

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT POLICY

Required Report - public distribution

Date: 1/20/2015 GAIN Report Number:

Costa Rica

Food and Agricultural Import Regulations and Standards -Narrative

FAIRS Country Report

Approved By: Erich Kuss, Agricultural Counselor Prepared By: Victor Gonzalez, Agricultural Specialist

Report Highlights:

Updated on 12/17/2014. Sections updated: Section I. Food Laws. Appendix I. Government Regulatory Agency Contacts.

Section I. Food Laws:

The Costa Rican legislation dealing with food and agricultural imports has not undergone significant change over the last 15 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 the Central American countries reached agreements on several regulations including labeling of packaged foods, nutritional labeling of food products, and additives.

Several government institutions use different procedures to control food and agricultural imports into Costa Rica.

According to the Central American Technical Regulation on General Labeling of Prepackaged Food Products (RTCA 67.01.07.10), published in Costa Rica as Executive Decree 37280-COMEX-MEIC 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.

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.

The above-mentioned labeling requirements are enforced by the Costa Rican Ministry of Economy's Labeling Department. The Ministry of Economy no longer approves or rejects labels. Instead, producers and importers must comply with current labeling regulations. Significant fines are applied to companies whose products are found in the marketplace without a label that complies with the current legislation.

REGISTRATION REQUIREMENTS/DOCUMENTS

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, the Ministry decides whether to grant registration. 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 will be the same as before (please see below), although the time required to obtain approval is expected to be reduced as compared to the time required before the implementation of the new system. However, the private sector still reports problems and delays as the number of applications for registration continues to increase over time. Additional information regarding the registration system may be obtained by visiting the following website:

http://www.registrelo.go.cr

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 the 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.

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 30th, 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:

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 of 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 too type of cover, 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 the production.
- Whenever an ingredient is the result of the mix of two or more ingredients, it can be stated as an ingredient in the list, provided it is accompanied by a list (in parenthesis) of its components stated in decreasing weight order. This requirement does not apply for composite ingredients with an established 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 with 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."

Type of ingredients	General names	
Refined oil different	Oil, together with the term "vegetal", "animal" as modified by the term	
from olive oil	"partially hydrogenated" or "totally hydrogenated", as applicable	
Refined fats	Fats, together with the term "vegetal", "animal", as applicable	
Starch	Different types of starch; chemically-modified starch	
	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	
	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	

• The following general names can be used for ingredients in each of the following kinds:

	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 mixes, as appropriate	All sorts of spice and spice extract in amounts not above 2% of product weight, either alone or mixed in the product	
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
Antiagglutinant agent	Antiagglutinant
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.

Net content and drained weight

- Net content must be stated in Systéme International Units as follows:
 - i. Volume, for liquid food products.
 - ii. Weight, for solid food products.
 - iii. Weight, for semisolid or viscose food products.
- In addition to stating net content, in the case of food packed in liquid the drained weight of the product must be stated in System International 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.

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.

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.

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.

Section III. Packaging and Container Regulations:

There are not 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 Executive Decree 37294-MEIC-COMEX-S on

September 27th, 2012. This regulation entered into effect on November 14, 2012. However, companies were allowed a transitory period of six months to use their stock of labels. The regulation is an adaptation of the Codex Stan 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.)

Section V. Pesticides and Other Contaminants:

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 (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) # 27630 RTCR 229: 1996 Límites máximos de residuos de plaguicidas en vegetales. (Maximum limits for pesticide residuals in vegetables).
- Decreto (Decree) # 27041-MAG-MEIC Norma 176: 1991 Agroquímicos. Toma de muestra.
- (Standard 176: 1991, Sampling agrochemicals).
- Decreto (Decree) # 27037-MAG-MEIC. (Equipment).

Registration of 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 Decree #28429 MAG-MEIC, dated February 14, 2001. 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".

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 will be provided until January 1st, 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: <u>http://www.reglatec.go.cr/etGuias.htm</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.

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 http://www.reglatec.go.cr

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:

Costa Rica has moved to an electronic customs system. The new system, known as TICA (Information Technology for the Customs System), intends to simplify procedures, improve the transparency of the decisions of customs officials, improve tax revenues, and improve the trustworthiness of the information used by customs. The system relies on several areas: a centralized customs database; a single customs declaration for imports, exports and transit of goods; the use of the internet for the transmission of customs declarations, the electronic payment of duties; and online operation 24/7, all year round. After initial opposition from several groups, the system has been implemented at different ports and border points of entry with success.

Costa Rica generally requires only invoices, bills of lading and airway bills to import goods. Mail shipments require only postal documentation. Imports of bulk agricultural and horticultural products require plant health certificates. Food Safety and Inspection Service (USDA/FSIS) certificates are required to import fresh and frozen meats. Under CAFTA-DR, Costa Rica agreed to apply the science-based disciplines of the WTO agreement on Sanitary and Phystosanitary Measures. Costa Rica also agreed specifically to undertake an equivalency determination for all establishments inspected by USDA's Food Safety Inspection Service. Costa Rica has already complied with this commitment. Prior to the equivalence determination, export plants had to be individually approved by Costa Rican authorities.

Most processed food products (canned, boxed, and pre-cooked goods) do not require plant health or animal health certificates, but exporters should check with their importers, who are ultimately responsible for knowing local regulations.

Imports of toxic substances, insecticides, pesticides and agricultural chemicals, require an import permit from the Costa Rica Ministry of Health as well as registration at the Ministry of Agriculture. The permit can be secured upon submission and approval of quantitative/qualitative analysis certificates and free-sale certificates, which must be provided by the exporter. These certificates must be authenticated by a Costa Rican consul in the United State or other country of origin.

Food products must be registered prior to importation. Labeling, according to the abovementioned regulations, may take place once the product enters the country but the product must be appropriately labeled before it reaches the point of sale. Violations of documentation laws lead to heavy fines. Consequently, great care must be taken to avoid errors and violations.

Costa Rican customs procedures are complex and bureaucratic, but they have improved somewhat since the passage of the 1995 General Customs Law. Most of the necessary processing is now accomplished electronically, and "one stop" import and export windows have significantly reduced the time required for customs processing.

Basic steps for exporting U.S. processed food products to Costa Rica

- Product must be registered with Ministry of Health or Ministry of Agriculture depending on the product.
 - a. Allow at least 30 days for registration process.
 - b. Registration fee is \$100 per product.
- Obtain Certificate of Free Sale issued by:
 - a. For wines and liquor: Department of the Treasury Alcohol and Tobacco Tax and Trade Bureau
 - b. For other agricultural products: State Departments of Agriculture or State Departments of Health. For processed meat products, Costa Rica accepts FSIS Form 9060-5 "Export Certificate of Wholesomeness" as equivalent to the Free Sale Certificate.
 - c. Certificate must obtain an Apostille from a Department of State office of the State that issued the certificate of free sale.
- Send documentation to the importer.
- Importer submits documents to Ministry of Foreign Relations for translation into Spanish.
- Importer contacts Customs Agent.
- The importer provides the Customs Agent with the following documents: commercial invoice, bill of lading or airway bill depending on the transportation means to be used, and copy of the importer's identification document (passport, cedula or legal documentation in the case of a business entity).
- Customs Agent determines the type of import permits which are required and requests them on behalf of the importer. (May include: country of origin, certificate of analysis, fisheries certificate, fumigation certificate, health certificate, phytosanitary certificate, inspection certificate).
- After receiving necessary permits, Customs Agent completes a Customs Import Form to submit to the Customs Office where product will enter the country.
- Product may be subject to a random sampling physical inspection procedure upon arrival.
- Customs agent pays import duties.
- The product is cleared for market and the importer may retrieve the product.

Product labels must be in Spanish and include: registration number given by Ministry, product name, list of ingredients, net content and drained weight (in metric system), name and address of manufacturer and importer, country of origin, lot ID, dating and preservation instructions, instructions for use, and any other required information applicable to the specific product.

Import-related procedures can be summarized as follows:

- The importer contacts a customs agent, since according to article 33 of the General Customs Law, the customs agent is the only person authorized by the Customs Department to provide customs services.
- The importer provides the customs agent with the following documents: Commercial invoice, bill of lading or airway bill depending on the transportation means to be used, and copy of the importer's identification document (passport, cedula or legal documentation in the case of a business entity).
- The customs agent classifies the imported product and determines the type of import permits (phytosanitary etc.), if any, are required.
- The customs agent may request the permits on behalf of the importer. However, prior to this, the product must have been registered at the Ministry of Health or Ministry of Agriculture, depending on the product.
- Once the necessary permits have been processed, the customs agent fills the Declaracion Aduanera de Importacion (Customs Import Form) and submits it to the Customs office where the product is expected to enter the country.
- Under normal procedures, customs uses a random sampling process to physically inspect the product. The process will indicate whether that product needs to be physically inspected or not.
- Once the product is inspected by customs (if selected for inspection), the customs agent proceeds to pay the duties¹. Customs then provides a copy of the Customs Import Form, with the statement "Levante de Mercancia" (Cleared Product), and the importer or its representative can pick up the product.

¹ Taxes are calculated in accordance with the Central American Tariff and Customs Valuation Act (Ley de Valoración Aduanera y al Arancel Centroamericano --S.A.C.).

Appendix I. Government Regulatory Agency Contacts: 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, extention 221 or 247 Fax: (506) 2291-2015 http://www.meic.go.cr/reglatec/

Registration of Agrochemicals

Registro de Insumos Agrícolas del Ministerio de Agricultura y Ganaderia

Apartado 70-3006, Barreal, Heredia, Costa Rica

Telephone: (506) 2549-3502 http://www.sfe.go.cr/

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 http://www.ministeriodesalud.go.cr/

Adriana Herrera Asesora de Importación PROCOMER Autoridad Sanitaria del Ministerio de Salud Ventanilla Unica del Comercio Exterior (VUCE) Telephone: (506) 2299-4815 Fax: (506) 2233-4962 e-mail: aherrera@procomer.com 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 <u>http://www.sfe.go.cr/importaciones/index.html</u> <u>http://www.sfe.go.cr/informacion_general/Cuarentena%20Vegetal.html</u>

Ing. Tatiana León

Jefe, Ventanilla Única Servicio Fitosanitario del Estado (SFE) Ministerio de Agricultura – Promotora del Comercio Exterior de Costa Rica (PROCOMER) Phone: (506) 2233-9918 Fax: (506) 2258-3383 E-mail: <u>tleon@sfe.go.cr</u> <u>http://www.sfe.go.cr/insumos_agricolas/como%20importar.html</u> <u>http://www.sfe.go.cr/informacion_general/Cuarentena%20Vegetal.html</u>

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

Dr. Bernardo Jaén

Director, Servicio Nacional de Salud Animal (SENASA) Ministerio de Agricultura y Ganadería Phone: (506) 2260-8300 x2007 Fax: (506) 2262-0221 E-mail: <u>bernardo.jaen@senasa.go.cr</u> <u>inspecarnes@protecnet.go.cr</u>

For information on import requirements for meats and other products of animal origin please contact:

Dr. Julio Cesar Jiménez

Director de Cuarentena Animal Servicio Nacional de Salud de Animal (SENASA) Ministerio de Agricultura y Ganadería Phone: (506) 2587-1600 / 2260-9046 Fax: (506) 2296-2976 / 2260-9046 E-mail: jjimenez@senasa.go.cr http://www.senasa.go.cr/direccioncuarentena.html

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 E-mail: <u>reinsa@ice.co.cr</u> <u>http://www.reinsa.com</u>