

Business Handbook

Rules & Regulations

For The Export Of Food

- *UNITED STATES OF AMERICA*

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INTRODUCTION

Regulations governing the import of food products in most countries are extremely stringent. However, while most health and safety requirements are provided for in the form of legislations, ensuring food safety and quality standards is continuous process.

Food manufacturers interested in venturing into the export market must therefore keep close tabs on these developments, besides being well-versed in the import procedures of each country.

The publication of MATRADE's Business Handbook series on the export of food shall cover selected countries to provide pertinent information on their respective food regulations and import procedures. However, exporters are advised to make use of the contacts and access the websites and reference materials listed in the Handbook for more detailed information specific to their products.

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I. IMPORT REGULATIONS

RELATED LAWS

- The Food, Drug and Cosmetic Act (FD & C Act) governs food safety, labelling regulations and quality standards for imported food.
- The FD & C Act requires all food manufacturers to implement good manufacturing practices (GMP) for personnel, building, facilities, equipment, sanitation and product process control to provide assurance that the product is safe and clean.
- The Food Safety and Inspection Services (FSIS) is responsible for the enforcement of the Federal Meat Inspections Act and the Poultry Products Inspection Act. Exports of meat and meat products from Malaysia are presently not allowed into the USA.
- The Nutrition Labelling and Education Act requires nutrition labelling for most food products. Under the label's Nutrition Fact's panel, it is mandatory for manufacturers to provide information on :-
 - Total calories
 - Calories from fat
 - Total fat
 - Saturated fat
 - Cholesterol
 - Sodium
 - Total Carbohydrate
 - Dietary fibre
 - Sugar
 - Vitamin A
 - Vitamin C

- Calcium
 - Iron
- If a claim is made about any other item, or if a food is fortified or enriched with the following items, nutrition information for these components becomes mandatory. These are :-
 - polyunsaturated fat
 - potassium
 - monounsaturated fat
 - soluble fibre
 - insoluble fibre
 - calories from saturated fat
 - sugar alcohol
 - vitamin A
 - percentage of vitamin A present as beta carotene
 - other essential minerals and vitamins
 - These mandatory and voluntary components are the only items allowed on the 'Nutrition Facts' panel. Ingredient labelling is required on all food that has more than one ingredient. All nutrients must be declared as a percentage of the Daily Values, based on 2000 calorie diet.
 - In some circumstances variations in the format of the nutrition panel are allowed while others are mandatory variations, for example label of food for children.
 - The serving size is the basis for reporting each food's nutrient content. The serving sizes that appear on food labels are based on FDA established list of "Reference Amounts Customarily Consumed per Eating Occasion". These reference amounts are part of the regulations and are divided into 139 FDA - regulated food product categories.
 - As regulations are frequently changed, food manufacturers

must remain current with requirements. Legal requirements for food labelling can be accessed on the FDA's website.

- The Food Labelling Guide available on the food section of FDA's website, addresses in detail the Nutrition Labelling and Education Act requirements.
- It is the responsibility of the food manufacturer to ensure that the product complies with the provisions of the FD&C Act, Nutrition Labelling and Education Act and related regulations.

Low Acid Canned Food Regulations

- In addition to entry forms by US importers, all exporters of low acid canned food or acidified low acid canned food to the USA must register and file processing information with FDA before shipping these products. This information must be forwarded to FDA for each produce at the time of importation in order to ensure compliance with registration and process filling acceptance. The registration and process filling forms are available on the web at no cost.

II. REGULATORY AUTHORITIES

- The United States of America has several laws and procedures to ensure the safety of imported food. In addition to these regulations, the safety of food products exported to the USA are regulated by various authorities through premarket clearance, mandatory production practices, plant inspection as well as random and on going sampling of products.

- The surveillance on import of food products into the USA is under the responsibility of several departments:-
 - Egg products, meat and poultry products are regulated by the Food Safety and Inspection Services of the United States Department of Agriculture (USDA).
 - Fruits, vegetables and other plants are regulated by the Animal Plant Health Inspection Services of USDA.
 - The Environmental Protection Agency (EPA) determines the safety of pesticide products, sets tolerance levels for pesticide and publishes detection's for the safe use of pesticides.
 - All other food and food related products are regulated by the Food and Drug Administration (FDA).

III. IMPORT PROCEDURES

- To ensure that FDA is notified of all food products (except meat and poultry, which is regulated by US Department of Agriculture), the importer must file an Entry Notice and Entry Bond with the US Customs service. FDA will be notified by Customs of the food import. If FDA does not wish to examine the import, the product is allowed to be distributed into the USA.
- If FDA decides to examine the product, a sample will be taken for evaluation. If the product does not comply with US regulations, FDA will issue a Notice of Detention and the importer is allowed to make the product comply with US Regulations or if that is not possible, product will be reexported or destroyed.

- It is thus important for the exporter and importer to work closely to ensure product complies with US regulations on imported food products. (See Annexe for FDA import procedure flow chart).

IV. STANDARDS, QUALITY AND LABELLING REQUIREMENTS (ADDITIVES)

- FDA monitors unsafe pesticide levels in food and the standards on the composition, quality, nutrition and safety of food and colour additives. Approved food additives are published in the Code of Federal Regulations (CFR) which can be accessed through the Internet.

Low Acid Canned Food

- The Low Acid Canned Food (LACF) regulations require that all manufacturers of LACF packaged in sealed containers or Acidified Food (AF), submit details of the processing plant and process for filing with FDA before food is distributed in the USA.
- Under LACF regulations, all hermetically sealed containers of a low acid processed food must be marked with an identification code visible to the eye indicating where product is packed, contents, year and date of packing.
- The LACF regulations require that manufacturers of LACF to register with FDA on Form FDA 2541 and FDA 2541a. Upon submission of Form 2541, FDA will assign a Food Canning Establishment number (FCE). Form 2541a is to provide information on the processing method used in LACF.

A Low Acid Canned Food means a product with :-

- Finish equilibrium pH value greater than 4.6 and a water activity greater than 0.85
 - Sealed in a hermetic (airtight) container
 - Receives heat treatment
 - Normally stored under non-refrigerated condition.
- The following foods are not considered low-acid canned foods. Therefore, processors of these foods do not have to register and file processing information for these products:
 - Acid foods (natural or normal pH equal to 4.6 or below)
 - Alcoholic beverages
 - Fermented foods (when the pH of the food is reduced to 4.6 or less by the growth of acid producing micro-organisms)
 - Foods processed under the jurisdiction of the meat and poultry inspection program of the United States Department of Agriculture under the Federal Meat Inspections Act and the Poultry products Inspection Act
 - Foods with water activity (a_w) of 0.85 or below
 - Foods which are not thermally processed
 - Foods which are not packaged in hermetically sealed containers
 - Foods stored, distributed and retailed under refrigerated conditions (such products must be conspicuously labelled - e.g, PERISHABLE, KEEP REFRIGERATED)
 - Tomatoes and tomato products having a finished equilibrium pH less than 4.7.

- Acidified Food means :-
 - Low acid food to which acid or acid food is added for purpose of reducing the pH to a finished equilibrium pH of 4.6 or below. It has a water activity greater than 0.85 and is stored under non-refrigerated conditions.
- The following foods are not considered acidified foods. Therefore, processors of these foods do not have to register and file processing information for these products:
 - Acid foods (natural or normal pH equal to 4.6 or below)
 - Acid foods (including such foods as standardised and non-standardised food dressings and condiment sauces) that contain small amounts of low-acid foods and have a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid food. If there is a question about whether a product is covered under the regulations, food manufacturers should describe the product, submit a quantitative formula, list pH ranges for each ingredient and submit pH data on finished product from several production lots to FDA.
 - Alcoholic beverages
 - Carbonated beverages
 - Fermented foods
 - Food with water activity (a_w) of 0.85 or below
 - Foods stored, distributed, and retailed under refrigerated conditions
 - Jams, jellies, or preserves covered by 21 CFR 150.

Fish and Fishery Products

- Export of fish and fishery products is subject to importer's verification that manufacturers have adopted HACCP to ensure that product is not adulterated under Section 402 of the Food, Drug and Cosmetic Act, processed under insanitary condition and have written verification procedures for ensuring that product was processed in accordance with Part 123 of Code Federal Regulations (CFR).
- Importers must ensure that seafood-processing firms have HACCP Plan as defined under Part 123 of CFR and related provisions. Importers are liable for entry of adulterated food into the USA. Thus importers must be satisfied that seafood that is imported were produced subject to a HACCP system and proper sanitation controls.

V. GENERAL RANGE OF IMPORT DUTIES FOR FOOD PRODUCTS

PRODUCTS	HS CODE	RATES OF DUTIES
Crustaceans, shelled or not, fresh, chilled, frozen, dried, salted, etc.	0306	Free
Other Seafood, ie: Molluscs, squid, cuttlefish	0307	Free
Fish, fresh or chilled, not fillet	0302	Free
Coconuts, Brazil Nuts, Cashews, fresh or dried	0801	Free
Dates, Figs, Pineapples, Guavas, Mangoes	0804	0.44-29.8 cents/kg
Pepper, dried, crushed or ground	0904	Free
Spices, ie: ginger, saffron, turmeric	0901	Free - 4.8%
Coconut Copra, Palm Kernel	1513	Free
Palm Oil and its fractions	1511	Free
Prepared or preserved fish and caviar	1604	Free - 20%
Prepared or preserved crustaceans, mollusks, and other aquatic invertebrates	1605	Free - 10%
Sugar confectioneries (not cocoa)	1704	Free - 12.2%
Cocoa butter, fat and oil	1804	Free - 10%
Bread, pastry, cakes, biscuits and other bakers wares	1905	Free - 4.5%
Prepared or preserved fruits, nuts and other edible part of plants	2008	Free
Prepared or preserved mushrooms or truffles	2003	Free - 11.2%
Prepared or preserved vegetables	2005	Free - 11.2%
Sauces, mixed condiments and seasoning	2103	Free - 7.5%

FDA Enforcement

- FDA sets standards, verifies records and undertakes inspection. It is the exporters responsibility to ensure the food manufactured is safe for consumption.
- If a company violates any law, FDA will either encourage the company to rectify the problem or recall the product. FDA inspectors regularly visit factories to ensure that companies comply with FDA regulations.
- All imported food is subject to checks at the point of entry into USA.

VI. USEFUL CONTACTS

1. Food and Drug Administration (FDA)
5600 Fishers Lane
Rock Ville, MD 20857, USA
Tel : 1-301-5941218
Fax : 1-301-5940413
2. United States Department of Agriculture (USDA)
1400 Independence Ave. SW
Washington DC 20250, USA
Tel : 1-202-7206400
Fax : 1-202-7207990
Website: [http:// www.usda.gov](http://www.usda.gov)
3. Food Quality Control Department
Ministry of Health, Malaysia
Block E, Office Complex
Jalan Dungun
Damansara Heights
50490 Kuala Lumpur
Malaysia

Tel : 603-2540088/2540162
Fax : 603-2537804
E-mail : zamanhuri@dph.gov.my
Website : <http://dph.gov.my/division/fqc/index.htm>

4. Information on Food Quality and Standards and HACCP
Department of Veterinary Services
Ministry of Agriculture, Malaysia
8th & 9th Floor, Wisma Chase Perdana
Off Jalan Semantan
Damansara Heights
50630 Kuala Lumpur
Malaysia
Tel : 603-2540077
Fax : 603-2540092

VII. USEFUL WEBSITES

Access to latest FDA documents and messages, provides information on food safety, nutrition and cosmetic information, Food Labelling, Food Additives, Imported Food Inspection Procedure etc.

- FDA's Centre for Food Safety and Applied Nutrition (CFSAN):-
<http://www.fda.gov>
- Guide to Inspection of Low-Acid Canned Foods.
http://www.fda.gov/ora/inspect_ref/igs/lacftp101.html
- FDA's Food Labels Information.
<http://www.cfsan.fda.gov/label.html>
- FDA's Import Programme. Information related to products subject to FDA's control
http://www.fda.gov/ora/import/ora_import_program.html

**VIII. FOOD - RULES AND REGULATIONS FOR
UNITED STATES OF AMERICA AVAILABLE
AT MATRADE BUSINESS LIBRARY**

<u>TITLE</u>	<u>CALL NO.</u>
<u>UNITED STATES OF AMERICA</u>	
<u>Common Labelling Law for Food Products.</u> [s.l] : [s.n],[199-.] [n.p]	INFO FILE (LABEL- LING)
<u>Critical Steps Towards Safer Seafood/Paula Kurtzwei</u> [s.l] : U.S Food and Drug Administration, 1999 [n.p]	INFO FILE (FDA)
<u>Critical Controls for Juice Safety.</u> [s.l] : U.S Food and Drug Administration, 1999 [n.p].	INFO FILE (FDA)
<u>Exporters encyclopedia 1999/2000.</u> [s.l] : Dun & Bradstreet, 1999 [v.p].	I 382.603 EXP
<u>HACCP : a state-of-the-art approach to food safety</u> [s.l] : U.S Food and Drug Administration, 1999 (HACCP) [n.p].	INFO FILE (HACCP)
<u>Harmonized tariff schedule of the United States</u> (1999) Washington, D.C : United States International Trade Commission, [1999] [n.p]	T 382.7 HAR (USA)

Hazard Analysis and Critical Control Point Principles INFO FILE
And Application Guidelines (HACCP)

[s.l.] : U.S Food and Drug Administration,
1997

[n.p].

Malaysia Standard : Food Safety according to Hazard INFO FILE
Analysis and Critical Control Point SystemShah Alam: (HACCP)

Department of Standards Malaysia, 1999.

17 p.

Seminar on Exporting Food Products to USA : Rules S
and Regulations. (Kuala Lumpur : Pan Pacific Hotel, 382.6
27 Mei 1996)

[v.p]

- Regulation on Food Safety in USA
- Low Acid Canned Food
- Good Manufacturing Practices (GMP) in Manufacturing, Packing or Holding Human Food
- Detention Record Malaysia's Food Export
- Fish and Fishery Products
- FDA's Seafood HACCP Regulation
- Seafood HACCP Implementation
- Centre for Food Safety and Applied Nutrition

Seminar on The USA Food Import Regulations S
(25 August 1999 : MATRADE Seminar 641.3
Room, Kuala Lumpur) SEM

[v.p].

- Guide to Inspection of Acidified Food Manufactures.
- Guide to Inspection of Low Acid Canned Food Manufacturers.
- Establishment Registration and Process Filling for Acidified and Low Acid Canned Foods.

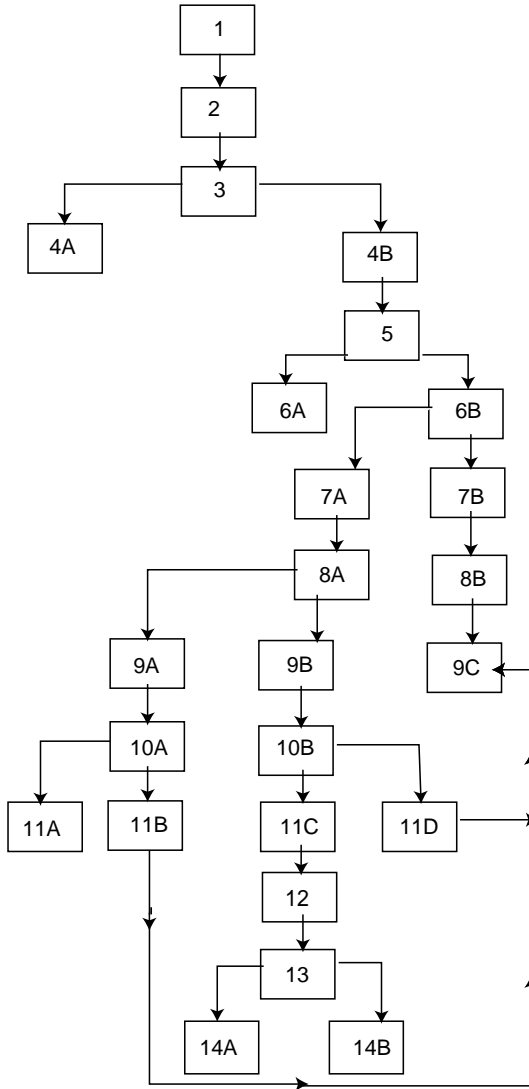
Supplement 1 to Harmonized Tariff Schedules of the United States (2000). Washington : United States Government Printing Office, 2000 (USA) [v.p]. T 382.7 SUP

Trade Regulations USA : Use of PVC film in the food industry in the United States Federal Register, Vol. 51, No. 22, 3 February [n.p]. INFO FILE (RULES & REGULATION)

U.S Customs Regulations Standard Importer Compliance Manual. Allegan : Boskage Commerce, [2000]. [v.p]. USA 382.7 UNI

U.S Import Regulations. Washington, D.C : U.S. Custom Service, 1998. [v.p]. USA 382.5 UNI

FDA IMPORT PROCEDURES



1 Importer or agent files entry documents with U.S. Customs 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 346, CF 3461 ALT, CF 7501 or alternative).
- Copy of commercial invoice, and
- Surety to cover potential duties, taxes and penalties

3 FDA reviews Importer's Entry Documents to determine if a physical examination, wharf examination, sample examination should be made.

4A Decision is made not to collect a sample. FDA sends a "May Proceed Notice". Shipment is released as far as FDA is concerned.

4B Decision is made to collect a sample based on:

- Nature of the product,
- 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 dock to another port or warehouse (contact U.S. Customs for details).

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

6A 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.

6B 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.

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.

7A 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.

7B Consignee, true owner, importer of record, or a designated representative either responds to the Notice of Detention and Hearing or requests an extension of the hearing period.

8A 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.

8B 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.

9A 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 level of contaminants and defects in food for human use, many be presented.

- 9B) 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.
- 9C) 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. Customs.
- 10A) FDA collects follow-up sample to determine compliance with guidelines.
- 10B) FDA evaluates the reconditioning procedure proposed by the importer. A bond is required for payment of liquidated damages.
- 11A) 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.
- 11B) 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).
- 11C) 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”

- 11D 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 of FDA Form FD 766.
- 12 Importer completes all reconditioning procedures and advises FDA that the goods are ready for inspection/sample collection.
- 13 FDA conducts follow-up inspection/sample collection to determine compliance with the terms of the reconditioning authorization.
- 14A FDA analysis finds that the sample is in compliance. A Release Notice is sent to the importer and to U.S. Customs. The charge 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.
- 14B FDA analysis finds that the sample is still not in compliance. Charges for FDA supervision are assessed on FDA Form 790. Copies are sent to U.S. Customs which is responsible for obtaining total payment including expenses incurred by their personnel.

IMPORTERS CAN SPEED FOOD ENTRIES!

- Determine before shipment that the product to be imported is legal.
- Have private laboratories examine samples of foods to be imported and certify the analysis of the processor. While not conclusive, these analysis might serve as an indication of the processor's ability to produce acceptable, legal products.
- Become acquainted with FDA's legal requirements, before contracting for a shipment.
- Request assistance from the FDA District Office responsible for your port of entry.
- Know the food importing procedures described on this information sheet.