

## IMPORTING FOOD PRODUCTS INTO THE UNITED STATES: U.S. RULES,

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## **REGULATIONS AND PROCEDURES**

**GENERAL REQUIREMENTS OF U.S. LAW** - Under provisions of the U.S. law contained in the U.S. Federal Food, Drug and Cosmetic Act (FD&C Act), importers of food products intended for introduction into U.S. commerce are responsible for ensuring that the products are safe, sanitary, and labeled according to U.S. requirements. The Food and Drug Administration (FDA) is not authorized under the law to approve, certify, license or otherwise sanction individual food importers, products, labels or shipments. Importers can import foods into the United States without prior sanction by FDA, as long as the facilities that produce, store or otherwise handle the products are registered with FDA, and, prior notice of incoming shipments is provided to FDA.

Imported food products are subject to FDA inspection when offered for import at U.S. ports of entry. FDA may detain shipments of products offered for import if the shipments are found not to be in compliance with U.S. requirements.

**FACILITY REGISTRATION** - The U.S. Public Health Security and Bioterrorism Preparedness and Response Act of 2002 require that food facilities (other than private homes and individual farms) producing, storing or otherwise handling food products intended for sale in U.S. interstate commerce be registered with FDA. Registration of facilities can be performed on the internet, and is free of charge. For information and instructions on how to register a facility, please see FDA's web page on the subject at the following link:

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/OnlineRegistration/default.htm>

Please note that a U.S. agent residing in the United States must be listed for each foreign facility being registered.

**PRIOR NOTICE OF INCOMING SHIPMENTS:** The Bioterrorism Preparedness Act of 2002 also requires importers to provide prior notice to FDA for each import shipment of food products. Prior notice of shipments must be performed over the FDA website. Information about the prior notice requirements and instructions on providing prior notice is available at the following FDA link:

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/PriorNoticeofImportedFoods/default.htm>

Help with the registration and prior notice processes is available from the FDA Registration and Prior Notice Help Desk at 866-521-2297; email [FURLS@fda.gov](mailto:FURLS@fda.gov).

**SAFETY AND SANITATION** - The FD&C Act requires that foods imported into and sold in U.S. commerce not bear or contain any poisonous or deleterious substances which may render them injurious to health, nor consist in whole or in part of any filth, putrid, or decomposed substances, or otherwise be unfit for food. (Examples include evidence of rodent or insect infestation, or the presence of pesticides prohibited in foods or amounts of allowable pesticides in excess of established tolerances.) Foods must not be prepared, packed, or held under unsanitary condition whereby the products become contaminated with filth, or rendered injurious to health.

Manufacturers are not required to provide any sort of test results to the FDA as a condition of producing, marketing or distributing food products, nor does FDA accept samples of food products offered for testing by manufacturers, importers or distributors. Under the requirements of U.S. food law, manufacturers and distributors are expected to take necessary and reasonable steps to ensure the safety and sanitation of their food products.

**GOOD MANUFACTURING PRACTICES:** Processors of food products sold in U.S. commerce should be familiar with and employ the U.S. Current Good Manufacturing Practices for foods (GMPs). The GMPs set forth basic considerations manufacturers and distributors should take into account to keep food clean and safe during manufacturing, processing, packing and holding. The GMPs are contained in Part 110 of Title 21 of the U.S. Code of Federal Regulations. They can be accessed at the following web link to Title 21 provisions:

[http://www.access.gpo.gov/nara/cfr/waisidx\\_03/21cfr110\\_03.html](http://www.access.gpo.gov/nara/cfr/waisidx_03/21cfr110_03.html)

and guidance site:

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/CurrentGoodManufacturingPracticesCGMPs/default.htm>

**ACTION LEVELS:** Importers of certain commodities should be aware that FDA has issued "Defect Action Levels" (DALs) for some food commodities for natural and unavoidable defects, such as mold, insect filth and mammalian excreta. These DALs specify the maximum allowable amounts of these defects in shipments of these products. FDA's DAL list can be accessed at this link to the FDA website:

Defect action levels guidance document:

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Sanitation/ucm056174.htm>

OR

<http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/sanitation/ucm056174.htm#CHPT3>

FDA also has established action levels for poisonous and deleterious substances in certain foods. Like the DALs for natural and unavoidable defects, these action levels establish for the listed commodities the maximum allowable amounts of the listed substances. The FDA Action Levels for Poisonous and Deleterious Substances can be accessed at this link to the FDA website:

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ChemicalContaminantsandPesticides/ucm077969.htm>

**RETAIL LABELING** - Provisions of the FD&C Act, the U.S. Fair Labeling and Packaging Act, and the Nutrition Labeling and Education Act require that retail packages and containers of food products sold in U.S. interstate commerce bear labels in English (Spanish acceptable in Puerto Rico) that include specific information: the identity of the product, the name and address or phone number of the responsible firm (may be the manufacturer or distributor, foreign or domestic), a list of ingredients in descending order or predominance in the product, the net weight of contents in both English and metric terms, and in most cases nutritional information. This information is required to be presented in that ensures that the information is accessible to consumers under normal conditions of purchase and use. Smaller manufacturers may qualify for exemption from the requirement for nutrition labeling. Imported products are required include a label statement indicating the country of origin of the product. Detailed information about U.S. labeling requirements can be obtained from FDA's web page on the subject at the web address: Guidance on food labeling

<http://www.fda.gov/Food/LabelingNutrition/FoodLabelingGuidanceRegulatoryInformation/default.htm>

This link introduces the guidance on food labeling showing all CFRs on the subject. The second link on the FDA site subject index are regulations which cover all types of food labeling rules including nutritional labeling, health and nutrient claims, reference sizes for nutrition labeling. Also on this webpage is a link to information about the small business exemption from nutrition labeling, including qualifications for the exemptions, and instructions on how to apply for it.

**NUTRITION LABELING:** For developing nutrition labeling information, manufacturers may choose to employ the services of a commercial laboratory equipped to perform analyses of foods to determine nutrient content. Manufacturers can also examine the U.S. Department of Agriculture's food nutrient database to determine if the database provides information from which they can derive the appropriate nutrient information for their products. The database can be accessed at this link:

[http://www.nal.usda.gov/fnic/cgi-bin/nut\\_search.pl](http://www.nal.usda.gov/fnic/cgi-bin/nut_search.pl) .

**LABELING BULK CONTAINERS** - Bulk containers of food products offered for import into the United States should include the following information in English on the outside of the container: the identity of the product, the name and address or phone number of a responsible firm (can be the distributor, manufacturer, importer, import agent, or consignee), the net weight of contents in English Measurement (pounds/ounces), a list of ingredients contained in the product, and the country of origin of the product.

**ALLERGENS IN FOOD PRODUCTS AND ALLERGEN LABELING** - Food manufacturers should be aware that FDA has issued guidance about food allergens and allergen labeling of products. Agency guidance and compliance policy on the matter is available at these links to the FDA website:

<http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074944.htm>.

In addition, in 2004 the U.S. Congress passed the Food Allergen Labeling and Protection Act, which will require more explicit listing of allergenic ingredients on the labels of retail food products. FDA advises manufacturers to check the FDA website during this year to keep apprised of the new requirements and their implementation:

<http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/default.htm>

**STANDARDS OF IDENTITY** - Under authority of the FD&C Act, FDA has promulgated "standards of identity" for a number of food product categories. These standards establish minimum ingredient

requirements for the various foods covered by the standards. These requirements must be met in order for a food legally to be sold bearing the statement of identity covered by the standard. The standards for foods are contained in **Parts 130 – 169** of Title 21 of the U.S. Code of Federal Regulations:

<http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1>

**LOW ACID CANNED AND ACIDIFIED FOODS** - Depending on what they contain and how they are processed and packaged, certain canned or bottled foods are "low acid canned foods" (LACF) or "acidified foods" (AF). An LACF product is a thermally processed product packed in a hermetically sealed container with an acid content above pH 4.6, containing enough water ("water activity") to allow the growth of anaerobic microorganisms. To ensure the safety of food in U.S. commerce, LACF products are regulated more rigorously than most other foods in order to protect the products from contamination during processing by dangerous microorganisms and their toxins, such as *C. botulinum*. Processors may "acidify" their low-acid canned food products by adding acidic ingredients in order to adjust the pH and inhibit microbial growth. Such products are called "acidified foods (AF)." Foreign facilities whose LACF/AF products are imported into the United States are required to register their establishments with FDA's LACF office, and, to file processing information for each LACF/AF product intended for import into the United States. A quick reference of approximate pH values for various types of food products is available at this FDA link: <http://www.cfsan.fda.gov/~comm/lacf-phs.html>. For more information on LACF and AF products and their requirements, including information on how to register facilities and file processing information, see FDA's web page on this subject at the link:

<http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/AcidifiedLow-AcidCannedFoods/EstablishmentRegistrationThermalProcessFiling/Instructions/ucm2007436.htm>

For FDA's help with the registration process, and with determining whether your products are or are not LACF/AF products requiring facility registration and process filing, you may contact the agency's LACF office directly at the email address [lacf@cfstan.fda.gov](mailto:lacf@cfstan.fda.gov); telephone 301-436-2411. The U.S. regulations imposing the requirements for LACF/AF foods are contained in Parts 113 and 114 of Title 21 of the U.S. Code of Federal Regulations:

<http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=200321>.

**FOOD ADDITIVES** - FDA also regulates additives used in food products. New food additives must be approved or reviewed by FDA before marketing. FDA also regulates food packaging materials and food contact substances. Packaging materials must be safe for use, and must not impart deleterious substances or off-flavors or odors into the packaged product. Information about FDA's regulation of

food ingredients, additives, packaging materials and food-contact substances is available at FDA's website on the matter: <http://www.fda.gov/Food/FoodIngredientsPackaging/ucmo64228.htm>

FDA's list of approved food additives is contained in its list of Everything Added to Food in the United States (EAFUS). The EAFUS link is on the above webpage in the left-hand column near the bottom of the page. The specific regulations in Title 21 of the U.S. Code associated with each substance in the EAFUS list are listed in the far right column of the list. (A link to Title 21 provisions is included above in this document.)

**FOOD SECURITY** – Food manufacturers, processors, and transporters should be aware that FDA has issued food-security guidance designed to protect their operations against the potential for bioterrorism. FDA's guidance can be accessed at this link to the FDA website:

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm083049.htm>

**BOTTLED WATER PRODUCTS** – In addition to the other applicable requirements listed here, special requirements apply to bottled water products. FDA has promulgated a separate set of GMPs specifically for water bottling plants. These are contained in Part 129 of Title 21. In addition, FDA has promulgated regulations that stipulate definitions for various terms that may appear on the retail labels of bottled water products. These are contained in Part 165 of Title 21. You can access Part 165 provisions through the following link to Title 21 provisions:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm>

**HACCP REQUIREMENT FOR JUICE PRODUCTS** – In addition to the other applicable requirements listed here, most juice products are required to be processed in a facility that has in place a Hazard Analysis and Critical Control Point (HACCP) safety plan. Importers of juice products are required to take "affirmative steps" to ensure that facilities producing products intended for the U.S. market have an operational HACCP plan. See the following FDA link for more specific information on affirmative steps for importers: <http://www.cfsan.fda.gov/~comm/juicimp.html>. Information about the HACCP requirement for juice products is available at this link to the FDA website:

<http://www.fda.gov/food/foodsafety/hazardanalysiscriticalcontrolpointshaccp/juicehaccp/default.htm>

**HACCP REQUIREMENT FOR SEAFOOD PRODUCTS** – In addition to the other applicable requirements listed here, seafood products are required to have been processed in a facility that has in place an operational Hazard Analysis and Critical control Point (HACCP) safety plan. Importers are

required to take "affirmative steps" to assure that facilities producing products intended for the U.S. market have an operational HACCP plan: Information about the HACCP requirement for seafood products is available at this link to the FDA website:

**GOOD AGRICULTURAL PRACTICES FOR FRESH FRUITS AND VEGETABLES** – FDA recommends that fruit and vegetable growers producing products intended for introduction into U.S. commerce follow certain practices to avoid contamination of the products with disease-causing organisms. FDA's full recommendations are contained in its Guide to Minimize Microbial Hazards on Fresh Fruits and Vegetables, viewable at the following link:

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064574.htm>

**PESTICIDES:** Tolerances for pesticides allowed on specific agricultural products are set by the U.S. Environmental Protection Agency (EPA). An FDA inspection of an imported agricultural commodity may test for the presence of pesticides for which EPA has not established tolerances for that commodity. Import shipments of a food commodity containing pesticides for which tolerances have not been established for that commodity may be refused entry or detained. EPA can be contacted through that agency's website at this link: <http://www.epa.gov/>.

Specific information about what pesticides are allowed, and what amounts, in various foods is available at the following EPA link: <http://www.epa.gov/pesticides/food/viewtols.htm>.

**PHYTOSANITARY AND ANIMAL PEST CONSIDERATIONS:** Certain food products from some countries are prohibited import into the United States, or are allowed import under restricted conditions, because of the threat of animal or plant pests and diseases. These phytosanitary restrictions are administered by the US Department of Agriculture's Animal and Plant Health Inspection Service: <http://www.aphis.usda.gov/>.

**MEAT AND POULTRY PRODUCTS** – Most meat and poultry, and combination products such as frozen casseroles and pizzas containing 3 percent or more meat by weight, are regulated by the U.S. Department of Agriculture's Food Safety and Inspection Service: <http://www.fsis.usda.gov/>. FSIS can be reached by email at FSIS. [Regulations@usda.gov](mailto:Regulations@usda.gov).

#### **The Agricultural Marketing Service (AMS)**

carries out a wide range of programs aimed at facilitating the marketing of agricultural products, assuring consumers of a quality food supply, and assuring ensuring fair trading practices. AMS offers

voluntary grading service to provide the industry with an impartial, third-party certification of quality and condition of any fresh or processed product. This certification can help to provide a basis for assuring a quality product, verify compliance with contract terms as an aid to selling, and/or help settle claims for damage incurred in transit or storage. The Agricultural Marketing Service (AMS) provides the following services: (a) **Quality Standards:** In cooperation with industry, AMS develops and maintains quality standards for hundreds of products. Products include: fresh fruits, vegetables, and specialty crops, processed fruits and vegetables, milk and other dairy products, cattle, hogs, and sheep, poultry and eggs, cotton, tobacco, organic products; (b) **Grading and Certification:** Quality grading (a user-fee service) based on the standards developed for each product. Grading services are often operated cooperatively with state departments of agriculture

### **Food Safety Modernization Act of 2011**

FDA conducts its seafood safety oversight activities in conformance with its statutory authorities, which have recently been expanded by the [Food Safety Modernization Act](#) (FSMA). FSMA represents the first major overhaul of FDA's food safety law in more than 70 years and will transform FDA's food safety program. FSMA closes significant and longstanding gaps in FDA's food safety authority, with new safeguards to prevent, rather than react, to food safety problems, and gives FDA important new tools to ensure that imported seafood is as safe as domestic seafood.

### **Importing food product samples:**

All of the above requirements applicable to foods imported for sale in the United States also apply to imported samples of food products, except that product samples do not have to include nutrition information on the labels. However product sample labels must include the other required label information: statement of identity, net weight of contents, listing of a responsible firm, and ingredients list. FDA recommends that food product samples be labeled "not for sale" on both individual and bulk packaging.

### **Arrival at point of entry:**

When a food shipment is offered for import into the United States, the shipment must be declared by the importer or broker/agent to the U.S. Customs and Border Protection office at the port of entry by the filing of an "entry notice" and acquisition of a bond. Customs then will notify FDA staff of the presence of the shipment. FDA may inspect and sample the shipment to ensure its compliance with U.S. requirements. More detailed information on FDA import procedures can be found on the agency's web page on Imports and Exports at the web link :

[http://www.ita.doc.gov/exportamerica/AskTheTIC/qa\\_food\\_beverage.pdf](http://www.ita.doc.gov/exportamerica/AskTheTIC/qa_food_beverage.pdf)

The second item on this page, "FDA Import Procedures," contains a detailed flow-chart of the process.

Additional information on the FDA Import and Import Inspection system is available from the link

<http://www.fda.gov/ora/import/default.html> or

<http://www.fda.gov/ForIndustry/ImportProgram/default.htm>

Importers will need to know the FDA product codes for products in order to complete the on-line Import Prior Notice procedure. To determine the appropriate product code for a particular product, consult the FDA webpage on developing product codes at

<http://www.accessdata.fda.gov/SCRIPTS/ORA/PCB/PCB.HTM> .

Information on U.S. Customs forms, procedures, bond acquisition, duties, if any, and country-of-origin labeling requirements may be obtained from any Customs Service office or from that agency's web site

At <http://www.cbp.gov/linkhandler/cgov/newsroom/publications/trade/iius.ctt/iius.pdf>

#### **FDA field office inspection**

Inspections of FDA-regulated food shipments offered for import into the United States are carried out by inspectors with the agency's Office of Regulatory Affairs. ORA offices are located throughout the United States at ports of entry. Local FDA/ORAs can also be a point of contact for importers with ports of entry within the region covered by a particular FDA/ORAs office. Local, regional and district FDA/ORAs are listed at this FDA link:

[http://www.fda.gov/ora/inspect\\_ref/iom/iomoradir.html](http://www.fda.gov/ora/inspect_ref/iom/iomoradir.html) .

## **CANADA**

### **Introduction**

The regulation of the importation of food into Canada is the shared responsibility of several federal agencies and departments. The primary federal bodies involved are the Canadian Food Inspection Agency, Canada Border Services Agency and the Department of Foreign Affairs and International Trade. In some provinces, importers may also have to meet specific provincial requirements for certain products. For information on provincial government services and programs, consult the reference telephone numbers listed under *Provincial and Territorial Information* [in Appendix II](#).

## Requirements for Imported Foods

### Import Procedures and Documents

#### Canada Border Services Agency Requirements

In order to obtain the release of a commercial shipment at the Customs office, the following documents are required:

- Two copies of the cargo control document. This document may be a manifest, waybill or some other approved document obtained from the carrier or freight forwarder.
- Two copies of an invoice to support the value of the goods. This invoice provides information concerning the shipment including: details regarding the importer and exporter, a description of the goods, the value of the goods, the country of origin and destination of the goods, and the currency of settlement. A Canada Customs' invoice or a commercial invoice containing all the required information is necessary for goods with a value of \$1,600 or greater. An additional copy of the invoice is required in cases where the importer or broker intends to transmit the final accounting data through CADEX (Customs Automated Data Exchange).
- Two copies of a fully completed B3 form, for all shipments for commercial use in Canada, regardless of value. The B3 document is used for duty and tax purposes. A third copy of this form is required by Statistics Canada for shipments valued over \$1,600.
- All permits, certificates, licenses or other documentation required by Canada Border Services Agency or other government departments for the release of food shipments. Generally, original documents are necessary.

Special programs exist to speed the transit time through Customs. The Pre-Arrival Review System (PARS) allows Customs to process release information before the goods arrive, thus accelerating release or referral of goods when they do arrive. The Frequent Import Release System (FIRST) processes repetitive importations of low risk shipments with a significant savings in time.

#### General requirements

That all food products must meet. It outlines, for example, the legislative basis of one of the foremost concerns of the Canadian import policy, the health and safety of the food supply, Good Importing Practices, Canadian labeling requirements (including net quantity declaration), and health and safety concerns during the transport of food.

## Canadian Food Legislation

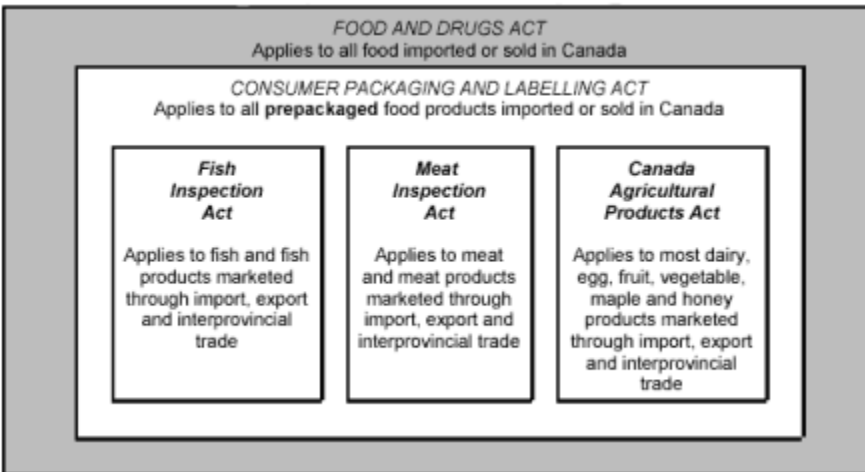
The *Food and Drugs Act* and *Regulations* is the primary legislation that applies to all food sold in Canada, whether imported or domestic. This legislation sets out minimum health and safety requirements, as well as provisions preventing fraud or deception (labelling, composition, packaging, treatment, processing, sale and advertising).

Various statutes contain standards or specifications that complement or further define the food standards set out in the *Food and Drugs Act* and *Regulations*. The *Consumer Packaging and Labelling Act* and *Regulations*, for example, establish labeling and net quantity requirements for consumer packaged goods for sale in Canada. The *Canada Agricultural Products Act* and associated *Regulations*, the *Fish Inspection Act* and *Regulations* and the *Meat Inspection Act* and *Regulations* also contain food standards. However, these statutes are primarily intended to ensure the marketability of food products traded internationally and interprovincially, through a combination of safety, quality and grading standards. Several federal statutes are designed to protect Canadian agriculture, fish stocks, forestry, industry and wildlife from the introduction of animal and plant diseases and pests: the *Health of Animals Act* and *Regulations*, the *Plant Protection Act* and *Regulations*, and the *Fish Health Protection Regulations* of the *Fisheries Act*. These statutes restrict the importation of certain foods from specific areas of concern or require phytosanitary certificates, permits or other documentation.

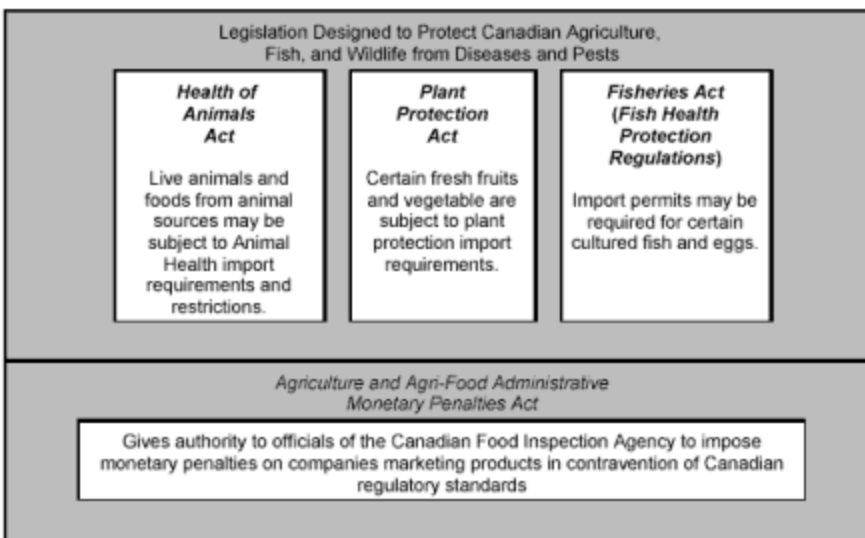
To permit the Canadian Food Inspection Agency (CFIA) to take effective enforcement action against importers and domestic companies marketing products that do not meet Canadian regulatory standards, the *Agriculture and Agri-Food Administrative Monetary Penalties Act* will allow regional CFIA officials to issue monetary penalties for non-compliance with provisions of the seven agri-food Acts to which this legislation applies.

[Appendix I of this Guide provides brief descriptions](#) of these and other federal statutes relevant to the importation of food. The list, however, is not exhaustive. There may be health and safety requirements in other federal or provincial acts.

## Key Federal Legislation



[Food and Drugs Act - Applies to all food imported or sold in Canada](#)



[Legislation designed to protect Canadian Agriculture, Fish and Wildlife](#)

## Health and Safety

To ensure a safe and nutritious food supply, all foods sold in Canada, whether domestic or imported, must meet the health and safety requirements of the *Food and Drugs Act and Regulations*. Enforcement is provided for in criminal law.

Section 4 of the *Food and Drugs Act* prohibits the sale of an article of food that:

- a. has in or upon it any poisonous or harmful substance;

- b. is unfit for human consumption;
- c. consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance;
- d. is adulterated; or
- e. was manufactured, prepared, preserved, packaged, or stored under unsanitary conditions.

### **Good Importing Practices**

Good Importing Practices are proper food handling procedures that facilitate the identification and control of problems that may be encountered at all stages of importation, from the planning stages through to the final distribution in Canada. Adherence to Good Importing Practices should ensure compliance with the health and safety requirements of Canadian legislation. Proposed amendments to the *Food and Drug Regulations* will make this voluntary code of practice into a regulatory requirement. A booklet entitled "[Good Importing Practices - Code of Practice for Use By Canadian Food Importers](#)" may be obtained from the Canadian Food Inspection Agency Import Service Centre. ([For contact information, see Appendix II.](#))

### **Labeling**

All foods packaged for consumer use and imported into Canada must comply with basic food labeling requirements specified by the *Food and Drugs Act and Regulations* and the *Consumer Packaging and Labeling Act and Regulations*.

Labeling requirements include the common name of the food, a list of ingredients and components, the name and address of the responsible party, a net quantity declaration in metric and a best before date when required. The Nutrition Facts table is mandatory for most prepackaged foods with some exceptions and exemptions. The format and information provided must comply with the Guidelines on Nutritional Labelling developed by Health Canada and also with the *Food and Drug Regulations*. Agricultural and fish products for which standards exist under the *Meat Inspection Act, Canadian Agricultural Products Act* and associated Regulations, and the *Fish Inspection Act* may have additional labelling requirements (e.g. grade or country of origin).

All mandatory labelling information and nutritional labelling, other than the name and address of responsible party, is required to be declared in both French and English.

**It should be noted that Canadian labelling requirements may differ significantly from those of the United States and other countries.** As an example, the United States' Nutrition Labelling Information (Nutrition Facts) is not currently permitted on products imported into Canada.

The Canadian Food Inspection Agency has Single Access Food Labelling Service offices across the country serving the business community. These offices, located in major urban centres, provide labelling information for all food except fish. (See [Appendix II.](#))

The Guide to Food Labeling and Advertising is a comprehensive reference document providing current federal food labeling and advertising policies and regulatory requirements. The [Guide](#) is now available on the Canadian Food Inspection Agency website

at: <http://www.inspection.gc.ca/english/fssa/labeti/guide/guidee.shtml>.

## Net Quantity

In Canada, net quantity declarations on consumer packaged products must be expressed in metric units of weight (grams or kilograms), volume (millilitres, litres) or count (when applicable). The manner of declaring net quantity and the method of determining the accuracy of net quantity declarations for consumer packaged products, as well as commercial, industrial or institutional products, are based on the average system. The average system is prescribed in the *Consumer Packaging and Labelling Act and Regulations*, in the case of consumer packaged products, and the *Weights and Measures Act and Regulations*, in the case of commercial, industrial or institutional products.

The average system is based on three criteria:

- the average net content of all packages in a lot must not be less than the declared net quantity;
- only a specified number of samples in a lot are allowed to contain less than the declared net quantity by more than the prescribed tolerance (as set out in the *Consumer Packaging and Labelling Regulations*); and
- no more than one sample in a lot may contain less than the declared net quantity by more than twice the prescribed tolerance.

Sampling procedures for the average system are designed to be closely representative of the lot of merchandise being tested.

The *Weights and Measures Act and Regulations* prescribe the manner of net quantity declarations for food products sold in bulk and clerk-served foods sold at retail.

Additional information on the application and interpretation of these regulatory requirements can be obtained from the Canadian Food Inspection Agency Import Service Centre or Measurement Canada. ([For contact information, see Appendix III.](#))

## Transportation

Food products require more careful handling than other commodities. Food should not be shipped with dangerous or hazardous goods (chemicals, auto parts, etc.). Food shipments that have been contaminated by incompatible goods in the container/truck may be refused entry into Canada. Temperature sensitive goods, such as frozen food or fresh fruits, require a climate controlled shipping environment.

Requirements for safe transportation of goods should be part of the agreement between traders and carriers.

## Food Allergens

<http://inspection.gc.ca/food/consumer-centre/food-allergens/eng/1330450829791/1330450993196>

A variety of foods can cause adverse reactions in hypersensitive individuals. These reactions can vary from minor to life-threatening. Most adverse food reactions are caused by the following foods or their derivatives:

- peanuts
- tree nuts (e.g., almonds, Brazils, cashews, hazelnuts, macadamias, pecans, pinenuts, pistachios, walnuts)
- sesame seeds
- milk
- eggs
- fish
- crustaceans (e.g., crab, crayfish, lobster, shrimp)
- shellfish (e.g., clams, mussels, oysters, scallops)
- soy
- wheat
- sulphites.

If these foods and their by-products or derivatives are not labeled or are incorrectly labeled, or if inadvertent carry-over occurs during manufacture, the results can be serious and sometimes fatal.

Importers are encouraged to identify these ingredients on food labels when they appear as ingredients or components. It is also recommended that the plant source of all forms of hydrolysed plant proteins, starches, and lecithin be identified (e.g., hydrolysed soy protein, modified wheat starch, soy lecithin).

Experience has shown that undeclared ingredients may occur as a result of:

- carry-over of product through incomplete cleaning of food contact surfaces and utensils, sometimes because of poor equipment design;
- inappropriate use of rework materials containing ingredients causing adverse reactions;
- ingredient changes, substitutions or additions not reflected on the label;
- product in wrong packages because of mix-up of packaging material;
- printing error or omission from list of ingredients;
- unknown ingredients in raw materials;
- use of incorrect common names to describe products/ingredients (e.g., mandelonas for reformed peanuts);
- labelling exemptions.

Despite all possible precautions, the presence of allergens cannot always be avoided. Consequently, a policy on precautionary labelling has been developed, which allows industry to voluntarily label products that may inadvertently contain substances capable of causing severe adverse reactions (e.g., "May contain peanuts").

### **Addition of Vitamin and Mineral Nutrients to Food**

The addition of vitamins, minerals and amino acids to food is regulated by the *Food and Drugs Act and Regulations*. Section D.03.002 of the *Food and Drug Regulations* specifies which foods may be enriched and with which nutrients. (There are limited exceptions to this regulation.)

Canadian requirements for the addition of nutrients to food may differ significantly from the United States and other countries.

Vitamins and/or mineral supplements are regulated as drugs in Canada. For further information on these products, contact the Therapeutic Products Directorate of Health Canada.

## Novel Foods - Biotechnology

Canada has a stringent process for evaluating the safety of novel foods, including foods derived through genetic modification (biotechnology). New novel food regulations under the *Food and Drugs Act and Regulations* (Division 28) require that manufacturers and importers of novel foods notify Health Canada of their intention to market a new product in Canada. This pre-market notification allows Health Canada to conduct a thorough safety assessment of the product.

In addition, the Canadian Food Inspection Agency conducts assessments of plants with novel traits, including transgenic plants, and/or products derived from them such as fruit, tubers and grains to evaluate their risk to the agricultural and forestry environment. Consequently, special import requirements of these products exist. Importers should contact the Canadian Food Inspection Agency prior to importation to verify if import permits are required.

## Foods Containing Food Additives

The use of food additives is strictly controlled by the *Food and Drugs Act and Regulations*. The food additive tables in Division 16 of the Regulations prescribe which additives may be used in foods sold in Canada, to which foods they may be added, for what purposes, and at what levels.

Canadian requirements and the list of acceptable food additives may differ from those of the United States and other countries. Products containing non-permitted food additives may be refused entry into Canada.

In the absence of specifications under the *Food and Drug Regulations*, food additives must conform to specifications in the Food Chemicals Codex, Fourth Edition, 1996 (as required by Section B.01.045 of the *Food and Drug Regulations*).

The labels on food additive preparations must include either:

- a quantitative statement of the amount of each additive present, or
- directions for use which, if followed, will produce a food that does not contain additives in excess of the maximum levels as prescribed in Division 16 of the *Food and Drug Regulations*

## Food Colour

Synthetic food colours are unique because they are the only additives that must be certified by the Health Products and Food Branch, Health Canada before being used in foods. Regulations concerning food colors are listed in Division 6, and Table III of Division 16 of the *Food and Drug Regulations*.

Before a color destined for use in food may enter the country or be distributed for use, it must be certified. Health Products and Food Branch officials both administer and audit a certification program for manufacturers of food color.

Manufacturers who participate in this program can obtain "self-certification status".

Only manufacturers with "self-certification status" may apply to certify a food color. A 100-gram sample of the dye, a certificate of analysis and analytical data must be forwarded to the Health Products and Food Branch in Ottawa. If the request for certification is approved, a certificate number (CN) is issued by the Food Research Division, and the Canadian importer is supplied with a letter indicating that the specific lot of dye (identified by lot number and quantity) has been assigned a specific CN. This number covers only the color and shipment identified in the letter.

A copy of the letter must be presented by the importer to Canada Border Services Agency before the dye is released from Customs. At present, certificates issued by the United States Food and Drug Administration (FDA) are also acceptable in Canada.

Procedures for Food Color Lakes are somewhat similar, except that they must be manufactured from a certified color. Identification Numbers (IN) are issued instead of CN numbers.

Further information on the certification program can be obtained from the Health

## Food Irradiation

Irradiation of food is regulated by the *Food and Drugs Act and Regulations*. Only the following foods are currently allowed to be irradiated in Canada: potatoes, onions, wheat, flour, whole wheat flour, whole or ground spices and dehydrated seasoning preparations.

Special labeling requirements apply to irradiated foods and foods containing irradiated ingredients.

Irradiated foods not in compliance with the *Food and Drugs Act and Regulations* are not permitted for sale in Canada.

## **Canadian Food Inspection Agency's Automated Import System (CFIA-AIS, AIRS, ITS) AIS (Automated Import System)**

The Canadian Food Inspection Agency's new Automated Import System (CFIA-AIS) is a computerized system for the management of all imported products regulated by the Agency. This program is designed to speed up the importation of CFIA goods at the border, which often have additional specific import requirements. It also allows inspectors to focus on high risk commodities.

The CFIA-AIS interfaces electronically with the Canada Border Services Agency and links the two agencies into an electronic, single-window of service.

The program is comprised of various modules that work together as an information provision system and a tracking system.

#### **AIRS (Automated Import Reference System)**

The [Automated Import Reference System](http://www.inspection.gc.ca/english/imp/airse.shtml) (<http://www.inspection.gc.ca/english/imp/airse.shtml>) is a comprehensive reference system that provides detailed information on import requirements for all Canadian Food Inspection Agency commodities.

#### **ITS (Import Tracking System)**

The Import Tracking System (ITS) enables Canadian Food Inspection Agency personnel to trace shipments from the point of arrival to their final destination. It allows for effective scheduling of inland inspections and monitoring of import activities.