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Food and Agricultural Import Regulations and Standards Report

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 certificates 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):

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. The United Kingdom will remain a member of the EU until March 29, 2019 (see "Brexit"). Montenegro, the Former Yugoslav Republic of Macedonia, Turkey, Albania and Serbia are candidates to join the EU.

Brexit

On March 29, 2017, the U.K. officially informed the European Council of its intent to leave the EU. It will remain a member of the EU until March 29, 2019. At the time of the writing of this report, negotiations on the withdrawal from the U.K. are still ongoing and there is still a lot of uncertainty surrounding the procedures and documentary requirements for entering products into the U.K. For all exports arriving in the U.K. after March 29, 2019, exporters should check the specific export requirements for the U.K. The U.S. Department of Agriculture, <u>Foreign Agricultural Trade Office</u> at the Embassy in London can be consulted for the latest information.

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 might 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 by certain EU neighboring countries.

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.

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 Food and Drug Administration (FDA). Approved establishments may be subject to EU inspection. All EU-approved establishment lists are available on the USEU website.
- iii. 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 that issue health certificates (FSIS, APHIS and AMS) have all included this requirement in their export libraries. The new Official Controls Regulation (OCR) Regulation (EU) 2017/625, which repeals Regulation (EC) No 854/2004 from 14 December 2019 onwards, maintains the basic import requirements listed above.

Plants and plant products

EU import requirements for plants and plant products are mostly harmonized. While for veterinary products there are numerous model certificates for specific animal and products, there is only one model certificate for exports and one model certificate for re-exports of 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 at 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.

In the limited number of cases where certification of a particular product is 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 <u>GAIN</u> 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, <u>Commission Decision 2007/275/EC</u> 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.

New import conditions for composite products are scheduled to start applying from April 21, 2021 onwards and details on these changes will be included as they become available in future.

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 with <u>Commission Regulation</u> 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:
 - o such products do not require refrigeration before opening;
 - o they are packaged proprietary brand products for direct sale to the final consumer; and
 - o 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

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: Food and Drug Administration

http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/default.htm

• FSIS: Food Safety and Inspection Service, USDA

Export Requirements for the European Union:

 $\underline{https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products/export-library-requirements-by-country/European-Union}$

• NOAA: National Oceanic and Atmospheric Administration

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

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 <u>Council Directive 2002/99/EC</u> and <u>Regulation (EC) No 854/2004</u> 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 United States (APHIS, FSIS, AMS, NOAA) provide links in the export sections of their website to the certificates that they issue for export to the EU.

New framework legislation has been published which updates and further clarifies the abovementioned general principles of certification. However, this legislation has no immediate effect on the certificates issued by the regulatory agencies. FAS cooperates closely with the regulatory 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 most 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 also voluntary certificates which may help reduce the level of import controls. For example, EU legislation does not require that almonds 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 AgUSEUBrussels@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
- Pet raptors
- Captive bred raptors
- Research dogs, cats and ferrets
- Pet dogs, cats and ferrets
- Pet birds
- Aquaculture animals
- Ornamental aquatic 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 (https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/iregs-for-animal-product_exports/ct_iregs_animal_product_exports_home).

Materials for human consumption

- Collage and gelatin Raw material in the production of collagen intended for human consumption
- Collagen and gelatin TREATED animal byproducts for the production of gelatin and collagen for human consumption
- Collagen and gelatin UNTREATED animal byproducts for the production of gelatin and collagen 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
- 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
- Insect-origin processed animal protein not including pet foods
- 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
- Pet Supplements
- 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)
- 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.

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

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.

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 animal health restrictions for poultry. Fresh poultry meat from areas listed on the FSIS website is not eligible for export or transit through the EU. Processed poultry products continue to be eligible provided the product has undergone the appropriate heat treatment.

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 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 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. Industry may apply for inclusion on these lists via the Export Listing Module (ELM). Please visit Online Applications for Export Lists for a link to this electronic system and step-by-step instructions. 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: 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 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: <u>Processed Egg and Processed Egg Products Worksheet</u> (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

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. For more information, please see FDA Office of Regulatory Affairs Document FMD-16: Processing Requests for Inclusion on an FDA Fish and Fishery Products Export Health 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 <u>Exporting Seafood to the European Union</u> – <u>December 2017 update</u>) 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

Industry may apply for inclusion on these lists via the Export Listing Module (ELM). Please visit Online Applications for Export Lists for a link to this electronic system and step-by-step instructions. Exporters wishing to obtain export certificates for those products should contact the FDA Bulk Collagen Gelatin Export listing group at BulkCGExport-LM-OFS@fda.hhs.gov and provide the required information. For more information see:

https://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/ExportLists/ucm562755.htm

Product	Official	U.S. Issuing Agency	Title/Comments

	Journal Reference/ Model from the Official Journal		
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 the above email address to request the appropriate certificate	Model Certificate for Imports of Gelatin Intended for Human Consumption
Collagen Intended for Human Consumption	2016/759 or 2003/863		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	<u>2016/759</u>	FDA is the Competent Authority - Contact CFSANExportCertification@fda.hhs.gov	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 <u>Annex I</u>	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 <u>Annex II</u>	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 <u>Annex I</u>	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 is available publically at https://pcit.aphis.usda.gov/PExD/signIn and also reflects bilateral work plans and changes in pest status. It covers both EU harmonized and member State specific requirements. The contact information for APHIS-PPQ -Export Services is: PPQExportServices@aphis.usda.gov.

The <u>APHIS Plant Health Export Information site</u> provides also additional information on <u>Wood Packaging</u> <u>Materials</u> and on certification programs such as the European Union Ash Systems Approach Program for lumber.

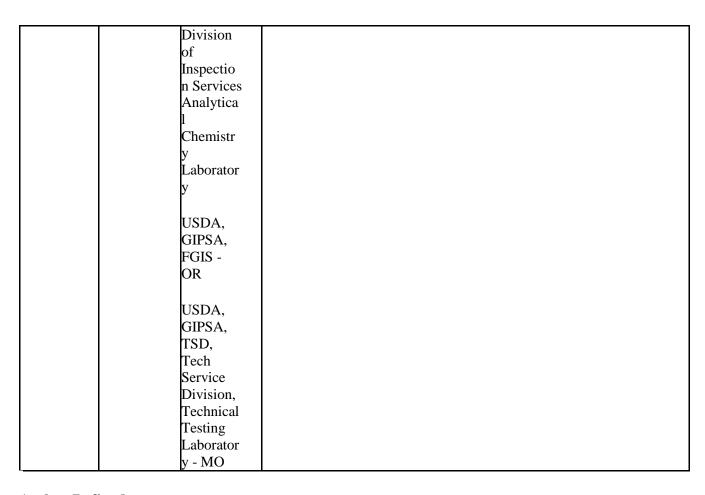
K. OTHER PLANT CERTIFICATES

Product	Official	U.S.	Title/
	Journal	Issuing	Comments
	Referenc	Agency/	
	e/ Model	U.S.	
	from the	Agency	
	Official	Form	
	Journal		
Wheat	642/2010	FGIS	Quality Certificate for high quality wheat: Without the certificate, a
(other			security must be paid until tests are done to show that the product
than			meets EU standards.
Durum)			Federal Grain Inspection Service (FGIS) contact information:
			https://www.ams.usda.gov/resources/fgis-field-offices
Malting	1064/200	FGIS	Certificate of conformity: Quality Certificate providing access to the
barley	9		50,000 MT TRQ. The security that is paid upon import is reduced for
			goods shipped with the certificate
			Federal Grain Inspection Service (FGIS) contact information:
			https://www.ams.usda.gov/resources/fgis-field-offices
Corn	2007/137	FGIS	Commodity Inspection Certificate
gluten	<u>5</u>		Federal Grain Inspection Service (FGIS) contact information:
feed			https://www.ams.usda.gov/resources/fgis-field-offices
		CRA	CRA: Certificate of Conformity was updated in February 2017.
			See also Corn Refiners Association (CRA) http://www.corn.org/wp-
			content/uploads/2009/12/Feed2006.pdf pp.8-9
Corn	2015/244	Louisiana	Certificate of Origin is required to import under the TRQ of Reg
Gluten	7	Maritime	937/2006
Meal	art 57-59	Chamber	Louisiana Maritime Chamber of Commerce cooperates with Corn
Tariff	and	of	Refiners Association (https://corn.org/about-cra/staff/)
Code	Annex	Commerc	
23031011	22-14	e	
	special		
	non-		
	preferenti		
	al import		
	arrangem		
	ents		

Food Suppleme nts Classified under EU Tariff Code 2106 90 98	2017/132 9		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 2106 90 98. See also GAIN report E17048.
Fresh fruits and vegetable s	543/2011 Annex III		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 Agreemen t between the European Communi ty and the United States of America on trade on wine Annex III 2018/273 5 VI1 Form,	(Departm ent of the Treasury - Alcohol and Tobacco Tax and Trade Bureau) is the competen t authority	Commercial Document to accompany wine products originating in the United States. Imports of wine into the EU must be accompanied by a "VII" document, published in Commission Delegated Regulation (EU) 2018/273. This is a certificate of origin and analysis issued in the country of origin. As a result of the U.SEU 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 Commission's website: http://ec.europa.eu/agriculture/wine/lists/06.pdf (*) 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 2016/182 1 Annex 9	MS or -Arizona	Certificate of Authenticity for Fresh 'Emperor' Table Grapes For tariff calculation purposes 2016/1821 amends 2658/87.

Tobacco	EU Tariff Schedule 2016/182	re Certificat e of Authentic ity for Fresh 'Emperor' Table Grapes. Tobacco Assoc. of U.S	Certificate of Authenticity for Tobacco For tariff calculation purposes 2016/1821 amends 2658/87
Peanuts	Annex 9 None		Regulation 2017/1269 stipulates that 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; however, shipments are no longer benefitting from the reduced testing level for aflatoxin upon entry in the EU.
Almonds	2015/949 Annex II	USDA/A MS is the competen t authority for the PEC program. Shipping Point Inspection Within the California Department of Food and Agriculture is responsible for signing the PEC certificate as the local competen t authority	Use of this certificate not mandatory but regulation mandates that consignments with this certificate are controlled at less than 1%. 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 https://www.ams.usda.gov/services/lab-testing/aflatoxin . For further information see https://www.ams.usda.gov/services/lab-testing/aflatoxin .
Organics	2016/184 2	USDA/A MS	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.

Sprouts and Sprouted	211/2013	FDA	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 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.
Hop Cones Hop Powders Saps and Extracts of Hops	1295/200 8	Washingt on Departme nt of Agricultu re State Chemical and Hop Lab Idaho Departme nt of Agricultu re Division of Plant Industries Hop Inspectio n Lab Oregon Departme nt of Agricultu re Commodi ty Inspectio n Division California Departme nt of Food and Agricultu re	Attestation of Equivalence
		(CDFA- CAC)	



Author Defined:

Appendix II: Related FAS Reports

Report	Title	Date
Number		Released
E17086	EU-28 FAIRS Export Certificate Report – 2018	12/20/2017
	IS SUPERSEDED BY THE CURRENT REPORT	
AU1808	Austria FAIRS Export Certificate Report	11/16/2018
E18020	Belgium-Luxemburg FAIRS Export Certificate Report	3/15/2018
BU1801	Bulgaria FAIRS Export Certificate Report	1/26/2018
HR1709	Croatia FAIRS Export Certificate Report	1/2/2018
EZ1810	Czech Republic FAIRS Export Certificate Report	11/1/2018
FR1804	France FAIRS Export Certificate Report	1/25/2018
GM18046	Germany FAIRS Export Certificate Report	11/20/2018
<u>IT1846</u>	Greece FAIRS Export Certificate Report	12/17/2018
HU18010	Hungary FAIRS Export Certificate Report	11/28/2018
<u>IT1774</u>	Italy FAIRS Export Certificate Report	1/24/2018
	Lithuania FAIRS Export Certificate Report	1/2/2017
NL7045	Netherlands FAIRS Export Certificate Report	1/5/2018
	Poland FAIRS Export Certificate Report	1/5/2018
RO1728	Romania FAIRS Export Certificate Report	1/3/2018

<u>SP1712</u>	Spain FAIRS Export Certificate Report	6/19/2017
	UK FAIRS Report	02/08/2017
	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