General Technical Import Requirements
United States of America

Contents

Introduction

The criteria used to determine what foods and food products may be imported (admissibility) is complex. A number of factors result in constant changes to their admissibility. Several U.S. government agencies are involved in the import process. Various factors determine which agency is best suited to address a particular question or matter.

- The U.S. Department of Agriculture (USDA) establishes criteria used to permit certain plants, animals, and foods to enter the United States, and has final say on admissibility of a particular food. **http://www.usda.gov/wps/portal/usda/usdahome**
- The **Food and Drug Administration (FDA)** provides **general information on importing foods**.
- The USDA's **Animal and Plant Health Inspection Service (APHIS)** provides detailed information on **importing agricultural products**, including **procedures for importing foods**.
- **Customs and Border Protection (CBP)** provides **guidelines for permitted and prohibited items**, including foods, you may bring with you when you enter the United States.

The admissibility of fresh and packaged foods can change at any given time due to **pest infestations** and the outbreak of **diseases**.

Pre-Embarkation

Air Waybill

Air freight shipments require Air Waybills, which can never be made in negotiable form. Air Waybills are shipper-specific (i.e. USPS, Fed-Ex,UPS, DHL, etc).

Bill of Lading

A bill of lading is a contract between the owner of the goods and the carrier (as with domestic shipments). For vessels, there are two types: a straight bill of lading, which is non-negotiable, and a negotiable or shipper's order bill of lading. The latter can be bought, sold, or traded while the goods are in transit. The customer usually needs an original as proof of ownership to take possession of the goods.

Commercial Invoice

A commercial invoice, signed by the seller or shipper, or his agent, is acceptable for CBP purposes if it is prepared in accordance with Section 141.86 through 141.89 of the CBP Regulations, and in the manner customary for a commercial transaction involving goods of the kind covered by the invoice. Importers and brokers participating in the Automated Broker Interface may elect to transmit invoice data via the Automated Invoice Interface or EDIFACT and eliminate the paper document. The invoice must provide the following information, as required by the Tariff Act:

- The port of entry to which the merchandise is destined

- If merchandise is sold or agreed to be sold, the time, place, and names of buyer and seller; if consigned, the time and origin of shipment, and names of shipper and receiver
- A detailed description of the merchandise, including the name by which each item is known, the grade or quality, and the marks, numbers, and symbols under which it is sold by the seller or manufacturer to the trader in the country of exportation, together with the marks and numbers of the packages in which the merchandise is packed
- The quantities in weights and measures
- If sold or agreed to be sold, the purchase price of each item in the currency of the sale
- If the merchandise is shipped for consignment, the value of each item in the currency in which the transactions are usually made, or, in the absence of such value, the price in such currency that the manufacturer, seller, shipper, or owner would have received, or was willing to receive, for such merchandise if sold in the ordinary course of trade and in the usual wholesale quantities in the country of exportation
- The kind of currency
- All charges upon the merchandise, itemized by name and amount including freight, insurance, commission, cases, containers, coverings, and cost of packing; and, if not included above, all charges, costs, and expenses incurred in bringing the merchandise from alongside the carrier at the port of exportation in the country of exportation and placing it alongside the carrier at the first U.S. port of entry. The cost of packing, cases, containers, and inland freight to the port of exportation need not be itemized by amount if included in the invoice price and so identified. Where the required information does not appear on the invoice as originally prepared, it shall be shown on an attachment to the invoice.
- All rebates, drawbacks, and bounties, separately itemized, allowed upon the exportation of the merchandise
- The country of origin
- All goods or services furnished for the production of the merchandise not included in the invoice price

If the merchandise on the documents is sold while in transit, the original invoice reflecting this transaction and the resale invoice or a statement of sale showing the price paid for each item by the purchaser shall be filed as part of the entry, entry summary, or withdrawal documentation. The invoice and all attachments must be in the English language, or shall be accompanied by an accurate English translation. Each invoice shall state in adequate detail what merchandise is contained in each individual package. If the invoice or entry does not disclose the weight, gauge, or measure of the merchandise necessary to ascertain duties, the importer of record shall pay expenses incurred to obtain this information prior to the release of the merchandise from CBP custody.

Each invoice shall set forth in detail, for each class or kind of merchandise, every discount from the list or other base price that has been or may be allowed in fixing each purchase price or value. When more than one invoice is included in the same entry, each invoice with its attachments shall be numbered consecutively by the importer on the bottom of the face of each page, beginning with number 1. If an invoice is more than two pages, begin with number 1 for the first page of the first invoice and continue

in a single series of numbers through all the invoices and attachments included in one entry. If an entry covers one invoice of one page and a second invoice of two pages, the numbering at the bottom of the page shall be as follows: Inv. 1, p.1; Inv. 2, p.2; Inv. 2, p.3, etc. Any information required on an invoice may be set forth either on the invoice or on the attachment.

Packing List

Considerably more detailed and informative than a standard domestic packing list, it lists seller, buyer, shipper, invoice number, date of shipment, mode of transport, carrier, and itemizes quantity, description, the type of package (such as a box, crate, drum, or carton), the quantity of packages, total net and gross weight (in kilograms), package marks, and dimensions, if appropriate. Both commercial stationers and freight forwarders carry packing list forms. A packing list may serve as a conforming document. It is not a substitute for a commercial invoice.

Certificate of Origin for Claiming Benefits Under Free Trade Agreements

Special certificates may be required for countries with which the United States has free trade agreements (FTAs).

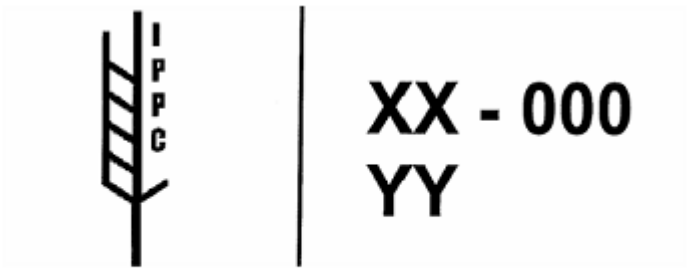
Wood Packaging Material Rule

On September 16, 2005, CBP began enforcing the U.S. Department of Agriculture's and Animal and Plant Health Inspection Service's import regulation as: Pallets, Crates, Boxes, and Dunnage used to support or brace cargo to be treated and marked.

In cases of noncompliance, the wood packing materials will be subject to immediate export along with the accompanying cargo. The approved treatments for wood packaging material are:

- Heat treatment to a minimum wood core temperature of 56'C for a minimum of 30 minutes, or
- Fumigation with methyl bromide

To certify treatment, the wood packing materials must be marked with the following International Plant Protection Convention (IPPC) logo. Paper certificates of treatment will not be accepted. For further information, please see the APHIS Website at **www.aphis.usda.gov**.



XX represents the ISO country code.
000 represents the unique number assigned by the national plant protection organization.
YY represents either HT for heat treatment or MB for methyl bromide fumigation.

Post-Embarkation

Generally, the process of importing into the United States is governed by Customs laws and regulations which are administered by the U.S. Customs and Border Protection (CBP). CBP has primary responsibility for regulating and facilitating international trade, collecting import duties, and enforcing United States trade laws. All merchandise coming into the United States clears CBP and is subject to duty unless specifically exempted by law. CBP clearance involves a number of steps: entry, inspection, appraisement, classification, and liquidation. Information must be filed with CBP for all goods imported into the United States. This information, presented in an "entry notice," must be filed with CBP by the importer of record. Frequently, a Customs broker files the entry notice on behalf of the importer of record. (The importer of record is the party holding the bond and is responsible for entry. The importer of record may be the broker, consignee, or true owner of the goods.) The person presenting entry information to CBP is known as the "filer." In order that the merchandise may be delivered to the importer or owner while review of the entry is taking place, a monetary bond is obtained. The bond contains a condition for the redelivery of an imported shipment, or any portion of it, upon demand of CBP.

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 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 customs house broker.
- A Commercial Invoice or Pro-Forma Invoice if a commercial invoice cannot be produced.
- Packing List if appropriate
- Other necessary documents to determine merchandise admissibility.
- A bond which is normally posted with Customs to cover any potential duties, taxes, and penalties that may accrue after release of the cargo

Arrival at Point of Entry:

When a food shipment is offered for import into the United States, the shipment must be declared by the importer or broker/agent to the U.S. Customs and Border Protection office at the port of entry by the filing of an “entry notice” and acquisition of a bond. Customs then will notify FDA staff of the presence of the shipment. FDA may inspect and sample the shipment to ensure its compliance with

U.S. requirements. More detailed information on FDA import procedures can be found on the agency's web page on Imports and Exports at the web link:
http://www.ita.doc.gov/exportamerica/AskTheTIC/qa_food_beverage.pdf

"FDA Import Procedures," contains a detailed flow-chart of the process. Additional information on the FDA Import and Import Inspection system is available from the link
http://www.fda.gov/ora/import/default.html or
http://www.fda.gov/ForIndustry/ImportProgram/default.htm

Importers will need to know the FDA product codes for products in order to complete the on-line Import Prior Notice procedure. To determine the appropriate product code for a particular product, consult the FDA webpage on developing product codes at
http://www.accessdata.fda.gov/SCRIPTS/ORA/PCB/PCB.HTM .

Information on U.S. Customs forms, procedures, bond acquisition, duties, if any, and country-of-origin labeling requirements may be obtained from any Customs Service office or from that agency's web site at **http://www.cbp.gov/linkhandler/cgov/newsroom/publications/trade/iius.ctt/iius.pdf**

FDA Field Office Inspection

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

CBP Suggestions to Exporter for Faster Clearance of Merchandise

1. Include all information required on your customs invoices.
2. Prepare your invoices carefully. Type them clearly. Allow sufficient space between lines. Keep the data within each column.
3. Make sure that your invoices contain the information that would be shown on a well-prepared packing list.
4. Mark and number each package so it can be identified with the corresponding marks and numbers appearing on your invoice.
5. Show a detailed description on your invoice of each item of merchandise contained in each individual package.
6. Mark your goods legibly and conspicuously with the country of origin unless they are specifically exempted from country-of-origin marking requirements, and with such other marking as is required by the marking laws of the United States.
7. Comply with the provisions of any special laws of the United States that may apply to your goods, such as laws relating to food, drugs, cosmetics, alcoholic beverages, radioactive materials, and others.

8. Observe the instructions closely with respect to invoicing, packaging, marking, labeling, etc., sent to you by your customer in the United States. He or she has probably made a careful check of the requirements that will have to be met when your merchandise arrives.
9. Work with CBP to develop packing standards for your commodities.
10. Establish sound security procedures at your facility and while transporting your goods for shipment. Do not give narcotics smugglers the opportunity to introduce narcotics into your shipment.
11. Consider shipping on a carrier participating in the Automated Manifest System (AMS).
12. If you use a licensed customs broker for your transaction, consider using a firm that participates in the Automated Broker Interface (ABI).

FDA Import Program

The **Food and Drug Administration (FDA)** regulates the importation of food. All commercial imports of food and beverage products require the importer files. Prior Notice with the FDA, and foreign manufacturers and/or distributors of food products must register with the FDA before they may readmit their goods for resale. These requirements DO NOT apply to food accompanying a traveler into the U.S. or sent by an individual to the U.S. for personal consumption.

The importation of seafood is governed by the FDA, the **National Marine Fisheries Service (NMFS)** and the **Fish and Wildlife Service (FWS)**. The importation of marine mammals is also under the jurisdiction of the NMFS and FWS.

Importers can import foods into the United States without prior sanction by FDA, as long as the facilities that produce, store or otherwise handle the products are registered with FDA, and, prior notice of incoming shipments is provided to FDA. Imported food products are subject to FDA inspection when offered for import at U.S. ports of entry. FDA may detain shipments of products offered for import if the shipments are found not to be in compliance with U.S. requirements.

FDA Requirements and Regulations

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

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

Facility Registration

The U.S. Public Health Security and Bioterrorism Preparedness and Response Act of 2002 require that food facilities (other than private homes and individual farms) producing, storing or otherwise handling food products intended for sale in U.S. interstate commerce be registered with FDA. Registration of facilities can be performed on the internet, and is free of charge. For information and instructions on how to register a facility, please see FDA's web page on the subject at the following link: **http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/OnlineRegistration/default.htm** . Please note that a U.S. agent residing in the United States must be listed for each foreign facility being registered.

Prior Notice of Incoming Shipments

The Bioterrorism Preparedness Act of 2002 also requires importers to provide prior notice to FDA for each import shipment of food products. Prior notice of shipments must be performed over the FDA website. Information about the prior notice requirements and instructions on providing prior notice is available at the following FDA link: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/PriorNoticeofImportedFoods/default.htm

Canned Foods

Canned foods (low acid canned foods, or LACF products, and acidified food canned food products) are subject to special FDA permit controls, which are implemented through FDA Food Canning Establishment (FCE) regulations and FDA Scheduled Process Identification (SID) filings.(See thermally processed foods and Acidified foods in the standards section)web address: CFR 21 part 113 and for acidified foods CFR 21(114).
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm

FCE Registration

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

Scheduled Process Identification

Any low acid canned food processor, which is required to submit an FDA FCE registration, must also submit to FDA a scheduled process filing form. The canned food manufacturer's Scheduled Process must

be electronically transmitted to and reviewed (and accepted) by FDA's Center for Food Safety and Applied Nutrition (CFSAN) before any canned food import shipments occur.

Food Contaminants & Adulteration

The FD&C Act requires that foods imported into and sold in U.S. commerce not bear or contain any poisonous or deleterious substances which may render them injurious to health, nor consist in whole or in part of any filth, putrid, or decomposed substances, or otherwise be unfit for food. Under this provision of the FFDCA, FDA oversees the safety of the U.S. food supply (domestic and imports), in part, through its monitoring programs for natural toxins (e.g., mycotoxins), pesticides, and anthropogenic (e.g., industrial chemicals, such as dioxins; cooking or heating related chemicals, such as acrylamide; trace elements, such as lead) contaminants in food and the assessment of potential exposure and risk. (Examples include evidence of rodent or insect infestation, or the presence of pesticides prohibited in foods or amounts of allowable pesticides in excess of established tolerances.) Foods must not be prepared, packed, or held under unsanitary condition whereby the products become contaminated with filth, or rendered injurious to health.

Chemical Contaminants

- **Acrylamide**
- **Dioxins and PCBs**
- **Ethyl Carbamate**
- **Furan**
- **Melamine**
- **Perchlorate**
- **Radionuclides**

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

Filth and Extraneous Materials

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

Defect action levels guidance document:

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

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

FDA also has established action levels for poisonous and deleterious substances in certain foods. Like the DALs for natural and unavoidable defects, these action levels establish for the listed commodities the maximum allowable amounts of the listed substances. The FDA Action Levels for Poisonous and Deleterious Substances can be accessed at this link to the FDA website: **http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ChemicalContaminantsandPesticides/ucm077969.htm**

- See also **The Defect Action Level Handbook**

Metals

- **Lead**

Retail Labeling

Provisions of the FD&C Act, the U.S. Fair Labeling and Packaging Act, and the Nutrition Labeling and Education Act, and the Food Allergen Labeling and Consumer Protection Act of 2004, require that retail packages and containers of food products sold in U.S. interstate commerce include specific information. (See also general labeling requirements.)

Nutritional 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. Manufactures can also examine the U.S. Department of Agriculture's food nutrient database to determine if the database provides information from which they can derive the appropriate nutrient information for their products. The database can be accessed at this link: **http://www.nal.usda.gov/fnic/cgi-bin/nut_search.pl** .

Labeling Bulk Containers

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

Allergens in Food Product and Allergen Labeling

Food manufacturers should be aware that FDA has issued guidance about food allergens and allergen labeling of products. Agency guidance and compliance policy on the matter is available at these links to the FDA website: **http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074944.htm**.

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

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

Standards of Identity

Under authority of the FD&C Act, FDA has promulgated "standards of identity" for a number of food product categories. These standards establish minimum ingredient requirements for the various foods covered by the standards. These requirements must be met in order for a food legally to be sold bearing the statement of identity covered by the standard. The standards for foods are contained (Standards window).

U.S. Code of Federal Regulations: **http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1**

"Low acid canned foods" (LACF) or "acidified foods" (AF) are thermally processed product packed in a hermetically sealed container with an acid content above pH 4.6, containing enough water ("water activity") to allow the growth of anaerobic microorganisms or products that had their pH adjusted by the addition of an acid ingredient. LACF products are regulated more rigorously than most other foods in order to protect the products from contamination during processing by dangerous microorganisms and their toxins, such as C. botulinum. Foreign facilities whose LACF/AF products are imported into the United States are required to register their establishments with FDA's LACF office, and, to file processing information for each LACF/AF product intended for import into the United States. **http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/AcidifiedLow-AcidCannedFoods/default.htm**

Food Additives

FDA regulates additives used in food products. New food additives must be approved or reviewed by FDA before marketing. FDA also regulates food packaging materials and food contact substances. Chapter 5 - Food, Colors, and Cosmetics

Food Security

Food manufacturers, processors, and transporters should be aware that FDA has issued food-security guidance designed to protect their operations against the potential for bioterrorism.

Pesticides

Tolerances for pesticides allowed on specific agricultural products are set by the U.S. Environmental Protection Agency (EPA). An FDA inspection of an imported agricultural commodity may test for the presence of pesticides for which EPA has not established tolerances for that commodity. Import

shipments of a food commodity containing pesticides for which tolerances have not been established for that commodity may be refused entry or detained.

Phytosanitary and Animal Pest Considerations:

Certain food products from some countries are prohibited import into the United States, or are allowed import under restricted conditions, because of the threat of animal or plant pests and diseases. These phytosanitary restrictions are administered by the US Department of Agriculture's Animal and Plant Health Inspection Service:

http://www.aphis.usda.gov/

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

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.

Food Safety Modernization Act of 2011

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

Useful links

Food Safety

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

Fruits and Vegetables Import Requirements (FAVIR)

http://www.aphis.usda.gov/favir/