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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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ARGENTINA: FOOD AND AGRICULTURAL IMPORT REGULATIONS AND STANDARDS (FAIRS) 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 was taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped.

Executive Summary

Argentina is the second largest country by land area, and third largest country by population in South America. It is a presidential republic with the third highest GDP per capita in South America. The capital, Buenos Aires, and its surrounding suburbs, accounts for nearly one-third of the country's population. On December 10, 2019 the new President of Argentina, Alberto Fernandez was inaugurated after defeating incumbent President Mauricio Macri in a general election.

The United States has an overall trade surplus with Argentina, but a trade deficit in food and agricultural products. In CY 2019, the US exported \$226 million dollars in food and agricultural products to Argentina, and Argentina exported \$1.68 billion dollars in the same categories. Typically, major US exports to Argentina include seeds, food ingredients, prepared food, alcoholic beverages, and livestock genetics. Thanks to a drought in 2018, Argentina imported substantial volumes of soybeans for processing from the US in 2018 and early 2019, but barring another major weather event, this trade is not expected to continue.

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. No major overhaul of the CAA is currently being debated in the Argentine Congress. The primary goal of the CAA is the protection of public health and maintaining consumers' confidence in the safety and quality of food products distributed within Argentina. CAA incorporates regulations and standards agreed upon within MERCOSUR. Argentina is a founding member of MERCOSUR, a South American trading bloc which includes Brazil, Paraguay, and Uruguay as full members in good standing. In June 2019, MERCOSUR and the EU announced agreement on an FTA linking the two blocs. However the agreement has not yet been implemented and the new administration of President Alberto Fernandez has expressed caution over the speed at which MERCOSUR is negotiating potential FTAs with new trading partners.

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

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 1400 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 enforce the CAA standards. The CAA is updated by joint resolutions from MAGyP and the Ministry of Health. To access CAA please refer to this link.

The National Food Commission (CONAL), an advisory body with representatives from the Ministry of Health 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), CAA incorporates standards agreed upon within Mercosur, which are influenced by standards from the European Union, Codex Alimentarius and the U.S. Food and Drug Administration.

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

MAGyP, through INV - https://www.argentina.gob.ar/inv, regulates the production and distribution of wine.

The Ministry of Health, through INAL, within the ANMAT https://www.argentina.gob.ar/anmat, regulates consumer-ready food products, health supplements and alcoholic and non-alcoholic beverages, excluding wine.

Import Authorization System

<u>General Resolution 3823/2015</u> established the Sistema Integral de Monitoreo de Importaciones (SIMI), an integrated system for import control through automatic (AIL) or non-automatic import licenses (NAIL) (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. 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

General Resolution AFIP No. 3615/2014 established a container information system through a web-based database, <u>Registry of Containers</u>. 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>Animal-Origin Products</u>: Prior to entry, labels for animal-origin products must be submitted to SENASA for pre-approval. Typically, the importer submits the labels to SENASA as part of the import license application, and SENASA provides feedback directly to the Argentine importer about the label approval status. However, exporters can apply directly to SENASA if they so choose. The 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 may be found in the USDA Food Inspection and Safety Service export library <u>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. U.S. non-animal origin processed foods may be imported in their original packaging with English labels, however, 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 at the country of origin 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) (Not mandatory but recommended for marketing purposes)
- Storage, preparation and usage instructions when required
- Nutritional information

Wine:

For wine imports a label must be affixed to each imported bottle with the following information in Spanish:

- Brand
- Legal identification of the product (wine)
- Alcoholic grade
- Net content
- Country of origin
- Sugar content (if more than 6 milligrams per liter of sugar)
- Importer's name, address and INV registration number
- Other components other than wine
- Warning statements ("Beber con moderación" "Prohibida su venta a menores de 18 años")
- Acronym and analysis number (provided by INV once the product was analyzed and approved for free sale). All required statements must be printed on labels with legible fonts and clear colors, and the contrast must be easily identified by consumers. The legal identification of the product, alcoholic grade, net content, and country of origin must be printed on more than one label if the field of vision cannot be read without having to turn the bottle around.

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

Chapter 5 of the Argentine Food Code, sections 220-246 and Mercosur regulations (26/03 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 nutrition or health claim.

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 commercially presented 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 has been carried out, which shows the functionality assigned to it or its prebiotic component/s. That evaluation will be performed by an Evaluation Committee composed by 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 UFC/g during its period of minimum duration. The product will be commercially presented in a package that has proven to be safe, and whose label indicate the specific identification of its strains and the concentration of feasible cells of each of them (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 has been carried out, which show the functionality assigned to the probiotic strains that it contains. That evaluation will be performed by an Evaluation Committee composed by 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 the 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 (<u>Joint Resolution 11-E/2017</u>).

MERCOSUR continues to discuss modifications of the Technical Regulation for the Labeling of Pre-Packaged Foods (Resolution No. 26/03), including a mandatory allergen declaration, but no consensus has been reached so far 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 #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 been determined to be equivalent by SENASA.

Biotech Products

Biotech foods in Argentina do not have any specific labeling requirements.

Section III. Packaging and Container Regulations

Generally, Argentina does not impose special packaging or container-size requirements by product, however, there are some products, such as salt, that 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 <u>CAA</u>, Articles 184 and 185 establish the requirements for protecting food containers from external agents of alteration, contamination and adulteration from manufacture and processing to consumer use.

Per Article 186, the following materials are allowed:

- 1. Stainless steel, cast iron or whipped iron, coated or not with technically pure tin and chromed tin.
- 2. 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.
- 3. Tin, nickel, chromium, aluminum and other technically pure metals or their alloys with harmless metals.
- 4. Tin plate of first use.
- 5. Ceramic materials, baked clay glazed internally that does not yield lead or other compounds harmful to the acid attack: glass, marble and odorless woods.
- 6. Kitchen utensils of diverse metals, with antiadhesive coating or pure plytetrafluoroethylene (Teflon fluon etc)
- 7. Vegetable, animal or synthetic fiber materials, waterproofed or not with harmless materials.
- 8. 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.
- 9. Iron enameled or enameled that does not yield lead or other harmful compounds by acid attack.

And the use of:

- 1. Galvanized or galvanized iron.
- 2. The internal lining of containers, tubers, utensils or other elements with cadmium.
- 3. 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.

Section IV. Food Additive Regulations

Chapter XVIII of <u>CAA</u> 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 the main points under Chapter XVIII of the code, which summarize the scope of food additive regulations and laws, which are harmonized within MERCOSUR:

- a) FA must be safe by themselves, or through their action as additives.
- b) They must be included in the CAA positive list of FA.
- c) They must be exclusively used in food products included in CAA.
- d) They must comply with CAA requirements related to designation, composition, identification, and purity.

- e) They must not be used to deceive the consumer.
- f) The quantity of a FA added to a food product will be the minimum quantity necessary to reduce to a minimum any potential danger to consumers' health.
- g) FA must be marketed in closed original packages.
- h) A legend stating, "Exclusive Industrial Use (*Uso Industrial Exclusivo*)", with letters not smaller than 50 percent of the FA denomination and with good enhancement and visibility, 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 dioic (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 <u>Resolution GMC No. 105/94</u>.

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 Adjuvants

For active ingredient/s of the FA or technology adjuvant 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 technology adjuvants 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 technology adjuvant.
- Contaminants present in the FA or technology adjuvant, 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.

Section V. Pesticides and Other Contaminants

Overall, maximum residue levels (MRLs) in products for sale in Argentina are based on those recommended by Codex Alimentarius (SENASA Resolucion #256/2003).

SENASA Resolucion #256/2003 establishes tolerances or maximum residue levels of pesticides in agricultural products and by-products (Annex I); establishes a list of chemical and biological phytosanitary products which are exempt from the requirement of tolerance setting (Annex II); and includes in legislation in force a list of prohibited and restricted active ingredients (Annex III).

In addition, SENASA Resolution #934/2010 provides additional definitions, as follows:

Article 1 – Products for domestic consumption: Products and by-products which are imported or produced locally for domestic consumption must comply with national 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 that are 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> – "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.

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

SENASA requires additional product information that may not be provided through the monograph, 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 any registered products.

Further information is available on the FSIS Export Library at: https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products/export-

library-requirements-by-country/Argentina

SENASA: Plant Products

SENASA only accepts plant products from APHIS-approved facilities, and 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 #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</u>, <u>on-line</u> with Customs/AFIP before beginning operation 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 who then grants an AFIDI which specifies the type of sanitary certificate needed for importation. The exporter normally provides this information to USDA/APHIS for 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:

John Gilmore, Area Director APHIS International Services U.S. Department of Agriculture Brasilia, Brazil Tel. + (55-61) 3312-7589 John.F.Gilmore@aphis.usda.gov

INV: Wine

To register a wine product for importation, the process is as follows:

- The importer must be registered at INV
- An import permit must be issued by INV (form 1815-O. y M.)
- The import permit must be accompanied by an analytical certificate issued by the appropriate official laboratory or officially-recognized oenological laboratory of the country of origin. (The product must comply with the limits of analytical composition required by INV for similar locally manufactured products). However, exceptions are applied to wine products from countries that have signed a reciprocal agreement on oenological practices to facilitate trade (signatory countries are: Argentina, Australia, Canada, Chile, New Zealand, South Africa, and the U.S.) (Resolution No. C. 121/1993, modified by Resolution No. C. 36/2012)

- After the Customs process is completed, the importer must submit an "Importation for Domestic Consumption Certificate" (form OM -1993 SIM)
- A sticker must be affixed to each bottle (see Section II. Labeling Requirements).

Once the product arrives at the warehouse, the importer must request an analysis and shipment control by INV. If the analysis is verified, INV issues a Certificate of Free Circulation and the product is released.

Argentine wine importers often ask for the following U.S. certificates from U.S. wineries wishing to export to Argentina:

- Certificate of Country of Origin
- Certificate of Free Sale and Fit for Human Consumption
- Certificate from the Wine Institute with analysis of the product.

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 addressed announcing intention to register the product
- RNPA Application form
- Flow chart and monograph of 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 #876/1997</u>, consumer-ready food products from Mercosur countries 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 SENASA Resolution #816/2002).

Section VII. Other Specific Standards

Health supplements

The Ministry of Health's National Administration of Drugs, Food and Medical Devices (ANMAT), through INAL, regulates dietary supplements. In March 2019, Argentina submitted a project to modify Article 1381 of CAA related to dietary supplements, which was published for public comment. CONAL reviewed and incorporated several comments related to diet supplementation with vitamins and minerals, nutritional quality of proteins, incorporation of a positive list of herbs and plants, and elimination of labeling of health supplements, among others. In June 2019, CONAL representatives agreed to submit the project to administrative process.

Enriched Flour

By <u>Argentine Law #25630/2002</u>) and <u>Decree #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 the export market, 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.

Salt

<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.

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 search the following website: https://www.argentina.gob.ar/inpi

Section IX. Import Procedures

<u>Decree #1812/1992</u> supplements <u>Decree #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 registering the product, 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, has 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 in order 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 from Customs.
- 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.

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: relint@senasa.gob.ar

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-mail: comunicacion@inv.gob.ar

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: cira@cira.org.ar

Attachments:

No Attachments