



Required Report: Required - Public Distribution Date: September 10,2020

Report Number: CI2020-0015

Report Name: Food and Agricultural Import Regulations and Standards

Country Report

Country: Chile

Post: Santiago

Report Category: FAIRS Annual Country Report

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Report Highlights:

This report provides an overview of Chile's Decree 977 of 1997 of the Ministry of Health, also known as the Sanitary Regulation for Food Products (RSA by its name in Spanish) related to human health. This report also provides overall information on the specific requirements established by the Ministry of Agriculture intended to prevent the introduction of animal diseases and plant pests to Chile. As of August 31, 2020, Chile has not implemented any changes that could impact import of agricultural products.

DISCLAIMER: This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service in Santiago Chile for U.S. exporters of domestic food and agricultural products. All Chilean government documents/links in this report are in Spanish, but unofficial translated documents can be accessed through USDA Chile's website. While every possible care was taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

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Executive Summary:

Food and beverage products commercialized in Chile are regulated by the Ministry of Health and the Ministry of Agriculture.

Chile's Decree 977 of 1997 of the Ministry of Health, also known as the Sanitary Regulation for Food Products (RSA by its name in Spanish) establishes the regulatory framework for the production, processing, labeling, and marketing of domestic food and beverage products, the same regulation applies to imported products.

The role of the Ministry of Agriculture, through the Agricultural and Livestock Service (SAG) is to certify that the animals and plants consumed in Chile are safe and in the case of imports, that those products do not introduce animal diseases or plant pests to the country.

The United States is among the top three suppliers of food and agricultural products to Chile following neighbors Argentina and Brazil. U.S. main exports to Chile include beer, pork, poultry, dairy products, soybean meal, and beef. Chile is the second destination for U.S. consumer-oriented products in South America, after Colombia, reaching \$691 million in 2019, an increase of 9 percent from 2018.

Chile has an open economy highly depended on international trade. Chile has 29 trade agreements with 65 markets, which represent 67 percent of the world's population and 88 percent of the global Gross Domestic Product (GDP). In 2019, Chile signed trade agreements with Indonesia, Argentina, the United Kingdom. On August 13, 2020, Chile signed a Free Trade Agreement with Ecuador. The Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) is pending ratification from Congress.

Section I. Food Laws:

Chile's Ministry of Health (MOH) and the Ministry of Agriculture (MOA) regulate food products. While MOH's Office of Food and Nutrition regulates food and non-alcoholic beverages for human consumption, MOA's Agricultural and Livestock Service (SAG) regulates feed for animals, including pet food and feed supplements. In addition, SAG is responsible for enforcing some specific regulations

concerning alcoholic beverages, certification of organic foods, animal and plant quarantine, animal products for human consumption, and beef grading and labeling.

The MOH is permanently working on bringing Chile's Decree 977 into conformity with Codex Alimentarius' standards. A Sanitary Regulation for Food Products (RSA by its name in Spanish) Committee with representation from different agencies of the government meets regularly to review and propose updates.

The official version in Spanish of Decree 977, also known as Chile's Food Law, can be found here and the English version (unofficial translation) can be found here.

Food safety and sanitary regulations are applied both for domestically produced food products as well as imported ones. In the case of domestic food production, officials from MOH and SAG, conduct regular inspections of the producing establishments and supermarkets. In the case of imported products, MOH and SAG perform physical inspections as part of the import process. Non-compliance with Chilean regulations will result in the destruction of the product or the re-export of the imported product at the expenses of the importer. When SAG/MOH rejects a shipment, SAG officials may authorize further processing of the product for animal feed.

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

The MOA coordinates the Chilean Codex Committee for Latin America and the Caribbean (CCLAC) under the Agency for Quality and Food Safety (ACHIPIA). Chile has been the Secretariat for CCLAC since November 2014. In November 2016, CCLAC re-confirmed Chile for a second term until September 2020.

The SAG houses the SPS office that notifies to the WTO's SPS Committee while the Under Secretariat of International Economic Relations (SUBREI) is responsible for Technical Barriers to Trade (TBT) notifications.

Section II. Labeling Requirements:

General Requirements in English can be accessed on our website htpp://www.usdachile.cl. (See Title 2, Paragraphs 106 to 120 of Decree 977, MOH).

It is the responsibility of the importer to comply with all labeling provisions of the RSA. Any information required by the RSA that is not included in the original label, not in Spanish, or not shown as required shall be added on a sticker label. The importer is responsible for this procedure.

Labels must be in Spanish, but the information may be repeated in another language. Sticker labels may be used, but they must first be approved by the respective MOH's Regional Office.

All labels must bear the following information:

- 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;
- 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 may 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. Name of the MOH's Regional office that issued the resolution (date and number) authorizing the establishment that prepared or packed the product or authorized its importation;
- 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.
- 7. 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;

- 8. 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.
- 9. 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 MOH, 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.
- 10. 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.
- 11. Nutritional information pursuant to the provisions of Article 115 of this regulation. Please refer to section Requirements Specific to Nutritional Labeling below.
- 12. 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;
- 13. Instructions for use, the label must contain the necessary instructions, including reconstitution, where applicable, to ensure the correct use of the food;

14. 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.

15. 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: (Please review this section as exports may be subject to new specific certification or labeling requirements.)

Requirements Specific to Nutritional Labeling

(See Title 2, Article 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 (MOH). 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. 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 MOH, 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 md/day for iron and 800 mcg/day for vitamin A, as established in the Nutritional Guidelines of MOH.

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

Requirements for Critical Nutrients' Labeling

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 and Table N°2, 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 Tables 1 and 2 below.

The labeling regulation has been implemented gradually since 2016 as stated in the regulation/law.

Table N° 1: Content limits of energy, sodium, total sugars and saturated fats in solid foods.

Nutrient or Energy	Date of entry into force (June 27, 2016)	24 months following entry into force (June 2018)	36 months following entry into force (June 2019)**
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° 2: Content limits of energy, sodium, total sugars, and saturated fats in liquid foods

Nutrient or Energy	Date of entry into force (June 26, 2016)	entry into force	36 months following entry into force (June, 2019)**
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

^{**} notes latest implementation.

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:"
 - 1. Paragraph II Baby Formulas.
 - 2. Paragraph III Commercially Prepared Baby Foods (purées and solid foods), except for those with added sugar.
 - 3. Paragraph IV Food for infant use made from cereals, except for those with added sugar.
 - 4. Paragraph V Foods for medical or therapeutic purposes.
 - 5. Paragraph VII Foods for Weight Control Diets.
- D. The following foods under Title XXIX, "Supplementary Foods and Foods for Athletes:"
 - 1. Paragraph I. Food Supplements.
 In Paragraph II, about foods for athletes, those that comply with the requirements described in Article 540, letters a), b), c) and d).
- 1. 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)
Under 30 cm2	Symbol on container packaging
Greater than 30 and less than 60 cm2	1.5 x 1.5 cm
Greater than 60 and less than 100 cm2	2.0 x 2.0 cm
Greater than 100 and less than 200 cm2	2.5 x 2.5 cm
Greater than 200 and less than 300 cm2	3.0 x 3.0 cm
Above or equal to 300 cm2	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 Nº 1



Refer to graphic manual of the "High in" descriptor in Title II, Paragraph II, Article 120 bis of Decree977, 1997, here.

According to this law, no advertising may be targeted towards children under the age of 14, if its nutritional composition contains energy, sodium, sugar or saturated fat in amounts excess of those detailed herein under Table N°1 and Table Nº2 of Article 120 bis,

For these purposes, advertising shall be construed as targeted towards this age group if it uses, among other elements, childish characters and figures, animations, cartoons, toys, children's music, where people or animals appear attracting the interest of those under the age of 14, or if it contains fantasy-based statements or reasons regarding the product or its effects, childish voices, language or expressions typical of youngsters, or situations that represent their daily life, such as school, breaks or children's games

Health Claims

See Sections II and Sections III of the FAIRS Export Certificate Report

Organic Labeling

Organic products have the same labeling requirements as any other normal product. There is a mandatory certification requirement for marketing and promotion of 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 MOH 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.

There are two initiatives in Congress (mandatory labeling requirement (Boletin 3818-11/2005) and the Biotech Framework (Boletin 4690-01/2006) that would establish mandatory labeling for food and bulk products that were manufactured with ingredients or additives that had been genetically modified, both initiatives are still pending vote.

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 contacting 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.

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 in descending order of proportion. 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. MOH 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 (except for dietetic products), conceals poor quality, or misleads the consumer regarding the quantity or nature of the food product. See Section VI for "fortified" or vitamin enriched foods.

Section V. Pesticides and Other Contaminants:

Chile follows the Codex guidelines for pesticide residues on food. The MOH is the competent authority responsible for establishing tolerance levels allowed in food products for pesticide residues, heavy metals, mycotoxin, and microbiological contamination, and for enforcement of the regulations.

Random controls are performed and the office responsible for these controls is:

Mrs. Paulina Chavez, Department of Food and Nutrition Ministry of Health, Monjitas 565, 10th floor, Santiago

Tel.: (56 2) 2574-0617 E-mail: pchavez@minsal.cl

Maximum tolerance levels are set for all approved pesticides. Codex maximum residue limits (MRLs) are accepted for imported food products. When there is no limit set by Codex, Chile would adopt the most restrictive limit between the ones set by the European Union (EU) and the United States.

The SAG regulates and approves the use of pesticides in Chile. For more information regarding approvals and/or maximum residue level, contact:

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

SAG's list of approved pesticides can be obtained here. For additional questions email: plaguicidas@sag.gob.cl.

<u>Section VI. Other Regulations and Requirements:</u>

Facility and Product Registration

Under the Ministry of Agriculture (MOA)

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, regarding 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 SAG; they can be renewed after a supervisory visit by SAG or by delegating the supervision to the local sanitary authority. Establishments that are authorized will be listed on the Official List of Plants authorized for 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

The 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, the plants that want to export to Chile need to be on the listed on the Food and Drug Administration (FDA)'s List of U.S. Dairy Product Manufacturers/Processors with Interest in Exporting to Chile. The list is updated quarterly and the instructions to be added on the list can be found here.

The authorization process does not apply to 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 (MOH)

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

Section VII. Other Specific Standards:

- 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 cannot be recycled.
- 2. Organic Foods and Health Foods: SAG regulates organic production and certification. 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 NCh 2439, 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".

For further information, contact:

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Av. Bulnes 197 Piso 3º Santiago
Tel.: (56 2) 2345-1531

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

3. **Health Foods or Sport Drinks:** Food supplements are those products specially made or prepared to supplement the diet for healthy purposes and to help maintain or protect characteristic physiological states such as adolescence, adulthood, or old age.

Their composition may correspond to a nutrient, a mixture of nutrients and other components naturally present in foods, including compounds such as vitamins, minerals, amino acids, lipids, dietary fiber, or their fractions. For more information see <u>Title XXIX</u>, <u>paragraph I Article 534 – 538</u>.

Sports foods are those food products formulated to meet the requirements of healthy individuals, especially those who engage in heavy and prolonged physical exercise.

These foods shall be composed of a food ingredient or mixture of food ingredients. One or more nutrients, such as carbohydrates, proteins, vitamins, minerals and other components naturally present in foods, such as caffeine or those expressly authorized in this Regulation, may be added to them. They shall be manufactured in accordance with the rules of good manufacturing practice. For more information see <u>Title XXIX</u>, <u>paragraph II</u>, <u>Article 539 – 541of Decree 977</u>.

- 4. **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.
- 5. **Vitamin Enrichment Requirements:** The MOH has established maximum limits for vitamins and minerals added for food. See table below. Resolution Nº 393 and Nº 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 MOH.

Vitamins	% RDA/Serving
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 MOH for each specific food product, according to the type of calcium salts used and the target population of the product.

- 6. **Novel Foods:** These types of products do not have any specific labeling requirements; they must comply with the same regulations as any other food product.
- 7. **Dietetic or Special Use Foods:** Chilean food regulation defines food for special diets as food specially prepared or processed to meet 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 MOH. Such foods are required to carry a statement of nutritional and health properties, as provided hereunder.

In additional 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 whereto 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".

For "gluten-free foods" denomination, Title 28, Paragraph 6, article 518 of Decree 977 establishes the maximum limit of gluten to 5 (mg/kg) milligrams per kilogram of final product.

<u>See Title 28, Paragraph 8 of Decree 977</u> 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, for weight-control diets, and low fat and low-calorie food products.

- 8. **Food Sanitation Laws/Guidelines**: Decree 977 contemplates articles on sanitation, but those requirements only apply to domestic production of foods, not to imports.
- 9. Marine Products: See Titles 12 (fish) and 13 (shellfish) of Decree 977.
- 10. **Animal Quarantine:** The process of animal quarantine begins in the country of origin depending on the specific sanitary requirements which are divided as "domestic animals and fertile eggs" and "non-domestic animals".

Once the animals arrive in Chile, they are subjected to a period of isolation under the official control of the SAG, the duration of the isolation will depend on the animal species to be imported.

During this period, SAG will verify the sanitary condition of the animals carrying clinical observations and performing laboratory testing to confirm the absence of infectious agents or the presence of antibodies to a disease absent from the national territory to discard, in a rapid and timely manner, the development of any pathological process that was in the incubation stage.

11. Wine, Beer and Other Alcoholic Beverages: SAG regulates the wine and alcoholic beverage industries. 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:

Joaquín 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 (VAT).

12. **Product Samples and Mail Ordered Shipments:** 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. In the case of the United States where the access to all products has zero tariffs, the implementation of the limits of 20 grams for solid product or 250 grams for additives is not relevant.

For mail ordered products is the customs office, at the international airport in Santiago, who determines if the package will be subject to inspection or not, in which case, they contact the MOH's Metropolitan Reginal Office to clear the product. The recipient of the product will need to provide an affidavit stating that the product is for not for sale and will need to give his/hers address, the process is held at the MOH's Metropolitan Reginal Office and the fee for inspection is of \$15.

Section VIII. Copyright and/or Trademark Laws:

Chile belongs to the World Intellectual Property Organization, (WIPO). 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 not WTO/TRIPS compliant. The U.S.-Chile Free Trade Agreement (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), that has not been ratified; the Trademark Law Treaty (1994); the Convention Related to the Distribution of Program - Carrying Signals Transmitted by Satellite (1974); to make efforts to accede the Patent Law Treaty (2000); the Hague Agreement Concerning the International Registration of Industrial Designs (1999); and the Protocol related to the Agreement Concerning the International Registration of Marks (1989).

The lack of use does not alienate the property of a registered trademark. Trademarks may be perpetually registered in periods of ten years at a time. Firms wishing to register their trademarks should contact Chile's Ministry of Economy, Departamento de Propiedad Industrial, Tel: (56-2) 2688-3124 or on the web at http://www.inapi.cl/, e-mail at inapi@inapi.cl.

Since 1992, Chilean law has set copyright protection at the author's life plus 50 years. The U.S.- Chile FTA aims to 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 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:

Please refer to 2020 FAIRS Certificate report for more detailed information.

For commercial imports to Chile, it is necessary to have a local agent or importer to clear customs.

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

The imports and certifications procedure implemented by SAG obtained ISO 9001 on a Quality Assurance System certification in June 2013. Under this inspection scenario, inspectors have little room for discretionary decisions and full enforcement of the law is required at the ports of entry.

SAG officials stress that all the information contained in either AMS or FSIS sanitary certificate matches the name, address, and official number on the packaging label (s) of the shipped product, otherwise, shipments will be rejected. On December 18, 2018, SAG notified FAS Santiago that it will no longer accept documents that do not comply with Chilean regulations after January 31, 2019.

For bovine meat, the complete enforcement of the Chilean Meat Law is required.

Things that SAG can no longer accept when dealing with imported bovine meat during the physical/visual 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 <u>FSIS Export Library</u>).
 - o The cut is mislabeled (the name of the cut on the label does not correspond to the cut).

Vegetable products:

Document verification:

• If the product comes to Chile with no certification from the Official Sanitary Authority (the Animal and Plant Health Inspection Service, APHIS) 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 does not 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 do 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 MOH on a case-by-case basis before the product is released by customs for sale in Chile, request for this certificate can be submitted on line here. MOH 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 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 "Arturo Merino Benitez" airport (Santiago's International Airport), the clearance process is handled by SEREMI de Salud, website: 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 (three working days). Forms should be obtained from the Customer Service Office (Oficina Atención al Usuario) of SEREMI de Salud, 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 SEREMI de Salud's homepage www.asrm.cl under "Trámites", then "Alimentos" and in that page "Comercio Exterior"

Required Documents:

- 1. The original and five (5) copies of the Customs Destination Form #2003 ("Solicitud Certificado Destinación 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.

Clearance for Sale within Chile

MOH's regional office or *SEREMI de Salud* 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 four weeks, but usually only takes about seven days.

Required Documents:

- 1. Original and one copy of the Import Approval Form, #2004, ("Certificado de Uso Disposición") see the form on the USDA Chile website.
- 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 MOH, for example, trichinae for pork or salmonella for poultry. Pease see the individual product requirement on the <u>USDA Chile website</u>, Section II, Animal products.

Recommended Documents for Facilitating Clearance

A certificate of analysis of microbiological quality, and/or physical chemical analysis.

- 1. 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.
- 2. A technical sheet.
- 3. Labels or empty containers or packages.
- 4. 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: Trade Facilitation

Advance Rulings

The United States and Chile signed a Free Trade Agreement (FTA) in January 2004. Under the provisions of the FTA, Chile enforces all advance rulings commitments. The text of the agreement includes tariff classification as well as the rules of origin. Since January 1, 2015, all U.S. agricultural products exported to Chile are duty free and all quotas were eliminated. There are no pre-clearance programs for U.S. agricultural products exported to Chile.

E-Certification

For exports of plant products, animal feed, and live animals, APHIS and SAG agreed to use the electronic certification hub implemented by the International Plant Protection Convention (IPPC) starting July 1, 2020.

For products of animal origin or that contain ingredients of animal origin, SAG allows the use of electronic copies of the certificates to release shipments, with the compromise of presenting the original certificate within 60 calendar days. SAG and FSIS are working to implement e- certification for all products.

Import Fees

As described in Section IX, there are two inspections required for all food products, one with SAG and one with MOH.

Fees for SAG services are set by <u>Decree 142 of 1990</u> and are calculated according to the Chilean Monthly Tax Unit (UTM by its name in Spanish). The UTM is a unit of account used in Chile for tax and penalty purposes, updated according to inflation, to see the UTM value of the corresponding month please see <u>here</u>. The import inspection service costs 1 UTM, in the case of samples, shipments with no commercial, and shipments with a commercial value less than 1.35 UTM, value the cost for inspection is 0.25 UTM.

Fees for MOH services varies depending on the service, the issuing of the Certificate of Custom Destination (CDA) and the Certificate of Use and Disposal (UYD), both applications are done by the importer and can be done on line in the corresponding Regional Office of the Ministry of Health. The CDA varies between \$32 and \$157 (Exchange Rate with the Chilean peso \$800 per dollar), and the UYD varies between \$36 and \$147. The variation depends on the size of the shipment.

Common Delays

Regarding SAG inspections, common delays occur when the official certificate issued in the U.S. does not contain the complete or the correct information, in which case it is necessary to issue an in lieu certificate to release the shipments. SAG is very diligent on verifying that the name, number and address of the exporting establishment, as well as the description of the product corresponds to the information provided by the sanitary authority of the United States on the official list of establishments authorized to export to Chile.

MOH inspection delays may occur depending on the workload of the corresponding office.

Appendix I. Government Regulatory Agency Contacts:

WTO Entry Point (s)

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)

Subsecretaria de Relaciones Económicas Internacionales Ministerio de Relaciones Exteriores Teatinos 180, piso 9, Santiago

Tel.: (56 2) 2827-5447

Fax: (56 2) 2380-9494

E-mail: tbt Chile@subrei.gob.cl Website: http://www.subrei.gob.cl

Sampling and Inspection of Imported Foods in the Metropolitan Area

Servicio de Salud Metropolitano del Ambiente (<u>SEREMI de Salud Metropolitano</u>)

Avenida Bulnes 174, Santiago

Tel.: (56 2) 2576-4989

Compliance with Pesticide Residue Regulations

División Protección Agrícola Servicio Agrícola y Ganadero (SAG) Ministerio de Agricultura Av. Bulnes 140, piso 3, Santiago

Tel.: (56 2) 2345-1201

Website: https://www.sag.gob.cl/ambitos-de-accion/plaguicidas-y-fertilizantes

Mrs. Paulina Chavez, Ministry of Health, Monjitas 565, 10th floor, Santiago

Tel.: (56 2) 2574-0617 E-mail: pchavez@minsal.cl

Chilean Standards

Instituto Nacional de Normalización – INN Matías Cousiño 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 Maratón No, 1000, Ñuñoa Santiago

Tel.: (56 2) 2575-5101 (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 Líbano 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 Santiago, Chile Office of Agricultural Affairs Avenida Andres Bello 2800 - Las Condes Santiago

Tel.: (56 2) 2330-3704 Fax: (56 2) 2330-3203

E-mail: <u>AgSantiago@fas.usda.gov</u> Website: <u>www.usdachile.cl</u>

Author Defined:

According to the RSA, MOH reserves the right of testing all food products that are produced domestically or imported to the country. For reference please take a look at Title V of the RSA that you can find on the our website here.

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 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 FSIS export library.

Attachments:

No Attachments