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Food and Agricultural Import Regulations and Standards - Certification

FAIRS Export Certificate Report 2015

Approved By:

Mariano J. Beillard, Regional Agricultural Attaché

Prepared By:

Andres Barahona and Mariano J. Beillard

Report Highlights:

This report identifies Ecuador's import requirements for foreign export certificates, highlighting current procedures and identifying the relevant local agencies with oversight over these issues. An export certificate matrix and outline is included. This report supplements the FAS Quito Food and Agricultural Import Regulations (FAIRS) 2015 report.

This report was prepared by the USDA/Foreign Agricultural Service in Quito, Ecuador for U.S. exporters of domestic food and agricultural products. While every possible care has been taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies is not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

Section I. Export Certificates Required by Ecuador (Matrix)

Product (s)	Title of Certificate	Attestation Required on Certificate	Purpose	Requesting Ministry
Imported Processed Foods and Beverages	Certificate of Free Sale	The products are authorized for free sale and human consumption in the country of origin.	To obtain Sanitary Registration	ARCSA (Ministry of Health)
Imported Processed Foods and Beverages	Good Manufacturing Practices Certificate or HACCP Certificate	The plant where products are manufactured counts with this certificate.	To obtain Sanitary Registration	ARCSA (Ministry of Health)
Imported Nuts and Some Dry Fruits	Phyto-Sanitary Certificate	The product is safe for human consumption. It is free of pest or disease.	To obtain Sanitary Registration	ARCSA (Ministry of Health)
Organic Products	Organic Certification	The product is organic.	To obtain Sanitary Registration	ARCSA (Ministry of Health)
Imported Plant Products	Phyto-Sanitary Certificate	Fulfills health requirements according to import permit and sanitary inspection. (See, APHIS website).	To obtain Health Certificate and Import Permit	AGROCALIDAD (Ministry of Agriculture)
Imported Animal Products	Sanitary Certificate	Fulfills health requirements according to import permit and sanitary inspection. (See, APHIS and FSIS websites).	To obtain Health Certificate and Import Permit	AGROCALIDAD (Ministry of Agriculture)
Imported Animals	Zoo-Sanitary Certificate	Fulfills health requirements according to import permit and sanitary inspection. (See, APHIS website).	To obtain Health Certificate and Import Permit	AGROCALIDAD (Ministry of Agriculture)
Imported Processed Food and Beverages	Certificate of Conformity	The product has been produced under the Ecuador specific INEN standard.	To obtain Import Permit	Ministry of Industries
Imported Animal Feed and Animal Supplements	Certificate of Free Sale	The products are authorized for free sale in the country of origin.	To obtain Certificate of Registration	AGROCALIDAD (Ministry of Agriculture)

Section II. Purpose of Specific Export Certificate(s)

- A. Certificate of Free Sale:** The Ministry of Health's National Sanitary Control and Regulation Agency (ARCSA) requires a certificate of free sale as proof that food and beverage products are sold in the country of origin and are fit for human consumption. This certificate, normally issued by the U.S. state's Health Department where the product is manufactured, is required in order to obtain the sanitary registration of a product.
- B. Good Manufacturing Practices Certificate or HACCP Certificate:** The Ministry of Health's National Sanitary Control and Regulation Agency requires a Good Manufacturing Practices or HACCP certificate as proof that food and beverage products were produced under practices that make the product safe for human consumption. This certificate is required in order to obtain the sanitary registration of a product.

- C. Phyto-Sanitary Certificate (nuts and dried fruits):** The Ministry of Health's National Sanitary Control and Regulation Agency requires a phyto-sanitary certificate to verify the quality of nuts and some dry fruits intended for retail sale. This certificate is required in order to obtain the sanitary registration of a product.
- D. Organic Certificate:** The Ministry of Health's National Sanitary Control and Regulation Agency requires an organic certificate to attest that the product intended for retail sale is organic. This certificate is required in order to obtain the sanitary registration of a product.
- E. Phyto-Sanitary Certificate:** The Ministry of Agriculture's Sanitary/ Phyto-Sanitary agency (AGROCALIDAD) requires a phyto-sanitary certificate to prevent the introduction of foreign pests and diseases. Certificates are issued by the sanitary authority in the country of export.
- F. Sanitary Certificate:** AGROCALIDAD requires a sanitary certificate to prevent the introduction of foreign pests and diseases. Certificates are issued by the sanitary authority in the country of export.
- G. Zoo-Sanitary Certificate:** AGROCALIDAD requires a sanitary certificate to protect animal health and ensure foreign animal diseases are not introduced into Ecuador. Certificates are issued by the sanitary authority in the country of export.
- H. Certificate of Conformity:** The Ministry of Industries requires that products listed in COMEX Resolution 116 (see, Appendix I) count with a certificate of conformity that substantiates product quality. This certificate can be replaced by an INEN import permit once the importer submits a manufacturer's datasheet (which includes among others the production process followed, ingredients list, and plant quality certifications).
- I. Certificate of Free Sale:** AGROCALIDAD requires a certificate of free sale in order to register animal feed and supplements. Registration is a mandatory prerequisite for the import of these products.

Section III. Specific Attestations Required on Export Certificate(s)

- A. Certificate of Free Sale:** ARCSA requires that the certificate declare that the product is authorized free for sale and is fit human consumption in the country of origin.
- B. Good Manufacturing Practices Certificate or HACCP Certificate:** ARCSA requires certification that manufacturing plants count with this certifications.
- C. Phyto-Sanitary Certificate (nuts and dried fruits):** ARCSA requires that the certificate attest that specific nuts and dried fruits are fit for human consumption and are free of any pests or diseases.
- D. Organic Certificate:** ARCSA requires that the organic certification provide proof that the product is recognized as an organic product in the country of origin.

- E. Phyto-Sanitary Certificate:** The certificate's attestation will vary by product. Requirements and specifications are accessible on the [APHIS FAVIR](#) website.
- F. Sanitary Certificate:** The certificate's attestation will vary by product. Requirements and specifications are accessible on the [APHIS LIBRARY](#) and [FSIS EXPORT LIBRARY](#).
- G. Zoo-Sanitary Certificate:** The certificate's attestation will vary by species. Requirements and specifications are accessible on the [APHIS LIBRARY](#) website.
- H. Certificate of Conformity:** As per COMEX Resolution 116, conformity certificates must contain production lot numbers and state under which INEN standard the product was manufactured.
- I. Certificate of Free Sale:** AGROCALIDAD requires that the certificates of free sale state that the product is free for sale in country of origin.

For additional information, see:

- APHIS: Animal Plant Health Inspection Service, www.aphis.usda.gov.
- FSIS: Food Safety and Inspection Service, www.fsis.usda.gov.
- AMS: Agricultural Marketing Service, www.ams.usda.gov.

Section IV. Government Certificate's Legal Entry Requirements

- A. Certificate of Free Sale:** A certificate of free sale is required for sanitary registration procedures. Once the product obtains its sanitary registration, ARCSA issues a new certificate which is utilized to nationalize imported product. Sanitary registration is valid for five years. A new certificate of free sale is required when renewing the sanitary registration. This certificate is normally issued by the U.S. state's Health Department where the product is manufactured. An [apostille certificate](#) must be affixed to the original certificate.
- B. Good Manufacturing Practices Certificate or HACCP Certificate:** Certificates are extended by accredited organizations. This certificate is required in order to obtain the sanitary registration of a product. Sanitary registration is valid for five years. A new Good Manufacturing Practices or HACCP certificate is required when renewing the sanitary registration. An [apostille certificate](#) must be affixed to the original certificate.
- C. Phyto-Sanitary Certificate (nuts and dried fruits):** A certificate is required for the sanitary registration of: 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. A phyto-sanitary certificate is needed for each shipment. An [apostille certificate](#) must be affixed to the original certificate.
- D. Organic Certificate:** Certificates from accredited institutions are required. For U.S. products, USDA's organic certificate is the most reliably recognized certification. Sanitary registration is

valid for five years. A new organic certificate is required when renewing the sanitary registration. An [apostille certificate](#) must be affixed to the original certificate.

- E. Phyto-Sanitary Certificate:** Animal and Plant Health Inspection Service (APHIS) issues U.S. phyto-sanitary certificates (form 577). These certificates must be signed and stamped by an APHIS accredited official. Normally these certificates are valid for 90-days and for a single shipment. Certificates must be issued in accordance with protocol requirements.
- F. Sanitary Certificate: The Food Safety and Inspection Service (FSIS)** issues certificates for animal products such as meat and meat products; APHIS issues certificates for different products such as eggs. Forms utilized include FSIS form 9060 and APHIS forms 16-4. A single use original certificate must accompany the product at the time of entry.
- G. Zoo-Sanitary Certificate:** Animal and Plant Health Inspection Service issues Zoo-Sanitary Certificates (form 7001). Forms must be signed and stamped by an accredited APHIS veterinarian. Certificates must be issued in accordance with protocol quarantine requirements for the particular specie. The original certificate must accompany the animal at the time of entry.
- H. Certificate of Conformity:** Certificates of conformity must be issued by an organization accredited by the [Ecuadorian Accreditation Service](#) (*Servicio de Acreditación Ecuatoriano*). Conformity certificates must contain production lot numbers and accompany the product at the time of entry. This Certificate can be replaced by an INEN import permit once the importer submits a manufacture's datasheet (which includes among other documentation the production process, ingredients list, and plant quality certifications). Currently for U.S.-origin food products, an importer self-declaration is being accepted on a case-by-case basis.
- I. Certificate of Free Sale:** AGROCALIDAD requires a certificate of free sale in order to register animal feed and supplements. Registration is a mandatory prerequisite for the import of these products; the validity of the registration is two years. Once the product is registered, import permits will still be required but a certificate of free sale will not be required again during the registration's duration. AGROCALIDAD requires certificates to be issued by the U.S. Food and Drug Administration. An [apostille certificate](#) must be affixed to the original certificate.

Section V. Other Certification/Accreditation Requirements

Sanitary Registration: ARCSA requires sanitary registration to ensure food safety. For more information food and beverage registration, see our FAIRS Ecuador Country Report 2014.

Meat Plants Accreditation: AGROCALIDAD requires that meat production plants be registered prior to it issuing import permits.

Poultry Farms: AGROCALIDAD requires that the poultry farms producing eggs and poultry meat and products for export to Ecuador be registered. Ecuador reserves the right to request biosecurity certification.

Appendix I.

List of Tariff Codes that require Certificates of Conformity [\(COMEX Resolution 116\)](#).