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# Colombia

# **Food and Agricultural Import Regulations and Standards -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 II. LABELING REQUIREMENTS; SECTION III. PACKAGING AND CONTAINER REQUIREMENTS; SECTION VI. OTHER REGULATIONS AND REQUIREMENTS; SECTION VII. OTHER SPECIFIC STANDARDS: Food samples; and APPENDIX I. GOVERNMENT REGULATORY AGENCY CONTACTS.

#### 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: <u>https://www.invima.gov.co/leyes-en-normatividad-institucional.html</u>). 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) oversees trade flows through the Ministry of Commerce, Industry and Tourism (MINCIT). All responsibilities in dealing with Colombian foreign trade have been transferred to the MINCIT including the issuance of import licenses and the registration of imports.

#### 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 and Resolution 333 of 2011, issued by the MHSP. The regulation establishes technical standards for labeling of domestic and imported packaged food products and raw materials for food production, for human consumption (including sample-size and institutional use packaged products). The most basic objective of labeling 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 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 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 of the product.

Labeling regulation applies 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 <a href="https://www.invima.gov.co/normatividad/resoluciones-normatividad.html?start=100">https://www.invima.gov.co/normatividad/resoluciones-normatividad.html?start=100</a>. 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:

<u>https://www.invima.gov.co/images/stories/resoluciones/Res\_333\_de\_feb\_2011\_Rotulado\_nutricional.p</u> <u>df</u>

The following information must be included on food product labels:

- 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. 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 shelf life;
- 8. Conditions for product conservation.

All the required information for labeling must be provided by the producer/manufacturer, importer or 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 subject 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 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, 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.

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**

This is regulated primarily through Decree 3249 of 2006. In relation to 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 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. Decree 272 of 2009 states that labels and advertisement of dietary supplements should not contain false overstatements on 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 diet 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**

Colombian nutritional labeling requirements are established by Resolution 333 of February 10, 2011. The technical ruling on nutritional labeling is outlined for packaged 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 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."* However, 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 0.5g 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 Resolution sets 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. Labeling must be displayed in Spanish; although text in another language may be also included. 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 most basic piece of legislation on food additives is Decree 2106 of July 26, 1983 issued by the MHSP, which can be retrieved at

<u>https://www.invima.gov.co/images/stories/aliementos/decreto\_002106\_1983.pdf</u>. It is a common practice by regulatory authorities in Colombia to accept those food additives accepted by the Codex Alimentarius and the United Nations Food and Agriculture Organization/World Health Organization.

Furthermore, Resolution 2606 of July 27, 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 produces 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 April 5, 1991.

The GOC is working on a "positive" additive list. When a product is declared as being 100% natural, it could 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 is one of the sanitary and phytosanitary (SPS) regulatory authorities in Colombia. ICA's established 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 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 laboratory analysis fees.

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**

The regulatory basis for 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 any 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.

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. 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.

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 intermediate risk products are valid for 7 years; and,
- 3. Product notifications for low risk products are valid for 10 years.

INVIMA 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 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 registration holder is the Colombian importer, then the U.S. exporter must start a new registration process, specifying the new importer(s) name.

The INVIMA registration is valid only under the product specifications submitted by the registration applicant during the application process (e.g., product description and size). If such specifications change, then the registration holder must inform INVIMA in writing.

The information that INVIMA requires for the registration can be found in the following link: <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. A complete list of documents required by INVIMA to issue a new product registration can be found at: <u>https://www.invima.gov.co/index.php/tramites-y-servicios/tr%C3%A1mites.html#cuáles-</u> <u>son-los-requisitos</u>.

It should be noted that the GOC implemented The Hague Convention of October 5, 1961 with Law 455 of August 4, 1998 to facilitate import documentation. The above listed required documents must carry an "apostille" stamp. The "apostille" stamp is provided by different U.S. state authorities, including a notary or a State Secretary or Under Secretary. This procedure replaced the notarization requirement formerly undertaken by the Colombian Embassy/Consulates 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 MINCIT. U.S. exporters seeking to sell to a Colombian importer should verify that the importer has obtained the legal authority to import agricultural products from the MINCIT, and for specific products, with other government authorities including INVIMA and ICA. Once registered, the importer or importing company has the legal right to import any agricultural product. 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>.

#### **Minimal Descriptions**

Products entering Colombia shall comply with the minimal descriptions mentioned in Resolution 057 of April 13, 2015, issued by the MINCIT and the National Department of Taxes and Customs (DIAN).

The information requested in the resolution can be accessed using the product HS codes, 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 057 of 2015 at <a href="http://www.andi.com.co/cse/Documents/Res.%20057%20de%202015%20-%20descripciones%20minimas.pdf">http://www.andi.com.co/cse/Documents/Res.%20057%20de%202015%20-%20de%202015%20-%20descripciones%20minimas.pdf</a>

### 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, but they do need an animal or plant health import 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 zoo-sanitary and/or SPS requirements. Additionally, for some products (including some dairy products), importer must also obtain a "Visto Bueno" approval by INVIMA.

Such permits are referred by ICA as "zoo-sanitary and phytosanitary documents." These permits must be requested by the importer and requires 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 MOCIT. The importer should also 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. Whenever ICA issues new import health requirements, Colombia must notify the WTO and allow a period for comment.

In order for ICA to issue the permit, the product must:

- 1. Come from a USDA inspected facility that is registered with INVIMA, although ICA maintains the approved list.
- 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 official 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.

#### **Sanitary Certificates**

Decree 539 of 2014 issued by the MHSP establishes that importers must submit a "sanitary certificate" for any batch or lot of food products imported into Colombia. This certificate must be issued by a competent authority in food safety in the country of origin. For "low" risk products, this requirement has been 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 starting on April 1, 2017, the GOC (ICA/INVIMA) will only accept USDA-AMS sanitary certificates for dairy exports to Colombia.

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.

# New Regulation on Food Registration and Import Documentation

Decree 539 establishes <u>import requirements at ports of entry (POE)</u> 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 registration; 3) Foods that are exempt of product registration must complete the INVIMA form for food raw materials; and, 4) Sanitary Certificates from the country of origin (Certificates of Free Sale for food considered not to be "high risk" products). Furthermore, Decree 539 seeks to establish a new framework for the registration of high-risk food products of animal origin (except for meat), including dairy and fish products imported into Colombia. This new framework ("habilitation) would include the inspection of plants in the United States as a requirement for registration. FAS-Bogota has been working with the GOC on the modification of Decree 539 to consider the "recognition" of the inspection and food safety control systems in the United States for the aforementioned category of products, in order to avoid the original Colombian "plant-by-plant" approach. FAS-Bogota expects to see the GOC to notify such modification to the WTO in early 2017.

Decree 539 of 2014, in combination with Resolutions 2674 of 2013 and 719 of 2015, has also had an impact on food registration and import documentation. For instance, under this new regulation, products such as tomato sauce, mayonnaise, juices, and fortified foods have been classified as high-risk products. As a result, if imported from the U.S. they must be accompanied by a Certificate of Free Sale, but also by a "Sanitary Certificate" issued by a competent authority in the United States. Such competent authority is not well defined and certainly created grave problems since April 2015 and July 2016. FAS-Bogota was able to have INVIMA provide an alternative way of meeting this new 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).

# 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. Sergio Alfonso Troncoso Rico Dirección de Alimentos y Bebidas INVIMA Carrera 10 No 64 -28 Bogotá D.C.- Colombia

To avoid potential Port-of-entry problems, before shipping the product it will be critical 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 (as of December, 2016)

https://afrodita.ica.gov.co/VW\_CONSULTAS\_PROD\_PAIS/ShowVW\_CONSULTAS\_PROD\_PAIST able.aspx

#### **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 2016 are as follows:

Below is the CTPA TRQ schedule for certain agricultural products:

Product	Base Duty	TRQ (MT) 2017	TRQ Annual Increase	Phase Out Period	Safeguard Trigger Level
Yellow Corn	25%	2,680,191	5.0%	12 years	
White Corn	20%	174,213	5.0%	12 years	
Rice	80%	98,448	4.5%	19 years (6 of grace)	120% of TRQ
Sorghum	25%	26,675	5.0%	12 years	

Dried Beans	40.2%	20,101	5.0%	10 years	130% of TRQ
Animal Feeds	10%- 25%	247,918	5.0%	12 years	
Pet Food	28%	12,695	8.0%	8 years	
Chicken Leg Quarters	164.4%			18 years (5 of grace)	130% of TRQ
Poultry Parts	70.0%	32,898	4.0%	18 years (10 of grace)	
Spent Fowl	20%	478	3.0%	18 years	130% of TRQ
Standard Quality Beef	51.2%	2,681	5.0%	10 years	140% of TRQ
Variety Meats	51.2%	6,067	5.5%	10 years	
Pork Meat	30%	Unlimited		5 years	
Crude Soybean Oil	24%	37,960	4.0%	10 years	
Glucose	28%	13,401	5.0%	10 years	
Milk Powder	33%	8,858	10.0%	15 years	
Cheese	20%- 33%	3,720	10.0%	15 years	
Yogurt	20%	177	10.0%	15 years	
Butter	33%	886	10.0%	11 years	]
Processed Dairy Products	20%	1,772	10.0%	15 years	
Ice Cream	20%	531	10.0%	11 years	]
Maple Syrup	5%	Unlimited		5 years	

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>.

#### Value Added Tax

The 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 <u>http://estatuto.co/?e=710</u>); 2) exemption rates for certain products and services in the agricultural sector entitled to compensation and reimbursement (Article 477 <u>http://estatuto.co/?e=630</u>); and, 3) the overall rate of 16% for products and services not classified under previous legislation. It should be noted that both chambers of the Colombian Congress recently passed the so-called Tax Reform bill, which needs to be reconciled and sanctioned by President Santos.

#### 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 Deputy 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.*" The importer has to get approval from the MOCIT through the VUCE at <a href="http://www.vuce.gov.co">http://www.vuce.gov.co</a>. 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 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. <a href="http://www.invima.gov.co/images/pdf/normatividad/alimentos/resoluciones/resoluciones/2013/resolucion-34419-2013.pdf">http://www.invima.gov.co/images/pdf/normatividad/alimentos/resoluciones/2013/resolucion-34419-2013.pdf</a>

#### **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. Furthermore, importers have reported that INVIMA has been accepting the registration of not-enriched wheat flour products, on a case-by-case basis.

# 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 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 <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. 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

All import forms and fee payments can now be accessed online at MOCIT's VUCE website: <u>www.vuce.gov.co</u>.

The product must be registered with INVIMA. See section above on *Product Sanitary 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 on a sticker on the package. Health Certificates or Certificate of Free Sale must comply with the requirements in "CIRCULAR 400-1846-13."

#### Processed Food for Industrial/Foodservice Usage

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 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)

HS: 02.01-/02-/03

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 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: <a href="http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products/export-library-requirements-by-country/Colombia">http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products/export-library-requirements-by-country/Colombia.</a>

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 (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 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.

For transformed beef and pork products, the product 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-b439-48c3-9366-451bc0173183/Official-Listing-Eligible-Suppliers-EV-Program-100313.pdf?MOD=AJPERES</u>

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 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.

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, 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 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, 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. 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 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 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 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 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 (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 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 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 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 litters.

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 the Colombian Congress issued Law 1816 in December 2016. This law is is expected to bring 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 will come into effect on January 1, 2017.

#### **Appendix I. Government Regulatory Agency Contacts:**

Maria Paula Arenas, Director Trade Relations Ministry of Commerce, Industry and Tourism Calle 28 No. 13 A – 15 Bogotá, Colombia Tel: (57-1) 6067676 Ext. 1634 E-mail: <u>marenas@mincit.gov.co</u> Web site: <u>www.mincit.gov.co</u>

Juan Andres Angulo Mosquera Deputy Manager for Animal Health ICA Carrera 41 No. 17-81 Bogotá, Colombia Tel: (57-1) 332-3700 ext. 1201 Fax: (57-1) 287-2128 E-mail: <u>subgerencia.pecuaria@ica.gov.co</u> Web site: <u>www.ica.gov.co</u> Sergio Troncoso, Deputy Director Food and Alcoholic Beverages INVIMA Carrera 10 No 64 -28 Bogotá D.C.- Colombia Tel: (57-1) 294-8700 Ext. 3920/3922 Fax: (57-1) 294-8700 Ext. 3920 E-mail: <u>invimasal@invima.gov.co</u> Web site: www.invima.gov.co

Ana Luisa Diaz Deputy Manager for Plant Health ICA Carrera 41 No. 17-81 Bogotá, Colombia Tel: (57-1) 332-3700 ext. 1301 Fax: (57-1) 287-2128 E-mail: <u>subgerencia.agricola@ica.gov.co</u> Web site: <u>www.ica.gov.co</u>

#### **Appendix II. Other Import Specialist Contacts:**

Office of Agricultural Affairs U.S. Embassy – Bogota Carolina Lorduy, Executive Director Cámara Industria Alimentos (Food pdts.) Unit 3030 Box 0105 APO AA 34004 Tel: (57-1) 275-2406 Fax: (57-1) 275-4525 E-mail: <u>agbogota@fas.usda.gov</u>

Luz S. Kuratomi, 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. 2419 Fax (57-1) 347-3196/98 E-mail: <u>lkuratomi@andi.com.co</u>

#### ANDI

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