

IMPORT SPECIFIC REQUIREMENTS: USA AND CANADA

FOOD PRODUCTS OF NON-ANIMAL ORIGIN

Contents

USA 3

 Introduction 3

 Canned Foods 4

 Seafood & Juice (HACCP)..... 5

 Alcoholic Beverages 6

CANADA..... 6

Alcoholic Beverages 6

Fresh Fruits and Vegetables 7

Fruit and Vegetable Products - Processed 8

Grains 8

Infant Formula (Human Milk Substitutes) 9

Margarine..... 9

Maple Products..... 9

USA

Introduction

FDA food regulations and FDA beverage regulations cover domestic and imported food safety, food adulteration (contamination), and food labeling (misbranding). FDA's food regulatory authority is very far-reaching, and includes:

- Fresh produce (fresh fruits and vegetables), usually concerned with pesticide residues or microbiological contamination;
- processed foods (dry goods, canned foods, acidified foods, prepared meals, etc.), usually interested in microbiological contamination, insect, bird, rodent or other animal filth, submission of scheduled process documentation for canned foods, and all food labeling requirements, such as Nutrition Labeling in foods and beverages;
- dietary supplements and nutritional supplements, related to dietary ingredient and finished product safety, Dietary Supplement Facts labeling, and other permissible dietary supplement labeling and marketing claims;
- infant formulas, with respect to conformity to FDA minimum nutrition requirements and product labeling requirements;
- fruit and vegetable juices, carbonated drinks, and functional beverages (such as energy drinks and antioxidant drinks), usually considering safe and permissible food additives and ingredients, safe color additives, percent-juice declarations, juice labeling requirements and Nutrition Facts labeling for all types of beverages and drink products;
- bottled water, related to conformity to FDA's regulatory bottled water standards, chemical contamination and microbiological contamination;
- dairy products (cheeses, milk and milk products, yogurts, etc.), many of which are standardized foods and must meet specific FDA regulatory food standards;
- seafood products (fin fish, crustaceans, etc.), usually for compliance with processing requirements (HACCP, or Hazard Analysis and Critical Control Point regulations), microbiological contamination, decomposition (and histamine production), and anti-biotic or other animal drug use in aquaculture seafood;
- food ingredients (nutritive ingredients and non-nutritive ingredients), with respect to generally recognized as safe (GRAS) status,

- functional food ingredients (emulsifiers, anti-caking agents, etc.), related to appropriate intended uses and declaration in food label ingredient declarations
- food color additives, natural flavors and artificial flavors, spices, seasonings, and vitamins added to food
- food contact surfaces (containers, utensils, food manufacturing surfaces, beverage containers and food containers), and
- some alcoholic beverages (beer, wine)

Most foods do not require FDA approval before being sold in the U.S. Most individual food items also do not require food registration or listing. Some food products are subject to special and additional regulations, including low acid canned foods (LACF), acidified foods (AF), infant formulas, pasteurized grade A dairy products, food colors, food contact surfaces and food contact materials, and alcoholic beverages (although alcoholic beverages are permitted for sale in the U.S. by the Bureau of Alcohol Tobacco and Firearms, Tax and Trade Bureau (TTB)). FDA regulates imported foods differently by requiring some pre-market review or FDA approval prior to importing food for commercial distribution in the U.S

Some foods are “standardized foods” because FDA has established food standards for them. These additional requirements apply to a variety of foods, ranging from milk chocolate to salad dressings; and yogurt and fruit preserves to bottled water. Most foods, however, are non-standardized foods. If a food is a standardized food, it must meet the standard established by FDA or the food will be considered adulterated and misbranded. All foods are subject to specific food naming regulations, and that applies to standardized foods and non-standardized foods alike.

Canned Foods

Canned foods (low acid canned foods, or LACF products, and acidified food canned food products) are subject to special FDA permit controls, which are implemented through FDA Food Canning Establishment (FCE) regulations and FDA Scheduled Process Identification (SID) filings.

FCE Registration

All low acid canned food (LACF) and acidified canned food manufacturers must submit a Food Canning Establishment (FCE) Registration with FDA before exporting to or distributing canned foods in the United States. The FDA FCE Registration is in addition to FDA’s Bioterrorism Act Food Facility Registration requirement. When the FCE Registration is submitted to FDA, the manufacturer must also submit to FDA its Scheduled Process filings for all of its commercially sterile, acidified and low-acid

canned foods to obtain a Scheduled Process Identification (SID) Number from FDA for each specific canned food and aseptic or acidified food process.

Scheduled Process Identification

Any low acid canned food processor, which is required to submit an FDA FCE registration must also submit to FDA a scheduled process filing form. The canned food manufacturer's Scheduled Process must be electronically transmitted to and reviewed (and accepted) by FDA's Center for Food Safety and Applied Nutrition (CFSAN) before any canned food import shipments occur.

Seafood & Juice (HACCP)

FDA has issued specific processing regulations (good manufacturing practices or GMP regulations) governing seafood products and juices. These regulations, called FDA Hazard Analysis and Critical Control Point (HACCP) regulations, require all seafood and many juice processors to identify the hazards that have the potential of contaminating the product through the stream of raw materials into the processing facility, or through the processing steps themselves which, if such hazards occurred, would render the food products unsafe for consumers. The HACCP regulations require seafood and juice manufacturers to identify, define, and monitor Critical Control Points (CCPs) in their processing steps to minimize, reduce or eliminate these hazards and thereby reduce the safety risks associated with such products. The HACCP regulations apply to domestic and foreign seafood and juice manufacturers alike.

Foreign Seafood or Juice Manufacturers

Under FDA HACCP regulations, seafood processors and juice manufacturers and importers must comply with federal regulations related to HACCP planning and management. "HACCP Plan" refers to documented procedures which ensure food safety by analyzing food processing to discover and mitigate risks associated with biological, chemical, and physical contamination. Compliant HACCP plans include the following basic elements:

- 1: Conduct a hazard analysis;**
- 2: Determine the critical control points (CCPs);**
- 3: Establish critical limits;**
- 4: Establish monitoring procedures;**
- 5: Establish corrective actions;**
- 6: Establish verification procedures; and**
- 7: Establish record-keeping and documentation procedures.**

Alcoholic Beverages

Any person or firm wishing to engage in the business of importing into the United States distilled spirits, wines containing at least seven percent alcohol, or malt beverages must first obtain an importer's basic permit from the Alcohol and Tobacco Tax and Trade Bureau (TTB) of the U.S. Treasury Department. TTB is responsible for administering the Federal Alcohol Administration Act, 27 U.S.C. 201 et seq. and 27 CFR Subchapter A. Under this act, TTB has the authority to:

- Prevent consumer deception,
- Require that labels on alcohol products provide consumers with "adequate information" regarding the identity and quality of the products, and
- Prohibit false or misleading statements.

Distilled spirits imported in bulk containers whose capacity is more than one gallon can be only withdrawn from CBP custody by individuals to whom it is lawful to sell, or otherwise dispose of, distilled spirits in bulk. A copy of a bill of lading or other document such as an invoice, showing the name of the consignee, the nature of the contents, and the quantity the shipment contains must, at the time of importation, accompany each bulk or bottled shipment of imported spirits or distilled or intoxicating liquors. http://www.ttb.gov/pdf/ttbp51008_laws_regs_act052007.pdf

<http://www.ttb.gov/>

CANADA

Alcoholic Beverages

The *Importation of Intoxicating Liquors Act*, a federal statute, gives the provinces and territories full control over the importation of intoxicating liquor into their jurisdictions. (Note: there are certain exceptions, such as bulk importations by licensed distillers and brewers for blending purposes). Consequently, importers should consult the appropriate provincial or territorial liquor authority before considering the importation or interprovincial trade of intoxicating liquor.

Standards of identity and labeling requirements for alcoholic beverages exist in the *Food and Drugs Act and Regulations*, the *Consumer Packaging and Labelling Act and Regulations* and the *Excise Act and Regulations*. Standardized container size requirements for wine exist in the *Consumer Packaging and Labelling Regulations*.

In addition to the basic food labelling provisions, alcoholic beverages are subject to further requirements, such as the declaration of alcohol content by volume. The Guide to Food Labelling and Advertising provides a thorough overview of the labelling requirements for alcoholic beverages.

Fresh Fruits and Vegetables

Fresh fruits and vegetables, including nuts and edible fungi, are regulated by the *Fresh Fruit and Vegetable Regulations* under the *Canada Agricultural Products Act*. These regulations cover quality, labelling, packaging, grading, and health and safety requirements.

Commercial importers of fresh fruits and vegetables must have a Produce Licence issued by the Canadian Food Inspection Agency or be a member of the Dispute Resolution Corporation (DRC). Each shipment of fresh produce must be accompanied by a Confirmation of Sale form in triplicate, which is the importer's evidence that there is a firm purchase agreement. This form is reviewed by a Customs officer at the products' point of entry, and relayed to the Canadian Food Inspection Agency.

To ensure compliance with Canadian standards for safety, quality, labelling, packaging and grading, all shipments of fresh produce are subject to examination upon entry into Canada by an inspector of the Canadian Food Inspection Agency.

Special requirements also exist for the importation of products shipped in bulk.

To prevent the introduction and spread of plant diseases and pests, fresh fruits and vegetables are subject to the *Plant Protection Act and Regulations*. Consequently, the Canadian Food Inspection Agency requires import permits and/or phytosanitary certificates for certain fresh fruits and vegetables from specific countries or states.

For detailed information regarding Canadian [import requirements for fresh fruit and vegetables](http://www.inspection.gc.ca/english/fssa/frefra/cdnreqe.shtml), refer to the Canadian Food Inspection Agency (CFIA) website at:

<http://www.inspection.gc.ca/english/fssa/frefra/cdnreqe.shtml>

Information on Canadian plant protection requirements may be found at

<http://www.inspection.gc.ca/english/imp/airse.shtml>

Fresh fruit and vegetables derived from a plant with a novel trait (i.e., derived from biotechnology) are considered novel foods (see section on novel foods).

http://active.inspection.gc.ca/tech/extsite.asp?url=http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._285/index.html

Fruit and Vegetable Products - Processed

Processed fruit and vegetable products include canned and frozen fruits and vegetables as well as some other fruit and vegetable products (vegetable soup, prepared mustard, spaghetti in tomato sauce, etc.).

Imported product must comply with the *Processed Products Regulations* under the *Canada Agricultural Products Act*. These regulations cover quality, labelling, packaging (including standardized sizes), grading, and health and safety requirements.

Each shipment must be accompanied by an Import Declaration form in duplicate, which indicates that the products meet the requirements of the *Processed Products Regulations* and were processed under sanitary conditions, and that they were sound, wholesome and fit for human consumption at time of shipment. At present, there is no federal requirement for importers of processed fruits and vegetables to be licensed.

All shipments are subject to inspection by the Canadian Food Inspection Agency at their destination point.

The section, "Low Acid Foods in Hermetically Sealed Containers", contains further information.

http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.%2C_c._291/page-1.html

Grains

Tariff Rate Quotas for wheat, barley and their products were instituted on August 1, 1995.

Consequently, an import permit issued by the Department of Foreign Affairs and International Trade is required to import these products.

For detailed information regarding [Canadian phytosanitary import requirements](#), refer to the Canadian Food Inspection Agency (CFIA) website at:

<http://www.inspection.gc.ca/english/plaveg/grains/grainse.shtml>

Please note that grains derived from a plant with a novel trait (i.e., derived from biotechnology) are considered novel foods (see section on novel foods).

The Canadian Grain Commission and the Canada Border Services Agency may also have requirements regarding the importation of grains into Canada and should be contacted prior to importation.

Infant Formula (Human Milk Substitutes)

The composition and labelling of foods for infants are regulated under Division 25 of the *Food and Drug Regulations*. In the case of new infant formulas and those which have undergone a major change, manufacturers and importers are required to notify Health Canada of their intention to market the products. The information to be submitted in this "pre-market notification" is outlined in Division 25 of the Regulations. It permits Health Canada to conduct a thorough safety assessment for the proposed product.

Margarine

Effective January 1, 1995, margarine was placed on the *Import Control List* established under the *Export and Import Permits Act*. Therefore, an import permit issued by the Department of Foreign Affairs and International Trade is required to import margarine.

The *Food and Drug Regulations* outline standards of identity and composition for both margarine and calorie-reduced margarine. Certain provinces may also have restrictions on the addition of colour to margarine.

Maple Products

Maple products include maple syrup, maple sugar, soft maple sugar, maple butter and maple taffy, that are obtained exclusively from maple sap.

Imported maple products must meet the requirements of the *Maple Products Regulations* under the *Canada Agricultural Products Act*. These regulations cover quality, labelling, packaging (including

standardized sizes), grading, and health and safety requirements. At present, there is no federal requirement for importers of maple syrup and maple products to be licensed.

All shipments are subject to inspection at their destination point by the Canadian Food Inspection Agency