

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

Required Report - public distribution

Date: GAIN Report Number:

Peru

Food and Agricultural Import Regulations and Standards Report

FAIRS Annual Country Report 2018

Approved By:
Kirsten Luxbacher
Prepared By:
Alvaro Loza

Report Highlights:

This report outlines Peru's regulatory requirements for food and agricultural product imports. The following sections of the FAIRS Country Report are updated in 2018: Section I, item 1.4; Section V: Labeling Requirements item 5.2; Section VI: Other Specific Standards; and Appendix I: Government Regulatory Agency Contacts. Hyperlinks to ministries, agencies, and legal documents are provided throughout the report.

Section I. Food Laws:

Peru has a thorough, well-developed food safety and regulatory system. Regulations are generally science-based, though the risk assessment and rule-making process is time-consuming and arduous. The Ministry of Health's Directorate General for Environmental Health (<u>Dirección General de Salud Ambiental</u> - DIGESA) is the U.S. Food and Drug Administration's (FDA) counterpart; DIGESA regulates the registration and supervision of processed foods and beverages. The Ministry of Agriculture's National Food Safety and Quality Service (<u>Servicio Nacional de Sanidad y Calidad Agroalimentaria</u> - SENASA) develops and implements Peru's sanitary and phytosanitary regulations. SENASA's U.S. Government counterparts are the Animal and Plant Health Inspection Service (APHIS) and the Food Safety and Inspection Service (FSIS).

Peruvian standards and input requirements do not usually impede imports of U.S. food and agricultural products. In general, market access issues are associated with customs clearance procedures, harmonized-tariff-system (HS) classification errors, and inadequate or improperly completed import-export documentation.

1.1. General Health Law – Law No 26,842 (July 20, 1997)

Peru's General Health Law provides the legal framework for sanitary surveillance regulations and oversight of food and beverage products. The provisions are implemented through rules, decrees and supreme resolutions published in the official gazette (<u>El Peruano</u>).

DIGESA is responsible for implementing Peru's processed food product regulations. Regulations establish:

- The production and trade of food and beverage products for human consumption is subject to sanitary standards.
- The import, manufacture, trade, distribution or storage of food and beverage products that have been adulterated, contaminated, altered or declared unfit for human consumption is prohibited.
- Food and beverage products manufactured locally, as well as in a foreign country, can only be traded under a corresponding certificate of sanitary registration.
- The import of food and beverage products is forbidden from countries where distribution or consumption of the product due to associated health risks is prohibited.
- Personnel involved in the production, handling, transportation, conservation, storage, and supply
 of food and beverage products must comply with sanitary standards to avoid product
 contamination.
- Facilities manufacturing, processing, and supplying food and beverage products must control sanitary quality and food safety in accordance with the Ministry of Health's requirements.

1.2. Regulation for the Sanitary Inspection and Control of Food and Beverages – Supreme Decree 007-98-SA (September 25, 1998)

The Regulation for the Sanitary Inspection and Control of Food and Beverages implements the provisions of the General Health Law and the General Principles of Food Safety included in the Codex Alimentarius (CODEX). This regulation sets general hygiene standards, health conditions and

requirements for the production, transportation, manufacture, storage, marketing, preparation, and sale of food and beverage products for human consumption. It establishes:

- The conditions, requirements, and procedures for the registration, modification, and cancellation of sanitary registrations for food and beverage products.
- The regulations for the inspection of the activities and services related to the production and distribution of food products.
- Food safety measures and sanctions.
- The organoleptic characteristics, chemical composition, and microbiological conditions that apply to food and beverage products.
- Food quality and safety standards for food and beverage manufacturers based on the Hazard Analysis and Critical Control Points (HACCP) system.

1.3. Legislative Decree to strengthen the food safety of industrialized food products including fishery and aquaculture products. – Legislative Decree No 1,290 (December 28, 2016)

Legislative Decree No 1,290 (December 28, 2016) aims to establish preventive systems to guarantee food safety, to improve administrative procedures, and to strengthen sanitary surveillance and inspection related to industrialized food products intended for human consumption. This law also regulates fishery and aquaculture products in all phases of production. The scope of the law applies to domestic and imported products. For imported processed food products, the National Sanitary Authority (DIGESA) will grant a sanitary authorization to the importer responsible for the safety of the food product. The aforementioned sanitary authorization is automatically approved for a determined period and it is granted to the food product. Prior to this, the incumbent must present the free sale certificate or its equivalent issued to the manufacturer of the food product by the competent authority of the country of origin. This law replaced Legislative Decree No. 1,222.

1.4. Law On the Promotion of a Healthy Diet – Law No 30,021 (May 17, 2013)

<u>Law No 30,021</u>, aims to reduce obesity-associated health problems by discouraging the advertisement, sale, and consumption of certain processed foods and beverages. Article 10 of the law requires the placement of warning labels on processed foods and non-alcoholic beverages with certain levels of sugar, salt, saturated fat or trans fats. It delegates the responsibility for determining what those levels should be to the Ministry of Health. The warning labels developed under the law advise consumers to "avoid excessive consumption" or, in the case of trans fats, to "avoid consumption" entirely.

On June 17, 2017, Peru approved Supreme Decree 017-2017-SA, which serves as the implementing regulation of Law 30,031. This implementing regulation entered into force six months after the publication of the Supreme Decree. This regulation supersedes previous technical parameters and annuls any food list recommending items to be sold at school kiosks.

Chapter II of Supreme Decree 017-2017-SA establishes technical parameters. The following are the technical parameters to be considered under this implementing regulation:

Technical	Implementing Time Frame	
Parameter	Six (6) Months from the	Thirty nine (39) Months from the

	Approval of the Public Warning Manual	Approval of the Public Warning Manual
Sodium in Solid Food	Greater or equal to 800 mg/100 g	Greater or equal to 400 mg/100 g
Sodium in Drinks	Greater or equal to 100 mg/100 ml	Greater or equal to 100 mg/100 ml
Total Sugar in Solid Food	Greater or equal to 22.5 g/100 g	Greater or equal to 10 g/100 g
Total Sugar in Drinks	Greater or equal to 6 g/100 ml	Greater or equal to 5 g/100 ml
Saturated Fat in Solid Food	Greater or equal to 6 g/100 g	Greater or equal to 4 g/100 g
Saturated Fat in Drinks	Greater or equal to 3 g/100 ml	Greater or equal to 3 g/100 ml
Trans Fats	According to current regulation	According to current regulation

On June 14, 2018, Peru's Government published the last version of the Manual (<u>Supreme Decree 012-2018-SA</u>). The technical parameters will be implemented 39 months from the approval of the Public Awareness Manual. This Manual can be updated based on scientific evidence, information related to healthy eating, and international regulations on the subject with an advance notice of no less than twelve months from entry into force.

The Warning Label Manual for The Law on the Promotion of a Healthy Diet was approved in June 2018. Manufacturers will need to comply with the Manual by June 2019, at which point they will be able to use temporary stickers for an additional six months before needed to use packaging that confirms with the Manual. A detailed description of the labeling requirements is found in Section 5.

Sanitary Supervision Agencies (Title II, Supreme Decree 007-98-SA)

- **Ministry of Health/DIGESA:** Responsible for the sanitary surveillance of food and beverage manufacture, distribution and marketing.
- **Ministry of Agriculture/SENASA:** Responsible for the sanitary surveillance of fresh fruits and vegetables and animal products (e.g., dairy and meats) for human consumption.
- Ministry of Production/National Fisheries Health Service (SANIPES): Responsible for the sanitary surveillance for the capture, transport, and processing of seafood products, as well as sanitary conditions at ports.
- Local Municipalities: Responsible for the sanitary surveillance of establishments trading and manufacturing food and beverages operating within their jurisdictions. Municipalities work closely with DIGESA.

Sanitary Registration of Processed Food and Beverages (Title VIII, Supreme Decree 007-98-SA)

DIGESA is responsible for registering, re-registering, modifying, suspending, and canceling the sanitary registrations of food and beverage products in Peru. This includes the following:

- Oversees the sanitary registration of all processed food and beverage products in Peru.
- Defines industrial food and beverages as finished products for human consumption that result from the physical, chemical or biological processing of animal, plant, or mineral inputs. Food additives are also included.
- Establishes which food and beverages are not subject to health registration, including: a) those in natural conditions, packed or not (e.g., grains, fruits, vegetables, meats and eggs); b) free samples; and c) products donated by foreign charities.
- Establishes that a product's sanitary registration permits its manufacture, import, or sale by the registration holder. Said entity is responsible for the sanitary quality and safety of the food or beverage being sold in Peru.
- Establishes product groups for sanitary registration purposes using a qualitatively similar mix of basic ingredients and food additives that identify the group as such.

1.4. Food Safety Law – Legislative Decree 1,062 (June 28, 2008)

This regulation establishes the legal framework that ensures the application of food safety standards throughout the food chain. Animal feed is also included within the law's range. Suppliers of food products must comply with the sanitary and quality regulations approved by Peru's sanitary authority. An official certificate issued by the country-of-origin's health authority is needed for the importation of fresh agricultural products. For processed food products, they will need a free sale certificate issued by a competent institution in the U.S. (i.e. FDA, State Department of Agriculture, etc.), in order to obtain the sanitary registration number prior their importation.

The Food Safety Law establishes the Sectorial Food Safety Commission (COMPIAL). The purpose is to coordinate public-private sector activity ensuring compliance with the provisions of the Food Safety Law. The Ministries of Agriculture, Health, and Production form the Sectorial Food Safety Commission.

The Food Safety Law establishes specific functions for the participating agencies. DIGESA, as Peru's food safety authority, establishes the general food and beverage hygiene standards for products in the human consumption chain. SENASA monitors and supervises food safety standards applicable to agricultural products (i.e., primary products and animal feed). The Institute of Fisheries Technology (ITP) is the fishery sector's sanitary authority; it monitors the capture, extraction, transport, surveillance, and processing of aquatic products, as well as issues sanitary certificates for fish and fish products.

The Food Safety Regulation, approved by Supreme Decree 004-2011-AG (April 27, 2011), comes with the endorsement of the Ministries of Agriculture and Health; it establishes guidelines for ensuring the food safety of primary and feed products within Peru and abroad.

1.5. Law for Promotion of Organic and Ecologic Production (Law 29,196 / January, 2008)

The law aims to promote the sustainable and competitive development of organic production in Peru. The Ministry of Agriculture (MINAGRI) is the governing body of organic production. The following units of MINAGRI oversee organic production:

- General Direction for Agricultural Promotion: Promotes organic production.
- National Service of Agricultural Health (SENASA): Oversees the organic production throughout the country and establishes regulations and sanctions for national and foreign organic products.
- National Institute for Agriculture Innovation (INIA): Coordinates with public and private institutions regarding research on organic production.

1.6. Ministry of Agriculture – Legislative Decree 997 (March 13, 2008)

The Ministry of Agriculture is responsible for promoting and developing Peru's agricultural sector.

- National Service of Agricultural Health (SENASA): Develops, promotes, and enforces the prevention, control, and eradication of animal diseases and plant pests.
- National Institute for Agricultural Innovation (INIA): Designs and executes national strategy for agricultural research.
- National Water Authority (ANA): Oversees the sustainable use of water resources in river basins.
- National Forest and Wildlife Service (SERFOR): Oversees the sustainable use and conservation of forest and wildlife resources.

1.7. The National Service of Agricultural Health (SENASA)

SENASA is responsible for enforcing regulations that govern domestic and imported animals, plants, and animal and plant products and by-products to prevent the introduction of foreign and exotic animal and plant diseases.

- Animal Health Office: Enforces regulations governing the import and export of live animals, semen, embryos and by-products of animal origin, as well as the registration of veterinary products. In cooperation with Peru's state governments, SENASA enforces laws and regulations to protect and improve animal health, control and eradicate animal diseases (e.g., foot-and-mouth disease) and prevent the introduction of foreign and exotic animal diseases. SENASA's regulatory responsibilities for live animals and animal genetics is similar to those of APHIS/Veterinary Services.
- Plant Health Office: Protects plant health and prevents the introduction and spread of foreign pests. Its functions are similar to those of APHIS/Plant Protection and Quarantine. All U.S.-origin unprocessed plant products (e.g., bulk grains, fresh fruits and vegetables, nuts, or seeds) exported to Peru must be accompanied by an APHIS phytosanitary certificate. SENASA inspects products as part of customs clearance procedures.
- Farming, Livestock and Food Safety Inputs Office: Responsible for supervising seed quality, control, and registration for agricultural chemical pesticides, pharmaceuticals, and food and biological products for animals. It is also responsible for organic certification, organic production oversight, and agricultural production safety.
- Callao Port and Airport Inspection Stations: These stations enforce agricultural health regulations involving the trade of domestic and imported agricultural products.

1.8. The Ministry of Health – Legislative Decree 584 (April 18, 1990)

The Ministry of Health oversees Peru's national health system.

- **Directorate General of Environmental Health (DIGESA):** Drafts regulations and oversees implementation. It is divided into three sections, which oversee basic health services (water and drainage), ecological and environmental protection, and food safety. The food safety section is equivalent to the U.S. Food and Drug Administration (FDA).
- **Directorate General of Pharmaceutical Products and Drugs (DIGEMID):** Registers, modifies, discontinues, and cancels the sanitary registration of sweeteners, diet products, and health products.

1.9. Ministry of Production (PRODUCE) – Law 27779 (July 2002).

The Ministry of Production drafts, implements and oversees policies applicable to the Fisheries, Small and Medium Size Industries (MYPE), and industry subsectors. PRODUCE establishes the regulatory framework for the extractive, productive, and transformation activities of the fishery and industry subsectors. The Fish Health Service (SANIPES) and National Quality Control Institute (INACAL) are under PRODUCE's jurisdiction.

1.10. National Fish Health Service (SANIPES) – Law 30063 (July 7, 2013)

The Ministry of Production's National Fish Health Service is responsible for regulating the food safety of fishery products, aquaculture, and fish feed inputs in order to guarantee public health.

1.11 National Quality Control Institute (INACAL) – Law 30224

The law creates the National Quality Control System to promote and guarantee the fulfillment of the National Policy for Quality Control that aims to increase competitiveness and consumer protection. The law also creates the National Quality Control Institute (INACAL) which is a technical entity attached to the Ministry of Production. INACAL adopted part of INDECOPI's functions and became the competent authority regarding standardization, accreditation and metrology.

1.12. Peru's Customs (SUNAT) – Law 24,829 (June 8, 1998)

SUNAT-Customs monitors and enforces the collection of customs duties and fines and combats smuggling. It operates throughout Peru's ports and airports, working in tandem with private customs agencies.

1.13. Ministry of Foreign Trade and Tourism (MINCETUR) – Law 27,790 (July 23, 2002)

MINCETUR is responsible for defining, leading, coordinating, regulating, and supervising foreign trade and tourism in Peru. As the lead trade agency, it negotiates trade agreements in coordination with other ministries (i.e., the Ministries of Foreign Affairs and Economy and Finance).

1.14. National Institute for the Defense of Competition and for the Protection of the Intellectual

Property (INDECOPI) – Law Decree 25,868 (November 24, 1992)

INDECOPI promotes competition, protects intellectual property, and quality.

- Office of Consumer Protection: Protects consumer rights, including consumers' right to be properly informed about goods and services.
- Office of Repression of Unfair Competition: Enforces advertising regulations to protect consumers. Penalizes unfair practices.
- Office of Dumping and Subsidies: Regulates market distortions caused by subsidized or below market value imports.
- Office of Market Access: Monitors the activities of the public administration to prevent market access barriers.

1.15. Ministry of the Environment – Legislative Decree 1,013 (May 13, 2008)

The Ministry of the Environment designs, implements, and supervises national and sectorial environmental policies. It is responsible for the promotion of the sustainable use of natural resources, and implementing conservation efforts to prevent the degradation of the natural resources.

Section II. Food Additives Regulations:

(Title VII, Supreme Decree 007-98-SA)

- Sanitary Quality of Inputs and Food Additives: These must meet DIGESA's sanitary standards and health quality requirements.
- Allowed Additives: food additives do not need an import permit. Only <u>CODEX permissible</u> food additives are allowed. All others are forbidden and cannot be kept within food and beverage product manufacturing facilities. Flavorings accepted by the U.S. FDA and the Flavor and Extractive Manufacturing Association (FEMA) are permissible.

Section III. Pesticides and Other Contaminants:

SENASA regulates pesticides, herbicides and fungicides used in the fumigation of agricultural products. Peru adheres to the Andean Community's (CAN) Decision No. 436 and Resolution 630 regarding registrations and control of chemical pesticides for agricultural use. In 2014, the Peruvian Congress enacted Law 30190 that modified the Legislative Decree 1059 related to the *General Law of Agricultural Health*. The law modified Article 14 of the LD 1059 related to pesticides for agricultural use. SENASA drafted the implementing regulation for Law 30190 that was approved by the Supreme Decree 001-2015-MINAGRI, establishing the Regulation of the National System of Pesticides for Agricultural Use. All the pesticides for agricultural use that are produced, formulated, packed, imported, distributed or commercialized in the country must be with SENASA. The pesticide for agricultural use registration is mandatory for the following products:

- 1. Chemical pesticides for agricultural use
- 2. Biological pesticides for agricultural use
- 3. Plant growth regulators
- 4. Atypical pesticides

The procedures for the registration of each category vary depending on precedent. For those products that do not have a precedent, the applicant first needs to request a permit at SENASA to carry out efficacy evaluation trials prior to the registration of each product. SENASA's requirements to grant authorization for the aforementioned trials is listed and described in Annex two of Supreme Decree 015-2015-MINAGRI. They subsequently need to get a permit from SENASA to import samples for those trials. The "Efficacy Evaluation Trial" permit has a validity of one year.

Section IV. Packaging and Container Regulations:

4.1 Packaging

(Title VIII, Supreme Decree 007-98-SA)

Packaging material must be free from substances that could affect the food safety of the food product. Packaging must ensure the product's sanitary quality and composition. The Ministry of Health determines sanitary standards, setting maximum allowed limits for impurities and residues. Packaging made of metals, alloys and or of plastic should not:

- Contain impurities consisting of lead, antimony, copper, zinc, chromium, iron, tin, mercury, cadmium, arsenic, or other metals or metalloids deemed hazardous to human health in quantities or at levels above the maximum permissible limits.
- Contain residual styrene, vinyl chloride, acrylonitrile monomers or any other residual monomers or substances that can be considered hazardous to human health in quantities or at levels above the maximum permissible limits.

Laminates, varnishes, films, coatings and other parts of the package that come into contact with food and beverage products are subject to the provisions of this Decree. The use of packages that are used for non-food products or products that are not fit for human consumption is prohibited. Packages manufactured from previously used recycled paper, cardboard or plastic are prohibited, except, packages made of PET containers (polyethylene terephthalate) for food industry and certified by a local Conformity Assessment Body accredited by INACAL or any other foreign entity accredited by the International Laboratory Accreditation Cooperation (ILAC) or the Inter American Accreditation Cooperation (IAAC).

Returnable containers can be recycled for beverage production if they are washed and disinfected or treated with any other process that guarantees the food safety standards of the containers under the manufacturer responsibility.

Section V. Labeling Requirements:

INACAL's Metrology Office oversees food and beverage product labeling, inspection and advertising (Supreme Decree 007-98-SA). Penalties are levied based on the offense and intent.

5.1 General Requirements

All food and beverage products packaged for sale must be labeled in accordance with the provisions established in INDECOPI's Peruvian Technical <u>Standards NTP 209.038:2009 (Reviewed in 2014 – PACKED PRODUCTS LABELING</u>, as well as per article 117 of Supreme Decree 007-98-SA. An adhesive Spanish language label needs to be applied before an imported product reaches the point-of-sale. The information should include:

- Name of the product.
- Food additives and ingredients and instructions for use.
- Manufacturer's name and address.
- Importer's name, commercial name and address, phone, taxpayer's identification (RUC). Note this information may appear on a separate adhesive label.
- Sanitary registration number.
- Expiration Date (shelf life, established by the manufacturer) as stipulated by Codex or the applicable Peruvian sanitary standard.
- Production lot code and special conservation conditions (if any).
- Net weight or volume of the content.
- Country of origin.

Legislative Decree 1,304 pertains to the labeling requirements of value-added products. Labeling is mandatory for all value-added products consumed, imported or manufactured and sold in Peru. Supreme Decree 020-2005-PRODUCE lists the products subject to this law. The list is subject to periodic revision. Labels must include the name of the product, its country of manufacture, and product validity (including date of expiration, conditions for storage, and additional observations). Should an imported product not meet these requirements, the importer is authorized to re-label the product prior to clearing customs. INDECOPI monitors compliance with labeling requirements at the retail/wholesale level.

5.2 Other Specific Labeling Requirements.

Supreme Decree 007-2015-SA (April 18, 2015), establishes technical parameters for labeling sugar, salt, and saturated fats contained in food and non-alcoholic beverage products. The following are the parameters established for 100 grams of solid food or 100 milliliters of liquid.

Content	Beverages	Solid Food
Sugar	Equal or lower than 2.5 grams	Equal or lower than 5 grams
No it		Equal or lower than 300 milligrams (equivalent to 120 milligrams of sodium
Saturated Fats	Equal or lower than 0.75 grams	Equal or lower than 1.5 grams

This Decree tasks the Ministry of Health with updating technical parameters based on studies, scientific information, and national and international practices. The following food categories are exempted from these parameters:

- Non-industrialized food and non-alcoholic beverage products.
- Foods with minimal processing (cut, sliced, deboned, pealed, cleaned, milled, pasteurized, refrigerated, frost, defrost).
- Prepared food products for immediate consumption.

Law On the Promotion of a Healthy Diet - WARNING LABEL MANUAL

The Ministry of Health published the *Warning Label Manual* (the Manual) for food labeling under the *Law on the Promotion of a Healthy Diet* on August 18, 2017. The Manual establishes detailed specifications for the inclusion warnings on the front of package labels of products that exceed the limits for salt, sugar, saturated fat, and trans-fats established in the *Law on the Promotion of a Healthy Diet* (Law 30,021).

On June 2018, the Ministry of Health approved the Manual (<u>Supreme Decree 012-2018-SA</u>). It has an implementing period of six months after its final version publication. In the case of foreign food products, the regulation does not have any specification on whether the warning signs must be placed in the original packaging or on a sticker after the nationalization of the product. DIGESA is currently working on the procedure to include the warning signs on the foreign products' label.

The format of the warning label is as follows:

ALTO EN GRASAS SATURADAS

EVITAR SU CONSUMO EXCESIVO

CONTIENE GRASAS TRANS

EVITAR SU CONSUMO

EVITAR SU CONSUMO

EVITAR SU CONSUMO

EVITAR SU CONSUMO

Gráfico 1: Advertencias publicitarias

Advertising warnings should be clear, legible, prominent, and understandable. The label should be placed on the front side of the product's packaging, according to the following specifications and details included in Annex 1 of the *Warning Label Manual*:

• Shape: Octagon

Color: Red, black, and whiteFont: Helvetica LT Std – Bold

• Inside the octagon:

- a. For processed foods exceeding the technical parameters for sodium, sugar, and saturated fat content, the text must read "HIGH IN," followed by: "SODIUM," "SUGAR," or "SATURATED FATS" in one or more independent symbols.
- b. For processed food exceeding the technical parameters for trans-fat content, the text "CONTAINS TRANS FAT" shall be included.

Under the octagon, and inside a rectangle framed with a black line and with a white background:

- a. For processed food exceeding the technical parameters for sodium, sugar and saturated fat content, the following text shall be included: AVOID EXCESSIVE CONSUMPTION
- b. For processed food exceeding the technical parameters for trans-fat content the following text shall be included: AVOID CONSUMPTION
- Advertising warnings shall be located in the upper right area on the front side of the package, containing or surrounding the product unit.
- In the event that the processed product requires more than one warning, the order below shall be followed from left to right and top to bottom:
 - a. High in sodium
 - b. High in sugar
 - c. High in saturated fats
 - d. Trans fats content
- If the total area of the package's front side is up to 20 cm², the warning shall be included in the package that contains it.

There are four sizes for advertising warnings, which shall be determined based on the total area of the package's front side or main side, as established in the table below:

Package's front or main side area	Size of advertising warnings
Up to 20 cm ²	3 cm wide x 3,72 cm high (in a package containing the
	product)
From 20 to 40 cm ² of area	1,5 cm wide x 1,86 cm high
From 40 to 100 cm ² of area	2,0 cm wide x 2,48 cm high
From 100 to 200 cm ² of area	2,5 cm wide x 3,10 cm high
Larger than 200 cm ² of area	6,0 cm wide x 3,72 cm high

For cylindrical packages, the area of the rectangle formed by the diameter and the cylinder height shall be considered as the front side area.

Section VI. Other Specific Standards:

6.1 Endangered Species

The Natural Resources Service (INRENA) is responsible for promoting the sustainable use and conservation of natural resources and endangered species. IRENA regulates the export and import of

endangered animal and plant species. Peru is party to the Convention of the International Trade in Endangered Species of Wild Flora and Fauna (CITES).

6.2 Marine Products

The Ministry of Production's Vice-Ministry of Fisheries (PRODUCE) regulates commercial fishing along with the transport and processing of landed catch. It also ensures sanitary conditions within ports. PRODUCE issues research import permits. Resolution 409-98-PE (August 25, 1998) regulates inspection programs for canned, frozen, and cured fish.

6.3 Biotechnology Products

On December 9, 2011, the Government of Peru approved Law 29,811, establishing a ten-year moratorium on the cultivation of genetically modified organisms. The law designates the Ministry of Environment as the lead agency for biotechnology. The moratorium includes three exceptions: 1) laboratory research; 2) use in pharmaceuticals and veterinary products; and 3) use in food, animal feed and in food processing.

On November 14, 2012, Peru passed Supreme Decree 008-2012-MINAM establishing the implementing regulation for enforcing a ten-year moratorium on the planting of biotechnology crops. The Ministry of Agriculture and Irrigation and its dependent agencies SENASA (Peru's sanitary and phytosanitary authority) and INIA (the National Agricultural Research Service) are relegated to a secondary regulatory enforcement and research role.

In 2016, Peru issued the Executive Decree N° 006-2016-MINAM with a procedure and plan for surveillance and early detection of genetically engineered organisms, by which Peru's Ministries of Agriculture (MINAGRI), Environment (MINAM), and Production will enforce the ten-year moratorium on biotechnology. On July 24, 2016, Executive Decree N° 011-2016-MINAM listed the specific commodities restricted under the biotechnology moratorium. These regulations do not change any requirements for domestic producers.

6.4. Milk and milk products regulation - Supreme Decree 007-2017 - MINAGRI

This regulation sets specific technical parameters and sanitary requirements for milk (raw, pasteurized, UHT, evaporated and powder) and milk products (cheese and yogurt) of bovine origin destined for human consumption. These indicators are aligned with CODEX standards for milk and milk products. The terms "milk" and "milk product" are aligned with CODEX standard 206-1999. The scope of the regulation applies for foreign products considering the following HS Codes: 0401.10; 0401.20; 0401.40; 0401.50; 0402.10.10; 0402.10.90; 0401.21.11;0402.21.19; 0402.2191; 0402.21.99; 0402.29.11; 0402.29.19; 0402.29.9; 0402.29.99; 0402.91.10; 0403.10 and 0406.10

6.5 Veterinarian drugs residues in food products - Ministerial Resolution 372-2016/MINSA

The resolution approves the Sanitary Technical Regulation (<u>NTS 120-MINSA/DIGESA</u>) that sets the maximum residues level (MRL) for veterinarian drugs in food products destined for human consumption. The MRLs are listed in the Annex of the Regulation.

6.6. Pesticide MRL on food for human consumption Ministerial Resolution 1006-2016/MINSA

The resolution approves the Sanitary Technical Regulation (<u>NTS 128-MINSA/DIGESA</u>) that sets the maximum residues level (MRL) for pesticides in food products destined for human consumption. The MRLs are listed in the Annex of the Regulation.

Section VII. Facility and Product Registration Requirements:

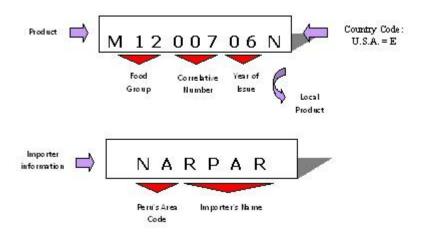
7.1 Food and Beverage Sanitary Registration Law 26,842 (July 20, 1997) – Title VIII of Supreme Decree 007-98-SA (September 25, 1998)

The registration process must be initiated by a SUNAT registered company, in possession of a valid tax identification number (RUC). DIGESA registration information must be uploaded to the VUCE website (*Ventanilla Unica de Comercio Exterior*). This site handles formalities for goods transiting, entering, or leaving Peru. Requirements include:

- Simplified Trade System Form (SUCE *Solicitud Unica de Comercio Exterior*) must be filled out on the VUCE website
- A physical/chemical and microbiological quality analysis from the manufacturer's quality control laboratory or by a laboratory in Peru accredited by INACAL or any other international accreditation entity recognized by the International Laboratory Accreditation Cooperation or the Inter-American Accreditation Cooperation
- Bromatological analysis results issued by a laboratory accredited by INACAL or any other international accreditation entity recognized by the International Laboratory Accreditation Cooperation or the Inter American Accreditation Cooperation
- List of ingredients and quantitative compositional analysis of food additives, identified by their generic name and international numeric reference (SIN Code)
- Conservation and storing conditions
- Information about the packaging indicating the type and material used
- Lifetime information of the product under normal conservation and storing conditions Identification system of the production batch
- Labeling information
- Payment of administrative fees

Along with the signed application form, the importer needs to present the certificate of free sale and use. The certificate is requested by the supplier. The label must comply with local regulations (see Section II - Labeling Requirements) and the registration receipt must be presented. All documentation cannot be older than one year. A Spanish language translation of the documentation must be attached.

Product sanitary registration is issued per product or group of products, as well as per manufacturer. A product group consists of those products elaborated by the same manufacturer and with the same qualitative composition of basic ingredients and food additives.



The code numbering of the sanitary registration is based on the certificate of free sale and use. DIGESA regulates processed food products and their manufacture in accordance with CODEX.

Table 1: Sanitary Registration, Classification by Product Groups

Food and Beverage Category	Food and Beverage Category
 Milk and dairy products Ice cream and Ice cream mixtures Oil and fats Freeze-dried, dehydrated or concentrated products Cereals, pulses and by-products Sugars, honey and by-products Confectionery Bakery and pastries Special diet food 	 Meat and meat products Hydro biological products (seafood) Eggs and egg products Salt, species, condiments and sauces Fruits and other vegetables (including tubers and mushrooms) Prepared food Beverages Stimulant and spirit beverages Canned food Food additives

Sanitary registration or renewal occurs only if the application complies with all established requirements. This procedure should take no more than seven working days. Verification of the product's sanitary quality is carried out after sanitary registration or renewal. Sanitary registration of food and beverages are valid for five years from date of issue. Renewals must occur between seven and sixty days of the registration's date of expiry.

7.2 Certificate for Sanitary Registration of Current Registered Food and Beverages

- Registered food and beverage products can be imported and sold by anyone. DIGESA will issue a sanitary registration certificate on behalf of the interested party.
- The product's importer and seller have the same responsibilities as the original sanitary registration's holder. The importer's name, address, and RUC must be printed or labeled for each individual package sold to consumers.

The sworn affidavit must include the requesting company's contact information, the products (commercial) name, the product's original sanitary registration holder and registration number, and the payment receipt.

7.3. Sanitary Registration for Fisheries

The Institute of Fisheries Technology (ITP) within the National Fisheries Health Service (SANIPES) is responsible for issuing the sanitary registration for fishery and aquaculture products for their further commercialization in the country. The validity of the registration is for five years.

<u>Technical Protocol of Sanitary Registration for Imported Fishery, Aquaculture and thermally-processed low-acid canned Fishery Products (PTRSI)</u>

In order to obtain the PTRSI, the incumbent must present the following documents. This procedure should take no more than seven working days.

- a. Application letter addressed to the director of SANIPES.
- b. Forms:

F08-DSANIPES/IH-PR-09-FORMULARIO 8 for imported fishery and aquaculture products. The following information is required from the manufacturer:

- Name of the product.
- Brand.
- Packaging (type, material and volume).
- Species (common and scientific name).
- Ingredients.
- Additives.
- Conservation and warehousing conditions.
- Expiration date.
- Coding system.
- Labeling (name, brand, manufacturer, address, registration number, etc.).
- Processing flow diagram (all the processing stages).
- Signature of the legal representative of the registering company.

F06-DSAPINES/IH-PR-09 – FORMULARIO 6 for thermally processed low-acid canned fishery products. The following information is required from the manufacturer:

- Name of the product.
- Brand.
- Packaging (type, material and volume).
- Species (common and scientific name).
- Ingredients.
- Additives.
- Packaging features (tin, aluminum, glass).

- Packaging size (inches or millimeters).
- Coding system.
- Labeling (name, brand, manufacturer, address, registration number, etc.).
- Programmed heat treatment (initial temperature, time lapse, process temperature, cooling-off type, containers stowage pattern and thermal treatment source).
- Signature of the legal representative of the registering company.
- c. Free sale certificate issued by the sanitary authority of the country of origin.
- d. Administrative fees receipt.

7.4. Organic Production Accreditation.

According to the Supreme Decree 010-2012-AG, SENASA is responsible for registering and approving the accreditation entities for organic production. The Supreme Decree 061-2006-AG establishes the National Registry of Organic Production Accreditation Entities (NROPA). The interested entities can apply to one or more of the following sectors: plant production; animal production; apiculture; wild crafting; processing and commercialization.

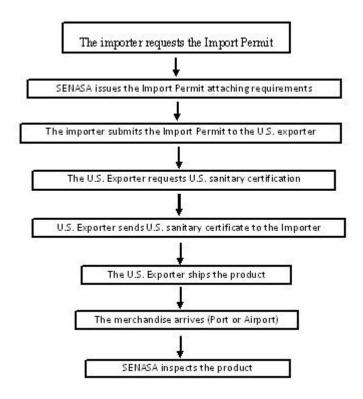
The technical regulations for organic production (Supreme Decree 044-20006-AG), indicates that foreign organic products must comply with dispositions listed in this regulation and be certified by an authorized entity of the NROPA. The foreign manufacturer must provide the importer all of the documentation that gives the organic accreditation status in the country of origin in order to obtain SENASA's validation.

Section VIII. Other Certification and Testing Requirements:

8.3 Import Procedures for Animal and Plant Products

Prior to shipment, an import permit must be opened with SENASA. A copy of the permit must be forwarded to the exporter. The exporter must provide the importer with an official health certificate from the country of origin. SENASA's port inspectors verify compliance with import requirements. For new to market animal and plant products, a risk assessment must be carried out in accordance with the Andean Community, World Trade Organization, CODEX or World Organization for Animal Health recommendations, as well as per the sanitary requirements of the exporting country.

Certificates for animal and plant products and by-products must be error free, contain no pen or ink changes, or have any other type of amendments. If applicable, the product must be packaged in food safe packaging and labeled in accordance with U.S. regulations. The product must identify its content, net weight and the facility where it was produced.



a. Fresh, Chilled and Frozen Products or By-products of Animal Origin

Tariff (HS) codes for animals and animal by-products are subject to SENASA import requirements as per Supreme Decree 051-2000-AG and Resolution 191-2000.

Table 2: Chapter/ HS Codes, Subject to SENASA Import Requirements

Chapter/ HS Code	Description
Chapter 1	Live Animals
Chapter 2	Meat and Edible Meat Offal
Chapter 4	Milk, Dairy and Egg Products
Chapter 5 – HS 0504	Sausage Casings
Chapter 5 – HS 0511	Bovine Semen and Embryos
Chapter 41	Raw Hides, Skins and Leathers
Chapter 51	Wool and Animal Hair

b. Fruits and Vegetables, Commodities and Raw Agricultural Products

Tariff (HS) codes for plants and plant products subject to SENASA import requirements as per Supreme Decree 032-2003-AG and Resolution 299-2003.

Table 3: Chapter/ HS Codes, Subject to SENASA Import Requirements

Chapter/HS Code	Description
Chapter 6	Live Trees and Plants, Bulbs, Roots and
Chapter 0	Flowers
Chapter 7	Edible Vegetables and Tubers
Chapter 8	Edible Fruits and Nuts
Chapter 9	Coffee, Tea and Spices
Chapter 10	Cereals
Chantar 11	Products of the Milling Industry, Malt and
Chapter 11	Starches
Chapter 12	Oilseeds, Miscellaneous, Grains, Hay and
Chapter 12	Straw
Chapter 14	Other Vegetable Products
Chapter 17 – HS 1701 and 1702	Sugars and Syrups
Chapter 18 – HS 1801 and 1802	Cocoa, Grains and Waste
Chapter 21 – HS 2101 and 2103	Miscellaneous and Edible Preparations
Chapter 23 – HS 2302, 2306, 2308, and 2309	Food Industry Waste, Prepared Animal Feed
Chapter 24 – HS 2401	Tobacco, Not manufactured
Chapter 44 – HS 4401, 4403-4409, 4411-4413, and	Wood
4415	W Ood
Chapter 52 – HS 5201-5203	Cotton and Cotton Waste

SENASA, on January 4, 2003, issued phytosanitary risk requirements for seeds and vegetables. Quarantine procedures along with risk categories were issued on August 24 and October 3, 2003. On July 18, 2005, SENASA issued specific plant health requirements for imported botanical seeds. On October 26, 2005, SENASA published its pest quarantine list.

Table 4: SENASA's U.S. Counterparts, Products of Animal and Plant Origin

U.S. Agency	Health Certificate Required
Animal Health Inspection	Fresh fruits and vegetables; live animals and animal by-products
Service (APHIS)	(including biological genetic material)
Food Safety and Inspection	Meats and by-products, for human consumption
Service (FSIS)	
Agricultural Marketing	Milk and dairy products
Service (AMS)	

SENASA, on February 28, 2005, issued Directorial Resolution 0105-2005 approving the Phytosanitary Procedures Manual for wood packaging material.

c. Processed Food Products

DIGESA's sanitary registration certificate (SRC) must accompany all processed food products, alcoholic beverage, and non-alcoholic beverage import documents.

d. Appeals System for Disputed or Rejected Product

Customs General Law – Supreme Decree 129-2004-EF (September 12, 2004) regulates SUNAT procedures and sanction mechanisms. SUNAT notifies import infringements in writing, permitting the importer a 20-day period to rectify and fulfill all import requirements. Appeals are filed with Peru's National Customs Office and the Ministries of Economy and Justice.

Section IX. Import Procedures:

9.1 Import Procedures – Supreme Decree 011-2005-EF (January 26, 2005)

The <u>U.S.-Peru Trade Promotion Agreement</u> (PTPA) provides duty-free access for two-thirds of U.S. food and agricultural products. Customs clearance procedures require:

- A paid SUNAT Customs Unique Declaration (DUA) filed by a customs agent
- An authenticated copy of the airway bill or bill of lading
- Authenticated copy of the commercial invoice and a packing list
- An authenticated photocopy of the insurance document
- Processed food products require an authenticated copy of the DIGESA RSA
- Animals, plants and by-products thereof require a SENASA sanitary certificate
- Dispatch authorization (if requested)

SUNAT channels imports along a green, orange, or red lane. The green lane permits entry of the product upon payment of duties. The orange lane requires additional documentation review, while the red lane requires both a document review and physical inspection.

Anticipated Dispatch Customs Clearance Procedures

Anticipated dispatch clearance is a pre-arrival procedure. An importer is required to submit all customs clearance paperwork, as well as their RUC and a list of ten previous DUAs from within the past 12-months. The importer must not have incurred customs fines in excess of \$3,300.

9.2 Simplified Import Customs Clearance Procedures for Samples

Simplified import custom clearance procedures apply to samples with no commercial value (i.e., gifts that do not exceed \$1,000 FOB or products less than \$2,000 FOB), and to samples with a commercial value that do not exceed \$2,000 FOB. Alcoholic beverage samples always have a commercial value and are subject to import taxes and tariffs. Samples should be made unsellable by means of cuts, perforations, inscriptions, or unsealing. Once the Simple Declaration is processed, the merchandise is subject to inspection. The owner of the merchandise, the consignee or the customs agent must submit:

- A SUNAT's Simple Declaration form
- Airway bill, bill of lading, or postal notification letter
- Commercial invoice and insurance letter
- Identification card, passport, or RUC number
- Processed food products require an authenticated copy of DIGESA's RSA
- Animal and plant and their by-products require a SENASA sanitary certificate

Section X. Copyright and/or Trademark Laws:

INDECOPI ensures trademark, copyright and intellectual property protection.

10.1 Trademarks

<u>INDECOPI's</u> Distinctive Marks Office is responsible for the registration of trademarks, brands, commercial names, slogans and *appellation d'origine* (i.e. designation of origin). Its procedures are guided by CAN Decision 486 – Industrial Property for Andean Countries – and <u>Legislative Decree 823</u> for Intellectual Property Rights. Peru is a signatory of the <u>Paris Convention for the Protection of Industrial Property</u>; in compliance with the WTO agreements on trade-related aspects of Intellectual Property Rights.

Appendix I. Government Regulatory Key Agency Contacts:

Ministry of Agriculture and Irrigation

Minister: Fabiola Muñoz

Av. La Universidad 200, La Molina, Lima 12. Tel: (511) 209-8800; www.minag.gob.pe

National Food Safety and Quality Service (SENASA)

Director General: Pedro Molina

Av. La Molina 1915, La Molina, Lima 12.

Tel: (511) 313-330; Fax: (511) 313-14861 www.senasa.gob.pe

• Plant Health: Moises Pacheco

• Animal Health: Dr. Mercedes Flores

• Food Safety: Gerard Blair

• Port Callao: Dr. Julio Fernandez

• Airport Callao: Dr. Erasmo Justiniano

Ministry of Health

Minister: Elizabeth Tomas

Av. Salaverry 801, Jesús María, Lima 11.

Tel: (511) 315-6600; Fax: (511) 431-0093; www.minsa.gob.pe

General Environmental Health Bureau (DIGESA)

Director General: Percy Montes

Las Amapolas 350, Urbanización San Eugenio, Lince, Lima 14.

Tel: (511) 442-8353/8356; Fax: (511) 422-64041 www.digesa.minsa.gob.pe

Food safety and Sanitary Registration. Director: Maria Eugenia Nieva; Tel: (511) 442-8353

Directorate General of Pharmaceutical Products and Drugs (DIGEMID)

Director General: Jesús Susana del Rocío Vásquez Lezcano Av. Parque de las Leyendas cdra. 1 s/n, San Miguel, Lima 33.

Tel: (511) 631-43001 Fax: (511) 555-5760; http://www.digemid.minsa.gob.pe/

Ministry of Foreign Trade and Tourism (MINCETUR)

Minister: Edgar Vásquez

Calle Uno Oeste 50-60, Urb. Corpac, San Isidro, Lima 27

Tel: (511) 513-6100; www.mincetur.gob.pe

Ministry of Environment

Minister: Lucía Ruíz

Av. Javier Prado Oeste 1440, San Isidro, Lima 27.

Tel: (511) 611-600; Fax: (511) 611-6000 Annex: 1634; www.minam.gob.pe

National Institute for the Defense of Competition and for the Protection of the Intellectual Property (INDECOPI)

President: Ivo Gagliufi

Calle de la Prosa 138, San Borja

Tel: (511) 224-7777; www.indecopi.gob.pe

Ministry of Production\National Fisheries Health Service (SANIPES)

Executive President: Maria del Carmen Abregú Báez Location: Carretera a Ventanilla Km. 5.2, Callao.

Tel: (511) 715-0180

Surquillo Location: Domingo Orue 165, Piso 7, Surquillo. Tel: (511) 213-85701 www.sanipes.gob.pe

Appendix II. Other Import Specialist Technical Contacts:

U.S. Embassy Lima – USDA\Foreign Agricultural Service

Av. La Encalada cdra. 17, Monterrico, Lima 33

Tel: (511) 434-3042; Fax: (511) 434-3043; E-mail: Aglima@usda.gov

For a list of authorized laboratories in Peru, please refer to **INACAL**.