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Food and Agricultural Import Regulations and Standards Report

FAIRS Annual Country Report

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Report Highlights:

This report outlines Ecuador's requirements for food and agricultural product imports. The following sections of the FAIRS Country Report are updated in 2018: Section VII: Facility and Product Registration Requirements and Section VIII: Other Certification and Testing Requirements. This report also reflects restructuring of Ministries in Ecuador which has changed competent authorities in some cases. Hyperlinks to ministries, agencies, and legal documents are provided throughout this updated report.

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This report was prepared by the Office of Agricultural Affairs (OAA) of the USDA/Foreign Agricultural Service in Quito, Ecuador for U.S. exporters of food and agricultural products. While every possible care has been taken in preparation of this report, information provided may no longer be complete or precise as some import requirements are subject to frequent changes. It is highly recommended that U.S. exporters ensure that all necessary custom clearance requirements have been verified with local authorities through your foreign importer before the sales conditions are finalized. FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

Section I. Food Laws:

Ecuador's accession to the World Trade Organization (WTO) occurred on January 21, 1996. The country's Foreign Trade Law prohibits any economic, administrative, or technical practice that limits or discourages foreign and or domestic trade, free competition, or the local production of goods and services. Legislation only sanctions WTO specified corrective measures.

Ecuador maintains a number of tariff and non-tariff barriers that impede the importation of food and agricultural products. While the import tariffs are not excessive, technical barriers and sanitary/phytosanitary (SPS) restrictions are often problematic. Importers raise concerns that these measures are not established with the intent of protecting human, animal or plant health, but rather to restrict trade and limit the outflow of foreign exchange (i.e., dollars). Trade sources comment that Ecuador suffers from weak, inefficient government institutions that reinterpret the application of rules and their requirements. Administrative procedures are often deemed by importers to be cumbersome, requiring excessive documentation.

Food safety responsibilities are shared by the Ministries of Agriculture and Livestock (MAG) and Public Health (MoPH). Several agencies within these ministries handle the technical and administrative processes of prior authorization, inspection, and control of local and imported food and agricultural products.

Current rulemaking aims to build upon the Food Security Law (April 2006), which prohibits the development, use, and trade (including imports) of GE-derived products for human consumption. Despite the law being deemed unenforceable by the country's Attorney General, Congress in December 2006 passed a new health law expanding upon the earlier legislation's provisions: incorporating a prohibition against the acceptance of GE content food donations in the absence of a harmlessness analysis certificate. Ecuador has failed to enforce this legislation given its lack of an adequate control and certification system.

A food sovereignty provision is enshrined in the 2008 constitution. The [Organic Law on Food Sovereignty](#) (May 2009) expands upon the constitutional provision by banning genetically-engineered crops and their seeds from Ecuador. Imports are only permissible with prior presidential authorization and approval of the National Assembly.

A. The Official Register

The Official Register (*Registro Oficial - ROE*) is Ecuador's equivalent of the U.S. Federal Registry. As such, the country's laws, rules of application, executive decrees, ministerial agreements, and national standards, enter into force the day after publication in the registry. The exception is when a specific date is otherwise established. Ecuador's constitutional court publishes the [Official Register](#), informing the general public and stakeholders of new laws and other legal dispositions.

B. Ministry of Agriculture and Livestock

The Ministry of Agriculture is responsible for ensuring sustainable agricultural development by directing and evaluating all agricultural and livestock activities. Laws and regulations governing MAG's activities include:

1. [Organic Law of Rural Lands and Ancestral Territories](#) (ROE 711, March 14, 2016): Regulates the use and access to ownership of rural land and outlines how property ownership must fulfill social and environmental functions. Regulates the ownership, administration, and redistribution of rural land as a production factor to guarantee food sovereignty, improve productivity, promote a sustainable and balanced environment and grant legal security to rights holders.
2. [Animal Health Law](#) (ROE 409, March 31, 1981): Aims to prevent, control, and eradicate illnesses in the national livestock population. The Ministry of Public Health and MAG are responsible for controlling the quality of animal origin products in the human food chain. These ministries are responsible for issuing food recalls and prohibiting trade in products deemed harmful to consumers. The law requires MAG authorization and sanitary certification prior to the export or import of animals and their by-products.
3. [Plant Health Law](#) (ROE 475, January 18, 1974): Aims to prevent and control the outbreak of plagues, illnesses and pests that could adversely affect local agricultural crop production. The law establishes regulations, conditions, and prohibitions for the export, import, domestic trade, and the production of certain plant products.
4. [Seeds Law](#) (ROE 594, May 26, 1978): Regulates seed import-export requirements and trade in seeds and seed by-products. Seed exporters-importers are required to register with the MAG.
5. [Law for the Formulation, Manufacture, Import, Trade and Use of Pesticides and Similar Products for Agricultural Use](#): The law requires that importers, manufacturers, and distributors of pesticides and similar products used in agriculture register with the MAG. The law regulates the transport, storage, labeling, and advertisement of these products, and sets maximum residue levels for pesticides. This law is governed by the Andean Community (CAN) Decision 436 (amended by CAN decision 684, May 21, 2008).
6. [Food Sovereignty Law](#) (ROE supplement 583, May 5, 2009): The [Organic Law on Food Sovereignty](#) (LORSA) declares Ecuador to be free of genetically-engineered crops and seeds.

7. Rural Land Law (ROE supplement 711, March 14, 2016): The Organic Law on Rural Lands and Ancestral Territories regulates the use of rural land and its agricultural potential. It also creates the agricultural public information systems with purpose of generating, managing, and providing timely information to producers and economic agents involved in agricultural production, agricultural markets, and services related to rural land.

Agencies of the Ministry of Agriculture and Livestock

1. AGROCALIDAD (i.e., the national sanitary and phytosanitary authority): This agency seeks to prevent the introduction and spread of (non-native) pests and diseases and is responsible for eradicating animal and plant pests and diseases. It enforces domestic legal norms, as well as regional and international standards regulating the import-export, manufacture, formulation, distribution, domestic trade, and end-use of agricultural products, pesticides, and veterinary products. AGROCALIDAD issues sanitary and phytosanitary certificates, harmlessness analysis, good agricultural practices, product quality, and production chain certificates.
2. Domestic and International Trade Office: This office reports to the Under Secretary for Agricultural Commerce. It collects and analyzes agricultural trade intelligence and production data; suggests policy and legislative changes; processes import authorization requests; and remits import authorization requests to AGROCALIDAD for sanitary certification and to the Under Secretary for final approval.

Note: Prior import authorization and license requirements for food and agricultural products are contained in the [Foreign Trade and Investment Council's](#) (COMEX) Resolutions 585 and 590. These identify a positive list of agricultural products subject to prior MAG import authorization or licensing. These rulings apply to non-Andean Community of Nations products.

C. Ministry of Public Health

The Ministry of Public Health's National Control and Surveillance System (ARCSA) regulates the entry and consumption of (imported) processed food products, beverages, food additives, and pesticides. Laws and regulations governing its activities include:

1. Health Law (ROE Supplement 423, December 22, 2006): Requires importers to obtain a sanitary notification permit prior to the import, trade, production, storage, or transportation of processed food, beverages, food additives, and pesticides for domestic, agricultural, or industrial use. The law charges the Ministry of Public Health and its agencies with the responsibility for the inspection and control of all processed foods, beverages, and food additives. The law prohibits the import, trade, utilization, or development of foodstuffs derived from genetically modified organisms without prior authorization. Technical and scientific analysis documentation (acceptable to Ecuador's national sanitary authority) must be submitted. This law also specifies labeling instructions for GE content food products. Food donations containing GE content are subject to the same review and authorization process, and are subject to an interagency review/control system. The GE-related provisions of this law have yet to be enforced.
2. Sanitary Control and Notification Regulation ([ARCSA-DE-067-2015-GGG](#), December 2015):

Regulates the sanitary notification (registration) process for imports and domestically produced food and beverage products. It stipulates that sanitary notification is required prior to the import and distribution of food products. This regulation however provides differing requirements for domestically produced and imported products.

3. [Food Regulation](#): This regulation requires that all imported food products be authorized for free sale. It specifies container, packaging, labeling requirements, as well as manufacturing processes. The regulation also regulates the transportation, distribution, and trade of food.
4. [Consumer Defense Law](#): Guarantees consumers' rights to quality goods and services at fair prices. The law applies to all private and public entities that import, export, manufacture, or distribute goods and services. It requires that consumers are given sufficiently clear and complete information to make informed decisions about a product or service they purchase. The consumer defense law establishes the product content information to be included on a label (including price, in the local currency), and weights expressed in Standard International Units of Measurement (SI). This law also requires the labeling of GE content food. The law's provisions, especially the GE-related ones, have yet to be enforced.
5. [Regulation for the Authorization and Control of Food Publicity and Promotions](#) (February 18, 2011): Regulates the promotion of food products. It affects promotional events for established, new-to-market, and imported food products.
6. [Labeling Regulation](#) (November 15, 2013): Regulates processed food products' nutritional labeling, as well as GE-content information.

D. Other Institutions Involved in Foreign Trade

The Ministry of Foreign Affairs (MoFA): The lead foreign affairs agency. It works with the Office of the President to coordinate with MAG and the Ministry of Production, Foreign Trade, and Investment on policies and the enforcement of trade agreements. MoFA participates in commercial negotiations.

Ministry of Production, Foreign Commerce and Investment: The Moreno administration fused the Ministry of Industries and Productivity and the Ministry of Foreign Commerce to create this ministry. It chairs Ecuador's Foreign Trade Council and is the lead agency for trade negotiations. The ministry is responsible for trade, investment and industrialization policies. It seeks to improve Ecuador's business environment and increase domestic and international competitiveness.

Ecuadorian National Standards Institute (INEN): Ecuador's technical standards setting body. Ecuador's technical standards, called NTEs, define the characteristics of raw materials, intermediate products, and finished products marketed in Ecuador. INEN establishes inspection, analysis, measurement, and classification methodologies. It administers the local quality certification system, and implements and enforces the use of the International Measurement System. INEN enforces compliance with national technical standards, and serves as the Codex point-of-contact.

Foreign Trade Council (COMEX): Created as part of the Production, Commerce, and Investment Code (ROE 351, December 29, 2010), COMEX approves commercial policies and coordinates foreign

trade.

Ecuadorian Customs Service (SENAE): Governed by the [Organic Code of Production, Trade and Investments](#), SENAE is responsible for borders and ports. It enforces the collection of import duties and taxes.

Laws and regulations governing international trade include:

Foreign Trade Law (ROE 82, June 9, 1997): Prohibits any practice or administrative measure limiting free competition or that obstructs domestic or international trade. The law allows for corrective actions to be applied in cases contemplated under WTO regulations.

Section II. Food Additives Regulations:

Ecuador's Health Law, Food Regulation, and INEN's technical standard 2074-96 (NTE INEN 2074-96) established regulations and standards for food additives and their use. The Food Regulation stipulates that the import of food additives and their in-country utilization is permissible when: 1) use is innocuous to human health and 2) enters with the proper sanitary notification.

Technical standard NTE INEN 2074-96 is based on Codex standards and the FDA regulations. This standard establishes a positive list of allowed additives, regulations for tolerance levels, and a list of prohibited substances for human consumption. This positive list is periodically checked and modified according to new scientific, technological, and toxicological studies. NTE INEN 2074-96 and other technical standards and norms are available for sale. U.S. exporters may obtain copies by contacting INEN directly (see Appendix I).

Section III. Pesticides and Other Contaminants:

The Formulation, Manufacture, Import, Trade, and Use of Pesticides Law requires manufacturers, importers and distributors to declare the chemical composition of pesticides. AGROCALIDAD's Plant Health Unit is the lead agency for applying this law and enforcing its requirements.

Ecuador has not set its own maximum tolerance levels. In lieu of these, Ecuador applies Codex maximum residue limits (MRL). Other maximum tolerance levels established by internationally recognized institutions (e.g., the U.S. Environmental Protection Agency) are also accepted. MAG will detain agricultural products suspected of being contaminated with excessive pesticides or similar products. If testing confirms an excessive MRL level, the product will be destroyed without compensation.

Section IV. Packaging and Container Regulations:

Ecuador's Food Labeling regulations stipulate:

Food containers must have an adequate shape, capacity, and seals. No further explanation of what is deemed “adequate” is available.

- Containers should be made of the proper materials, adequate for the physical-chemical nature of the food to be contained. Product protection, conservation, and identification must be guaranteed throughout a product’s shelf life.
- Meet national technical standard (NTE) established for each product or group of products.
- Label must promote recycling or re-use of the packaging material or container.

Section V. Labeling Requirements:

A. General Requirements

Ecuador’s Health Law, Sanitary Notification process, and the Food Labeling regulations, and INEN’s technical standards 1334-1:2011, 1334-2:2011, and 1334-3:2011 (NTE INEN 1334-1:2011, NTE INEN 1334-2:2011 and NTE INEN 1334-3:2011) provide labeling requirements for processed food products.

Food containers must have a printed or affixed label. Imports will be allowed to clear Customs once a Spanish language sticker label is affixed that meets the requirements needed for the product to be marketed in Ecuador. An expiration date (i.e., “good through”), lot number, the sanitary notification code, the list of ingredients, and name of the importer reading “*Importado por...*” are required.

A label is not permissible that contains words, pictures or other representations highlighting a product’s medicinal, therapeutic, preventive, curative, nutritional, or special features which may misrepresent the real nature, origin, composition or quality of the product.

When small product size limits the possibility of listing all required food label information, the required information must alternatively be printed on the larger packaging container that contains several units of the product. This is the case for candy, chocolate, and most confectionery products. Ecuador’s solid waste management regulations require that every product label must promote recycling or re-use of the packaging material or container.

Ecuadorian standards do not differ significantly from those established by the United States. Standards are based on Codex and U.S. Food and Drug Administration (FDA) stipulations. Ecuador accepts FDA standards in the absence of a local standard.

B. Nutritional Labeling Specific Requirements

The Ministry of Public Health’s Food Labeling regulation (November 29, 2013/ Executive Agreement 4,522 and published in the Official Registry as R.S. SP134) stipulates that all processed food products sold in Ecuador must contain a traffic light signal on the label highlighting sugar, salt, and fat content (see the below picture for an example).

Ecuador’s NTE INEN 1334-2:2011 specifies the minimum package nutritional labeling requirements for processed food products. Ecuador is basing this standard on Codex and FDA guidelines. Ecuador

refers to the United Nations' Food and Agriculture Organization (FAO) and World Health Organization (WHO) for recommended daily intake (RDI) values.



Mandatory Nutritional Labeling, Exceptions and Special Dispositions

Foods Containing Insignificant Quantities of Nutrients: An insignificant quantity is defined as permitting the declaration “zero.” The exception applies to total carbohydrates, dietary fiber and protein for which an insignificant quantity is defined as being less than one gram. Products exempted include grain coffee, tea leaves, soluble tea, and unsweetened coffee, as well as dehydrated vegetables for seasoning, flavor extracts, and food colorings.

Dietary Supplements: The exception does not apply to dietary supplements packaged as conventional foods (e.g., breakfast cereals), subject to NTE INEN 1334-2:2011 requirements.

Packaged Food: These products are exempt only if they are shipped in bulk and are not meant for direct consumer sales, but are imported for use by the food processors (e.g., bulk-packaged sweet corn to be re-packaged and sold as a vegetable mix).

Fresh Food Products: Fresh fruits and vegetables and seafood (fresh/frozen) are exempt.

Genetically-Engineered Ingredients: Ecuador's Food Labeling Regulation and INEN's technical standard 022 (NTE INEN 022) stipulate that all processed food products with a GE content of 0.9

percent or greater are required to state on the front panel label that the product contains GE content in Spanish “*CONTIENE TRANSGENICOS.*” The word “*TRANSGENICO*” must be included after the ingredient on the ingredients list

Section VI. Other Specific Standards:

A. Wine, Beer and other Alcoholic Beverages

Imports of alcoholic products require prior Ministry of Public Health authorization in addition to sanitary a notification. For container requirement purposes, imports must comply with INEN regulations PyM 1992-20, PyM 1992-17, and PyM 1992- 21. Alcoholic products and beer must incorporate the following text on their front label:

- “*Importado por...* (name of the representative or importing company),” alcohol-by-volume, and the capacity of the bottle in cubic centimeters.
- A health advisory note stating: “*Advertencia: El consumo excesivo de alcohol causa graves daños en su salud y perjudica a su familia. Ministerio de Salud Pública.*” The warning must appear on the main or secondary label and indicate that it complies with Disposition 1,828 of the decree issued on June 10, 1994.

Alcoholic products and imported beers sold in Ecuador that do not fulfill these requirements are considered contraband material by the local authorities.

B. Products Samples and Mail Order Shipments

Import and export regulations establish that samples are exempt from the payment of import duties, value-added tax (IVA), and special consumption tax (ICE) when the cost-insurance-freight (CIF) value does not exceed \$400 or its equivalent in other currencies. However, a fixed cost of \$42 per package will be applied to each shipment. Merchandise exceeding this value will pay (for the excess) the established tariff for imports.

For exemption treatment, samples without commercial value are required to:

- Be shipped by the manufacturer, its representative, or the authorized exporter.
- The addressee shall be a company or an importer dedicated to this commercial activity.
- The documentation (commercial invoices, transportation invoices or others concerning the shipment), shall contain marks and notations clearly indicating that the products are samples without commercial value.
- Product samples must carry a statement indicating that these are samples without commercial value, whose sale is forbidden. Customs may mark samples with perforations or break seals in order to impede their sale.

Correspondence and small packages (up to four kilograms) are exempt from taxes but will pay the fixed cost mentioned above. Other types of packages and international postal cargo leaving or entering the country, with or without commercial purposes and made by any type of mail agency, are subject to the payment of the corresponding taxes in relation to their normal CIF value.

Similarly small packages, other packages, and postal cargo and samples without commercial value, exempt or not of taxes, whose CIF values do not exceed \$160 will clear Customs with a simplified declaration. Although samples can be permanently imported, the nationalization process is prone to complications. For samples that will be used as an ingredient in the development of a food product, obtaining a sanitary authorization is recommendable.

The import (and export) by mail of products such as narcotics, explosives, tobaccos, liquors, inflammable products and other dangerous or contaminant substances are forbidden.

C. Animal Imports

- Animals must come from zones in which no infectious/contagious illnesses were present, during a specific period of time prior to shipment. Ecuador follows World Organization for Animal Health (OIE) standards.
- Animals must be immunized (following AGROCALIDAD mandated vaccinations).
- Laboratory test/exam results indicating a negative presence of infectious/contagious diseases.
- Animals should be treated for parasites, as well as should be in good physical condition without clinic symptoms of infectious/contagious diseases.

D. Plant/Plant Material Imports

- The product must be free of soil or of animal or vegetal products in decomposition.
- Use of poor quality, re-used, infected or infested packaging material is prohibited.
- The plant breeding material must come from a country or area known to be free of pathogens or diseases.
- AGROCALIDAD requires that products be accompanied by a fumigation or quarantine treatment certificate signed by the competent authority in the country-of-origin.

Authorized animal species and plant varieties can be found in the [APHIS library](#).

Section VII. Facility and Product Registration Requirements:

A. Facility Registration

AGROCALIDAD Resolutions [003](#) and [217](#) mandate the registration of processing facilities for veterinary inputs for livestock (including veterinary drugs, feed, and supplements) and for livestock products and byproducts prior to import permit authorization.

Meat Plants and Dairy Facilities Accreditation: AGROCALIDAD requires the registration of meat production plants and dairy facilities prior to the issuance of import permits.

Poultry Farms: AGROCALIDAD requires the registration of poultry farms producing eggs and poultry meat and products for export to Ecuador. It reserves the right to request biosecurity certification.

Livestock Genetics Export Facilities: AGROCALIDAD requires the registration of livestock genetics facilities and quarantine facilities (in the case of live animals) prior to issuance of import permits.

B. Product Registration

Exporters of plant and animal products to Ecuador must be registered with AGROCALIDAD. A sanitary notification must be obtained from the Ministry of Public Health's National Control and Surveillance System (ARCSA) to import processed products.

Registration of Agricultural and Livestock Inputs

Individuals or companies importing or producing agricultural and livestock inputs (seeds, plants and plant breeding material, improved animals, semen, fertile eggs and embryos) must register with AGROCALIDAD. The validity of the registration is indefinite, but it can be canceled due to non-compliance with the dispositions stated in different laws and accompanying regulations.

Registration of Processed Products

ARCSA regulates the entry and consumption of (imported) processed food products, beverages, food additives, food supplements, and pesticides. Before any of these products are imported to Ecuador, a sanitary notification must be obtained. A detailed overview of this process is provided in Section VIII.

Section VIII. Other Certification and Testing Requirements

A. Sanitary Notification

To protect consumer health, Ecuador's Health Law establishes that all national or foreign processed food products and additives must obtain sanitary notification prior to their import and sale in Ecuador. The Sanitary Notification Regulation [067](#) (December 2015) stipulates that the sanitary notification petition can be filed by the (foreign) manufacturer or by its Ecuadorian legal representative. In either case, the notification belongs to and will be issued on behalf of the manufacturer, unless specifically requested otherwise. Several notifications can be issued for different holders if applicable, as long as each applicant fulfills all the requirements. A different notification number will be issued for each notification holder.

The sanitary notification for imported products is granted by confirmation (or equivalence) 10 to 15 working days after filing a "correct" application with the National Sanitary Control and Regulation

Agency (ARCSA) and payment received. There is a procedure in place to review documentation in case of observations to documents; filers will be advised of any observations within three days. The sanitary notification can be requested by product or by line of production.

In the case of line of production the processing plant must have a certification in place equivalent or higher than the Good Manufacturing Practices Certification issue by ARCSA (Ex: HACCP). In the case of sanitary notification by line of production, all products manufactured under the same process will use one sanitary notification number.

The sanitary notification is valid for a period of five years. The notification fee is approximately \$904 per item (applies to items originating outside of Ecuador). Before the notification takes place, the product must pass a certified laboratory analysis (costing roughly \$400). In the case of sanitary notification by line of production the cost is around \$1900. The down side of using sanitary notification by line of production is that certifications are usually issued on a yearly basis, so if the certification is expired at the time of production a new sanitary notification number will need to be requested.

Applications must be electronically filed with the ECUPASS system and include: 1) the name and address of the person or entity under whose name the sanitary notification is requested; 2) name, phone, and full address of the manufacturer; 3) product name in full, including the brand name; 4) product description; 5) an ingredient list or composition formula (in percentages) used in the product (including additives) declared by the manufacturer in descending order; 6) production code interpretation; 7) shelf life; 8) packaging information declaring the type of container and content expressed in International Measurement System (SI) units and conservation conditions, and; 9) the signatures of legal representative of the company and technical expert.

Additional documentation includes:

- The manufacturer's certification or the product owner's authorization granting the importer permission to register the product.
- A certificate of free sale, sanitary/phytosanitary certificate, or an export certificate issued by the competent authority in the country of export.
- A technical report describing the product's general processing procedures.
- Description and interpretation of the batch code.
- Physical and chemical specification of the packaging/container material in any format issued by the packaging manufacturer or distributor.
- An original product label and the project label in Spanish-language that meets INEN technical standards and related regulation.
- A phytosanitary certificate is required for: 1) walnuts without shell; 2) almonds; 3) hazelnuts; 4) raisins; 5) prunes, and; 6) pine nuts for human consumption that have not undergone a transformation process.
- Organic products must be accompanied by corresponding organic certification verified by AGROCALIDAD.

Nutrition table statements on the product label must be supported by a signed technical report issued by an INEN-accredited lab. This can be requested during the post-issuing inspection along with a stability study/card, a signed technical declaration of the product's shelf life, or its maximum consumption time.

ARCSA Regulation 028 (February 2017) regulates food supplements, or products that claim a specific nutritional characteristic. For these products, in addition to the requirements listed above, the following need to be presented:

Quality of the finished product:

- Organoleptic and physicochemical specifications established by the manufacturer and those applied under the Ecuadorian Technical Standard for Nutritional Supplements (NTE INEN 2983), such as levels of aflatoxins, heavy metals, value of peroxides;
- Microbiological specifications according to the limits established in the Ecuadorian Technical Standard for Nutritional Supplements (NTE INEN 2983);
- Physical and chemical specifications of the primary packaging material issued by the manufacturer or distributor.

Intentional benefits or nutritional and health claims:

- Guidelines established in NTE INEN 1334 – 3 Food Products for Human Consumption, Part 3 Requirements for Nutritionals and Healthy Declarations must be taken as reference. In the absence of national guidelines, international official standards are accepted, such as: Codex Alimentarius, EFSA (European Food Safety Authority), FDA (Food and Drug Agency), official monographs or scientific articles.

Prior to requesting a sanitary notification, an importer/distributor will need to obtain from the Ministry of Health a sanitary certificate from the storage facility where imports will be warehoused (a cost of \$180). A new sanitary notification permit is needed when a product's composition, conservation process, nature of its container, or manufacturer changes. A new permit is also required if not obtained by line of production whenever there is a substantial modification (more than 1 percent) of: 1) colorings; 2) flavorings; 3) sweeteners; 4) conservation agents, and/or; 5) nutritional additives. Non-Spanish language documents must be translated. Foreign documentation must be authenticated by the Ecuadorian consulate of jurisdiction or have an *apostille certificate* affixed.

In the case of processed foods that are imported and then packaged, they must obtain the sanitary notification as a foreign product for importation; when packaged it must obtain the sanitary notification as a national product for later commercialization.

According to industry sources, the sanitary notification regulation provides a registration exemption for food ingredients that are utilized by local food manufacturers in final products that enter with their own sanitary registration. To be eligible to import product under this provision, the product must arrive with prior authorization. Obtaining approval is highly cumbersome, requiring proof that the ingredient will not be commercialized prior to undergoing substantive transformation. This authorization/certificate needs to be requested on ECUPASS system for each shipment.

B. Sanitary and Phytosanitary Certification

Importers of animal and plant products must request an import permit from AGROCALIDAD prior to shipment. Prior administrative authorization must also be requested for the import of most commodities, which requires approval from both AGROCALIDAD and the Ministry of Agriculture's Under Secretary of Agricultural Commerce.

The exporter must be registered with AGROCALIDAD and needs to provide the importer with the official country of origin health certificate for each product. For U.S.-origin animals, plants, and animal and plant derived products, Ecuador only accepts health certificates issued by USDA's Animal and Plant Health Inspection Service (APHIS) and USDA's Food Safety and Inspection Service (FSIS).

An Import Customs Declaration (import permit - DAI) is required. Certain imports require Ministry of Agriculture or Ministry of Public Health import authorization. For Ministry of Agriculture requests, these are submitted to the Directorate for Domestic and International Trade. The following must be included in the request:

- The Import Customs Declaration (DAI) (see Section IX - Import Procedures).
- Requisition Note (original and three copies).
- Pro-forma Invoice (original and three copies).
- Prior Import Authorization form (original and three copies).
- For imports of animals and other products of animal origin, the importer must include a payment receipt of the import fee at the National Agricultural Development Bank (BNF).

An individual or collective pedigree certificate must be included for the import of pets and breed-certified animals.

AGROCALIDAD verifies the documentation and issues the corresponding sanitary or phytosanitary permit. If the documents are not in correct order, AGROCALIDAD will return the application to the Domestic and International Trade Directorate denying import authorization.

An AGROCALIDAD sanitary or phytosanitary permit specifies under what conditions and what type of treatment products are allowed to enter Ecuador. Despite a product being granted a sanitary or phytosanitary certificate, ultimately final import approval rests with the Under Secretary of Agricultural Commerce.

For dairy products that are regulated by AGROCALIDAD, CAN Resolution 1352 requirements are applied. In order to fulfil the requirements under this resolution AMS Sanitary Certificate for Exports is accepted.

C. Control of Products at Retail/Wholesale Distribution

The Ministry of Public Health has oversight of processed food products and additives sold in Ecuador. If a product does not meet the minimum quality standards, or lacks sanitary registration, it can be confiscated and destroyed. The Ministry of Public Health in coordination with the Ministry of Agriculture controls products of animal origin destined for human consumption. Trade in items deemed

harmful to human health is prohibited.

AGROCALIDAD or other designated entities may inspect commercial and industrial facilities storing and selling seeds to verify the health status of the plant breeding material. If plant pests or infectious diseases are present, staff will declare either an “Observation Zone” or “Quarantine Zone.” If necessary, infected material will be destroyed.

D. Conformity Certificate

Ecuadorian National Standards Institute, in accordance with COMEX Resolution 016, requires a conformity certificate for products listed in the resolution. Each imported processed food product lot must be certified as having been produced according to INEN standards. Importers are allowed, alternatively, to present a manufacturer data sheet (*ficha técnica*) that details product formula or the manufacturing process followed. Currently, an importer self-declaration is being accepted on a case-by-case basis.

Section IX. Import Procedures:

Ecuadorian importers expect that their exporting counterparts will obtain all necessary export permits and licenses and arrange for logistics to the U.S. shipping port. Imports in Ecuador are handled at the individual level or by a company. An import customs declaration (import permit - DAI) is required. Certain imports require Ministry of Agriculture or Ministry of Public Health import authorization.

Ecuador’s Customs Authority requires that food and agricultural product imports are filed with an import customs declaration form. Documentation requirements include:

- Requisition Note (mandatory).
- Authorizations or Licenses (if needed): If the type of good requires it, it is necessary to obtain authorizations in a Ministry or other public entity (see Section VI, Other Regulations and Requirements).
- Insurance Certificate (if needed).
- Import Verification Request (if needed): Based on risk. The request has to be completed and then delivered to the verification company along with the requisition note.
- Certificate of Inspection (*Certificado de Inspección*): This certificate is issued by the verification company, and only in goods exceeding FOB value of \$2,000. If a good enters Ecuador without the certificate of inspection, it cannot be released.
- Certificate-of-Origin (if needed).
- Shipment Manifest (mandatory).
- Bill of Lading (mandatory).
- Commercial Invoice (*Factura Comercial*) (mandatory).
- Customs Declaration-of-Value (DAV) (mandatory): the DAV is a sworn declaration that the consigned value is real. It is completed by the importer in the ECUPASS system.
- Products requiring an import permit need be accompanied by all the specific requirements requested for the product.

- An ARCSA food sanitary registry for processed food products or a health certificate for animals, plants, or animal or plant by-products that meets AGROCALIDAD's import requirements.

Once the customs agent transmits the import customs declaration, Customs assigns an inspection control channel. Control channel inspections range from a simple documentation review to the physical inspection of products. Any discrepancies between the import customs declaration and the shipment will lead to delays and possible shipment confiscation. Customs does permit the re-export of products. FAS Quito cautions exporters not to send samples or extra promotional items not included on the import customs declaration. Import documents do not need to be translated into Spanish.

Customs Clearance Steps

- The import declaration is submitted to the corresponding Customs district, which verifies the data and confirms compliance with all requirements. If there are no objections, the declaration will be accepted, and the district will assign a validation number. Once the declaration is accepted, it is final and cannot be amended.
- Document revision or visual examination of the goods, establishing product nature, quantity, value, and tariff classification.
- In the visual examination, the verification company checks the merchandise, verifies that the security seal has not been tampered with, and compares the declaration with the actual load. If correct, the document review follows. If not consistent, the verification company will verify that the difference is within a margin of tolerance (maximum 10 percent of the taxes) and the importer will pay the same. Taxes are paid on actual quantity; differences exceeding 10 percent are considered illegal shipments.
- The physical examination takes additional time. Seventy percent of the containers at the port of Guayaquil are held more than 15 working days.
- The verification company carries out the document revision. This consists of verifying that what was declared matches the accompanying documents on the import customs declaration. If there are no objections, the Customs district will authorize the payment of tariffs, which will be done through an authorized bank. Subsequently, Customs will confirm payment and authorize the delivery of the merchandise.
- Customs may demand a guarantee of 20 percent of the total amount to be paid within a maximum period of 60 days. If the commercial invoice is missing in the declaration, the merchandise can be removed with a guarantee. The time period allowed for presenting a new invoice is 30 days. However, if the certificate-of-origin is missing it is recommended to leave the merchandise with Customs until the new certificate arrives.
- Appeals need to be made within 20 days of Customs' action/notification.

Specific Rules for Agricultural Imports

Inspection of agricultural products in the country-of-origin is a legal requirement. Verification companies hired for this purpose will carry out the inspection. Ecuador's animal and plant health laws stipulate that agricultural and livestock products (except industrialized products) can only arrive at

seaports and airports where AGROCALIDAD is present.

Airports: Quito and Guayaquil

Seaports: Guayaquil, Manta, Esmeraldas, and Puerto Bolívar

Terrestrial Ports: Tulcan, Macara, and Huaquillas

Section X. Copyright and/or Trademark Laws:

Ecuador's Intellectual Property Law (May 19, 1998) regulates and guarantees intellectual property. The law covers inventions, trademarks, commercial logos and models, commercial and industrial secrets, brand names, distinctive appearances of businesses and commercial establishments and any other intellectual creation for agricultural, industrial or commercial use. The law applies to both Ecuadorians and foreign nationals.

A. Trademarks

Trademark registration applications are filed with the National Institute of Intellectual Property (IEPI). The initial request to register a trademark made in a WTO member state, the Andean Community, or through the Paris Agreement for the Protection of Industrial Property grants the applicant the priority right for a period of up to six months in which to file the trademark application in Ecuador.

A trademark registration is valid for 10 years from the date of its concession and it can be renewed. The applicant must pay the IEPI a fee of \$208 plus an additional \$260 fee for testing, \$28 for annual maintenance fee, and a \$54 trademark title fee. Legal representation fees may exceed \$1,000. The renewal of a trademark must be requested six months prior to its expiration.

B. Brand Names

Brand names are registered with the National Institute of Intellectual Property. Procedures for registration are the same as followed for trademark registration. Registration entails benefit for the registration holder. The right to exclusive use is premised on the brand name's public and continuous use in trade for a period of no less than six months. Brands are protected without the obligation of registration. Brand name registrations do not have maximum validity times.

Appendix I. Government Regulatory Agency Contacts:

MINISTRY OF FOREIGN RELATIONS

Address: Carrión E1-76 y Avda. 10 de Agosto, Quito, Ecuador

Phone: (593 2) 299-3200 · www.cancilleria.gob.ec/

MINISTRY OF PRODUCTION, FOREIGN COMMERCE AND INVESTMENT

Address: Av. Malecón Simón Bolívar #100 y Calle 9 de Octubre, Guayaquil, Ecuador

Phone: (593 4) 259-1370 · www.comercioexterior.gob.ec/

MINISTRY OF PUBLIC HEALTH

Address: Avda. República del Salvador 36-64 y Suecia, Quito, Ecuador

Phone: (593 2) 381-4400 · www.salud.gob.ec/

- Under Secretary of Health Surveillance
Phone: (593 2) 381-4400
- National Health Surveillance Control Department
Phone: (593 2) 381-4400
- Food Safety Office
Phone: (593 2) 381-4400

MINISTRY OF AGRICULTURE AND LIVESTOCK

Address: Eloy Alfaro 30-350 y Amazonas, Quito, Ecuador

Phone: (593 2)-396-0100 and 396-0200 · www.agricultura.gob.ec/

Ecuadorian Agricultural Quality Guarantee Agency (AGROCALIDAD)

Phone: (593 2) 254-4476 · Fax: (593 2) 222-8448

- Plant Health Directorate
Phone: (593 2) 254-8823 Ext. 131 · Fax: (593 2) 222-8448 Ext. 130
- Animal Health
Phone: (593 2) 254-8823 Ext. 136 · Fax: (593 2) 222-8448 Ext. 133
- Agricultural Products Food Safety Control and Register Division
Phone: (593 2) 254-3319 · Fax: (593 2) 222-8448

MINISTRY OF AQUACULTURE AND FISHERIES

Address: puerto pesquero artesanal de san mateo, manta, ecuador

Phone: (593 5) 266-6109 · www.acuaculturaypesca.gob.ec/

CODEX COMMITTEE IN ECUADOR

Phone: (593 2) 256-5626 · Fax: (593 2) 256-7815 · www.codexalimentarius.net/

ECUADORIAN NATIONAL STANDARDS INSTITUTE (INEN)

Address: Baquerizo Moreno E8-29 y Diego de Almagro, Quito, Ecuador

Phone: (593 2) 252-8556 and 256-5626 · Fax: (593 2) 2567815 <http://www.normalizacion.gob.ec/>

- Normalization Directorate
Phone: (593 2) 250-1885

NATIONAL SANITARY CONTROL AND REGULATION AGENCY (ARCSA)

Address: Ciudadela Samanes, Av. Francisco de Orellana y Av. Paseo del Parque. Bloque 5 Guayaquil, Ecuador

Phone: (593-4) 372-7440 · www.controlsanitario.gob.ec/

- Quito Office
Address: Juan León Mera N19-16 y Av. Patria, Edificio Senplades, planta baja
Phone: (593 2) 222-9865

ECUADORIAN CUSTOMS SERVICE (SENAE)

- General Manager Office – GUAYAQUIL
Address: Av. Malecón Simón Bolívar #100, Piso 13 Edificio La Previsora
Phone: (593 4) 373 1030
- District Manager Office – QUITO
Address: Nuevo Aeropuerto Internacional Mariscal Sucre - Parroquia de Tababela - Conector Alpachaca-Centro Logístico de Carga
Phone: (593 2) 394-5830 · www.aduana.gob.ec/
- District Manager Office
Address: Seaport
Phone: (593 4) 248-1166 and 248-1879
- Aero Cargo Deputy Manager Office
Address: Simón Bolívar Airport
Phone: (593 4) 228-7834 and 228-7827
- Regional Deputy Manager Office
Address: Av. 10 de Agosto 1731 y San Gregorio - Edificio Epsilon
Phone: (593 4) 321-5019

NATIONAL INSTITUTE OF INTELLECTUAL PROPERTY

Address: Avda. República 396 y Diego de Almagro - Edificio Fórum 300, Quito-Ecuador
Phone: (593 2) 394-0000 · www.iepi.gob.ec/

- Trademarks Department
Phone: (593 2) 250-8000 Ext. 235
- Patents Department
Phone: (593 2) 255-4887 Ext. 220 · Fax: (593 2) 254-3894

Appendix II. Other Import Specialist Contacts:

U.S. Embassy Quito, Foreign Agricultural Service (FAS) Office of Agricultural Affairs

Physical Location: Avda. Avigiras E12-170 y Ave. Ely Alfaro, Quito, Ecuador
Phone: (593-2) 398-5323, E-mail: agquito@fas.usda.gov

For additional information, see www.fas.usda.gov. See also to our Exporter Guide, Food and

Agricultural Import Regulations and Standards Export Certificate, and Food Processing Ingredients Sector GAIN reports.

CAMARA DE AGRICULTURA

Primera Zona

Address: Avda. NN. UU. 1084 y Amazonas, Torre B-Edificio La Previsora, 8vo. Piso-Oficina 805, Quito-Ecuador

Phone: (593 2) 225-7618 and 227-4187, Fax: (593 2) 225-7618

Segunda Zona

Address: Carchi 809 y 9 de Octubre, Guayaquil-Ecuador

Phone: (593 4) 239-4449, Fax: (593 4) 239-4449

Tercera Zona

Address: Galápagos 237 entre Guayas y Remigio Tamariz, Cuenca-Ecuador

Phone: (593 7) 288-5930, Fax: (593 7) 288-3870