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Food and Agricultural Import Regulations and Standards (FAIRS) - Narrative

FAIRS Country Report

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Report Highlights:

This report is an annual update of the food import standards and enforcement mechanisms in Colombia. The following sections were updated: SECTION III. PACKAGING AND CONTAINER REQUIREMENTS; SECTION VI. OTHER REGULATIONS AND REQUIREMENTS: Product Registration, Health Certificates, Export Establishment Registration, Import Duties; SECTION VII. OTHER SPECIFIC STANDARDS: Food samples; SECTION VIII. COPYRIGHT AND/OR TRADEMARK LAWS: Protection of Property Rights and SECTION IX. IMPORT PROCEDURES

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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

The basic piece of legislation dealing with food products and human health in Colombia is Law 9 of January 24, 1979 (see text of law on: www.invima.gov.co/normatividad/alimentos). All decrees and regulations produced since then are based on the above-mentioned Law.

Congressional Law 1122 of January 9, 2007 in article 34 establishes the food and feed safety regulatory roles for the Ministry of Health and Social Protection (MHSP) - National Institute for the Surveillance of Food and Medicines (INVIMA) and the Ministry of Agriculture and Rural Development (MARD) - Colombian Institute for Agriculture and Livestock (ICA).

The Government of Colombia (GOC) maintains control over imports through the Ministry of Commerce, Industry and Tourism (MOCIT). All responsibilities in dealing with Colombian foreign trade have been transferred to the MOCIT including the issuance of import licenses and the registration of imports. The GOC has increased INVIMA and ICA's inspection and food safety policy making role and would like to create more specific rules for products or groups of products that will facilitate trade.

SECTION II. LABELING REQUIREMENTS

General Requirements

The current prevailing labeling regulation for food products in Colombia is mandated by Resolution 5109 of December 29, 2005 issued by the MHSP. The regulation establishes technical standards for labeling of domestic and imported packaged food products and raw materials for food for human consumption (including sample-size and institutional use packaged products). The basic reason for labels is to provide comprehensive and clear information to allow consumers to make informed decisions about the products they purchase. The information must be factual and true and not mislead consumers.

The information must be provided in Spanish either on the label or on an authorized sticker/label affixed to the product. Whenever the imported product label is written in a language other than Spanish, a complementary label can be used to provide the information required by Resolution 5109. 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 US date is registered by

MM/DD/YYYY; whereas in Colombia the date is registered DD/MM/YYYY. An importer can amend label requirements during or after nationalization of the product.

Labeling regulations apply to products in chapters 2 through 21 (except chapter 13 and 14) of the tariff schedule. The Spanish text of Resolution 5109 can be downloaded from www.invima.gov.co/invima///normatividad/doc. 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.

The following information must appear on food product labels:

1. Name of the product.
2. List of ingredients in decreasing order of 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 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. Sanitary 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.

Labels for raw materials for food products must contain 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 identification.
7. Expiration date or minimum useful life.
8. Conditions for product conservation.

The above required information must be provided by the producer/manufacturer and can be consigned to the product by the producer/manufacturer, the importer or the distributor. In order to facilitate the issuance of the sanitary certificate for entry, the coded or ciphered information for lot identification and expiration dates on the packages of raw materials can be interpreted with a document issued by the producer/manufacturer and validated by Colombian regulatory authorities. 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.

Requirements for other specific labeling requirements

Radiated Food Products and/or Food Raw Materials

When a product has been subjected to ionizing radiation, this condition has to be declared 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 whenever it is used, it has to be visible after 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, but 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.

Dietary Supplements

Regulated via Decree 3249 published on September 18, 2006. In relation to labeling for imported dietary supplements, labels will be accepted from the country of origin 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 it can be placed over the original label. The GOC has been particularly instructive that supplement labels must avoid misleading information that can confuse customers. The Decree 272 of 2009 states that labels and advertisement of dietary supplements should not contain information that exaggerates in the product composition, origin, effects, or hold preventive, rehabilitative or therapeutic indications. The label and/or sticker for dietary supplements must contain basically the same information as labels for food products in addition to 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 diet supplement contains artificial sweeteners, a warning should appear on the package to prevent its consumption by people with kidney problems. A warning should also be written in a clear way when the product contains substances that may cause allergies.

Nutritional Labeling

Colombian nutritional labeling requirements are established by Resolution 333 of February 10, 2011. The technical ruling on nutritional labeling is outlined for packaged and/or bottled food products, both domestically produced and imported. The resolution does not cover nutritional labeling for products destined for infant children, which is covered by Resolution 11488 of 1984. The nutritional labeling must be written in Spanish although another language may appear. A sticker may be used, but must provide the required information in a prominent way. 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 obligatory 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, and content of other nutrients when there is a declaration of nutritional or healthy properties including food for infants. Whenever there is an issue regarding nutrition values in food products not considered in resolution 333, Colombia follows Codex Alimentarius guidance.

Colombia's food labeling law also regulates a label's physical presentation and wording which should avoid comments and illustrations that may induce confusion or mislead consumers.

Health claims are specifically forbidden in Article 272 of the basic Law 9 of January 24, 1979. A translation of this short article reads as follows: *"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"*. Resolution 288 of January 31, 2008 only permits these references when the properties contribute to reduce diseases risks.

Food containing Trans or Saturated fats

Resolution 2508 of August 29, 2012, establishes that in any packaged food that contains trans fat and/or saturated, the importer must declare and include in the nutritional information table when trans and/or saturated fat content is equal to or greater than 0.5 g per serving, regardless of the origin of the fat.

Additives Labeling

Resolution 1506 of May 6, 2011, regulates additives used in the processing of food for human consumption. The Resolution establishes the general labeling requirements for additives used in the processing of food for human consumption and the specific mandatory and voluntary information to be displayed on labels. The labeling must be written in Spanish although another language may appear. These labels can be affixed to the product during or after the nationalization process in warehouses or

storage facilities inspected, surveyed and controlled by regulatory authorities and the information provided must correspond to the original label.

SECTION III. PACKAGING AND CONTAINER REQUIREMENTS

The main concern with respect to food packaging and containers is to preserve the sanitary integrity of the food product by establishing requirements for containers that are in direct contact with the product. Resolution 834 of March 26, 2013 specifies that all materials and substances used to produce food packages and containers must be registered in the FDA positive list and follows most of the FDA standards.

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 ADDITIVE REGULATIONS

The basic piece of legislation on food additives is in Decree 2106 of July 26, 1983 issued by the MHSP. The Colombian decree can be found on INVIMA's website at:

www.invima.gov.co/normatividad/alimentos/decretos. It is common practice by regulatory authorities to accept those food additives accepted by the Codex Alimentarius and the United Nations Food and Agriculture Organization/World Health Organization.

Resolution 2606 of July 27, 2009, provides general requirements for food additives and establishes INVIMA's Food Additives Committee which authorizes additives to foodstuffs. Additives can be used only if it produces benefits for foodstuffs, does not represent health risks, maintains nutritional facts and provides nutritional composition recommended for specific groups of consumers (e.g infant children). Food additives for groups of preservatives, acidulates, buffers, pH regulators and antioxidants are authorized by Resolutions 4125, 4126 and 4124 of April 5, 1991.

The GOC is working on a positive additive list document. When a product is declared as being 100% natural, it cannot 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, anti-foaming agent, anti-oxidizing, aroma agent, bleaching, natural or artificial dye, clarifying agent, natural or artificial sweetener, emulsifier, enzymes, thickener, foaming, stabilizing agent, gasifying agent, gelling agent, moisture agent, anti-moisture agent, volume enhancer, propelling substances, acidity regulators or alkalifiers, emulsifying salts, preservatives, color retaining substances, substances for flour treatment, glossy agent.

SECTION V. PESTICIDES AND OTHER CONTAMINANTS

ICA is the sanitary and phytosanitary (SPS) regulatory authority for rules established by Decree 1843 of 1991 and subsequent resolutions. ICA's established regulations on pesticides are applied with the regulatory coordination 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 on August 22, 2007 establishing 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 May 2, 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 the National Laboratory for Farming Inputs or the National Laboratory for Livestock Inputs administered by ICA. The interested party, either the producer/manufacturer or importer, must pay any fees for analysis.

Resolution 2155 issued on August 2, 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

All processed retail food items, including products imported in bulk for repackaging for retail use without further processing, must be registered and approved by INVIMA. According to Decree 3075 of 1997, product registration is NOT required for:

- Products that are not subject to any transformation, such as grains, fruits, fresh vegetable, honey, etc.
- Products of animal origin not subject to any transformation process.
- Products used as raw materials by the food industry or Hotel-Restaurant-Institutional (HRI) sector in food preparation.

A transformed product is defined by the GOC as having been subjected to processing that resulted in a change in its internal structure.

Most of the product registration process can be completed via the internet. After issuing the product registration, INVIMA analyzes the documents provided by the importer and may request additional information. Product samples may also be taken from the shelf to conduct laboratory tests.

MHSP through Resolution 2674 of 2013 establishes a period of product registration validity in Colombia based on risk. Article 39 states:

1. Product registrations for high risk materials are valid for 5 years;
2. Product permissions for intermediate risk materials are valid for 7 years; and,
3. Product notifications for low risk materials are valid for 10 years.

INVIMA submitted a list of products based on a risk criteria to the WTO for comments in 2014. Once the list is vetted and approved, INVIMA will begin to establish the periods for product registration/permission/notification validity.

The INVIMA registration is only for the applicant (exporter or importer) and the specified manufacturer. Whenever the U.S. exporter wants to change its Colombian importer, there are two approaches:

1. If the U.S. exporter is the applicant for the INVIMA registration, he must submit an application for registration modification to INVIMA;
2. If the Colombian importer is the applicant, the U.S. exporter must initiate a new registration process, specifying the new importer(s). Afterwards, the US exporter may change the importer(s) whenever necessary. It is recommended that the U.S. exporter conduct the registration process and changes through a legal representative in Colombia.

The INVIMA registration is valid only for the specifications (e.g., product description and size) mentioned in the registration. If another form or presentation of the same product is to be imported, the registering company needs to inform INVIMA in writing of the new product.

The INVIMA registration of processed foods requires: (1) completion of the registration form; (2) obtain a Certificate of Legal Representation; and, (3) obtain a Certificate of Free Sale stating that the products are approved for human consumption in the United States. This certificate needs to be issued by a U.S. government (state, local or federal) public health authority. Although not required, the INVIMA registration can be expedited if a description of the manufacturing process and a list of the ingredients is submitted, including any additives, preservatives, and colorings/dyes.

Colombia implemented The Hague Convention of October 5, 1961 with Law 455 of August 4, 1998 to facilitate import documentation. The above listed documents must carry an “apostille” stamp. The “apostille” stamp is produced by different U.S. state authorities, including a notary or a State Secretary or Under Secretary. This procedure replaced the notarization by the Colombian Embassy or a Consulate in the United States and by the Ministry of Foreign Affairs in Bogota. A translator approved by the 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 MOCIT. U.S. exporters seeking to sell to a Colombian firm should ascertain that the Colombian importer has obtained the legal authority to import agricultural products by completing the MOCIT registration process. Once registered, the importer or importing company has the legal right to import any agricultural product. Every importer (company or person) must buy an electronic signature from the Ministry of Finance. All of these procedures can be accomplished by accessing the online Unique Window for Foreign Trade (VUCE) at www.vuce.gov.co.

Minimal Descriptions

Products entering Colombia shall comply with the minimal descriptions mentioned in Resolution 25 of February 21, 2013, issued by the National Department of Taxes and Customs (DIAN). The information requested in the resolution can be accessed from the product HS code, and must be provided in Spanish. For certain products where translation is not applicable, the product must be registered in the original language. See Resolution 25 of 2013 at <http://www.mincit.gov.co/documentos.php?id=326>

Sanitary Permit

Products used as raw materials by the food industry or HRI sector in food preparation do not need an INVIMA registration, but they do need a sanitary permit from ICA and comply with the 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. The import permit details the zoosanitary and/or SPS requirements.

The request for the zoosanitary certificate issued by ICA must come with complete information to avoid delays and possible rejections. ICA authorities specifically request: Port of Departure (e.g. Miami, USA), Destination (complete address and city in Colombia), and Trip (e.g. Miami to Barranquilla, if travel is direct, or Miami to Dominican Republic to Barranquilla).

The Colombian importer must first obtain the import permit from ICA before requesting an import license from the MOCIT. The importer should provide the exporter with the ICA import permit so the U.S. Department of Agriculture (USDA) can reference the permit with bilateral compliance agreements. 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. Whenever ICA issues new import health requirements, Colombia must notify the WTO and allow a period for comment. Once implemented, both USDA Food Safety Inspection Service (FSIS) and the Animal Plant Health Inspection Service (APHIS) place the Colombian sanitary requirements on their respective web pages.

INVIMA authorities have indicated that they may require a sanitary certificate for imports of processed food products, but no timeline for implementation has been set. The certificate would require general information on the importer, product origin and destination, product identification (type of product, units, quantity, and temperature in Celsius, lot number and expiration date). And, the certificate would need to be signed by an INVIMA inspector.

For ICA approval, the product must:

1. Come from a USDA inspected facility that is registered with INVIMA, although ICA maintains the approved list. Also, non-dairy and meat establishments must be registered with ICA;
2. Be free of disease;
3. Be inspected by USDA prior to its shipment and include the USDA health export certificate; and,

4. Be inspected by an ICA veterinarian upon arrival in Colombia. Usually the shipment is inspected at the port by both INVIMA and ICA to verify the compliance with the import regulations and sanitary requirements.

Health Certificates

In “CIRCULAR 400-1846-13” INVIMA established the requirement for the submission of health certificates for any batch or lot of food products imported into Colombia. The health certificates must be issued by a competent authority involved in food safety regulation, including federal, state and, in some cases, municipal entities. The health certificate must state that the food products in the shipment are suitable for human consumption. Products referred to as “high risk” in Article 3, Decree 3075 of 1997 need to present the certificate of the following federal authorities: FSIS and/or FDA.

For those groups of foods and raw materials that are not considered “high risk,” INVIMA requires the following documentation/information to be included with the shipment: suitability of the product for human consumption; manufacturer’s name; name of the exporting country; product name; and batch identification. Such information can be obtained through the Certificate of Free Sale issued by the competent authority and supported with a manufacturer’s quality statement and/or analysis certificate that identifies the product names and batch or lot identification.

Decree 539 of 2014 issued by the MHSP establishes import requirements at ports of entry (POE) including: 1) Preliminary import approval issued by INVIMA through the VUCE, following the guidelines of Decree 4149 of 2004, and Decree 2078 of 2012; 2) product health registration; 3) Foods that are exempt of product health registration must complete the INVIMA form for food raw materials; and, 4) Health Certificates from the country of origin (Certificates of Free Sale for food considered not to be “high risk” products). Once verified, the import requirements could include taking random samples and applying laboratory tests. After that procedure, INVIMA will issue a food safety inspection certificate which states that the product inspected is suitable for human consumption.

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. As well, beef products must also originate from establishments approved under the USDA Agricultural Marketing Service Export Verification Program (EV).

In order to register with INVIMA, 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:

INVIMA
 Dirección de Alimentos y Bebidas
 Carrera 10 No 64 -28
 Bogotá D.C.- Colombia

To avoid potential POE problems, before shipping product it will be critical to verify the listing of the U.S. exporting establishment after submitting the required registration information through the following web site: https://www.invima.gov.co/images/pdf/inspeccion_y_vigilancia/direccion-alimentos/acceso-mercados/30-09-2014/Copia%20de%20CONSOLIDADO%20ESTABLECIMIENTOS%20AUTORIZADOS%20POR%20EL%20INVIMA%20-%202026-09-2014.pdf.

Pre-Shipment Certification

Since July 1, 1999, the Colombian Government eliminated prior inspection and certification of imported food products at the port of origin as part of an effort to facilitate trade.

Import Duties

The U.S.-Colombia Trade Promotion Agreement (CTPA) entered into force on May 15, 2012. This comprehensive trade agreement eliminates 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 2015 are as follows:

Product	Base Duty	TRQ (MT) 4 th Year	TRQ Annual Increase	Phase Out Period	Safeguard Trigger Level
Yellow Corn	25%	2,431,013	5%	12 years	
White Corn	20%	158,016	5%	12 years	
Rice	80%	90,152	4.50%	19 years (6 of grace)	120% of TRQ
Sorghum	25%	24,310	5%	12 years	
Dried Beans	40.20%	18,233	5%	10 years	
Animal Feeds	10%- 25%	224,869	5%	12 years	
Pet Food	28%	10,884	8%	8 years	
Chicken Leg Quarters	70%	30,416	4%	18 years (10 of	130% of TRQ

				grace)	
Poultry Parts	164.40%			18 years (5 of grace)	
Spent Fowl	20%	450	3%	18 years	130% of TRQ
Standard Quality Meat	51.20%	2,431	5%	10 years	140% of TRQ
Variety Meats	51.20%	5,451	5.50%	10 years	
Pork Meat	30%	Unlimited		5 years	
Crude Soybean Oil	24%	35,096	4%	10 years	
Glucose	28%	12,155	5%	10 years	
Milk Powder	33%	7,321	10%	15 years	
Cheese	20%- 33%	3,075	10%	15 years	
Yogurt	20%	146	10%	15 years	
Butter	33%	732	10%	11 years	
Processed Dairy Products	20%	1,464	10%	15 years	
Ice Cream	20%	439	10%	11 years	

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

Value Added Tax

The basic piece of legislation dealing with the value-added tax (VAT) is Law 1607 of 2012 issued by the Ministry of Finance. The tax regime establishes: 1) exclusion rates or 0% for unprocessed goods (Article 424 <http://estatuto.co/?e=710>); 2) exemption rates for certain products and services in the agricultural sector entitled to compensation and reimbursement (Article 477 <http://estatuto.co/?e=630>); and, 3) the overall rate of 16% for products and services not classified under previous legislation.

The VAT for liquors and wine is applied based on the customs value plus an additional fee/markup that depends on the percentage of alcohol content.

SECTION VII. OTHER SPECIFIC STANDARDS

Food samples

Resolution 3772 of 2013 and Resolution 34419 of 2013 issued by MHSP establishes the procedures to request authorization to ship food samples to Colombia. Food product samples can be sent to Colombia for market testing purposes with a prior notification to INVIMA's Deputy Director for Food and Alcoholic Beverages (invimasal@invima.gov.co). The request to INVIMA must establish the name of the product, producer details, amount, type of food product, rationale for market entry, , expiration date and number of units in the shipment. The samples must contain the phrase "*muestra sin valor*

comercial, prohibida su venta”. The importer has to get approval from the MOCIT through the VUCE at <http://www.vuce.gov.co>. All these procedures must be completed prior to shipping the samples. When the samples arrive in Colombia, they have to be nationalized following the procedures of a standard imported product. Samples shipped via express mail or post parcel are subject to the Colombian import regulations, especially those related to sanitary certificates. 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/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

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 lax customs enforcement and the Colombian Constitutional Court invalidating the law 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 MOCIT acts as the Colombian patent and

trademark office and details can be found at www.sic.gov.co. 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 uses of previously known or patented products.

Industry sources have reported that there are issues with patents for Living Modified Organism (LMO) technologies. MOCIT 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. U.S. companies suffered trade losses due to copyright piracy and intellectual property violations.

SECTION IX. IMPORT PROCEDURES

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

The MOCIT has replaced the registration of importers by the electronic application for import licenses. The whole import procedures such as formats to fill out and fee payments can now be carried out by internet by accessing the VUCE website: www.vuce.gov.co.

The product must be registered with INVIMA. See section above on *Product Health Registration*. A sample label may be submitted to help the registration process.

If the food is sold in retail packages, it must be labeled. Labels must be in Spanish and contain the product name, name and address of importer, name and address of producer, net contents in metric units, list of ingredients, INVIMA registration number, recommended method of storage, and product expiration date. This information may be provided by the application of a sticker to the package. Health Certificates or Certificate of Free Sale must comply with the requirements in “CIRCULAR 400-1846-13”.

Processed Food for Institutional Uses

Processed 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 (decree 3075 of 1997), 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 complete a form with detailed information about the raw materials and methods of processing for the product.

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

HS: 02.01-/02-/03

A transformed product is defined by the GOC as having been subjected to processing that resulted in a change in its internal structure.

The current regulation for a meat product in Colombia is mandated by Decree 1500 of May 4, 2007 issued by the MHSP; and, modified by the Decree 2270 of November 3, 2012.

The importer applies for an ICA animal health import permit (zoosanitary certificate) that is issued normally after 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 with a date after the Colombian import permit was issued by ICA. Steps to follow by importers are explained above in the section *Importer Registration, Import Registration and Import Licensing*. Documentation and clerical errors represent the most persistent problems at ports of entry. Detention or rejection of shipments has 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 the 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 (fresh, chilled or frozen)

HS: 02.10-

The current regulation for a meat product in Colombia is mandated by Decree 1500 of May 4, 2007 issued by the MOSP; partially modified by the Decree 2270 of November 3, 2012. Chapter IX of the Decree 1500 establishes the import requirements and considerations by Colombian authorities with ICA and INVIMA for issuing the import authorization.

For transformed beef and pork products, the product must be registered with INVIMA. See previous section on “Product Health Registration”. Steps to follow for importers are explained above in the section “Importer Registration, Import Registration and Import Licensing”. Before importing meat products, the importer must complete an import request 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 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 important to accompany shipments with 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 MOSP. Chapter IX in the mentioned Decree establishes the import requirements of Colombian authorities ICA and INVIMA require for issuing import authorizations.

An ICA veterinarian inspects the imported poultry meat product upon arrival in Colombia and ensures 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 stating what is required in the ICA’s sanitary import permit. Simultaneously, there is an INVIMA inspector to verify that the imported product meets INVIMA conditions for human consumption. Detention or rejection of shipments has occurred due to the appearance unsanitary packaging. An outline of the procedures/protocols for meat and poultry inspection at ports of entry remain unclear with decisions often left to the subjective determination of the inspecting official.

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

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 at INVIMA. 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. Labels must be in Spanish and contain the product name, name and address of importer, name and address of producer, net contents in metric units, list of ingredients, INVIMA registration number, recommended method of storage, and product expiration date. This information may be provided by the application of a sticker to the package.

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 procedures are 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.

Processed Fruit and Vegetables

The product must be registered with INVIMA. See section above titled “Product Health Registration.” A sample label may be submitted to expedite the registration process.

If the food is sold in retail packages, it must be labeled. Labels must be in Spanish and contain the product name, name and address of importer, name and address of producer, net contents in metric units, list of ingredients, INVIMA registration number, recommended method of storage, and product expiration date. This information may be provided by the application of a sticker 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 Government of Colombia issued Decree 616 of February 28, 2006, establishing the technical norms for the conditions to be met by 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 (that must be longer than 6 months since the product arrives in the country);
5. Storage recommendations;
6. Total and net weight in grams or kilograms.

Note: Milk 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 shown 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's 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 MOSP 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 apt because of radiation will be re-exported to the country of origin and this cost will be paid by the importer.

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 August 9, 2012 issued by the MOSP. 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 his 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 by either the exporter or the importer with INVIMA. 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 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 permitted 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.

APPENDIX I. GOVERNMENT REGULATORY AGENCY CONTACTS

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APPENDIX II. OTHER CONTACTS

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