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GAIN Report

Global Agricultural Information Network

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Food and Agricultural Import Regulations and Standards - Certification

FAIRS Export Certificate Report

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Report Highlights:

This guide provides an overview of export health certificates needed for exporting plants, animals, foods and other animal origin products to the European Union. U.S. regulatory agencies have been informed of the wide range of certificate changes that have occurred in the past months and have updated their export manuals to reflect those changes. Sections updated: All sections.

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

WHAT IS NEW

All sections of the previous FAIRS Export Certificate Report have been updated to reflect EU certification requirements at the time this report was written. For the most recent update, also check the referenced website of the agencies issuing the certificates.

This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service in Brussels, European Union (EU), 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 BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.**

The document requirements for exporting animals, plants and food to the EU are extensive. EU member states are: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom. Montenegro, the Former Yugoslav Republic of Macedonia, Turkey, Albania and Serbia are candidates to join the EU. In June 2016, the U.K. voted in a referendum to leave the EU. Until negotiations on an exit agreement between the U.K. and the other 27 Member States are concluded, the U.K. remains a member of the EU.

Certification requirements are developed at EU level and model certificates are published in the Official Journal of the European Union. The EU requires that U.S. certifying agencies use these standard formats. It should be noted, however, that certain certificates may not be available to exporters if the concerned products have never been exported to the EU before or if the relevant U.S. authority is not in a position to provide the guarantees as required by the EU.

While certification requirements are developed at the EU level, the Member State inspection services are responsible for enforcement of EU legislation through inspection of imported goods and the corresponding certificates.

The application of the EU certification system is not limited to full EU members. EU certification requirements are also fully or partly imposed by EFTA counties (Liechtenstein, Iceland, Norway, and Switzerland) and increasingly also by certain EU neighboring countries, often in preparation for their future EU membership.

Section II. Purpose of Specific Export Certificate(s)

EU legislation calls for many health and supervisory requirements that are meant to guarantee that imports meet the standards of production in Member States. Unfortunately for exporters, the EU's rules on certification for imports are complicated and some minor differences across Member States continue

to exist.

In general, health certificates are required for all products of animal origin imported in the EU and phytosanitary certificates are needed for all plant products that could introduce pests into the EU. In accordance with EU legislation, certain products may have quality certificates that allow for reduced import duties. Other voluntary EU certificates allow for less stringent import control regimes.

Import requirements for animals and animal products are harmonized across the EU in a three-part process. First, 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. Secondly, 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), the Food and Drug Administration (FDA), and the Agricultural Marketing Service (AMS). Approved establishments may be subject to EU inspection. All EU-approved establishment lists are available on the USEU website. Lastly, animal or public health certificates based on the model certificates published by the European Union 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 imposes 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/EC](#); Annex IV.6 and [Regulation \(EC\) No 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 which issue health certificates (FSIS, APHIS and AMS) have all included this requirement in their export libraries.

EU 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 of the Food and Agriculture Organization of the United Nations (see: <http://www.phytosanitary.info/information/export-certification-manual>). Phytosanitary certificates are issued by APHIS inspectors, who attest to specific requirements of EU legislation by making additional declarations in the relevant boxes.

In the limited number of cases where certification of a particular product may be partially or not harmonized, such products would be subject to the rules of the individual Member State. Member States are likely to have differing certification requirements for non-harmonized products, so it is advisable that exporters seek guidance on the current requirements by consulting the country-specific FAIRS export certificate reports referenced at the end of this report or by contacting the local FAS Post. Post contact information is available from: https://apps.fas.usda.gov/overseas_post_directory/. It should be noted that the U.S. regulatory agencies issuing export certificates usually make mention of any Member State specific requirements in their export libraries and guides.

Product samples destined for human consumption have to comply with the food regulations applicable in the EU. In order to send product samples to commercial trade shows, it is advised to make contact with the FAS office in the Member State where the trade shows takes place. Please also contact our Member

State FAS office or the EU APHIS office (Xavier.Mennig@aphis.usda.gov) for export of food samples for technical or research purposes. Shipments to free zones and sea vessels only need to fulfill EU animal health requirements as these goods are not subject to EU public health requirements.

Fairs Export Certificate Reports for individual Member State are also available through the [GAIN search engine](#).

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 United States 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.

The “Product Decision Tree” also demonstrates which products are not covered by the scope of the legislation, e.g. because they contain less than 50 percent of egg product/processed fish product/honey/gelatin/snails/etc. These products do not require an EU composite product certificate. They are however still subject to general EU public health rules and also to any existing specific national public health conditions, which may include Member State specific certificates.

In order to have a more harmonized Member State application of EU legislation, [Commission Decision 2007/275/EC](#) 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/EC 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. With [Commission Implementing Decision \(EU\) 2016/1196](#) an important update to the list of products that has to undergo veterinary inspection has been published. This decision restricts the lists of products that are exempt from veterinary inspection, especially affecting the food supplement sector. Although Member States have to start applying the new lists as of January 1, 2017, there are still many outstanding questions on the practical implementation of this decision. For more information see http://ec.europa.eu/food/animals/vet-border-control/faq_en.

Personal Consignments

On May 1, 2009, clearer EU rules on the introduction of personal consignments of products of animal origin into the EU by travelers or through the post entered into force ([Commission Regulation 206/2009](#)).

Travelers are in general not allowed to bring in meat, milk, or their products.

There is an exemption for powdered infant milk, infant food, and special foods or special pet feed required for medical reasons, if weighing less than 2 kilograms and provided that:

- such products do not require refrigeration before opening;
- they are packaged proprietary brand products for direct sale to the final consumer; and
- the packaging is unbroken unless in current use.

For fishery products (including fish and certain shellfish such as prawns, lobsters, dead mussels and dead oysters), travelers are allowed to bring in up to 20 kilograms or the weight of one fish if this is higher.

For other animal products, such as honey, live oysters, live mussels and snails for example, travelers are allowed to bring in up to 2 kilograms.

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

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 and a link to the relevant pages on their websites.

AMS: Agricultural Marketing Service, USDA
European Union Health Certification Program
<http://www.ams.usda.gov/services/imports-exports/eu-dairy-exports>

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: Food and Drug Administration
<http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/default.htm>

FGIS: Federal FGIS Federal Grain Inspection on Service, GIPSA: Grain Inspection, Packers and

Stockyards Administration, USDA

<http://www.gipsa.usda.gov/fgis/contactfgis.aspx>

FSIS: Food Safety and Inspection Service, USDA

Export Requirements for the European Union:

<https://www.fsis.usda.gov/wps/portal/fgis/topics/international-affairs/exporting-products/export-library-requirements-by-country/European-Union>

NOAA: National Oceanic and Atmospheric Administration

http://www.seafood.nmfs.noaa.gov/export/export_certification/export_certification.html

Section IV. Government Certificate's 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 (<http://eur-lex.europa.eu/en/index.htm>) 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/EC/ and Regulation (EC) No 854/2004 of the European Parliament and of the Council:

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 as well as that of the border inspection Member State, or be accompanied by certified translations into all relevant languages. A Member State may, however, 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, 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. For example, EU legislation does not require that nuts and peanuts be accompanied by an aflatoxin certificate. However, shipments with these certificates are less tested and/or controlled upon entry in the EU.

Even though there is often no legal requirement for quality certificates, they may be necessary to operate in the market place because of the quality guarantee they offer to operators. Several private food safety and quality management and certification schemes are available to operators in the food chain.

FAS/USEU’s website (<http://www.usda-eu.org/>) provides a broad range of useful information on EU import rules and food laws and allows easy access to USEU reports, trade information and other practical information. For more information, contact AgUSEU.Brussels@fas.usda.gov.

Appendix I. Electronic Copy or Outline of Each Export Certificate

A. APHIS CERTIFICATES FOR ANIMALS AND GENETICS

IMPORTANT: The list of APHIS health certificates for the EU provided below should be seen in conjunction with the additional information on EU import requirements (for instance on establishment registration) 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 (<http://www.aphis.usda.gov/regulations/vs/iregs/animals/>).

- Bovine Embryos
- Bovine Semen
- Live Equines
- Equine Semen
- Equine Embryos

- Ovine/Caprine Semen
- Ovine/Caprine Embryos
- Live Swine
- Swine Semen
- Hatching eggs, non-ratite
- Day-old chicks, non-ratite
- SPF eggs certificate
- Captive Bred Birds
- Raptors
- Research dogs, cats and ferrets
- Pet dogs, cats and ferrets
- Pet birds
- Aquaculture animals

The APHIS website also provides information on the animal health requirements that must be met by travelers taking their pet to a Member State of the European Union (see <https://www.aphis.usda.gov/aphis/pet-travel>).

B. APHIS CERTIFICATES FOR ANIMAL PRODUCTS

IMPORTANT: The list of APHIS health certificates for the EU provided below should be seen in conjunction with the additional information on EU import requirements (for instance on establishment registration) 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 (<http://www.aphis.usda.gov/regulations/vs/iregs/products/>).

Materials for human consumption

- Collagen - Veterinary certificate for raw material in the production of collagen intended for human consumption
- Gelatin - Veterinary Certificate for raw material in the production of gelatin intended for human consumption

Materials NOT for human consumption

Animal by-products for the manufacture of products for purposes other than human or animal consumption

- Antibodies (purified antibodies derived from cell cultures)
- Apiculture by-products (including beeswax)
- Artemia cysts (aquatic invertebrate cysts or “eggs”) and derivatives
- Blood Products - for livestock feed
- Blood - blood products from EQUIDAE animals intended for technical purposes
- Blood - treated blood products from livestock not including equidae animals
- Blood - untreated blood products (not including those from equidae animals)
- Collagen (For purposes other than human consumption)
- Display Items (for trade shows)
- Egg products intended for livestock feeding
- Fat - Rendered Animal-Origin Fat for the Production of Biodiesel

- Feathers - June 2011
- Fish meal and fish oil
- Furs
- Gelatin (For purposes other than human consumption)
- Hair/Wool
- Hides - fresh or chilled hides and skins of ungulates
- Hides - treated hides and skins of ungulates
- Hydrolyzed proteins
- Intermediate Products
- Invertebrate cysts (aquatic) See Artemia cysts
- Laboratory/ zoo animal food (animal-origin foods for laboratory and zoo animals)
- Manure including guano
- Milk and milk-based/derived products not for human consumption
- Pet Food (Canned)
- Pet Food (Chews)
- Pet Food (Processed Pet Food Other than Canned)
- Pet Food Ingredient: Flavoring innards (includes digests)
- Pet Food Ingredient: Unprocessed Animal By-Products
- Pig Bristles
- Research and Diagnostic Samples
- Trade Samples - (Not including display items for trade shows)
- Trophies - having been submitted to a complete taxidermy treatment
- Trophies (Partially treated game trophies consisting only of hides, skins, bones, horns, hooves, claws, antlers, and/or teeth of ungulates or birds)
- Used cooking oil – See yellow grease
- Yellow grease (used cooking oil)
- 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.

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 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 also 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 issues these transit certificates even though they relate to animal health. Currently, there are no animal health restrictions on U.S. meat, cooked poultry, and egg products exported to the EU, however, exporters should check the pre-requisite flock health certification required in the FSIS export library for raw poultry. Any changes to the animal health status will be included in these requirements.

In addition, 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 <http://www.ams.usda.gov/services/imports-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 an EU Health Certificate, the manufacturers must have their final production, blending, and/or packing facility listed on the FDA Dairy Plant Reference List of EU-approved facilities.

Exporters should check whether they have been included in this list

(https://webgate.ec.europa.eu/sanco/traces/output/US/MMP_US_en.pdf).

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 US 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 US 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 US Military Installation.

Detailed information is provided on the on-line procedures to obtain these documents. The AMS site contains also specific guidance for exporters of whey protein supplements.

For more information, contact:

Carrie L. Sayasithsena

National Program Coordinator, All Products, Grade Labels, Resident Programs, Export Certification
202-720-9381

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 the Food and Drug Administration (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, and balut and other similar ethnic delicacies. For more information on jurisdiction

overlap for commercial products regulated by either or both FDA and USDA please refer to <http://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM127390.pdf>

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>.

Note: The model certificate of Regulation 1664/2006 was superseded by Regulation [2016/759](#).

G. NOAA CERTIFICATES FOR SEAFOOD

See: http://www.seafood.nmfs.noaa.gov/export/export_certification/export_certification.html

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.

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 European Union (EU). The program offers three documents required for export to the European Union. They are:

- EU export health certificate;
- EU IUU catch document for fisheries products harvested in the United States, to prevent, deter, and eliminate illegal, unregulated, and unreported (IUU) fishing; and,
- 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 illegal, unregulated, and unreported (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.

For additional information on exporting seafood to the EU, consult Exporting Seafood to the European Union – October 2016 Update (<http://www.seafood.nmfs.noaa.gov/pdfs/howtoexportseafood2016.pdf>) or contact stephane.vrignaud@trade.gov.

H. FDA CERTIFICATES

(<http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/ucm467666.htm#eu>)

The US Food and Drug Administration issues all EU export certificates for gelatin and collagen for human consumption. FDA will only issue certificates to exporters that have been included in the EU approved list of collagen and gelatin establishments.

https://webgate.ec.europa.eu/sanco/traces/output/US/GEL_US_en.pdf

https://webgate.ec.europa.eu/sanco/traces/output/US/COL_US_en.pdf

Exporters wishing to be added to the shippers list should contact the FDA Bulk Collagen Gelatin Export listing group at BulkCGExport-LM-OFS@fda.hhs.gov.

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	Model Certificate for Imports of Gelatin Intended for Human Consumption
Collagen Intended for Human Consumption	2016/759 or 2003/863	Gelatin Export listing group at the above email address to request the appropriate certificate	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 the FDA Bulk Collagen Gelatin Export listing group at the above email address for any questions on the certification of these products or products containing these ingredients	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/EC L210/49 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/EC L210/51 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

	96/510/EC L210/55 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
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J. APHIS PLANT HEALTH CERTIFICATES

For the latest information on APHIS certificates, please check the APHIS website at:

https://www.aphis.usda.gov/aphis/ourfocus/planthealth/SA_Export.

Product	Official Journal Reference/ Model from the Official Journal	U.S. Issuing Agency/ U.S. Agency Form	Title/Comments
Plants and plant products (including seeds)	2000/29/EC, L169/99 Annex VII, A	APHIS PPQ Form 577	Phytosanitary Certificate (*)
Plants and plant products for re-export	2000/29/EC, L169/99 Annex VII, B	APHIS PPQ Form 579	Phytosanitary Certificate for Re-export (reforwarding) (**)

(*) Directive 2000/29/EC contains a list of all plants/foods of plant origin that are banned in the EU. Plants that are not on this list are allowed to enter the EU, provided the “special requirements” laid down in part A of Annex IV are met. The special requirements are specific for each of the plants/foods mentioned. Examples are requirements for specified heat and other treatments or for sourcing from pest free areas. The exporting country’s plant protection authorities must guarantee that these special requirements are met. Guarantees are made in the form of a phytosanitary certificate, on which space is provided for the necessary declarations attesting to the specific requirements of EU legislation. USDA’s APHIS issues phytosanitary certificates for goods consigned from the United States. Plants/foods for which no special requirements are listed may enter the EU without any guarantees and do not require a phytosanitary certificate from the exporting country.

(**) In the case in which nuts consigned from the United States originate in another country, the phytosanitary requirements in Council Directive 2000/29/EC for import from the country of origin must be verified.

Product	Official Journal Reference/ Model from the Official Journal	U.S. Issuing Agency/ U.S. Agency Form	Title/Comments
Processed plant		APHIS	There is no

products		PPQ Form 578	specific reference to EU legislation. Issued on a case-by-case basis.
Hardwood Lumber	2002/757/EC	U.S. National Hardwood Lumber Association (NHLA) For additional information see: http://www.nhla.com/kilndryingcertification	Certificate of Kiln Drying (*)

(*) Until 31 December 2026, Member States are authorized to accept the Certificate of Kiln Drying as an alternative to the APHIS phytosanitary certificate if the wood has been treated under the Kiln Drying Sawn Hardwood Lumber Certification Program which is approved by APHIS and operated by the U.S. National Hardwood Lumber Association (NHLA). NHLA is responsible for signing the certificate. The derogation to 2000/29/EC is published as [2013/780/EU](#).

K. OTHER PLANT CERTIFICATES

Product	Official Journal Reference/ Model from the Official Journal	U.S. Issuing Agency/ U.S. Agency Form	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.
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
Corn gluten feed	2007/1375	FGIS	Commodity Inspection Certificate
		CRA	CRA: Certificate of Conformity. Update expected in spring 2017. See also Corn Refiners Association (CRA) http://www.corn.org/wp-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 Reg 937/2006 Louisiana Maritime Chamber of Commerce cooperates with Corn Refiners Association. Contact Cassandra Kuball at CRA for additional info (mail to CKuball@corn.org).
Food Supplements	2015/2447 art 57-59 and	List of names of non-	Certificate of Origin is required to import under the TRQ of Reg 624/2013 .

Classified under EU Tariff Code 2106 90 98	Annex 22-14 special non-preferential import arrangements	governmental U.S. organizations empowered by the U.S. Government to issue certificates of origin for the benefit of the tariff quota applicable under order number 09.0096 for imports in the EU of food preparations originating in the USA	For the latest information, please check http://www.usda-eu.org/trade-with-the-eu/tariffs/tariff-rate-quotas/ .
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/EC Agreement between the European Community and the United States of America on trade on wine Annex III	TTB (Department of the Treasury - Alcohol and Tobacco Tax and Trade Bureau) is the competent authority	Commercial Document to accompany wine products originating in the United States. Reg 555/2008 covers imports from non-EU countries. According to this regulation, imports of wine into the EU must be accompanied by a “VII” document, i.e. 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 provides detailed information on certification of U.S. wine for export to the EU on its website . The list of approved U.S. wine producers and laboratories delegated to draw up the document is published on the European
	555/2008 VII Form, Annex IX		

			<p>Commission's website: http://ec.europa.eu/agriculture/wine/lists/06.pdf</p> <p>(*) 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 now allowed to self-certify that the grape juice will not be used in wine-making.</p>
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. Hard copy only	<p>Certificate of Authenticity for Fresh 'Emperor' Table Grapes</p> <p>For tariff calculation purposes 2016/1821 amends 2658/87.</p>
Tobacco	EU Tariff Schedule 2016/1821 Annex 9	Tobacco Assoc. of U.S Hard copy only	<p>Certificate of Authenticity for Tobacco</p> <p>For tariff calculation purposes 2016/1821 amends 2658/87</p>
Peanuts	2015/949 Annex II	USDA/AMS is competent authority for the Pre Export Check program. Certificates are signed by USDA or representative (State Inspectors).	<p>Use of this certificate is not mandatory but regulation mandates that consignments with the certificate are controlled at less than 1%.</p> <p>This certificate is only issued if aflatoxin testing is done according to EU protocol in USDA approved laboratory. See also http://www.ams.usda.gov/services/lab-testing/aflatoxin.</p> <p>For further information see also the American Peanut Council.</p>
Almonds	2015/949 Annex II	USDA/AMS is the competent authority for the PEC	<p>Use of this certificate not mandatory but regulation mandates that consignments with this certificate are controlled at less than 1%.</p>

		<p>program. Shipping Point Inspection Within the California Department of Food and Agriculture is responsible for signing the PEC certificate as the local competent authority</p>	<p>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 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 See also http://www.ams.usda.gov/services/lab-testing/aflatoxin. For further information see Almond Board of California</p>
Organics	1235/2008 Annex V	<p>EU Certificate of Inspection (PDF) The list of USDA accredited agents and the model EU certificate are available from the USDA AMS website.</p>	<p>Beginning June 1, 2012, the equivalence arrangement between the U.S. and the EU entered into force. This means that as long as the terms of the arrangement are met, organic products certified to the USDA or EU organic standards may be labeled and sold as organic in both countries. This applies to all U.S. organic products exported to the EU, with the exception of crops produced using antibiotics (streptomycin for fire blight control in apples and pears).</p>
Sprouts and Sprouted Seeds	211/2013	FDA	<p>FDA is working with USDA to establish an export program for seeds for sprouting. For the latest information, please contact Michael.wehr@fda.hhs.gov.</p>
Hop Cones Hop Powders Saps and Extracts of Hops	1295/2008	<p>Washington Department of Agriculture State Chemical and Hop Lab</p> <p>Idaho Department of Agriculture Division of Plant Industries Hop Inspection Lab</p> <p>Oregon</p>	Attestation of Equivalence

		Department of Agriculture Commodity Inspection Division California Department of Food and Agriculture (CDFA-CAC) Division of Inspection Services Analytical Chemistry Laboratory USDA, GIPSA, FGIS - OR USDA, GIPSA, TSD, Tech Service Division, Technical Testing Laboratory - MO	
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Related FAS reports

Report Number	Title	Date Released
E15054	EU-28 FAIRS Export Certificate Report – 2015 IS SUPERSEDED BY THE CURRENT REPORT	
RO1626	Romania FAIRS Export Certificate Report	12/28/2016
	UK FAIRS Report	12/12/2016
AU1610	Austria FAIRS Export Certificate Report	11/17/2016
EZ1614	Czech Republic FAIRS Export Certificate Report	12/21/2016
NL6041	The Netherlands FAIRS Export Certificate Report	12/13/2016
IT1659	Italy FAIRS Export Certificate Report	12/6/2016
HU16005	Hungary FAIRS Export Certificate Report	12/5/2016
BU1546	Bulgaria FAIRS Export Certificate Report	12/17/2015

GM15027	Germany FAIRS Export Certificate Report	7/29/2015
SP1609	Spain FAIRS Export Certificate Report	5/19/2016
E16060	EU FAIRS Country Report	12/09/2016
	FAIRS reports prepared by the FAS offices in the different Member States. http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/fairs-reports/	
E17007	Phytosanitary Requirements for EU Imports of Nuts	1/25/2017
E17004	Exporting Food Supplements to the European Union	1/11/2017