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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 of plant-based meat/dairy alternatives, nutritional labeling, biotechnology, and new information on sustainable packaging policies and trade facilitation in Colombia. 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 Moises.Huerta@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 were 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 in South America. In 2020, the United States exported \$2.9 billion to Colombia, which cemented its position as Colombia's top supplier of food and agricultural products with nearly 50 percent imports market share. In 2021, despite the slow economic recovery resulting from Covid-19, U.S. exports grew 18 percent between January and July. All export categories have displayed double digit growth in 2021. The U.S.-Colombia Trade Promotion Agreement (CTPA) has expanded opportunities and market potential for many agricultural products. Top exports have historically included bulk commodities such as corn and soybeans, which combined, accounted for over half of total exports in 2020.

Colombia is a highly regulated yet growing market for U.S. exporters of food and agricultural products. U.S. bulk commodity exports to Colombia are expected to remain a strong category and U.S. consumeroriented exports hold great potential for further growth in the coming years. Certainly, local currency devaluation to the U.S. dollar and the slow economic recovery from the Covid-19 pandemic are key factors. In 2021, Colombia expects 8 percent economic growth, which is above the expected growth rate of the Latin American region. In recent years, income and population growth in Colombia have driven demand for most imported agricultural products. Despite the significant impact of Covid-19 on certain U.S. food exports to Colombia, corn, soybean meal and soybean oil imports will likely continue to experience steady growth over the next several years, and the United States will remain a key supplier for Colombia. Growing demand from the animal feed and pet food industries, which have been steadily increasing in recent years, will be a key factor.

This report contains general information on Colombia's main policies and regulations for the importation of food and agricultural products into the country. U.S. exporters are encouraged to pay special attention to the role key sanitary and phytosanitary agencies, such as INVIMA and ICA, play prior and upon the arrival of shipments at ports of entry in Colombia, as well as in the registration of their products and manufacturing facilities in the United States. Further, this report contains a section on trade facilitation and key government and private sector players.

SECTION I. FOOD LAWS

Food laws and regulations are fairly structured in Colombia, and their development and implementation is distributed among legislative and executive branches of government. However, similar to other

developing countries, the Colombian government continually faces challenges in the enforcement of regulations and requirements for food products. Notably, in recent years, FAS Bogota has seen protectionism on the rise in Colombia, which has created hurdles for U.S. exporters, including, for example, a 4-month government ban on imported ethanol in 2020.

Food laws and regulations in Colombia stem primarily from provisions under <u>Law 9 of 1979</u>. Since then, the government of Colombia (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), the National Institute for the Surveillance of Food and Medicines (INVIMA), the Ministry of Agriculture and Rural Development (MARD), and the Colombian Institute for Agriculture and Livestock (ICA). 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

<u>Resolution 5109 of 2005</u> and <u>Resolution 333 of 2011</u>, both issued by the MHSP, are the primary source of labeling regulation for food products in Colombia. 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. The information must be true and not misleading.

Information 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 and 333. In certain cases, in the absence of English labels, INVIMA will authorize Spanish labels to be affixed to the product during or after the nationalization process at authorized warehouses or storage facilities. However, INVIMA will require original labels that to, at the very least, include expiration date and lot number.

When food products or food raw food materials originate in countries where information on the expiration date and/or minimum shelf life ("best before...") information is not required, the importer must get prior approval from INVIMA by providing that information in a document issued by the producer/manufacturer. Note: a U.S. date is registered MM/DD/YYYY, whereas in Colombia the date is registered DD/MM/YYYY. An importer can amend label requirements 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.

It should be noted that in June 2021, the MHSP issued <u>Resolution 810</u>, which establishes new nutritional labeling requirements for all processed foods imported into or produced in Colombia. This new measure is expected to introduce a series of new labeling requirements, including front-of-package

nutritional labeling (FOPNL) information. Resolution 810 will go into effect in December 2023, at which point Resolution 333 will expire. More recently, in July 2021, Colombian Congress enacted Law 2120, widely known in the country as the "Junk Food Bill." This new legislation is expected to lead to further changes to current labeling requirements for food products in Colombia. MHSP and other relevant government bodies are currently working on the implementation of Law 2120, which in fact could result in a revision of Resolution 810.

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 manufacturers' written declaration to INVIMA/ICA inspectors with lot numbers 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;
- Sulphites 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 disclaimed 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 2012, 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 <u>IVC-INS-LI15</u> establishing the frequency that importers must present laboratory results to satisfy that products labeled as non-GMO do not contain detectable modified genetic material. These guidelines avoid delays at ports of entry as lot-by-lot testing is not always required, which preserves product shelf life, and alleviates testing costs. The testing requirement does not apply when the main ingredients are not included in the list of genetically engineered (GE) foods attached to INVIMA communication <u>4000-3988-19</u>.

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 <u>4000-1071-18</u>.

Regarding labeling for GE materials (seeds or other plant reproductive materials and animal products), ICA issued <u>Resolution 946</u>, stating that GE derived materials should be identified as "Genetically Modified Organisms" or, in Spanish, Organismo Modificado Geneticamente.

Dietary Supplements

These supplements are regulated primarily through Decree 3249 of 2006.

(https://www.minsalud.gov.co/Normatividad_Nuevo/DECRETO%203249%20DE%202006.pdf) Regarding labeling 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. Decree 272 of 2009 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"; "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.

Nutritional Labeling

Resolution 333 of 2011 establishes the nutritional labeling requirements for most packaged food products. This regulation does not cover nutritional labeling for products destined for infant children, which is set by Resolution 11488 of 1984. Nutritional labeling must be displayed in Spanish at a minimum and could be complemented with a sticker. For imported food products, the sticker may be used to indicate the percentages of daily intake per the above resolution. The portion size declared on the label must be determined from the reference quantities established by Resolution 333. In November 2020 the MHSP issued Resolution 2013 to help reduce sodium intake in Colombia. This measure sets mandatory maximum sodium content limits for 59 processed food categories ranging from snacks to processed meats and dairy products. The measure, which will be applied to domestic and imported products, sets out compulsory reduction goals for each category 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. For more information on Resolution 2013 of 2020, please see the following GAIN report.

The following nutrients require mandatory declaration:

- Energy content (total calories, fat calories);
- Protein content;
- Total fat;
- Saturated fat;
- Trans fats;
- Cholesterol;
- Sodium;
- Carbohydrates;
- Dietary fiber and sugars;
- Vitamin content (A and C);
- Iron and calcium;
- Content of vitamins and minerals other than those mentioned above when they have been included into the product;
- Saturated fat proteins, monounsaturated fat, polyunsaturated, soluble and insoluble fiber, polyalcohol's, potassium;
- Content of other nutrients when there is a declaration of nutritional or healthy properties including food for infants.

INVIMA follows Codex Alimentarius guidance when facing issues regarding nutrition values in food products not considered in Resolution 333.

Colombia's food labeling regulation also establishes the way labeling should be displayed and the appropriate wording to be used. Misleading statements or illustrations must be avoided.

Health claims on labels should be carefully crafted. Article 272 of the Law 9 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 2011, the GOC published Resolution 333 that sought to establish the technical rules to label packaged foods for human consumption. Article 20 of this regulation sets the requirements for health claims on food packages.

Food containing Trans or Saturated fats

<u>Resolution 2508</u> of August 29, 2012, establishes that packaged food products that contain saturated and/or trans fats equal or greater than 0.5 grams per serving should include this information on the nutritional information table.

Additives Labeling

Resolution 1506 of May 6, 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 333. These regulations are premised on the ultimate goal of providing 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 <u>Resolution 2310</u> of 1986, producers must label these products as an "*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 (<u>Resolution 2162</u> of 1983), producers are advised to also use the expression "*imitation of (meat product)*" on the product label. As part of the oversight INVIMA conducts on behalf of MHSP, prior to and at 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. PACKAGE AND CONTAINER REGULATIONS:

The main concern regarding food packaging and containers is 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:

- <u>Resolution 683 of 2012</u>
- <u>Resolution 4142 of 2012</u>
- <u>Resolution 4143 of 2012</u>
- <u>Resolution 834 of 2013</u>
- <u>Resolution 835 of 2013</u>

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 happen frequently due to the presence of foreign material (e.g. dust, wood chips, etc.) in the bottom of containers. USDA is closely working with INVIMA on applying a more practical approach to container and box cleanliness based on product risk. However, it is highly 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 <u>Decree 1500</u>.

Considered the world's second most bio-diverse country, Colombia has taken a regional leadership in environmental-friendly policies. In 1993, Colombia enacted the Law on Environmental Management, which constituted a sound policy and institutional legal framework for an environmental management system and a path for further environmental regulations. Certainly, the country faces great environmental challenges resulting from poorly-regulated extractive industries, extensive cattle farming contributing to land degradation, deforestation and greenhouse gas emissions, and a high exposure of its population to harmful levels of air pollution. Amidst a challenged integration of environmental policies within the country's national policy framework and the growing relevance of sustainable practices in the food and agricultural sector, Colombia's food industry has played an increasingly active role in engaging with the Colombian government on a circular-economy approach on food packaging regulations and objectives. Under President Duque's leadership and as part of a large inter-agency coordination, in November 2018, the Colombian government launched the <u>National Circular Economy Strategy</u>. 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 <u>Resolution 1407</u>, 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 at ensuring that 30 percent of containers and packaging materials on the market are reused by 2030. The MESD has also set a goal to achieve, by 2030, that 100 percent of single-use plastics placed on the market are reusable, recyclable, or compostable (degraded by organisms, biologically). Meanwhile, Colombian Congress is expected to review a bill that would ban single-use plastics other than for medical purposes by 2030. In parallel, promoting the formalization of recyclers remains a key unresolved government task. Informal recycling of paper, cardboard, plastic and metal is quite significant, and the main source of income for the nearly 30,000 Colombian informal recyclers. In

Bogota, Colombia's capital city, it is estimated that over half of all the recycling is conducted by informal recyclers, which further illustrates challenges in waste separation at source in cities and towns throughout Colombia. Finally, it is worth noting that the MHSP is drafting regulation pertaining to food and drinks packaging from a food safety angle. These regulatory developments will likely be in line with the ongoing efforts by the MESD.

SECTION IV. FOOD ADDITIVES REGULATIONS:

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

Furthermore, <u>Resolution 2606 of 2009</u> sets general requirements for food additives and establishes INVIMA's Food Additives Committee, which authorizes the use of certain food additives. Additives can be used only if it brings benefits for foodstuffs, maintains nutritional components, provides nutritional composition recommended for specific groups of consumers (e.g. infant children), and does 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.

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 listed below can be used in food followed by the substance specific name and (voluntarily) the international identification number:

• Flavor enhancer, acid, agglutinating agent, anti-agglutinating agent, anti-compacting agent, antifoaming 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, glossy agent.

SECTION V. PESTICIDES AND OTHER 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.

Maximum Residue Levels

The MHSP issued <u>Resolution 2906</u> in 2007, which establishes national standards for pesticide Maximum Residue Limits (MRLs). The list of admitted pesticides can be found on INVIMA's web site (<u>www.invima.gov.co</u>) under "*Normatividad/Alimentos/Resoluciones*." Maximum Residue Limits for veterinary drugs are listed in <u>Resolution 1382</u> of 2013, which follows the Codex Alimentarius CAC/LMR 2-2012. 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, a sample is taken and analyzed by ICA. The interested party, either the producer, manufacturer or importer, must pay laboratory testing fees.

<u>Resolution 2155</u> of 2012 established the following maximum residue levels 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 REGULATIONS AND REQUIREMENTS

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, etc.
- 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.

The 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; and,
- 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. Being the registration holder allows U.S. exporters to easily change/add new importers for their products in Colombia. 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 in order 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 at: <u>https://www.invima.gov.co/8-pasos-para-obtener-su-registro-sanitario-de-alimentos</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.

Following the Hague Convention of 1961 and Law 455 of 1998, the U.S. certificate of free sale used for the product registration application must have an "apostille" stamp. The "apostille" stamp is provided by different U.S. state authorities, including a notary or a State Secretary or Under Secretary. 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. All of these procedures can be completed online at the "Unique Window for Foreign Trade" (VUCE) at <u>www.vuce.gov.co</u>.

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 and agricultural inputs, including seeds and organic food.

Such permits are referred 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), etc.

The Colombian importer must <u>first</u> obtain the import permit from ICA <u>before</u> 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

<u>Decree 2478</u>, 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 Standard (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:

Sr. Carlos Alberto Robles Cocuyame Dirección de Alimentos y Bebidas INVIMA Carrera 10 No 64 -28 Bogotá D.C.- Colombia

To avoid potential issues at POE, 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.

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). Below is the CTPA TRQ schedule for certain agricultural products:

| Product | Base Duty | TRQ (MT) 2022 | TRQ Annual Increase | Phase Out Period | Safeguard Trigger Level |
|---|-----------|------------------|---------------------------|---------------------------------|----------------------------|
| Yellow Corn | 25% | 3,420,679 | 5.0% | 12 years | |
| White Corn | 20% | 222,344 | 5.0% | 12 years | |
| Rice | 80% | 122,685 | 4.5% | 19 years (6 of grace) | 120% of TRQ |
| Sorghum | 25% | 34,207 | 5.0% | 12 years | |
| Dried Beans | 40.2% | Unlimited | 5.0% | 10 years | 130% of TRQ |
| Animal Feeds | 10%-25% | 316,413 | 5.0% | 12 years | |
| Pet Food | 28% | Unlimited | 8.0% | 8 years | |
| Chicken Leg Quarters (fresh, chilled, frozen) | 164.4% | 40,026 | 4.0% | 18 years (5 years of grace) | 130% of TRQ |
| Processed chicken leg quarters | 70% | | | 18 years (10 years of grace) | |
| Spent Fowl | 20% | 554 | 3.0% | 18 years | 130% of TRQ |
| Standard Quality Beef | 51.2% | Unlimited | 5.0% | 10 years | 140% of TRQ |
| Variety Meats | 51.2% | Unlimited | 5.5% | 10 years | |
| Pork Meat | 30% | Unlimited | | 5 years | |
| Crude Soybean Oil | 24% | Unlimited | 4.0% | 10 years | |
| Glucose | 28% | Unlimited | 5.0% | 10 years | |
| Milk Powder | 33% | 14,266 | 10.0% | 15 years | |
| Cheese | 20%-33% | 5,992 | 10.0% | 15 years | |
| Yogurt | 20% | 285 | 10.0% | 15 years | |
| Butter | 33% | Unlimited | 10.0% | 11 years | |
| Processed Dairy Products | 20% | 2,853 | 10.0% | 15 years | |
| Ice Cream | 20% | Unlimited | 10.0% | 11 years | |
| Maple Syrup | 5% | Unlimited | | 5 years | |

| Product | Commitment | (MT) YTD as of September | %TRQ Filled YTD as of Sep. 27, 2021 |
|-------------|------------|-----------------------------|--|
| White Corn | 211,756 | 211,756 | 100.0% |
| Milk Powder | 12,969 | 12,969 | 100.0% |

| Chicken Leg Quarters | 38,486 | 23,151 | 60.2% |
|-----------------------------|-----------|---------|--------|
| Cheese | 5,447 | 2,532 | 46.5% |
| Yogurt | 259 | 87 | 33.6% |
| Yellow Corn | 3,257,789 | 601,018 | 18.45% |
| Animal Feeds | 301,346 | 67,601 | 22.4% |
| Processed Dairy Products | 2,594 | 313 | 12.1% |
| Ice Cream | 778 | 45 | 5.8% |
| Rice | 117,402 | 9,403 | 8.0% |
| Sorghum | 32,578 | 0 | 0% |
| Butter | 1,297 | 0 | 0% |
| Spent Fowl | 538 | 0 | 0% |
| Source: DIAN | | | |

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

RICE: http://www.col-rice.org/

POULTRY: http://www.colom-peq.org/

SECTION VII. OTHER SPECIFIC STANDARDS

Food samples

<u>Resolution 3772 of 2013</u> and <u>Resolution 34419 of 2013</u> issued by MHSP establishes the procedure 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. Samples must contain the phrase "*muestra sin valor comercial, prohibida su venta.*" A sample with no commercial value cannot be sold. The importer must get approval from MINCIT through the VUCE at <u>http://www.vuce.gov.co</u>. All these requirements 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

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

| 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. Given the pressure exerted by local importers, the Ministry of Health is currently conducting a review of this enrichment requirement. Now, INVIMA requires the fortification of domestic and imported food products that contain wheat flour.

SECTION VIII. COPYRIGHT AND TRADEMARK LAWS

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, including commitments made under CTPA. 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, and 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. MINCIT acts as the Colombian patent and trademark office and details can be found at <u>www.sic.gov.co</u>. ICA is the regulatory authority in charge of the issuance of plant variety protection-related and agro-chemical patents. The MHSP is responsible of 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 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, U.S. companies are concerned that 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. MINCIT takes an excessive amount of time to grant patents, resulting in the biotechnology industry to be reluctant to introduce new technologies in Colombia. In addition, the Colombian law pertaining IPR, <u>Law 1032 of June 22, 2006</u>, Article 306 for usurpation of intellectual property, lacks strong enforcement.

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. Colombia is not a member of the Brussels Convention related to the Distribution of Program-Carrying Signals Transmitted by Satellite.

Although weakly enforced, 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: <u>www.vuce.gov.co</u>.

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 the MHSP.

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 of May 4, 2007</u> issued by the 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 at:

http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products/export-library-requirements-by-country/Colombia.

Article 5 of <u>Decree 2270 of 2012</u> states that frozen meat cannot be thawed and sold as a chilled or refrigerated product in retail establishments. Finally, 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 the Decree 2270 of November 3, 2012. Chapter IX of the 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 previous section on "Product Registration." The steps importers must follow are explained above in the section "Importer Registration, Import Registration and Import Licensing." 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, an export establishment approval if part of the USDA Agricultural Marketing Service EV program and/or export establishment approved by FSIS. The U.S. export establishment will need to be registered with INVIMA. List of EV approved establishments can be obtained from: http://www.fsis.usda.gov/wps/wcm/connect/9978cd33-b439-48c3-9366-451bc0173183/Official-Listing-Eligible-Suppliers-EV-Program-100313.pdf?MOD=AJPERES

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.

Poultry Meat (whole birds), Not Transformed

The current regulation in Colombia is mandated by Decree 1500 of May 4, 2007 issued by the MHSP. Chapter IX in the mentioned Decree establishes the import requirements of Colombian authorities 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. Detention or rejection of shipments has occurred due to the "unsanitary packaging appearance" and the presence of foreign material on the bottom of containers.

If the meat will be sold in retail packages, it must be labeled individually. Labels must be in Spanish at a minimum 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)

HS: 02.07-13./14./26./27.35./36. and 16.02-31.00.10/32.00.10/39.00.10

Any U.S. plant exporting these products must be registered with INVIMA and ICA. Please refer to *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.

Mechanically Deboned Chicken or Pork

HS: 16.02.39

The U.S. plants exporting these products need to be registered at INVIMA, following the indications for *poultry parts* given above. Detention or rejection of mechanically deboned chicken has occurred during port inspections due to the unsanitary appearance of packages or the presence of foreign material on the bottom of containers.

Fresh Fruit and Vegetables

The import procedure is explained above under *Sanitary Permits* 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/pest. Products are expected to have been inspected by USDA prior to its shipment and is 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 above titled "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 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.

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. In the process to update 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, imports and exports. 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 6 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.

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, and 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 of 1997</u>. Besides, it is necessary to fulfill labeling requirements for powdered milk set by Decree 1673 of May 13, 2010.

In order to control the entry of imported milk contaminated with radiation, the 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 the <u>Decree 1686 of 2012</u> issued by the Ministry of Health. This decree sets the sanitary requirements that alcoholic beverages producers must follow during the manufacturing, processing, hydration, packaging, storage, distribution, transportation, marketing, sale, export and import 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. The registration number can cover a type of wines for different presentations if they are produced by the

same winery and under the same technical process, e.g. burgundy wines in bottles (750 cubic centimeters) or half bottles.

Wine must be labeled. Labels must be in Spanish at a minimum 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. 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.

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 Law 1816 in December 2016. This law brought Colombia into compliance with its trade commitments under the WTO and trade agreements with the U.S., Canada, and the EU. 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

As agriculture remains a key element to foster economic growth in Colombia, its government has found trade facilitation to be a useful approach to enhance Colombia's agricultural trade. The GOC has made various efforts to boost agricultural exports, which are limited to a handful number of products such as cut flowers, bananas, and coffee. The Duque administration, which began in 2018, has repeatedly stressed the importance of agriculture and economic opportunities in rural areas to foster sustainable peace, following the 2016 peace accord signed with the Revolutionary Armed Forces of Colombia (FARC). Colombia's agricultural trade has been increasing over the years, supported by 16 trade agreements the government has signed, including FTAs with the United States and the European Union.

Colombia's President Ivan Duque has prioritized trade facilitation for his administration, and in late 2018 tasked an inter-agency working group with the responsibility of addressing Colombia's commitments under the TFA. This trade facilitation working group is chaired by the Ministry of Trade, Industry and Tourism, and members include:

Public sector

- National Food and Drug Surveillance Institute (INVIMA)
- Institute of Agriculture and Livestock (ICA)
- Tax and Customs National Authority (DIAN)
- Antinarcotics Police (POLFA)
- Presidential Advisory Office for the Private Sector

- Directorate for National Planning (DNP)
- Superintendence of Ports
- Ministry of Transportation

Private sector:

- Association of Colombian Exporters (ANALDEX)
- National Business Association of Colombia (ANDI)
- Federation of Colombian Customs Brokers (FITAC)
- Business Alliance for Secure Commerce (BASC)

Recent Developments and Future Projects in Trade Facilitation in Colombia

The GOC has generally relied upon international cooperation to implement trade facilitation measures. Recent projects include work with the Global Alliance for Trade Facilitation (GATF), the Interamerican Development Bank (IDB) and USDA. Programs have included assistance to improve INVIMA's port inspection system for food imports, which resulted in an estimated reduction of 30 percent in physical inspections at Colombian ports of entry. Additionally, Plant and Animal Health Authority (ICA) has relied on international cooperation to facilitate the use of electronic phytosanitary export certificates for Colombian agricultural producers. As for future trade facilitation projects, Colombia is expected to integrate customs system (MUISCA) with the Single Window for Foreign Trade (VUCE), which are currently used by Colombian importers and exporters separately and administered by DIAN and MINCIT. Additionally, Colombia is expected to improve the coordination among border control authorities to reduce the burden of repeated inspections and the exchange of information between customs and other control authorities and port operators to reduced customs clearance times.

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APPENDIX I. KEY GOVERNMENT CONTACTS

APPENDIX II. OTHER CONTACTS

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|--|------------------------------------|
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Attachments:

No Attachments