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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) Country Annual 2023 report.

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.

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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 Nuts and Some Dry Fruits	Phytosanitary Certificate	The product is safe for human consumption. It is free of pests 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	Phytosanitary Certificate	Fulfills health requirements according to import permit and sanitary inspection. (See, <u>APHIS</u> website).	To obtain a Health Certificate and an Import Permit	AGROCALIDAD (Ministry of Agriculture)
Imported Animal Products	Sanitary Certificate	Fulfills health requirements according to import permit and sanitary inspection. (See, <u>APHIS</u> and <u>FSIS</u> websites).	To obtain a Health Certificate and an Import Permit	AGROCALIDAD (Ministry of Agriculture)
Imported Animals	Zoo-Sanitary Certificate	Fulfills health requirements according to import permit and sanitary inspection. (See, <u>APHIS</u> website).	To obtain a Health Certificate and an 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 if there is one for a specific product.	To prove compliance with standards	Ecuadorian National Standards Institute
Imported Animal Feed and Animal Supplements	Certificate to Foreign Government	The products are authorized for free sale in the country of origin.	To obtain a Certificate of Registration	AGROCALIDAD (Ministry of Agriculture)

Section I. List of All Export Certificates Required By Government (Matrix)

Dairy Products and By-Products	Sanitary Certificate for Exports	Fulfills health requirements according to import permit and sanitary inspection, such as the product is safe for human consumption and the processing treatment the product has received.	To obtain a Health Certificate and an Import Permit	AGROCALIDAD (Ministry of Agriculture)
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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 is typically issued by an individual state's health department in the state where the product is manufactured. USDA maintains a <u>website</u> listing state contacts for Certificates of Free Sale. Additionally, the U.S. Food and Drug Administration (FDA) offers export certificates for most food products. Exporters can apply for <u>FDA certificates</u> on FDA's website. It is required in order to obtain the sanitary registration of a product in Ecuador.
- B. **Phytosanitary Certificate (nuts and dried fruits):** The Ministry of Health's National Sanitary Control and Regulation Agency requires a phytosanitary 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.
- C. **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.
- D. **Phytosanitary Certificate:** The Ministry of Agriculture's Sanitary/Phytosanitary agency (AGROCALIDAD) requires a phytosanitary certificate to prevent the introduction of foreign pests and diseases. Certificates are issued by the sanitary authority in the country of export.
- E. **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.
- F. **Zoo-Sanitary Certificate:** AGROCALIDAD requires a zoo-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.
- G. **Certificate of Conformity:** The Ecuadorian National Standards Institute requires that imported products comply with individual INEN norms by product when one exists. A conformity certificate is required if the authorities think it is necessary after the import has taken place. It is the responsibility of the importer to provide it.
- H. **Certificate to Foreign Government:** AGROCALIDAD requires this certificate in order to register animal feed and supplements. Registration is a mandatory prerequisite for the import of these products.

I. **Sanitary Certificate for Exports:** AGROCALIDAD accepts this certificate for dairy products to comply with CAN Resolution 1352 and as part of the import permit requirements.

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 to be sold freely and is fit for human for consumption in the country of origin. There is no required format for this certificate.
- B. **Phytosanitary 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. There is no required format for this certificate. FAS suggest confirming language with importer.
- C. **Organic Certificate:** ARCSA requires that the organic certification provide proof that the product is recognized as an organic product in the country of origin. There is no required format for this certificate.
- D. **Phytosanitary Certificate:** The certificate's attestation will vary by product. Requirements and specifications are accessible on the <u>APHIS</u> website.
- E. **Sanitary Certificate:** The certificate's attestation will vary by product. Requirements and specifications are accessible on the <u>FSIS EXPORT LIBRARY</u>.
- F. **Zoo-Sanitary Certificate:** The certificate's attestation will vary by species. Requirements and specifications are accessible on the <u>APHIS LIBRARY</u> website.
- G. **Certificate of Conformity:** Conformity certificates must state under which INEN standard the product was manufactured.
- H. **Certificate to Foreign Government:** AGROCALIDAD requires that the certificates state that the product is free for sale in its country of origin.
- I. **Sanitary Certificate for Exports:** AGROCALIDAD requires that information regarding pasteurization process and temperature is included on this certificate and contain attestation that the product comes from raw material from an area free of diseases and that it is safe for consumption.

Section IV. Government Certificates 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 the imported product. A 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 a U.S. state's health department in the state where the product is manufactured. An *apostille* certificate must be affixed to the original certificate.
- B. Phytosanitary 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

phytosanitary certificate is needed for each shipment. An <u>apostille certificate</u> must be affixed to the original certificate.

- C. **Organic Certificate:** Certificates from accredited institutions are required. For U.S. products, USDA's organic certificate is the most reliably recognized certification. A new organic certificate is required when renewing the sanitary registration. An <u>apostille certificate</u> must be affixed to the original certificate.
- D. Phytosanitary Certificate: USDA's APHIS issues U.S. phytosanitary 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.
- E. **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.
- F. **Zoo-Sanitary Certificate:** USDA APHIS issues 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 species. The original certificate must accompany the animal at the time of entry.
- G. **Certificate of Conformity:** Certificates of conformity must be issued by an organization accredited by the <u>Ecuadorian Accreditation Service</u> (*Servicio de Acreditación Ecuatoriano*).
- H. Certificate to Foreign Government: AGROCALIDAD requires a certificate 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 this certificate 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 <u>apostille certificate</u> must be affixed to the original certificate.
- Sanitary Certificate for Exports: The Agricultural Marketing Services (AMS) issues this certificate for dairy products. A standard language is currently being negotiated to create a standardized certificate. The original certificate must accompany the products at the time of entry.

Section V. Other Certification/Accreditation Requirements

Sanitary Notification: ARCSA requires sanitary notification to ensure food safety. For more information about food and beverage sanitary notification and the ways to obtain it, see <u>FAS Quito's</u> <u>FAIRS Ecuador Annual Country Report 2023</u>.

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

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

Livestock Genetics Export Facilities: AGROCALIDAD requires that livestock genetics facilities, and quarantine facilities in the case of live animals, be registered prior to it issuing import permits.

Products for Animal Consumption: AGROCALIDAD requires the registration of plants where feed or products used on animals are produced prior to issuance of import permits.

For further information on plants registrations with AGROCALIDAD see our FAIRS Ecuador Annual Country Report 2023.

Appendix I. Electronic copy, scanned copy or Outline of Export Certificates

A. Certificate of Free Sale:

State of California Secretary of State

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7.	by par / por	Secretary of	State, State of C	California					
8.	Nº sous nº bajo el número	90028							
9.	Seal / stamp: Sceau / timbre: Selto / timbre:			10. Signature Signature: Firma:	9:	XXXXXXXX			
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- B. **Phytosanitary Certificate (nuts and dried fruits):** There is no required format for this certificate. FAS suggest confirming language with importer.
- C. Organic Certificate: N/A

D. Phytosanitary Certificate:

No phytosanitary certificate can be issu	ued until an application is completed (7 C	(FR 353)			FORM APPROVED OMB NO. 0579-0052				
UNITED STATES DEPAR	TMENT OF AGRICULTURE	PLACE OF	FOR OFFICIAL US	E ONLY					
		PLACE OF	SAMP	PLE	USDA				
TO: THE PLANT PROTECT	RY CERTIFICATE	NO.	FPC XXX	XXXX					
SAM	IPLE	DATE INSP		~~~~					
		CERTIF	ICATION						
procedures and are considered t	plant product or other regulated artic to be free from the quarantine pests ntracting party including those for re	, specified b	y the importing contracti	pected and/or tested accor ing party and to conform w	ding to appropriate official ith the current phytosanitary				
	DISINFESTATIO	N AND/OR	DISINFECTION TREAT	MENT					
1. DATE			2. TREATMENT						
3. CHEMICAL (active ingredient)			4. DURATION AND TEMP	PERATURE					
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	ADDIT	IONAL DEC	LARATION						
SAMPLE		P	APPO	S	AMPLE				
16. DATE ISSUED	17 NAME OF ALTHORIZED OFFICE	B (Der er C	rin fi	18. SIGNATURE OF AUTH	Page 1 of 1				
T6. UATE ISSUED	17. NAME OF AUTHORIZED OFFICE	rk (Type or Pi	ang	10. SIGNATURE OF AUTH	URIZED OFFICER				
No liability shall attach to the certificate.	United States Department of A	griculture	or to any officer or rep	presentative of the Depa	artment with respect to this				
PPQ Form 577	FEB 20	001		Previous edition	s are obsolete after 6/30/01				

E. Sanitary Certificate:

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0583-0153. The time required to complete this information collection is estimated to average 25 minutes per response, including the time for reviewing instruction, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

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17. REMARKS						
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18. I CERTIFY that the meat, meat food proc inspection and were found sound and healthy and wholesome. 19. I CERTIFY that the poultry, poultry produ postmortem inspection and passed in accord and fit for human consumption.	and that it has been inspect	ed and passed specified above d regulations of	as provided by la came from birds the United States	w and regulati that were offic Department c	ons of the Department ally given an antemori of Agriculture and are v	and is sour
Inspection and were found sound and healthy and wholesome. 19. I CERTIFY that the poultry, poultry produ postmortem inspection and passed in accord and fit for human consumption.	v and that it has been inspect cts or poultry food products s ance with applicable laws an NED BY A CERTIFYING OF 120. CERTIFYING	ed and passed above dregulations of FICIAL OF MEA	as provided by la came from birds the United States	w and regulations that were office that were office to be a series of the series of th	ons of the Department ally given an antemori of Agriculture and are v	and is sour
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United States Food Safety Department of and Inspection Agriculture Service

Washington, D.C. 20250

PROTOCOL FOR THE IMPORT OF U.S. BEEF AND BEEF PRODUCTS INTO ECUADOR / PROTOCOLO PARA LA IMPORTACION A ECUADOR DE CARNE VACUNA Y DE PRODUCTOS DE ORIGEN VACUNO PROCEDENTE DESDE LOS ESTADOS UNIDOS

The official competent authority must certify the compliance of the following requirements: / La Autoridad Oficial Competente deberá certificar el cumplimiento de los siguientes requisitos:

- The United States has been free of FMD for at least 12 months without vaccination, and have been free from rinderpest and CBPP for at least 24 months without vaccination. The United States is free of Rift Valley fever for 24 months. / Los Estados Unidos han estado libres de fiebre aftosa por lo menos 12 meses sin vacunación, y han estado libres de peste bovina y de perimeumonía contagiosa bovina por lo menos durante 24 meses sin vacunación. Los Estados Unidos está libre de la Fiebre del Valle del Rift durante 24 meses.
- 2. The United States have an active BSE surveillance that meets or exceeds international standards set by the World Organisation for Animal Health-OIE. / Que los Estados Unidos de América tienen un programa activo de vigilancia de EEB que cumple o excede los estándares internacionales establecidos por la Organización Mundial de Sanidad Animal-OIE.
- 3. The meat comes from animals that were born and raised in the United States or raised in the United States for at least 60 days prior to slaughter and that the feeding of ruminants with ruminant origin meat-and-bone meal and greaves is prohibited in the United States, and this prohibition has been effectively enforced. / Que la carne, provieme de animales que han nacido y criados en los Estados Unidos, o se crió en los Estados Unidos por lo menos 60 días antes de su sacrifico y que la alimentación de rumiantes con harinas de carne y hueso y chicharrones de origen rumiante está prohibido en los Estados Unidos y esta prohibición ha sido implementada efectivamente.
- 4. The meat or meat products were derived from animals that passed ante mortem and post mortem inspection by Food Safety and Inspection Service (FSIS) official. / Que la carne y sus productos fueron derivados de animales que fueron inspeccionados ante mortem y post mortem por un inspector oficial del Servicio de Inspección e Inocuidad Alimentaria (FSIS).

Signature of FSIS Inspection Official:

Page 1 of 3

Certificate Edition: 3/21/2014 FSIS Form 2630-9 (6/86)

EQUAL OPPORTUNITY IN EMPLOYMENT AND SERVICES



United States Food Safety Department of and Inspection Agriculture Service Washington, D.C. 20250

Date Issued: 8-8-2019

Certificate Number:

- 5. The beef and beef products were not contaminated with the following specified risk materials: the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum) and dorsal root ganglia of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine from all cattle. / Que la carne y sus productos fueron producidos y manipulados de manera tal que asegura que dichos productos no contienen y no han sido contaminados con los siguientes materiales específicos de riesgo: para bovinos de 30 meses de edad y mayores: encéfalo, cráneo, ojos, ganglio trigémino, médula espinal, columna vertebral (excepto las apófisis transversas, alas del sacro y las vértebras de la cola) y ganglios de la raíz dorsal; y para bovinos de cualquier edad, las amígdalas y el ileon distal del intestino pequeño.
- 6. The meat or meat products were produced and handled in a manner that ensures that such products do not contain and are not contaminated with mechanically separated meat from the skull and vertebral column from cattle over 30 months old. / Que la carne y sus productos fueron producidos y manipulados de manera tal que asegura que dichos productos no contiene y no han sido contaminados con carne mecánicamente separada del cráneo y de la columna vertebral de bovinos mayores de 30 meses de edad.
- 7. The competent authority of the country of origin, certifying that the meat or edible parts of cattle being exported, is fit for human consumption and is freely sold in USA. / La Autoridad Nacional Competente del país de origen, certifique que las carnes o partes comestibles del bovino que se exporten, sean aptos para el consumo humano y se comercializa libremente en USA.
- 8. The product comes from cattle that have not been stunned prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or by pithing. / El producto procede de bovinos que no fueron aturdidos antes de ser sacrificados, mediante inyección de aire o gas comprimido en la bóveda craneana, ni mediante corte de la médula.
- 9. The meat and meat products come from slaughter or processing establishments operating under the supervision of the FSIS. / Que la carne y sus productos provienen de plantas de sacrificio o de procesamiento certificadas por las Autoridades Federales, que operan bajo la supervisión del FSIS

Page 2 of 3

Certificate Edition: 3/21/2014 FSIS Form 2630-9 (6/86)

EQUAL OPPORTUNITY IN EMPLOYMENT AND SERVICES

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 United States
 Food Safety
 Washington, D.C.

 Department of
 and Inspection
 20250

 Agriculture
 Service
 Service

 Date Issued:
 8-8-2019
 Certificate Number: 8

- 10. The slaughtering and processing plant where the meat was processed has an established Hazard Analysis and Critical Control Points (HACCP) system and is officially approved for export by the competent official authorities of USDA, FSIS. / Que la planta de sacrificio y procesamiento donde se procesó la carne, tiene establecido el Sistema de Análisis de Peligros y Puntos Críticos de Control (HACCP) y está oficialmente autorizado para la exportación por la Autoridad Oficial Competente de USDA.
- 11. The meat products were packed in authorized containers which have the mark of inspection that includes the number of the plant and a label that includes the product name, lot number, net weight and the pack date. / Que la carne y sus productos fueron empacados en contenedores autorizados que tienen el sello de inspección que incluye el número de la planta y una etiqueta que incluye el nombre del producto, el número del lote, el peso neto y la fecha de empaque.
- 12. The means of transport, handling and loading conditions meet the hygiene requirements of the United States. / Los medios de transporte, manipuleo y condiciones de la carga cumplen con los requerimientos de higiene de los Estados Unidos.
- 13. The meat and its products are transported in containers or thermo refrigerated vehicles and are monitored to ensure that they maintain proper temperatures cooling or freezing. / Que la carne y sus productos son transportados en contenedores o vehículos termos refrigerados que son monitoreados para asegurar que mantienen temperaturas apropiadas de refrigeración o congelación.
- 14. The feeding of ruminants with meat and bone meal and greaves of ruminant origin has been banned in the United States and the ban has been effectively enforced. / Que la alimentación de los rumiantes con harinas de carne y hueso y chicharrones de origen rumiante está prohibida en los Estados Unidos y esta prohibición ha sido efectivamente implementada.
- 15. The meat and meat products were not derived from animals imported from Canada for immediate slaughter. / Que la carne y sus productos no son derivados de animales importados de Canadá para sacrificio inmediato.

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XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Printed Name: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Title/Professional Degree: Consumer Safety Inspector
Page 3 of 3

Certificate Edition: 3/21/2014 FSIS Form 2630-9 (6/86)

EQUAL OPPORTUNITY IN EMPLOYMENT AND SERVICES

F. Zoo-Sanitary Certificate:

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JUL 2014

G. **Certificate of Conformity:** It is the importer's responsibility to provide a certificate of conformity if needed.

H. Certificate to Foreign Government:

	UMAN SERVICES	Public Health Service
		Food and Drug Administratio 2098 Gaither Road Rockville, Maryland 2085
Certificate No.		
CERT	FICATE TO FOREIGN GOVERNMEN	<u>vr</u>
	United States products into foreign co following information concerning the p	
Name of Product(s)	Name of Manufacture	riDistributor, Address
See Attached List (One Page)	Manufacturer:	
	Distributor:	
	ind the manufacturing/distribution site(DA under the Federal Food, Drug, and	
of America at this time. The mai periodic inspections. The last suc	a(s) may be marketed in, and legally e sufacturing plant(s) in which the prod h inspection showed that the plant(s), it good manufacturing practice require the second second second second second second second second second second second second second second the second sec	act(s) is produced is subject to at that time, appeared to be in
	Export Team Leader Regulatory Policy and Systems Branch Office of Compliance	
	Center for Devices and Radiological Health	r.
This certificate expires 24 month from the date notarized.	Center for Devices and Radiological Health	9
	Center for Devices and Radiological Health	
from the date notarized. COUNTY OF MONTGOMERY	Center for Devices and Radiological Health	
from the date notarized. COUNTY OF MONTGOMERY STATE OF MARYLAND	Center for Devices and Radiological Health	

I. Sanitary Certificate for Exports:



Attachments:

No Attachments