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# **Report Name:** Food and Agricultural Import Regulations and Standards Export Certificate Report

**Country:** Italy

**Post:** Rome

**Report Category:** FAIRS Export Certificate Report

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**Report Highlights:**

Italy, as part of the European Community, has implemented EU regulations for the import of products of animal and plant origin. The U.S. export certification requirements for most products destined for the EU and Italy have been harmonized. The few products not yet harmonized are subject to Italian regulations which can be found in this report.

## *TABLE OF CONTENTS*



## SECTION I: EXPORT CERTIFICATES REQUIRED BY ITALY AND PRODUCTS COVERED

Disclaimer: This report was prepared by the USDA/Foreign Agricultural Service in Rome, Italy for U.S. exporters of domestic food and agricultural products. While every possible care was 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 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 the importing country's rules and regulations as interpreted by the border officials at the time of product entry.

This report should be read in conjunction with the Italy FAIRS Food and Agricultural Import Regulations and Standards report, which can be found on the Post's website at https://it.usembassy.gov/embassy-consulates/rome/sections-offices/fas/.

All EU Member countries accept the "Community Acquis" (*i.e.*, the entire body of EU laws and obligations associated with the treaties and international agreements to which the EU is a party. EU Member States share a customs union, a single market in which goods can move freely, a common trade policy, and a common agricultural and fisheries policy.

The EU food legislation has been translated into the 24 official languages in use in the EU-28 (including Italian) and is published in the Official Journal. The Eurlex website provides free access to European Union laws.

It is important to note that when EU-wide legislation is incomplete or absent, Member States' laws apply, often resulting in different rules in different Member States. All imported products must meet Italian requirements in cases where EU regulatory harmonization is not yet complete. The competent Italian authority needs to be consulted on a case-by-case basis to address requirements for non-harmonized products.

Imported products to Italy must meet existing Member State requirements and products must be accompanied by the proper certification at port of arrival. In general, health certificates are required for all imported products of animal origin and phytosanitary certificates are needed for all plant products that could introduce pests into the EU. Unlike veterinary products, there is only one model certificate

for all plant products in accordance with international regulations laid out by the International Plant Protection Convention (IPPC) of the Food and Agriculture Organization of the United Nations.

In Italy, food safety is the primary responsibility of the Italian Ministry of Health, while food production is the primary responsibility of the Italian Ministry of Agriculture.

**USDA FAS Contact in Rome, Italy**

Office of Agricultural Affairs, Foreign Agricultural Service, U.S. Embassy Rome, Italy
Address: Via Veneto, 119a - 00187 Rome, Italy
Tel: (011)-(39)-06-4674-2396
Fax: (011)-(39)-06-4788-7008
E-mail: agrome@fas.usda.gov
Webpage: https://it.usembassy.gov/embassy-consulates/rome/sections-offices/fas/

FAS Italy publishes numerous market and commodity reports available through the Global Agricultural Information Network (GAIN) at: https://gain.fas.usda.gov/#/

**SECTION II: PURPOSE OF SPECIFIC EXPORT CERTIFICATE**

Export certificates must be in the official language of Italy, which is Italian. The import of special products must be approved by the Italian Ministry of Health. Usually, the importer (or possibly the U.S. exporter) applies to the Ministry with all the relevant details. There is no set form for this kind of application. In general, health certificates are required for all products of animal origin imported in the EU and Italy, and phytosanitary certificates are needed for all plant products that could introduce pests into the EU and Italy.

**Products of animal origin**

Import requirements for animals and animal products are harmonized across the EU in a three-part process:

i. The EU must recognize a country as eligible to export a particular animal or animal product. The EU recognizes the United States for all animal products. However, in absence of an approved U.S. residue plan for horsemeat, the United States has effectively been restricted from exporting horsemeat to the EU since 2011.

ii. The EU requires lists of approved establishments based on submissions from U.S. government agencies. Only those products processed at approved establishments may enter the EU. The U.S. agencies involved in listing are the Food Safety and Inspection Service (FSIS), the Animal and Plant Health Inspection Service (APHIS), and the U.S. Food and Drug Administration (FDA). Approved establishments may be subject to EU inspection.

iii. Animal or public health certificates based on the model certificates published by the EU and signed by U.S. officials must accompany all shipments. The U.S. certifying agency will cross out or delete any statements in the model certificate that are not applicable.

The EU and Italy impose a number of general requirements for all veterinary certificates. Of these, there is one in particular that has repeatedly caused rejections of shipments at EU borders. In accordance with Council Directive 2002/99 Annex IV.6 and EC Regulation 854/2004 Annex VI.6, certificates must be issued before the consignments to which they relate leave the control of the competent authority. The U.S. regulatory agencies that issue health certificates (FSIS, APHIS, and the Agricultural Marketing Service (AMS)) have all included this requirement in their export libraries, as subsequently referenced in this report. The new EU Official Controls Regulation (OCR) 2017/625, which repeals EC Regulation 854/2004 from December 14, 2019 onwards maintains the basic import requirements listed above.

**Plants and plant products**

EU and Italian import requirements for plants and plant products have also been harmonized and are published in a single directive. Unlike veterinary products, there is only one model certificate for all plant products in accordance with international regulations laid out by the International Plant Protection Convention (IPPC) of the Food and Agriculture Organization of the United Nations. For more information, see the export certification guide on the IPPC website. Phytosanitary certificates are issued by APHIS inspectors who can attest to specific requirements of EU legislation by making additional declarations in the relevant box.

**Composite Products - Products Subject/Not Subject to Veterinary Certification**

U.S. exports of composite products are continuing to be restricted due to burdensome certification requirements introduced in a 2012 European Commission Regulation. Composite products are defined as foodstuffs intended for human consumption that contain processed products of animal origin and ingredients of plant origin.

Composite products include a wide variety of products, including cheesecakes, high protein food supplements, pizza, and lasagnas. While the U.S. is eligible to ship hormone-free meat, dairy products, egg products, and fishery products separately, it is often no longer possible to ship the composite products that combine these eligible ingredients.

All composite products containing a processed meat product are subject to a veterinary check. Generally speaking, composite products that contain more than 50 percent of animal origin products also require a certificate, and there are certification requirements concerning the heat treatment for all dairy products. The EU has created a model health certificate for imports of composite products, which was implemented in 2012. A detailed "Product Decision Tree" to clarify the scope of the legislation was made available by the European Commission in 2013. This guidance greatly expanded the number and types of products affected by the legislation. The Decision Tree is included in the further guidance that was developed and published in 2015 to address a wide range of implementation questions related to the import and transit of composite products.

In order to have a more harmonized Member State application of EU legislation, Commission Decision 2007/275 publishes a list of animals and animal products that are subject to veterinary checks. This regulation also provides clarification on which composite products are subject to veterinary checks. Products subject to veterinary checks typically need to be accompanied by a veterinary certificate, issued by the competent authority in the United States. Commission Decision 2007/275 also lists certain composite products such as cakes and confectionery that are not subject to veterinary checks, provided they are shelf stable and properly packaged and labeled.

According to the Commission Implementing Regulation 2019/2007, new import conditions for composite products are scheduled to start applying from April 21, 2021 onwards.

## SECTION III: SPECIFIC ATTESTATION REQUIRED ON EXPORT CERTIFICATE

Whenever the EU publishes model veterinary certificates for use by eligible third country suppliers, U.S. regulatory agencies will cross-out or delete any statement that refers to health situations that are not relevant to the United States. Certificates for plants and plant products are issued by APHIS inspectors who attest to the specific requirements of EU legislation with the necessary declarations in the space provided on the phytosanitary certificate.

### U.S. Competent Authorities

The U.S. issuing agencies are identified by their acronyms. Following is a list of these agencies:

- **AMS: Agricultural Marketing Service, USDA**
  European Union Health Certification Program
  https://www.ams.usda.gov/content/european-union-health-certification-program

- **APHIS: Animal and Plant Health Inspection Service, USDA**
  International Animal Export Regulations:
  http://www.aphis.usda.gov/regulations/vs/iregs/animals/
  International Animal Products Export Regulations:
  http://www.aphis.usda.gov/regulations/vs/iregs/products/
  Plant Export Services:
  https://www.aphis.usda.gov/aphis/ourfocus/planthealth/sa_export/export_services_program

- **FDA: U.S. Food and Drug Administration, HHS**
  http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/default.htm

- **FSIS: Food Safety and Inspection Service, USDA**
  Export requirements for the European Union:
  https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products/export-library-requirements-by-country/European-Union

- **NOAA: National Oceanic and Atmospheric Administration, DOC**
  https://www.fisheries.noaa.gov/topic/seafood-commerce-certification

## SECTION IV: GOVERNMENT CERTIFICATE LEGAL ENTRY REQUIREMENTS

EU food legislation is characterized by a constant flow of new regulations and directives, amendments to existing legislation and implementation rules. EU laws are translated into the 24 official languages in use in the EU-28 and published chronologically in the Official Journal. Directives define the result that must be achieved, but leave to each Member State the choice of form and methods to transpose the directive into national laws (usually within 2-3 years after adoption). Regulations are binding in their entirety and automatically enter into force on a set date in all Member States. Amendments to EU legislation are usually published in new and separate Directives and Regulations, making it difficult to be sure of all possible amendments when doing research. Consolidated texts (*i.e.*, the consolidation of a basic legal act and subsequent amendments into one text) are available on the European Commission's website. When legislation is referenced in this guide, it is implied that all further amendments also apply. Where possible, this guide links directly to the consolidated versions of referenced EU legislation. The Eurlex website provides free access to European Union laws.

For all veterinary health certificates, the EU applies the following general principles of certification as defined in Council Directive 2002/99 and Regulation 854/2004:

1. The representative of the competent authority of dispatch issuing a certificate to accompany a consignment of products of animal origin must sign the certificate and ensure that it bears an official stamp. This requirement applies to every page of the certificate; all must be signed and stamped.

2. Certificates must be written in the official language(s) of the destination Member State (for Italy, they must be in Italian) as well as that of the border inspection Member State, or be accompanied by certified translations into all relevant languages. However, a Member State may consent to accept certificates written in one of the official languages of the European Community other than its own.

3. The original version of the certificate must accompany consignments on entry into the Community.

4. Certificates must consist of:

(a) a single sheet of paper; or
(b) two or more pages that are part of a single and indivisible sheet of paper; or
(c) a sequence of pages numbered so as to indicate that it is a particular page in a finite sequence; *e.g.*, '*page 2 of 4 pages.*'

5. Certificates must bear a unique identifying number. Where the certificate consists of a sequence of pages, each page must indicate this number.

6. The certificate must be issued before the consignment to which it relates leaves the control of the competent authority in the country of dispatch.

The EU requires the use of standardized certificates based on a model published in the Official Journal. The main certifying agencies in the U.S. (APHIS, FSIS, AMS, and NOAA) provide links in the export sections of their website to the certificates that they issue for export to the EU. FAS

cooperates closely with these agencies to ensure that up-to-date version of the certificates are made available to exporters.

An overview of harmonized EU official certificates that have been published in the Official Journal is given in Appendix 1. This overview should make it possible to find the necessary information for each export certificate concerning issuing agencies, validity, *etc*.

## SECTION V: OTHER CERTIFICATION/ACCREDITATION REQUIREMENTS

In accordance with EU regulations, health certificates are mandatory for imports of animal products as are phytosanitary certificates for imports of plant products. Some products may also take additional certificates, such as the quality certificate which allows for reduced import duties or marketing products under a specific label, as in the case of organic products. There are voluntary certificates that may help reduce the level of import controls.

### Live blood worms

APHIS has reviewed and updated the conditions for the export of live blood worms to Italy and decided that these animals should be exported with a live animal health certificate rather than an animal product certificate. A copy of the new bilingual (English/Italian) certificate can be downloaded from the APHIS website at:
http://www.aphis.usda.gov/regulations/vs/iregs/animals/downloads/it_anlid_fb_hc_ab.pdf

### Non-human primates

Research and diagnostic samples from non-human primates. Italy does not require any certification for samples from non-human primates that are:

- Embedded on microscope slides; or
- Suspended in formalin; or
- Suspended in alcohol.

For other samples, Italy requires the health certificate for export of samples (other than processed DNA samples, and those embedded completely on micro slides, or preserved in alcohol or formaldehyde) from non-human primates intended for scientific research.

Prior to endorsement of the above referenced health certificate, APHIS must inspect the collection facility to verify the pertinent criteria. In addition, lab reports as referenced in the certificate will be required for each source animal. For more information, please contact your local Veterinary Services Field Office. More information can be viewed on the APHIS website at:
https://www.aphis.usda.gov/regulations/vs/iregs/products/downloads/it_cert_nhp.pdf

**Quick-frozen vegetables**

Italy requires that all third country establishments that intend to export quick-frozen vegetables register with the Italian Ministry of Health (article 10 of Legislative Decree 1/27/1992 n. 110 implementing Directive 89/108). The ministry defines such items as foodstuffs which have undergone a suitable freezing process known as 'quick-freezing' whereby the zone of maximum crystallization is crossed as rapidly as possible, depending on the type of product, and the resulting temperature of the product (after thermal stabilization) is continuously maintained at a level of -18°C or lower at all points. Italy gives the following EU regulations as the basis for its regulation: Regulation 852/2004 on the hygiene of foodstuffs; Commission Regulation 37/2005 on the monitoring of temperatures in the means of transport, warehousing, and storage of quick-frozen foodstuffs intended for human consumption; and Council Directive 89/108 on the approximation of the laws of the Member States relating to quick-frozen foodstuffs for human consumption.

In order to notify Italian authorities, the establishment must complete an application with specific attachments and address it to the following office:

Ufficio II della DGSAN
Ministero della Salute
Viale Giorgio Ribotta, 5 - 00144 Rome, Italy

The application should be sent through the Italian Embassy in Washington, with the following requested documentation:

- Application form completed by the exporting Food Business Operator (FBO);
- Technical report concerning the main features of the production plant;
- Statement of the local competent authority of the country of origin that the quick-frozen vegetables exported to Italy are produced in compliance with Council Directive 89/108, and that the legislation in force in the country of origin is equivalent to the EU legislation.

The Italian Ministry of Health reviews all of the documentation and has the right to ask for additional documents or call a meeting with the applicants. Once the third country establishment is approved by the Italian authorities, the list is updated and posted on the website of the Ministry of Health, and the company is allowed to export quick-frozen vegetables to Italy.

## APPENDIX I: ELECTRONIC COPY OR OUTLINE OF EACH EXPORT CERTIFICATE

### A. APHIS CERTIFICATES FOR ANIMALS AND GENETICS

**IMPORTANT:** The list of certificates provided below should be seen in conjunction with the additional information on EU import requirements provided at: https://www.aphis.usda.gov/aphis/ourfocus/importexport. The APHIS website is updated on a regular basis to incorporate all developments in EU import requirements for all products under APHIS jurisdiction.

**Annelids**

- Annelids – Health certificate for the import of live annelids into Italy – August 2015

**Aquaculture**

- Aquaculture animals for farming, relaying, or put and take fisheries, and/or intended for open ornamental facilities – Annex IV, Part A, Commission Regulation 1012/2012 – February 2013
- Ornamental aquatic animals intended for closed ornamental facilities – Annex IV, Part B, Commission Regulation 1012/2012 – February 2013
- Live bivalve molluscs, echinoderms, tunicates, and marine gastropods intended for human consumption – Annex V, Part A, Commission Regulation 1250/2008 – May 2009

**Aquatic turtles**

- Aquatic turtles – Commercial – Animal health certificate for imports into Italy from the United States of water turtles

  ***Note:*** *The import of Mauremide caspica, Chelydra serpentina, and Macroclemmis temminchi species is prohibited.*

**Bovine Embryos**

- Bovine embryos, Annex II – Health certificate for *in vivo*-derived embryos collected in accordance with Council Directive 89/556 – November 2013
- Bovine embryos, Annex III – Health certificate: i*n vitro*-derived embryos, conceived using semen complying with Council Directive 88/407 (eligible for intra-Community trade) – August 2013
- Bovine embryos, Annex IV – Health certificate: *in vitro*-derived embryos, conceived using semen coming from an approved semen collection/storage center (excluded from intra-Community trade) – August 2013
- Bovine embryo collection/production team inspection – Checklist – September 2014

  *List of EU-approved bovine embryo collection and production teams (click on "United States" at bottom of the page).*

**Birds (non-Poultry)**

***Note:*** *Import conditions for birds intended for zoos, conservation programs, and research are determined by the importing country. The importer should request this information from the government of the Member State of destination.*

- Captive bred birds – Health certificate – March 2013

***Note:*** *"Captive bred birds" is defined as "birds that have not been caught in the wild, but have been born and bred in captivity from parents that mated or had gametes otherwise transferred in*

*captivity." This does not apply to poultry (fowl, turkeys, guinea fowl, ducks, geese, quail, pheasants, partridges), pigeons, ratites, birds for conservation programs, pets, or birds intended for zoos.*

- Checklist for approval of captive bred bird breeding establishments – March 2013
- Captive bred raptor – Health certificate – February 2013

***Note:** Raptors eligible for export to the EU are captive bred raptors which do not fall into these categories:*

- *pet birds accompanying their owner*
- *birds imported for conservation programs approved by the competent authority of the Member State of destination*
- *birds intended for zoos, circuses, amusement parks*
- *research birds*

*Captive bred raptors must originate from an approved breeding bird establishment meeting these conditions.*

**Bovine Semen**

- Bovine semen Model 1 – Health certificate for imports into and transits through the EU of bovine semen dispatched from a semen collection center where the semen was collected – June 2015
- Bovine semen Model 2 – Health certificate for bovine semen collected, processed, and stored before 31 December 2004 and dispatched from a collection center where the semen was collected – November 2011
- Bovine Semen Model 3 – Health certificate for imports into and transits through the EU of bovine semen dispatched from a semen storage center
- Bovine semen collection center – Checklist/Questionnaire – September 2017
- Bovine semen storage center – Checklist/Questionnaire – February 2012

*List of EU-approved bovine semen collection centers and bovine semen storage centers (click on "United States" at bottom of the page).*

**Canine Semen**

- Canine Semen – Veterinary certificate for introduction and import into Italy of canine semen from third and EU countries – June 2015

**Commercial rabbits/hares**

***Note:** Exporters must obtain an import permit from the Italian Ministry of Health. Requests can be made to:* l.presutti@sanita.it.

**Equine Embryos**

- Model 1 – Equine embryos collected after September 30, 2014 – Health certificate – October 2018
- Model 2 – Equine embryos collected after August 31, 2010 and before October 1, 2014 – Health certificate – October 2018
- Equine embryo collection/production team – Checklist

***Note:*** *List of EU-approved equine embryo collection teams (scroll to bottom of the page and click on "United States").*

**Equine Semen**

- Model 1 – Equine semen collected after September 30, 2014 and dispatched from the semen collection center of origin – Health certificate– October 2018
- Model 2 – Equine semen collected after August 31, 2010 and before October 1, 2014 and dispatched from the semen collection center of origin – Health certificate – October 2018
- Model 3 – Equine semen collected before September 1, 2010 and dispatched from the semen collection center of origin – Health certificate – October 2018
- Model 4 – Equine semen dispatched from a semen storage center – Health certificate – October 2018
- Equine semen collection center – Checklist – October 2018
- Equine semen storage center – Checklist – October 2018

***Note:*** *List of EU-approved equine semen collection centers and equine semen storage centers (scroll to bottom of the page and click on "United States")*

**Live Horses**

- Equine – Permanent admission – Individual registered horse, registered equine animal, or equine animal for breeding and production – Health certificate – October 2018
- Equine – Temporary admission of registered horse for less than 90 days – Health certificate – October 2018
- Equine – Transit of live equidae – Health certificate – October 2018
- Equine – Re-entry of registered horses for racing, competition, and cultural events after temporary export for less than 30 days – Health certificate – October 2018
- Equine – Re-entry of registered horses in FEI-organized equestrian events after temporary export for less than 90 days – Health certificate – October 2018
- Equine – Re-entry of registered horses after temporary export for less than 90 days in specific race events in Australia, Canada, the United States of America, Hong Kong, Japan, Singapore, the United Arab Emirates, or Qatar – Health certificate – October 2018
- Addendum for horses exported to EU from the United States staying less than 60 days in the EU, with subsequent direct travel to Canada – April 2017

**Live Swine**

- Breeding swine – Health certificate – January 2018

**Ovine/Caprine Semen**

- Ovine and caprine semen – Health certificate – Nov 2016
- Ovine and caprine semen collection center inspection – Checklist – August 2010

***Note:*** *Additional information about export of ovine/caprine semen to the EU.*

**Ovine/Caprine Embryos**

- Ovine and caprine embryos – Health certificate – November 2016
- Ovine and caprine embryos – Certificate of approval – September 2010
- Ovine and caprine embryos – Checklist/questionnaire – September 2010

***Note:*** *Additional information about export of ovine/caprine semen and embryos to the EU.*

**Poultry**

- Hatching eggs, non-ratite – Health certificate – March 2016
- Day-old chicks, non-ratite – Health certificate – March 2016

***Note:*** *Part II of the day-old chick certificate must be issued by an accredited veterinarian within 10 days prior to export and must be endorsed by APHIS. Part III of the certificate must be issued on the day of hatch and does not need APHIS endorsement. The accredited veterinarian must apply a stamp to Part III containing his/her name, company name, and accreditation number. The original copy of Part III must be attached to Part II of the certificate.*

- SPF eggs certificate – September 2009
- Less than 20 poultry (not ratite, hatching eggs, or day-old chicks)

**Research / Lab Animals**

- Research dogs, cats, and ferrets – Health certificate for research animals destined for bodies, institutes, or centers approved in accordance with Annex C to Directive 92/65

**Swine Semen**

- Porcine semen health certificate – March 2012
- Porcine semen collection center – Checklist/questionnaire – March 2012

***Note:*** *Additional information about export of porcine semen to the EU.*
*List of EU-approved porcine semen collection centers (click on "United States" at bottom of page).*

For species not listed, the requirements are not known. However, exporters wanting to ship livestock whose requirements are not listed above, should have the interested party (importer/buyer) in the country of destination apply for an Import Permit at the appropriate ministry. This Import Permit will most likely outline the specific requirements.

**Note:** Bilingual health certificates (English/Italian) are available for some species/commodities. Please refer to the following link: https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/international-standard-setting-activities-oie/regionalization/sa_by_country/sa_i/ct_animal_italy for available bilingual health certificates. It is the responsibility of the exporter to obtain a bilingual certificate if it is not available on the Member State link.

## B. APHIS CERTIFICATES FOR ANIMAL PRODUCTS

**IMPORTANT:** The list of certificates provided below should be seen in conjunction with the additional information on EU import requirements provided on the APHIS website. The APHIS website is updated on a regular basis to incorporate all developments in EU import requirements for all products under APHIS jurisdiction.

All EU harmonized certificates (all certificates located in English under the European Union general information file) must be in both English and Italian if the "Entry BIP in EU" listed in section I.16 of the certificate is located in Italy. Exporters should not present these certificates to APHIS for endorsement unless they are prepared with all text in both English and Italian. Exporters should work with their importers to create the bilingual versions. Note: if a consignment is entering the EU through Italy, but destined to a different EU country, that country may also require a third language to be included.

### Animal Products for Human Consumption

- Abomasums and derivatives (including "rennets" and "rennin") for the production of materials for human consumption – August 2016
- Chondroitin sulfate, hyaluronic acid, other hydrolyzed cartilage products, chitosan, glucosamine, rennet, isinglass and amino acids – August 2017
- Collagen and gelatin – Raw materials for the production of gelatin and collagen for human consumption for TRANSIT of the European Union
- Collagen and gelatin – Treated animal byproducts for the production of gelatin and collagen for human consumption (TCG) – For certificates dated on or before December 14, 2019 for consignments which will clear into the EU by March 13, 2020
- Collagen and gelatin – Treated animal byproducts for the production of gelatin and collagen for human consumption (TCG) – For certificates dated any time
- Collagen and gelatin – Untreated animal byproducts for the production of gelatin and collagen for human consumption (RCG) – For certificates dated on or before December 14, 2019 for consignments which will clear into the EU by March 13, 2020

- Collagen and gelatin – Untreated animal byproducts for the production of gelatin and collagen for human consumption (RCG) – For certificates dated any time

**Animal Products not for Human Consumption**

TRACES: Information on requirement for facilities to be listed on TRACES (July 2015)

Guidelines for Preparation of EU Regulation 142/2011 Export Certificates – November 2019

Facilities must be approved by APHIS in compliance with EU Regulation 142/2011 to export the below commodities. Any exceptions would be noted in the specific article. Please contact your veterinary service center for details on how to request required approvals and certificates.

- Animal by-products for the manufacture of products for purposes other than human or animal consumption – Chapter 8
- Antibodies (purified antibodies derived from cell cultures) – May 2012
- Apiculture by-products (including beeswax) – May 2017
- Artemia cysts (aquatic invertebrate cysts or "eggs") and derivatives – June 2012
- Blood products for livestock feed – Chapter 4 (B)
- Blood – blood products from equidae animals intended for technical purposes – Chapter 4 (A)
- Blood – treated blood products from livestock not including equidae animals – Chapter 4 (D)
- Blood – untreated blood products (not including those from equidae animals) – Chapter 4 (C)
- Collagen (for purposes other than human consumption) – Chapter 11
- Dicalcium Phosphate – Chapter 12
- Display items (for trade shows) – APHIS facility approval not required – March 2011
- Egg products intended for livestock feeding – Chapter 15 – February 2012
- Fat – Rendered animal-origin fat for the production of biodiesel – Chapter 10 (B)
- Feathers – June 2011
- Fish meal and fish oil – May 2013
- Furs – May 2012
- Gelatin (for purposes other than human consumption) – Chapter 11
- Hair/wool
- Hides – fresh or chilled hides and skins of ungluates – Chapter 5 (A)
- Hides – treated hides and skins of ungulates – Chapter 5 (B)
- Hydrolyzed proteins – Chapter 12
- Insect-origin processed animal protein – not including pet foods – May 2017
- Intermediate products – Importer declaration for the import from third countries and for the transit through the European Union of intermediate products to be used for the manufacture of medicinal products, veterinary medicinal products, medical devices, in vitro diagnostics, and laboratory reagents – Chapter 20
- Invertebrate cysts (aquatic) - See Artemia cysts
- Laboratory/zoo animal food (animal-origin foods for laboratory and zoo animals) – May 2011
- Manure including guano – Chapter 17
- Milk and milk-based/derived products not for human consumption
- Pet food (canned) – Chapter 3 (A)

- Pet food (chews) – Chapter 3 (C)
- Pet food (processed pet food other than canned) – Chapter 3 (B)
- Pet food ingredient: flavoring innards (includes digests) – Chapter 3 (E)
- Pet food ingredient: unprocessed animal by-products – Chapter 3 (F)
- Pet supplements (animal-origin) – January 2018
- Pig bristles – Chapter 7 (A)
- Research and diagnostic samples – APHIS facility approval not required – May 2012
- Trade samples (not including display items for trade shows) – APHIS facility approval not required
- Tricalcium Phosphate – Chapter 12
- Trophies having been submitted to a complete taxidermy treatment – November 2011
- Trophies partially treated game trophies consisting only of hides, skins, bones, horns, hooves, claws, antlers, and/or teeth of ungulates or birds – Chapter 6 (A)
- Used cooking oil – see yellow grease
- Yellow grease (used cooking oil) – August 2011
- Wool – See hair/wool

## C. FSIS CERTIFICATES FOR MEAT, POULTRY, EGG PRODUCTS

IMPORTANT: The list of FSIS health certificates for the EU provided below should be seen in conjunction with the additional information on EU import requirements provided on the FSIS website. The FSIS website is updated on a regular basis to incorporate all developments in EU import requirements for all products under FSIS jurisdiction.

FSIS issues health certificates for the following products shipped to the EU with the intention to be sold on the EU market:

- Fresh meat: beef and bison, pork, poultry, and wild boar.

- Further processed products from fresh meat that is eligible for certification to the EU, whether the fresh product is sourced inside or outside the U.S.

- Egg products under FSIS authority: egg products under the authority of FSIS are liquid, frozen, or dried eggs, with or without ingredients.

The European Union requires specific certificate models for “fresh meat,” “meat preparations,” and “meat products.” These terms are defined in EU legislation and explained on the FSIS website. The European Union also requires a specific certificate model for animal casings.
Only meat and poultry slaughtered, processed, and stored at EU approved establishments may be certified for export to the EU. Detailed information is available from section XIV “Plant Approval Process” in the FSIS export library.

Advisory - Exporters should verify that the shipping date on any export certificate or accompanying shipping documents does not precede the FSIS signature date on the certificate. Failure to do so can result in the detention of the shipment at the Port of Entry into the European Union.

The exporter should check with their importer whether letterhead certificate for each product type, in one shipment, should have a unique number in Box I.2, which is the serial number of the corresponding 9060-5, Meat and Poultry Export Certificate of Wholesomeness.

Effective January 24, 2017, FSIS changed the instructions to its field inspectors on "in-lieu-of" or replacement certificates. The date on these replacement certificates henceforth has to be the current date. In addition, FSIS is now limiting the time for which a replacement certificate can be issued without re-inspection to ninety calendar days for products that are not frozen or not shelf stable and to 364 calendar days for frozen or shelf stable products. FSIS is limiting the reasons a replacement certificate can be issued to specific conditions. FSIS is also modifying the conditions needed to issue a replacement certificate when the destination country changes (FSIS Notice 83-16).

An important feature of all EU-specific export certificates is the requirement for the application of an Export Stamp identifying the Certificate Number indicated on FSIS Form 9060-5 Export Certificate of Wholesomeness. The Export Stamp must be applied in the area on the certificate provided for an "Official Stamp" in the signature block on the last page of the certificate as well as at the bottom of each preceding page of the certificate along with the signature. The Export Stamp must be applied in a color of ink other than black. The signature of the FSIS official signing the certificate must be in a color of ink other than black.

Transit Certificates: Meat, poultry, or egg products destined for a non-European Union country, for ships' stores, or for U.S. military use that is transiting through, is destined for a U.S. military base within, or is being temporarily stored in an EU Member State must have the appropriate transit certificate. This also applies to composite products defined by the EU as "foodstuffs intended for human consumption that contain both processed products of animal origin and products of plant origin and includes those where the processing of primary product is an integral part of the production of the final product".

FSIS also signs the Certificates of Authenticity for beef and bison that allow for imports in the EU at reduced tariffs under specific Tariff Rate Quotas.

**D. AMS CERTIFICATION FOR DAIRY PRODUCTS**:

See: https://www.ams.usda.gov/services/imports-exports/dairy-exports/eu-dairy-exports

Dairy products fall under FDA jurisdiction; however, FDA has delegated authority to sign health certificates to USDA's Agricultural Marketing Service (AMS). In order to obtain a EU health certificate, the manufacturers must have their final production, blending, and/or packing facility listed on the FDA Dairy Plant Reference List (pdf) of EU-approved facilities. Industry may apply for inclusion on these lists via the Export Listing Module (ELM). Please visit on-line applications for export lists for a link to this electronic system and step-by-step instructions.

The AMS website provides all necessary information allowing U.S. exporters to obtain one of the following certificates for the EU from the AMS dairy grading branch:

- **Dairy EU Health** – the milk HTB health certificate for consignments of milk and milk based products shipping directly to the EU.
- **Dairy EU Transit** – the milk transit/storage health certificate for milk and milk based products shipping through the EU to a third non-EU country, cruise vessel, or U.S. military installation.
- **EU Composite Health** – the dairy composite health certificate for milk and milk-based composite products shipping directly to the EU.
- **EU Composite Transit/Storage** – for milk and milk-based composite products shipping through or being stored in the EU before shipping through to a third non-EU country, cruise vessel, or U.S. military installation.
- **EU Raw Milk Products Health** – the EU RMP health certificate for products made from unpasteurized raw milk, i.e. aged raw milk cheeses shipping directly to the EU.
- **Dairy EU Storage** – the milk transit/storage health certificate for milk and milk-based products being stored in the EU prior to shipping to a non-EU country, cruise vessel, or U.S. military installation.

Detailed information is provided on the on-line procedures to obtain these documents. The AMS site also contains specific guidance for exporters of whey protein supplements. For replacing certificates, please refer to article 5 of Commission Implementing Regulation 2019/628.

For more information, contact:
William Francis
william.francis@usda.gov

**E. AMS CERTIFICATION FOR EGGS AND EGG PRODUCTS**

See: http://www.ams.usda.gov/services/imports-exports/eggs-egg-products

Also in the egg sector, FDA has delegated the authority for export certification to USDA's Agriculture Marketing Service (AMS). The AMS Livestock, Poultry, and Seed Division is responsible for the export certificates for the food products containing eggs or egg products that are regulated by FDA. In addition to shell eggs, FDA-regulated egg products include hard boiled eggs, cooked omelets, frozen egg patties, imitation egg products, egg substitutes, noodles, cake mixes, freeze-dried products, dietary foods, dried no-bake custard mixes, egg nog mixes, acidic dressings, mayonnaise, milk and egg dip, foods containing egg extracts, French toast, sandwiches containing eggs or egg products, balut, and other similar ethnic delicacies.

The AMS Livestock, Poultry, and Seed Division issues the certificates based on exporter request in the form of a worksheet: Processed egg and processed egg products worksheet (EU only).

## F. AMS CERTIFICATION FOR HONEY

See:
https://www.ams.usda.gov/services/imports-exports/honey
https://www.ams.usda.gov/sites/default/files/media/HoneyEuropeanUnionCertification.pdf

The new model official certificate for the entry into the European Union for placing on the market of honey and other apiculture products intended for human consumption is available at: Commission Implementing Regulation 2019/628.

## G. NOAA CERTIFICATES FOR SEAFOOD

See: https://www.fisheries.noaa.gov/content/export-certification

FDA has delegated the authority for export certification of fish and fishery products to the U.S. Department of Commerce National Oceanic and Atmospheric Administration (NOAA). However, establishments wishing to export fish and fishery products to the EU still need to apply to FDA for inclusion on the EU export certificate list. To apply for the EU seafood export list, please contact the FDA coordinator in your district.

The NOAA Seafood Inspection Program is the competent authority within the U.S. Government for issuance of certain certificates required for export of fish and fishery products to the EU. The program offers three documents required for export to the EU. They are:

- EU export health certificate;
- EU IUU (illegal, unregulated, and unreported) catch document for fisheries products harvested in the United States, to prevent, deter, and eliminate IUU fishing;
- EU "Annex IV" catch document for products harvested in a country other than the United States, but being exported through the United States to the EU, to prevent, deter, and eliminate IUU fishing.

Under EU regulations, an export health certificate is required as well as one of the two catch documents. These certificates must be requested and issued prior to shipment of product. Procedures to request EU health certification are available from the NOAA website.

The current U.S. simplified fishery products certificate, covered by U.S.-EU veterinary equivalency agreement (Council Decision 98/258), will not be impacted by Commission Implementing Regulation 2019/628 for the products coming directly from the U.S. However, in the case of triangular trade, for products first imported into the U.S. and re-dispatched to the EU without substantial processing in the U.S., NOAA will issue fishery products certificates according to Commission Implementing Regulation 2019/628.

For additional information on exporting seafood to the EU, contact stephane.vrignaud@trade.gov.

## H. FDA CERTIFICATES

| Product | Official Journal Reference/Model from the Official Journal | U.S. Issuing Agency | Title/Comments |
|---|---|---|---|
| Gelatin intended for human consumption | 2016/759 or 2003/863 | FDA is the competent authority. Contact the FDA bulk collagen gelatin export listing group at BulkCGExport-LM-OFS@fda.hhs.gov to request the appropriate certificate. | Model certificate for imports of gelatin intended for human consumption. |
| Collagen intended for human consumption | | | Model certificate for imports of collagen intended for human consumption. |
| Highly refined chondroitin sulphate, hyaluronic acid, other hydrolysed cartilage products, chitosan, glucosamine, rennet, isinglass, and amino acids intended for human consumption | 2016/759 | FDA is the competent authority. Contact CFSANExportCertification@fda.hhs.gov to request the appropriate certificate. | Model certificate for imports of highly refined chondroitin sulphate, hyaluronic acid, other hydrolysed cartilage products, chitosan, glucosamine, rennet, isinglass, and amino acids intended for human consumption. |

## I. PEDIGREE AND ZOOTECHNICAL CERTIFICATES

| Product | Official Journal Reference/ Model from the Official Journal | Title/Comments |
|---|---|---|
| Live Animals | 96/509 Annex I | Pedigree and zootechnical certificate for the importation of semen from pure-bred breeding animals of the bovine species, pure-bred breeding pigs, pure-bred breeding sheep and goats which have not undergone performance test and genetic value assessment. |
| | 96/509 Annex II | Certificate for the limited importation of untested semen from pure-bred breeding animals of the bovine species, pure-bred and breeding pigs, pure-bred breeding sheep and goats to be used for genetic evaluation. |
| | 96/509 Annex I | Pedigree and zootechnical certificate for the importation of pure-bred breeding animals of the bovine species, pure-bred breeding pigs, sheep and goats. |

## J. APHIS PLANT HEALTH CERTIFICATES

See: https://pcit.aphis.usda.gov/PExD/signIn

APHIS is responsible for issuing phytosanitary certificates. The resource for foreign country requirements for certifying officials is the Phytosanitary Export Database (PExD) managed by the APHIS Plant Protection and Quarantine (PPQ) Phytosanitary Issues Management (PIM) Export Services (ES) unit. This unit interprets and updates all foreign requirements according to APHIS' ability to meet U.S. export policies. The PExD website covers both EU harmonized and Member State specific requirements. The contact information for APHIS-PPQ-Export Services is: PPQExportServices@aphis.usda.gov.

The APHIS Plant Health Export Information site provides also additional information on wood packaging materials and certification programs such as the European Union Ash Systems Approach Program for Lumber.

## K. OTHER PLANT CERTIFICATES

| Product | Official Journal Reference/Model from the Official Journal | U.S. Issuing Agency | Title/Comments |
|---|---|---|---|
| Wheat (other than durum) | 642/2010 | FGIS | Quality certificate for high quality wheat. Without the certificate, a security must be paid until tests are done to show that the product meets EU standards.<br>Federal Grain Inspection Service (FGIS) contact information: https://www.ams.usda.gov/resources/fgis-field-offices |
| Malting barley | 1064/2009 | FGIS | Certificate of conformity: quality certificate providing access to the 50,000 MT TRQ. The security that is paid upon import is reduced for goods shipped with the certificate.<br>FGIS contact information: https://www.ams.usda.gov/resources/fgis-field-offices |
| Corn gluten feed | 2007/1375 | FGIS | Commodity inspection certificate.<br><br>FGIS contact information: https://www.ams.usda.gov/resources/fgis-field-offices |
| | | CRA | Certificate of conformity was updated in February 2017.<br>See also Corn Refiners Association (CRA) http://www.corn.org/wp- |

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| | | | content/uploads/2009/12/Feed2006.pdf (pp.8-9). |
| Corn gluten meal (Tariff Code 23031011) | 2015/2447 art. 57-59 and Annex 22-14 special non-preferential import arrangements | Louisiana Maritime Chamber of Commerce | Certificate of origin is required to import under the TRQ of Regulation 937/2006.<br><br>Louisiana Maritime Chamber of Commerce cooperates with the Corn Refiners Association. |
| Food supplements classified under EU (Tariff Code 21069098) | 2017/1329 | None | Implementing Regulation 2017/1329 removed the certificate of origin requirement issued by a U.S. Chamber of Commerce for goods shipped within the U.S. specific tariff rate quota for food supplements under CN code 21069098. |
| Fresh fruits and vegetables | 543/2011 Annex III | None | Certificate of conformity with the community marketing standards for fresh fruit and vegetables. No U.S. agency issues this certificate. Imports to the EU can be certified at the border. |
| Wine, grape juice (*), or grape must | 2006/232 Annex III Agreement between the European Community and the United States of America on trade on wine<br>2018/2735 VI-1 Form | TTB | Commercial document to accompany wine products originating in the United States.<br><br>Imports of wine into the EU must be accompanied by a "VI-1" document, published in Commission Delegated Regulation 2018/273. This is a certificate of origin and analysis issued in the country of origin. As a result of the U.S.-EU wine agreement, the U.S. can follow a simplified procedure and use the commercial document to accompany wine products originating in the United States in Annex III of the Agreement. Wine producers that have received individual approval of the competent authorities may draw up the document. TTB (Department of the Treasury - Alcohol and Tobacco Tax and Trade Bureau) provides detailed information on certification of U.S. wine for export to the EU on its |

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| | | | website. The list of approved U.S. wine producers and laboratories delegated to draw up the document is published on the European Commission's website: http://ec.europa.eu/agriculture/wine/lists/06.pdf<br><br>(*) As of July 1, 2013, U.S. operators can start using a simplified VI-1 commercial document to accompany grape juice exports to the EU. The U.S. Government no longer needs to sign certificates attesting that grape juice destined for the EU market is produced in accordance with EU wine-making practices. U.S. exporters of grape juice are allowed to self-certify that the grape juice will not be used in wine-making. |
| Fresh 'Emperor' table grapes | EU Tariff Schedule 2016/1821 Annex 9 | USDA/AMS, or Arizona Department of Agriculture, or California Department of Food and Agriculture | Certificate of authenticity for fresh 'Emperor' table grapes.<br><br>For tariff calculation purposes 2016/1821 amends 2658/87. |
| Tobacco | EU Tariff Schedule 2016/1821 Annex 9 | Tobacco Association of U.S. | Certificate of authenticity for tobacco. For tariff calculation purposes 2016/1821 amends 2658/87. |
| Peanuts | None | | Regulation 2017/1269 stipulates that the U.S. pre-export program for peanuts is no longer recognized by the EU. There is no restriction on the export of U.S. peanuts. |
| Almonds | 2015/949 Annex II | USDA/AMS is the competent authority for the PEC program. Shipping point inspection within the California Department of Food and | Use of this certificate is not mandatory.<br><br>The USDA Agricultural Marketing Service started to issue PEC almond certificates on August 1, 2015. The almond PEC program builds on and replaces the Voluntary Aflatoxin Sampling Plan (VASP) program, which stopped being required in September |

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| | | Agriculture is responsible for signing the PEC certificate as the local competent authority. | 2014 when the EU voted to remove California almonds from Special Measures (removal from 1152/2009). A PEC certificate is only issued if aflatoxin testing is done according to EU protocol in USDA approved laboratory.<br><br>See also: http://www.ams.usda.gov/services/lab-testing/aflatoxin.<br>For further information, see Almond Board of California. |
| Organics | 2016/1842 | USDA/AMS | The EU has implemented a new system of electronic certificates of inspection for imports of organic products in the EU as of October 19, 2017. The electronic certificates replace the paper-based certificates of inspection. The electronic certificates are accessible through the EU's Trade Control & Expert System (TRACES). More information here: https://ec.europa.eu/agriculture/organic/sites/orgfarming/files/quick_reference_guide.pdf |
| Seeds for sprouting | 2019/628 | AMS | A new seed for sprouting certificate is required as of Dec 14, 2019 by Commission Implementing Regulation 2019/628. |
| Hop cones, hop powders, saps, and extracts of hops | 1295/2008 | Washington Department of Agriculture - State Chemical and Hop Lab<br><br>Idaho Department of Agriculture - Division of Plant Industries<br>Hop Inspection Lab<br><br>Oregon Department of Agriculture - | Attestation of equivalence. |

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| | | Commodity Inspection Division<br><br>California Department of Food and Agriculture (CDFA-CAC) - Division of Inspection Services Analytical Chemistry Laboratory<br><br>USDA, GIPSA, FGIS, TSD, Tech Service Division, Technical Testing Laboratory (MO) | |

**Attachments:**

No Attachments