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Report Highlights:

This report is an annual update of the food import standards and enforcement mechanisms in Colombia. It includes updates on labeling, biotechnology, and Colombia's nutrition and trade facilitation policies. For assistance on trade policy and port issues in Colombia, U.S. exporters are encouraged to contact FAS Bogota at agbogota@fas.usda.gov or jose.quintero@usda.gov.

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DISCLAIMER: This report was prepared by the Office of Agricultural Affairs of the Foreign Agricultural Service of the United States Department of Agriculture (USDA-FAS) in Bogota, Colombia, for U.S. exporters of 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. All the regulations presented in this document in the form of links are in Spanish. FINAL IMPORT APPROVALS OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

EXECUTIVE SUMMARY

The Colombian market is the leading destination for U.S. agricultural exports to South America. In 2023, the United States exported \$3.7 billion of agricultural products to Colombia, a one percent increase over 2022. The United States is Colombia's top supplier of food and agricultural products. Bulk commodities, such as corn and soybeans, accounted for almost half of total U.S. exports to Colombia in 2023. Colombia is a highly regulated, yet growing market for U.S. exporters of food and agricultural products.

On August 7, 2022, Colombia began a new political chapter with the inauguration of President Gustavo Petro. President Petro's administration has advanced the implementation of nutrition policies in Colombia, including passing healthy taxes for ultra-processed food, implementing front-of pack labeling regulations through Resolution 2492 of 2022, and setting maximum thresholds of sodium for processed products through Resolution 2013 of 2020. On May 19, 2023, the Colombian Congress enacted Law 2294, which develops the main policy guidelines and plans for Petro's government from 2022 to 2026. Law 2294 followed the enactment of Law 2277, issued by the Colombian Congress in December 2022, by which the country adopted new healthy taxes for sugar drinks and processed food high in sodium, added sugars, and fats. Healthy taxes entered into force in November 2023, with a rate of 15 percent by 2024, and will increase to 20 percent by January 2025.

This report contains general information on Colombia's policies and regulations for the importation of food and agricultural products. U.S. exporters are encouraged to pay special attention to the role sanitary and phytosanitary agencies within the government of Colombia (GOC), such as the National Institute for the Surveillance of Food and Medicines (INVIMA) and the Colombian Institute for Agriculture and Livestock (ICA), play prior and upon the arrival of shipments at ports of entry in Colombia. These agencies also play key roles in the registration of foreign products and manufacturing facilities.

SECTION I. FOOD LAWS

Food laws and regulations are very dispersed in Colombia, and in some cases, they have not been updated since the 1980s. Food laws and regulations in Colombia stem primarily from provisions under Law 9 of 1979. Since 1979, the GOC has issued subsequent regulations related to food safety and quality, labeling, product registration, and import procedures. Government agencies responsible for food policy development and implementation include the Ministry of Health and Social Protection (MHSP), INVIMA (housed under MHSP), the Ministry of Agriculture and Rural Development (MARD), and ICA (housed under MARD). Additionally, the Colombian Ministry of Commerce, Industry and Tourism

(MINCIT) and the National Tax and Customs Directorate (DIAN) are responsible for the administration of overall import-export operations and customs procedures, respectively.

SECTION II. LABELING REQUIREMENTS

General Requirements

In the case of raw materials destined for foodservice and the food industry, the primary source for labeling regulations is <u>Resolution 5109 of 2005</u>. These regulations establish labeling requirements for domestic and imported packaged food products and raw materials for food production and foodservice. The main goal is to provide comprehensive and clear information for consumers to make informed decisions about the products they purchase.

On June 13, 2023, <u>Resolution 2492 of 2022</u> came into force setting new requirements for front-of pack labeling (FOPL) for processed products for human consumption (See GAIN <u>Report CO2022-0026</u>). Resolution 2492 amended <u>Resolution 810 of 2021</u>, including changes to the appearance of the labels and thresholds. Both regulations are aimed to implement <u>Law 2120 of 2021</u> enacted by the Colombian Congress, widely known in the country as the "Junk Food Bill."

Among the changes that Resolution 2492 of 2022 introduced are the mandatory use of octagonal-shape warning symbols for processed products with excess sugar, sodium/salt, saturated and trans fats, and products containing any amount of sweeteners. The thresholds for these nutritional standards are based on nutrition profiles suggested by the Pan American Health Organization (PAHO). Resolution 2492 of 2022 also prohibits making health claims on products containing one or more front-of pack labels. For imported products, the use of a complementary label that complies with the rules set forth in Resolution 2492 and Resolution 810 is allowed. This complementary label must be affixed before the commercialization of the product, either before, during or after the nationalization process. The complementary label must be attached in a visible place and the use of stickers is permanently permitted in the case of warning symbols and without INVIMA's authorization.

Nutritional information in packaged food for human consumption must be provided in Spanish either on the label or, under certain circumstances, on an authorized sticker/label affixed to the product. Whenever the label on the imported product is written in a language other than Spanish, an additional label can be used to provide the information required by Resolutions 5109, 810, and 2492. However, INVIMA will require original labels that, at the very least, include expiration date and lot number.

When food products or raw food materials originate in countries where information on the expiration date and/or minimum shelf life is not required, the importer must get prior approval from INVIMA by providing that information in a document issued by the producer/manufacturer. Note, U.S. dates are registered as MM/DD/YYYY, whereas in Colombia the date is registered as DD/MM/YYYY. An importer can amend labels during or after nationalization, but prior to the sale of the product. However, this "labeling adjustment" does not extend to lot numbers or expiration dates. As such, wrong lot numbers or expiration dates may result in the rejection or destruction of shipments.

The following information must be included on food product labels that are required to have product registration with INVIMA (including retail products):

- 1. Name of the product
- 2. List of ingredients in decreasing order by weight content

- 3. Net content and drained weight in metric units (i.e., grams, kilograms)
- 4. Name and address of producer or processor
- 5. Name and address of the importer (in the case of imported products)
- 6. Lot identification or "L" to identify production date, expiration date, minimum shelf-life, etc. This information could be in numbers, numbers and letters, bars, punched data or grooves.
- 7. Each package must carry the expiration date and/or the minimum shelf-life in a legible, visible, and indelible way. Also, labels must include information on product preservation.
- 8. Instructions for product use
- 9. Product registration number issued by INVIMA

When the individual package for sale is smaller than 10 square centimeters (about 1.6 square inches), the label may not contain the ingredient list, lot identification, expiration date, and conservation and use instructions.

Imported boxes containing "raw material" for food service operators or food processors, including poultry and meat, must be labeled with the following information:

- 1. Name of the raw material
- 2. List of ingredients
- 3. Net content
- 4. Name and address of the producer or importer
- 5. Country of origin
- 6. Lot numbers
- 7. Expiration date or minimum shelf life
- 8. Conditions for product conservation

Although it is not mandatory, several importers have found it helpful to submit a manufacturer's written declaration to INVIMA/ICA inspectors with lot number information and expiration dates. No affixed sticker or label is allowed for expiration date and/or minimum shelf-life ("Best before....") information. This must be directly affixed to the packaging. When the product consists of, or contains any, of the listed food products or ingredients that may cause allergies, they must be declared with their specific names as follows:

- Breakfast cereals containing grain gluten (wheat, rye, oats, barley, spelt or any grain hybrid or product)
- Crustacean and their products
- Eggs and by-products
- Fish and fishery products
- Peanuts, soybeans and their products
- Milk and dairy products, including lactose
- Nuts and derived products
- Sulfites in concentration of 10 milligrams per kilogram or higher

Radiated Food Products and/or Food Raw Materials

When a product has been subject to ionizing radiation, this condition must be disclosed next to the name of the product in a visible way. A brief description of the radiation process after the product name is also required. The use of the international symbol for radiated products is discretionary, but when used, it must be displayed near the product name.

Biotechnology

In 2011, MHSP issued <u>Resolution 4254</u> establishing labeling requirements for food derived from modern biotechnology. The resolution requires labeling information for product health and safety, such as potential allergenicity. Labeling must also address the functionality of the food and identify significant differences in the essential characteristics of the food.

Resolution 4254 does not accept the use of statements such as "GMO free" or "does not contain GMO," unless the manufacturer demonstrates and sustains that the claim is truthful and not misleading. On April 22, 2020, INVIMA issued communication IVC-INS-LI15, establishing the frequency that importers must submit laboratory results to certify that products labeled as "non-GMO" do not contain detectable modified genetic material. These guidelines reduce delays at ports of entry as lot-by-lot testing is not always required, helping preserve product shelf life and alleviate testing costs. The testing requirement does not apply when the main ingredients are not included in the list of Genetically Engineered foods (GE) attached to INVIMA communication 4000-3988-19.

An increased number of imported packaged products entering the Colombian market now bear the "Non-GMO Project Verified" or the "Non-GMO/GE Process Verified" legends, which, as per current regulation, are considered equivalent to "GMO-free" claims. Therefore, manufacturer/importers must provide a supplementary label that clarifies the scope of the legend to be able to commercialize their products as per INVIMA communication 4000-1071-18.

Dietary Supplements

These supplements are regulated primarily through <u>Decree 3249 of 2006</u>. For imported dietary supplements, original labels could be accepted if they contain the information required in Article 21 of Decree 3249 in Spanish. The use of a sticker containing the Spanish information is also acceptable and can be placed over the original label. The GOC requires that supplemental labels must avoid misleading information that can confuse consumers. <u>Decree 272 of 2009</u> states that labels and advertisement of dietary supplements should not contain false or misleading statements about the product composition, origin, effects, or therapeutic indications. The label and/or sticker for dietary supplements must contain the same information as labels for food products. However, it should also include warnings such as "this product is not useful for the diagnosis, treatment, healing or prevention of any disease and it does not meet the requirements of a balanced nutrition" or "keep this product out of the reach of children."

When a dietary supplement contains artificial sweeteners, a warning should appear on the package to prevent its consumption by people with certain medical conditions. A warning should also be written in a clear way when the product contains substances that may cause allergies.

MHSP has released a draft of amendments to the current dietary supplement regulation, such as changes in the documentation needed to request sanitary permits for the commercialization of these products in the Colombian market, such as good manufacturing practices certificate, and advertisement of dietary supplements addressed to children. U.S. exporters are highly encouraged to monitor further developments for dietary supplements regulations in Colombia. For further questions on regulations of dietary supplements, please reach out to <a href="https://organication.org/licenses/by-nc-unitary-colombia-based-colombia-

Nutritional Labeling

Since June 2023, <u>Resolution 810</u> of 2021, amended by Resolution 2492 of 2022, set new nutritional labeling requirements for most packaged food products. The new regulation covers nutritional labeling requirements and warning labeling for processed foods with content considered high in sodium/salt, added sugars saturated fats, trans fats, and any amount of sweeteners. Resolution 810 does not cover nutritional labeling for products destined for infant children, which is set by <u>Resolution 11488 of 1984</u>, as well as one ingredient products with no additives, bulk food, meat and edible meat products, and food products used as raw materials in the food industry.

On December 13, 2022, MHSP issued Resolution 2492 by which it set new requirements for the amount, size, and shape of front-of pack labels (stop-sign shapes) and a new regulation on the use of health claims for processed products (see GAIN Report CO2022-0026). Exhaustion of old labels issued according to Resolution 810 of 2021 and Resolution 333 of 2011 was authorized until February 28, 2023, for which companies should file a request with INVIMA. The use of stickers is permanently permitted in the case of warning symbols and without INVIMA's authorization. The deadline to recall non-compliant products from the market was June 14, 2024. After this date, all products must comply with Resolution 2492. The new regulation also sets a special transition period for returnable packaging.

Resolution 810 requires that nutritional labeling be displayed in Spanish at a minimum. In case the original label includes information in another language or in Spanish, it could be complemented with a sticker in a visible place, translated with the labeling requirements established in Resolution 810. Stickers can be used before, during, or after the nationalization process (in any case before the commercialization of the product). The portion size declared on the label must be determined from the reference quantities established by Resolution 810.

The following nutrients require mandatory declaration under Resolution 810:

- Energy content (total calories, fat calories)
- Protein content
- Total fat
- Saturated fat*
- Trans fat
- Total carbohydrates
- Total sugar*
- Added sugar
- Dietary fiber*
- Sodium
- Vitamin A*
- Vitamin D*
- Iron*
- Zinc*
- Calcium*
- Content of other nutrients when there is a declaration of nutritional or healthy properties

*Nutrient claims are not mandatory in products that contain less than the values established in Resolution 810, unless the label makes nutritional claims. In case it is not declared, the nutritional table must include that the product does not contain a significant source of the nutrient.

According to Resolution 810, the following claims are not permitted in nutritional labeling:

- Claims that are not based on scientific evidence
- Claims that suggest, indicate, represent, or imply that the product is useful or effective to treat or heal any disease or physiological disorder
- Claims that medical or health associations endorse the product with advertising or marketing purposes
- Claims that promote the excessive consumption of any product
- Claims that are contrary to the healthy intake habits set in public policies
- Claims that affirm that the product by itself is sufficient to substitute any principal meal or is sufficient to substitute the advisable energy and nutrients intake
- Claims that suggest or express that the intake of product will grant extraordinary skills once it is taken

The nutritional information table must include only the claim of mandatory nutrients and optional nutrients. The nutrients claim must be done on a numeric basis and must be made per 100 grams of food or portion, in the case of solids or semi-solids, and per 100 ml per product or portion in the case of liquids.

Colombia's food labeling regulation also establishes how labeling should be displayed and the appropriate wording to be used, especially in the case of nutritional and healthy claims. Misleading statements or illustrations must be avoided. For warning labeling, this applies only to processed products with added sodium/salt, sugars, saturated and trans fats, and whose content is above the thresholds established in Resolution 810, amended by Resolution 2492. Warning symbols also apply for processed products with any amount of added sweeteners. In case the product surpasses the nutrient quantities, an octagonal-shape warning label that states "excess in," must be placed in front of package. The same obligation applies to processed products that contain any amount of sweeteners. The dimensions and colors of the octagonal-shape warning symbol are specified under Resolution 2492, which also prohibits the use of nutritional and healthy claims in case the processed food has one or more warning labels.

Health claims on labels should be carefully crafted. Article 272 of <u>Law 9</u> of January 24, 1979 states: "It is forbidden to allude to medical, preventative or healing proprieties or any false specifications about the real nature, origin, composition or quality of food and beverages, on labels or any other publicity."

In November, 2020 the MHSP issued Resolution 2013 with the goal of reducing sodium intake in Colombia. This measure sets mandatory maximum sodium content limits for 59 processed food categories ranging from snacks to processed meats to dairy products. The measure, which will be applied to domestic and imported products, sets out compulsory reduction goals for each category of processed products listed in Resolution 2013 for November 2022 and November 2024. Colombia's food safety authority, INVIMA, will be tasked to enforce this regulation for imported products at ports of entry and through a conformity assessment requirement. Non-compliant products will be allowed to remain in the market until November 2025. Beyond this date, local producers and importers are expected to remove non-compliant products from the market. On December 6, 2023, the MHSP issued

Resolution 2056, by which it amended Resolution 2013, allowing U.S. exporters to utilize self-declarations to certify compliance with maximum sodium levels in processed products. The amendment came after a short period where third-party certifications issued by accredited bodies became mandatory to certify compliance of processes products with the sodium regulation. Resolution 2056 also excludes food service and inputs used as raw materials for food industry from Resolution 2013 of 2020 (See GAIN Report 2023-0030).

Food Containing Trans or Saturated Fats

Resolution 2508 of August 29, 2012, and Resolution 810, amended by Resolution 2492, establish the regulation for providing a nutritional information table in packaged food products that contain saturated and/or trans fats. It is not mandatory to declare saturated fat content in the nutritional information table as long as the packaged food contains less than 0.1 grams or 0.1 ml of saturated fat per 100 grams or 100 ml. However, there is an exception if there are nutritional claims on the packaging related to fat content. In case saturated fat is not declared, the nutritional table must include that the product is not a significant source of saturated fat. Trans fats must be declared and its content expressed in milligrams. According to Resolution 2492, warning labeling may apply to packaged food rich in saturated and trans fats.

MHSP has released a draft of a new regulation that would prohibit the use of trans fats in the processing of food destined for human consumption and food service. In case this regulation is finally issued, it would contain a phase out period of 36 months once it is issued.

Additives Labeling

Resolution 1506 of 2011 regulates additives used in the processing of food for human consumption. This regulation sets the general labeling requirements for additives used in the processing of food for human consumption and the specific mandatory and voluntary information displayed on labels. Labeling must be displayed in Spanish at a minimum. These labels, if needed, can be affixed to the product during or after the nationalization process in warehouses or storage facilities by the port of entry.

Plant-based Meat/Dairy Alternatives

Like other food products, plant-based meat and dairy alternatives must follow all the labeling requirements set out by Resolution 5109 and Resolution 810, amended by Resolution 2492. These regulations aim to provide truthful and useful information for consumers. As such, producers must be mindful about the descriptions and claims displayed on the labels of plant-based meat and dairy alternatives to avoid misleading consumers and facing regulatory challenges with MHSP or INVIMA. For plant-based dairy alternatives, pursuant to Resolution 2310 of 1986, producers must label these products as an "Imitación de" followed by the type of dairy product in Spanish, which in English translates to "imitation of (dairy product)." As for plant-based meat alternatives, while there is no specific labeling guidelines under the current regulation for processed meat products (Decree 2162 of 1983), producers are advised to also use the expression "Imitación de" followed by the type of meat product in Spanish on the product label. As part of the oversight INVIMA conducts on behalf of MHSP, prior to and upon arrival of food shipments entering Colombia, importers are required to meet all labeling requirements and both product description and nutritional/health claims. On a voluntary basis and at a fee, producers can request a label review by INVIMA prior to shipping to Colombia to avoid issues at ports of entry.

SECTION III. PACKAGING AND CONTAINER REGULATIONS

Regulations related to food packaging in Colombia aim to preserve the sanitary integrity of the food product by establishing requirements for materials that are in direct contact with the product. The following is a list of regulatory elements to consider:

- Resolution 683 of 2012 (sanitary requirements for food containers)
- Resolution 4142 of 2012 (sanitary requirements for metal containers)
- Resolution 4143 of 2012 (sanitary requirements for plastic containers)
- Resolution 834 of 2013 (sanitary requirements for cellulosic based containers)
- Resolution 835 of 2013(sanitary requirements for glass and ceramic containers)

U.S. meat and poultry exporters should note that INVIMA conducts rigorous physical inspections of incoming shipments at ports-of-entry. Shipment detentions or rejections can happen due to the presence of foreign material (e.g. dust, wood chips, etc.) in the bottom of containers or stained boxes. It is recommended that exporters take due diligence in working with their plant or cold storage of export to ensure container cleanliness and labeling compliance. Exporters should be aware of the provisions under Decree 1500, by which the MHSP set the rules for the inspection, surveillance, and control system for domestic and imported meat, meat products, and meat derivatives.

Considered the world's second most biodiverse country, Colombia has prioritized climate policies in the past several decades. In November 2018, the Colombian government launched the National Circular Economy Strategy. This strategy, the first of its kind in the region, is premised on six priority action lines, including consumer product packaging. Government environmental regulations stem primarily from Colombia's Ministry of Environment and Sustainable Development (MESD). In 2018, the MESD issued Resolution 1407, which sets forth requirements for the disposal and recycling of consumer product packaging. Under this regulation, individual and collective businesses must submit to the MESD their use, disposal, and recycling management plans for paper, cardboard, plastic, glass, and metal packages. Progress reports are due annually and should aim to ensure that 30 percent of containers and packaging materials on the market are reused by 2030. By 2030, 100 percent of single-use plastics in the market will be replaced with reusable, recyclable, or compostable material (degraded by organisms biologically). Meanwhile, on July 7, 2022, Colombian Congress enacted Law 2232, by which it aims to reduce the production and consumption of single-use plastic by 2030.

SECTION IV. FOOD ADDITIVES REGULATIONS

The primary source of regulations on food additives is <u>Decree 2106 of 1983</u>, issued by MHSP. Regulatory authorities in Colombia will generally accept food additives that are already accepted by the Codex Alimentarius and the United Nations Food and Agriculture Organization/World Health Organization.

Furthermore, Resolution 2606 of 2009 sets general requirements for food additives and establishes INVIMA's Food Additives Committee, which authorizes the use of certain food additives. Additives can only be used if there are benefits for foodstuffs, they maintain nutritional components, they provide nutritional composition recommended for specific groups of consumers (e.g. infant children), and they do not pose a risk to human health. Food additives for groups of preservatives, acidulates, buffers, pH regulators and antioxidants are authorized through Resolutions 4125, 4126, and 4124 of 1991.

Since 2021, the GOC is working on a "positive" additive list. When a product is declared as being 100 percent natural, it should not contain additives. The generic additive names can be used in food followed by the substance's specific name and (voluntarily) the international identification number. These names include flavor enhancer, acid, agglutinating agent, anti-agglutinating agent, anti-compacting agent, anti-foaming agent, anti-oxidizing, aroma agent, bleaching, natural or artificial dye, clarifying agent, natural or artificial sweetener, emulsifier, enzymes, thickener, foaming, stabilizing agent, gasifying agent, gelling agent, moisture agent, anti-moisture agent, volume enhancer, propelling substances, acidity regulators or alkalifiers, emulsifying salts, preservatives, color retaining substances, substances for flour treatment, and glossy agent.

SECTION V. PESTICIDES AND CONTAMINANTS

ICA's regulations on pesticides are applied in accordance with regulatory standards of the Andean Community of Nations (CAN), a regional trade bloc that includes Colombia, Ecuador, Peru, and Bolivia. These regulations can be found in <u>CAN Decision 436</u> and the CAN adoption of the Andean Technical Handbook for Registration and Control of Chemical Pesticides for Agricultural Use. According to <u>Resolution 1580 of 2022</u> issued by ICA, all individual or legal entities that produce, package, formulate, supply, import or export chemical pesticides for agricultural use must register with ICA.

Maximum Residue Levels

MHSP issued <u>Resolution 2906</u> in 2007, which establishes national standards for pesticide Maximum Residue Limits (MRLs). MRLs for veterinary drugs are listed in <u>Resolution 1382</u> of 2013, which follows the <u>Codex Alimentarius CAC/LMR 2-2012</u>. When there is no Codex MRL information for a specific product (either imported or domestically produced) or there are serious doubts about its pesticide content, ICA takes and analyzes a sample. The interested party, either the producer, manufacturer, or importer, must pay laboratory testing fees.

<u>Resolution 2155</u> of 2012 established the following MRLs of contaminants in canned vegetables assessing milligrams per kilogram of the final product:

- Lead (0.10)
- Arsenic (1.0)
- Cadmium (0.05)
- Tin (100)

SECTION VI. OTHER REQUIREMENTS, REGULATIONS, AND REGISTRATION MEASURES

Product Registration

Food product registration in Colombia is regulated by <u>Resolution 2674 of 2013</u>, <u>Resolution 3168 of 2015</u>, and <u>Resolution 719 of 2015</u>. All food items intended for direct sale to final consumers in Colombia must be registered with INVIMA, which is responsible for the issuance of a sanitary registration/permit/notification (based on the "risk" associated to the product). Product registration is not required for:

- Natural food products that have not been subject to a transformation process, such as grains, fresh fruits and vegetables
- Animal-origin food products (chilled/frozen) that have not been subject to any transformation process
- Products used as inputs by foodservice operators or food processors for food preparation or manufacturing

The GOC defines a transformed product as one subject to processing, which results in a significant change of its internal structure.

Most of the product registration process can be completed online. Upon receiving product registration applications, INVIMA analyzes the documents submitted by the applicant (U.S. manufacturer or local importer) and may request additional information.

MHSP, through Resolution 719 of 2015, set an official classification of food products for human consumption based on their risk to public health. Additionally, Resolution 2674 of 2013 establishes three types of product registrations based on the registered product risk to public health and sets the respective periods of validity:

- 1. Product registrations for "high risk" products are valid for 5 years
- 2. Product permits for "medium risk" products are valid for 7 years
- 3. Product notifications for "low risk" products are valid for 10 years

INVIMA's product registration can be issued to the foreign food producer or the local Colombian importer. It is highly recommended for U.S. exporters to hold the INVIMA registration. However, it is common that local importers will apply for such registration in accordance with their foreign suppliers. U.S. exporters can more easily change/add new importers for their products in Colombia if they are the registration holder. This process is administered by INVIMA and is defined as a "registration modification." On the other hand, if the product registration holder is the Colombian importer, then the U.S. exporter must start a new registration process to change/add importers for their products in Colombia.

INVIMA's port inspectors are expected to verify that imported products registered with INVIMA follow the product specifications (e.g. product description, labeling, portion sizes, etc.) included on their product registrations. If such specifications change, then the registration holder must request a modification to their product registration with INVIMA.

The information that INVIMA requires for product registration can be found on its <u>website</u>. This information includes a complete application form, a Certificate of Free Sale assuring that the products are authorized for human consumption in the United States, information of the local importer, etc. According to <u>Law 455 of 1998</u>, the U.S. certificate of free sale used for the product registration application must have an "apostille" stamp. U.S. companies are encouraged to review whether the apostille stamp is provided by a Secretary State office (for documents that were originated or issued in the state level), or by the <u>Department of State</u> for federal-level apostille. An official translator, approved by the Colombian Ministry of Foreign Affairs, must translate these documents into Spanish.

Importer Registration, Import Registration, and Import Licensing

Every Colombian importer must be registered with MINCIT. U.S. exporters seeking to sell to a Colombian importer should verify that the importer has obtained the legal authorization to import food and agricultural products from MINCIT and, depending on the type of product to be imported, other government authorities including INVIMA and ICA. Additionally, every importer (company or person) must obtain an "electronic signature" from the Ministry of Finance. These procedures can be completed online at the "Unique Window for Foreign Trade" (VUCE) at www.vuce.gov.co.

Minimum Description

Products entering Colombia shall comply with the "minimum description" requirements under <u>Resolution 057 of 2015</u>, issued by the MINCIT and DIAN. For certain products where translation is not applicable, the product must be registered in the original language.

Animal/Plant Health Import Permit

As previously mentioned, products used as inputs by the food industry or foodservice sector in food preparation do not need an INVIMA registration. However, they do need an animal or plant health import permit from ICA and to meet labeling regulations. ICA is responsible for the issuance of import permits for animal products, vegetables, fruits, grains, pet food, dairy products, poultry, and agricultural inputs, including seeds and organic foods.

Such permits are referred to by ICA as "zoo-sanitary and phytosanitary documents." These permits must be requested by the importer and require the submission of several pieces of information/documentation to avoid delays and possible rejections. Such information includes the name of the importer, product description, name and address of the foreign exporter, departure port (e.g. Miami, USA), destination port (complete address and city in Colombia), and registered facility where the product is processed.

The Colombian importer must first obtain the import permit from ICA before requesting an import license from MINCIT. The importer should then provide the U.S. exporter with the ICA import permit before the U.S. exporter can apply for the appropriate "Export Certificate" from the U.S. Department of Agriculture (USDA). USDA then issues an export certificate referencing the requirements in ICA's import permit. No shipments should be loaded and transported without the submission of the sanitary permit.

Export Sanitary Certificates

Decree 2478, issued by the MHSP in 2018, establishes food import requirements at ports of entry (POE). This decree establishes that importers must submit a "sanitary certificate" for any batch or lot of "medium" or "high" risk food products imported into Colombia, including all animal-derived products such as dairy, seafood, meat, and poultry. This certificate must be issued by the food safety authority in the country of origin. For U.S. exports, these authorities include USDA's Food Safety Inspection Service (FSIS), USDA's Animal and Plant Health Inspection Service (APHIS), USDA's Agricultural Marketing Service (AMS), and the U.S. Department of Commerce's National Oceanic and Atmospheric Administration (NOAA).

Export Establishment Registration

Colombia and the United States have an agreement that provides import eligibility of meat and poultry products with a packaging origin from any USDA federally inspected establishment. The GOC will only recognize those establishments that are listed in the USDA FSIS Meat and Poultry Inspection Directory.

In order to register with INVIMA and ICA, exporting establishments must provide the following information:

- Country of origin
- Establishment name
- Establishment number
- Address
- Email address
- GPS location
- Products that will be exported to Colombia with their Harmonized System (HS) Code
- Mode of preservation (e.g. chilled or refrigerated)

The information should be provided in a formal letter and sent via courier or private post to:

Sra. Alba Rocío Jiménez
Dirección de Alimentos y Bebidas
INVIMA
ajimenezt@invima.gov.co
Carrera 10 No 64 -28
Bogotá D.C.- Colombia

To avoid potential issues at port of entry, before shipping the product it will be helpful to verify the listing of the U.S. exporting establishment after submitting the required registration information on both INVIMA and ICA websites.

In connection with dairy products, seafood and egg products, GOC is working on the implementation of new procedures for registering export establishments according to Decree 2478, which are expected to come into force in 2025 and will transfer jurisdiction of facility registration from ICA to INVIMA. While this process continues, INVIMA and ICA have committed to continuing to recognize the list of establishments duly registered with the U.S. government. In this regard, ICA and INVIMA agreed on an extension for the establishments already registered with ICA until 2025.

Import Duties

The U.S.-Colombia Trade Promotion Agreement (CTPA) entered into force on May 15, 2012. This comprehensive trade agreement eliminated tariffs on over 80 percent of U.S. exports of consumer and industrial products to Colombia. All remaining tariffs will be eliminated within 15 years, except for rice (19 years) and poultry (18 years).

Table 1: CTPA TRQ Schedule for Sub-Set of Agricultural Products

Product	TRQ (MT) 2025	TRQ Annual Increase	Phase Out Period	Safeguard Trigger Level
Yellow Corn	Unlimited	5.0%	12 years	
White Corn	Unlimited	5.0%	12 years	
Rice	140,003	4.5%	19 years (6 of grace)	120% of TRQ
Sorghum	Unlimited	5.0%	12 years	
Dried Beans	Unlimited	5.0%	10 years	130% of TRQ

Animal Feeds	Unlimited	5.0%	12 years	
Pet Food	Unlimited	8.0%	8 years	
Chicken Leg Quarters (fresh, chilled, frozen) Processed chicken leg quarters	45,024	4.0%	18 years (5 years of grace) 18 years (10 years of grace)	130% of TRQ
Spent Fowl	605	3.0%	18 years	130% of TRQ
Standard Quality Beef	Unlimited	5.0%	10 years	140% of TRQ
Variety Meats	Unlimited	5.5%	10 years	
Crude Soybean Oil	Unlimited	4.0%	10 years	
Glucose	Unlimited	5.0%	10 years	
Milk Powder	18,987	10.0%	15 years	
Cheese	7,975	10.0%	15 years	
Yogurt	380	10.0%	15 years	
Butter	Unlimited	10.0%	11 years	
Processed Dairy Products	3,797	10.0%	15 years	
Ice Cream	Unlimited	10.0%	11 years	

Data source: <u>United States Trade Representative</u> (USTR)

Table 2: TRO Commitments and Fill Rates in 2024

Product	TRQ Commitment for 2024 (MT)	TRQ Filled	% TRQ Filled YTD as of September
Milk Powder	17,261	16, 2024 17,261	16, 2024 100%
Chicken Leg Quarters	43,292	2,189	5%
Cheese	7,250	3,790	52%
Yogurt	345	0	0%
Processed Dairy Products	3,452	186	5%
Rice	133,975	146,243	-9,16%
Spent Fowl	587	0	0%

Data source: <u>DIAN</u> and <u>Col-Rice</u>

For further information on specific agricultural products based on the Harmonized Tariff Schedule (HS) please refer to Section 2 of the following link: https://ustr.gov/trade-agreements/free-trade-agreements/colombia-tpa/final-text

For further information on exporting rice to Colombia and the TRQ process, please visit: http://www.col-rice.org/

For further information on exporting poultry to Colombia and the TRQ process, please visit: http://www.colom-peq.org/

SECTION VII. OTHER SPECIFIC STANDARDS

Food Samples

<u>Resolution 3772 of 2013</u>, <u>Resolution 34419 of 2013</u>, and <u>Resolution 14623 of 2018</u> establish the procedures to request authorization to ship food samples to Colombia. Food product samples can be sent to Colombia for market testing purposes with a prior notification to INVIMA's Director for Food and Alcoholic Beverages (<u>invimasal@invima.gov.co</u>). Such a request to INVIMA must include the name of the product, producer details, amount, type of food product, reason for market entry, expiration date and number of units in the shipment.

While food samples are exempt from the obligation to have a sanitary registry, as a general rule, most of the other sanitary requirements may apply, such as the obligation to comply with animal/plant health permits issued by ICA (see Section VI. Other Regulations and Requirements), depending on the risk category of the product set on Andean Resolution 1153, and Annex 12 of the Joint Circular issued by the Ministry of Commerce and ICA. In this regard, U.S. companies are highly encouraged to verify the sanitary permits that may apply depending on the type of products.

For processed products that must comply with maximum sodium levels under <u>Resolution 2013</u> (See <u>GAIN Report 2023-0017</u> and <u>GAIN Report 2023-0030</u>), samples must comply and certify sodium levels, according to Resolutions 2013 and 2056, before its nationalization. Samples must also comply with Colombian labeling requirements, including nutrition and front-of pack labeling information set in Resolution 810 and Resolution 2492.

Samples must contain the phrase "*muestra sin valor comercial, prohibida su venta*" (in English, "a sample with no commercial value, cannot be sold"). The importer must get approval from MINCIT through the <u>VUCE</u>. All these requirements must be met prior to the shipping of the samples. When the samples arrive in Colombia, they must be "nationalized" following the procedures that any imported product follows. Samples shipped via express mail or post parcel are subject to the Colombian import regulations. After a product is registered and imported into Colombia, INVIMA inspectors may take product samples at random to conduct laboratory tests.

Enriched Wheat Flour

<u>Decree 1944 of 1996</u> states that wheat flour sold in Colombia must be fortified with vitamin B1, vitamin B2, niacin, folic acid and iron. The addition of calcium may be an option. The quality of the micronutrient must comply with the technical specifications of the Codex Alimentarius, Food Chemical Codex, and INVIMA.

Table 3: Minimum Amount of Micronutrients in Enriched Wheat Flour Sold in Colombia

Micronutrient	Minimum Amount (mg/Kg)	Presentation
Vitamin B1 or Thiamin	6 mg	Thiamine mononitrate
Vitamin B2 or Riboflavin	4 mg	Vitamin B2 Riboflavin
Niacin	55 mg	Niacin Nicotinamide
Folic acid or foliate	1.54 mg	Folic Acid Folic Acid
Iron	44 mg	Ferrous Fumarate Iron, Reduced Iron, Ferrous Sulfate
Calcium (Optional)	1.280 mg	Calcium Carbonate, Monocalcium Phosphate

Furthermore, in May 2015, the Ministry of Health published Circular 400-1378-15, which requests all importers (and INVIMA registration holders) of products whose main ingredient is wheat flour to send their technical specifications to INVIMA. Between 2022 and 2024, the Ministry of Health conducted a review of this enrichment requirement, which may lead to the mandatory addition of other nutrients if the review leads to an amendment to the current regulation. This review also assesses derived processed products that use wheat flour as a main ingredient, as well as corn flour and its derived products.

SECTION VIII. GEOGRAPHICAL INDICATIONS, TRADEMARKS, BRAND NAMES AND INTELLECTUAL PROPERTY RIGHT

Protection of Property Rights

Colombia has been on the Special 301 "Watch List" since 1991. Key concerns include customs duties enforcement and the Colombian Constitutional Court invalidating the law that regulates intellectual property rights for the protection of new variety plants by which Colombia ratified UPOV91 convention. Colombia, a WTO member, has ratified legislation to meet its obligations under the Uruguay Round Agreement on Trade-Related Aspects of Intellectual Property Rights. Colombia is a member of the World Intellectual Property Organization, the Paris Convention for the Protection of Industrial Property, the Berne Convention for the Protection of Literary and Artistic Works, the Treaty on the International Registration of Audiovisual Works, and the 1978 Union for the Protection of New Plant Varieties. Colombia is a signatory to the Patent Cooperation Treaty.

In Colombia, granting, registration, and administration of intellectual property rights (industrial property and copyright) are carried out by four separate government entities. Colombia currently lacks a unified Intellectual Property Rights (IPR) registration system. The Superintendency of Industry & Commerce (SIC), MINCIT's watchdog regarding competition, acts as the Colombian patent and trademark office. ICA is the regulatory authority in charge of the issuance of plant variety protection-related and agrochemical patents. MHSP is responsible for the issuance of pharmaceutical patents, while the Ministry of Interior oversees the issuance of literary copyrights. Each of these entities suffers from significant financial and technical resource constraints. Moreover, the lack of uniformity and consistency in IPR registration and oversight procedures limits the transparency and predictability of the IPR enforcement regime.

Patents and Trademarks

The main regulation for patents and trademarks in Colombia is <u>Andean Decision 486</u>. The patent regime in Colombia currently provides a 20-year protection period for patents. Provisions covering protection of trade secrets and new plant varieties have improved Colombia's compliance with its World Trade Organization – Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) obligations. However, the Colombian government does not provide patent protection for new use of previously known or patented products.

Industry sources have reported that there are issues with patents for Living Modified Organism (LMO) technologies, including the excessive amount of time it takes to grant patents. In addition, the Colombian law pertaining to IPR, <u>Law 1032 of June 22, 2006</u>, Article 306 for usurpation of intellectual property, lacks strong enforcement.

Finally, U.S. companies are advised to be aware of Colombia's Geographical Indications (GI) regime when trademarks include references to geographic places or generic terms when the latter may incur risk of confusion for consumers, which are protected under Colombian regulation. More information on protected GI in Colombia may be found on SIC's <u>website</u>. Please, note that GI need to be registered in Colombia in order to be legally protected. On this regard, U.S. companies are advised to follow the procedures set in Andean <u>Decision 486 of 2000</u>.

Copyrights

The <u>CAN Decision 351</u> on the protection of copyrights has been in effect in Colombia since January 1, 1994. <u>Law 44 of 1993</u> and Colombia's civil code include some provisions for IPR enforcement and have been used to combat infringement and protect rights. Colombia is a member of the Berne and Universal Copyright Conventions, the Buenos Aires and Washington Conventions, the Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations, the Geneva Convention for Phonograms, the WIPO Copyright Treaty, and the WIPO Performances and Phonograms Treaty.

Law 44/93 significantly increased penalties for copyright infringement, specifically empowering the Attorney General's office to combat piracy. Ineffective anti-piracy enforcement in Colombia adversely affects employment, job creation and revenues, both in the United States and Colombia. Some U.S. companies have suffered trade losses due to copyright piracy and intellectual property violations.

SECTION IX. IMPORT PROCEDURES

High-Value, Consumer-Ready Food Products for Retail Sale

All import forms and fees information can now be accessed online at MINCIT's VUCE website: www.vuce.gov.co.

The product must be registered with INVIMA if it will be sold directly to final consumers. See section above on "Product Registration." A sample label may be submitted to help the registration process.

Food for Industrial/Foodservice Usage

Products used as raw inputs by the food industry or the hotel-restaurant-institutional sector in food preparation do not require an INVIMA product registration but must follow the labeling guidelines for raw materials per Resolution 5109 of December 29, 2005 issued by MHSP. Food for industrial usage is

excluded from complying with nutrition and front-of pack labeling and the maximum levels for sodium regulation set in Resolution 2013.

Beef and Pork, Not-Transformed (Fresh, Chilled or Frozen)

Transformed products are defined by the GOC as those subject to processing that resulted in a change in its internal structure. The current regulation for meat products in Colombia is set by <u>Decree 1500</u> of May 4, 2007 issued by MHSP.

The importer must apply for an ICA animal health import permit (zoo-sanitary certificate) that is commonly issued within 48 hours. The import permit lists the sanitary statements that the exporting country's official sanitary authority must certify for the specific product. No product should be shipped without an export sanitary certificate issued by FSIS, whose issuance date should be after the Colombian ICA import permit's issuance date. Steps to follow by importers are explained above in the section "Importer Registration, Import Registration, and Import Licensing." Documentation and clerical errors are considered the most common problem at ports of entry. Detention or rejection of shipments have occurred due to non-compliance with SPS or labeling requirements, the appearance of unsanitary packaging, and the presence of foreign material on the bottom of containers. Detailed information about sanitary certificates and requirements can be obtained on FSIS's website. Error! Hyperlink reference not valid.

Article 5 of Decree 2270 of 2012 states that frozen meat cannot be thawed and sold as a chilled or refrigerated product in retail establishments. Decree 1500 of 2007 requires slaughter dates be on product labels before shipments are released into commerce but after the import clearance. Although not an import requirement enforced at ports, Colombian importers will likely ask for this information from exporters to use as needed after import clearance.

Beef and Pork, Transformed

The current regulation for a meat product in Colombia is mandated by Decree 1500 of May 4, 2007 issued by the MHSP; partially modified by <u>Decree 2270</u> of November 3, 2012. Chapter IX of Decree 1500 establishes the import requirements and considerations of Colombian authorities (ICA and INVIMA) for issuing import authorizations.

Processed beef and pork products sold at retail must be registered with INVIMA (see "Product Registration" section). The steps importers must follow are explained above in the "Importer Registration, Import Registration and Import Licensing" section. Before importing meat products, the importer must complete an import request form through the VUCE website. Also, it is necessary to obtain a zoo-sanitary certificate issued by ICA and an export establishment approval if part of the USDA Agricultural Marketing Service Export Verification program and/or export establishment approved by FSIS. The U.S. export establishment will need to be registered with INVIMA. More information on registering approved establishments for the export of meat products can be found on the FSIS Exporter Library page for Colombia.

If the meat is sold in retail packages, it must be labeled individually and include nutritional information (see previous section). Labels must be in Spanish and contain the product name, name and address of importer, name and address of producer, net contents in metric units, list of ingredients (if any), INVIMA registration number, recommended method of storage, and product expiration date. In the case

of food for industrial purposes, food of a single ingredient with no additional additives, or food without or with minimal processing, no obligation for nutrition or front-of pack labeling applies (see GAIN Report CO2022-0026).

It is not recommended by Colombia to label products as both "Keep Refrigerated" and "Keep Frozen", as this may lead to delays at the port at the moment of requesting the nationalization of the products with INVIMA.

On any retail ready products, slaughter date may be expressed as a date or a date range in the labeling (see GAIN Report CO2023-0003). Packing date, expiration or use by date, must be declared as a single date with the day written with numbers and not with letters, the month with the first three letters or in numerical format, and then the year indicated with its last two digits in numerical format (e.g., DD/MM/YY). Information must appear in a bilingual label (English/Spanish).

Poultry Meat (whole birds), Not Transformed

The current regulation in Colombia is mandated by Decree 1500 of May 4, 2007, issued by MHSP. Chapter IX in the mentioned Decree establishes the import requirements of ICA and INVIMA to issue import authorizations.

INVIMA/ICA inspectors will inspect the imported poultry meat product upon arrival in Colombia to ensure that the product comes from a U.S. inspected export establishment that is registered with INVIMA, is free of disease, has been inspected by USDA prior to its shipment, and is accompanied by a USDA export certificate. Simultaneously, an INVIMA inspector will verify that the imported product meets INVIMA conditions for human consumption.

If the meat will be sold in retail packages, it must be labeled individually. Labels must be in Spanish and should contain the product name, name and address of importer, name and address of producer, net contents in metric units, list of ingredients, INVIMA registration number, recommended method of storage, and product expiration date. This information may be affixed to the package, according to Resolution 5109.

Poultry Parts (fresh, chilled or frozen)

Any U.S. plant exporting these products must be registered with INVIMA and ICA. Please refer to the "Export Establishment Registration" section above for import procedures for poultry parts. If the meat is sold in retail packages, it must be labeled individually. Labels must be in Spanish at a minimum and contain the product name, name and address of importer, name and address of producer, net contents in metric units, list of ingredients, INVIMA registration number, recommended method of storage, and product expiration date.

On any retail ready products, slaughter date may be expressed as a date or a date range in the labeling (see GAIN Report CO2023-0003). Packing date, expiration or use by date, must be declared in a single date with the day written with numbers and not with letters, the month with the first three letters or in numerical format, and then the year indicated with its last two digits in numerical format (e.g., DD/MM/YY). Information must appear in a bilingual label (English/ Spanish).

Mechanically Deboned Chicken or Pork

The U.S. plants exporting these products need to be registered with INVIMA, following the indications for poultry parts provided above. Detention or rejection of mechanically deboned chicken can occur during port inspections due to the unsanitary appearance of packages or the presence of foreign material on the bottom of containers. U.S. companies are advised to be aware of the good sanitary appearance of packages, especially in the case of stained boxes in order to avoid the risk of detention and rejection of shipments.

Fresh Fruit and Vegetables

The import procedure is explained above under the "Sanitary Permits" section issued by ICA. An ICA official will inspect the imported fresh produce upon arrival in Colombia. The ICA official will ensure that the product meets the wholesomeness conditions and is free of disease/pests. Products are expected to have been inspected by USDA prior to shipment and accompanied by a USDA export certificate that complies with the sanitary requirements listed in the import permit. The ICA phytosanitary import permit's issuance date must be before APHIS's export certificate.

Processed Fruit and Vegetables

These products must be registered with INVIMA (see section on "Product Registration"). A sample label may be submitted to expedite the registration process. If the product will be sold in retail packages, it must be labeled individually. Labels must be in Spanish and contain the product name, name and address of importer, name and address of producer, net contents in metric units, list of ingredients, INVIMA registration number, recommended method of storage, and product expiration date. In case of food for industrial purposes, food of a single ingredient with no additional additives or food without or with minimal processing, no obligation for nutrition or front-of pack labeling applies (See GAIN Report CO2022-0026).

Milk

ICA's Directorate of Border Protection manages a list of milk manufacturing plants authorized to export to Colombia. Plants must be added to this list prior to exporting to Colombia even for samples of no commercial value. Currently, INVIMA is working on the implementation of new procedures for export establishment registration, which are expected to come into force in 2025. With the implementation of these procedures, INVIMA (not ICA) will be responsible for updating and maintaining the registry for manufacturing plants authorized to export milk and dairy products to Colombia. While this process continues, ICA will continue managing the list for manufacturing plants authorized to export to Colombia.

In the process of updating the legislation on different food sectors, the GOC issued <u>Decree 616 in 2006</u>, which established the technical requirements for milk for human consumption at production, processing, bottling, transportation, commercialization, importation, and exportation. Currently, the GOC is working on an update of Decree 616 of 2006, which may introduce important changes to the current regulation.

Currently, imported milk used as a raw material for the food industry must carry the following labeling information in Spanish:

- 1. Milk brand and type of milk (whole, skimmed, semi-skimmed)
- 2. Country of origin

- 3. Production date and/or production lot number
- 4. Expiration date must be longer than 12 months from date of arrival in Colombia
- 5. Storage recommendations
- 6. Total and net weight in grams or kilograms

U.S. exporters of dairy products, particularly milk powder, should make sure their shipments meet Colombia's physical and chemical property requirements pursuant to Decree 616, particularly lactic acid lower and upper limits. Please note that production date and/or production lot number and expiration date must be printed on the original packaging at the country of origin. The use of stickers for production date and/or production lot number and expiration date is forbidden.

On July 3, 2024, Colombia's Ministry of Commerce issued <u>Resolution 192</u> by which it initiated a countervailing duty (CVD) investigation into U.S. milk powder. In the framework of this CVD investigation, on September 16, 2024, the Ministry of Commerce issued <u>Resolution 271</u> by which it set a provisional duty of 4.86 percent to U.S. milk powder for up to four months. A final determination is expected to be adopted by the end of 2024.

Whenever milk is imported in hermetic packages ready to be sold to the public, the product should meet the requirements established by Resolution 5109 of December 29, 2005. The country of origin and the number of sanitary registrations must be displayed in Spanish. Powdered milk imported in bags or hermetic packages ready to be sold to the public must meet the requirements established by <u>Decree 3075</u> of 1997. It is necessary to fulfill labeling requirements for powdered milk set by <u>Decree 1673</u> of 2010.

To control the entry of imported milk contaminated with radiation, MHSP will follow the recommendations of the International Atomic Energy Agency under the International Commission on Radiological Protection and the World Health Organization. Imported milk found not suitable because of radiation will be re-exported to the country of origin, and the importer is to pay the associated fees. Imported powdered milk will follow the import procedures described for any processed food product.

Wine

The current prevailing alcoholic beverages regulation in Colombia is mandated by <u>Decree 1686 of 2012</u> and <u>Decree 162 of 2021</u>. Both of these regulations are issued by the Ministry of Health. These decrees set the sanitary requirements that alcoholic beverages producers must follow during the manufacturing, processing, hydration, packaging, storage, distribution, transportation, marketing, sale, exportation, and importation to ensure safety.

The Colombian importer must register the company with the local Chamber of Commerce. This grants the legal recognition for the importing company as a subject of protection and taxing. The product must be registered with INVIMA by either the U.S manufacturer/exporter or the Colombian importer. Only wines of the same brand, of different aging times and denomination of origin, and that have similar physical and chemical characteristics may be protected under the same sanitary registry. In the case of sparkling and bubbly wines, the products must be under the same classification set under Article 3 of Decree 1686 of 2012.

Wine must be labeled. Labels must be in Spanish and contain the product name, name and address and city of producer and importer if applicable, place of production, sanitary registration number issued by

INVIMA, percentage of alcohol, net contents and a statement indicating that excessive consumption of alcohol is harmful to health and that the sale of intoxicating beverages to minors is prohibited. In the case of products that are manufactured outside of Colombia, the label must clearly indicate the origin of the product. The use of a complementary label is allowed in order to declare the mandatory legends, as well as the sanitary registry number granted by INVIMA, name, address, and city of the importer. The use of stickers to declare expiration date and the batch and degree of alcohol is prohibited. The product warning should occupy at least 10 percent of the label. All this information must be printed on the label prepared by the wine producer/exporter. Imported bottled wine is allowed in containers not exceeding two liters.

Currently, the MHSP is working on an amendment to Decree 1686, which would eliminate the requirement for a good manufacturing practices (GMP) certificate issued by the manufacturer in order to request a sanitary registry. This amendment is expected to enter into force in 2025 and will facilitate the registration process within INVIMA. In the case of the United States, since 2021, MHSP and INVIMA recognize that the certificate of free sale issued by the Tax and Trade Bureau of the U.S. Department of Treasury is equivalent to a GMP and satisfies the requirements for a GMP certificate for the purposes of the sanitary registration process. Certificates of free sale, as well as any other document required to request for a sanitary registry for alcoholic beverages in Colombia and issued by any U.S. government authority, must be apostilled.

Article 78 of Decree 1686 requires a quality certificate issued by the manufacturer considering the lots imported. The quality certificate needs to be in Spanish and specify name and description of the product, composition, date of production, and expiration dates. It should be noted that Colombian Congress issued <u>Law 1816 in December 2016</u>. This law brought Colombia into compliance with its trade commitments under the WTO and trade agreements with the United States, Canada, and the European Union. It removed the discriminatory tax system as well as the anti-competitive practices conducted by local liquor producers before 2016. This bill went into effect on January 1, 2017.

SECTION X. TRADE FACILITATION

In August 2020, Colombia formally adhered to the World Trade Organization (WTO) Trade Facilitation Agreement (TFA), which required legislative approval and legal review by Colombia's Constitutional Court. Colombia's commitment to trade facilitation will be tested in the coming years as it implements the WTO TFA's obligations and its latest Customs Code (Decree 1165 of 2019).

Trade Facilitation in Agricultural Trade

On May 22, 2024 the Colombian Ministry of Finance and Public Credit issued <u>Decree 659 of 2024</u>, by which it partially modified Colombia's customs regime, introducing, among other changes, mandatory advanced import declaration to all products exported to Colombia, including agricultural and food products. The new customs decree modification will require all importers and authorized economic operators (AEO) to report advanced declaration of all shipments to Colombia in a new system prior to the arrival of the cargo to Colombia. According to DIAN, importers must file the advanced declaration within a minimum of 48 hours for air transportation and four to five days for maritime transportation. Failure to present the advanced declaration paperwork may result in a fine of 1 percent of the FOB value and seizure of the merchandise. A late submission of the advanced declaration will result in a similar

value-based penalty at 80 percent of the fine, provided that it is submitted by paying the fine, thus obtaining legal validity. Many Colombian importers have expressed concern with the implementation of the Decree 659 of 2024, asserting the national government does not have the infrastructure, juridical, security, technology, or personnel capacity to manage the decree implementation. The obligation to submit advanced import declarations is supposed to enter into force once Colombia's customs electronic system is fully working, which is expected to be happened during the second semester of 2025.

APPENDIX I. GOVERNMENT REGULATORY KEY AGENCY CONTACTS

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Director of Trade Relations	Director of Food and Alcoholic Beverages
Ministry of Commerce, Industry and Tourism	INVIMA
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Website: <u>www.mincit.gov.co</u>	Website: <u>www.invima.gov.co</u>
Wilkien Ramírez	Claudia Moreno
Deputy Manager of Border Protection	Chief of International Affairs
ICA -Instituto Colombiano Agropecuario	Ministry of Agriculture and Rural Development
Avenida Calle 26 # 85b – 09	Avenida Jimenez # 7A-17
Bogotá, Colombia	Bogotá, Colombia
Tel. (57-1) 332-3700 ext. 1100	Tel. (57-1) 2543300 ext. 5385
E-mail: wilkien.ramirez@ica.gov.co	E-mail: claudia.moreno@minagricultura.gov.co
Website: www.ica.gov.co	Website: www.minagricultura.gov.co

APPENDIX II. OTHER IMPORT SPECIALIST TECHNICAL CONTACTS

Office of Agricultural Affairs	Juan Camilo Montes
U.S. Embassy Bogotá	Executive Director
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APO AA 34004	ANDI
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Laura Pasculli,	Pilar Ortiz
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Attachments:

No Attachments