



**Required Report:** Required - Public Distribution

**Date:** January 06, 2022

Report Number: AR2021-0039

# **Report Name:** Food and Agricultural Import Regulations and Standards **Country Report**

Country: Argentina

**Post:** Buenos Aires

**Report Category:** FAIRS Annual Country Report

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# **Report Highlights:**

This report provides overall information on regulations and standards for importing U.S. food and beverage products to Argentina. Post recommends U.S. suppliers interested in the Argentine market contact our office or local importers to discuss the rules and regulations applicable to import requirements for particular products.

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This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service in Buenos Aires, Argentina, for U.S. exporters of domestic food and agricultural products. While every possible care has been 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 PRODUCTS IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY."

# **Executive Summary**

Argentina, the second largest country by land and third largest by population in South America, had the third highest GDP per capita in Latin America in 2020. The capital, Buenos Aires, and its surrounding suburbs, account for nearly one-third of the country's population. Alberto Fernando assumed the Presidency in December 2019.

In CY 2020, the US exported \$144 million dollars in food and agricultural products to Argentina against Argentina's exports to the U.S. of \$1.79 billion. Major US exports to Argentina include seeds, food ingredients, prepared food, alcoholic beverages, and livestock genetics.

The Argentine Food Code (Código Alimentario Argentino – CAA) is the guiding legislation for the production, processing and marketing of both domestic and imported food and beverage products. The CAA also incorporates regulations and standards agreed upon within MERCOSUR, a South American trading bloc which includes Argentina, Brazil, Paraguay, and Uruguay. In June 2019, MERCOSUR and the EU announced an agreement on an FTA which is still pending ratification by EU member countries. In December 2020, the Fernandez administration signaled a desire to proceed with implementation.

Three government agencies regulate food and beverages in Argentina, namely:

SENASA/MAGyP – National Service of Agricultural Food Health and Quality (Ministry of Agriculture, Livestock, and Fisheries): animal and plant products and by-products, fishery and seafood products.

INAL/ANMAT/MS – National Food Institute/National Administration of Drugs, Food Products, and Medical Equipment (Ministry of Health): processed food and beverages, except wine.

INV/MAGyP: National Wine Institute (Ministry of Agriculture, Livestock, and Fisheries).

# Section I. Food Laws

#### Framework

The Argentine Food Code - Código Alimentario Argentino (CAA) establishes the regulatory framework for the production, processing and marketing of both domestic and imported food and beverage products. Its primary goal is the protection of public health and maintaining consumers' confidence in the safety and quality of food products distributed within Argentina.

Established by Law #18284 (1969) and enforced by Decree #2126 (1971) the CAA has over 1,400 articles divided into 22 chapters with technical regulations that establish sanitary and commercial identification provisions for domestic and imported food products. The CAA is implemented under the guidelines of Argentina's national food inspection system - Sistema Nacional de Control de los Alimentos (SNCA), under whose framework the Ministry of Agriculture, Livestock, and Fisheries (MAGyP) and the Ministry of Health (MS) enforce the CAA standards. The CAA is updated by joint resolutions from MAGyP and MS. To access CAA please refer to this link.

The National Food Commission (<u>CONAL</u>), an advisory body with representatives from the MS and MAGyP as well as private sector and consumer organizations, provides support to the SNCA. Provincial-level food regulatory agencies are also invited to participate in CONAL.

As a member of the Southern Cone Common Market (MERCOSUR), the CAA incorporates standards agreed upon within Mercosur, which are influenced by standards from the EU, Codex Alimentarius, and the U.S. Food and Drug Administration (FDA).

#### **Regulation**

Three government agencies regulate food and beverages in Argentina, namely:

MAGyP, through <u>SENASA</u>, is responsible for governing:

- fresh, chilled, frozen and thermo-processed products and by-products of animal, plant and seafood origin.

- mixed canned products (with animal and/or vegetable-origin content) containing over 60 percent ingredients of animal origin.

- food preparations containing over 80 percent ingredients of animal origin.

MAGyP, through <u>INV</u>, regulates the production and distribution of wine.

The MS, through INAL, within the <u>ANMAT</u>, regulates consumer-ready food products, health supplements and alcoholic and non-alcoholic beverages, excluding wine.

#### Import Authorization System

<u>General Resolution 3283/2015</u> established the Sistema Integral de Monitoreo de Importaciones (SIMI), an integrated system for import control through non-automatic import licenses (NAIL) or automatic (AIL) or link to <u>Official Resolution 5/2015</u>.

- NAIL: Agriculture-related products requiring a non-automatic import license include paper and pulp, wool, cotton products, and wood products (See HTS Codes included in Annexes II through XVII, Point (1) of Resolution 5/2015 (see link above) NAILs require detailed information on the import production process and may require an additional approval from the relevant technical authorities in Argentina.
- AIL: For all other products, the license application information required includes importer, origin country, HS code, product description, state of merchandise, number of units, and value of shipment in U.S. dollars (FOB).

#### **Container Registration**

<u>General Resolution AFIP No. 3615/2014</u> established a container information system through a web-based database, Registry of Containers. This system, which is applicable to both imports and exports, provides the Argentine government with container specific information that can be used to monitor and control container-based trade.

#### Import Taxes

Argentina imposes duties and taxes, such as a value added tax and/or a statistical tax, on many imported agricultural products, with some exceptions, per Decree No. 509/2007. Customs charges and other import costs are calculated based on cost, insurance and freight value of the product.

# Section II. Labeling Requirements

<u>Chapter 5 of the Argentine Food Code, Sections 220-246, and MERCOSUR regulations 26/03</u> and 46/03 provide the requirements for food labeling and advertising of food products. Resolution No. 26/03 defines labelling as 'any inscription, image or descriptive or graphic material that has been written, printed, marked, embossed or otherwise attached to the food package. Back-of-pack nutritional labeling is mandatory for products in Argentina even in the absence of a nutritional or health claim.

<u>Animal-Origin Products</u>: Labels for animal-origin products must be submitted to SENASA for pre-approval prior to entry. An importer may submit a label to SENASA for pre-approval independently or as part of the import license application. SENASA provides label status

feedback directly to the importer. A label must be affixed to the product prior to domestic distribution in Argentina.

Product specific labeling information for exports of U.S. fresh, chilled, frozen and thermoprocessed products of animal origin are available at <u>USDA's Food Safety and Inspection Service</u> <u>Export Library page for Argentina</u>.

<u>Non-Animal Origin Processed Foods</u>: Labels for other food and beverage products (see specific wine requirements below) must be submitted to INAL for pre-approval. Non-animal origin processed foods may be imported in their original packaging. If the original package label does not include the following information in Spanish, a sticker label in Spanish must be affixed to the retail package with the following information:

- Name (approved by INAL) and brand of the product.
- Identification of origin.
- Composition: ingredients in decreasing order of weight, and additives at the end of the list.
- Net weight or measure.
- Lot number.
- Expiration date.
- Manufacturer's name and address.
- Importer's name and address.
- Importer's National Register of Establishment number (RNE).
- National Register of Food Product number (RNPA).
- Storage, preparation and usage instructions when required.
- Nutritional information.

# Wine:

# Bottled Wine

Imported bottled wines may have printed labels in foreign languages but, for commercial distribution, they must supplement the information provided with the following additional requirements in Spanish:

- The importer's name, address, and registration #.
- The product's legal name must be included in a clear and highlighted way and must not be smaller than 1.50 millimeters (1.50 mm) high.
- The tags and boxes containing bottles and/or packages must have a printed indication key which identifies the lot number determined by the producer and/or wine bottling establishment. They key code will be preceded by the letter "L".

# Bulk Wine

Imported bulk wines intended to be bottled in Argentina must include the following information in their identifying tag:

- Country of origin.
- Font required: No less than three millimeters (3 mm) high, highlighted, horizontal, parallel to the base of the package/bottle/demijohn, and separated from other text on the label. When the bulk wine is shipped in bottles and demijohns, the denomination must be listed in all fixed elements affixed to the label.
- For carton, poly-laminated, and bag-in-box packages, the denomination must be printed on the two (2) largest and most visible sides of the package.

On May 18, 2021, <u>Joint Resolution 18/2021</u> was published in the Official Bulletin incorporating Article 236 on labeling of alcoholic beverages. It establishes that all labels on alcoholic beverages sold in Argentina must include a pictogram which consists of a circle with a crossed bar on the shape of a pregnant person (see below). A period was granted for companies to adjust to this new measure and **the standard will not be implemented until May 19, 2024.** 



Other Specific Labeling Requirements

### Expiration Date Information

Per CAA, the date duration on a label may be provided in any of the following ways:

- Best before ...
- Valid up to ...
- Validity ... Val ... (short form of validez, in Spanish)
- Is due ...
- Expiration date
- *Vto.* (short form of *vencimiento*, in Spanish)
- *Venc*. (short form of *vencimiento*, in Spanish)
- Preferably best before ...

Expiration dates are to be used on all products except:

- Fresh fruit and vegetables, including potatoes which have not been peeled, cut, or treated in a similar way
- Wines, liqueurs, sparkling wines, flavored wines, fruit wines, and sparkling fruit wines
- Alcoholic beverages that contain 10 percent or more alcohol

- Bakery and pastry products which, by the nature of their content, are usually consumed within 24 hours after manufacturing
- Vinegar
- Solid sugar
- Confectionery products which consist of flavored or colored sugars, such as candy
- Chewing gum
- Food quality salt (does not apply to enriched salts)
- Food products which have been exempted by specific MERCOSUR Technical Regulations.

#### Nutritional Claims

Article 235 Fifth of CAA (Joint Resolution 40/2004-SPRRS and 298/2004-SAGPyA) with Resolution No. 46/03 regulates nutritional labeling of consumer-ready packaged foods that are produced and marketed within MERCOSUR. Unless otherwise specified, nutritional labeling of packaged foods must include the following information (in Spanish, for imported products):

- Name of the product
- List of individual ingredients
- Net Contents
- Country of Origin
- Name and address of the importer
- Lot/batch number, expiration date and preparation and usage instructions, when relevant.

The label should be on the main face of the product, with the name of the product, its quality, in contrasting colors to insure visibility. The size of the letters and numbers must be, except for the net content listing, no less than 1 mm.

#### Prebiotics and Probiotics

### Prebiotics

The denomination of Food with Prebiotics refers to a food product that includes an added authorized prebiotic. The product will be sold in a package that has proven to be safe and whose label indicates the specific identification of its component/s. The product will be labeled: "... with prebiotics," by filling in the blank with the sales name of the food product. Food products manufactured with prebiotics will be authorized once a satisfactory *in vivo* trial evaluation shows the functionality assigned to it or its prebiotic component/s. The evaluation is conducted by an Evaluation Committee composed of specialized professionals from the Sanitary Authority or assigned by them on a case-by-case basis.

### Probiotics

The denomination of Food with Probiotics refers to a food product with a charge of feasible cells between 106 and 109 CFUg (colony-forming unit/gram) during its period of minimum duration. The product will be sold in a package proven to be safe, and whose label indicates the specific

identification of its strains and the concentration of feasible cells of each strain (UFC/g). The product will be labeled: "... with probiotics," by filling in the blank with the sales name of the food product.

Food products manufactured with probiotics will be authorized once a satisfactory *in vivo* trial evaluation confirms the functionality assigned to its probiotic strain(s). That evaluation will be performed by an Evaluation Committee composed of specialized professionals from the Sanitary Authority or assigned by them on a case-by-case basis.

In 2018, Argentina supported a proposal at Codex by the International Probiotics Association to advance harmonization of probiotic guidelines for use in foods and dietary supplements. For further information, please contact Post directly.

### Known Allergens on Prepackaged Foods

Joint Resolution #57/2010 and #548/2010 requires a declaration on an ingredient label if a trace, or any of the allergenic substances listed below, are present in a food as an ingredient. This information must be presented in contrasting colors to ensure visibility and include the following: "Contains ..." followed by the name of the substance and/or "Traces of ..."

- 1. Cereals, i.e., wheat, rye, barley, oats, and hybridized strains and products of these;
- 2. Crustaceans and products thereof;
- 3. Eggs and products thereof;
- 4. Fish and products thereof;
- 5. Peanuts and products thereof;
- 6. Soybeans and products thereof;
- 7. Milk and products thereof (lactose included);
- 8. Tree nuts and products thereof; and

9. Sulphur dioxide and sulfites in concentrations of more than ten milligrams per kilogram (10mg/kg).

In October 2017 Argentina introduced new allergen legislation which corresponds to the Codex list, except Argentina uses "Cereal, i.e. wheat, rye, barley, oats, or their hybridized strains and products of these – without reference to gluten (Joint Resolution 11-E/2017)).

MERCOSUR continues to discuss modifications of the Technical Regulation for the Labeling of Pre-Packaged Foods (<u>http://www.puntofocal.gov.ar/doc/r\_gmc\_26-03.pdf</u>), including a mandatory allergen declaration, but no consensus has been reached on proposed modifications.

### Precautionary Allergen Labeling

The declaration of the allergen substance must be stated as follows (filling in the blank with the name of the appropriate substance/s):

- "Contains ...," or
- "Contains traces of ...," or

• "Contains ... and traces of ..."

When there may be the possibility of accidental cross contamination during the manufacturing process, the precautionary language must be included in the label as follows:

- "May contain ...", or
- "May contain traces of ...," or
- "May contain ... and traces of ..."

To request authorization for the use of the precautionary phrase, the company must submit to the Sanitary Authority a sworn statement including the following language "that even having used GMP, there exists the possibility that there has been accidental cross contamination during the manufacturing process due to …," providing the appropriate justification for the incident.

#### Organic Products

Per <u>Decree No. 206/2001</u>, imported products labeled as "organic" must originate from a country whose organic standards have been approved by SENASA as equivalent to Argentina's. Otherwise, prior to export, imported organic products must be certified by an Argentine certifying agency approved by SENASA. The US National Organic Program has not yet been determined to be equivalent by SENASA.

#### <u>Natural</u>

In December 2020, CONAL announced that it will no longer permit the use of the term "natural" on food labels except when the sales denomination specifies it in the CAA. The term "natural" is currently regulated in natural flavorings or artificial flavorings identical to natural flavorings, natural yogurt, natural fermented milk, natural acidophilic milk, natural Kefir, natural Koumiss, natural curd, fish preserves, and natural mineral water.

#### Plant-based Meat/Dairy Alternative Products (Vegan/Vegetarian)

On September 10, 2021, CONAL published a draft bill for public comment (since closed) on the incorporation of Article 229 to the CAA related to the term "Vegan," which will be reserved for products containing no ingredients of animal origin and/or byproducts (including additives and processing aids). The draft bill also provides specifications on labeling requirements for these types of products.

#### **Biotech Products**

Biotech foods in Argentina do not have specific labeling requirements.

<u>Salt</u>

<u>Law No. 26.905</u>, "Sodium Intake – Maximum Values," requires the inclusion of warning messages about the health risks of a high-salt intake for consumers in meat products, flour products, soups, dressings, and pickled vegetables.

#### Front-of-Package Labeling (FOPL)

Argentina's FOPL draft bill, which had already been approved by the Senate a year ago, was passed on October 28, 2021, by the Chamber of Deputies and was signed into law shortly before the end of the Argentine legislative session. It requires that manufacturers of processed food products adopt a FOPL model based on black octagons to warn of excessive levels of sugar, sodium, calories, and total and saturated fat. Some legislators who supported passage of the law, did so with the understanding that the government would exempt certain products or modify its parameters. Prior to being implemented, regulations must be developed. The government will consider arguments by food manufactures and civil society groups as it considers how to apply the law. Some products may be exempted, such as dietary and dairy products, especially milk-replacement products and infant formula. It is also unclear whether the policy applies just to processed and further-processed products. Even after the Argentine government concludes its rule-making process, the new FOPL policy may need to be harmonized at the Mercosur level, which could lead to further amendment.

# Section III. Packaging and Container Regulations

Generally, Argentina does not impose special packaging or container-size requirements by product, however, some products, such as salt, do have specific requirements. Exporters should always make sure that their importing partners are aware of the latest changes in Argentine regulations.

Chapter IV of the CAA, Articles 184 and 185, establishes the requirements for protecting food containers from external agents of alteration, contamination and adulteration from manufacturing and processing to consumer use.

Per Article 186, the following materials are allowed:

- Stainless steel, cast iron or whipped iron, coated or not with technically pure tin and chromed tin.
- Copper, brass or bronze covered entirely by a layer of gold, silver, nickel, chrome or tin technically pure, except for the requirement of coating the boilers, vessels and pans for cooking of sweets and syrups, mortars, scale plates and dumbbells.
- Tin, nickel, chromium, aluminum and other technically pure metals or their alloys with harmless metals.
- Tin plate of first use.
- Ceramic materials, baked clay glazed internally that does not yield lead or other compounds harmful to the acid attack: glass, marble and odorless woods.
- Kitchen utensils of diverse metals, with antiadhesive coating or pure polytetrafluoroethylene (Teflon, fluon, etc.)

- Vegetable, animal or synthetic fiber materials, waterproofed or not with harmless materials.
- Different types of films based on regenerated cellulose authorized for packaging of food products in general. Must declare the exact composition of the films, analytical verification and final approval by the health authority.
- Iron enameled or enameled that does not yield lead or other harmful compounds by acid attack.

And the use of:

- Galvanized or galvanized iron.
- The internal lining of containers, tubers, utensils or other elements with cadmium.
- The materials (metals, plastic materials, etc.) which may yield to food, metal or metalloids in a higher proportion than those established in Article 156.

According to Article 186 bis, which focuses on paper and cardboard, the packing and cellulose equipment referred to in this Article shall be manufactured following good manufacturing practices, compatible with its use for direct contact with food. Only substances included in the "Positive List for Containers and Cellular Equipment in Contact with Foods," and the "Positive List of Resins and Polymers for Containers and Plastic Equipment" may be used for the manufacturing of the containers to which this document refers.

According to Article 186 Annex A, substances approved in the most recent official documents of the US FDA and/or German BGA and/or Italian legislation of the EEC, may also be incorporated into the Positive List.

Positive List for packaging and cellulose equipment in contact with food

- 1. Fibrous Raw Materials
- 2. Non-Fibrous Materials (Mineral Cargo)
- 3. Auxiliary Substances:
  - 3.1 Internal and superficial bonding agents
  - 3.2 Retention and drainage agents
  - 3.3 Dispersing and flotation agents
  - 3.4 Antifoaming agents
  - 3.5 Antimicrobial agents
  - 3.6 Conservatives
  - 3.7 Aluminum sulfate
- 4. Special Paper Improvers
  - 4.1 Agents that improve the mechanical properties of wet paper
  - 4.2 Moisture retention agents
  - 4.3 Optical Coloring and bleaching materials
  - 4.4 Coating agents and surface improvers

Article 185 tris. covers the general provisions for regenerated cellulose films in contact with food.

### Packaging Sustainability Measures

At the national level, Argentina's Ministry of Environment has developed the <u>Estrategia</u> <u>Nacional de Consumo y Producción Sostenibles</u> (National Strategy of Sustainable Consumption and Production), which includes the following law and strategy:

• National Law 27.454 - <u>Plan Nacional De Reducción De Pérdidas Y Desperdicio De</u> <u>Alimentos</u> (National Plan of Food Loss and Waste Reduction)

This law was created in 2018 by the Ministry of Agriculture, Livestock, and Fisheries, and it aims to propose and implement public policies, based on consensus with different sectors, that would reduce food loss and waste. In line with that goal, National Law 25.989 was passed to clarify food donation rules, which are within the jurisdiction of the Ministry of Health.

• <u>Estrategia Nacional para la Gestión de Residuos Sólidos Urbanos</u> (National Strategy for the Management of Solid Urban Waste)

The Ministry of Environment prepared this national strategy focusing on public health, environmental preservation, a significant reduction of waste and, finally, the disposal of solid urban waste in a sustainable way, eradicating and ultimately, closing open-air landfills.

At the municipal level, the Government of the City of Buenos Aires enforced Law 1.854 for the Gestión Integral de Residuos Sólidos Urbanos (Integral Management of Solid Urban Waste), whose main goal is to establish principles, obligations, and responsibilities for the management of solid urban waste within the City of Buenos Aires in an appropriate sanitary and environmental way, to protect the environment, human beings, and goods. In that regard, the concept "Zero Waste" was adopted. Decree 760/208 further defines concepts and terms included in Law 1.854.

More relevant Chapters and Articles of Law 1.854:

Chapter II

Article 8 promotes the following:

- 1. Reduction of waste and use of long-lasting or re-usable products.
- 2. Product recycling and sorting of products that can be recycled.
- 3. Sorting and composting and/or biodigestion of organic waste.
- 4. Measures towards the gradual replacement of disposable for reusable packagings and sorting of packagings and bottles to be collected separately by companies that use them.

<u>Article 9</u> establishes standards for the producer, importer, distributor, agent, or any other person responsible for placing a product in the market, which after use will become waste. That person will have the following obligations:

- 1. Manufacture products or use packages or bottles which minimize waste and facilitate reusing or recycling and allow disposal which is less harmful for human health and the environment.
- 2. Take charge of the waste management derived from his/her products, or participate in an organized system of waste management, or contribute to a public waste management system.

### Chapter XI

<u>Article 40</u>: In any of the methods of public procurement, any organization within the City of Buenos Aires must give priority to those products which have been produced using recycled or reused inputs.

Chapter XVIII

<u>Article 59:</u> As of the date of implementation of this law, it will be mandatory that solid urban waste is placed in biodegradable bags.

# Section IV. Food Additive Regulations

Chapter XVIII of CAA contains a positive list of authorized food additives (FA) in Article 1400 which incorporates CODEX-approved additives. In addition, additives used in food product imports must also be on the positive list maintained by MERCOSUR. If the additive in question is not on this list, an application for registration must be submitted to CONAL.

The following are key points under Chapter XVIII of the Code which summarizes the scope of food additive regulations and laws that are harmonized within MERCOSUR:

a) FA must be safe or through their action as additives.

b) FA must be included in the CAA positive list.

c) FA must be exclusively used in food products included in CAA.

d) FA must comply with CAA requirements related to designation, composition, identification, and purity.

e) FA must not be used to deceive the consumer.

f) FA quantity added to a food product must be the minimum quantity necessary to minimize any potential danger to consumers' health.

g) FA must be sold in closed original packages.

h) A legend stating "Exclusive Industrial Use (*Uso Industrial Exclusivo*)" with letters no smaller than 50 percent of the FA denomination and clearly visible must be placed on the label right below the denomination.

i) All authorized FA added to a food product must be included in the label of such product through language that indicate the types of FA used, such as: Authorized Antioxidant (Antioxidante Permitido), Authorized Emulsifier (*Emulsionante Permitido*), etc. In addition, food products which contain tartrazine, benzoic acid (or its calcium, potassium, or sodium salts), and sulphur dioxide (and derivatives) must be declared on the product label.

Through the FA transference principle, CAA establishes that all FA used in raw materials or other ingredients (including FA) which have been transferred to a food product will be exempt from the declaration in the list of ingredients, under certain conditions, as stated in <a href="http://www.puntofocal.gov.ar/doc/r\_gmc\_105-94.pdf">http://www.puntofocal.gov.ar/doc/r\_gmc\_105-94.pdf</a>.

Registration of Food Additives

Food Additives Used in Products of Animal Origin (registered at SENASA)

Main Documentation Required:

- Registration form of adjuvant additives, packages, and other related products
- Product technical specifications

- Technical specifications required by the company which owns the product to be authorized for each of its individual components

- Product protocols and trial reports authenticated by the Foreign Relations Ministry.
- Company's and processing establishment's RNEs.
- INAME-ANMAT Approval certificate (for hand washing products)
- Valid label, and label used in the country of origin.
- Product formula or monograph.

### Food Additives Used in Products of Vegetable Origin (registered at SENASA)

Main Documentation Required:

- Letter with letterhead indicating the intention of additive registration.
- Registration form.
- Copy of CUIT (tax identification number)
- Payment of fee.

### Presentation of Information for Registration of FA and Technology Ingredients

For active ingredient/s of the FA or ingredient technology accepted by international, regional, and/or national standards:

- Specify what international and/or national regulatory organizations have registered or partially evaluated active ingredients of FA or ingredient technology that will be registered. And under what number such active ingredients have been registered.

- Full technical, scientific and/or common name that identifies active ingredient/s.

- Last date of evaluation of active ingredient/s by international, national and/or regional regulatory organizations.

- Proposed technological function/s.
- Food product/s for which their use and doses are proposed.
- ADI for food product/s for which their use is proposed.

- Monograph of the manufacturing process: (1) flow diagram of the manufacturing process, (2) specify if active ingredient/s is/are obtained from raw material/s of natural origin, or of chemical or biotechnical synthesis.

- Degree of purity of the FA or ingredient technology.

- Contaminants present in the FA or ingredient technology, including quantitative specification.

- Qualitative and quantitative analytical methodology proposed for determining active ingredient/s and elements of accompanying (contaminant) substances.

For registration of Food Additives used in processed foods, see below, Section VI – INAL.

On February 9, 2021, Joint Resolution No. 12/2021 was published in the Official Bulletin amending Article 1398 of the CAA with the intention of updating specifications for additives using criteria that had been developed and adopted by international organizations such as FAO/WHO, JECFA, and FCC.

# Section V. Pesticides and Other Contaminants

<u>SENASA Resolution No. 934/2010</u> establishes requirements that must be met by agricultural products and byproducts for domestic consumption. A summary of the main points is provided below:

Article 1 – Products for domestic consumption: Products and by-products which are imported or produced locally for domestic consumption must comply with national maximum residue levels (MRLs) established in Annex I of the present resolution. Products and by-products not included in Annex I must comply with a default value of 0.01 mg/kg equivalent to the detection limit of the analytical method.

Article 2 – Products not traditionally grown in the country: Those imported agricultural products and by-products that are not traditionally grown in the country, and for which a national MRL of the active ingredient has not been established, will be allowed entry only if there is an MRL approved by Codex Alimentarius, and if the risk evaluation to the consumer carried out by the CSA does not indicate unacceptable risks.

Article 3 – Residues of prohibited compounds: For those residues of compounds which are persistent in the environment and were used as pesticides, but are no longer registered as such and can cause food contamination, the values set up by Codex Alimentarius will be adopted as extraneous MRLs.

# Section VI. Other Requirements, Regulations, and Registration Measures

Facility and Product Registration Requirements

### **SENASA: Animal Products, By-Products and Derivatives**

In compliance with <u>Decree 4238/68</u> (updated September 2018) – "Requirements for the Inspection of Animal Products, By-Products, and Derivatives Related to the approval of Animal Products, By-products, and Derivatives that are Manufactured or Used in Approved Establishments," all imported food products must be registered with SENASA prior to importation.

For product registration, SENASA requires a company-produced document that provides the descriptive aspects of the products being submitted for registration. U.S. producers may file the document directly with SENASA or by an importer as part of the import license application. Based on the descriptive characteristics of each product in the document, SENASA assigns each product a unique registration number that becomes a component of its product label. Please note: for beef and pork products, a U.S government authority signature is not required on a company document submitted for product registration to SENASA. For all other U.S. animal-origin and aquatic products, an official signature by the U.S. competent authority is still required on product registration documents.

SENASA requires additional product information that may not be provided through the registration document, FSIS Forms 9060-5 or 9060-7 and/or Letterhead Certificate, but which may be provided at the commercial level through various documentary resources usually provided by the importer. After a product is registered and receives its unique identification number, any Argentine importer(s) may apply for an import permit from SENASA for a registered product.

Further information is available on the FSIS Export Library at:

https://www.fsis.usda.gov/inspection/import-export/import-export-library/argentina

# **SENASA: Plant Products**

SENASA only accepts plant products from APHIS-approved facilities. SENASA reserves the right to prior inspection and approval of the establishments of origin by a SENASA official, when deemed necessary.

On January 30, 2019, <u>SENASA Resolution No. 76/2019</u> removed the Registry of Importers and Exporters of animals, plants, reproductive and/or propagative material, products, by-products and/or derivatives of animal or plant origin or merchandise which contain ingredients of animal or plant origin, from SENASA jurisdiction. As needed, SENASA will obtain information on importers/exporters from Customs' Registry of Importers and Exporters within the Federal Administration of Public Revenue (AFIP).

New market importers/exporters must <u>register one time, on-line, with Customs/AFIP</u> before beginning operations in Argentina. All importers/exporters must receive a tax identification number (CUIT), which serves as their registration number. CUITs are required to conduct many types of business operations in Argentina, by both foreign and domestic companies.

U.S. plant product imports must have a USDA Phytosanitary Certificate signed by an APHIS representative and an import certificate (AFIDI) issued by SENASA. The importer declares the import product characteristics (product name, destination and origin) to SENASA which then grants an AFIDI which specifies the type of sanitary certificate needed for importation. The exporter normally provides this information to USDA/APHIS to obtain the appropriate certificate.

SENASA holds the product at the port of entry for inspection and verification of the requirements as stated in the AFIDI. Once verified, SENASA issues an import certificate for Customs that allows the release of the product.

For more information on this certificate process, please contact the USDA/APHIS Regional representative:

Melody Maxwell, Area Director USDA APHIS International Services U.S. Department of Agriculture Brasilia, Brazil IS.South.America.Atl@usda.gov

### INV: Wine

Argentine requirements for the import of wines and musts are as follows (Law 14.878):

### Registration:

- The importer must be registered at INV. He/she obtains a registration number to control the importation process and make consultations related to that import operation or future importations.

- The importer must be registered at AFIP to initiate the registration process.
- A "Registration Certificate" is issued to the importer within 24 hours at no cost.
- Required documentation:
  - The importer must submit to INV, two copies of the "Registration Request as Importer of Wine Products," together with a copy of AFIP registration statement. All original copies of documents must be signed, including printed names. Once documentation is verified, a "Registration Certificate as Importer of Wine Products" is issued.

#### Import Procedure:

- The importer must complete a "Unique Import Guide," considered a sworn statement, informing INV about wine and must imports, and requesting controlled sampling. The statement serves as a safeguard for the transportation of imported products from Customs to the receiving wineries or must processing facilities. The guide includes the following information: importer's business name, registration #, address, name and address of the warehouse where the merchandise is stored, country of origin,, Customs at Port of Entry, date of entry, category #s, product type/s, harvest year, variety, quantity and type of bottles, liters, # of analysis at origin, C.I.F. value, identifying key code, place and date of submittal, importer's and government official's signature and stamp.

- Products to be imported must comply with limits of analytical composition required by similar domestically manufactured products.

- The "Import Guide" must be submitted at least 48 hours before the declared date of entry.
- Imported bottled wine products may have a country-of-origin tag affixed to the bottle, and it must include the following information (either in the tag or in an additional label): Wine type, as classified in Argentina (fine wine, table wine, sparkling wine, etc.)
- Color (red, white, rose)
- Sparkling wines are classified in relation with the sugar content (nature, extra brut, brut, sec, demi sec, dulce).
- Country of origin.
- Importer's name and address.
- Importer's INV registration #.
- Packaging capacity in cl, ml, or cc.
- Alcoholic content.
- Analysis # of Free Circulation.
- Legend: "Beber con moderación" and "Prohibida su Venta a menores de 18 años."

Note: Argentina's Law 14,878 - Art. 22 (1959) states that bulk imported wine products are not allowed to be mixed with other imported wines or with domestically produced wines.

- Required documentation:

- The importer must submit three original copies of the "Import Guide" at INV.
- He/she must also submit the original copy of the analysis of origin of each of the imported products, issued by official laboratory (or authorized laboratory by CSS) of the country of origin.
- Once all documentation is verified, the importer obtains two copies of the "Import Guide," which will be included in the Customs documentation package.
- Finally, the importer must submit a Customs document entitled "Import for Consumption."

# INAL: Processed foods, and alcoholic and non-alcoholic beverages, except wine

Processed products and alcoholic and non-alcoholic beverages, except wine, require product registration with INAL prior to importation by a registered importer. The registration requirements for imported processed foods are listed below:

An importer registered with the National Register of Establishments (RNE) applies for a National Register of Food Product Number (RNPA) with the following information:

- Letter announcing intention to register the product
- RNPA Application form
- Flow chart and document detailing the product manufacturing process, shelf-life, product specifications, shipping and storage requirements, quality controls, and packaging type
- List of ingredients and additives
- Original label and three copies
- Supplementary label and three copies
- Certificate of Free Sale and fit for human consumption issued by the sanitary authority of the country (or state) of origin, or guaranteed by the State Chamber of Commerce
- Payment of fee
- For food additives, technology adjuvants, and raw materials, tests must be submitted as per CAA requirements.
- Copy of the importer's RNE.

Once the RNPA has been issued and the product is at a port of entry, the importer obtains a Certificate of Free Circulation at INAL. The requirements are listed below:

- Letter requesting a Certificate of Free Circulation for the product/s
- Shipment information
- Copy of the invoice
- Bill of lading
- Copy of the RNE
- Copy of the RNPA + approved label
- Manufacturing date and shelf life
- Sanitary Certificate/Fit for Human Consumption Certificate (including lot #, invoice #, issued by the Competent Sanitary Authority electronic signature not accepted.)
- Certificate of aging (for alcoholic beverages, except wine), issued by CSA (Competent Sanitary Authority).

Once the importer has an RNPA for a given product, it is not necessary to register the product again for subsequent importations. However, a Certificate of Free Circulation for each shipment is required.

Per <u>Resolution No. 876/1997</u>, consumer-ready food products from Mercosur countries (Brazil, Paraguay, and Uruguay) are not subject to the registration process, except for certain specific products. An importer purchasing food products in Mercosur countries must submit a sworn declaration with the following attachments: free circulation/fit for human consumption certificate, issued by the sanitary/food safety authority of the country of origin; numeric identification (if applicable); original labels; lot number/s; total weight; and, in those cases when the exporter is not the manufacturer of the food product being imported, a certificate signed by the manufacturer stating that he/she is aware of the export operation to Argentina.

In the case of health supplements, the statements mentioned above also apply with slight differences. Instead of the RNE, importing establishments need to obtain from INAL a National Register of Establishment of Health Supplements number (RNESD). And instead of the RNPA, a National Register of Health Supplements number (RNSD) is needed. The requirements are as follows:

- Request register authorization at INAL
- Each presentation must be signed by the owner of the product, the local legal representative, and the technical director of the local establishment.
- Certificate of Free Sale from the country of origin, issued by the national or state sanitary authority, stamped by the Argentine Consulate, or certified by The Hague Convention Apostille.
- Analysis of the product for verification that it complies with CAA standards.
- The Argentine importer must have a technical director who will be responsible for: the genuine origin of the product, the legitimacy of the document, the shelf life of the product, the quality control of the shipment, the correct labeling, and the appropriate "warning" literature on each package or promotional material, when required.

### Other Certification and Testing Requirements

U.S. products and by-products of animal origin imports must originate from U.S. plants approved by the United States Department of Agriculture and the Food and Drug Administration and must be accompanied by an official health/sanitary certificate. While SENASA accepts products from any FSIS/FDA-approved facility, it reserves the right to prior inspection and approval of the establishments of origin, when deemed necessary. All U.S. meat plants exporting products and by-products of animal origin to Argentina may be audited by SENASA (See <u>SENASA Resolution No. 816/2002</u>).

# Section VII. Other Specific Standards

### Health supplements

The MS's National Administration of Drugs, Food and Medical Devices (ANMAT), through INAL, regulates health supplements. On December 29, 2020 <u>Joint Resolution No. 3/2020</u> was published in the Official Bulletin, which modified Articles 1381 and 1381 tris of the CAA. Besides establishing the definition of health supplements, the resolution sets up special requirements about labeling and composition of these types of products.

### Enriched Flour

By <u>Argentine Law No. 25.630</u> and <u>Decree No. 597/2003</u>, all flour-based products must be manufactured with enriched flour, with the exception of diet products, flours destined for the manufacturing of products for export flours for export, and organic flours (Law #25127). The required nutrients are as follows:

Nutrient	Quantity (mg/kg)
Iron	30
Folic Acid	2.2
Thiamin (Vitamin B1)	6.3
Riboflavin (Vitamin B2)	1.3
Niacin	13.0

Labels must show the content of each nutrient, the wording "Enriched Flour Law #25630 -Harina Enriquecida Ley N° 25630" in Spanish and the quantities listed in the table above.

#### Product samples

Products samples with low commercial value (under US\$100) are not subject to import duties. Post recommends that exporters coordinate with importers/agents to obtain a Certificate of Free Sale from INAL which is required for all samples.

# Section VIII. Trademarks, Brand Names, and Intellectual Property Rights

Although Argentina is a signatory, it has not ratified the World Intellectual Property Organization's (WIPO) Patent Cooperation Treaty (PCT). Therefore, brands and trademarks should consider registration in Argentina for proprietary protection. For additional information on brand, trademark, patent, or industrial design registration, please refer to the following website: <u>https://www.argentina.gob.ar/inpi</u>

# Section IX. Import Procedures

<u>Decree No. 1812/1992</u> supplements <u>Decree No. 2092/1991</u> regulating imported food and beverage products (both manufactured domestically and imported), except wine. The main articles of the decree state the following:

- Articles 2 and 3 state that sanitary and phytosanitary controls on imports of animal and vegetable origin not for retail sale will be carried out by SENASA prior to Customs release.
- Articles 5 and 6 state that consumer-ready food products that have proven stability and were registered in CAA will be tested and inspected by INAL only after Customs has released them to the domestic market. Once the importer has proven to INAL, at the time of registration that the product has been manufactured, packaged, and transported in accordance with Argentine sanitary regulations, INAL will issue a certificate of stability authorizing the shipment release from Customs without the need for inspection.

- Article 7 states that either when the importer of a consumer-ready product is unable to show the certificate of stability, or when the food product has suffered evident damage, INAL has the right to inspect and test the shipment before it is released from Customs.
- Article 8 states that, when there are justified reasons to presume risk for human, animal or plant health because of the introduction of food products to the country, any of the three above-mentioned agencies (SENASA, INAL, and INV) has the right to perform inspections to the shipments prior to product entry into Argentina provided that the importer is informed about this procedure.
- Article 10 states that, for all those food products that require previous inspection, the CSA, i.e. SENASA, INAL, and/or INV, have up to 30 days to issue the free sale certificate.
- Article 11 states that Customs will release the consumer-ready food products that have a stability certificate. In the case of those products requiring a previous inspection, Customs will need authorization from the CSA to release the shipment.
- Article 12 states that, if the CSA does not authorize the shipment release, Customs may allow the importer to transport the shipment to his/her warehouse. In that case, the product cannot be marketed until the appropriate certificates are submitted to Customs.
- Article 13 states that a random sample from every shipment will be taken by a Customs official before releasing the shipment.
- Article 14 states that, when the importer does not submit the authorization from CSA in the term established as per Article 10 of this Decree (30 days) due to his own fault, Customs and CSA will destroy or re-export the shipment and the importer will be liable to a fine, expenses and penal charges resulting from these procedures.
- Article 18 states that, in the case of imported consumer-ready foods, it is considered that CAA requirements are met when products come from the following countries/regions: Australia, Austria, Canada, Switzerland, Israel, U.S., Japan, Norway, New Zealand, EU, Sweden, and countries with specific food safety agreements with Argentina. In all of these cases, the food products must have been manufactured under the same controls as those products destined for human consumption in the domestic market of the country of origin.

# Section X. Trade Facilitation

<u>Advance ruling:</u> In January 2018, Argentina ratified the WTO Trade Facilitation Agreement and, under that framework, it allows advance rulings for the importation and exportation of all types of products included in the Harmonized Tariffs Schedule Code.

**<u>Pre-clearance programs</u>**: Currently, there are no pre-clearance programs operating in the U.S. for the export of fresh agricultural products to Argentina.

**E-certificates:** E-certificates are used by all regulatory agencies in Argentina governing agricultural, and food and beverage products, namely, SENASA, INAL, and INV. However, some still keep the option of carrying out on-site administrative procedures. E-certificates are permissible for products of animal, and plant products, fishery products, food and beverage products and wine products.

<u>Global ICPP e-Phyto Hub:</u> On July 7, 2020, pursuant to an agreement between APHIS and SENASA, the U.S. and Argentina implemented an Electronic Phytosanitary Certification system for trade in plant products. The e-phyto system was developed by the International Convention of Phytosanitary Protection (ICPP) and benefits bilateral trade by reducing paperwork and providing a more efficient, transparent and reliable system.

**Import fees:** Due to persistent high inflation and the government's power to alter fee structures with little warning, exporters should work with an importer regarding the most current import fees or contact Post for additional information.

**Delays:** Post is not aware of delays for any particular imported product at present.

# Appendix I. Government Regulatory Agency Contacts

### Servicio Nacional de Sanidad y Calidad Agroalimentaria (SENASA)

Coordinación de Relaciones Internacionales Avda. Paseo Colón 367, piso 5 Buenos Aires, Argentina Tel: (54-11) 4121-5353 E-mail: <u>relint@senasa.gob.ar</u>

### Instituto Nacional de Alimentos (INAL)

Relaciones Internacionales Estados Unidos 25 Buenos Aires, Argentina Tel: (54-11) 4342-5674; 4340-0800 E-mail: relaciones.internacionales@anmat.gov.ar

#### *Instituto Nacional de Vitivinicultura (INV)* San Martín 430 Mendoza, Argentina Tel: (54-261) 5216600 E-mails: <u>solinfo@inv.gob.ar</u>; <u>sergio\_montivero@inv.gob.ar</u>

Appendix II. Other Technical Import Contacts *Cámara de Importadores de la República Argentina (CIRA)* Avda. Belgrano 427, piso 7 Buenos Aires, Argentina Tel: (54-11) 4342-1101 E-mail: <u>cira@cira.org.ar</u>

# Attachments:

No Attachments