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GAIN Report

Global Agricultural Information Network

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Chile

Food and Agricultural Import Regulations and Standards - Narrative

FAIRS Country Report - Chile

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Report Highlights:

On June 26, 2015, the Ministry of Health published in the Official Gazette the new regulation for the Nutritional Labeling of Food. The final decree requires, among other things, a label (or labels) on the front of prepackaged food and beverages, in the shape of a stop sign if the item exceeds certain thresholds for saturated fat, calories, sugar, and sodium. One label will be required for each nutrient that exceeds the threshold. Therefore, one product could bear up to four labels covering anywhere from 18 to 42 percent of the package face.

Section I. Food Laws:

Chile actively participates in the World Trade Organization and the CODEX Alimentarius Commission. Chile is concerned that unscientific technical trade barriers may adversely affect its exports. As a result, the government supports the global standardization of sanitary and phytosanitary trading regulations.

The Chilean CODEX Committee is coordinated by the Ministry of Agriculture under the new Chilean Agency for Quality and Food Safety (ACHIPIA).

Notifications to the WTO related to Sanitary and Phytosanitary (SPS) issues are done by the SPS office within the Ministry of Agriculture, Agricultural and Livestock Service (SAG); notifications related to Technical Barriers to Trade (TBT) are done through the General Directorate of International Economic Relations (DIRECON). SAG is responsible for enforcing Chile's import regulations concerning alcoholic beverages, organic foods, animal and plant quarantine, animal products for human consumption, the grading and labeling of beef and some processed food products both for human and animal consumption including pet food, feed and feed supplements.

The Ministry of Health is responsible for food sanitation, including meat and poultry and the approval of food ingredients, labels, and packaging of processed foods. The Ministry is currently bringing Chile's food sanitation regulations into conformity with CODEX standards. _

The official version in Spanish of Decree 977 can be found in www.minsal.cl under "NORMATIVA", an English version (unofficial) can be found at www.usdachile.cl under food law.

Section II. Labeling Requirements:

General Requirements

(See Title 2, Paragraphs 106 to 112 of Decree 977, Ministry of Health)

All imported products shall comply with all labeling provisions hereunder. Any information required hereunder and not included on the original label, not in Spanish, or not shown as provided hereunder, shall be added on a label affixed permanently to the container, of adequate size and location, and including at least the information on the original label.

Importers who are importing food products in the Metropolitan Region (Santiago) should submit labels to the Secretaria Regional Ministerial de Salud (SEREMI de Salud) Bulnes 194, Santiago for review and approval prior to importation. For other regions importers have to submit requests to their Regional SEREMI de Salud offices. The other principal ports of entries are:

Iquique, contact: seremisalud.tarapaca@redsalud.gov.cl, Esmeralda 475, Iquique - Chile Teléfono: (57) 404 690

Valparaiso and San Antonio, contact: seremisalud.valparaiso@redsalud.gov.cl, Address: Melgarejo 669, Piso 6, Valparaíso, Chile - Teléfono: (56-32) 2571417 – 2571419

Talcahuano, contact: raguayo@slauddelbiobio.tie.cl, Address: Caupolicán 518 Of. 510, Concepción; Phone: 56-41-227044.

Labels must be in Spanish, but the information may be repeated in another language. Sticker labels may be used, but must first be approved. Labels must bear the following information:

1. Food Name: The name must specifically indicate the true nature of the food. Notwithstanding the name, the brand may be given. In substitute products, this condition must be clearly indicated. Next to the name or very close to it there must appear the additional words or phrases necessary to avoid errors or deceit regarding the true nature and physical condition of the food, including but not limited to the packing type or medium, the form of presentation, or the type of treatment it has undergone;
2. Net content expressed in units of the metric system or the international system, with the unit symbol or full word. No term with ambiguous meaning must accompany the values of net content. In addition to the declaration of net content, for food packed in a liquid medium, the drained weight of the food must be indicated in units of the metric system or the international system;
3. For domestic foods, the name or business name and address of the manufacturer, producer, processor, packer, or distributor, as applicable;
4. Country of origin must be clearly indicated in both domestic and imported products, in accordance with established labeling standards regarding this information, in Decree No. 297 of 1992, of the Ministry of Economy, Development, and Reconstruction, or in the legislation that replaces it;
5. Number and date of the resolution and the name of the Health Service authorizing the establishment that prepares or packs the product or authorizes its placement;
6. Date of manufacture or packaging date of the product. This must be legible, and placed in an area of the package that is easily located and must be stated in the following manner and order:
 - The day, using two digits
 - The month, using two digits or the first three letters of the month, and the year, using the last two digits.For products whose minimum duration is less than or equal to 90 days, the year may be omitted. For products whose minimum duration is no less than three months, the day may be omitted. The industry can identify the date of manufacture with the code corresponding to the production batch. In this case the latter's records must be available at all times to the health authority;
7. Expiration date or duration of the product. This information shall be placed on the packaging in a place that is easily located and with a prominent legend. The expiration date shall be indicated in the form and order set for the date of manufacture. The duration must be indicated in terms of days or months or years, as applicable, always using whole units, unless it is of "indefinite duration," in which case the information must be entered. For products identifying the date of manufacture with the code of the production batch, the duration must be labeled in terms of the expiration date, while those expressly indicating the date of manufacture may use the expiration date or duration period. Products with a label of "indefinite" must necessarily indicate the date of manufacture.
8. Ingredients, on the label must be included the list of all ingredients and additives that make up the product, with their specific names, in descending order of proportion, except for flavor and aroma

enhancers, pursuant to the provisions of Article 136 of this regulation.

When the food, ingredient, or derivative is or contains any of the substances that cause hypersensitivity (food allergens), as officially recognized by resolution of the Ministry of Health, published in the Official Gazette, the allergen(s) must be indicated in the list of ingredients, in letters of a size no less than the letters of the general ingredients, or with the heading "Contains ... " or similar. If the ingredient is a derivative of any of the allergens recognized by the resolution, then both the ingredient and the allergen must be labeled, as in the following example: casein (milk) or milk casein.

If the food is at risk of contamination, from production or processing to marketing, from said allergens, then any of the following phrases must be included after the list of ingredients: "May contain ... ", "Contains small amounts of ...", "Contains traces of ... " or "Made in lines that also process ...", listing the allergen in question.

9. Additives, the incorporation of additives must be indicated on the label, in descending order of concentration, with their specific names, with the exceptions noted in the corresponding title. Any food additive that has been used in raw materials and other ingredients in a food, and passes to the food in sufficient quantity to perform a technological function in it, must be included in the ingredient list.

10. Nutritional information pursuant to the provisions of Article 115 of this regulation. Please refer to section **Requirements Specific to Nutritional Labeling** below.

11. Storage instructions, in addition to the date of minimum duration, special conditions required for the preservation of food must be indicated on the label, if the validity of the date of minimum duration depends on its compliance. In the event that, once opened, the product requires refrigeration or another special environment, this should also be noted in the labeling;

12. Instructions for use, the label must contain the necessary instructions, including reconstitution, where applicable, to ensure the correct use of the food;

13. For imported products, the name and address of the importer. The importer must maintain a record of all items admitted into the country, for a minimum period of 90 days after the expiration date or the duration of the product, as appropriate. Foods of indefinite duration must be kept on record for at least three years.

This record must provide background information to the customs agency at destination, the health history of the product, the authorization for use and consumption, the codes of the production batches or dates of manufacture, expiration date, country of origin, type of product, brand, the name of the foreign supplier and must be, at all times, available to the Health Authority.

The code of the production batch or date of manufacture shall also be stamped on the package and thus distinguish, unequivocally, different production batches or lots.

Imported foods must comply with all other applicable labeling rules on everything not specifically regulated herein. The authorization for admittance and consumption shall be done item by item, being, therefore, subject to all the controls that the Health Authority needs to perform, as provided herein.

14. The food and/or raw material for human consumption, modified through biotechnology events that present different nutritional characteristics to those of the food and/or conventional feedstock, must list them on the label, pursuant to the provisions of Articles 113 and 115 to 120 of this regulation.

In the case of frequently imported items, where the import and consumption permits are issued by the same health agency, the health agency may authorize labeling in the country of origin. The agency must then publish a resolution authorizing subsequent imports and the label must show the date and number of the resolution, as well as the name of the authorizing agency. For food items imported under the above provision, the package label must have an indelible key number that shows the production batch or lot and all the other labeling standards. Import and consumption permits will be issued on an individual batch basis, each batch being subject to all the controls. Please see Section IX regarding the requirements for beef.

All food products in a container must be labeled including the institutional packed size. The only exception is for products imported without a commercial value and a volume of less than 20 kilos. These products cannot be sold in the local market.

Specific Requirements

(See Title V, Article 21 of Decree 239, Ministry of Agriculture)

All bovine meat commercialized in Chile must comply with what is established on the Meat Law and its implementing regulations as follows:

Cartons must have the following labeling information:

1. Name of cut in English and Spanish. Equivalent Chilean beef cut nomenclature must be provided on carton and product labels; a comparative beef nomenclature chart can be obtained from the FTA text. See Chapter 3, page 28 to 33 and please read point 4 of [Annex 3.17](#). The USDA, in collaboration with Chilean officials, developed an additional resource that contains names in English and Spanish for other cuts not mentioned in the beef nomenclature chart found in the FTA text. That resource is available on the [AMS Web site](#).
2. Establishment number, name, and address of the establishment where the product was packed.
3. Product certified for export on or after February 1, 2012, must include gross weight, net weight, and number of cuts in the carton. Product weights must be stated in metric units.
4. Day, month, and year of slaughter or packing.
5. USDA quality grade designation (cartons must contain only cuts of the same grade). According to the FTA text, only beef that has been graded by AMS may be exported to Chile. See Chapter 3, page 28 to 33 and please read point 6 of [Annex 3.17](#).
6. Equivalent Chilean grade designation must be provided on carton and product labels; grade designation comparison tables can be obtained from the FTA text. See page 28 to 33 and please read point 6 of [Annex 3.17](#).
7. Equivalent Chilean grade designation is not required for ground beef and trimmings.

The protective covering of the individual beef cuts inside the box must have the following labeling information:

1. Name of the cut.
2. Establishment number, name, and address where the product was packed.
3. Day, month, and year of slaughter or packing.

4. Product certified for export on or after February 1, 2012, must include USDA quality grade designation (the protective covering in which the cuts are placed must have the grade or grade shield on it).

Requirements Specific to Nutritional Labeling

(See Title 2, Paragraphs 113 to 120 of Decree 977)

Nutritional labeling is required for all processed food products. Nutritional claims must be scientifically recognized, shall neither encourage unnecessary consumption nor give the impression that consumption offers protection against sickness or any debilitating condition, and shall be approved by the Ministry of Health. A nutritional label must contain the following information.

1. Value of energy in calories.
2. Quantities of protein, available carbohydrates, and fats in grams (available carbohydrates being understood to mean total carbohydrates excluding dietary fiber).
3. Quantity of any other nutrient, dietary fiber, and cholesterol, concerning which a representation of properties is made. Cholesterol content shall be included in all food items representing nutritional or health-related claims in connection with fat or cholesterol.

Values are to be given per 100 g or 100 ml, and per serving. Number of servings in the container, size of the serving in domestic units and grams (g) or millimeters (ml) shall be stated.

Values given in the representation of nutrients shall be weighted average values derived from data specifically obtained from analyses of products representative of the product subject to representation.

In addition to the above three points nutritional information must include the following information:

- when a representation of nutritional properties is made regarding quantity or type of carbohydrates, total sugars shall be given. Quantity of starch and other carbohydrate constituents may be shown also. All this information shall be stated immediately following the representation of total carbohydrate content.
- When a representation of nutritional properties regarding dietary fiber is made, quantity and percentage of soluble and insoluble fiber shall be shown.
- when nutritional properties associated to quantity and type of fatty acids are specifically represented, quantities of saturated, monounsaturated, polyunsaturated fatty acids, and cholesterol shall be given immediately following representation of total fat content.

Representation of nutritional properties, representation of health-related properties, representation of nutrients, and supplementary nutritional information shall adhere to the technical standards issued on the subject by the Ministry of Health, to be published in the Official Gazette.

When a representation of nutrients is made, vitamins and minerals may also be listed if present in significant quantities, 5% or more of the recommended intake for the relevant population. For the

population over four years of age, the Daily Reference Dose (DRD) shall be used for energy, protein, vitamins, and minerals proposed in the Codex Alimentarius; for vitamin E, biotin, pantothenic acid, copper, and selenium, not specified in the Codex Alimentarius, the Reference Daily Intake (RDI) values proposed by the US Food and Drug Administration shall be used.

For infants and children under four years of age, pregnant and nursing women, the relevant RDIs shall be used as Daily Reference Dose. For iron and vitamin A during pregnancy the Daily Reference Dose shall be 30 mg/day for iron and 800 mcg/day for vitamin A, as established in the Nutritional Guidelines of the Ministry of Health.

Numerical information on vitamins and minerals shall be given in metric units, international system for 100 g or 100 ml, for one serving, in percentage of the recommended Daily Reference Dose, and per container if only one serving is contained therein. In addition, such information shall be given per serving on the label when the number of servings per container is shown.

Supplementary nutritional information that may be added to the representation of nutrients shall be intended to aid consumer understanding of the nutritional value of the food item concerned and help consumers to interpret the representation of nutrient(s).

- Calories
- Fat content
- Proteins
- Disposable carbon hydrates
- Sodium

Additionally, when the fat contents exceed 5 grams per serving the amounts of saturated, poly saturated and mono unsaturated fats and cholesterol must be listed on the label.

For additional information on labeling please contact the Labeling Department of the SEREMI:

Olivares Street # 1229 8° Floor
SANTIAGO

Phone: 56-2-2568-8423

Contact: Mr. Alejandro Rodriguez (alejandro.rodriguez@asrm.cl)

New requirements to be enforced in June 26 2016

When sodium, sugar or saturated fats have been added to a food product or foodstuff and its content is over the value defined herein under Table N°1, it shall label the nutritional characteristic or characteristics related to the added nutrient. Insofar as energy, its content shall be labeled when sugar, honey, syrup or saturated fats been added in excess of the amount defined in the aforementioned Table.

Table N° 1 Content limits for energy, sodium, total sugars and saturated fats in food.

	Energy kcal/100g	Sodium mg/100g	Total Sugar g/100g	Saturated Fat g/100g
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Max. for solid foods. Amounts above	275	400	10	4
	Energy kcal/100g	Sodium mg/100g	Total sugar g/100g	Saturated fats g/100g
Max. for liquid foods. Amounts above	70	100	5	3

The following food products or foodstuffs shall be excluded from the labeling obligation detailed herein under Paragraph 1:

A. Foods or mixes of them, which have no added sugar, honey, syrup, sodium or saturated fats.

B. Foods marketed in bulk, or in portions, or divided and those prepared upon request, even if they are packaged at the very moment of sale.

C. The following foods of Title XXVIII, "Foods for Special Diets:"

c.1 Paragraph II Baby Formulas.

c.2 Paragraph III Commercially Prepared Baby Foods (purées and solid foods), except for those with added sugar.

c.3 Paragraph IV Food for infant use made out of cereals, except for those with added sugar.

c.4 Paragraph V Foods for medical or therapeutic purposes.

c.5 Paragraph VII Foods for Weight Control Diets.

D. The following foods under Title XXIX, "Supplementary Foods and Foods for Athletes:"

d.1 Paragraph I. Food Supplements.

d.2 In Paragraph II, about foods for athletes, those that comply with the requirements described in Article 540, letters a), b), c) and d).

E. Zero-calorie, free-sugar tabletop sweeteners, regulated herein under Article 146.

The format for highlighting the nutritional characteristics detailed in the first paragraph herein shall be a label with an octagonal symbol with a black background and white border with the text inside reading "HIGH IN," followed by: "SATURATED FATS" "SODIUM", "SUGAR" or "CALORIES," in one or more separate symbols, as the case may be. The text shall be written in white capital letters. In addition, in the same symbol, the sentence "Ministry of Health" shall be written in white letters, according to diagram N°1 herein.

The referred symbol or symbols shall be placed on the main front product label.

The dimensions of the referred symbol or symbols will be determined according to the area of the label's main face, in accordance with the following chart:

Chart N° 1 Symbol Dimensions

Label Main Face Area	Symbol size (height/width)
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Under 30 cm ²	Symbol on container packaging
Greater than 30 and less than 60 cm ²	1.5 x 1.5 cm
Greater than 60 and less than 100 cm ²	2.0 x 2.0 cm
Greater than 100 and less than 200 cm ²	2.5 x 2.5 cm
Greater than 200 and less than 300 cm ²	3.0 x 3.0 cm
Above or equal to 300 cm ²	3.5 x 3.5 cm

For packages with a label's main front area between 30 cm² and smaller than 60 cm², the symbol or symbols shall be labeled on another visible front of the packaging.

Diagram N°1

Refer to graphic manual of the “High in” descriptor for more information at www.minsal.cl
The implementation of the new regulation will be gradually enforced according to the schedule established in tables 2 and 3 below.

Table N° 2: Content limits of energy, sodium, total sugars and saturated fats in solid foods.

Nutrient or Energy	Date of entry into force (June 26, 2016)	24 months following entry into force	36 months following entry into force
Energy kcal/100g	350	300	275
Sodium mg/100g	800	500	400
Total sugars g/100g	22.5	15	10
Saturated fats g/100g	6	5	4

Table N° 3: Content limits of energy, sodium, total sugars and saturated fats in liquid foods.

Nutrient or Energy	Date of entry into force (June 26, 2016)	24 months following entry into force	36 months following entry into force
Energy kcal/100g	100	80	70
Sodium mg/100g	100	100	100
Total sugars g/100g	6	5	5
Saturated fats g/100g	3	3	3

Chile's "micro enterprises" and "small businesses" defined in Chilean Law 20.416, which sets special rules for small size companies, will have a period of 36 months as of the date on which this Decree becomes effective to comply with the obligation of labeling the "HIGH IN" descriptor detailed in Article 120 bis.

Health Claims

See Sections V, Sections IV and Section VII.

Organic Labeling

Organic products have the same labeling requirements as any other normal product. There is a mandatory certification requirement to market organic products in Chile. Law 20089 from 01/17/2006 establishes that the labels “Organic product, ecological product or biological product” must be certified.

GMO Labeling

Biotechnology events that modify certain foods and/or alimentary raw materials for human consumption and novel foods, ingredients, and raw materials must be reviewed and specifically approved by the Ministry of Health at which point the product may be used in domestic and imported foods. (See Title 1, Paragraphs 3 of Decree 977)

Chile only allows transgenic seeds to be reproduced under strict field controls especially for export; there are no labeling requirements on these exported seeds. -

Currently there are two initiatives in Congress that would establish mandatory labeling for food and bulk products that were manufacture with ingredients or additives that had been genetically modified or were transgenic, both initiatives have not been voted to this date.

Section III. Packaging and Container Regulations:

Plastic packaging materials must not transfer more than 0.05 ppm of vinyl chloride or acrylonitrile or any other substance utilized in the manufacture of plastic elements that may be harmful to health. All plastic utensils, vessels, containers, packing, wrappings, sheets, film, parts of apparatus, piping, and accessories making contact with food items and raw materials thereof, shall not contain residual monomers amounting to more than 0.25% styrene, 1 ppm vinyl chloride, and 11 ppm acrylonitrile. Likewise, all objects made of plastics shall not release into food more than 0.05 ppm vinyl chloride or acrylonitrile, or other substance used in plastics manufacture that may be health hazards.

Plastic net bags are customarily used to pack citrus, onions and potatoes. They are also used for grapes and other fruits. Plastic trays with plastic film covers are used for a wide variety of fruits and vegetables.

In Chile recycling is voluntary; there is no mandatory program or symbol to be used on recyclable containers. The international symbol of three arrows forming a circle is commonly used by the industry when the containers are recyclable.

Section IV. Food Additives Regulations:

All additives must comply with the identification, purity and toxicity evaluation rules in accordance with the Codex Alimentarius. It is mandatory that additives be indicated on the label with their specific name, according to the International Numbering System (S.I.N.) and in decreasing concentration order. The exceptions to this rule are flavorings, which may be listed in a generic manner without any

ingredient detail. Only additives on the positive list found in Title 3, Paragraph II of Chile's food regulations (Decree 977) may be used. The Ministry of Health may add to this list by further decree, if there is a need. The addition of substances for therapeutic purposes (pharmaceutical ingredients) is prohibited. In addition, the use of an additive is prohibited if it significantly reduces the nutritional value of an important ingredient (with the exception of dietetic products), conceals poor quality, or misleads the consumer regarding the quantity or nature of the food product. See Section VII for "fortified" or vitamin enriched foods.

Section V. Pesticides and Other Contaminants:

Chile follows the Codex guidelines for pesticide residues on food. The Ministry of Health is responsible for establishing tolerance levels allowed in food products for pesticide residues, heavy metals, and mycotoxin and microbiological contamination and enforces the regulations. Random controls are performed and the office responsible for these controls is:

Mr. Carlos Pavletic
Ministry of Health
Mac-Iver 459 Piso 7°
Santiago
Tel.: (56 2) 2574-0493
E-mail: cpavletic@minsal.cl

Maximum tolerance levels are set for all approved pesticides. CODEX maximum residue limits are accepted for imported food products.

The Ministry of Agriculture's Agricultural and Livestock Protection Service (SAG) must approve the use of pesticides. This agency regulates the use of pesticides in Chile. For more information regarding approvals and/or maximum residue level, contact:

Mr. Octavio Herrera
División Protección Agrícola y Forestal
Agricultural and Livestock Protection Service (SAG)
Ministry of Agriculture
Av. Bulnes 140
Santiago, Chile
Tel.: (56 2) 2345-1201
Fax: (56 2) 2345-1203

A list of approved pesticides can be obtained through SAG's web page <http://www.sag.gob.cl>. Once you open the web page select: Plaguicidas, then autorización de plaguicidas, lista de Plaguicidas autorizados, then Download an EXCEL file for a list of approved pesticides, or send inquiries about pesticides to: plaguicidas@sag.gob.cl or Carolina.castro@sag.gob.cl

Section VI. Other Regulations and Requirements:

According to the Chilean Sanitary Code, also known as the Food Law, the Ministry of Health reserves the chance of testing all food products that are imported to the country or that are produced

domestically, for reference please take a look to Title V of the Food Law that you can find at www.usdachile.cl on the English version.

There are no mandatory quality certification standards for fruits and vegetables.

As a result of the U.S.-Chile FTA, U.S. meat grading standards are now accepted in Chile. Since Chile provides grades for all parts of bovine animal, be sure to consult both the AMS Verification Program (<http://www.ams.usda.gov/>) and the FSIA export library (http://www.fsis.usda.gov/Regulations_&Policies/Chile_Requirements/index.asp)

For required documents please refer to Section IX. Import procedures below and to the FAIRS – Export Certificate Report at:

<http://gain.fas.usda.gov/Lists/Advanced%20Search/AllItems.aspx>

Section VII. Other Specific Standards:

1. Consumer Packaging or Municipal Waste Disposal: Containers and wrappers used in the distribution of food products must be made or lined with materials that will resist the transfer of toxic or contaminating substances that might modify the organoleptic or nutritional nature of the products. The packaging in immediate contact with the food can-not be recycled.

2. Weights and Measures: The net content must be expressed on the label in units of the metric system. For those food products packed in a liquid medium, the drained content of the product must also be indicated.

3. Vitamin Enrichment Requirements: The Ministry of Health has established maximum limits for vitamins and minerals added for food. See table below. Resolution N° 393 and N° 394 dated February 20, 2002 are the applicable regulations. Beyond these levels, the food becomes a food supplement and it must receive specific approval from the Ministry of Health.

	% RDA/Serving
Vitamins	
Hydro-soluble vitamins	50
Vitamin C	100
E and K oil-soluble vitamins	100
A oil-soluble vitamins	25
D oil-soluble vitamins	40

The above limits do not apply to foods designed for special regimes, such as foods fortified to address a specific public health need. A calcium fortification limit is set by the Ministry of Health for each specific food product, according to the type of calcium salts used and the target population of the product.

4. Novel Foods: These types of products do not have any specific labeling requirements; they have to comply with the same regulations as any other food product.

5. Diet or Special Use Foods: Chilean food regulation defines food for special diets as food specially prepared or processed to meet particular nutrition demands owing to specific physical, physiological, or metabolic conditions. The composition should be substantially different from ordinary food of similar nature, if any. Synthetic ingredients replacing lipids, carbohydrates, diet fiber, and other nutrients used in such food shall, for authorization purposes, adhere to technical standards issued on the subject by the Ministry of Health. Such foods are required to carry a statement of nutritional and health properties, as provided hereunder.

In addition to nutritional information and general labeling, description of essential characteristics of the product should be stated close to the name of the food. The total quantity of specific nutrients or other components where to the essential characteristic is due that makes such food appropriate for a special diet should be stated per 100 g or per 100 ml or per serving.

Food for weight control should state in their nutritional information the phrase “Food for weight control”. The same happens with low-fat and/or low-calorie foods, which besides the main designation of the food name and the nutritional information; it should state the category or essential characteristic of the food as “low-...” or “...-free”.

See Title 28, Paragraph 8 of Decree 977 regarding infant formula, regarding commercial preparations of children’s food, food for low-sodium diets, cereal-based processed foods for children, food for low-sodium diets, gluten-free diets, for weight-control diets, and low fat and low calorie food products.

6. Food Sanitation Laws/Guidelines:

Decree No. 725, 1968.

Decree No. 2763, 1979.

Decree No. 977, August 6th, 1996.

Decree No. 807, February 3rd, 1998.

Decree No. 1844, November 10th, 1998.

Decree No. 855, July 31st, 1999.

Decree No. 475, January 13th, 2000.

Decree No. 897, February 8th, 2000.

Decree No. 824, March 9th, 2000.

Decree No. 90, April 28th, 2000.

Decree No. 165, May 26th, 2000.

Decree No. 238, May 26th, 2000.

Decree No. 287, February 28th, 2002.

Decree No. 253, January 20th, 2003.

Decree No. 79, June 24th, 2003.

Decree No. 81, July 24th, 2003.

Decree No. 115, November 25th, 2003.

7. Fish and Seafood: See Titles 12 (fish) and 13 (shellfish) of Decree 977

8. Animal Products: The Ministry of Health's (MOH) regional offices have the authority to enforce strict salmonella testing on imports or domestic production of fresh and frozen poultry as a quarantine measure. If any samples of a shipment are found to be positive for salmonella, the shipment may not enter the country or be destined to human/animal consumption. However, the MOH make very random sampling. Also there are strict animal health and sanitary requirements including materials that can be used during processing. Cooked poultry meat may enter Chile under the conditions specified in Regulation No. 1552 of March 28, 2008, issued by the Division of Livestock Protection, SAG. There is an equivalency agreement established between SAG and FSIS that allows each agency to certify plants to export to each country.

The most current requirements to export frozen and chilled poultry meat from the U.S. to Chile are governed by SAG's Resolution # 3817/2006, all the information about the letterhead certificate can be found at FSIS website at

http://www.fsis.usda.gov/Regulations_&Policies/Chile_Requirements/index.asp

Information on cooked poultry meat or poultry products can be found at SAG's website (www.sag.gob.cl)

The current red meat import requirements are available on SAG's web page. Resolution # 833, which establishes the Sanitary Requirements for Imports of Red Meat (beef), states that:

- the bovine meat being imported must be covered by an official certificate issued by the corresponding sanitary authority in the country of origin (the US Food Safety Inspection Service [www.fsis.usda.gov] in the United States), in which it is indicated the zone and the place of origin of the animal, the name of the slaughter house and its number, the identification of the product, the specie of the animal, the number of boxes in the shipment, the quality and grade of the meat, the name of the cuts, the identity of the exporter and importer and the means of transport. The grading certificate has to be attached to the health certificate.
- Animals must come from an area free of Foot and Mouth Disease, Bovine Pest, Bovine Contagious Pleuropneumonia and BSE.
- Animals and products must comply with the requirements in Resolutions #3138, which establishes the requirements for approving production facilities in the country of origin and Resolution #1150, which is an amendment to the general requirements of importing animals and by-products.
- In the case of beef, the product must be labeled according to Decree 239/1993 of the Ministry of Agriculture, in Spanish at the point of production. The resolution also establishes that a label has to be inserted on each cut (between the meat and the plastic) and another in the box. Further

conversation with the authority concluded on the possibility, only to the U.S., to put the label of the cut outside the plastic.

To get the import requirements from SAG's web page go to www.sag.gob.cl and under "*Importaciones*" , click on:

"Agriculturas" for plants

"Forestales" for Forestry

"Pecuaria" for livestock

For additional information from SAG you can contact:

Dr. Victor Ramirez

Bulnes 140

Santiago, Chile

Tel.: (56 2) 2345-1401

E-mail: hector.escobar@sag.gob.cl

9. Wine, Beer and Other Alcoholic Beverages: The wine and alcoholic beverage industries are regulated by the Servicio Agrícola y Ganadero. Labels on wine may indicate origin, variety of grape, and year of harvest when at least 75% of the grapes used to produce the wine fit the description used. The expression "*Estate Bottled*" or similar expressions may be used when the wine comes from grapes grown on lands owned or rented by the vineyard and located in the same geographical area as the denomination of origin. SAG's authority to enforce the labeling law is found under law No. 18.455. For further information, contact:

Joaquin Almarza

Servicio Agrícola y Ganadero

Departamento Protección Agrícola

Subdepartamento Viñas y Vinos

Av. Presidente Bulnes No. 140

Santiago

Phone: (56-2) 2345-1369

Fax: (56-2) 2345-1203

Email: vinas@sag.minagri.gob.cl

Wine, beer and other alcoholic beverages of domestic and/or import origin are subject to a tax which is 27% for alcoholic beverages (i.e. liquor, whisky, etc.) and 15% for wine and beer. Additionally all alcoholic beverages are subject to a 19% Value Added Tax.

10. Organic Foods and Health Foods: The market for organic foods within Chile is small, but domestic production is growing. With a view toward developing the industry, the National Institute of Standards (Instituto Nacional de Normalización) in 1999 established Norma NCh2439, which

establishes the voluntary principles or rules for the production (with set periods for certification), packaging, labeling and sale of organic products for export. Norma Nch 2079, approved in March 2000, establishes the general criteria for the accreditation of organizations certifying products as "organic." The Agriculture and Livestock Service (Servicio Agrícola y Ganadero – SAG) regulates organic production and certification, they can be reached at:

Contact: Claudio Cardenas

Jefe de Sub departamento Agricultura Orgánica

Servicio Agrícola y Ganadero

Av. Bulnes 197 Piso 3°

Santiago

Tel.: (56 2) 2345-1531

E-mail: claudio.cardenas@sag.gob.cl

11. Product Samples: A sample is considered of no commercial value when its weight does not exceed 20 kilograms of solid product. In the case of additives, or granulated products, the limit is 250 grams. In the case of higher quantities for personal use or for laboratory samples, these must be certified through a notary public letter. This letter is necessary for Customs clearance.

12. Irradiated Foods: Chile permits the irradiation of food products. See Title 6 of Decree 977 for further information (<http://www.usdachile.cl/usaeng/home.htm>) under Food Law. The irradiation of foods shall be done in conformity with the Code of Good Irradiation Practices of the International Consultative Group for Irradiation of Foods established under the auspices of the Food and Agricultural Organization of the United Nations (FAO), the International Atomic Energy Agency and the World Health Organization. When more than 5% of a product's ingredients have been treated with radiation or ionizing energy, the label must indicate very close to the product name the treatment employed, using phrases such as: "*treated with ionizing energy*", "*processed with ionizing energy*" or "*preserved with ionizing energy*". It may also carry the logo or symbol, internationally acknowledged for these effects. Decree 977 does not limit the use of radiation to particular food products.

Section VIII. Copyright and/or Trademark Laws:

Chile belongs to the World Intellectual Property Organization, and patents, trademarks, industrial designs, models, and copyrights are protected in Chile by the provisions of the International Convention for the Protection of Industrial Property (the Paris Convention).

However, Chile's intellectual property regime is currently not WTO/TRIPS compliant.

The U.S.-Chile FTA requires Chile to accede to several international IPR agreements; the Patent Cooperation Treaty (1984), which has been ratified, the International Convention for the Protection of New Varieties of Plants (1991), the Trademark Law Treaty (1994) the Convention Relating to the Distribution of Programme-Carrying Signals Transmitted by Satellite (1974), and do efforts to accede the Patent Law Treaty (2000), the Hague Agreement Concerning the International Registration of Industrial Designs (1999) and the Protocol relating to the Madrid Agreement Concerning the International Registration of Marks (1989).

Ownership of the trademark is not prejudiced by lack of use in cases where the registered party makes use of the mark in other countries, and trademarks may be

perpetually registered in periods of ten years at a time. Firms wishing to register their trademarks should do so with the Ministry of Economy, Departamento de Propiedad Industrial, Tel: (56-2) 2688-3124 or on the web at <http://www.dpi.cl/>

Since 1992, Chilean law has set copyright protection at the author's life plus 50 years. The U.S.-Chile FTA should strengthen copyright protection in Chile. It stipulates that authors, performers and producers have exclusive rights to authorize or prohibit reproductions of their work, and that the term of protection is not less than the life of the author and 70 years after the authors death, or not less than 70 years from the end of the year of the first publication of the work, if the term is not based on the life of a person. As part of the FTA, the Government of Chile also confirmed its commitment to use only legitimate computer software. With implementing legislation and good enforcement, the FTA should, therefore, help U.S. companies who have been suffering estimated annual losses of some \$50 million due to copyright infringement in Chile.

Section IX. Import Procedures:

A. Customs Clearance

A local agent or importer is absolutely necessary to clear food products for sale and distribution in Chile.

Products regulated by SAG (See section I) will be first reviewed by SAG and then by the regional office of the Ministry of Health. This inspection includes a documentary and a physical inspection.

Imports and certifications procedure implemented by the Agricultural and Livestock Service (SAG) of the Ministry of Agriculture obtained ISO 9001 certification in June 2013. Under this new inspection scenario, inspectors have little room for discretionary decisions and full enforcement of the law is required at the ports of entry.

Following a modernization of all services I the Livestock and Agricultural Service (SAG) of the Ministry of Agriculture, in June 2013 SAG was accredited and certified under ISO 9001 on a Quality Assurance System. The so called IMPORT INSPECTION CONTROL that covers plants, animal products, agricultural supplies, and all products regulated by SAG instructs officials to a strict compliance with the import regulations. Therefore, any deviation from the norm is almost impossible.

The regulations have not changed but from now, the inspectors have little room for arbitrary decision, the ISO certification obligates the inspectors to follow and enforce present regulations, a process that is standard to all trading partners.

For bovine beef and beef products, the complete enforcement of the Meat Law is required.

The document inspection:

- If the certificate does not contain the grading, or the grading is illegible or was amended or is incomplete SAG gives five days to correct the certificate, this allows U.S. exporters to obtain a in lieu certificate from FSIS.

Things that SAG cannot longer allow when dealing with bovine beef on the in situ inspection.

- Re- label boxes or individual packages after arriving to Chile.
- If four or more boxes of the sample taken for inspection have any of following mistakes the shipment will be rejected:
 - The label does not contain all the information required (see FSIS Export Library).
 - The cut is mislabel (the name of the cut on the label does not correspond to the cut).
 - The label on the boxes does not correspond to the labels on the cuts.

Vegetable products:

Document verification:

- If the product comes to Chile with no certification from the Official Sanitary Authority or if the product is not regulated in Chile, the shipment will be rejected.

Physical verification:

- If the shipment contains soil or the species does not match what the certification says, the shipment will be rejected.
- Adulteration of the labels leads to the rejection of the shipment.
- In the case of live pest interception, the shipment will be rejected if:
 - It is a quarantine pest or,
 - There is no effective treatment to control the pest or there are no means of verification of the effectiveness of the treatment or,
 - There are no authorized companies in Chile to apply the treatment or,
 - In the case of plants or parts of plants that need quarantine post entry, if this is a quarantine pest or the identification of the pest is not possible due to the evolutionary stage.

Pesticides:

Physical inspection:

- If the information on the Certificate does not coincide with the information on the label and is not possible to obtain a reasonable explanation or rectification, the shipment is rejected.

Fertilizers

Document verification:

- If the importer is not able to present the product's composition the shipment is rejected

Physical inspection:

- If the composition declared in the documents does not coincide with the information on the

product the shipment is rejected.

Wine, alcoholic beverages, ethyl alcohol and vinegar

- If the product uses a protected geographical indicator's name that doesn't correspond to the indicator, the shipment must be rejected.
- If the raw materials of the products or their mixture are not authorized to be imported to Chile (energy drink with alcohol, etc.) the shipment will be rejected.
- If the information on the documents does not coincide with the products on the shipment, the shipment will be rejected.

All food shipments must obtain a Certificate of Use and Disposal from the Ministry of Health on a case-by-case basis before the product is released by customs for sale in Chile. The Ministry of Health has 100% inspection requirement and a high percentage of sampling and analysis although their processing time is relatively efficient and the cost for the service is nominal. The U.S. government is working with the Ministry of Health to develop a database that will facilitate trade and reduce duplicate testing analysis.

The procedure for obtaining permission to import food products begins in the Health Service Office at the port of entry. For example, if the port of entry is "Comodoro Arturo Merino Benitez" airport (Santiago's International Airport), clearance is handled by SESMA (Metropolitan Environmental Health Service, web site: www.asrm.cl).

The first step is to request "customs destination approval", which authorizes the retrieval of the products from Customs and their transfer to bonded storage, where they must be stored intact and separate from other goods pending sampling and inspection by health authorities. Obtaining "customs destination approval" usually takes 72 hours (3 working days). Forms should be obtained from the Customer Service Office (Oficina Atención al Usuario) of SESMA, located in Av. Bulnes 194, Santiago, from Monday through Friday, between 8:30 to 15:00. Fees are assessed by weight in kilograms. For more information check SESMA's homepage www.asrm.cl under "Alimentos" - "Fiscalización".

Required Documents:

1. The original and five (5) copies of the Customs Destination Form #2003 ("Solicitud Certificado Destinacion Aduanera").
2. A photocopy of the resolution certifying to the sanitary condition of the warehouse to which the products will be moved upon leaving customs.
3. Air waybill, ocean bill of lading, or product invoice.

B. Clearance for Sale within Chile

The Health Service Office of the region where the products are being stored conducts the sampling and

testing of products. Depending on the potential health risk and the necessary tests involved, this process may take up to 4 weeks but usually only takes about 7 days.

Required Documents:

1. Original and one copy of the Import Approval Form, #2004, (“Certificado de Uso y Disposición ” see the form at the website <http://www.usdachile.cl/usaeng/home.htm> under Import Requirements.
2. For fresh and raw seafood: A cholera-free certificate, if cholera is detected in the country of origin.
3. For meats: The sanitary certificate must include a declaration that the meat is free of hormones.
4. For all meats and poultry, the product must comply with the regulations of the Ministry of Health, for example, trichinae for pork or salmonella for poultry. Please see the individual product requirement on the website <http://www.usdachile.cl/usaeng/home.htm> under Import Requirements, Section II, Animal products.

C. Recommended Documents for Facilitating Clearance

1. A certificate of analysis of microbiological quality, and/or physical chemical analysis.
2. A Health Certificate and/or Certificate of Free Sale issued by a recognized public health department in the country of origin confirming that the product is fit for human consumption, is sold freely throughout the country, and if processed, describing the product.
3. A technical sheet.
4. Labels or empty containers or packages.
5. For irradiated foods:
 - a) A certificate indicating the dosage level and a description of the packaging.
 - b) A certificate issued by the competent government agency authorizing the plant to irradiate food products.
 - c) A certificate recognizing that the plant is included in the international inventory of irradiation plants.

Certificates issued in the country of origin should be completed in or translated into Spanish. Fees for sampling and conducting tests are calculated according to product weight in kilograms.

Section X. Facility and Product Registration

Under the Ministry of Agriculture

As per Resolution 3138 of 1999 from SAG and its further modifications, all establishments (slaughtering plant, cold storage, warehouses, processing plant), with interest to export their animals or animal products to Chile need to be authorized. The authorization is based on the verification and analysis of the technical and scientific information and in meeting the specific health requirements, with regard to the sanitary quality of the animals and the safety of the products. Authorizations will be valid for two years by means of a resolution from the Service; they can be renewed after a supervisory visit by SAG or by delegating the supervision to the local sanitary authority. Establishment authorized will be listed on the Official List of Plants Authorized to Export to Chile.

Resolution 1459 of 2003 from SAG recognizes as equivalent the inspection system applied by the Food Safety Inspection Service (FSIS) of USDA on bovine, ovine, porcine meats and their process products (for human and animal consumption) destined to Chile and therefore delegates the authority to authorize U.S. establishments that want to export to Chile in FSIS. All establishments under Federal supervision are eligible to export to Chile. Modification on the list of establishments under Federal supervision need to be notified.

Resolution 441 of 2008 from SAG recognizes as equivalent the inspection system applied by the Food Safety Inspection Service (FSIS) of USDA on poultry meats and their process products (for human and animal consumption) destined to Chile and therefore delegates the authority to authorize U.S. establishments that want to export to Chile in FSIS. All establishments under Federal supervision are eligible to export to Chile. Modification on the list of establishments under Federal supervision need to be notified.

In the case of dairy products, and as an agreement while negotiating the U.S. and Chile FTA, the plants that want to export to Chile need to be on the listed on the Food and Drug Administration (FDA)'s list. The list is updated quarterly and the instructions to be included on the list can be found in the following link.

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ImportsExports/ucm078936.htm>

Are excluded from the authorization process the establishments that produce industrialized food products (for human or animal consumption) with ingredients of animal origin that submit their process monograph, which analysis determines that they don't represent a sanitary risk. Products authorized under this method are listed on the Official list of products authorized by monograph to be exported to Chile. A copy of the guide to prepare the process monograph can be found in the FAIRS Certificate report.

Under the Ministry of Health

There is no product registration under the Ministry of Health. Products are authorized as they are imported into Chile. Samples of the required certification can be found on **Section IX. Import Procedures**

Appendix I. Government Regulatory Agency Contacts:

WTO Entry Points

Sanitary/Phytosanitary (SPS)

Servicio Agrícola y Ganadero (SAG)
Departamento de Asuntos Internacionales
Avenida Bulnes 140, piso 5
Santiago

Tel: (562) 2345-1575
Fax: (56 2) 2345-1578
E-mail: sps_chile@sag.gob.cl
Website: <http://www.sag.cl/>

Technical Barriers To Trade (TBT)

Dirección de Relaciones Económicas Internacionales
Ministerio de Relaciones Exteriores
Teatinos 180 piso 9
Santiago
Tel.: (56 2) 2827-5100
Fax: (56 2) 2380-9494

Enforcement of Food Regulations

Departamento de Alimento y Nutrición
Ministerio de Salud
Mac-Iver 459, piso 8
Santiago
Tel.: (56 2) 2574-0474

Sampling and Inspection of Imported Foods

Servicio de Salud Metropolitano del Ambiente (SESMA)
Av. Bulnes 174
Santiago
Tel.: (56 2) 2576-4989
Website: <http://www.asrm.cl/>

Compliance with Pesticide Residue Regulations

Division Protección Agrícola
Servicio Agrícola y Ganadero (SAG)
Ministerio de Agricultura
Av. Bulnes 140, piso 3
Santiago
Tel.: (56 2) 2345-1201
Fax: (56 2) 2345-1203
Website: <http://www.sag.cl/>

Mr. Carlos Pavletic
Ministry of Health

Mac-Iver 459 Piso 7°
Santiago
Tel.: (56 2) 2574-0493
E-mail: cpavletic@minsal.cl

Chilean Standards

Instituto Nacional de Normalización - INN
Matias Couseño 64, piso 6
Santiago
Tel.: (56 2) 2445-8800
Fax: (56 2) 2441- 0429
E-mail: info@inn.cl
Website: <http://www.inn.cl/>

Appendix II. Other Import Specialist Contacts:

Analysis of Products for Compliance with Existing Food Regulations

Chilean Institute of Public Health
Avenida Marathon No, 1000, Ñuñoa
Santiago
Tel.: (56 2) 2575-5101
Fax: (56 2) 2575-5202
E-mail: oirs@ispch.cl
Website: <http://www.ispch.cl/>

Instituto de Nutrición y Tecnología de los Alimentos - INTA
Universidad de Chile
Av. El Libano 5524
Casilla 138 Correo 11
Santiago
Tel.: (56 2) 2978-1411 / 2978-1400
Fax: (56 2) 2221-4030
Website: <http://www.inta.cl/>

U.S. Embassy
Office of Agricultural Affairs
U.S. Embassy
Andres Bello 2800 - Las Condes
Santiago
Tel.: (56 2) 2330-3704
Fax: (56 2) 2330-3203
E-mail: AgSantiago@fas.usda.gov
Website: www.usdachile.cl

