Section 1

PRODUCE AND OTHER PLANT PRODUCTS - FDA and USDA have jointly issued guidance regarding practices in growing, harvesting, sorting, packing, and storage operations to reduce microbial food safety hazards for fresh fruits and vegetables. For guidance documents available for fruits, vegetables and nuts please refer to the Produce and Plant Products Guidance for Industry guides at:

- Produce and Plant Products Guidance for Industry: FDA Home → Food → Guidance, Compliance & Regulatory Information → Guidance Documents (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/default.htm)

- The general Good Agricultural Practices (GAPs) guidance document (AKA the green guide) can be found at: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/UCM064574

- The Good Agricultural Practices (GAPs) guidance document for fresh-cut fruits and vegetables can be found at Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables can be found at: FDA Home → Guidance, Compliance & Regulatory Information → Guidance Documents (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064458.htm)

- The Draft Guidance for Industry for fresh tomatoes can be found at: Guide to Minimize Microbial Food Safety Hazards of Tomatoes can be found at: FDA Home → Guidance, Compliance & Regulatory Information → Guidance Documents (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm173902.htm)

- The Draft Guidance for Industry for fresh melons can be found at: Guide to Minimize Microbial Food Safety Hazards of Melons can be found at: FDA Home → Guidance, Compliance & Regulatory Information → Guidance Documents (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm174171.htm)

- The Draft Guidance for Industry for leafy greens can be found at: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens can be found at: FDA Home → Guidance, Compliance & Regulatory Information → Guidance Documents (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm174200.htm)

FDA has also issued two guidance manuals for practices to minimize food safety hazards in producing sprouts (sprouted seeds). These can be found at:

- Sprouted Seeds Guidance: FDA Home → Food → Guidance, Compliance & Regulatory Information → Guidance Documents (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm120244.htm)
- Sampling and Microbial Testing Of Spent Irrigation Water During Sprout Production: FDA Home → Food → Guidance, Compliance & Regulatory Information → Guidance Documents (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm120246.htm)

FRUIT AND VEGETABLE JUICE PRODUCTS - Most fruit and vegetable juice products are required to have been processed in a facility that has an operational Hazard Analysis and Critical Control Point (HACCP) safety plan in place. Information about the mandatory HACCP requirement for juice products is available at:

- Juice HACCP Guidance for Industry: FDA Home → Food → Guidance, Compliance & Regulatory Information → Guidance Documents (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Juice/ucm072557.htm)
- Juice, Guidance of Industry: FDA Home → Food → Guidance, Compliance & Regulatory Information → Guidance Documents → Juice (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Juice/default.htm)

Section 2

PHYTOSANITARY AND ANIMAL PEST CONSIDERATIONS - Certain food products from some countries are prohibited for import into them United States, or are allowed for 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 (APHIS): http://www.aphis.usda.gov/.

Please visit the following link for information on Plant Import and Export (including minimally processed and non-processed fruits and vegetables):
http://www.aphis.usda.gov/plant_health/index.shtml

Overview: http://www.aphis.usda.gov/import_export/index.shtml

Plant Imports (including seeds, plants, fruits, vegetables and some plant products- e.g. rice, corn): http://www.aphis.usda.gov/import_export/plants/plant_imports/index.shtml

General information on USDA's import program:
http://www.fsis.usda.gov/Regulations_&_Policies/Import_Information/index.asp

ORGANIC FOODS: The USDA oversees the National Organic Program (Farming, Certification, Labeling, etc.) and the Export/Import of Organic Products program. Please visit the following website for additional information:

- www.usda.gov → Agriculture → Organic Certification (http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_1OB?navid=ORGANIC_CERTIFICATIO&parentnav=AGRICULTURE&navtype=RT)

Section 3

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), foreign manufacturers, exporters, importers, owners or consignees of food products intended for introduction into U.S. interstate commerce need to ensure that the products are safe, sanitary, and labeled according to U.S. requirements. All imported food is considered to be interstate commerce. All imported products are required to meet the same standards as domestic goods. Imported foods must be wholesome and safe to eat; cosmetics must be safe and made from approved ingredients; and all foods and cosmetic products must contain informative and truthful labeling in English.
The Food and Drug Administration (FDA) is not authorized under the law to approve, certify or license food importers and does not sanction individual 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, provide prior notice of incoming shipments to FDA and adhere to FDA regulations that apply to the products that are being imported. 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. Both imported and domestically-produced foods must meet the same legal requirements in the United States.

- *Good Importer Practices*: FDA Home → Regulatory Information → Guidances (*http://www.fda.gov/RegulatoryInformation/Guidances/ucm125805.htm*)

- For general information about FDA's Import Program please visit: FDA Home → For Industry → Import Program (http://www.fda.gov/ForIndustry/ImportProgram/default.htm)

  http://www.fda.gov/ForIndustry/ImportProgram/ImportProgramOverview/default.htm

- Import and Exports, Guidance for Industry: FDA Home → Food → Guidance, Compliance & Regulatory Information → Guidance Documents → Imports and Exports (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ImportsExports/default.htm)

FACILITY REGISTRATION- The U.S. Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires 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. Known as BT Registration, registration of food facilities under this Act can be accomplished on the internet and is free of charge. For information and instructions on how to register a facility, please visit:

- FDA Home → Food → Guidance, Compliance & Regulatory Information → Registration of Food Facilities (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/default.htm)

- FDA *strongly encourages* electronic registration at FDA Industry System: http://www.access.fda.gov/.
- Food Facility Registration helpdesk: **800-216-7331**
- An electronic version of the Food Facility Registration booklet, in various languages, can be found at: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm113822.htm

Facility BT Registration is required for both domestic and foreign firms providing food for consumption in the U.S. Please note that a U.S. agent residing in the United States must be listed for each registered foreign facility.

PRIOR NOTICE OF INCOMING SHIPMENTS - The Bioterrorism Preparedness Act of 2002 also requires anyone with knowledge of a food being imported or offered for import to the U.S. to provide prior notice to FDA for each import shipment of food products. Prior notice can be provided in either of two ways:

1. The Bureau of Customs and Border Protection (CBP, formerly the U.S. Customs Service) has modified the Automated Broker Interface of the Automated Commercial System (ABI/ACS) found at the following websites to allow prior notice to be submitted to FDA through the existing interface between CBP and FDA:

- CBP ABI System Overview: http://www.cbp.gov/xp/cgov/trade/automated/automated_systems/acs/acs_abi_contact_info.xml
- CBP ABI System: http://www.cbp.gov/xp/cgov/trade/automated/automated_systems/abi/

2. The Prior Notice System Interface (PNSI) is available to individuals or companies who cannot, or choose not to, file through CBP. PNSI submissions are required for prior notice for shipments through international mail; In-Bond entries or admissions into Foreign Trade Zones by carriers or others who do not need to make a full CBP entry at the time of filing the prior notice; filers or brokers who need to file CBP entries at a time the CBP/FDA interface is not available, and others who simply prefer to use an interactive system. For more information on prior notice procedures please visit:

    a. Prior Notice of Imported Foods: FDA Home → Food → Guidance, Compliance & Regulatory Information → Prior Notice of Imported Foods (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/PriorNoticeofImportedFoods/default.htm)

    b. FDA Industry System: http://www.access.fda.gov/

    c. Prior Notice telephone hotline available 24 hours 7 days a week: **866-521-2297**

    d. An electronic version of the Prior Notice booklet, in various languages, can be found at: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm113822.htm

NOTE: Importers need to obtain the FDA product codes for each product in order to complete the on-line Import Prior Notice procedure. To determine the appropriate product code for a

particular product, please visit the following FDA webpage to learn how to develop product codes:

- FDA Home → Food → Guidance, Compliance & Regulatory Information → Prior Notice of Imported Foods → Product Code Builder Tutorial (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/PriorNoticeofImportedFoods/ucm125839.htm)

- Product Code Builder Application: http://www.accessdata.fda.gov/scripts/ora/pcb/pcb.cfm

NOTE: For more information concerning Importer Security Filing with Customs and Border Protection (CBP), please visit the link below. Also, refer to CBP's Security Filing "10+2" program; for information pertaining to their prior notice requirements:

- CBP's Cargo Security: http://www.cbp.gov/xp/cgov/trade/cargo_security/

U.S. AGENTS- Foreign firms that want to import foods to the U.S. are required to have a U.S. agent in order to import the products into the U.S.; this is required by the Bioterrorism Act of 2002. Foreign facilities must designate a U.S. agent, who lives or maintains a place of business in the U.S. and is physically present in the U.S., for purposes of registration. The U.S. agent may be authorized to register the facility. An U.S. agent is also required for the importation of drugs and medical devices.

The U.S. agent:

- can be any person that resides or maintains a place of business in the U.S. and is physically present in the U.S.
- acts as a communications link for both routine and emergency communications
- will be contacted by FDA if an emergency occurs, unless the foreign facility opts to designate a different emergency contact.
- FDA Home → Food → Food Defense & Emergency Response → Regulatory Information (http://www.fda.gov/Food/FoodDefense/Bioterrorism/FoodFacilityRegistration/ucm063630) - additional information on US agents.
- FDA Home → Food → Guidance, Compliance & Regulatory Information → Guidance Documents (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm082703.htm) - here you can find additional information on who can be an U.S. agent and their responsibilities.

ARRIVAL AT PORT 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 at the following web link, "Importing Food Products Into the United States":

- FDA Home → For Industry → Import Program → Import Program Overview (http://www.fda.gov/ForIndustry/ImportProgram/ImportProgramOverview/default.htm)

- Investigations Operations Manual (IOM): Chapter 6 of the IOM covers procedures used by USFDA field inspectors when examining/screening import entries - http://www.fda.gov/ICECI/Inspections/IOM/default.htm

- Regulatory Procedures Manual (RPM)- Chapter 9 of the RPM, "Import Operations and Actions", covers USFDA import regulatory and enforcement procedures - FDA Home → Inspections, Compliance, Enforcement, and Criminal Investigations → Compliance Manuals → Regulatory Procedures Manual (http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm)

Information on U.S. Customs forms, procedures, bond acquisition, duties, if any, may be obtained at the Bureau of Customs and Border Protection (CBP) website: http://www.cbp.gov/.

NOTE: The U.S. Customs and Border Patrol (CBP) has implemented new requirements under the 10+ 2 Law for the importation of cargo to the U.S. by vessels through their Importer Security Filing System. Please visit the following website for additional information on the new U.S. customs requirements: http://www.cbp.gov/xp/cgov/trade/cargo_security/carriers/security_filing/

SAFETY AND SANITATION - The FDCA requires that foods imported into or produced in the U.S. and sold in U.S. commerce not bear or contain any poisonous or deleterious substances nor consist in whole or in part of any filth (example- evidence of rodent or insect infestation), putrid, or decomposed substances, or otherwise be unfit for food. Foods must not be prepared, packed, or held under unsanitary conditions whereby the products may have become contaminated with filth, or rendered injurious to health. In addition, the presence of no-tolerance pesticides or in amounts in excess of established tolerances are not allowed.

Under the requirements of U.S. food law, manufacturers and distributors are required to take necessary and reasonable steps to ensure the safety and sanitation of their food products. Manufacturers and distributors should be aware that FDA has issued Defect Action Levels (DALs) for some food commodities to allow for certain levels of 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 has also established action levels for certain poisonous and deleterious substances and food commodities. Like the DALs for natural and unavoidable defects, these action levels establish the maximum allowable amounts of the listed substances in selected commodities.

Both, the FDA's DAL list and the FDA Action Levels for Poisonous and Deleterious Substances can be found at:

- FDA Home → Food → Guidance, Compliance & Regulatory Information → Guidance Documents → Sanitation

(http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Sanitation/default.htm)

GOOD MANUFACTURING PRACTICES - Processors of food products sold in U.S. commerce need to be familiar with and comply with 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. These basic GMPs are contained in Part 110 of Title 21 of the U.S. Code of Federal Regulations:
http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=110&showFR=1
In addition, please refer to the set of FDA's food safety regulations published in Title 21 CFR to discover specific regulations that may apply to your manufacturing operation:
http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm

RETAIL LABELING - Provisions of the FDCA, 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 is acceptable in Puerto Rico, a U.S. territory) that include specific information: the identity of the product, the name and address or phone number of the responsible firm (manufacturer or distributor), a list of ingredients in descending order of predominance in the product, the net weight of contents in both English and metric terms, and in most cases nutritional information.
This information must be presented to consumers under normal conditions of purchase and use. . FDA's Food Labeling Guide can be found at the link provided below. The Food Labeling Guide has been prepared to assist manufacturers in preparing labels that meet the regulatory requirements. Further links on the Food Labeling Guide's page connect to the Food Labeling Guide's appendices, which cover allowable health claims on food labels and reference sizes for nutrition labeling.

Detailed information about U.S. labeling requirements can be obtained at::

- FDA Home → Food → Guidance, Compliance & Regulatory Information → Guidance Documents
(http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/default.htm)
(http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/default.htm)

Please visit the following site for a training video on Food Labeling:
http://www.fda.gov/Food/InternationalActivities/ucm151737.htm

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 Nutrient Data Laboratory: http://www.nal.usda.gov/fnic/cgi-bin/nut_search.pl.
Smaller manufacturers may qualify for an exemption from the requirement for nutrition labeling; please visit webpage listed below for more information.

FDA has developed its own Nutrition Labeling Manual, which provides technical instructions to manufacturers on how to develop and use nutrition databases for food products:

- FDA Home → Food Guidance, Compliance & Regulatory Information → Guidance Documents (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm063113.htm)

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 (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:

- FDA Home → Inspections, Compliance, Enforcement, and Criminal Investigations → Inspections → Inspection Guides (http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074944.htm)

- FDA Home → Inspections, Compliance, Enforcement, and Criminal Investigations → Compliance Manuals → Compliance Policy Guides (http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074552.htm)

Please visit the following FDA website for more general information on food allergens:
Information about Food Allergens:

- FDA Home → Food → Resources for You → Consumers → Selected Health Topics → Information about Food Allergens (http://www.fda.gov/Food/ResourcesForYou/Consumers/SelectedHealthTopics/ucm119075.htm)

LACF FACILITY REGISTRATION AND SCHEDULED PROCESS REVIEW - In addition to BT Registration required for food facilities, low-acid canned food and acidified (LACF/AF) food manufacturers producing food in cans, jars, and pouches must register with the FDA as a food canning establishment. A Food Canning Establishment (FCE) number will be assigned to each processing plant location. Every LACF/AF facility must also submit to the FDA details of the manufacturing process (scheduled process) for each LACF/AF product it manufactures prior to attempting to export the product to the U.S. The FDA needs to review the manufacturing process of LACF/AF products prior to allowing importation of these products into the U.S. A Submission Identifier (SID) will be assigned to each LACF/AF product once reviewed by FDA.
Please visit the following links for information on FCE registration and on how to submit information of scheduled processes:

- FDA Home → Food → Guidance, Compliance & Regulatory Information → Guidance Documents →Acidified and Low-Acid Canned Foods, Guidance for Industry (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/AcidifiedandLow-AcidCannedFoods/default.htm)

You can also contact the LACF help desk via mail, phone and/or email at:

LACF Information and Help Center
LACF Registration Coordinator (HFS-303)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
Phone: 301-436-2411
Email: LACF@FDA.HHS.GOV

HEALTH CLAIMS AND NUTRIENT CONTENT CLAIMS - Food labels are permitted to contain when:

- **Health claims** describe a relationship between a food or food component and reducing the risk of a disease or a health-related condition. Example of a health claim: "While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease."
- **Nutrient content claims** are label claims that characterize the level of a nutrient in a food, or compare the level of a nutrient in a food to that of another food. Examples of nutrient content claims: "Fat free," "low sodium," "high in calcium," "lean," "reduced cholesterol."

For an overview of U.S. law and regulations on health claims and nutrient content claims, please visit:

- FDA Home → Food → Labeling & Nutrition → Label Claims

http://www.fda.gov/Food/LabelingNutrition/LabelClaims/default.htm