FOOD AND AGRICULTURAL IMPORT REGULATIONS AND STANDARDS REPORT (FAIRS)

UNITED STATES OF AMERICA

Last Updated: April 2001
Section(s) Last Updated: SECTIONS I, II, IV, V,VI, VII, APPENDIX A; APPENDIX B, APPENDIX C - GOVERNMENT EXPORT CERTIFICATION DOCUMENTS (new).

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I. FOOD LAWS

The United States is a founding member of the ***World Trade Organization (WTO)***, formally the General Agreement on Tariffs and Trade (GATT), and subscribes to its underlying principle of most-favored-nation (MFN) or equal market access for virtually all countries. Imports are generally subject only to relatively low and transparent import duties; quality and grade standards on certain fresh horticultural products; and to those restrictions necessary to protect human, animal, and plant health.

In the United States, food safety is a shared responsibility. Several departments of the United States government share jurisdiction over ensuring the safety of the American food supply. With only a few exceptions, these agencies do not approve, license or issue permits for either domestic products shipped in interstate commerce or international trade. However, the U.S. Government has instituted several laws and procedures to ensure food safety. In addition to strict regulations, safety and wholesomeness of U.S. food products are safeguarded through pre-market clearances, mandatory production practices, inspections and random, ongoing sampling. The food safety standards that apply to domestically produced foods also apply to imported foods.

In 1997, the **Presidential National Food Safety Initiative** increased the efforts of the U.S. government to reduce food borne illness from farm-to-table. This initiative has resulted in strategic planning of the U.S. food safety efforts, improvements in the U.S. surveillance system and coordination among Federal, State, and local health authorities, improvements in risk assessment capabilities, increased inspection, expanded research, and consumer education. A strong science base drives all of these efforts. For example, the initiative has led to more processors of meat, poultry, and seafood adopting science-based systems such as the Hazard Analysis and Critical Control Point system to reduce foodborne illness. The U.S. government has also increased its research efforts to improve risk assessment of food borne pathogens. In addition, the Food and Drug Administration (FDA) has placed a greater emphasis on ensuring the safety of domestic and imported fresh produce and imported foods. This initiative has also resulted in increased training and educational programs directed at food producers and consumers to reduce food borne illness. The National Council on Food Safety recently released its Food Safety Strategic Plan. For more information see: http://www.foodsafety.gov.

U.S. FEDERAL REGISTER SYSTEM

Since the 1930's the U.S. Congress has delegated more and more responsibility to Federal department and agencies in the form of authority to issue detailed regulations. As more regulations were written over the years, a serious communications problem began to develop. There was no central publication system available to efficiently inform citizens and the business community about those regulations that affected them. In 1934, Congress recognized the need for a centralized system and enacted the **Federal Register Act,** which became law on July 26, 1935 (44 U.S.C. Chapter 15). The Act established a uniform system for handling agency regulations by requiring:

- o Filing of documents with the Office of the Federal Register;
- o Placement of documents for public inspection;
- o Publication of documents in the Federal Register; and
- o After a 1937 amendment, permanent codification of rules in the Code of Federal Regulations

The **Administrative Procedure Act,** which became law on June 11, 1946 (5 U.S.C. 551 et seq.), added several important requirements to the Federal Register System. This Act:

- o Introduced as a general requirement the right of the public to participate in the rulemaking process by commenting on proposed rules;
- o Required that the effective date of a regulation be not less than 30 days from the date of publication unless there was a good cause for an earlier date; and
- o Provided for publication of agency statements of organization and procedural rules.

These two Acts define the basic functions of the Federal Register system and provide the framework for the promulgation of U.S. government regulations.

The Food and Drug Administration (FDA) **is part of the Department of Health and Human Services (DHHS) and the Public Health Service (PHS).**

FDA is the scientific regulatory agency responsible for the safety of all foods (except meat, poultry, frozen and dried eggs and the labeling of alcoholic beverages and tobacco), cosmetics, drugs, biologics, medical devices, and radiological products. It is one of the oldest federal agencies whose primary function is consumer protection. The laws that provide FDA's regulatory authority for foods and cosmetics are as follows:

- The Pure Food and Drugs Act of 1906
- The Federal Import Milk Act (1928)
- The Federal Food, Drug, and Cosmetic Act of 1938, as amended
- The Public Health Service Act (1944)
- The Fair Packaging and Labeling Act (1966)
- The Infant Formula Act of 1980, as amended
- The Nutrition Labeling and Education Act of 1990
- Dietary Supplement Health and Education Act (1994)
- Food Quality Protection Act (1996)

The **U.S. Code of Federal Regulations (Title 21)** provides the rules that govern operation for food safety.

- o Parts 1 to 99, General Regulations for enforcement of FFDCA and Fair Packaging and Labeling Act; Color Additives
- o Parts 100-169, General regulations for labeling. Food Standards. Current Good Manufacturing Practices for food, bottled water, low acid canned food acidified foods. HACCP regulation for seafood (1996 edition)
- o Part 170-199, Regulations for food additives

o Parts 800-899 Regulations for imported milk, control of foodborne communicable disease, and food sanitation in interstate conveyances.

The Center for Food Safety and Applied Nutrition is one of the six centers within the FDA. The Center promotes and protects the public health and economic interest by ensuring that:

- Food is safe, nutritious, and wholesome, and cosmetics are safe.
- Food and cosmetics are honestly, accurately and informatively labeled.

FDA`s activities are directed toward the health of the nation against impure, unsafe, and fraudulently labeled foods, drugs, medical devices, cosmetics, and potential hazards from radiation-emitting equipment. FDA recognizes that it is not possible to grow, harvest, and process crops that are totally free of natural defects; therefore, the Agency has published **The Food Defect Action Levels**. These levels are established on the basis of no hazard to health. Any products that might be harmful to consumers are subject to regulatory action whether or not they exceed the defect levels.

Within the United States, compliance with the FD&C Act is secured through periodic unannounced inspections of facilities and products, analysis of samples, educational activities, and legal proceedings. It is the responsibility of the owner of the food in interstate commerce to ensure that the article complies with the provisions of the FD&C Act, the Fair Packaging and Labeling act and their implementing regulations. In general, these Acts require that the food product is safe, clean and wholesome and its labeling is honest and informative.

To control imperfections in other food and foodstuff, the U.S. Government has instituted food safety and labeling regulations and a small number of standards of identity and quality under provisions of the Food, Drug and Cosmetic Act (FD&C Act). Standards of identity that have been adopted for a variety of products must be met, or these products may be deemed to be out of compliance and subject to regulatory action. These standards give consumers some guarantee of the kind and amount of major ingredients in these products.

The Food and Drug Administration, over the last several years has adopted a food safety program based on preventative approaches. In 1994, FDA proposed regulations that would establish the **Hazard Analysis Critical Control Points (HACCP)** system for the seafood industry. FDA issued its final rule on HACCP for seafood in December 1995. Seafood HACCP became mandatory December 1997. In January 2000, FDA issued its final rule for Juice HACCP. HACCP has been endorsed by the National Academy of Sciences, the Codex Alimentarius Commission (and international food standard-setting organization), and the National Advisory Committee on Microbiological Criteria for Foods. In an August 1994 advanced notice of proposed rule-making, FDA announced that it is considering developing HACCP regulations for many other segments of the U.S. food supply. These would include both domestic and imported foods.

Centers for Disease Control and Prevention (CDC) investigate outbreaks of food borne illness and surveys and study various environmental and chronic health problems. It also administers national programs for prevention and control of vector-borne diseases (diseases transmitted by a host organism) and other preventable conditions.

U.S. Department of Agriculture (USDA)

USDA's regulatory activities are primarily enforced by the *Animal and Plant Health Inspection Service (APHIS), the Food Safety Inspection Service (FSIS), Grain Inspection Packers and Stockyards Administration (GIPSA)/Federal Grain Inspection Service (FGIS), and Agricultural Marketing Service (AMS).* In addition, the U.S. Customs Service participates in this effort by detaining of imports when USDA requirements have not been met.

The Animal and Plant Health Inspection Service (APHIS) is responsible for enforcing regulations governing the import and export of plants and animals and certain agricultural products. It issues regulations and conducts control programs to protect and improve animal and plant health for the benefit of people and their environment. In cooperation with State governments, APHIS administers Federal laws and regulations pertaining to animal and plant health and quarantine, humane treatment of animals, and the control and eradication of pests and diseases. It defends U.S. borders against entry of foreign pests and diseases, protects endangered species, makes sure veterinary biologics are safe, pure, potent, and effective, and ensures the safety of agricultural biotechnology products.

Within APHIS, the **Plant Protection and Quarantine (PPQ) Program** conducts programs and activities at various U.S. ports to prevent the introduction and spread of foreign pests. APHIS Veterinary Services (VS) has responsibility for protecting the health of livestock, poultry, and other animals. The laws APHIS enforces are numerous and varied. Some of the most important statutes and regulations are: Plant Quarantine Act; Plant Protection Act; Honey Bee Act; Federal Seed Act; Animal Import-Export Regulations (19 CFR 1306, 21 USC 103, 21 USC 105, and 21 CSC 134); Endangered Species Act (Plants); Swine Health Protection Act; Virus Serum Toxin Act. When feasible and volume warrants, foreign governments and exporter groups may request preclearance inspection and/or treatment by APHIS officers in the country of origin. Preclearance can ensure that the risk of introducing foreign pests into the United States is reduced.

The Food Safety Inspection Service (FSIS) is responsible for ensuring that meat (derived from cattle, sheep, swine, goats, and horses) and poultry products moving in interstate and foreign commerce are safe, wholesome for consumption, and accurately labeled. Under the **Federal Meat Inspection Act** and the **Poultry Products Inspection Act**, FSIS inspects all meat and poultry sold in interstate and foreign commerce, including imported products. Approximately 7,400 Federal inspectors carry out inspection laws in some 6,200 plants. Inspectors check animals before and after slaughter. They prevent diseased animals from entering the food supply and examine carcasses for visible defects that can affect safety and quality. FSIS also inspects products during processing, handling, and packaging to ensure that they are safe and truthfully labeled. To address specific concerns, inspectors can test for the presence of pathogenic microorganisms and violative drug and chemical residues. The Agency operates three field laboratories to provide analytical support.

Hazard Analysis Critical Control Points (HACCP) for Meat and Meat Product Production: FSIS is establishing new requirements for all meat and poultry plants to improve food safety. All U.S. slaughter and processing plants will be required to adopt the system of process controls to

prevent food safety hazards known as Hazard Analysis and Critical Control Points (HACCP). To verify that HACCP systems are effective in reducing contamination with harmful bacteria FSIS is setting pathogen reduction performance standards for Salmonella that slaughter plants and plants that produce raw, ground meat and poultry will have to meet. In addition, slaughter plants will be required to conduct microbial testing for Generic E. Coli to verify that their process control systems are working as intended to prevent fecal contamination, the primary avenue of contamination for harmful bacteria. FSIS is also requiring plants to adopt and follow written Standard Operating Procedures for sanitation to reduce the likelihood that harmful bacteria will contaminate the finished product.

In addition, through its **Meat and Poultry Hotline (1-800-535-4555)** and consumer education programs, FSIS informs the public on how to properly handle, prepare, and store meat and poultry products to minimize the growth of food borne pathogens.

Grain Inspection Packers and Stockyards Administration (GIPSA), Federal Grain Inspection Service (FGIS) facilitates the movement of U.S. grain into the marketplace by providing farmers, grain handlers, processors, exporters, and international buyers with information that accurately and consistently describes the quality and quantity of grain being bought and sold. Congress created FGIS under the U.S. Grain Standards Act of 1976 (USGSA) to manage the national grain inspection system and to institute a national grain weighing program. The goal of creating a single Federal grain inspection entity was to ensure the development and maintenance of uniform U.S. standards, to develop inspection and weighing procedures for grain in domestic and export trade, and to facilitate the marketing of U.S. grain. Under the USGSA and the Agricultural Marketing Act of 1946 (AMA), FGIS: Establishes and maintains official U.S. standards for grain; inspects and weighs all exported grain, oilseeds, and related products for domestic and export; and provides the agricultural industry with a national inspection and weighing system. It also monitors certain grain handling practices to prevent the deceptive use of the grading standards and official inspection and weighing results, and the degradation of grain quality through the introduction of foreign material, dockage, or other nongrain material to grain.
Provides voluntary fee for service pesticide residue testing, upon request.

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.

Fruits, Vegetables, and Nuts. Certain agricultural commodities (including fresh tomatoes, avocados, mangoes, limes, oranges, grapefruit, green peppers, Irish potatoes, cucumbers, eggplants, dry onions, walnuts and filberts, processed dates, prunes, raisins, and olives in tins) must meet United States import requirements relating to grade, size, quality, and maturity (7U.S.C. 608(e)). These commodities are inspected and an inspection certificate must be issued by the AMS to indicate import compliance.

Agricultural Research Service (ARS) conducts nationwide surveys of food intake by individuals and translates data on foods as consumed into forms that can be linked with pesticide residue data. Its mission is to provide access to agricultural information and to develop new technology and knowledge needed to solve technical agricultural problems of broad scope and high national priority.

Environmental Protection Agency (EPA)

EPA coordinates governmental action on behalf of the environment through integrating research, monitoring, standard setting, and enforcement activities. Among its many duties, EPA regulates pesticides. Through the **Office of Pesticide Programs (OPP)** EPA determines the safety of new pesticide products, sets tolerance levels for pesticide residues in foods, which FDA then enforces, and publishes directions for the safe use of pesticides. EPA also establishes water quality standards, including the chemical content of drinking water. These standards are used by FDA as guides in its regulation of bottled water sold in interstate commerce for human use.

Bureau of Alcohol, Tobacco and Firearms (ATF)

ATF is an agency of the Department of the Treasury, responsible for enforcing the laws that cover the production, distribution and labeling of alcoholic beverages, except wine beverage that contain less than 7 percent alcohol, which are the responsibility of FDA. ATF and FDA sometimes share responsibility in cases of adulteration, or when an alcoholic beverage contains food or color additives, pesticides or contaminants.

U.S. Custom Service, U.S. Department of Treasury

The U.S. Customs Service is an agency of the U.S. Department of Treasury responsible for the assessment and collection of import duties and taxes and the control of carriers, persons, and articles entering or departing the United States. The U.S. Customs Service was established by Congress in 1789 by the Customs Organization Act of 1789. The field organization consists of seven geographical regions further divided into 44 districts with ports of entry within each district. Customs enforces the provision of the Tariff Act of 1930, as amended, in addition to more than 400 laws of other agencies governing international traffic and trade. Title 19 USC 1304 and 19 USC1201 of the U.S. Code of Federal Regulations governs Customs.

National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration, **U.S. Department of Commerce (USDOC),**

NMFS oversees fisheries management in the United States, and through the 1946 Agricultural Marketing Act, provides a voluntary inspection service to the industry. The NMFS fishery Products Inspection Program offers a variety of professional inspection services which assures compliance with all applicable food regulations. In addition, product quality evaluation, grading and certification services on a product lot basis are also provided. Benefits include the ability to apply official marks, such as the U.S. Grade A. Process Under Federal Inspection (PUFI) and lot inspection marks.

The safety of seafood products is the responsibility of the Food and Drug Administration, but representatives of the two agencies cooperation in areas off food-plant sanitation and product wholesomeness. FDA issued its final rule on HACCP for seafood in December 1995. The seafood industry must implement HACCP by December 1997.

Federal Trade Commission (FTC):

FTC, Bureau of Consumer Protection has, among its duties, the regulation of advertising of foods. The **Division of Advertising Practices** protects consumers from deceptive and unsubstantiated advertising claims for alcohol, food, and over-the-counter drugs, particularly those claims relating to nutritional or health benefits of foods and safety and effectiveness of drugs or medical devices

U.S. State and Local Governments play an important role by adding their muscle to federal efforts, state and local governments put considerable energy into food inspection. Some of this is done cooperatively with federal agencies, both to maximize staff effectiveness and to ensure that state standards meet federal rules. There are cooperative federal and state programs for fish, dairy and other food product inspection. Roughly half the U.S. states have their own meat and poultry inspection programs. State inspected meat and poultry products may only be sold within that state. Local governments inspect restaurants, fast food spots and similar outlets. They can close establishments for sanitary violations.

II. LABELING REQUIREMENTS

According to the Federal Food, Drug, and Cosmetic Act (FD&C Act), a food label must contain specified information, displayed conspicuously and in terms that the ordinary consumer is likely to read and understand under ordinary conditions of purchase and use (403(f)). Details concerning type sizes, location, etc., of required label information are contained in FDA Regulations (21 CFR 101), which cover the requirements of both the Federal Food, Drug, and cosmetic Act and the Fair Packaging and Labeling Act. U.S. food labeling requirements are summarized as follows:

If the label of a food bears representations in a foreign language, the label must bear all of the required statements in the foreign language, as well as in English, (Note--The Tariff Act of 1930 requires all imported articles to be marked with the English name of the country of origin).

If the food is packaged, the following mandatory statements must appear on the label in the English language:

(1) **Name of the Food:** The common or usual name of the food must appear on the principal display panel, in bold type and in lines generally parallel to the base of the package as it is displayed. The form of the product must also be included--"sliced," "whole," or "chopped" (or other style)-- unless shown by a picture or unless the product is visible through the container. If there is a standard for the food (see page 17), the complete name designated in the standard must be used, limitations must be labeled as such (403(e) and 21 CFR 101.3).

(2) **Net Quantity of Contents:** An accurate statement of the net amount of food in the package. The required units of measure are the avoirdupois pound and the U.S. gallon but metric system measurements may also be used, if desired, in addition to the required declaration in "English" units. The quantity of contents declaration must appear on the principal display panel of the label in lines generally parallel to the base of the package when displayed for sale. If the area of the principal display panel of the package is larger than 5 square inches, the quantity of contents must appear within the lower 30 percent of the label. The declaration must be in a type size based upon the area of the principal display panel of the package (as listed in 21 CFR 101.105) and must be separated from the other information.

The net weight on packages containing 1 pound (avoirdupois) or more, and less than 4 pounds must be declared first in total avoirdupois ounces followed by a second statement in parentheses () in terms of pounds and ounces, or pounds and common or decimal fractions of the pound. (Example: Net Wt. 24 ounces (1 ½ pounds) or net Wt.24 oz. (1.5 lbs.) the contents of packages containing less than 1 pound must be expressed as total ounces. Drained weight rather than net weight is required on some products packed in a liquid that is not consumed as food, such as olives in brine.

Net volume of liquid products in packages containing 1 pint or more and less than 1 U.S. gallon must be declared first in total fluid ounces followed by a statement in parentheses () in terms of quarts, pints, and fluid ounces or fractions of the pint or quart. (Example: 40 fluid ounces (1.25 quarts) or 40 fluid ounces (1 1/4 quarts).) Volume of packages containing less than 1 pint must be declared in fluid ounces.

Packages 4 pounds or larger or 1 gallon or larger need not have their contents expressed in terms of total ounces; however, for such packages the contents must be stated in the largest unit weight or measure, with any remainder in ounces or common or decimal fractions of the pound; or in the case of gallons, the remainder in quarts, pints, and fluid ounces, or decimal fractions of the gallon. If the label of any food package also represents the contents in terms of the number of servings, the size of each serving must be indicated.

(3) **The name, street address, city, state and zip code of either the manufacturer, packer, or distributor:** This information must be placed on either the principal display panel or the information panel. The street address may be omitted by a firm listed in a current city or telephone directory. **Imported product labels** may omit the zip code. However, if the food is

not manufactured by the person or company whose name appears on the label, the name must be qualified "Manufactured for, " Distributed by, " or similar expression.

(4) **Statement of Ingredients:** The ingredients in a food must be listed by their common names in order of their predominance by weight. If the ingredient, itself, contains two or more ingredients, the sub ingredients are listed parenthetically by their common or usual name in descending order of predominance following the common or usual name of the ingredient. For example, enriched wheat in a bread product would be listed as ". . enriched wheat (wheat, iron, niacin, thiamine mononitrate, riboflavin, folic acid). The word "ingredients" does not refer to the chemical composition, but means the individual food components of a mixed food. If a certain ingredient is the characterizing one in a food (e.g., shrimp in shrimp cocktail) the percent of that ingredient may be required as part of the name of the food.

Food Additives and Colors are required to be listed as ingredients, but the law exempts butter, cheese, and ice cream from having to show the use of color. **Spices, flavors and color may be listed as such,** without naming the specific materials, but any artificial colors or flavors must be identified as such, and certain coal-tar colors must be names specifically (403(I) and 403(k)).

(5) **Nutrition Information:** The Nutrition Labeling and Education Act (NLEA), signed into law on Nov. 8, 1990, represents the first comprehensive revision of the food labeling requirements of the FD&C Act. Under the NLEA, nutrition labeling must appear on the food label or in accompanying labeling. FDA has specified a uniform format which must include the serving size, the number of servings per container and the nutrition content of the food per serving, including the amount of each of 11 nutrients specified in the statute, such as calories, sugars, and sodium. The law adds a new section to the FD&C Act which requires nutrition labeling for virtually all food products, replacing the existing FDA nutrition labeling regulations. The FDA has published " A Food Labeling Guide" to answers questions on the NLEA requirements, copies may be obtained the address below or downloaded from The Center for Food Safety and Applied Nutrition's home page http://www.cfsan.fda.gov (under "Program Areas" then "Food Labeling and Nutrition):

The Division of Compliance and Enforcement (HFS-810)
Office of Nutritional Products, Labeling and Dietary Supplements
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204
Telephone: (202) 205-5229

Dietary Supplements Containing New Dietary Ingredients.

According to Section 413(a) of the Food, Drug and Cosmetic Act (FD&C Act), as amended by the Dietary Supplement Health and Education Act of 1994 (DSHEA) [Title 21 of the U.S. Code section 350b(a) (21 U.S.C. § 350b(a))], a dietary supplement that contains a new dietary ingredient is adulterated unless it meets one of the following requirements:

(1) The dietary supplement contains only dietary ingredients that have been present in the food supply as an article used for food in a form in which the food has not been chemically altered; or

(2) There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe. In addition, at least 75 days before being introduced or delivered for introduction into interstate commerce in the U.S., the manufacturer or distributor of a dietary supplement containing a new dietary ingredient must provide the FDA with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

In other words, a dietary ingredient contained in a dietary supplement the manufacturer or distributor wishes to market in the U.S. must have been present in the U.S. food supply as an article used for food in the same chemical form as the dietary ingredient. If not, the manufacturer or distributor must explain to FDA in a 75-day premarket notification why it considers that the consumption of a new dietary ingredient is reasonably expected to be safe under the conditions recommended or suggested in the product's labeling. Title 21 of the Code of Federal Regulations section 190.6 (21 CFR § 190.6) outlines the information required to be included in this notification. A copy of 21 CFR § 190.6 is accessible through the following FDA Web site: **http://vm.cfsan.fda.gov/~lrd/fr97923e.html**.

The term "new dietary ingredient" means a dietary ingredient that was not marketed in the U.S. in a dietary supplement before October 15, 1994. [See section 413(c) of the act (21 U.S.C. § 350b(c).] There is no authoritative list of dietary ingredients that were marketed in dietary supplements before October 15, 1994. Therefore, the manufacturer or distributor is responsible for determining if an ingredient is a "new dietary ingredient" and, if not, for documenting that a dietary supplement that contained the dietary ingredient was marketed before October 15, 1994.

If a manufacturer or distributor wants to market a "new dietary ingredient" in a dietary supplement, it must be sure that the substance is considered to be a "dietary ingredient." [See section 201(ff)(1) of the FD&C Act (21 U.S.C. § 321(ff)(1)).] A dietary ingredient is a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any of the above dietary ingredients.

In addition, the product containing the dietary ingredient must be a dietary supplement. [See section 201(ff) of the act (21 U.S.C. § 321 (ff)).] The term "dietary supplement" means a product (other than tobacco) intended to supplement the diet that contains one or more dietary ingredients. A dietary supplement is limited to products that are intended for ingestion in tablet, capsule, powder, softgel, gelcap, and liquid form, that are not represented as conventional food or as the sole item of a meal or of the diet, and that are labeled as dietary supplements. Additionally, dietary supplements do not include products that are approved drugs, certified antibiotics, or licensed biologics. Dietary supplements also do not include products that are authorized for investigation as a new drug, antibiotic, or biologic (and for which substantial

clinical investigations have been instituted and for which the existence of such investigations has been made public), unless the product was marketed as a dietary supplement or as a food before it was approved as a drug, antibiotic, or biologic, or, in the case of investigational products, before the public disclosure of such investigations.

If a manufacturer or distributor is unsure whether a dietary ingredient is a "new dietary ingredient" under the FD&C Act, it may still submit a notification to FDA. Importantly, if a product containing a new dietary ingredient is marketed without the required notification, the product may be adulterated as a matter of law. Regardless of whether a premarket notification is required, it is the manufacturer's or distributor's responsibility to ensure that a dietary ingredient used in a dietary supplement is safe.

FDA's Web site that specifically addresses dietary supplement topics is: **http://vm.cfsan.fda.gov/~upplmnt.html**. In addition, FDA may be contacted at the following address or telecommunication numbers if dietary supplement manufacturers or distributors have questions about FDA requirements concerning premarket notifications for new dietary ingredients:

Division of Standards and Labeling Regulations (HFS-820)
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204
Phone: (202) 205-4168
Fax: (202) 205-5295

III. PACKAGING AND CONTAINER REGULATIONS (Pending completion)

IV. FOOD ADDITIVE REGULATIONS

Premarket approval is required for food additives. Food additives are defined as substances whose intended use results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food. Before marketing a food or color additive in the U.S. a manufacturer must petition FDA for its approval. The Office of Premarket Approval provides a centralized focal point for food additive review. Regulations governing food additives, including petition regulations, are outlined in the **21CFR Part 170-199.** Approximately 100 new food and color additive petitions are submitted to FDA annually. Specific information on food additives and premarket clearance can be found via the Internet/World Wide Web at: **http://www.cfsan.fda.gov** (under "Program Areas," select "Food Additives").

A food or color additive petition must provide convincing evidence that the proposed additive performs as it is intended. Animal studies using large doses of the additive for long periods are often necessary to show that the substance would not cause harmful effects at expected levels of human consumption. Studies of the additive in humans also may be submitted to FDA.

In deciding whether an additive should be approved, the agency considers the composition and properties of the substance, the amount likely to be consumed, its probable long-term effects and various safety factors. Absolute safety can never be proven. Therefore FDA must determine if the additive is safe under the proposed conditions of use, based on the best scientific knowledge available.

If an additive is approved, FDA issues regulations that may include the types of foods in which it can be used, the maximum amounts to be used, and how it should be identified on food labels. Additives proposed for use in meat and poultry products also must receive specific authorization from USDA. Federal officials monitor Americans' consumption of the new additive and results of any new research on its safety to assure its use continues to be within safe limits.

V. PESTICIDE AND OTHER CONTAMINANTS

The Environmental Protection Agency (EPA) establishes standards (tolerances) for used in production of agricultural products. Tolerance levels regulations are applied to all pesticide treated products intended for human and animal consumption produced in or entering the United States.

Food producers must use only those chemicals, which are registered for use on a specific commodity or group of specifically indicated commodities and only according to the direction on the pesticide label. The U.S. FDA and FSIS tests food products entering the United States for compliance with EPA regulations for pesticide residues. FDA and FSIS monitors for unsafe pesticide levels in food.

VI. OTHER REGULATIONS AND REQUIREMENTS

FDA Good Manufacturing Practices (GMP). The FD&C Act gives the Food and Drug Administration the authority to establish and impose reasonable requirements and standards on the production of food to protect against contamination. FDA requires processors to impose **Good Manufacturing Practices (GMP)** concerning personnel, buildings and facilities, equipment and product process controls when properly implemented, will protect the product from contamination. Sanitation provisions of the Food, Drug and Cosmetic Act require that foods be produced in sanitary facilities which ensure food is protected from contamination at all stages of production. These GMP regulations establish a minimum level of safety performance, which apply to all businesses. Such protection includes proper facility and warehouse construction, extermination and exclusion of rodents, inspection and sorting of raw materials, proper handling and storage of all food ingredients, use of clean equipment and sanitary constructed equipment, production and process controls, personnel hygiene, and supervision of personnel.

The Perishable Agricultural Commodities Act (PACA), is a law administered by the U.S. Department of Agriculture, Agricultural Marketing Service (AMS), to ensure fair trade practices among buyers and sellers of agricultural products. PACA protects produce grower and shipper assets, and is funded by licensing fees. **The Federal Seed Act** protects seed buyers from improper labeling claims. The **Plant Variety Protection Act** protects the integrity of plant

varieties and the intellectual property rights of plant breeders. For more information on AMS regulated trade protection laws contact:

Perishable Agricultural Commodities Act - AgBox 0242, Tel (202) 720-2272
Federal Seed Act - Bldg.. 506 BARC-E, Beltsville, MD Tel (301) 504-9237
Plant Variety Protection Act - 500 NAL, Beltsville, MD Tel (301) 504-5518

MILK AND CREAM

The importation of milk and cream (including sweetened, condensed milk) is subject to requirements of the Food, Drug and Cosmetic Act and the Import Milk Act. Information regarding how to obtain a permit is discussed in the Import Milk Act, 21 USC 141-149. These products may be imported only by holders of permits from the Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Regulations and Enforcement Branch, Division of Program and Enforcement Policy, Office of Plant and Dairy Foods and Beverages, (HFS-306), 200 C Street, NW., Washington, D.C. 20204; and the Department of Agriculture.

PLANT AND ANIMAL PRODUCTS

APHIS Import requirements depend on both the product and the country of origin. Plants and plant materials usually must be accompanied by a phytosanitary certificate issued by an official of the exporting country. Livestock and poultry must be accompanied by a health certificate, also issued by an official of the exporting country. Animal products, such as meats and hides, are restricted if they originate in countries that have a different disease status than the United States.

APHIS regulates the importation of animals that enter the country through land ports along the borders with Mexico and Canada. Imports of livestock and poultry from other countries must be quarantined at one of four animal import centers in Newburgh, N.Y., Miami, Fla., Los Angeles, Ca., Honolulu, Hawaii

Also, at many ports, APHIS officers inspect and sample seed imported from foreign countries to ensure that it is accurately labeled and free of noxious weeds. APHIS also maintains 14 plant introduction stations, the largest of which is at Miami, Fla., for commercial importation of plant materials. In addition to certifying to the health of agricultural exports, APHIS officials mount a proactive approach to the marketing of U.S. crops and livestock overseas.

MEAT AND MEAT PRODUCTS

All commercial shipments of meat and meat food products offered for entry into the United States are subject to the regulations of the Department of Agriculture and must be inspected by the Animal and Plant Health Inspection Service (APHIS) and the Food Safety and Inspection Service (FSIS) prior to release by U.S. Customs. Meat products from other sources (including, but not limited to wild game) are subject to APHIS regulations and the provisions of the Federal Food, Drug, and Cosmetics Act, enforced by the Food and Drug Administration.

Meat and poultry (including game and fowl), products can only be imported from countries and plants approved by the United States. The Federal Meat Inspection Act, requires countries that export meat and poultry to the United States to impose inspection requirements "at least equal to" U.S. requirements. Imported meat and poultry products are inspected in the country of origin just as domestic products are inspected in U.S. slaughter and processing plants. FSIS reviews foreign inspection systems to ensure that they are equal to the U.S. system. FSIS also reinspects imported meat and poultry products on a sample basis as they enter the United States. Data derived from import reinspection constitute a check on the effectiveness of foreign inspection systems.

To determine if a country is eligibility to export meat to the U.S., FSIS evaluates the country's entire inspection system. FSIS reviews the country's laws, regulations, directives, and other written materials that govern its inspection program; reviews administration; and conducts an on-site review of the country's inspection operations. A multi disciplinary team, typically composed of a veterinarian, chemist, food technologist, microbiologist, statistician, and compliance officer, conducts the review. After a country is granted eligibility to export its products to the United States, FSIS relies on the exporting country to certify plants and carry out daily inspection. Individual plants must apply to the country's national inspection authorities for certification to export to the United States. In turn, the chief inspection official in the country certifies to FSIS those plants that meet all applicable standards and are authorized to export to the United States. The number of reinspections in a given year are determined by the country's adherence to the requirements. There may be up to four inspections per year by FSIS.

At the U.S. port of entry all meat products are checked for transportation damage, labeling, general condition, and proper certification and residue level. Residue levels must have certification. U.S. requirements also require foreign countries to impose controls equivalent to those of FSIS to prevent species substitution. A product labeled beef, for example, must be beef and cannot contain a less expensive product. FSIS scientists have developed verification tests, which are quick and inexpensive.

The USDA Food Safety and Inspection Service Meat Export Library offers an Export Library System for computer users to obtain U.S. and foreign country specifications requirements for meat and meat products. *To connect to the Meat Export Library using a modem, call (202)501-7608.* For further information on the database *and certification for meat and poultry products* contact: FSIS, 1099 14th Street, Franklin Court, Suite 3700W, Washington, D.C. 20005 or telephone: (202) 501-6022; Fax: (202) 501-6029.

SEAFOOD PRODUCTS

All imported seafood is required to meet the same standards as domestic seafood products. Products that appear to be adulterated, misbranded, or manufactured, processed, or packed under insanitary conditions may be refused admission.

Some of the areas of safety concern in seafood are **Pathogens**— *Salmonella, Clostridium botulinum, Vibrio* spp., *Listeria* spp., *Staphylococcus aureus*, and enterotoxigenic *E. coli;* **Parasites** — nematodes, cestodes, and trematodes; **Marine Toxins** — paralytic shellfish

poisoning, neurotoxic, shellfish poisoning, diarrhetic shellfish poisoning, amnesic shellfish poisoning, and ciguatera fish poisoning; **Decomposition** — histamine, putrescine, and cadaverine; **Environmental Contaminants and Pesticides** — including methyl mercury and radionuclides, **Aquaculture Drugs** — unapproved drugs or unapproved applications, **Food and Color Additives** — unapproved or improperly declared; sulphites, borates, nitrate/nitrite, cyclamate, safrole, FD&C Yellow 5, and FD&C Red Approaches 4; and **Foreign objects** - metal fragments.

FDA also inspects seafood products for spoilage decomposition, filth, mold, proper labeling (including nutritional labeling), and economic deception such as short weights or specie substitution (the latter having the potential to cause serious allergenic effects in sensitive individuals).

Hazard Analysis Critical Control Point (HACCP): FDA regulation 21 CFR 123 requires that all seafood, domestic and imported must be processed under HACCP.

***Hazard analysis*:** Every processor shall conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed and to identify the preventive measures that the processor can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest.

Most of the commonly recognized safety related concerns in seafood are addressed in a FDA publication called the Fish and Fishery Products Hazards and Controls Guide. Processors are encouraged to use the Guide in developing and maintaining their HACCP programs. This is accessible from the FDA, CFSAN homepage: http://www.cfsan.fda.gov.

The HACCP plan: Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur.

Sanitation Standard Operation Procedure (SOP): Each processor should have and implement a written sanitation standard operating procedure and shall monitor to confirm implementation.

Determination of compliance: There must be evidence that all fish and fishery products offered for entry into the United States have been processed under HACCP. Title 21 CFR § 123.12 sets forth requirements for the determination and verification that imported fishery products are processed under HACCP conditions.

When importing fish or fishery products from a country with whom FDA does not have an Memorandum of Understanding, the U.S. importer must have written product specifications that ensure safe and sanitary product and take some type of affirmative step that demonstrates that measures are being taken to ensure that the imported product is in compliance with the regulation.

If assurances do not exist that the imported fish or fishery product has been processed under conditions that are equivalent to those required of domestic processors, the product will appear to be adulterated and will be denied entry.

SHELLFISH - MOLLUSCAN

Consumer concerns about molluscan shellfish are addressed through the National Shellfish Sanitation Program (NSSP). It is administered by FDA and provides for the sanitary harvest and production of fresh and frozen molluscan shellfish (oysters, clams and mussels). Participants include the 23 coastal shellfish-producing states and nine foreign countries.

The NSSP was created upon public health principles and controls formulated at the original conference on shellfish sanitation called by the Surgeon General of the US Public Health Service in 1925. These fundamental components have evolved into the National Shellfish Sanitation Program Manual of Operations. A prime control is proper evaluation and control of harvest waters and a system of product identification that enables trace back to harvest water.

FDA conducts reviews of foreign and domestic molluscan shellfish safety programs. Foreign reviews are conducted under a Memorandum of Understanding (MOU) which FDA negotiates with each foreign government to assure that molluscan shellfish products exported to the US are acceptable.

For information on certification requirements the import of *seafood products to the U.S. or to the European Union* contact FDA Office of Seafood on (202) 418-3150.

VII. OTHER SPECIFIC STANDARDS

FDA operates an oversight compliance program for **Low-Acid Canned Food (LACF)**, which is based on the Hazard Analysis Critical Control Point (HACCP) concept, and is focused on thermally processed, commercially sterile foods, including seafood such as canned tuna and salmon.

Low-Acid Canned Food and Acidified Foods Regulations: The U.S. FDA regulations require that all commercial processors of thermally processed low-acid foods (LACF) packaged in hermetically sealed containers, or of acidified foods (AF) register each processing plant. In addition, each production process, called a scheduled process, for LACF or AF must be submitted to FDA and accepted for filing by FDA prior to implementation

LACF regulations require that each hermetically sealed container of a low-acid processed food must be marked with an identifying code that must be permanently visible to the naked eye. The required identification must identify, in code, the establishment where the product is packed, the product contained therein, the year and day of the pack, and the period during the day when the product was packed. There is no requirement that a product be shipped within the United States

within a stipulated period. If a LACF product is properly processed, it will not require any special shipping or storage conditions.

FDA regulations require that scheduled processes for low-acid foods must also be established by qualified persons having expert knowledge of thermal processing requirements for low-acid food in hermetically sealed containers and having adequate facilities for making such determinations. All factors critical to the process are required to be specified by the processing authority in the scheduled process.

VIII. COPYRIGHT OR TRADEMARK LAWS

Protecting industrial rights is basically the responsibility of each company. Obtaining registered protection for your company's industrial property rights in the U.S. is a matter for private legal counsel. There are several provisions of U.S. law administered by various Government agencies, which may be helpful in affording protection against misuse of trademarks, trade names, copyrights, and patents.

Section 42 of the Trademark Act of 1946 (Section 1124, title 15 CFR) prohibits importation of articles bearing marks which are confusingly similar to or counterfeit of trademarks registered in the U.S. Patent and Trademark Office. Section 526 of the Tariff Act of 1930 (Section 1526, Title 19 CFR) requires the U.S. Customs Service to prohibit importation of foreign-made goods bearing marks which have been registered in the Patent and Trademark Office by a U.S. citizen or corporation if a copy of the certificate of registration has been filed with the U.S. Treasury Department. U.S. regulations require that a trademark or copyright owner record its mark or copyrighted work by application, which may be in the form a letter, to the Customs Commissioner, Washington, D.C., with payment of applicable fees.

IX. IMPORT PROCEDURE

Imported goods may not be entered into the U.S. legally until the shipment has arrived within the limits of the port of entry and delivery of the merchandise has been authorized by the U.S. Customs Service, U.S. Treasury Department. This is normally accomplished by filing the appropriate documents, either by the importer or by their agent. Customs entry papers may be presented before the merchandise arrives.

The Customs Service does not notify the importer of the arrival of a shipment. Notification is usually made by the carrier of the goods. The importer should make their own arrangements to be sure they or their agent is informed immediately so that the entry can be filed and delays in obtaining the goods are avoided. If documentation is not filed within 30 days of arrival the goods are sent to a general order warehouse to be held as unclaimed. The importer is responsible for storage charges, which are incurred during the period the merchandise is being held in the warehouse. After one year it is sold.

Entry of goods is made at the first port of arrival unless other arrangements are made prior to shipment from the country of origin for "in-bond" shipment to a farther port or to a bonded warehouse. If the importer is not able to be there to prepare and file the entry, commercial

brokers, known as customs brokers and licensed by the Customs Service, may act as the agent. Such brokers charge a fee for their services. A list of customs brokers may be obtained from a local customs office or the telephone directory.

DOCUMENTATION AND MERCHANDISE ENTRY

The U.S. believes that facilitating the release of legitimate imported merchandise is equal to the responsibility for collecting the proper import duties and enforcing its laws against illegal merchandise. The documents required by U.S. Customs are:

- Customs Entry form 3461
- Evidence of right to make entry, e.g. bill of lading. (Merchandise may be entered only by the owner, purchaser, or a licensed customshouse broker.
- A Commercial Invoice or Pro-Forma Invoice if a commercial invoice cannot be produced.
- Packing List, if appropriate
- A bond which is normally posted with Customs to cover any potential duties, taxes, and penalties the may accrue after release of the cargo.
- Other necessary documents to determine merchandise admissibility. For U.S. food exports the following official certification documents are available for the following agencies.

10 Steps to Faster Customs Clearance:

1. Make sure that your invoices contain the information that would be shown on a well prepared packing list.
2. Mark and number each package so that it can be identified with the corresponding marks and numbers appearing on your invoice.
3. Show on your invoice a detailed description of each item of goods contained in each individual package.
4. Mark your goods legibly and conspicuously with the name of the country of origin, unless they are specifically exempted from the country of origin marking requirements, and with such other marking as required by the marking laws of the United States. Exemptions and general marking requirements are detailed in Chapters 24 & 25 of "Importing into the United States."
5. Comply with the provisions of any special laws of the United States, which may apply to your goods, such as the laws relating to food, drugs, cosmetics, alcoholic beverages, and radioactive materials.
6. Observe closely the instructions with respect to invoicing, packaging, marking, labeling, etc., sent you by your customer in the United States. He has probably made a careful check of the requirements, which will have to be met when you arrive.
7. Work with U.S. Customs in developing packing standards for your commodities.
8. Establish sound security procedures at your facility and while transporting your goods for shipment. Do not allow narcotics smugglers the opportunity to introduce narcotics into your shipment.
9. Consider shipping on a carrier participating in the Automated Manifest System.

10. If you use a licensed customs broker to handle the transaction, consider using a firm that participates in the Automated Broker Interface (ABI).

ANIMAL AND PLANT PRODUCTS IMPORTS

APHIS, Plant Protection and Quarantine (PPQ) is responsible for ensuring that healthy seeds, plants, bulbs, timber, flowers, vegetables, fruits, and a multitude of other agricultural commodities can be exported without risk to agriculture and natural resources. APHIS' Veterinary Services (VS) unit ensures that animals and animal products, such as semen and embryos, can be exported from this country without threatening the animal health in their countries of destination. PPQ issues two kinds of phytosanitary certificates--those for domestic plants and plant products, and those for foreign plants and plant products offered for reexport. User Fees for Plant Exporters: Under direction from Congress, PPQ charges a user fee for issuing phytosanitary certificates. These fees cover the costs of providing certification services, and exporters must pay at the time the certificate is issued.

EXCERPT Program: Because of the sheer quantity of certificates that PPQ issues and because many countries have vastly different entry requirements for agricultural products, PPQ developed a database to track the phytosanitary requirements for many countries. This database, called EXCERPT, allows PPQ officers, State and county officials, and even industry members to access export information. The database also lists the status of endangered plant species, the commodities that are not eligible to be exported to specific countries, and any changes in other countries' entry requirements. It also identifies ports that are authorized to certify for export those endangered and threatened plants protected by the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). For example, PPQ officials at San Francisco, a CITES-approved port, can certify cacti for export.

ALCOHOLIC BEVERAGES

The Bureau of Alcohol, Tobacco and Firearms (ATF),U.S. Department of the Treasury is responsible for administering the Federal Alcohol Administration Act. Distilled spirits imported in bulk containers of a capacity of more than one gallon may be withdrawn from customs custody only by persons to whom it is lawful to sell or otherwise dispose of distilled spirits in bulk. Bulk or bottled shipments of imported spirits or distilled or intoxicating liquors must at the time of importation be accompanied by a copy of a bill of lading or other documents, such as an invoice, showing the name of the consignee, the nature of it contents, and the quantity contained therein (18 U.S.C. 1263). **U.S. Customs will not release alcoholic beverages destined to any state for use in violation of its laws, and the importation of alcoholic beverages in the mails is prohibited.**

In general, imported wine must conform to the metric standards of fill if bottled or packed on or after January 1, 1997. Imported distilled spirits, with some exceptions, must conform to the metric standards of fill if bottled or packed on or after January 1, 1980. Distilled spirits and wines bottled or packed prior to the respective dates must be accompanied by a statement to that effect signed by a duly authorized official of the appropriate foreign country. Malt beverages, including beer, are not subject to metric standards of fill. Imported wines in bottles and other

containers are required to be package, marked, branded and labeled in accordance with the regulations in 27 Code of Federal Regulations (CFR) Part 4.

Imported malt beverages, including alcohol-free and nonalcoholic malt beverages, are also required to be labeled in conformance with the regulations in 27 CFR Part 7. Each bottle, cask or their immediate container of imported distilled spirits, wines, or malt beverages must be marked for Customer purposes to indicate the country of origin of the alcoholic beverage contained therein, unless the shipment comes within one of the exceptions outlined in the regulations.

Labels affixed to bottles of imported distilled spirits and wine must be covered by certificates of label approval issued to the importer by the Bureau of Alcohol, Tobacco and Firearms. Certificates of label approval or photostatic copies must be filed with Customs before the goods may be released for sale in the United States. Certificate of label approval requirements must also be met for fermented malt beverages if similar to the Federal requirements (27 CFR Parts 4,5,7) The labeling of wine products containing less than 7% alcohol do not require certificates of label approval but must be labeled in accordance with FDA food labeling requirements.

In addition, importation of alcoholic beverages is subject to the specific requirements of the Food and Drug Administration. Certain plant materials when used for bottle jackets for wine or other liquids are subject to special restrictions under plant quarantine regulations of the Animal and Plant Health Inspection Service. All bottle jackets made of dried or unmanufactured plant materials are subject to inspection upon arrival and are referred to the Department of Agriculture. Public Law 100-690, codified under 27 U.S.C. 213-219A requires that a health warning appear on the labels of containers of alcoholic beverages bottled on or after Nov. 18, 1989:
Government Warning: (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risks of birth defects. (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery and may cause health problems.

APPENDIX A - MAJOR U.S. REGULATORY AGENCIES

U.S. DEPARTMENT OF AGRICULTURE:

Animal and Plant Health Inspection Service (APHIS), Plant Protection and Quarantine (PPQ) Importers must obtain a phytosanitary certificates for certain commodities to verify that the quarantine officials of the exporting country have examines the commodities for pests and disease prior to the commodities' departure from the country to ensure that they are not introduced into U.S. agriculture. For some commodities, there are no acceptable quarantine treatments that have been proven to destroy pests and diseases of concern; these commodities are not allowed to be imported. For information contact:

APHIS-PPQ, Permit Unit
4700 River Road, Unit 136
Riverdale, MD 20737-1236
Telephone: (301) 734-8645

Fax: (301) 734-5786

APHIS also maintains an automated information retrieval system, which is a “fax-back” dial-up service.

For Pest Permits: (301) 734-5055
For Plants and Plant Products (301) 734-5055
World Wide Web or URC is: http://www.aphis.usda.gov/ppq/bats/permits.html

Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS). Veterinary Services (VS).

Veterinary Services issues permits for the importation of animals, birds, and animal products. For permit applications and information about import requirements and user fee, contact:

APHIS-VS
National Center for Import/Export
4700 River Road, Unit 40
Riverdale, MD 20737-1231

Birds
Telephone (301) 734-5097
Fax: (301) 734-6402

Animal Products
Telephone (301)734-3261
Fax: (301)734-8226

Animals
Telephone (301)734-8145
Fax: (301)734-6402

Additional information is also available by facsimile through a completely automated document retrieval system. The direct dial number is: (301) 734-4952.

CITES LISTED ANIMALS AND ANIMAL PRODUCTS transported to the U.S. from the jungles, seas, and forests around the globe originate from a multitude of animals and animal products that are protected by the CITES treaty. These creatures and wildlife products, like furs, Barbary apes, and python-leather handbags, arrive daily at America’s ports, where they are inspected by Fish and Wildlife Services (FWS) officers. FWS wildlife inspectors determine whether or not the importation is legal and either releases the cargo or takes legal action against the importer. For more information about importing CITES-listed animals, call the FWS at (703) 358-2104. If you are in the United States you may call (800) 358-2104.

APHIS Veterinary Biologic’s is another APHIS unit that works closely with importers who are trading animal products. Biotechnology, Biologics, and Environmental Protection (BBEP)

Veterinary Biologics staff issues permits for the importation of veterinary biologics, such as vaccines, antiserums, diagnostic test kits, allergenic extracts, and immune stimulants. These permits are issued for research and development, transit shipment, and distribution and sale. To apply for a permit, contact:

USDA-APHIS-BBEP
Veterinary Biologics Staff
4700 River Road, Unit 148
Riverdale, MD 20737-1248
Telephone: (301) 734-7760
Fax : (301) 734-4314
Internet address: **http://www.aphis.usda.gov/vs/cvblpd**

FOOD SAFETY INSPECTION SERVICE (FSIS)

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) is responsible for ensuring that domestic and imported meat, poultry and eggs, and their products, are wholesome, unadulterated, and accurately labeled. For more information on FSIS contact:

Food Safety and Inspection Service
International Programs
Room 341-E Whitten Building
Washington, DC 20250
Tel. (202) 720-3473
Fax (202) 690-3856
World Wide Web: **http://www.usda.gov/fsis**

Exporters to the United States need to have a thorough understanding of the "Pathogen Reduction" program and the Hazard Analysis and Critical control Points (HACCP). Information may be obtained from:

National Technical Information Service (NTIS)
U.S. Department of Commerce
5285 Port Royal Road
Springfield, VA 22161.

AGRICULTURAL MARKETING SERVICE (AMS)

Customer Service Standards for Quality Grading and Certification,
Fresh Fruits, Vegetables, and Specialty Crops
Room 2056, South Building
Washington, DC 20250-6456
Tel: (202) 720-5870
Fax: (202) 720-0393
WebPage: http://www.ams.usda.gov

AMS Processed Products Branch
Room 0709, South Building
Washington, DC 20250-6456
Tel: (202) 720-4693
Fax: (202) 690-1087

Meat and Meat Products. To obtain information on quality grades and standards used in the commerce of meat and meat products contact:

Meat Grading & Certification
Livestock and Seed Division
Room 2628, South Building
Washington, DC 20250-6456
Tel: (202) 720-1246
Fax: (202) 690-4119

Cheese, Milk, and Dairy Products. Imported cheese and cheese products are subject to requirements of the Food and Drug Administration and the Department of Agriculture. Most importation of cheese require an import license and are subject to quotas administered by the Department of Agriculture, Foreign Agricultural Service, Washington, D.C. 20250. For quality grade and standards, and market news for milk and other Dairy Products, contact:

AMS Dairy Division
Room 2750, South Building
Washington, DC 20250-6456
Tel: (202) 720-3171
Fax: (202) 720-2643
World Wide Web: www.ams.usda.gov/dairy

Office of Plant and Diary Foods and Beverages
Center for Food Safety and Applied Nutrition
200 C Street, SW, HFS 307
Washington, DC 20204
TEL: (202) 205-5321
FAX: (202) 205-4422

For quality grade and standards, for poultry and eggs contact:

AMS Poultry and Eggs, Poultry Grading Branch
Poultry Division
Room 3938, South Building
Washington, DC 20250-6456
Tel: (202) 720-3271
Fax: (202) 690-3165

Cotton: AMS provides classification services to individual buyers, manufacturers, breeders, researchers, and others upon request and for a fee. For more detailed information contact:

AMS Cotton Division
Tel: (202) 720-3193
Fax: (202)690-1718

Tobacco: All imported burley and flue cured tobacco (leaf or chopped) is inspected by USDA/AMS Tobacco Division for pesticide residues and for quality grading. Tobacco, which is fire or air dried, is inspected for quality. All inspections are on a cost recovery basis.

AMS Tobacco Division, Standardization Branch
Room 511 - Annex, AG BOX 0280
U.S. Department of Agriculture
Tel (202) 205-0744
Fax (202) 205-1191

LABORATORY TESTING: AMS' Science Division provides centralized scientific support to AMS programs, including laboratory analyses, laboratory quality assurance, coordination of scientific research by other agencies for AMS, and statistical and mathematical consulting services. On a fee basis, AMS scientists provide testing services on a number of products including: Aflatoxin in peanuts; Imported tobacco-burley and flue-cured. For more information contact:

AMS Science & Technology Division
AgBox 0222
Tel: (202) 720-2158
Fax: (202) 720-6496

TRANSPORTATION PROGRAMS: AMS transportation programs bring together traffic managers, engineers, rural policy analysts, international trade specialists, and agriculture marketing specialists to help solve U.S. and world agricultural transportation problems. For more information contact:

AMS Shipper and Exporter Assistance - AgBox 0267, Tel (202) 690-1304, Fax: (202) 690-1340
AMS Marketing and Transportation Analysis - AgBox 0266 (202) 690-1303, Fax: (202) 690-3616.

PESTICIDE PROGRAMS: AMS administers laws authorizing pesticide residue testing of products at the wholesale level and requiring applicators of restricted pesticides to keep records of their work. Cooperating States operate the testing program, and AMS interprets the data. On request and on a fee basis, the Agency certifies pesticide residue levels in **exported** products. Formal names of the testing and record keeping activities are:

AMS Pesticide Data Program - Tel: (703) 330-2300 Fax: (703) 369-0678
AMS Pesticide Record keeping Program - Tel: (703) 330-7826 Fax: (703) 330-6110

The U.S. Food and Drug Administration monitors pesticide residues on **imported** fresh fruits and vegetables.

GRAIN INSPECTION PACKERS AND STOCKYARDS ADMINISTRATION (GIPSA), FEDERAL GRAIN INSPECTION SERVICE (FGIS):

FGIS facilitates the movement of U.S. grain into the marketplace by providing farmers, grain handlers, processors, exporters, and international buyers with information that accurately and consistently describes the quality and quantity of grain being bought and sold. For more information contact:

International Monitoring Staff
Grain Inspection, Packers, and Stockyards Administration
AgBox 3640
U.S. Department of Agriculture
Washington, DC 20250
Tel: (202) 720-0226
Fax: (202) 720-1015

To obtain more information from the Internet World Wide Web: **http://www.usda/gipsa /index.html**

U.S. FOOD AND DRUG ADMINISTRATION (FDA), DEPARTMENT OF HEALTH & HUMAN SERVICES.

Office of Constituent Operations
International Activities Staff, HFS-585
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration
200 C Street, S.W.
Washington, DC 20204-0001
Tel. (202) 205-4045
Fax (202) 401-7739
FDA Internet home page is http://www.fda.gov
The CFSAN home page is: http://www.cfsan.fda.gov

Office of Field Programs
Imports Branch, Division of Enforcement (HFS-606)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, DC 20204
Tel (202) 205-4606
Fax (202) 260-0208

Office of Premarket Approval (HFS-200)
Center for Food Safety and Applied Nutrition

Food and Drug Administration
1110 Vermont Avenue, N.W.
Washington, DC 20005
HFS-200
Tel (202) 418-3200
Fax (202) 418-3131

Office of Regulatory Affairs
Division of Import Operations
Food and Drug Administration
15800 Crabbs Branch, HFC-171
Rockville, MD 20855
TEL (301) 443-6553
FAX (301) 594-0413
http://www.fda.gov

ENVIRONMENTAL PROTECTION AGENCY (EPA).

Environmental Protection Agency
International Cooperative and Developing Countries
401 M Street, SW
Washington, DC 20460
Tel: (202) 260-7751 or (703) 305-5761

Environmental Protection Agency
INFOTERRA
401 M Street, SW
Washington, DC 20460
Tel: (202) 260-5917 or (202) 260-3928

THE U.S. CUSTOMS SERVICE cooperates with a number of other Federal agencies, and a **license** or **permit** from the responsible agency is necessary to import the following products: alcoholic beverages; animals and animal products; certain drugs; firearms and ammunition; fruits, nuts; meat and meat products; milk, dairy, and cheese products; plants and plant products; poultry and poultry products; petroleum and petroleum products; trademarked articles; vegetables. A general discussion of some of these classes of products has been covered, however, it is recommended that before attempting to import any of these products additional research should be under taken with the appropriate agency.

Office of Regulations and Rulings
U.S. Customs Service
1300 Pennsylvania Ave
Washington, DC 20229
Phone: (202) 927-2340
Fax: (202) 927-1879
Website: http:\\www.customs.ustreas.gov

BUREAU OF ALCOHOL, TOBACCO AND FIREARMS, DEPARTMENT OF THE TREASURY. Any person or firm wishing to import distilled spirits, wines, or malt beverages into the United States must first obtain an importer's basic permit from

The Bureau of Alcohol, Tobacco and Firearms
Department of the Treasury
Washington, D.C. 20226
Telephone: (202) 927-8110.
Website: http:\\www.atf.treas.gov

APPENDIX B - LOCAL CONTACTS and Various U.S. and World Food Safety Internet Sites

U.S. FEDERAL REGISTER: http://www.access.gpo.gov/nara/cfr-retrieve.html

WORLD TRADE ORGANIZATION (WTO): http://www.wto.org/

CODEX ALIMENTARIUS http://www.fao.org./waicent/faoinfo/nutritio/codex/codex.htm

U.S. Food and Drug Administration	**http://www.fda.gov**
Center for Food Safety and Applied Nutrition	**http://www.cfsan.fda.gov**
FDA Import information	http://www.fda.gov/ora/import/ora_import_program.html
Import detention information	http://www.fda.gov/ora/ids/ora_ids_homepage.html
Pesticide Analytical Manual (on-line)	http://vm.cfsan.fda.gov/~frf/pami3.html
Fish & Fishery Products HAACP Guide	**http://vm.cfsan.fda.gov/~dms/haccp-2.html** (or) http://www.cfsan.fda.gov
Product Registration (LACF)	**http://vm.cfsan.fda.gov/~comm/lacf-s1.html**
Food Safety Initiative	**http://vm.cfsan.fda.gov/~dms/fs-toc.html**
Dietary Supplements	**http://vm.cfsan.fda.gov/~dms/supplmnt.html**
Food Additives	**http://vm.cfsan.fda.gov/~lrd/food.add.html** (or) http://www.cfsan.fda.gov

United States Department of Agriculture	**http://www.usda.gov**
Agricultural Marketing Service (AMS)	http://www.usda.gov/ams/titlepag.htm
Pesticide Data Program Information	http://www.usda.gov/ams/index.htm
Fruit & Vegetables Division	http://www.usda.gov/AMS/fruitveg.htm
Food Safety and Inspection Service (FSIS)	http://www.usda.gov/agency/fsis/homepage.htm
Grain Inspector, Packers and Stockyards Administration (GIPSA)	http://www.usda.gov/gipsa/index.html
Federal Grain Inspection Service	http://www.usda.gov/gipsa/fgisover.html
Animal Plant Health Inspection Service (APHIS)	http://www.aphis.usda.gov/index.html
Foreign Agricultural Service (FAS)	http://www.fas.usda.gov

U.S. Environmental Protection Agency	**http://www.epa.gov**
Office of Pesticide Programs	http://www.epa.gov/internet/index.html

Food Quality Protection Act	http://www.epa.gov/opppsps1/fqpa/
U.S. Regulatory Status of Pesticides	http://www.epa.gov/pesticides/regstat.htm
Pesticide Tolerance Levels	

http://www.epa.gov/pesticides/food/viewtols.htm

U.S. Government Printing Office	**http://www.access.gpo.gov/index.html**
Federal Register	http://www.access.gpo.gov/su_docs/aces/aces140.html
Code of Federal Regulations	http://www.access.gpo.gov/nara/cfr/index.html
Federal Bulletin Board File Libraries	http://fedbbs.access.gpo.gov/liblist.htm

American Crop Protection Association	**http://www.acpa.org/**
1996 Food Quality Protection Act	http://www.acpa.org/public/issues/fqpa96.html
Ag on the Internet	http://www.acpa.org/public/interest/interest.html#Agriculture
"From Lab to Label: The Research, Testing & Registration of Ag. chemicals"	http://www.acpa.org/public/pubs/lab-labl.html

International Food Information Council	**http://ificinfo.health.org/**
Wright's Pest Law Home Page	**http://www.pestlaw.com/pestlaw.htm**
State Pesticide Regulatory Agencies	**http://ace.orst.edu/info/nptn/stateind.htm**
California Department of Pesticide Regulation	**http://www.cdpr.ca.gov/**
Chemical Ingredients Database (Info on EPA registered Pesticides)	http://www.cdpr.ca.gov/docs/epa/epachem.htm
Florida Ag. Information Retrieval System	**http://hammock.ifas.ufl.edu/**
Agricultural Info Center Database	**http://www.agnic.org/agdb/erdcalfr.html**
Pesticide Properties Database	**http://www.arsusda.gov/ppdb2.html**
National Marine Fisheries Service	**http://kingfish.ssp.nmfs.gov/iss/issue.html**
Online version of Worker Protection Standard	**http://ipmwww.ncsu.edu/safety/epawps_intro.html**

How to obtain a copy of the FDA Food Code:

You can access (and download) the *Food Code* from the FDA's home page at www.fda.gov. Choose Federal/State Food Programs (Milk, Retail, & Shellfish), then choose "Prime Connection", and choose "Food Code". A spiral-bound color version for $35 (order number PB97-133656) is available through the National Technical Information Service (NTIS). Call NTIS at 800/553-6847 or email orders@ntis.fedworld.gov to order. NTIS also offers a WordPerfect 6.1 version (PB97-501274) for $35. Finally, NTIS offers an enhanced electronic edition (diskette [PB97-502504] or CD-ROM [PB97-502496]) with hypertext links to other *Food Code* references and external documents for $60. A $4 handling fee applies to all pre-paid domestic orders. Expect one to two weeks for delivery. Overnight delivery costs an additional $25.

APPENDIX C - U.S. GOVERNMENT EXPORT CERTIFICATION DOCUMENTS

Agency: U.S. Department of Agriculture Programs ***Food Safety and Inspection Service (FSIS)***	International Program staff monitors requirements for meat and meat products for export.
FSIS Criteria for Eligibility to be Exported.	Must be from Federally Inspected Plant; Product must be reinspected; labeled to meet Foreign requirements; Handled under sanitary conditions
	Exporter obtains Foreign country's requirements from computerized information on all countries: (202) 501-7608
FSIS Veterinarian at plant or slaughterhouse must review, sign and issue the certificate(s).	**FSIS 9060-5 Certificate of Wholesomeness; and** **FSIS 9090-1 Certificate to Export to [country name], as required by importing country.**
Animal, Health Inspection Service (APHIS)	Plant Origin: PPQ 577 Phytosanitary Certificate:
Animal, Health Inspection Service (APHIS)	Animal Origin: Veterinary Health Certificate for Animal and Animal By-Products: VS FORM 16-4. Limited No# Processed Plant Products: PPQ 578 Export Certificate.
Agricultural Marketing Service (AMS)	**FV-146 Certificate of Quality and Condition (or Health) Processed Foods** Voluntary between Buyer and Seller wishing inspection of frozen and/or other processed food product; also **U.S. National Organic Program/ Accreditation of organic certifiers (CY 2001 Implementation date)**

Grain Inspection, Packers and Stockyards Administration (GIPSA) Technical Services Division	Offers quality assessment testing of many kinds of processed commodities. **The Technical Services Division/GIPSA (816) 891-0401. E-MAIL: dkendall@ gipsakc.usda.gov.**
Food Safety and Technical Services Division, Foreign Agricultural Service	**Radioactivity Letter** attesting to state of Testing of Agricultural Commodities for Radiation in the United States. E-MAIL: OFSTS@fas.usda.gov
Agency: U.S. Food and Drug Administration, Department of Health and Human Resources	**FDA 2678b Certificate for Export** (Certificate of Free Sale); also **EU Export Health Certificate (Seafood)**.
U.S. Chambers of Commerce	Certificates of Origin

APPENDIX D - U.S. WORLD TRADE ORGANIZATION (WTO) ENQUIRY POINT(S)

SPS Enquiry Point/Notification Authority
Office of Food Safety and Technical Services
U.S. Department of Agriculture (USDA)
14th & Independence Ave., S.W., Room 5545-South
Washington, D.C. 20250
E-mail: **ofsts@fas.usda.gov** or wilsonc@fas.usda.gov

Telephone: (202) 720-2239 or (202) 720-1301
Fax: (202) 690-0677

TBT Enqurity Point
National Center for Standards and Certification Information
National Institute of Standards and Technology (NIST)
U.S. Department of Commerce
Bldg. 820, Room 164
Gaithersburg, Maryland 20899

Telephone: (301) 975-4040
Fax: (301) 926-1559

E-mail: joanne.overman@nist.gov