment) is needed, together with a permit for distribution\textsuperscript{62}.

iii. Specific Import Control on Fruits and Vegetables

The Department of Agriculture, Ministry of Agriculture and Cooperatives, instead of the Thai FDA, monitors importation of fruits and vegetables.

\textsuperscript{60} Id. at 2.
\textsuperscript{61} Id. at 19.
\textsuperscript{62} Id. at 23.
Requirements for importing Fruits and Vegetables are as follows:

a. An import permit from DOA is required.

b. Upon the products arrival, the imported fruits or vegetables must be accompanied by a phytosanitary certificate issued by the appropriate Authority in the country of origin\(^63\).

According to the Plant Quarantine Act of B.E. 2507 (1964) and revised in B.E. 2542 (1999), the import of plants and plant products is categorized into 3 groups namely prohibited, restricted and unprohibited materials according to their economic importance and prevalence to plant pests and diseases at their place of origin. Following are import requirements of prohibited, restricted and unprohibited materials\(^64\).

1. Prohibited materials:

The import of the following items listed in Table 1 is not allowed. Exceptions are permitted only for cases approved in advance by the Department of Agriculture for the purpose of experimentation or research only.

   (1) Plants and plant products designated by the Ministerial Notification, shipped from the areas specify by the Ministerial Notification.

   (2) Plants, plants pests and diseases and carriers.

   (3) Soil and organic fertilizer\(^65\).

The requirement for importation of prohibited materials is set as follows:

(1) They must be imported via 3 plant quarantine stations namely; Bangkok International Airport, Bangkok Maritime Port and Bangkok General Post Office Plant Quarantine Station.

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\(^{63}\) Ibid.

\(^{64}\) Plant Quarantine Import Regulations Thailand.

\(^{65}\) Ibid.
2. Restricted materials

The import of the following items listed in Table 2 is allowed. The requirement for importation of restricted materials is set as follows:

(1) They must bear phytosanitary certificate issued by the proper government agency of the exporting country.

(2) They must be handled according to conditions prescribed by plant quarantine officer.

(3) Furthermore, importation of restricted materials, particularly, plants intended for propagation must be subjected to thoroughly examination.

3. Unprohibited materials

Plant materials other than those classified as prohibited and restricted materials are unprohibited materials. Permission and a Phytosanitary Certificate are not required for importation. However, the imported unprohibited materials have to be notified for inspection at ports of entry. All materials are subjected to inspection and also put under quarantine treatment or destruction if plant quarantine pests and diseases are found.

Apart from the above mentioned categories of food, import license is also required if import is done for trade and exhibition purpose and for academic research purpose.

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66 Ibid.
67 Ibid.
In general, food products are required to bear labels containing information in the Thai language such as the name, main ingredients, name and address of manufacturer, and other particulars of the food according to the Notification of the Ministry of Public Health No.194 (B.E.2544) on Label68.

68 Supra note 58 at 9.