USA-Non animal origin food products.

Contents

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 jam and preserves to bottled water (see Food and drug regulations in the section Standards). 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. See US –CANADA standards or check the Code of federal regulations Title 21 at the following web address: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm

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.(See thermally processed foods and Acidified foods in the standards section)web address: CFR 21 part 113 and for acidified foods CFR 21(114).

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm

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 Juice Manufacturers

Under FDA HACCP regulations, 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.

http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/JuiceHACCP/default.htm

Bottled water manufacturers

In addition to the other applicable requirements listed here, special requirements apply to bottled water.(See specific requirements) http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/BottledWaterCarbonatedSoftDrinks/ucm077065.htm

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/