

United States Department of Agriculture Foreign Agricultural Service

Global Agricultural Information Network GAIN REPORT

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

Required Report - public distribution

Date: 2/22/2019 GAIN Report Number: CO1826

Colombia

Food and Agricultural Import Regulations and Standards Report

FAIRS Annual Country Report

Approved By: Michael Conlon, Agricultural Counselor Prepared By: Moises Huerta, Agricultural Specialist

Report Highlights:

This report is an annual update of the food import standards and enforcement mechanisms in Colombia. The following sections were updated: SECTION II. LABELING REQUIREMENTS; SECTION; SECTION VI. OTHER REGULATIONS AND REQUIREMENTS; SECTION VII. OTHER SPECIFIC STANDARDS; and APPENDIX I. GOVERNMENT REGULATORY AGENCY CONTACTS. 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@fas.usda.gov DISCLAIMER: This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service in Bogota, Colombia, for U.S. exporters of domestic food and agricultural products. While every possible care was taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies 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. FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

Section I. Food Laws:

Food law in Colombia stems primarily from Law 9 of January 24, 1979 (https://www.invima.gov.co/leyes-en-normatividad-institucional.html). Since then, the government of Colombia (GOC) has issued several regulations related to food safety and quality, labeling, product registration, importing procedures, etc. Government agencies responsible for food policy development and implementation include the Ministry of Health and Social Protection (MHSP), National Institute for the Surveillance of Food and Medicines (INVIMA), 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

Resolution 5109 of 2005 and Resolution 333 of 2011, issued by the MHSP, are the primary source of labeling regulation for food products in Colombia. These regulations establish labeling technical standards 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.

Food products imported into the country to be sold in the food service and processing sectors do not need to apply for product registration with INVIMA and the boxes that may contain individual packages must provide all the labeling information required by Resolution 5109 of 2005.

This information must be provided in Spanish either on the label or 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. These labels can be affixed to the product during or after the nationalization process in warehouses or storage facilities inspected, surveyed and controlled by sanitary authorities. When food products or

food raw materials originate in countries where information on the expiration date and/or minimum shelf-life ("best before...") 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.

The Spanish text of Resolution 5109 can be downloaded from

https://www.invima.gov.co/normatividad/resoluciones-normatividad.html?start=100. The technical annex to Resolution 5109 follows the recommendations of the U.S. Conference on Weights and Measures (handbook NBS 130 of 1992, page 60) for the size of letters and numbers on the labels, and those of the European Union about the relationship between net content and the minimum size of characters on labels.

Resolution 333 of 2011 can be found at:

https://www.invima.gov.co/images/stories/resoluciones/Res_333_de_feb_2011_Rotulado_nutricional.p_df

The following information must be included on food product labels that are required to have product registration with INVIMA:

- 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 further food processing, including poultry and meat imported to be sold to foodservice and food processing clients, 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...."). 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.

Additional specific labeling requirements

Radiated Food Products and/or Food Raw Materials

When a product has been subject to ionizing radiation, this condition has to 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 has to be displayed near the product name.

Biotechnology

Regulated through the Resolution 4254 published on September 22, 2011. The resolution entered into force on June 26, 2012 and states that importers of biotech-derived raw materials that are genetically modified organisms (GMOs), or may contain GMOs, shall declare in the commercial invoice that each shipment contains GMOs intended for direct use as food for humans or for further processing. This applies only in those cases where the identity of GMOs is known. In cases where the identity of GMOs are not known, it should be identified as "may contain one or more GMOs" for direct use as food for humans or for further processing.

Food additives, food prepared at point of sale (restaurants), and foods containing one single ingredient or additive that contains Genetically Modified Microorganisms (GMMs) or food containing ingredients processed by enzymes produced by means of GMMs are exempt from Resolution 4254.

While Colombia remains generally open to agricultural biotechnology, asynchronous approvals for biotech events continue to lead to regulatory uncertainty for exports. Colombia is still reviewing its biotechnology regulatory framework, and as part of this review it is reviewing its policy towards low-

level presence (LLP). The GOC has initially proposed a 5% LLP threshold, and is expected to finalize its LLP threshold for imports soon. Additionally, the GOC is deciding how to implement mandatory labeling of foods derived from Genetically Modified Organisms (GMOs), after the Constitutional Court ruled in favor of mandatory labeling as part of Consumer Law 1480, Article 24. The law referred to labeling, but did not specifically address GMO labeling.

Dietary Supplements

They are regulated primarily through Decree 3249 of 2006. Regarding labeling for imported dietary supplements, original labels could be accepted as long as 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 has been clear on the fact that supplement 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 the 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.

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 will follow 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 manner in which 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."* Later in 2011, the GOC published Resolution 333 that sought to set the technical rules on labeling for 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

Resolution 2508 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, could be affixed to the product during or after the nationalization process in warehouses or storage facilities by the port of entry.

Section III. Packaging 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:

- Resolution 683 of 2012
- Resolution 4142 of 2012
- Resolution 4143 of 2012
- Resolution 834 of 2012
- Resolution 835 of 2013

Additionally, Colombia's legislation on municipal waste disposal is outlined in Decree 2981 of December 20, 2013, issued by the Ministry of Environment and Sustainable Development (MESD). The decree establishes regulatory guidelines for solid residues disposal and product recycling

(http://www.alcaldiabogota.gov.co/sisjur/normas/Norma1.jsp?i=56035#120).

Section IV. Food Additives Regulations:

The primary source of regulations on food additives is Decree 2106 of 1983, issued by the MHSP (<u>https://www.invima.gov.co/images/stories/aliementos/decreto_002106_1983.pdf</u>). 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, 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 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% 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 comprising Colombia, Ecuador, Peru and Bolivia. These regulations can be found in CAN Decision 436 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 Resolution 2906 in 2007, which establishes national standards for pesticide Maximum Residue Limits (MRLs). The long list of admitted pesticides can be found on INVIMA's web site (www.invima.gov.co) under "*Normatividad/Alimentos/Resoluciones*." Maximum Residue Limits for veterinary drugs are listed in Resolution 1382 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.

Resolution 2155 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) and Tin (100).

Section VI. Other Regulations and Requirements: Product Registration

The regulatory basis for food product registration in Colombia is Resolution 2674 of 2013, Resolution 3168 of 2015 and Resolution 719 of 2015. 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 raw materials by industry or the foodservice operators for food preparation (e.g. processed and raw poultry and meat sold to restaurants and food processors).

A transformed product is defined by the GOC 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 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/index.php/tramites-y-servicios/tr%C3%A1mites.html#cuáles-son-los-</u> <u>requisitos</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 the MINCIT. U.S. exporters seeking to sell to a Colombian importer should verify that the importer has obtained the legal authority to import food and agricultural products from the 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

Animal/Plant Health Import Permit

As previously mentioned, products used as raw material 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 meet labeling regulations. ICA is responsible for the issuance of import SPS 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 multiple 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 the 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 a sanitary 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 539, issued by the MHSP in 2014, 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. This certificate must be issued by the food safety authority in the country of origin. For "low" risk products, this requirement is satisfied with certificates of free sale. On the other hand, products referred to as "high risk" such as meat, dairy, and fish/seafood must be accompanied by a sanitary certificate from 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), respectively. It should be noted that since May 1, 2017, the GOC (ICA/INVIMA) will only accept USDA-AMS sanitary certificates for dairy exports to Colombia.

Furthermore, Decree 539 of 2014 established that importers of processed and unprocessed food (except for unprocessed meat) classified as medium or high risk (Resolution 719 of 2015) must submit a "sanitary certificate" upon arrival in Colombia. This certificate must be issued by a competent food safety authority in the country of origin.

Resolution 719 of 2015 provided a list of over 160 food products and classified nearly 80% of them as medium or high risk, including canned fruits and vegetables, juices, frozen food, sodas, etc. This created multiple port delays and rejections in 2015 and 2016 as for most of these products there was no U.S. federal authority that could issue "sanitary certificates." FAS-Bogota was able to have INVIMA provide an alternative way of meeting this new "sanitary requirement." For non-animal derived products (of low, medium, or high risk), INVIMA may consider, in the absence of a U.S. competent authority that could issue a sanitary certificate, a state-issued certificate of free sale and a letter from the manufacturer describing the shipment (lot numbers, expiration dates, production dates and other traceability information). Although this informal agreement with INVIMA has resulted in fewer shipments delayed at ports, it does not have a regulatory basis. As such, FAS-Bogota hopes to have the GOC modify Decree 539 to formalize the agreement reached with INVIMA.

Since May 1, 2017 dairy products produced in the United States and exported to Colombia must obtain a sanitary export certificate from USDA's Agricultural Marketing Services (USDA'AMS). For dairy products imported into the United States and then exported to Colombia, exporters need to obtain "sanitary certificates" from USDA's Animal and Plant Health Inspection Service (USDA-APHIS).

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:

https://www.invima.gov.co/images/pdf/inspecion_y_vigilancia/direccion-alimentos/accesomercados/21-12-2016/PUBLICACION-16-12-2016es.pdf (Pages 84-175; as of December, 2018)

https://afrodita.ica.gov.co/VW_CONSULTAS_PROD_PAIS/ShowVW_CONSULTAS_PROD_PAIST able.aspx

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). The TRQ's for 2019 are as follows:

Base TRO (MT) TRQ Annual Phase Out Safeguard Product 2019 Period Trigger Level Dutv Increase Yellow Corn 25% 2,954,911 5.0% 12 years White Corn 20% 192,069 5.0% 12 years 19 years Rice 80% 107,508 4.5% (6 of 120% of TRQ grace) 5.0% 12 years 25% 29.549 Sorghum **Dried Beans** 40.2% 22,162 5.0% 10 years 130% of TRQ 10%-Animal Feeds 273,329 5.0% 12 years 25% Pet Food 28% Unlimited 8.0% 8 years

Below is the CTPA TRQ schedule for certain agricultural products:

Chicken Leg Quarters (fresh, chilled, frozen)	164.4%		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%	507	3.0%	18 years	130% of TRQ
Standard Quality Beef	51.2%	2,955	5.0%	10 years	140% of TRQ
Variety Meats	51.2%	6,753	5.5%	10 years	
Pork Meat	30%	Unlimited		5 years	
Crude Soybean Oil	24%	41,057	4.0%	10 years	
Glucose	28%	14,775	5.0%	10 years	
Milk Powder	33%	10,718	10.0%	15 years	
Cheese	20%- 33%	4,502	10.0%	15 years	
Yogurt	20%	214	10.0%	15 years	
Butter	33%	1,072	10.0%	11 years	
Processed Dairy Products	20%	2,144	10.0%	15 years	
Ice Cream	20%	643	10.0%	11 years	
Maple Syrup	5%	Unlimited		5 years]

			%TRQ	
Product	TRQ Commitment for 2018 (MT)	TRQ Filled (MT) YTD as of Dec 28, 2018	Filled YTD as of Dec 28, 2018	
Yellow Corn	2,814,201	2,814,201	100.0%	
White Corn	182,923	182,923	100.0%	
Rice	102,879	102,879	100%	
Crude Soybean Oil	39,478	39,478	100.0%	
Milk Powder	9,744	9.744	100.0%	
Sorghum	28,142	25,207	89.6%	
Cheese	4,092	3,334	81.5%	
Pet Food	13,711	10,081	73.5%	
Ice Cream	585	78	13.4%	
Dried Beans	21,107	9,898	46.9%	
Glucose	14,071	3,338	23.7%	
Chicken Leg Quarters	34,214	23,409	68.4%	
Processed Dairy Products	1,949	400	20.5%	
Variety Meats	6,401	3,083	48.2%	
Yogurt	195	101	51.6%	

Animal Feeds	260,314	65,546	25.2%
Spent Fowl	492	0	0%
Standard Quality Meat	2,814	1,746	62.1%
Butter	974	51	5.3%
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>http://www.ustr.gov/trade-agreements/free-trade-agreements/colombia-fta/final-text</u>.

RICE: http://www.col-rice.org/ POULTRY: http://www.colom-peq.org/

Section VII. Other Specific Standards:

Food samples

Resolution 3772 of 2013 and Resolution 34419 of 2013 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 (invimasal@invima.gov.co). Such 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.*" (Sample with no commercial value, sale is prohibited). The importer has to get approval from the MINCIT through the VUCE at http://www.vuce.gov.co. All these requirements must be met prior to shipping the samples. When the samples arrive in Colombia, they have to 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. https://www.invima.gov.co/images/pdf/normatividad/alimentos/resoluciones/2013/resolucion-34419-2013.pdf

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, wherein 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. At the moment, INVIMA requires the fortification of domestic and imported food products that contain wheat flour.

Section VIII. Copyright and/or Trademark Laws:

Protection of Property Rights

Colombia has been on the Special 301 "Watch List" every year 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. The 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 in charge of the issuance of pharmaceutical patents, while the Ministry of Interior is in charge of 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, Law 1032 of June 22, 2006, Article 306 for usurpation of intellectual property, lacks strong enforcement.

Copyrights

CAN Decision 351 on the protection of copyrights has been in effect in Colombia since January 1, 1994. Law 44/1993 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 fee payments 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.

If the food 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. This information may be provided on a sticker on the package.

Food for Industrial/Foodservice Usage

Products used as raw materials 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. Article 4 of Decree 539 of 2014 mentions that importers must submit detailed information of these raw materials and the intended process.

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 Decree 1500 of May 4, 2007 issued by the MHSP; and, modified by Decree 2270 of November 3, 2012.

The importer applies for an ICA animal health import permit (zoo-sanitary certificate) that is issued normally 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 and the appearance of unsanitary packaging. 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 Decree 2270 states that frozen meat cannot be thawed, and sold as a chilled or refrigerated product in retail establishments. However, there is an exception when the thawing process is conducted exclusively for the processing and preparation of meat products.

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 have to 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: <u>http://www.fsis.usda.gov/wps/wcm/connect/9978cd33-b439-48c3-9366-</u> 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. This information may be provided by the application of a sticker to the package.

For fresh/chilled pork, it will be necessary for shipments to be accompanied by the following documents: health certificate (FSIS form 9060-5); letterhead certificate; industry/packer

affidavit/declaration; and, invoice and way documents.

Import Requirements for Poultry Meat (whole birds), Not Transformed

HS: 02.07

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." An outline of the guidelines/protocols for meat and poultry inspection at ports of entry remain unclear with decisions often left to the subjective determination of the inspector.

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 The plants exporting these products need to be registered with INVIMA and ICA. Please refer to *Export Establishment Registration* above in Section VI. Import procedures for poultry parts follow the same standards for Poultry meat.

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. This information may be provided on a sticker applied to the package, according to Resolution 5109.

Mechanically Deboned Chicken or Pork

HS: 16.02.39

The 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.

Fresh Fruit and Vegetables

HS: 07/08

The import procedure is explained above under *Sanitary Permits* issued by ICA. An ICA official will inspect the imported produce upon arrival in Colombia. The ICA official ensures that the product meets

the wholesomeness conditions and is free of disease/pest based on the fruit or vegetable, has 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. Again, the ICA phytosanitary import permit's issuance date must be before APHIS's export certificate.

Processed Fruit and Vegetables

The product 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. This information may be provided on a sticker applied to the package. The GOC does not classify frozen vegetables as a processed food; therefore, no country of origin labeling is required. An ICA official will inspect the imported produce upon arrival in Colombia.

Milk

HS:0402.10

The ICA 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 Decree 616 in 2006, 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.

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 registration 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 Decree 3075 of 1997. 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

HS: 22.04

The current prevailing alcoholic beverages regulation in Colombia is mandated by the Decree 1686 of 2012 issued by the Ministry of Health. The decree sets the regulations for the sanitary requirements of alcoholic beverages that must comply in their manufacture, processing, hydration, packaging, storage, distribution, transport, marketing, sale, export and import for human consumption.

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 as long as 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 warning should occupy at least 10 percent of the label. All of 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 has brought Colombia into compliance with its trade commitments under the WTO and trade agreements with the U.S., Canada, and the EU. It seeks to remove the discriminatory tax system as well as the anti-competitive practices conducted by local liquor producers. This bill came into effect on January 1, 2017.

Appendix I. Government Regulatory Agency Contacts:

Juan Carlos Cadena	Carlos Alberto Robles
Director of Trade Relations	Director of Food and Alcoholic Beverages
Ministry of Commerce, Industry and Tourism	INVIMA
Calle 28 No. 13 A – 15	Carrera 10 No 64 -28
Bogotá, Colombia	Bogotá D.C Colombia
Tel: (57-1) 6067676	Tel: (57-1) 294-8700

E-mail: invimasal@invima.gov.co Web site: <u>www.invima.gov.co</u>
Alejandra Farias
National Coordinator of Plant Quarantine (Acting)
ICA -Instituto Colombiano Agropecuario
Avenida Calle 26 # 85b – 09
Bogotá, Colombia
Tel: (57-1) 332-3700
E-mail: <u>cuarentena.vegetal@ica.gov.co</u>

Appendix II. Other Import Specialist Contacts:

Office of Agricultural Affairs U.S. Embassy – Bogota Unit 3030 Box 0105 APO AA 34004 Tel: (57-1) 275-4674 Fax: (57-1) 275-4525 E-mail: agbogota@fas.usda.gov Moises.huerta@fas.usda.gov

Laura Pasculli, Executive Director Cámara de Alimentos Balanceados (Feed) ANDI Calle 73 No. 8-13, Torre A, Piso 6 Bogota, Colombia Tel. (57-1) 326-8500 Ext. 2404 Fax (57-1) 347-3196/98 E-mail: <u>lpasculli@andi.com.co</u> Juan Camilo Montes, Executive Director Cámara Industria Alimentos ANDI Calle 73 No. 8-13, Torre A, Piso 6 Tel: (57-1) 326-8521/40 Fax: (57-1) 347-3196/98 E-mail: cmontes@andi.com.co Web site : <u>www.andi.com</u>

Jaime Jimenez, Executive Director Cámara Fedemol (wheat Millers) ANDI Calle 73 No. 8-13, Torre A, Piso 6 Bogota, Colombia Tel. (57-1) 326-8500 Fax (57-1) 347-3196/98 E-mail: jjimenez@andi.com.co