



Required Report: Required - Public Distribution

Date: September 30, 2021

Report Number: CI2021-0017

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 Sanitary Regulation for food Products (RSA by its name in Spanish) currently in force, as well as any other regulation with the potential of disrupting food trade. During 2021, two new laws were passed: one restricting single-use plastic, and the other establishing rules on the commercialization and advertising of alcoholic beverages.

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. 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.

Please contact this office if you have any comments, corrections or suggestions about the material contained in this report:

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Executive Summary:

The United States is among the top three suppliers of food and agricultural products to Chile, following neighboring Argentina and Brazil. Primary U.S. exports to Chile include beer, pork, poultry, dairy products, soybean meal, and beef. Chile is the third largest market in South America for U.S. agricultural products, after Colombia and Brazil and the main destination for U.S. consumer-oriented

products in South America. U.S. consumer-oriented product exports to Chile reached \$582 million in 2020.

Chile has an open economy highly depended on international trade. Chile has 30 trade agreements with 65 markets, which represent 67 percent of the world's population and 88 percent of the global GDP. The Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) is awaiting ratification in the Chilean congress.

Section I. Food Laws:

Chile's Ministry of Health (MOH) and Ministry of Agriculture (MOA) regulate food products. While the 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 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 RSA into conformity with *Codex Alimentarius*' standards. An RSA 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 Sanitary Regulation for Food Products (RSA), can be found <u>here</u>.

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 retailers. 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 expense of the importer. When SAG/MOH rejects a shipment, SAG officials may authorize further processing of the product for use as 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 Office. During 2014 to 2020, Chile was the Secretariat for Latin America and the Caribbean (CCLAC). SAG houses the SPS office that notifies to the WTO's SPS Committee while the General Secretariat of International Economic Relations (SUBREI) is responsible for Technical Barriers to Trade (TBT) notifications.

Section II. Labeling Requirements:

General Requirements in Spanish can be accessed on Chile's RSA. <u>(See Title II, Paragraphs 106 to 112</u> of Decree 977, MOH for original in Spanish):

Imported products shall 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 can be added on a sticker. The importer is responsible for this procedure.

Importers who are importing food products in the Metropolitan Region (Santiago) should submit labels to the MOH's Regional Office (*SEREMI de Salud*, Calle Bulnes #194, Santiago) for review and

approval prior to import. For other regions, importers have to submit requests to their respective MOH's Regional Office. Chile's main ports of entry are:

- Iquique
 - Email: seremisalud.tarapaca@redsalud.gov.cl,
 - Address: Esmeralda 475, Iquique, Chile
 - Phone: (+56) (57) 2404-690
- Valparaiso and San Antonio
 - Email: <u>seremisalud.valparaiso@redsalud.gov.cl</u>
 - o Address: Melgarejo 669, Piso 6, Valparaíso, Chile
 - Phone: (+56) (32) 2571-417 (+56) (32) 2571-419
- Talcahuano
 - o Address: O'Higgins 241, Concepcion, Chile
 - Phone: (+56) (41) 2726-100.

All 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:* Content volume must be expressed in metric units, 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 metric units.
- 3. *Domestic foods*: Include 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. *MOH's Regional Office*: The 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.

For products whose minimum duration is less than or equal to 90 days, the year may be omitted. For products whose minimum duration is more 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 records must always be available 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 format 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*: 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 the RSA.

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.

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 transformation in it, must be included in the ingredient list.

- 10. *Nutritional information*: Pursuant to the provisions of Article 115 of the RSA. 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. *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 product, brand, the name of the foreign supplier and must be, at all times, available to the Ministry of Health.

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. *Genetically engineered food:* 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 be listed on the label.

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.

All food products in a container must be labeled including the institutional packed size. The only exception is for food samples 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.

NEW - Alcohol Labeling Law

On August 6, 2021, Chile published <u>Law 21363 from the Ministry of Interior and Safety</u> that establishes rules on the commercialization and advertising of alcoholic beverages. According to the law, alcoholic beverage shall be understood as those with an alcoholic content equal to or greater than 0.5 percent.

The law mandates the use of the warning sign about the consequences of the harmful consumption of alcohol, and a legend dealing with the risks and consequences of such consumption, especially for atrisk populations such as pregnant women, drivers and minors. Beginning a year after the publication of the law and it will be the responsibility of the producer, in the case of domestic products, or the importer in the case of imports to comply.

Bovine meat labeling requirements

For the specific labeling requirements for bovine beef, please refer to the FSIS Export Library.

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 must be inserted on each cut (between the meat and the plastic) and another in the box. Chilean authorities created an exception for U.S. product, which allows the label to be on the outside of the plastic only if the product is packaged on a USDA labeled plastic bag.

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 three points above, 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, five percent 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).

For additional information on all labeling requirements, please contact"

- The Labeling Department of the SEREMI de Salud
 - Address: Padre Miguel de Olivares Street # 1229, 8° Floor, Santiago, Chile
 - Phone: (+56) (2)2568-8423

Requirements for Critical Nutrient 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. Energy 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	Liquid Foods	Solid Foods
Energy kcal/100g	70	275
Sodium mg/100g	100	400
Total sugars g/100g	5	10
Saturated fats g/100g	3	4

The following food products or foodstuffs shall be excluded from the labeling obligation:

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 out of 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).

E. Zero-calorie, free-sugar tabletop sweeteners, regulated 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 Figure N°1.

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 Table:

Table N° 2 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.

Figure Nº 1



Refer to graphic manual of the "High in" descriptor for more information at <u>www.minsal.cl</u>

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 here under Table N°1.

For these purposes, advertising shall not be directed to children under 14 years of age, and therefore cannot use childish characters and figures, animations, cartoons, toys, children's music, childish voices,

language or expressions typical of youngsters, or situations that represent their daily life, such as school, breaks or children's games, or anything that can attract their attention.

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 <u>Title 1, Paragraphs</u> <u>3 of Decree 977</u>).

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 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. A mandatory labeling requirement (Boletin 3818-11/2005) and the Biotech Framework (Boletin 4690-01/2006).

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 percent styrene, 1.0 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.

NEW - Packing Sustainable Measures

Single Use Plastics

On August 13, 2021, the Ministry of Environment published in the Official Gazette (the equivalent to the CFR), Law 21,368 that limits the use of single-use plastic products and encourages the reuse of

plastics. The measure will take effect six months after publication. This law is an addition to a 2016 measure setting new measures for waste management and recycling.

The new restrictions will prohibit the delivery of single-use plastic products to food service establishments, regardless of the material from which they have been made. The food service establishments most impacted will likely include supermarkets, restaurants, corner stores, and fast-food chains. Outside of food service, only returnable plastic bottles and non-plastic containers will be allowed.

Products immediately affected after the six-month implementation period are plastic wine glasses, cups, bowls, forks, spoons, knives, chopsticks, bowls, drink mixers, straws, plates, to-go food containers, trays, sachets (sugar, mustard, mayonnaise and ketchup), and any individual lids other than bottle caps. After this date the only way single use products can remain in the market is if they contain either compostable or recyclable material and carry a "certified plastic" certificate. Certified plastics will be required to meet two conditions: First, they must contain at least 20 percent of materials produced using renewable resources (ie non-petroleum); the required percentage will increase over time. Second, certified plastics must be composable, meaning that they must biodegrade completely within one year when placed in a compost pile with other organic compostable materials.

Single use plastic bottles will not be subject to the immediate ban, but producers and users will need to begin to adopt changes. The new law will require that an increasing amount of recycled plastic be included in bottle production. The recycled material must be of Chilean origin. By 2025, bottles will be required to contain 15 percent recycled material. Required percentages will increase to 25 percent by 2030, 50 percent by 2040, 60 percent by 2050, and 70 percent by 2060. Disposable plastic bottles will only be permitted if they meet the required recycled content percentage.

Industry representatives have expressed concern with meeting the required level of recycled materials. The Chilean recycling industry is not yet well developed.

This law falls under the umbrella of <u>Law 20920 of 2016</u> that establishes the framework for waste management, extended producer responsibility, and promotion of recycling.

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. The 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 Ministry of Health 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:

Office of Pesticides, Ministry of Health, Monjitas 565, 10th floor, Santiago Tel.: (+56 2) 2574-0617 E-mail: <u>pchavez@minsal.cl</u>

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.

Ministry of Agriculture's *Servicio Agricola y Ganadero* (SAG) must approve the use of pesticides. SAG regulates 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 <u>here.</u> For additional questions email: <u>plaguicidas@sag.gob.cl.</u>

Section VI. Other Regulations and Requirements, Regulations, and Registrations Measures

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), interested in exporting 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 are 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. As such, SAG delegates the authority to authorize U.S. establishments that want to export to Chile to 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.

Similarly, 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. As with beef, SAG delegates the authority to authorize U.S. establishments that want to export to Chile to 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 <u>here</u>.

Manufacturers of processed products (for human or animal consumption) containing animal ingredients, must complete a product registration, which includes a process monograph for the goods to be exported. The registration process for these establishments consists of submitting a process monograph for approval to SAG. The list of products exempt from this process can be found in <u>Regulation</u> <u>3081</u>. 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.

Section VII. Other Specific Standards:

1. **NEW** – Plant-based Meats and /or Dairy:

According to <u>Chapter VIII, Article 198 of Decree 977,</u> milk is the normal mammary secretion free of colostrum, from dairy animals, obtained by one or more milking, without any type of addition or extraction, intended for consumption in the form of liquid milk or for further processing. For labeling purposes, milk without another denomination is the product of the cow. Milk from other animals will be named according to the species they come from, as well as the products derived from it. The use of the name "milk" in plant-based drinks in not allowed in Chile.

There is no formal regulation for the use of the name meat, nevertheless, Article 107, of Decree 977, states that "the name shall specify the true nature of the food item. The brand name may be added to the name. In the case of substitute products, this condition shall be clearly stated.

Next to the name or very close thereto, additional wording shall appear as necessary to avoid misleading or deceiving in respect of the true nature and physical condition of the food including, but not limited to, the type or means of covering, form of presentation or type of treatment to which the item was submitted. The same rationale for milk should be used for meat.

2. Labeling Requirements for Follow-Up-Formula

(See Chapter XXVIII, Article 493 to 505 of Decree 977)

a) Origin of the proteins contained in the product. If at least 90 percent of the proteins come from milk, it shall be labeled "Milk-based infant formula"; if the product does not contain milk or any of its derivatives, it shall be labeled "does not contain milk or milk products".

b) Labeling of the available energy value (expressed in kcal), content of proteins, lipids and available carbohydrates (expressed in grams), which shall be expressed according to Article 91 of the RSA.

c) Labeling of other optional nutrients, which shall be labeled according to Article 491 of this Regulation.

d) Products containing a minimum of 1 mg of iron per 100 usable kcal shall have the designation "Formula with iron for infants".

e) It shall be indicated in prominent characters that the formula "DOES NOT SUSTITUTE BREAST MILK";

f) In the labeling and advertising of infant formulas, it is totally forbidden the use of the terms "humanized", "maternalized" or other similar terms and images that may induce an undue comparison with breastfeeding or discourage its practice, such as images of infants, women, baby bottles, among others.

g) In addition, the label of each package shall contain a clear, visible and easily legible message including the words "IMPORTANT NOTICE: BREAST MILK IS THE BEST FOOD FOR YOUR CHILD" or an equivalent statement that unequivocally expresses the superiority of breast milk over infant formulas.

h) The need to combine the infant food with complementary feeding appropriate to the child's development, from 6 months of age onwards, shall be stated.

i) The product intended for infants with special nutritional needs shall indicate the special need for which the formula is to be used and the dietary property or properties on which it is based.

j) It shall be informed that the product should be used only under the indication of a health professional.

k) It shall also be labeled the date of elaboration and expiration date and instructions on its correct preparation and use, as well as its storage and conservation before and after opening the package.

3. 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.

4. Vitamin Enrichment Requirements: The MOH 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 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.

- 5. 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.
- 6. Diet 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, 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.

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

8. Animal Products: The MOH's Regional Office (s) 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. MOH inspectors conduct random sampling of fresh and frozen poultry. In addition, 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. Information about the required letterhead certificate can be found at FSIS website at FSIS Requirements for Chile.

Information on cooked poultry meat or poultry products can be found at SAG's (<u>www.sag.gob.cl</u>) website, "<u>Productos de origen animal</u>" select Resolution 1.552/2008. The current red meat import requirements are available on SAG's web page at: <u>Resolution #</u> 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 species 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 must be attached to the health certificate.
- Animals must come from an area free of Foot and Mouth Disease, Bovine Pest, Bovine Contagious Pleuropneumonia, and Bovine Spongiform Encephalopathy.
- 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.

To access to the import requirements from SAG's web page, click on the following links:

- Requirements for plant products can be found in http://www.sag.gob.cl/ambitos-de-accion/productos-agricolas
- Requirements for forestry products can be found in <u>http://www.sag.gob.cl/ambitos-de-accion/productos-regulados</u>
- Requirements for livestock can be found in <u>http://www.sag.gob.cl/ambitos-de-accion/informacion-por-productos-exigencias-sanitarias-especificas</u>
- **9.** 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 percent 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:

Departamento Protección Agrícola Subdepartamento Viñas y Vinos Servicio Agrícola y Ganadero Av. Presidente Bulnes No. 140 Santiago Phone: (+56)(2) 2345-1369 Fax: (+56)(2) 2345-1203 Email: <u>vinas@sag.minagri.gob.cl</u>

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

10. 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:

Departamento de Agricultura Orgánica Servicio Agrícola y Ganadero Av. Bulnes 197 Piso 3º Santiago Tel.: (+56) (2) 2345-1531 E-mail: <u>claudio.cardenas@sag.gob.cl</u>

- **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. 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.
- **12. Irradiated Foods:** Chile allows the irradiation of food products. <u>See Title VI of Decree</u> <u>977</u>. 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 (IAEA), and the World Health Organization (WHO). When more than five percent 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, (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 <u>http://www.dpi.cl/</u>

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 FAIRS certificate 2021 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 new inspection scenario, inspectors have little room for discretionary decisions and full enforcement of the law is required at the ports of entry.

SAG authorities 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.

For bovine meat, the complete enforcement of the Chilean Meat Law is required. During the visual inspection of imported beef, SAG can no longer accept:

- Re- labeled 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 mislabeled (the name of the cut on the label does not correspond to the cut).

All food products need to obtain clearance from the Regional Office of the Ministry of Health before they are moved from the port of entry and commercialized in the country. The request for clearance can be done in line at 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 *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 <u>www.asrm.cl</u> 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 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 Disposición") see the form on the <u>USDA Chile website.</u>
- 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.

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:

- 1. It is a quarantine pest or,
- 2. There is no effective treatment to control the pest or there are no means of verification of the effectiveness of the treatment or,
- 3. There are no authorized companies in Chile to apply the treatment or,
- 4. 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.

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

Technical Barriers to Trade (TBT) Dirección 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: <u>tbt_chile@direcon.cl</u> Website: <u>http://www.direcon.cl</u>

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

pesticides Office, 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: <u>info@inn.cl</u> Website: <u>http://www.inn.cl/</u> 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: <u>oirs@ispch.cl</u> Website: <u>http://www.ispch.cl/</u>

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 Chilean Sanitary Code, also known as the Food Law, 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 <u>Title V of Decree 977</u>.

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

As a result of the U.S.-Chile Free Trade Agreement, 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 (<u>http://www.ams.usda.gov/</u>) and the <u>FSIS export library</u>.

Attachments:

No Attachments