

**Required Report:** Required - Public Distribution

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**Report Name:** FAIRS Export Certificate Report Annual

**Country:** Ecuador

**Post:** Quito

**Report Category:** FAIRS Export Certificate Report

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**Approved By:** Zeke Bryant

**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 2024 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 domestic food and agricultural products. While every possible care has been taken in preparation of this report, information provided may no longer be complete accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was 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 RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.**

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

| <b>Product(s)</b>                           | <b>Title of Certificate</b>       | <b>Attestation Required on Certificate</b>   | <b>Purpose</b>                                      | <b>Requesting Ministry</b>              |
|---|-----------------------------------|--|---|---|
| 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, <a href="#">APHIS</a> 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, <a href="#">APHIS</a> and <a href="#">FSIS</a> 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, <a href="#">APHIS</a> 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)   |
| Dairy Products and                          | Sanitary Certificate for          | Fulfills health requirements according to import permit  | To obtain a Health                                  | AGROCALIDAD (Ministry of                |

|             |         |   |                                  |              |
|-------------|---------|---|----------------------------------|--------------|
| By-Products | Exports | and sanitary inspection, such as the product is safe for human consumption and the processing treatment the product has received. | Certificate and an Import Permit | Agriculture) |
|-------------|---------|---|----------------------------------|--------------|

## Purpose of Specific Export Certificates

- 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 [website](#) 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 [FDA certificates](#) 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 II. 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 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 [APHIS](#) website.
- E. **Sanitary Certificate:** The certificate's attestation will vary by product. Requirements and specifications are accessible on the [FSIS EXPORT LIBRARY](#).
- F. **Zoo-Sanitary Certificate:** The certificate's attestation will vary by species. Requirements and specifications are accessible on the [APHIS LIBRARY](#) 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 III. 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 [apostille certificate](#) 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 [apostille certificate](#) 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 [Ecuadorian Accreditation Service](#) (*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 [apostille certificate](#) must be affixed to the original certificate.
- I. **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 IV. 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 [FAS Quito's FAIRS Ecuador Annual Country Report 2024](#).

**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 2024](#).

**U.S. Radiation Monitoring:** FAS Quito is unaware of any requirements to certify or attest to radioactivity for food imports to Ecuador.

# Appendix I. Electronic Copy, Scanned Copy or Outline of Export Certificates

## A. Certificate of Free Sale:

### State of California Secretary of State

| APOSTILLE<br>(Convention de La Haye du 5 octobre 1961)   |  |   |                              |
|--|--|---|------------------------------|
| <b>1. Country:</b><br>Pays / Pais:   |  | United States of America  |                              |
| <b>This public document</b><br>Le présent acte public / El presente documento público                            |  |   |                              |
| <b>2. has been signed by</b><br>a été signé par<br>ha sido firmado por   |  | XXXXXXXX XXXXXXXX   |                              |
| <b>3. acting in the capacity of</b><br>agissant en qualité de<br>quien actúa en calidad de                       |  | Chief, Food and Drug Branch, California Department of Public Health                 |                              |
| <b>4. bears the seal / stamp of</b><br>est revêtu du sceau / timbre de<br>y está revestido del sello / timbre de |  | State of California   |                              |
| <b>Certified</b><br>Attesté / Certificado  |  |   |                              |
| <b>5. at</b><br>à / en   |  | Sacramento, California  | <b>6. the</b><br>le / el día |
|  |  |   | 22nd day of September 2014   |
| <b>7. by</b><br>par / por  |  | Secretary of State, State of California   |                              |
| <b>8. N°</b><br>sous n°<br>bajo el número  |  | 90028   |                              |
| <b>9. Seal / stamp:</b><br>Sceau / timbre:<br>Sello / timbre:  |  |  |                              |
|  |  | <b>10. Signature:</b><br>Signature:<br>Firma:                                       | XXXXXXXX                     |

This Apostille is the trilingual model Apostille Certificate as suggested by the Permanent Bureau and developed in response to the 2009 Special Commission on the practical operation of the Hague Apostille Convention.  
 This Apostille only certifies the authenticity of the signature and the capacity of the person who has signed the public document, and, where appropriate, the identity of the seal or stamp which the public document bears.  
 This Apostille does not certify the content of the document for which it was issued.  
 This Apostille is not valid for use anywhere within the United States of America, its territories or possessions.  
 To verify the issuance of this Apostille, see: [www.sos.ca.gov/business/notary/apostille-search/](http://www.sos.ca.gov/business/notary/apostille-search/)

Cette apostille est le modèle d'Apostille trilingue tel que suggéré par le Bureau Permanent et élaboré en réponse à la Commission spéciale de 2009 sur le fonctionnement pratique de la Convention de La Haye Apostille.  
 Cette Apostille atteste uniquement la véracité de la signature, la qualité en laquelle le signataire de l'acte a agi et, le cas échéant, l'identité du sceau ou timbre dont cet acte public est revêtu.  
 Cette Apostille ne certifie pas le contenu de l'acte pour lequel elle a été émise.  
 L'utilisation de cette Apostille n'est pas valable en / au États-Unis d'Amérique, ses territoires ou possessions.  
 Cette Apostille peut être vérifiée à l'adresse suivante: [www.sos.ca.gov/business/notary/apostille-search/](http://www.sos.ca.gov/business/notary/apostille-search/)

Esta apostilla es el modelo trilingüe Certificado de Apostilla según lo sugerido por la Oficina Permanente y desarrollado en respuesta a la Comisión especial de 2009 sobre el funcionamiento práctico del Convenio de La Haya sobre Apostilla.  
 Esta Apostilla certifica únicamente la autenticidad de la firma, la calidad en que el signatario del documento haya actuado y, en su caso, la identidad del sello o timbre del que el documento público esté revestido.  
 Esta Apostilla no certifica el contenido del documento para el cual se expidió.  
 No es válido el uso de esta Apostilla en Estados Unidos de América, sus territorios o posesiones.  
 Esta Apostilla se puede verificar en la dirección siguiente: [www.sos.ca.gov/business/notary/apostille-search/](http://www.sos.ca.gov/business/notary/apostille-search/)



**DEPARTMENT OF PUBLIC HEALTH**

Post Office Box 997435  
Mail Station 7602  
Sacramento, CA 95899-7435  
(916) 650-6500  
(916) 650-6650



**FREE SALE CERTIFICATE - FOOD**

~~XXXXXXXXXX~~ INTERNATIONAL INC, USA  
20201 ~~XXXX~~ST.  
HAYWARD  
CA 94545

Registration No: 52574  
Application No : 39656

The California Department of Public Health (CDPH) regulates the production, manufacture, and sale of foods, drugs, medical devices, and cosmetics in California pursuant to the Sherman Food, Drug, and Cosmetic Law (California Health and Safety Code (HSC), Division 104, Part 5, [Section 109875 et seq.]). The above referenced firm manufactures and distributes FOOD products that were manufactured in the State of California by firms registered or licensed with the Department. Registered food processors are inspected by CDPH for compliance with the applicable provisions of the federal Good Manufacturing Practice (GMP) regulations for foods, which are adopted as California regulations.

The Department does not object to the sale of the following product(s) in this state nor its shipment to any other state or country.

This shipment consists of: **See Attached List**

This document was prepared for the country of : **Ecuador**

This certificate is not to be construed as either an expressed or implied warranty of any of the named products, nor shall it be used for advertising or other similar purposes.

This certificate expires one year after issuance.

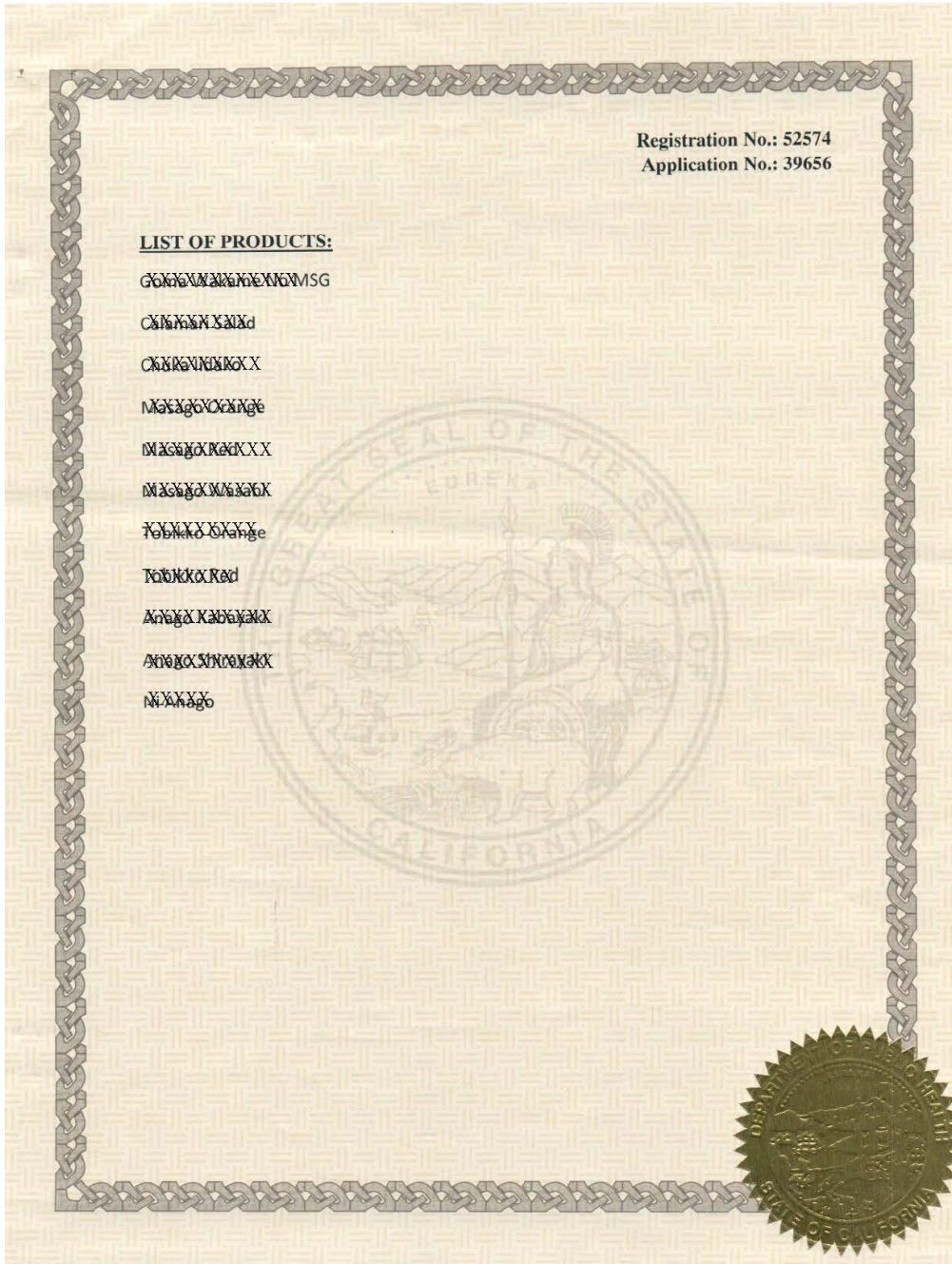
Dated at Sacramento, California, Friday, January 10, 2014

DEPARTMENT OF PUBLIC HEALTH  
OF THE STATE OF CALIFORNIA

~~XXXXXXXXXXXXXXXXXXXX~~  
~~XXXXXXXXXX~~, Section Chief  
Food and Drug Branch









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:**

|   |  |  |   |
|---|--|--|---|
| UNITED STATES DEPARTMENT OF AGRICULTURE<br>ANIMAL AND PLANT HEALTH INSPECTION SERVICE<br>PLANT PROTECTION AND QUARANTINE<br><br><b>PHYTOSANITARY CERTIFICATE</b>  |  | FOR OFFICIAL USE ONLY<br>PLACE OF ISSUE<br><b>SAMPLE</b> |  |
| TO: THE PLANT PROTECTION ORGANIZATION(S) OF<br><b>SAMPLE</b>  |  | NO.<br><b>FPC XXXXXXX</b>                                |   |
|   |  | DATE INSPECTED   |   |
| <b>CERTIFICATION</b>  |  |  |   |
| This is to certify that the plants, plant product or other regulated articles described herein have been inspected and/or tested according to appropriate official procedures and are considered to be free from the quarantine pests, specified by the importing contracting party and to conform with the current phytosanitary requirements of the importing contracting party including those for regulated non-quarantine pests. |  |  |   |
| <b>DISINFESTATION AND/OR DISINFECTION TREATMENT</b>   |  |  |   |
| 1. DATE   | 2. TREATMENT   |  |   |
| 3. CHEMICAL (active ingredient)   | 4. DURATION AND TEMPERATURE  |  |   |
| 5. CONCENTRATION  | 6. ADDITIONAL INFORMATION  |  |   |
| <b>DESCRIPTION OF THE CONSIGNMENT</b>   |  |  |   |
| 7. NAME AND ADDRESS OF EXPORTER<br><b>SAMPLE</b>  | 8. DECLARED NAME AND ADDRESS OF THE CONSIGNEE<br><b>SAMPLE</b>                                   |  |   |
| 9. NAME OF PRODUCE AND QUANTITY DECLARED<br><b>SAMPLE</b>   | 10. BOTANICAL NAME OF PLANTS<br><b>SAMPLE</b>  |  |   |
| 11. NUMBER AND DESCRIPTION OF PACKAGES<br><b>SAMPLE</b>   | 12. DISTINGUISHING MARKS<br><b>SAMPLE</b>  |  |   |
| 13. PLACE OF ORIGIN<br><b>SAMPLE</b>  | 14. DECLARED MEANS OF CONVEYANCE<br><b>SAMPLE</b>  |  |   |
|   | 15. DECLARED POINT OF ENTRY  |  |   |
| <b>WARNING:</b> Any alteration, forgery, or unauthorized use of this phytosanitary certificate is subject to civil penalties of up to \$250,000 (7 U.S.C. Section 7734(b)) or punishable by a fine of not more than \$10,000, or imprisonment of not more than 5 years, or both (18 U.S.C. Section 1001).   |  |  |   |
| <b>ADDITIONAL DECLARATION</b>   |  |  |   |
| <b>SAMPLE</b>   |  <b>NAPPO</b> |  | <b>SAMPLE</b>   |
| Page 1 of 1   |  |  |   |
| 16. DATE ISSUED   | 17. NAME OF AUTHORIZED OFFICER (Type or Print)   | 18. SIGNATURE OF AUTHORIZED OFFICER                      |   |
| No liability shall attach to the United States Department of Agriculture or to any officer or representative of the Department with respect to this certificate.  |  |  |   |

# 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.

**U.S. DEPARTMENT OF AGRICULTURE  
FOOD SAFETY AND INSPECTION SERVICE**

**Meat and Poultry Export Certificate of Wholesomeness**

A knowingly false entry or false alteration of any entry on this certificate may result in a fine of not more than \$10,000 or imprisonment for not more than 5 years or both (18 U.S.C. 1001). Additional penalties exist under the Federal Meat Inspection Act [21 U.S.C. 611(b) (1), (2), and (5), 21 U.S.C. 461] for an unauthorized or false alteration or misuse of this certificate.

|  |  |                          |  |  |  |   |  |
|--|--|--------------------------|--|--|--|---|--|
| 1. COUNTRY OF DESTINATION<br><b>ECUADOR</b>  |  | 2. ISO CODE<br><b>EC</b> |  | 5. CERTIFICATE NUMBER<br><b>MPM- XXXX</b>  |  | 6. CERTIFICATE TYPE<br><input checked="" type="checkbox"/> ORIGINAL<br><input type="checkbox"/> REPLACEMENT |  |
| 3. CONSIGNOR/EXPORTER (Applicant's name and address)<br><b>XXXXXX FOOD GROUP<br/>3100 XXXXXX STREET<br/>JACKSONVILLE, FL 32209</b> |  |                          |  | 7. EXPORT EST. NO. (Name and address)<br><b>XXXXXX<br/>XXXXX FOOD GROUP<br/>3100 XXXXX STREET<br/>JACKSONVILLE, FL 32209</b> |  |   |  |
| 4. CONSIGNEE/IMPORTER (Name and address)<br><b>XXXXXXXXXX<br/>XXXXXXXXXX<br/>QUITO<br/>ECUADOR</b>                                 |  |                          |  | 8. TOTAL NET WEIGHT<br><b>XXXX LBS</b>   |  | 9. TOTAL NO. OF PACKAGES<br><b>XXX</b>  |  |

| 10. DESCRIPTION OF PRODUCT<br>(Name of product) | 11. NET WEIGHT OF LOT <sup>1</sup> | 12. SPECIES | 13. NUMBER OF PACKAGES IN LOT <sup>1</sup> | 14. TYPE OF PACKAGES IN LOT <sup>1</sup> | 15. SHIPPING/ IDENTIFICATION MARKS <sup>1</sup> | 16. EST. NO. ON PRODUCT |
|---|------------------------------------|-------------|--|--|---|-------------------------|
| <b>130 CHUCK SH RIBL 4 RIB</b>                  | XXXX                               | BEEF        | X  | CASE                                     |   | B                       |
| <b>BEEF SIRLOIN FLAP BL LBP</b>                 | XXXX                               | BEEF        | X  | CASE                                     |   | B                       |
| <b>BEEF SKIRT CUTSOE CH LBP FZ</b>              | XXXX                               | BEEF        | X  | CASE                                     |   | B                       |
| <b>112A RIBS RIB ON 2B2</b>                     | XXXX                               | BEEF        | X  | CASE                                     |   | B                       |
| <b>BEEF SIRLOIN FLAP BL LBP</b>                 | XXXX                               | BEEF        | X  | CASE                                     |   | B                       |
| <b>BEEF COULETTE MUSCLE</b>                     | 3 XXXXX                            | BEEF        | X  | CASE                                     |   | BSX                     |
| <b>BEEF SIRLOIN FLAP BL LBP</b>                 | XXXX                               | BEEF        | X  | CASE                                     |   | B                       |
| <b>109E RIB EXPORT P2X2</b>                     | XXXX                               | BEEF        | X  | CASE                                     |   | B                       |
| <b>BEEF SHORT LOIN CH QX1 FZ</b>                | XXXX                               | BEEF        | X  | CASE                                     |   | B                       |


<sup>1</sup> As stated by applicant or contractor

17. REMARKS

18. I CERTIFY that the meat, meat food product or meat byproduct specified hereon is from animals that received both antemortem and postmortem inspection and were found sound and healthy and that it has been inspected and passed as provided by law and regulations of the Department and is sound and wholesome.

19. I CERTIFY that the poultry, poultry products or poultry food products specified above came from birds that were officially given an antemortem and postmortem inspection and passed in accordance with applicable laws and regulations of the United States Department of Agriculture and are wholesome and fit for human consumption.

NOT VALID UNLESS SIGNED BY A CERTIFYING OFFICIAL OF MEAT AND POULTRY INSPECTION PROGRAM

|   |   |   |
|---|---|---|
| By order of the<br>Secretary of Agriculture | <br>20. CERTIFYING OFFICIAL'S NAME AND TITLE<br><i>[Signature]</i> | 21. DATE SIGNED (MM/DD/YYYY)<br><br><i>08/08/2019</i> |
|---|---|---|

This certificate is receivable in all courts of the United States as prima facie evidence of the truth of the statements therein contained.  
This certificate does not excuse failure to comply with any of the regulatory laws enforced by the United States Department of Agriculture



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
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**

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

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

1. 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 perineumonía 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, proviene 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 sacrificio 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: XXXXXXXXXXXXXXXXXXXX  
XXXXXXXXXXXXXXXXXXXX



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

Date Issued: 8-8-2019

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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 especificos 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*

Signature of FSIS Inspection Official: XXXXXXXXXXXXXXXXXXXX



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

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- 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.*

Signature of FSIS Inspection Official: XXXXXXXXXXXXXXXXXXXXXXXXXXXX  
XXXXXXXXXXXXXXXXXXXXXXXXXXXX  
 Printed Name: XXXXXXXXXXXXXXXXXXXXXXXXXXXX  
XXXXXXXXXXXXXXXXXXXXXXXXXXXX  
 Title/Professional Degree: Consumer Safety Inspector



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

H. **Certificate to Foreign Government:**

 DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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Food and Drug Administration  
2098 Gaither Road  
Rockville, Maryland 20850

Certificate No. [REDACTED]

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

| <u>Name of Product(s)</u>       | <u>Name of Manufacturer/Distributor, Address</u>                           |
|---------------------------------|--|
| See Attached List<br>(One Page) | Manufacturer:<br>[REDACTED]<br>Islamabad - Pakistan                        |
|                                 | Distributor:<br>WILFRIEDY MED. CO. INC.<br>[REDACTED]<br>Chicago, IL 60616 |

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

[REDACTED]

Export Team Leader  
Regulatory Policy and  
Systems Branch  
Office of Compliance  
Center for Devices and  
Radiological Health

This certificate expires 24 months from the date notarized.

COUNTY OF MONTGOMERY  
STATE OF MARYLAND

Subscribed and sworn to before me this 26 day of May month 2005 year.

[REDACTED]

[REDACTED]

CHRISTOPHER MORRIS  
NOTARY PUBLIC, STATE OF MARYLAND  
County of Montgomery  
My Commission Expires January 1, 2009





# I. Sanitary Certificate for Exports:



UNITED STATES OF AMERICA  
SANITARY CERTIFICATE FOR EXPORTS



Country of Origin: USA  
Certification Authority: U.S. Department of Agriculture, Agricultural Marketing Service  
Reference Number of this Certificate: DX-800698839-8

I. Exporter (Name and Address)

[Redacted]

II. Identification of the Dairy Products (Information Supplied by the Manufacturer or Exporter)

Product Description: [Redacted]  
Condition or Kind of Treatment: pasteurized  
Type of Packaging: 25 kg. bag  
Number of Packages: 1600  
Total Net Weight: 40000 kg  
Required Temperature, Storage and Transportation: ambient  
Validity Date (Shelf Life): May 18, 2020

III. Origin of the Products: (Information Supplied by the Manufacturer or Exporter)

[Redacted]

Plant #: [Redacted] Plant #: [Redacted] Plant #: [Redacted]

IV. Product Destination: (Information Supplied by the Manufacturer or Exporter)

Origin: Baltimore  
Destination: [Redacted]  
[Redacted]  
Ecuador, 170508  
ECUADOR

Method of Transport: ocean

V. Sanitary Certification

- (1) The United States of America is free from Foot & Mouth Disease and Rinderpest.
- (2) The product was manufactured in facilities inspected and approved by the competent authority and subjected to regular audits or inspections aimed at ensuring that the processing is properly and hygienically carried out, to produce a product that is fit for human consumption.
- (3) The product was manufactured from milk or milk products that received a pasteurization treatment or adequate safeguards have been taken with the aim of avoiding public health hazards arising from pathogenic organisms associated with milk.
- (4) To the best of our knowledge, the product contains no harmful levels of contaminants.

December 7, 2018

MD XXXX XXXXX  
Export Certificate Coordinator  
USDA, Dairy Grading

Date Signed

Attachments:

No Attachments