

AGRIBUSINESS SERIES

Export Handbooks

THE UNITED STATES MARKET

Guide to Identify the Primary Official Requirements to
Import Fresh and Processed Agricultural Products

Inter-American Program for the Promotion of Trade,
Agribusiness and Food Safety

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This document was prepared by the Interamerican Program for the Promotion of Trade, Agribusiness and Food Safety, with headquarters in Miami, FL, and supported by the Directorate for Agribusiness Development of IICA. The primary author is Mr. Daniel Rodriguez Saenz, Agribusiness Specialist for IICA, who counted with the support of Ms. Eugenie Gamboa, bachelor in Business Administration with emphasis in International Trade and intern at the Interamerican Program for the Promotion of Trade, Agribusiness and Food Safety. Mr. Quentin B. Kubicek, Agricultural Health & Food Safety Specialist for IICA assisted in editing the English version.

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The Interamerican Institute for Cooperation on Agriculture (IICA) through the activities of the Area for Agribusiness Development, helps its member countries identify and take advantage of market opportunities and help strengthen public and private institutions for the development and promotion of agribusinesses.

In January 2004, and thanks to the efforts of this Strategic Area, IICA set in motion the Interamerican Program for the Promotion of Trade, Agribusiness and Food Safety, with headquarters in Miami, FL, USA.

This initiative was created as response to the mandate of providing technical cooperation to strengthen the entrepreneurial capacities of the small and medium size agro-entrepreneurs in IICA member countries. It was also created to provide cooperation in the identification of market opportunities and with the aim to provide useful information to facilitate the decision making process to enhance trade.

The activities conducted to date, by the Directorate for Agribusiness Development and the Interamerican Program for the Promotion of Trade, Agribusiness and Food Safety, have identified a set of specific needs common to all the medium and small size agro-entrepreneurs in the Americas. The most important topics identified, are analyzed and presented under the general title of "Agribusiness Series". The objective of this Series is to enhance the competitive position of these agro-entrepreneurs. The section "Export Handbooks" contains a series of documents focused on providing instruments to facilitate the decision making process to successfully access international markets.

This document entitled "The United States Market: Guide to identifying the primary official requirements to import fresh and processed agricultural products", contains general information about each one of these requirements and facilitates access to official information of the US Government. As such, this is an informative document, that does not intend to present an exhaustive analysis of all aspects included in the current legislature, but rather be a guide document that allows access to more detailed information for all agro-exporters, and at the same time, allow

them to know, in an expedited fashion, all the requirements that could affect the success of their companies when exporting to USA.

The document was prepared based on information that is presented over the web by different official institutions. We would like to warn the reader and users of this guide that all official requirements could be modified, therefore it is recommended to visit official sources before any definitive action is taken.

To facilitate the access to the official information presented in this document, the Interamerican Program for the Promotion of Trade, Agribusiness and Food Safety, by way of its information system www.infoagro.net/agronegocios, put to the service of all the readers an electronic search system to help them to identify and access the specific requirements for the products that they want to export. Additional to the information regarding the USA, is information regarding requirements for the European Union and Canada.

This document has been prepared by Mr. Daniel Rodriguez Saenz, Agribusiness Specialist assigned to the Directorate for Agribusiness Development, who counted with the help and support of Ms. Eugenie Gamboa, intern at the Interamerican Program for the Promotion of Trade, Agribusiness and Food Safety. Mr. Quentin B. Kubicek, Agricultural Health & Food Safety Specialist assisted in editing the English version.

We hope that this guide will become an instrument of permanent consultation for small and medium agro-entrepreneurs. We also hope to contribute to the strengthening of their competitiveness and to the improvement of their conditions of livelihood.

Sincerely,

Miguel Garcia Winder

*Director for Agribusiness Development
Interamerican Program for the Promotion of Trade,
Agribusiness and Food Safety
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Food imports in the United States are subject to the fulfillment of diverse laws and regulations destined to protect human, animal, plant, and environmental health, as well as to guaranteeing that certain minimum requirements of quality and food safety are met.

This guide tries to present in a concise, easy, and comprehensive manner the primary requirements imposed by the United States of the America legislation for the import of produce (fruits and vegetables) and processed agricultural products and to facilitate the fulfillment of such requirements by small and medium sized agro- entrepreneurs of the Americas. It also intends to support the effort of those public and private institutions that promote exports.

To reach this objective, the guide has been structured as follows:

The first section makes reference to the US government agencies that are responsible for the regulation of produce and processed agricultural products imports.

The second section presents those requirements whose fulfillment is mandatory for all the agro-alimentary products that enter the USA. The information presented makes reference to the USA Public Health Security and Bioterrorism Preparedness and Response Act and to the newly enacted regulation for the usage of wood pallets.

The third section presents the requirements that produce must meet before they enter into the USA. This information will identify which products are admissible in the USA according to the country of origin; what are the maximum amounts of pesticides that may remain in or on foods; and to determine if there are specific Marketing Orders or quality standards.

The fourth section presents the requirements that processed products must meet before they enter into the USA. It makes reference to Good Manufacturing Practices (GMP), food labeling, acidified or low acid canned foods, colorants and food additives, ingredients and packaging and the hazard analysis and critical control points (HACCP).

Finally the fifth section contains reference to other elements that have an important role to identify possibilities of access to the USA market. The reader will find information related to organic products, tariffs, trade mark registration, and import quotas.





I. PRIMARY GOVERNMENT AGENCIES AND THEIR RESPONSIBILITIES

Regulations related to the imports of produce and processed agricultural products into the United States is not centralized but rather, depending on the type of product, several agencies and departments may be responsible for regulatory enforcement. Following are the primary agencies responsible for the importation of these products into the United States of the America.

The Animal and Plant Health Inspection Service is an agency of the United States Department of Agriculture (**USDA-APHIS**) responsible for the protection and promotion of the health of the agricultural sector. APHIS is responsible for the evaluation and assessment of those risks associated with the import of agricultural products.

The Agricultural Marketing Service is an agency of the United States Department of Agriculture (**AMS-USDA**) responsible for facilitating the marketing of agricultural products in domestic and international markets and promoting a competitive and efficient domestic marketplace. AMS is responsible for the establishment of quality norms and standards for produce.

The **Environmental Protection Agency (EPA)** is responsible for protecting human and environment health. EPA registers pesticide use in the US, prescribes labeling and other regulatory requirements to prevent unreasonable adverse effect on consumer or environmental health. EPA establishes the maximum legally permissible levels for pesticide residues in domestic or imported foods.

The **Food and Drug Administration (FDA)** is an agency of the Department of Health & Human Services responsible for protecting consumers against impure, unsafe, and fraudulently labeled food. FDA is responsible of the safety of all foods, with the exception of meat, poultry and some products containing eggs which are responsibility of the USDA.

Throughout the activities of the Center for Food Safety and Applied Nutrition (CFSAN) the FDA is responsible for the regulation of the following aspects:

- Anti Bio-terrorism Act
- Acidified and low-acid canned products
- Food additives, ingredients and packaging
- Food labeling
- Seafood and fish
- Inspection of pesticide residues in processed foods
- HACCP

To obtain additional information on each one of the agencies indicated above, Table 1 contains their respective internet addresses.

TABLE 1. INTERNET ADDRESSES OF THE PRIMARY INSTITUTIONS RESPONSIBLE FOR THE IMPORT OF FRESH AND PROCESSED AGRICULTURAL PRODUCTS INTO THE USA	
AGENCY	Web Address
USDA – APHIS	http://www.aphis.usda.gov
USDA – AMS	http://www.ams.usda.gov/fv
EPA	http://www.epa.gov/epahome/aboutepa.htm
FDA	http://www.cfsan.fda.gov

Source: Rodriguez, D. IICA, 2005.



II. GENERAL REQUIREMENTS

Within the framework of the United States of America legislation, there is a series of general regulations that apply to all food products without distinction as if they are fresh or processed.

This section makes reference to the USA Public Health Security and Bioterrorism Preparedness and Response Act, commonly known as the Anti Bioterrorism Law. This Law was promoted as response to the terrorist attacks of September 11th, 2001 and consists of a series of legal dispositions whose purpose is to improve the USA's ability to prevent and respond to a terrorist attack including one with biological agents, and also with the intent to improve the management of emergencies and the welfare of public health.

Reference is also made to the implementation of the directive issued to regulate the use of wood pallets in international trade (Food & Agriculture Organizations's International Plant Protection Convention ISPM 15) that affects all the wood pallets that enter the USA.

USA PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT

The Act for Public Health Security and Bioterrorism Preparedness and Response consists of five titles, the third one, entitled, "Protecting Safety and Security of Food Drug Supply", establishes a series of conditions that affect or could affect food exporters to the USA. A summary of each one of these requirements and their possible implication for exporters is presented.

Section 305: Registration of Food Facilities. This requirement establishes that anyone who wishes to export food products to the United States of America should be previously registered in an exporter data base, administered by the FDA. To be included in this data base, the exporters should submit the completed questionnaire "Facilities Registration" to the FDA.

The facilities subject to this requirement are those that manufacture, process, pack, or hold foods destined to human or animal consumption within the USA, according to FDA jurisdiction. As it was indicated in the previous section, FDA regulates all the food products with exception of meat, poultry and some products manufactured with eggs, whose responsibility falls with the USDA.

The "Facility Registration" must be done only once and has no cost. However it is advised that in case that there are any changes in the original information an exporter should update his registration or register again.

To obtain more information about this process, you can access the following internet address:

<http://www.cfsan.fda.gov/~dms/fsbtact.html#oct2003>

Sección 307: Prior Notice of Imported Food Shipments.

The FDA requests that any shipment of food or feed subject to the "Bioterrorism Act" be notified prior to its arrival into the United States with the intention to review, evaluate and, make judgment of the information presented, and to determine if the products need to be inspected or not.

The prior notification should be done by completing the respective questionnaire that needs to be received and confirmed by the FDA no more than five days before or less than two hours prior to the arrival of the shipment by land; four hours if by railroad; or eight hours if by ship.

If you require further information on this subject, as well as to obtain a copy of the required questionnaire to present the prior notification, it is recommended that you access the following internet address:

<http://www.cfsan.fda.gov/~dms/fsbtact.html#pn>

Section 306: Maintenance and Inspection of Records for

Foods. With the aim to improve the control and supervision of food products that are sold within the USA, the FDA request that exporters and importers establish and keep appropriate records related with the manufacturing, processing, packaging, distribution, reception, storage, and imports of all the products that are exported to the USA.

This requirement is obligatory for all persons (individuals, societies, corporations, and associations) that manufacture, process, packs, transport, distribute, receive, store, or import food and feed products, as well as for all foreigners that transport food to the USA.

Foreign entities are excluded, except those that use their own means to transport food into the USA.

To obtain more information with regard to this topic you can visit the following internet address:

<http://www.cfsan.fda.gov/~dms/fsbtact.html#pn>

Despite the fact that at the present time it is not obligatory to maintain records for those foreign companies that do not use their own means of transportation to send products into the USA, it is advisable that all companies maintain their own record system to assure proper traceability.

Section 303: Administrative Detention.

Administrative detention consists on the administrative authority the FDA has to retain or to seize food or feed products if they have evidence or credible information that the food shipped represents a threat of negative and grave consequences for the health or can cause death to humans or animals within the USA.

To obtain more information with regard to this topic you can visit the following internet address:

<http://www.cfsan.fda.gov/~dms/fsbtact.html#pn>

Additionally, visiting the Directorate for Agribusiness Development and the Interamerican Program for the Promotion of Trade, Agribusiness and Food Safety information system at www.infoagro.net/agronegocios you will find

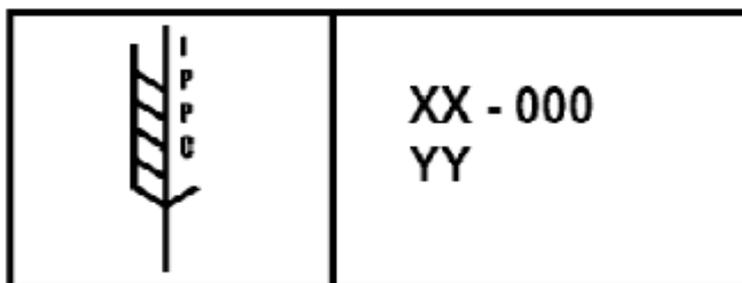
the document entitled "What every agro-exporter needs to know about the Bioterrorism Law", which offers detailed information on this law and on each of the sections discussed above.

WOOD PACKAGING

Since September 16, 2005, all wood packaging material entering the USA must be treated to prevent pest infestations and be marked, as noted below, on two sides confirming that the wood has been treated according to the Food and Agriculture Organizations's International Plant Protection Convention (IPPC) International Standards for Phytosanitary Measures (ISPM) 15: "Guidelines for regulating wood packaging material in international trade".

Two treatments have been approved: heat treatment and fumigation with methyl bromide.

With regard to the required mark, all wood packaging must contain the following seal:



- The symbol at the left represents the symbol for the International Plant Protection Convention (IPPC)
- XX, represents the country code where the wood was treated
- 000, this is the number assigned to the wood packaging producer by the National Organization for Plant Protection.
- YY represents the type of treatment used (Heat Treatment = HT, fumigation with Methyl Bromide = MB)

The implementation of the ISPM 15 standard will take place in three phases:

- Phase 1: September 16, 2005 through January 31, 2006 USDA shall implement an Informed Compliance via account managers and notices posted in connection with cargo that contains noncompliant wood packaging material. This stage of the enforcement phase has concluded.
- Phase 2: February 1, 2006 through July 4, 2006 USDA shall reject violative crates and pallets and refuse entry into the USA. . Informed compliance via account managers and notices posted in cargo with other types of non compliant wood packaging material (dunnage, blocking and bracing) shall remain enforce through July 5, 2006.
- Phase 3. Beginning July 5, 2006. USDA will fully enforce ISPM 15 on all articles of regulated wood packing materials entering USA. Non compliant regulated wood packaging material will be refused and not be allowed to enter USA.

ISPM 15 establishes that any shipment that contains pallets or crates made using wood packaging material that does not meet the criteria established in the ruling, will be returned to the country of origin. This implies that if a single pallet, within a container, is not properly treated or marked, all the contents of the container will be returned to the country of origin. At the present time the regulation does not allow for the treatment of foreign wood packaging in USA.

To identify those companies that treat wood packaging materials according to the regulations established in the ISPM 15, it is recommended that exporters and shippers contact their national plant protection organization for a list of these companies.

For more information on this topic, approved treatments of wood packaging material and marks we recommend the reader visit the following internet address: <http://www.aphis.usda.gov/ppq/wpm/>

III. REQUIREMENTS FOR THE ENTRANCE OF PRODUCTS

The first thing that a person interested in exporting produce into the USA needs to do is to verify if these products can enter the market or if they have some type of phytosanitary restriction. This process is known as admissibility verification. This section describes the steps that are needed to determine if a product is admissible depending of the country of origin. Following information is presented regarding the maximum permissible limits of pesticides residues in food, marketing orders and quality standards.

PRODUCT ADMISIBILITY

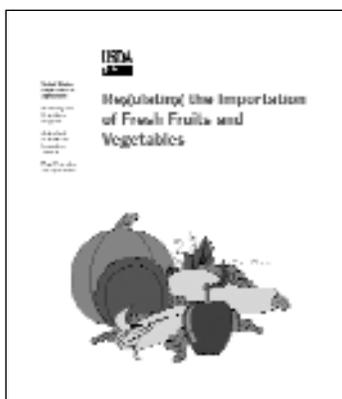
Quarantine regulations issued by the USDA for plants can be of two classes: prohibitory or restrictive. The prohibitory class does not allow the entry of products for which there is no approved treatment for quarantine pests which does not guarantee complete control. The restrictive class allows the entry of product that are treated or are under an inspection process. The process to identify if a product can or cannot enter into the market is known as product admissibility verification.

To determine if your product is admissible or not, you must follow the next steps:

1. Access the PPQ Electronic Manuals

http://www.aphis.usda.gov/ppq/manuals/online_manuals.html

2. In *"Port Programs, Plant Import: Nonpropagative Volume of Manuals"*, select *"Fruits and Vegetables"*.
3. Select the document *Fruits and Vegetables "Regulating the importation of fresh fruits and vegetables"*.



4. Look for the respective country
5. Verify if the product is included in the list. If the product is not included in the list it is because it is not admissible. It is recommended to verify this information with the USDA representative located at the US Embassy in the respective country or to directly contact APHIS.

MAXIMUM PERMISSIBLE LIMITS FOR PESTICIDES RESIDUES ALLOWED IN FOOD

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes EPA to oversee the registration of all pesticides used in the USA and also authorizes EPA to establish the limits of tolerance for pesticide residues that can be found in domestic or imported food products.

The tolerance limits (maximum permissible limits) of pesticide products can be identified in two ways:

- a. By agricultural product which allows determining the maximum limits to different agrochemicals in a specific product; or

- b. By chemical product which allows determining the maximum tolerance in a specific agricultural product.

This information can be obtained accessing the following internet address:

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

MARKETING ORDERS

The marketing orders and marketing agreements are instruments designed to enhance the marketing of fruits, vegetables and specialty crops and stabilize market conditions for fruits and vegetables marketed within the USA. Marketing orders are voluntary instruments requested by an agricultural commodity sector or within a specific geographical region. Federal oversight is provided by the USDA's Agricultural Marketing Service (AMS) to guarantee the fulfillment of these orders and agreements on behalf of producers and handlers of fruits, vegetables, and specialty crops.

Marketing orders and agreements may: maintain the high quality produce that is on the market; standardize packages and containers; regulate the flow of product to market; establish reserve pools for storable commodities; and authorize production research, marketing research and development, and advertising.

Once the establishment of an order is approved, the order becomes mandatory to all the agents related to the product in a specific region (for example citrus in Florida). Generally these orders do not operate the entire year, but only during some months, that in most cases coincides with the time of local production.

Marketing orders specify that each time that a new marketing order with regard to the grade, size, quality, or degree of ripeness of the product is issued that it be applicable to imported products.

At the present time, there are marketing orders applicable to oranges and grapefruits, avocado, nectarines, peaches, kiwi, apricot, cherries, prunes, grapes, olives (excluding Spanish varieties), potatoes, onions, cantaloupes, hazelnut, dates, raisins, tomatoes and nuts.

If you want more information as well as to know what orders are currently operating you can access the following internet address:

<http://www.ams.usda.gov/FV/moab.html>

QUALITY STANDARDS

The USDA's Agricultural Marketing Service (AMS) promotes the program known as Product Classification and Quality Certification as a means to facilitate the marketing of fresh and processed fruits and vegetables within the USA. With this purpose AMS has defined official quality standards for more than 158 products. These norms describe the quality attributes that need to be met by a product in order to be classified within specific categories, it is expected that with these actions the industry will have a common language at the time of purchasing or selling those products.

The utilization of these norms is not mandatory for the imported products, unless there is a specific reference to a quality grade defined by AMS or that these are included within a Marketing Order.

The list of products for which there are quality standards, as well as the general quality norms, can be accessed at the following internet address:

<http://www.ams.usda.gov/standards/stanfrfv.htm>

IV. REQUIREMENTS FOR THE ENTRY OF PROCESSED PRODUCTS

All food products marketed in the USA must comply with the health and safety standards defined by the Food, Drug and Cosmetic Act (FDCA) which is administered by the Food and Drug Administration (FDA). The FDCA prohibits the interstate trade of food that is not properly labeled or that is adulterated. FDA also regulates the additives and colorants that can be used in foods.

To guarantee the fulfillment of the FDCA, the FDA has established the following requirements: implementation of good manufacturing practices, food labeling, acidified and low acid canned products, food additives, ingredients and packaging, and Hazard Analysis and Critical Control Points (HACCP).

GOOD MANUFACTURING PRACTICES (GMP)

The FDCA gives FDA the authority to establish and impose reasonable sanitary norms for the production, processing, handling, and other measures of food. The FDA requires that any food processor apply good manufacturing practices (GMP) in labor, buildings and facilities, equipment and production process, to assure that all the food produced is safe. This applies to either, local processors as well as to those in foreign countries that desire to export products into the USA.

In the following internet address you may find current GMP guidelines:

<http://vm.cfsan.fda.gov/~lrd/cfr110.html>

FOOD LABELING

The FDA has federal oversight for label requirements under FDCA and the Fair Packaging and Labeling Act (FPLA). FDCA defines the requirements for most processed food products, for example bread, cereal, canned, and frozen foods, snacks, desserts, and beverages. FDCA requires two types of labeling for all processed food: general and nutritional. Fresh agricultural products are considered to be conventional food.

A summary of the general and nutritional labeling requirements is presented in the following paragraphs. If you need more information on this topic, it is recommended to visit the following internet address: <http://www.cfsan.fda.gov/label.html>. Additionally, in the following internet address you will find a guide to help you meet the labeling requirements provided by the FDA: <http://www.cfsan.fda.gov/~dms/flg-toc.html>.

General Food Labeling: The general food labeling information must be presented in English, using measurement units of the English system. For imported foods the country of origin they should be specified. For the general food labeling it is necessary to consider the following elements:

- The common or usual name for the food
- The exact net content (weight, volume)
- The name and address of the producer, packager or distributor
- The complete list of ingredients, listed in descending order of the amount present in the final product

Nutrition Labeling: To comply with the nutrition labeling, the manufacturers should present information with regard the following nutrients. The different components are listed in the order that should appear in the label. The voluntary components are denoted by an asterisk, the rest are obligatory:

- Total Calories
- Calories From Fat
- Calories From Saturated Fat*
- Total Fat

- Saturated Fat
- Polysaturated Fat*
- Monosaturated Fat*
- Cholesterol
- Sodium
- Potassium
- Total Carbohydrates
- Dietary Fiber
- Soluble Fiber*
- Insoluble Fiber*
- Sugars
- Sugar Alcohol*
- Other Carbohydrates*
- Protein
- Vitamin A
- Percent of Vitamin A Present as Beta-carotene*
- Vitamin C
- Iron
- Other essential vitamins and minerals*

Nutrient Content Claims: These are claims that determine, either by direct affirmation or inference, the level of a certain nutrient in a food. For example “low in fat” or “high in oats”. Following there is a list with allowed affirmations:

- Free
- Low (*can be related to fat, saturated fat, sodium, cholesterol, or calories*)
- High...Good source of
- Reduced
- Less
- Light
- More

For each one of these claims, the legislation has defined the parameters that must be met. For further information please refer to Appendixes A and B of the guide distributed by FDA available at the following internet address:

www.cfsan.fda.gov/label.html

Health Claims: FDA currently allows 11 types of claims that can relate a nutrient or a food with the risk to certain diseases or with other health aspects. The allowed claims are:

- Calcium and osteoporosis
- Fat and cancer
- Saturated, cholesterol, and coronary heart disease
- Fiber-containing grain products, fruits, vegetables and cancer
- Fruits, vegetables and grain products that contain fiber and risk of coronary heart disease
- Sodium and hypertension
- Fruits, vegetables and cancer
- Folic acid and neural tube defects
- Dietary sugar alcohols and dental caries
- Soluble fiber from certain foods, such as whole oats and phylum seed husk and heart disease
- Plant sterol esters and coronary heart disease

For each one of the approved claims, FDA has defined the requirements for food and the affirmations as such; additionally the FDA provides models for the use in each one of them. In the Appendix C of the FDA labeling guide, you can find further information with regard to this topic.

To facilitate the comprehension of the health claims, following you will find an example for the relationship between sodium and hypertension.

TABLE 2. Example of Health Claim			
Approved Claim	Food Requirement	Required Terms	Example of Claim
Sodium and Hypertension 21CFR 101.74	Low Sodium	Low sodium- "Sodium", "High blood pressure" Includes physician statement (Individuals with high blood pressure should consult their physicians) if claim defines high or normal blood pressure	Diets low in sodium may reduce the risk of high blood pressure a disease associated with many factors

Source: Labeling Guide FDA.

ACIDIFIED AND LOW-ACID CANNED FOODS

FDA recognizes as low acid foods any food, other than alcoholic beverages with a finished equilibrium pH value greater than 4.6, a water activity greater than 0.85 and that are sold in hermetically sealed containers. On the other hand, the FDA considers as acidified products those products that have a pH of 4.6 or below and have a water activity greater than 0.85.

FDA regulations establish that all manufacturers of low acid or acidified products that wish to market their product within the USA must register their plants to obtain the Food Canning Establishment Number (FCE), additionally for each product that they wish to market they must obtain a registration known as the Submission Identifier (SID).

For more information regarding FDA requirements for registration, processing and manufacturing these types of products, you can review the following internet address:

<http://www.cfsan.fda.gov/~comm/lacf-toc.html>.

FOOD ADDITIVES AND COLORANTS

FDA has prepared a list of all substances that have been approved for use as food colorants. If you wish to know what food colorants are approved you can find the corresponding list at the following internet address:

<http://www.cfsan.fda.gov/~dms/col-toc.html>

Any new colorant should be approved by FDA before it can be used in food that is marketed within the USA. Once they are approved, the FDA determines in which food they can be used, as well as the maximum permissible quantities and how this colorant needs to be identified in the label.

FOOD INGREDIENTS AND PACKAGING

FDA has defined a list of substances that can be used as direct or indirect additives in food. Direct additives are considered to be those additives that are added directly to the food, while indirect additives are those substances

that indirectly enter in contact with the food, for example the packaging materials. The list of permissible substances can be found in the following internet address:

<http://www.cfsan.fda.gov/~lrd/foodadd.html>

For further information on additives you can visit also the following internet addresses:

- Direct additives: <http://www.cfsan.fda.gov/~dms/eafus.html>
- Indirect additives: <http://www.cfsan.fda.gov/~dms/opa-indt.html>

HACCP (HAZARD ANALYSIS AND CRITICAL CONTROL POINTS)

FDA has adopted the food protection system known as HACCP which has world wide recognition as a systematic and preventive approach that considers all the biological, chemical and physical risks by anticipating and preventing them, and to avoid diseases caused by food that have been improperly managed during production and distribution stages.

At the present time, this system is mandatory for all seafood products and for orange juice production. Additionally there is a voluntary program for Grade A dairy products.

For further information you can consult the following internet address:

<http://www.cfsan.fda.gov/~lrd/haccp.html>

V. OTHER IMPORTANT ASPECTS THAT NEED TO BE CONSIDERED

In this section, other elements that have an important role in identifying if products from Latin America and the Caribbean have access to the USA are presented. Specifically the reader will find information relative to tariffs, import quotes, and trade mark registration. A brief reference to the requirements that need to be met by those products that are intended to be marketed as "organic" within the USA is also presented.

TARIFFS

Tariffs are fiscal charges that governments impose as a percentage of the value of the product to be imported. In some cases, particularly with respect to agricultural products, special tariffs are applied and in some cases they are expressed as a fixed monetary amount per quantity or volume of an imported product.

Tariffs, for both fresh and processed agricultural products, can be identified by each particular product or a tariff fraction in the following internet address:

<http://dataweb.usitc.gov/scripts/tariff2004.asp>

IMPORT QUOTAS

A contingent or import quota is a volume or amount of the total imports of a specific product, that a country commits to accept in its market as part of the minimum access market quota or regular access quota that is given to other particular country without restrictive measurement for such product.

In the USA, import quotas are administered by the US Custom Service and there are two types:

Absolute Quotas. These consist on limits to the physical quantities that can be imported into the USA during a specific period of time, either from specific countries or as a whole. Once this quota is met, further imports are not allowed.

Tariff Rate. These permit the importation of goods at a preferential tariff rate during a specific period of time, known as the quota period. Once the quota has been reached, the product can continue to be imported, but the tariff will be higher.

To obtain further information on this topic, it is recommended to visit the following internet address:

<http://www.usitc.gov/tata/hts/bychapter/index.htm>

TRADE MARK REGISTRATION

A trade mark is a word, symbol, design or a combination of these elements that allow a product or service that a person or organization produces to be differentiated in the market.

Registering a trade mark is important since it is evidence of exclusive property within a specific country, in this case in the USA and grants possibilities to protect the owner's rights in case of possible violators.

The United States Patent and Trademark Office (USPTO) is the entity responsible for processing applications of trademark registrations and determines if an applicant meets or not with the requirements to be granted a federal registration.

To obtain more information on how to present an application for registration of a trade mark, you can visit the following internet address:

<http://www.uspto.gov/main/trademarks.htm>.

ORGANIC PRODUCTS

Organic growers that want to participate in the National Organic Program (NOP) of the USDA must abide by NOP requirements. Only products that are produced and handled in accordance with provision of the NOP can be labeled as organic. The NOP defines all the requirements for the production, processing, packaging, labeling, storage, and distribution of organic products. The only possible way to market a product as organic in the USA is to be sure that it has received the certification approved by the USDA.

If you desire more information about the organic products, as well as a list of possible certification agents in your country you can visit the following internet address:

<http://www.ams.usda.gov/nop/indexIE.htm>

VI. LIST OF REQUIREMENTS THAT NEED TO BE MET BY EXPORTERS ACCORDING TO THE TYPE OF PRODUCT

To facilitate the identification and fulfillment of the primary requirements that are required to enter into the USA market, following you will find a list of the actions that need to be taken according to the type of product.

EXPORTERS OF FRESH AGRICULTURAL PRODUCTS

Exporters of fresh agricultural products must be sure to comply with the following aspects:

1. Register as an exporter with the FDA according to what is determined by the "Anti Bioterrorism Act".
2. Comply with the requirements of previous notification according to what is requested by the "Anti Bioterrorism Act".
3. Be sure that wood packaging materials meet ISPM 15 norm.
4. Verify that the products are admissible into the USA.
5. Assure that all the products meet the requirements related with the maximum level of pesticides residues permitted in food and phytosanitary requirements.
6. Verify the existence of Marketing Orders and comply with them if they are active.

7. Verify the existence of quality standards especially in the case that the buyer is requesting specific grades.
8. Know the tariffs that must be paid by the product at the time of entrance into the USA.
9. Identify the existence of import quotas into the USA.
10. Register the trademark in case that there is interest to sell the product with your own brand.
11. Meet the requirements set by the National Organic Program of USDA if you desire to sell your product as organic.

EXPORTERS OF PROCESSED PRODUCTS

Exporters of processed agricultural products must be sure to comply with the following aspects:

1. Register as an exporter with the FDA according to what is determined by the "Anti Bioterrorism Act".
2. Comply with the requirements of previous notification according to what is requested by the "Anti Bioterrorism Act".
3. Be sure that wood packaging materials meet ISPM 15 norm.
4. Meet the GMP requirements.
5. Meet all labeling requirements.
6. In case of producing low acid or acidified foods, be sure that each one of the products to be exported has the Food Canning Establishment Number (FCE) and the Submission Identifier (SID).
7. Meet all FDA requirements for food colorants.
8. Meet all FDA requirements for direct and indirect additives.
9. Be sure to have an approved HACCP system in place, if the products are orange juice or seafood.
10. Know the tariffs that must be paid by the product at the time of entrance into the USA.
11. Identify the existence of import quotas into the USA.
12. Register the trademark in case that there is interest to sell the product with your own brand.
13. Meet the requirements set by the National Organic Program of USDA if you desire to sell your product as organic.

