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Date: 1/12/2016 GAIN Report Number:

Costa Rica

Food and Agricultural Import Regulations and Standards -Narrative

FAIRS Country Report

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Report Highlights:

This report outlines Costa Rica's requirements for food and agricultural product imports. Most sections of the report have been updated and hyperlinks for relevant regulatory agencies and regulations have been provided throughout the report.

Disclaimer: This report was prepared by the USDA/Foreign Agricultural Service in San José, Costa Rica for U.S. exporters of domestic food and agricultural products. While every possible care has been taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since

its preparation, or because clear and consistent information about these policies is not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

Section I. Food Laws:

The Costa Rican legislation dealing with food and agricultural imports has not undergone significant change over the last few years. However, the process of consolidation of a Central American Customs Union has resulted in changes in some regulations such as the harmonization of registration and nutritional labeling requirements throughout the region as well as new microbiological criteria for food products. Additional regional regulations were harmonized during 2012 as Central American countries reached agreements on several regulations, including labeling of packaged foods, nutritional labeling of food products, and additives. Regional Technical Standards for different food products have also been introduced over time, and work on standards for specific food products continues in the region. It is therefore important for exporters to review the introduction of new regulations periodically. Exporters can visit the following Ministry of Foreign Trade website for updates on new regulations: Resoluciones COMIECO Also, a comprehensive list of food regulations is available at the Ministry of Health's processed food registration website at the following link: Food Product Regulations

Several government institutions are involved in the procedures to control food and agricultural imports into Costa Rica. The main ones are the Ministry of Health, the Ministry of Agriculture (MAG), and the Ministry of Economy, Industry and Commerce (MEIC).

The Ministry of Agriculture has responsibility over imports of fresh plant and animal origin products, veterinary products, animal feed, and agricultural inputs such as fertilizer and pesticides. The Ministry of Health is responsible for the registration of processed food products and has oversight over food additive regulations. Labeling requirements are enforced by the Costa Rican Ministry of Economy's Consumer's Support Department. The Ministry of Economy does not approve or reject labels. Instead, producers and importers must comply with current labeling regulations. Significant fines and other measures, such as removal of the product from the marketplace, are applied to companies whose products are found without a label that complies with the current legislation.

Costa Rica, as part of the Central American Customs Union, also signed the Central American Technical Regulation on "Nutritional Labeling of Prepackaged Food Products for Human Consumption for the Population Older than 3 Years." This regulation was published in Costa Rica as Executive Decree 37100 COMEX-MEIC-S. This regulation entered into effect on July 2, 2012, and requires listing nutrients such as total fat, saturated fat, carbohydrates, sodium, protein and energetic value in the label of prepackaged food products.

Facility Registration:

With the exception of dairy products processing plants, Costa Rica does not require facility registration. Dairy product exporters should contact the Costa Rican Ministry of Agriculture's National Animal Health Service to verify whether the product intended to be exported requires registration. The process (which is documentary and does not require audits/inspections) is handled by SENASA's Quarantine Department (see Appendix I: Government Regulatory Agency Contacts for contact information).

Product Registration:

Imported food products must be registered prior to importation at the Ministry of Health's Registration

and Control Department (Ministerio de Salud, Dirección de Registros y Controles.) Registration is valid for five years and products are usually registered by importers. However, once a product is registered it may be imported by a company other than the one which originally registered it. For this reason, importers sometimes ask suppliers to share in the costs for the registration process. If a company wants to import a product that has already been registered, the company must still pay the full registration fee, which is currently set at \$100 per product.

According to the Ministry of Health's regulations, once all the required information is submitted, Ministry of Health officials review the information and grant or deny the registration. If the registration is denied, the importer is informed of the reason(s), for instance, missing information, and is allowed to submit the required documentation. The Ministry of Health has one month after all the required documentation is submitted to process the registration request. However, because of the large number of registration requests, the registration process may take longer to complete. According to industry sources, the registration process for new products currently varies from one to two months, with waiting times increasing during peak periods (near Easter Week, or in the months prior to year end.)

The Ministry of Health implemented a new digital registration process for products under its supervision, including drugs, processed food products, cosmetics, bio-medical equipment, and natural products. The implementation of the new system has proceeded in stages, starting with drugs during October and November of 2013. Processed food products began registration using the new system during November and December of 2013. Registration, renovation, and post-registration changes are now completed using the new system. The new system has several goals, such as reducing the number of pending registration requests, reducing the waiting time to obtain approval of an application, standardizing the procedures, and eliminating paperwork. The new system operates with a digital signature and digital copies of the required documentation. The required documentation is the same as before (please see below), although the time required to obtain approval is expected to be reduced. However, the private sector still reports problems and delays as the number of applications for registration continues to increase over time. According to importers, although the digital system has accomplished the stated goal of simplification, the bottleneck continues to be the lack of sufficient personnel at the Ministry, who ultimately have to review the applications. Additional information regarding the registration system may be obtained by visiting the following website: <u>Registrelo</u>

According to a government decree, for registration purposes, food products are classified as food products, additives, and raw materials. According to the General Health Law, if a product claims to have health related benefits, the products will be classified as a medicine or drug and the registration process may be different from that described below.

To register a product, the following documents must be submitted:

- Registration request form signed by the legal representative of the company.
- Free sale certificate issued by the health or other appropriate authority of the country of origin, indicating that the products being exported to Costa Rica are allowed for free sale and consumption in the country of origin. This document no longer needs to be authenticated by the Costa Rican consul or countersigned by the Costa Rican Ministry of Foreign Relations. Since Costa Rica joined the Hague Convention on Apostille, effective on December 14, 2011, the free

sale certificate now only requires an Apostille issued in the United States by the State Department of the state where the free sale certificate was issued. The document may include one or several products and must be less than two years old. If the document is written in a language other than Spanish, it must be accompanied by an official translation.

- Original label of the product. If the label is in a language other than Spanish, an official translation of the label must also be attached. If the label is printed directly on the container, an original container and a copy of the label must be submitted.
- Paid receipt of the registration fee, which according to current regulations is \$100 per product.

Additional Information

The certificates must be submitted in Spanish. If they are submitted in another language, an official translation from the Ministry of Foreign Relations must accompany the certificate.

Additional information on the registration process as well as specific forms to be filled out may be obtained by contacting the Ministry of Health's Services Platform at the phone number listed in the contacts section in Appendix I.

Post has been informed that the Ministry of Health is planning to make some changes to the registration process during 2016. The changes are intended to facilitate registration of food products that are considered as "low risk." Post will report on the changes in a separate report as soon as they are implemented.

Requirements to Renew the Registration of Imported Food Products

Registration must be renewed every five years. The same requirements listed above are needed for renewal.

Requirements for the Importation of Processed Foods for Exhibition or Tasting Purposes

On April 30, 2007, the GOCR published a regulation for the importation of food products for tasting and exhibition purposes. According to this regulation, the importer must fill out a form indicating the name, brand, quantity and origin of the products to be imported. The form also asks whether the products are for exhibition or tasting, where the activity is going to be held and the dates of the event. The products must be labeled with a sticker indicating: "Prohibida su venta" (Not for sale). Products imported for tasting and exhibition cannot be sold. The products imported under this procedure must comply with any sanitary or phytosanitary requirements that apply to the specific product. The import authorization will be resolved by the Ministry of Health within 10 working days.

Section II. Labeling Requirements:

According to the Central American Technical Regulation on General Labeling of Prepackaged Food Products (RTCA 67.01.07.10), published in Costa Rica as <u>Executive Decree 37280-COMEX-MEIC-S</u> in June 2012, with an implementation date of November 14, 2012, all imported food products must have labels in Spanish. Despite this language requirement, other languages may be used as well, as long as the required information is also included in Spanish. The information below must appear on the product

label in Spanish, except when indicated otherwise by a national standard or by the Codex *Alimentarius*. Stick-on labels are allowed.

- Product name.
- Net content and drained weight in international system units.
- Artificial color and flavors (if any).
- Ministry of Health registration number
- Ingredients listed in decreasing order, by weight.
- Importer's name and address.
- Lot number and expiration date.
- Country of origin.
- Preservation and use instructions.

Mandatory Labeling of Previously Packed Food Products

The information below must be clearly shown on the label of prepackaged food products, as applicable to the product to be labeled, except when otherwise stated by a national regulation or standard in the Codex *Alimentarius*:

Name of food product

- The product's name must clearly indicate the nature of that food product and normally it must be a specific, rather than a general name.
- If one of several names for a food product has been established in Costa Rica's national standards or in a standard in the Codex *Alimentarius*, at least one of these names must be used.
- In the absence of these names, a common or usual name established by common use must be used as a descriptive term, in order to avoid deceiving or misleading consumers.
- A coined, imaginary, factory name or trademark can be used, provided one of the names mentioned in the above regulations is also used.
- Traditionally required words or phrases must appear on the label, next to or very near the name of the food product. This is intended to avoid deceiving or misleading the consumer in relation to the nature and status of the product, including but no limited to type, presentation, status, and treatment of the product, e.g., dehydration, concentration, reconstitution, or smoke treatment.

List of ingredients

- Except in the case of single-ingredient food products, a list of the ingredients must appear on the product label.
- The term "Ingredients" must be written before the list or as the first word in the list.
- All ingredients must be listed in decreasing weight order at the time of production.
- Whenever an ingredient is the result of the mix of two or more ingredients, it may be stated as an ingredient in the list, and it can be accompanied by a list (in parenthesis) of its components stated in decreasing weight order. This requirement does not apply to composite ingredients with a specific name in a national standard or in a standard in the Codex *Alimentarius*, accounting for less than 25 percent of the food product, except for food additives that play a technological role

in the finished product.

- Added water must be indicated in the list of ingredients, except when it is a part of an ingredient, such as brine, syrup, or broth used in a composite food product and stated as such in the list of ingredients. Volatile ingredients (such as water and others) used in the manufacturing process need not be stated.
- As an alternative to general declarations in this section, in the case of condensed and dehydrated food products intended for reconstitution, ingredients can be stated in order of proportion in the reconstituted product, provided an indication such as this is included "Product ingredient when prepared as per this label."

•	The following	general names	can be used	for ingredients ir	n each of the fo	llowing kinds:

Type of ingredients	General names
Refined oil different from olive oil	Oil, together with the term "vegetable," "animal" as modified by the term "partially hydrogenated" or "totally hydrogenated," as applicable
Refined fats	Fats, together with the term "vegetable," "animal," as applicable
Starch	Different types of starch; chemically-modified starch
Fish	All sorts of fish, whenever fish is an ingredient for other food product, provided the label and presentation of the product do not refer to a specific type of fish
Poultry	All sorts of poultry, whenever poultry is an ingredient for other food product, provided the label and the presentation of the product do not refer to a specific type of bird
Cheese	All sorts of cheese, whenever that cheese or mix of different types of cheese is an ingredient for other food product, provided the label and the presentation of the product do not refer to a specific type of cheese
Spices or spice	All sorts of spice and spice extract in amounts not above 2% of product
mixes, as	weight, either alone or mixed in the product
appropriate	
Aromatic herbs or aromatic herbs mixes	All aromatic herbs or parts of aromatic herbs in amounts not above 2% of product weight, either alone or mixed in the product
Base gum	All sorts of gum mixes used to manufacture base gum for chewing gum manufacturing
Sugar, dextrose, or glucose	All sorts of sacarose, monohydrated dextrose and anhydrous dextrose
Casein	All sorts of caseins
Cocoa butter	Cocoa butter obtained either through pressure, extraction, or refining
Candied fruit	All sorts of candied fruit in amounts no above 10% of product weight

- Despite what is stated in relation to general names, lard, shortening, and tallow must always be stated by specific name.
- In the case of food additives allowed for food products in general, the following general names must be used together with the specific name or identification number accepted in the general legislation.

Flavor intensifier	Acid
Antiaglutinant agent	Antiaglutinant
Antisparkling agent	Antioxidant
Dying agent	Sweetener
Emulsifier	Thickener
Sparkling agent	Stabilizer
Gasifer	Freezing agent
Moisturizing agent	Volume expander
Starter	Acidity regulator
Emulsifier salt	Preservative substance
Color preserver	Flour treating substance
Glazing substance	

- The following general titles can be used in the case of specific food additives listed as authorized additives in the national lists of food additives or in the Codex *Alimentarius*:
 - Scents and aromatizing substances.
 - Modified starches.
 - The terms "scents" can be modified by other terms such as "natural," "natural-like," "man-made" or a combination of these.
- Aids in the manufacturing and transference of food additives:
- All food additives used in raw materials or other food ingredients and thus transferred in significant quantities to accomplish a technological function in the food product, will appear in the list of ingredients.
- Food additives transferred to food products in quantities below those required to accomplish a technological function in the food product, as well as aids in product manufacturing, will not appear in the list of ingredients.

Hypersensitivity

All food additives and ingredients that may cause an allergy or an undesired effect in people, such as skin irritation, inflammation of respiratory ways, among others, must be declared even though they may only be present in the food product without forming an essential part of it. Examples of these products include: eggs and egg products, fish and fish products, gluten containing cereals, peanuts, milk and milk products.

Net content and drained weight

Net content must appear in the same visual field as the name of the product.

- Net content must be stated in the International System of Units as follows:
 - i. Volume, for liquid food products (Ml, Liters, etc).
 - ii. Weight, for solid, semisolid or viscose food products (grams, kg, etc).

• In addition to stating net content, in the case of food packed in liquid the drained weight of the product must be stated in the International System of Units. For these purposes, "liquid" must be understood as water, water solutions of salt or sugar, fruit juice, vegetables, fruit and vegetable preserves only, and vinegars, either pure or mixed.

Name and address

The manufacturer's name and address as well as those for the packer, distributor, importer, exporter or seller of the product must be stated. In the case of imported products, the name and address that should appear is that of the importer or local distributor.

Country of origin

- The name of the country of origin must be stated.
- For labeling purposes, whenever food products undergo manufacturing treatments that result in a change of nature in a country different than their country of origin, the latter country will be held as the product's country of origin.

Lot ID

The lot ID must appear on each package, either written in plain language or in code, printed in any manner, provided it is un-erasable. The product's expiration date can be used as lot ID.

Dating and preservation instructions

- Unless otherwise determined in a national standard or a standard in the Codex *Alimentarius*, the following dating procedure will be applied:
 - i. The expiration date must be stated.
 - ii. This will include, at least, month and day for products with minimum expiration dates not beyond three months. Month and year for products with minimum expiration dates beyond three months. In the case of December, only the year must be stated.
 - iii. The expiration date must be stated with "Better before" to indicate a specific day, and "Better before the last day of" in all other cases.
 - iv. The words stated in (iii) above must be accompanied by the date itself or a reference to the place where the date is printed.
 - v. Day, month, and year (in that that order) must be stated in numerical, non-coded, order. The name of the month can be fully written.
 - vi. Despite regulation 4.7.1. (i), no indication is required for minimum expiration dates in the case of fresh fruit and vegetables, including potatoes not yet peeled, cut or treated in any other way. The same is true for: liquor wines, sparkling wine, aromatized wines, fruit wines, and sparkling fruit wines and alcoholic beverages with 10% alcohol or more per volume; bakery goods that, due to their nature, are intended for consumption at most 24 hours after manufacturing; vinegar, salt as food ingredient, solid sugar; candy goods made of aromatized and colored sugar; chewing gum; and specific food products exempted by Product Committees, either from national or from the Codex.

• In addition to the expiration date, any special conditions required for preservation must be stated in the label, provided validity of the expiration dates depends on these.

Instructions for use

The product label must indicate all directions required for product use, including reconstitution, if needed, in order to ensure appropriate use of the product.

Additional Mandatory Requirements

Quantity labeling of ingredients

- Whenever the label indicates the existence of one or more valuable, characterizing ingredients, or when this effect results from describing the food product, the initial percentage of the ingredient at the time of manufacturing must be stated.
- Likewise, when a product label highlights a low content of one or more ingredients, the percentage of the ingredient in the final product must be stated.
- Reference made in the name of a food product to a given ingredient will not imply, per se, it is given special relevance. Reference made in the product label to an ingredient used in a small quantity or merely as an aromatizer will not imply, per se, it is given special relevance.

Ministry of Health Registration Number

All products must have a Ministry of Health Registration Number, showing that the product was registered with the Ministry of Health.

Exemptions from Mandatory Labeling Requirements

Except in the case of spices and aromatic herbs, small units with package surface of less than 10 cm^2 can be exempted of those requirements stated in the above subsections.

Optional Labeling

• Labels can show any information or graphic illustration as well as written, printed, or graphic matters, provided these do not contradict mandatory requirements in these regulations, including those related to statements of properties and deception, as established in the Labeling Regulation under General Principles, Section 3.

Quality specifications

Quality specifications (when used) must be easily understandable and must not be misleading in any manner whatsoever.

Presentation of Required Information

Background

• Labels applied to prepackaged food products must be placed so that they do not split from the

package.

- The data that must appear on the label, as per these regulations or as per any other standard, either national or from the Codex *Alimentarius*, must be written in clear, visible, un-erasable, easy-to-read characters, to be read by consumers in normal purchase and use circumstances.
- When the package is wrapped, this must contain all data required. Otherwise, the product label must be easily readable through the outer wrapping or the wrapping must not obscure it.
- The food product name and net content must be prominently stated so that they are easily visible.

Language

- The product label must be written in Spanish, whenever the label is not originally written in that language. A supplementary label can be used instead of a new one. In that case, the label must contain, in Spanish, all the information required.
- When a new or supplementary label is used, the information provided must fully and accurately reflect the information given in the original label.
- If a product's original label does not contain all the information required by the local regulations, the missing information should be included in the supplementary label.
- Multilingual labels are allowed as long as the information in other languages does not interfere with the information in the Spanish language.

Section III. Packaging and Container Regulations:

There are no specific packaging or container size requirements at this time. Food service and warehouse type importers sell their products in larger size containers. Most retailers sell their products in sizes that are more convenient for consumers in terms of price and contents.

Section IV. Food Additives Regulations:

Costa Rica signed Central American Technical Regulation 67.04.54.10. "Processed Foods and Beverages, Food Additives" and published it as <u>Executive Decree 37294-MEIC-COMEX-S</u> on September 27, 2012. This regulation entered into effect on November 14, 2012. The regulation is an adaptation of Codex Standard 192-1995 (Rev. 6-2005) General Standard on Food Additives. A copy of the current list may be obtained at the Registration and Controls Management Office (Dirección de Registros y Controles) of the Ministry of Health. (See appendix for address).

The additive regulation allows the use of flavors and aromas of aromatic substances or mixtures of substances, obtained from physical or chemical processes of isolation, or natural forms of synthesis, accepted by any of the following internationally recognized entities: JECFA, FDA, FEMA, and the European Union.

Additives different from flavors or aromas are discussed in Annexes I, II and III of the regulation. Annex I specifies, for each food additive to which JECFA has assigned a numerical ID, the food categories (or the foods) for which the use of the additive is recognized, the maximum dose of use in each food or category of food, and its technological function.

Annex II offers the same information as Annex I, but presented in numerical order by food category.

Annex III shows the list of additives with a non-specific JECFA ID whose use in food in general is authorized in *quantum satis* doses, and according to the good manufacturing practices principles described in point 4.2 of the regulation.

The regulation created a Central American Food Additive Commission in charge of updating the lists of additives included in the regulation. Enforcement of this regulation in Costa Rica is the responsibility of the Ministry of Health.

Section V. Pesticides and Other Contaminants:

Pesticides residues are regulated by Decree #35301-MAG-MEIC-S, issued on April, 2009. The Maximum Residue Levels (MRLs) applied are those approved by Codex *Alimentarius*. In the absence of a Codex MRL, the Ministry of Agriculture (MAG) uses U.S. Environmental Protection Agency (EPA) or European Union MRLs, whichever has a higher nominal value. The list of MRLs can be consulted through the following link: <u>Costa</u> <u>Rica MRLs</u> current as of 12/03/2015. MRL testing and enforcement is conducted by the Ministry of Agriculture through the National Phytosanitary Service (SFE).

Testing is conducted according to regulation AE-RES-PO-04 "Muestreo de los productos vegetales no procesados en los puntos de ingreso" (Sampling of non-processed plant products at the point of entry). This regulation has been in effect since August, 2013. The regulation requires sampling of the first six shipments of a particular product made by an importer. The regulation also indicates that the MAG has the right to sample when they consider there is a need to do so, for instance, if there are conditions in the shipment that lead them to believe that there could be a need to sample, unusual odors or visible decomposing product, for example. Also, according to this regulation, if after six consecutive sampling procedures there is no detection of the presence of residues above the limit, the product will be classified in the corresponding group, according to the criteria set forth in Annex #3 of the regulation. In the case of fresh fruit, it would require sampling every 10 shipments. Annex 1 indicates the number of primary samples to be taken according to the weight of the shipment. For instance, for shipments greater than 500 kg, a minimum of 10 samples will be collected. The importers have the right to appeal within three days of the notification of residue findings.

Aflatoxin Levels

Aflatoxin levels in grains are regulated in Costa Rica by Executive Decree 27980-S of 07/1999. The Decree indicates that the maximum level of aflatoxins allowed in corn, rice, beans, wheat, and other cereals is 20 ug/kg, based on Codex *Alimentarius*. According to Executive Decree 27964 of 06/1999, the maximum level of aflatoxins allowed in peanuts is 15 ug/kg.

Aflatoxin tests are conducted on behalf of the Government by the University of Costa Rica's Center for Grains and Seed Research <u>CIGRAS</u>

The Ministry of Agriculture is responsible for regulating agricultural chemical residues in foodstuffs. Every chemical, biological, biochemical or related substance for agricultural use must be registered at the Ministry of Agriculture, Department of Agricultural Inputs Control (Departamento de Control de Insumos Agrícolas), and also at the Department of Toxic Substances of the Costa Rican Ministry of Health (Ministerio de Salud, Departamento de Sustancias Tóxicas).

Registration requirements may be waived for products in transit, products used in research and products used to fight specific plant health problems.

The procedures and requirements for registration, import, export, production, storage, distribution, transportation, repackaging, mixing, research, sale and use of these substances are described in the technical regulation for each type of agricultural input, including pesticides, fertilizers, biological and biochemical substances and related agricultural substances. Costa Rican pesticide regulations are based primarily on EPA and Codex regulations. A list of approved pesticides can be obtained from the Department of Agricultural Inputs Control (for address, see the contact section of this report).

An official permit is required for imports and customs clearance of all kinds of pesticides, fertilizers, raw materials, and related substances for agricultural use. This is issued by the Ministry of Agriculture, at the Single Foreign Trade Office (Ventanilla Única de Comercio Exterior.)

The legal grounds to control these products are provided by the following acts and decrees:

- Ley de Protección Fitosanitaria (Plant Health Protection Act) 7664 del 8 abril de 1997.
- Decreto (Decree) # 26921-MAG: Reglamento a la Ley de Protección Fitosanitaria. (Regulations of the Plant Health Protection Act).
- Decreto 33495-MAG-MINAE-S-MEIC, Regulation on Registration of Pesticides.
- Decreto 36549-MAG-MINAET-S, Creation of a Single Window for Pesticide Registration.
- Decreto 37982-COMEX-MEIC-MAG, RTCA 65.05.54.09 Fertilizantes y Enmiendas de Tipo Agricola, Requisitos para el Registro, La Gaceta #218 12 de noviembre, 2013. (Central American Technical Regulation on Registration Requirements for Fertilizers and Ammendments of Agricultural Type.)
- Decreto (Decree) # 24337-MAG-S (La Gaceta, #115, June 16, 1995): Reglamento sobre registro, uso y control de plaguicidas agrícolas y coadyuvantes. (Regulations on registration, use, and control of agricultural pesticides and products).
- Decreto (Decree) # 28429-MAG-MEIC RTCR 316: (Gaceta #31, February 14, 2000): Reglamento para inscribir fertilizantes. (Regulation on registration of fertilizers).
- Decreto (Decree) # 27973-MAG-MEIC-S RTCR 318: 1998 Laboratorio para el análisis de sustancias químicas, biológcas de uso en la agricultura. (Analysis lab for chemical and biological substances used in agriculture).
- Decreto (Decree) # 27041-MAG-MEIC Norma 176: 1991 Agroquímicos. Toma de muestra. (Standard 176: 1991, Sampling of agrochemicals).
- Decreto (Decree) # 27037-MAG-MEIC. (Equipment).

Registration by legal entities and persons

Every legal entity or person engaged in importing, exporting, registering and repackaging chemical and/or biological substances or application equipment for agricultural use must be registered with the Costa Rican Plant Health Service (Servicio Fitosanitario del Estado).

Procedure for imports/customs clearance of registered products

An authorization form must be completed, as explained below:

- The form must be signed by the manager of the importing firm (indicating registration number.)
- It must be signed by the representative of the importing firm.
- The MAG registration number must be indicated.
- The production lot number must also be indicated.
- A photocopy of the invoice must be added, as well as B/L, the air bill of lading or trucking bill of lading (depending on the means of transportation used.)

Registration

No legal or natural person will be allowed to import, export, manufacture, prepare, store, distribute, transport, repack, advertise, manipulate, mix, sell or use chemical, biological, or similar substances for agricultural use that are not registered in accordance with the requirements listed in the Regulation on registration, use, and control of agricultural chemicals.

Companies must submit to the Department of Agricultural Inputs the completed registration form as well as all documents required (which differ depending on whether they relate to individuals or companies).

The Registration Program will determine whether to register an agricultural chemical based upon physical and chemical properties – both of the active ingredient and of the prepared product – the analytical methods used to determine the active ingredient and the analysis of residues in crops, toxicological studies of the product, agronomic use based on biological effectiveness tests supervised by the Costa Rican Ministry of Agriculture, effects upon the environment, tolerance or maximum limits for residues in each crop and appropriate labeling of the product. Proof of effectiveness will be required whenever necessary. Product information will be evaluated on the basis of international toxicology and environmental performance standards. Legal imports of pesticides are allowed only in compliance with all regulatory and technical requirements.

Registration of equipment

The registration of equipment used to apply chemical, biological, biochemical or similar substances for agricultural purposes will ensure to users the quality and the characteristics of the product as claimed by manufacturers. Also, it will guarantee the import, manufacturing, distribution, marketing, and use of equipment in land and air applications, in addition to provision of spare parts and service.

Registration of chemical products

To register agricultural chemicals, technical and support products, the interested party must submit a registration application, plus two copies signed by that party and the company's manager. The application form must include:

- Name and address of the party seeking to register a product and company's registration number.
- Manager's name and address.
- Generic and trade names, kind, type and composition of products to be registered, as well as name of the manufacturing company.
- Credit note covering the cost for two analyses of the product, in order to determine its identity and quality.
- Material, type and size of product package, to ensure that packaging material can resist the chemical and physical effects from the product.
- Name and address of the resident manager's office, in the case of artificial persons.

Registration of pesticides

The original registration form plus two copies must be accompanied by a list in Spanish of the pesticide's characteristics, plus the following information:

- Chemical and physical properties of active ingredient.
- Characteristics of formulated product.
- Method of analysis.
- Data required (DSTMT) by the Costa Rican Ministry of Health regarding the hazardous nature of the product in relation to the environment and human health.
- Use required.
- Chemical, physical, and biological effects resulting from the use of the pesticide.

In the case of pesticide imports, the application form for registration must be accompanied by:

- An official document indicating registration date and number in the country of origin as well as type of formulation and concentration, if no previous local registration exists.
- Brand name certification of product to be registered.
- Patent certification for the product.

Registration of fertilizers

In the case of fertilizers, registration is based on Executive Decree 37982-COMEX-MEIC-MAG, RTCA 65.05.54.09 Fertilizantes y Enmiendas de Tipo Agricola, Requisitos para el Registro. (Central American Technical Regulation on Registration Requirements for Fertilizers and Ammendments of Agricultural Type.) To register the product, a new file containing all data required is developed. As in the case of pesticides, the file is submitted to the Input Department Registration Unit for review, approval and registration, once fees are paid. The registration application must be submitted on standard paper to the Ministry of Health, with a copy signed by the company's legal representative. This process must be carried out for each product to be registered.

Imports of product samples of agricultural inputs

A special permit is issued for research or evaluation purposes, for the company's exclusive use, to deal with emergencies, and to exempt the form from compliance with MAG-MEIC Decree #24037 and from product labeling requirements. To apply for the permit, a firm must:

- 1. Submit the customs clearance authorization form approved by the Registration Department and signed by the company's manager and the company's legal representative.
- 2. Add a copy of the invoice.
- 3. Complete a questionnaire (in the case of fertilizers and pesticides) as required.

The following must be added to the above-mentioned questionnaire:

• An application form indicating the name, address, capacities, legal domicile, ID card number, phone number, and postal office box number or legal address of the applicant. Also the goal of the research must be stated, as well as the name of the professionals involved and their

membership number in the appropriate association.

• A complete description of the research to be carried out.

A product label must be submitted with the questionnaire and approved to obtain authorization for the product's free use in Costa Rica after customs clearance. This procedure must be carried out prior to the product's arrival in the country to avoid customs clearance difficulties. Prior to starting the procedure, the requirements stated in 1 and 2 above must be complied with, and the application form plus the description must be submitted to the Registration Office or to PROCOMER's Single Foreign Trade Office (Ventanilla Única de Comercio Exterior.)

Marginal notes

Upon request of the interested party and upon submission of all documents required, that party will be allowed to:

- 1. Change or expand the country (or countries) of origin.
- 2. Change the brand name.
- 3. Transfer the registry property or recall registration.
- 4. Make other changes that will not result in an alteration of the structural and functional nature of the registered good.

The Pesticide and Fertilizer Department (Departamento de Abonos and Plaguicidas) is located in Sabana Sur, San José, with working hours Monday through Friday, 7:30 a.m. through 4:00 p.m. Phone: (506) 2549-3400.

Source: Ley de Protección Fitosanitaria (Plant Health Protection Act) Number 7664: http://www.sfe.go.cr

Section VI. Other Regulations and Requirements: DIETETIC FOODS

Under the General Health Act, the Costa Rican Ministry of Health requires that dietetic food products be registered at the Drug Control Department rather than at the Food Control Department. This is based in Article 104 of that Act, which defines as medicine all kinds of dietetic foods, foods with any kind of medical substances added, and foods or products claiming health benefits.

The definition for dietetic foods (as defined by the General Health Act, Article 104) is as follows: "Dietetic products are those products used to treat abnormal physical states and to reestablish or modify the individual's organic functions. Foods with medical substances added are included in this definition."

Foods used for nutritional treatments recommending maximum daily dosages or whose consumption must be restricted in order for the product to achieve its purpose, must also be registered at the Drug Control Department.

The definition of dietetic foods does not include lite products, low-cholesterol products or high fiber content products, which do not have medical substances added, are not used to reestablish an individual's organic functions, so are not restricted in their consumption. Lite products such as lite fruit cocktails, low-fat milk and lite butter are not considered dietetic foods. Products labeled salt-free, sugar-

free, or with vitamins or minerals added, are not considered dietetic foods according to criteria used by the Costa Rican Ministry of Health.

Before registering a dietetic product, the importer must register in Costa Rica the U.S. laboratory manufacturing it (usually a lengthy procedure that sometimes turns out to be costly.)

STATEMENTS REGARDING HEALTH PRODUCTS

This is defined as any implicit or explicit assertion written on the label of a food product, including dietetic supplements, which includes reference from third parties, written declarations (trademarks including terms such as "heart"), symbols (a heart symbol), or illustrations which characterize the relation of any substance with a disease or health condition. Implicit health declarations include those declarations, symbols, illustrations or other forms of communication which suggest, within the context in which they are presented, that a relation exists between the presence or the level of a substance in the food and a health-related condition. These statements are allowed within certain limits and must comply with the regulations of Appendix A-General Guidance on the Declaration of Properties-of the General Labeling Regulation Decree #26012.

NUTRITIONAL INFORMATION

Nutritional information labeling is mandatory when statements about the nutritional properties of a product are made. The following are examples of these types of statements:

- Reduced in Energy
- Fortified or enriched
- Calcium contributes to the development of teeth and bones
- Free of sodium
- Low fat content

When statements of that kind are included in the product's labeling, the label will have to comply with the Central American Technical Regulation 67.01.60:10 "Nutritional Labeling of Prepackaged Foods for Population older than 3 years." This regulation was implemented by Costa Rica through Executive Decree 37100-COMEX-MEIC-S of 02/20/2012, and amended by Executive Decree 37295-COMEX-MEIC-S of 06/18/2012.

If a product does not point out any nutritional properties, then nutritional labeling is not required. However, if the information is included voluntarily, the labeling will have to comply with the regulation.

A transitory period was provided until January 1, 2013 for companies to adjust their labeling to comply with the new Central American Nutritional Regulation. The new regulation is more comprehensive and covers aspects such as the nutrients that must be shown in the label (total fat, energetic value, saturated fat, carbohydrates, sodium and protein for instance). It also makes reference to complementary nutritional information and statements of nutritional and health related properties.

The Ministry of Economy provides guidelines on the application of different labeling regulations in the following website under "Guias de Etiquetado": <u>http://www.reglatec/principal.jsp</u>

COMPLEMENTARY NUTRITIONAL INFORMATION

Complementary nutritional information is information that aims to facilitate the consumer's understanding of the nutritional value of the food product and to help him/her interpret the statement about the nutrient. There are several ways to present information that can be used in the labels of food products (e.g. graphs, tables and others).

The use of complementary nutritional information on the label of food products is optional and supplements the declaration of the nutrients. Complementary nutritional information on the label should be accompanied by educational programs for the consumer in order to increase his/her understanding ability and to allow for a better use of the information.

NUTRITIONAL LABELING WITH NUMBER OF PORTIONS

The label of a food product stating the number of portions contained must indicate immediately after the statement the net portion size (in terms of weight, volume and number.) It may be stated in different units (cups, tablespoons, etc.) as long as it does not lead to confusion. Whenever nutritional information is required, the statement of the net quantity of the portion must be constant; for instance: 10 portions of 1 cup (250 ml).

DEFINITION OF THE REFERENCE QUANTITY GENERALLY CONSUMED IN ONE MEAL

In order to determine the size of the food portions not included in this standard, the following information must be provided:

- Portion size used in dietetic guides recommended by the authorities.
- Portion size recommended in the literature.
- Portion size used in other countries.

Since the reference quantity and also the stated portion size in the label reflect the amount of food generally consumed, these should only be based on the edible part of the food, excluding bones, seeds, skin and other non-edible parts.

The reference quantity must be based on the main use of the food; for example, milk as a beverage and not as an addition to cereal.

The reference quantity for products used as ingredients for other preparation but to be consumed just as they are purchased (for example, butter), must be based on the form they are purchased.

The statement of nutrients must be made based on the food as it is packed, with the exception of foods canned in water, brine or oil, and whose covering is not generally consumed (for examples, cherries, capers). In these cases, the statement of nutrients must be on the drained product.

IRRADIATED FOOD PRODUCTS

- All food products treated with ionizing radiation must indicate, in writing, the treatment close to the product name. As shown below, the use of the international symbol indicating the product was irradiated is optional, but when used, it must be placed close to the product name.
- Whenever irradiated products are used as ingredients of other food product, this must be stated in

the list of ingredients.

• Whenever a single-ingredient product is manufactured using irradiated raw materials, the product label must contain a statement indicating the treatment.

ALCOHOLIC BEVERAGES

Alcoholic beverages have specific labeling regulations that complement some of the requirements of the general labeling regulation. <u>Executive Decree 38413-COMEX-MEIC-S</u> of 05/30/2014 implemented Central American Technical Regulation 67.01.05.11 "Alcoholic Beverages. Fermented Alcoholic Beverages. Labeling Requirements," and 67.01.06.11 "Alcoholic Beverages. Distilled Alcoholic Beverages. Labeling Requirements."

Costa Rica's certification requirements are described in the FAIRS Export Certification Report, and are specifically related to the importation of live animals, animal genetics, and fresh products of plant or animal origin.

Section VII. Other Specific Standards:

Costa Rica has 135 technical regulations, 68 executive decrees and 12 general laws that affect food products. Specific regulations may be found in the Ministry of Economy's website at <u>http://www.reglatec.go.cr/reglatec/principal.jsp</u> Also, many specific food regulations and standards are available at the Ministry of Health's "Registrelo" (Register it) website at the following link: <u>Food</u> <u>Product Regulations</u>

Section VIII. Copyright and/or Trademark Laws:

In April 2002, the United States moved Costa Rica from the Special 301 Priority Watch List to the Watch List, where it remains. Inadequate enforcement of Costa Rica's intellectual property laws (IP) remains a U.S. concern. Costa Rica's CAFTA-DR entry into force on January 1, 2009 required new legislation regarding IPR, giving the country the legal framework for adequately enforcing IPR protections. To date, initiatives, including the formation of an intergovernmental IPR commission and the training of judges and prosecutors on IPR laws, have not produced significant improvements in the prosecuted by the Attorney General of Costa Rica, a fact that is frequently attributed to scarce resources and the higher priority that the Attorney General appears to have placed on prosecuting other types of criminal behavior.

Though the pace of improvement remains slow, the CAFTA-DR provides for improved standards for the protection and enforcement of a broad range of IPR, which are consistent with U.S. and international standards, as well as with emerging international standards, of protection and enforcement of IPR. Such improvements include state-of the-art protections for patents, trademarks, test data, and digital copyrighted products such as software, music, text, and videos; and further deterrence of piracy and counterfeiting. As examples of agreeing to international standards, Costa Rica joined the International Union for the Protection of New Varieties of Plants (UPOV) and ratified the Budapest Treaty in 2008 as part of the process to implement CAFTA-DR.

The implementation of CAFTA-DR IPR provisions strengthens Costa Rica's IPR protection regimes and harmonizes conformance with WTO norms. The agreement also criminalizes end-user piracy, providing a strong deterrence against piracy and counterfeiting. CAFTA-DR requires all member countries to authorize the seizure, forfeiture, and destruction of counterfeit and pirated goods and the equipment used to produce them. It mandates both statutory and actual damages for copyright infringement and trademark piracy. This is intended to serve as a deterrent against piracy, and ensures that monetary damages can be awarded even when it is difficult to assign a monetary value to the violation.

Costa Rica committed under CAFTA-DR to protect test data and trade secrets submitted to the government for the purpose of product approval. Further, although there is no effective means of providing protection for plant varieties in Costa Rica's TRIPS Agreement, Costa Rica committed to the UPOV Convention as part of its implementation process for CAFTA-DR. Problems remain, however, for pharmaceutical companies seeking to protect the use of data submitted for regulatory approval, in that such data are not being protected from unfair commercial use by unauthorized third parties.

Counterfeiting of well-known trademarks occurs frequently in Costa Rica. Legal recourse against these practices is available but may require protracted and costly litigation. In the past, Costa Rican authorities have raided businesses and confiscated property, especially clothing, that infringed on registered trademarks. CAFTA-DR enforcement provisions in the implementing legislation passed in 2008 are designed to help reduce copyright piracy.

Section IX. Import Procedures:

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Appendix I. Government Regulatory Agency Contacts: U.S. Government:

Foreign Agricultural Service (USDA/FAS)

Office of Agricultural Affairs, San José, Costa Rica Telephone: (011-506) 2519-2333, 2334, 2028, 2285, 2288 Tel-Embassy: (011-506) 2519-2000 Fax: (011-506) 2519-2475 Email-FAS: <u>agsanjose@usda.gov</u>

Mailing Address

Office of Agricultural Affairs FAS/San Jose Unit 2507 APO AA 34020-2507

Physical Location

Embajada de los Estados Unidos Frente al Centro Comercial de Pavas San Jose, Costa Rica

In-Country Mailing Address

Embajada de los Estados Unidos Apartado 920-1200, Pavas San Jose, Costa Rica

Animal and Plant Health Inspection Service (USDA/APHIS)

Contact information:

100 metros Norte y 75 Este de la Casa de Oscar Arias Rohrmoser, San José, Costa Rica Telephone: (011-506) 2519-2237

Local Government:

Guidelines for the Labeling of Food Products

Dirección de Mejora Reguladora y Reglamentación Técnica, Ministerio de Economía, Industria y Comercio (MEIC) Apartado 10216-1000, San José, Costa Rica Telephone: (506) 2291-2164, extentions 221 and 247 Fax: (506) 2291-2015 http://www.meic.go.cr/web/44/reglamentacion-tecnica-y-codex

Registration of Agrochemicals

Registro de Insumos Agrícolas del Ministerio de Agricultura y Ganaderia Apartado 70-3006, Barreal, Heredia, Costa Rica Telephone: (506) 2549-3502 <u>http://www.sfe.go.cr</u>

Registration of Food Products

Dirección de Atención al Cliente, Plataforma de Servicios, Ministerio de Salud Apartado 10123-1000, San José, Costa Rica Telephone: (506) 2257-7821 Fax: (506) 2299-4815 <u>http://www.ministeriodesalud.go.cr</u>

Imports of Processed Food Products

PROCOMER Autoridad Sanitaria del Ministerio de Salud Ventanilla Unica del Comercio Exterior (VUCE) Telephone: (506) 2299-4815 Fax: (506) 2233-4962 http://www.procomer.com

Import requirements for the following products may be obtained from the Costa Rican Animal and Plant Health Protection Department of the Ministry of Agriculture:

- Plant seeds
- Processed vegetables
- Grains
- Biological control agents
- Vegetable products not including plant seeds
- Spices for consumption or processing
- Vegetable products and by-products
- Propagation material
- Fruit
- Fertilizers, registration and labeling

- Laboratory for residue analysis and chemical and biological substances of agricultural use
- Registration and labeling of biological and biochemical pesticides
- Registration and examination of application equipment for agricultural, chemical and biological substances.
- Maximum residue levels of pesticides in vegetables.

For information on plant product requirements please contact:

Departamento de Cuarentena Vegetal Servicio Fitosanitario del Estado (SFE) Phone: (506) 2549-3400 Fax: (506) 2260-8296 http://www.sfe.go.cr/perfiles/int_importacion.html

Servicio Fitosanitario del Estado (SFE) Departamento de Insumos Agrícolas Phone: (506) 2549-3816 Fax: (506) 2258-3383 http://www.sfe.go.cr/perfiles/intro_registro_agroquimicos.html

For questions regarding requirements for imports of live animals and products of animal origin please contact:

Servicio Nacional de Salud Animal (SENASA) Ministerio de Agricultura y Ganadería Phone: (506) 2260-8300 Fax: (506) 2262-0221 http://www.senasa.go.cr/senasa/sitio/index.php/secciones/view/7

For information on import requirements for live animals, meats, and other products of animal origin (including dairy products) please contact:

Servicio Nacional de Salud de Animal (SENASA) Ministerio de Agricultura y Ganadería Phone: (506) 2587-1600 / 2260-9046 Fax: (506) 2296-2976 / 2260-9046 http://www.senasa.go.cr

Appendix II. Other Import Specialist Contacts: Asociación de Agentes de Aduana de Costa Rica Tel : (506) 2258-6869 Fax : (506) 2223-9329 E-mail: info@agentesaduaneros.com, aduanero@racsa.co.cr

Compañía de Registros Internacionales, S.A. Phone: (506) 2257-9914 Fax: (506) 2221-8279 http://www.reinsa.com