



Required Report: Required - Public Distribution

Date: October 01, 2021 **Report Number:** E42021-0073

Report Name: FAIRS Export Certificate Report Annual

Country: European Union

Post: Brussels USEU

Report Category: FAIRS Export Certificate Report

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Report Highlights:

This guide provides an overview of 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

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DISCLAIMER

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.

Executive Summary

Import requirements for food and feed, animals and plants are harmonized between the Member States of the European Union (EU). The EU's regulations applicable to imports include specific model certificates with pre-defined attestations on animal, plant, or public health or on the quality specifications of a product. This report provides an overview of all certificates that are harmonized in EU regulations, and guides exporters to the authorities in the United States that have the authority to issue these certificates. Most of the certificates required by the EU as a condition for entry are issued by the Animal and Plant Health Inspection Service (APHIS), the Food Safety Inspection Service (FSIS), the Agricultural Marketing Service (AMS), the National Oceanic and Atmospheric Administration (NOAA) and the Food and Drug Administration (FDA). This report also lists other EU harmonized certificates that can be requested by exporters on a voluntary basis from an authorized entity in the United States with the aim to facilitate import controls or to benefit from reduced duties in the EU.

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.

The EU currently consists of 27 Member States with approximately 445 million consumers. 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 and Sweden. The United Kingdom (U.K.) left the European Union on January 31, 2020¹ . Montenegro, North Macedonia, Turkey, Albania and Serbia are candidates to join the EU.

All EU Member countries accept the "Community acquis," i.e. the entire body of EU laws and obligations associated with the treaties and international agreements to which the EU is a party. EU Member States share a customs union, a single market in which goods can move freely, a common trade policy and a common agricultural and fisheries policy. As part of these common policies, the EU has created a vast number of model certificates that are binding in all of the EU Member States.

Following an update of the EU's Animal Health Law (<u>Regulation (EU) 2016/429</u>), which entered into force on April 21, 2021, the EU has updated all required certificates for products of animal origin. Models of the new certificates for food of animal origin were published in <u>Commission Implementing</u> <u>Regulation (EU) No 2020/2235</u>, as amended by <u>Commission Implementing Regulation (EU) 2021/1471</u>. The transitional provisions of Regulation 2020/2235 allow for the continued use of the old certificates until March 15, 2022, provided that the certificates are signed before Jan 15, 2022. At the time of writing this report, U.S. Government agencies had not yet switched to any of the new models. FAS cooperates closely with the regulatory agencies to ensure that their export libraries are up-to-date and that the currently applicable certificate versions are made available to exporters.

In 2017, the European Union adopted a new framework regulation for official controls (<u>Regulation (EU)</u> 2017/625). The Official Controls Regulation (OCR) provides the legal basis for the verification by EU officials of most of the certification information provided in this report. This regulation is further supplemented by several important regulations including <u>Commission Delegated Regulation (EU)</u> 2019/625 with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption and <u>Commission Delegated Regulation (EU)</u> 2019/2124 setting the rules for official controls on goods in transit or transshipment. Exporters who face problems at EU borders linked to the implementation of these regulations are encouraged to contact FAS Brussels (<u>AGUSEUBrussels@usda.gov</u>) or one of the FAS offices in the Member State of import. Post contact information is available from <u>https://apps.fas.usda.gov/overseas_post_directory/</u>.

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.

¹ Brexit: The United Kingdom withdrew from the European Union as of February 1, 2020. The Agreement on the withdrawal of the UK from the EU entered into force on the same date. This Agreement provided for a transition period, which ended on December 31, 2020. During the transition period, EU law was applicable to and in the United Kingdom. On December 24, 2020, the EU and UK negotiators reached <u>an agreement</u> that sets out the rules on the new partnership between the EU and UK which started to apply from January 1, 2021. More information: <u>https://ec.europa.eu/info/relations-united-kingdom/new-normal/consequences-brexit_en</u>

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.

Transit Certificates: The appropriate transit certificate issued by the competent U.S. Government agency must accompany food shipments that physically enter the European Union without being released within the EU market. Those foods only need to fulfill EU animal health requirements as these goods are not subject to EU public health requirements.

The conditions for the authorizations of transit of consignments of products of animal origin and composite products are outlined in <u>Commission Delegated Regulation (EU) 2019/2124</u>. These cover the entry of goods into EU territory that are further transported:

- to a border control post in order to leave the Union territory
- to an approved warehouse
- to a NATO or U.S. military base located in the Union territory
- to a vessel leaving the Union, where the consignment is intended for ship supplying purposes

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.

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.

Products of animal origin

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

 Country Approval: The EU must recognize a country as eligible to ship a particular animal or animal product to the EU based on its animal health status and the guarantees these countries have provided in the area of food safety, including residue controls. The United States is approved by the EU for a wide range of 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. Shellfish is restricted from all U.S. states except Washington State and Massachusetts.

- <u>Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 outlines the list</u> of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and the Council
- <u>Commission Implementing Regulation (EU) 2021/405 outlines the list of third countries</u> or regions thereof authorized for the entry into the Union of certain animals and goods intended for human consumption
- <u>Commission Decision of 16 March 2011 on the approval of plans submitted by third</u> <u>countries in accordance with Article 29 of Council Directive 96/23/EC</u>
- Establishment Approval: 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 up-to-date lists of eligible third country establishments are available from:

<u>https://webgate.ec.europa.eu/sanco/traces/output/non_eu_listsPerCountry_en.htm</u>. 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.

• Product Certification: Animal or public health certificates based on the model certificates published by the European Union in <u>Commission Implementing Regulation (EU) 2020/2235</u> 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 <u>Commission Implementing Regulation (EU) 2020/2235</u>, 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, AMS and NOAA) have all included this requirement in their export libraries.

Plants and plant products

EU import requirements for plants and plant products are 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 <u>export certification</u> <u>guide</u> at the <u>IPPC website</u>. Phytosanitary certificates are issued by APHIS inspectors, who can attest to the specific requirements of EU legislation.

Composite Products

<u>Regulation (EU) 2019/625</u> defines composite products 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. U.S. exports of "composite products" continue to be restricted due to burdensome certification requirements. While the U.S. is eligible to ship hormone-free meat, dairy products, egg products, and fishery products separately, it is often not possible to ship the composite products that combine these eligible ingredients.

Exporters should be aware that in parallel with the aforementioned changes to the composite product certificate that was triggered by an update of the EU's Animal Health Law, the EU also made changes to the categories of composite products that require U.S. Government-issued health certificates. The new system is no longer based on the percentage of ingredients of animal product in the final product, as was the case until April 21, 2021. The new system that went into effect on April 21, 2021 establishes three categories of composite products: (1) non-shelf stable composite products, (2) shelf stable composite products that contain meat products and (3) shelf stable composite products that do not contain meat products. All processed products of animal origin have to be sourced from EU-approved establishments. The EU continues to require composite product certificates for all non-shelf stable products and for shelf stable composite products with a meat ingredient.

For shelf stable products not containing meat, no certificates signed by the U.S. Government are required. For these products, the representative of the importer must declare that the goods meet the relevant EU requirements, using the "Private Attestation" model form.

More information on the import conditions for composite products is available on the European Commission's <u>website</u>. This website also includes a compilation of <u>Questions & Answers</u> intended to clarify a multitude of practical questions that have been raised on the new rules.

- Products Subject/Not Subject to Veterinary Checks and Certification

The list of animal origin products subject to official controls at border posts was updated in <u>Commission Implementing Regulation (EU) 2021/632</u>. Composite products listed in <u>Commission</u> <u>Delegated Regulation 2021/630</u> are exempted from checks at the border because of their low risk. The list includes products such as biscuits, confectionary and food supplements. All consignments to be presented at the border control posts have to undergo documentary checks. Identity and physical checks are carried out at a frequency depending on the risk linked to the specific animals or goods. The criteria to determine and modify the frequency of rates are established by the Commission.

Products outside of Regular Commercial Channels

<u>Commission Delegated Regulation (EU) 2019/2122</u> provides details on the exemptions of official controls at the border for animal origin goods that could enter the EU outside of regular commercial channels. In cases where goods are not exempted from border controls, one of the certificates covered by this report, or other export documentation may be required. The rules on the following specific situations are covered:

- Animals intended for scientific purposes
- Research and diagnostic samples
- Plants, plant products and other objects intended for scientific purposes
- Products of animal origin and composite products on board means of transport operating internationally which are not unloaded and are intended for consumption by the crew and passengers
- Goods which form part of passengers' personal luggage and are intended for personal consumption or use
- Small consignments of goods sent to natural persons which are not intended to be placed on the market
- Pet animals

Product samples destined for human consumption generally must 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 show will take place. Please also contact our <u>Member State FAS office</u> or the EU APHIS office (<u>Xavier.Mennig@aphis.usda.gov</u>) for export of food samples for technical or research purposes.

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 meeting the conditions laid down in the regulation.

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 Dairy Health Certification Program <u>https://www.ams.usda.gov/services/imports-exports/dairy-exports/eu-dairy-exports</u>
 - Certification for Eggs and Egg Products <u>http://www.ams.usda.gov/services/imports-exports/eggs-egg-products</u>
 - Certification for Honey <u>https://www.ams.usda.gov/services/imports-exports/honey</u>
 - Certification for Seeds for Sprouting <u>https://www.ams.usda.gov/content/usda-announces-seed-sprouting-export-certification-program</u>
- APHIS: Animal and Plant Health Inspection Service, USDA
 - International Animal Export Regulations <u>http://www.aphis.usda.gov/regulations/vs/iregs/animals/</u>
 - International Animal Products Export Regulations <u>http://www.aphis.usda.gov/regulations/vs/iregs/products/</u>
 - Plant Export Services <u>https://www.aphis.usda.gov/aphis/ourfocus/planthealth/SA_Export</u>
- FDA: Food and Drug Administration
 <u>http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/default.htm</u>
- FSIS: Food Safety and Inspection Service, USDA Export Requirements for the European Union: <u>https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products/export-library-requirements-by-country/European-Union</u>
- NOAA: National Oceanic and Atmospheric Administration <u>https://www.fisheries.noaa.gov/content/export-certification</u>

Section IV. Government Certificate Legal Entry Requirements

EU food legislation is characterized by a constant flow of new regulations. EU regulations are translated into the 24 official languages in use in the EU-27 and published chronologically in the Official Journal. Regulations are binding in their entirety and automatically enter into force on a set date in all Member States. Amendments are published in new and separate 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 Eur-lex website (<u>http://eur-lex.europa.eu/en/index.htm</u>) provides free access to European Union laws.

In 2017, the European Union adopted the <u>Official Controls Regulation (OCR)</u> which provides the legal basis for the verification by EU officials of EU health certificates. This regulation also provides for electronic certification using the EU's Integrated Management System for Official Controls (IMSOC). The United States does not issue certificates in IMSOC and continues to use paper certificates.

For all veterinary health certificates that are provided in paper format, the EU applies the following general principles of certification as defined in <u>Regulation (EU) 2020/2235</u>.

- In addition to the signature of the official veterinarian/certifying officer, the certificate shall bear an official stamp. The color of signature shall be different to the color of the printing. This requirement also applies to stamps other than those embossed or watermarked.
- Where the model certificate contains statements, the statements which are not relevant shall be crossed out, initialed and stamped by the certifying officer, or completely removed from the certificate.
- The certificate shall consist of:
 - o a single sheet of paper; or
 - several sheets of paper where all sheets are indivisible and constitute an integral whole; or
 - a sequence of pages numbered so as to indicate that it is a particular page in a finite sequence.
- Where the certificate consists of a sequence of pages, each page shall indicate the unique certificate code and bear the signature of the official veterinarian or certifying officer and the official stamp.
- The certificate shall be issued before the consignment to which it relates leaves the control of the competent authorities of the third country issuing the certificate.
- The certificate must be in the official language or in one of the official languages of the Member State of the border control post of entry into the Union. However, a Member State may accept certificates in another official EU language.

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.

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 frequently 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 marketplace 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 (<u>http://www.usda-eu.org/</u>) 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 <u>AgUSEUBrussels@fas.usda.gov</u>.

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 (<u>http://www.aphis.usda.gov/regulations/vs/iregs/animals/</u>).

- 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 (<u>https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/iregs-for-animal-product-exports/ct_iregs_animal_product_exports_home</u>).

Materials for human consumption

- Collagen 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
- Pet Supplements

- 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)
- 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/exportlibrary-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 <u>FSIS export library</u>.

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.

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: The appropriate transit certificate issued by the competent U.S. Government agency must accompany food shipments that physically enter the European Union without being released on the EU market

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 <u>Online Applications for Export Lists</u> for a link to this electronic system and step-by-step instructions or contact <u>CFSANExportCertification@fda.hhs.gov</u>. Exporters should check whether they have been included in this list (<u>https://webgate.ec.europa.eu/sanco/traces/output/US/MMP_US_en.pdf</u>).

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:

- EU HTB Dairy Health Certificate for heat treated dairy products
- EU Composite
- EU Composite Transit
- EU Transit

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

For more information, contact William Francis (<u>william.francis@usda.gov</u>) or John Kelly (<u>John.Kelly2@usda.gov</u>)

E. AMS Certification for Eggs and Egg Products

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

Also in the egg sector, FDA has delegated the authority for export certification to USDA's Agriculture Marketing Service (AMS). The AMS Livestock, Poultry and Seed Division is responsible for the export certificates for the food products containing eggs or egg products that are regulated by FDA. In addition to shell eggs, FDA-regulated egg products include hard boiled eggs, cooked omelets, frozen egg patties, imitation egg products, egg substitutes, noodles, cake mixes, freeze-dried products, dietary foods, dried no-bake custard mixes, egg nog mixes, acidic dressings, mayonnaise, milk and egg dip, foods containing egg extracts, French toast, sandwiches containing eggs or egg products, 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 the FDA/USDA jurisdictional chart (https://www.fda.gov/media/113432/download, Exhibit 3-1).

The <u>AMS Livestock, Poultry and Seed Division</u> 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

G. AMS Certification for Seeds for Sprouting

See: <u>https://www.ams.usda.gov/content/usda-announces-seed-sprouting-export-certification-program</u>

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

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 the <u>U.S. Commercial Service Guide</u> for How to Export to the EU or contact <u>stephane.vrignaud@trade.gov</u>.

I. FDA Certificates

(https://www.fda.gov/food/exporting-food-products-united-states/food-export-certificates)

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 <u>Online</u> <u>Applications for Export Lists</u> for a link to this electronic system and step-by-step instructions. For more information see: (<u>https://www.fda.gov/food/food-export-lists/collagen-and-gelatin-exports-european-union</u>)

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. It should be noted that despite several updates by the EU of the collagen and gelatin certificate, the collagen and gelatin certificates of <u>Commission Decision 2003/863</u> continue to be valid for bovine and porcine material.

FDA is also the competent authority for highly refined products such as chondroitin sulphate, hyaluronic acid, other hydrolyzed cartilage products, chitosan, glucosamine, rennet, isinglass and amino acids intended for human consumption for which the EU requires health certificates.

Certification required by the EU for these products may not be available to exporters. Contact <u>CFSANExportCertification@fda.hhs.gov</u> (240-402-2307).

J. Pedigree and Zootechnical Certificates

<u>Commission Implementing Regulation (EU) 2020/602 of 15 April 2020 amending Implementing</u> <u>Regulation (EU) 2017/717 as regards the model forms of zootechnical certificates for breeding animals</u> <u>and their germinal products</u>

K. APHIS Plant Health Certificates

https://pcit.aphis.usda.gov/pcit/faces/signIn.jsf

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 (launch PExD from https://pcit.aphis.usda.gov/pcit/faces/signln.jsf) 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@usda.gov.

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

L. 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	<u>642/2010</u>	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.

Durum)			Federal Grain Inspection Service (FGIS) contact information: https://www.ams.usda.gov/resources/fgis-field-offices
Malting barley	2020/1988	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 Federal Grain Inspection Service (FGIS) contact information: https://www.ams.usda.gov/resources/fgis-field-offices
Corn	<u>2007/1375</u>	FGIS	Commodity Inspection Certificate
gluten feed			Federal Grain Inspection Service (FGIS) contact information: 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)
			https://corn.org/wp-
			<pre>content/uploads/2018/10/Feed2006.pdf</pre>
			pp.8-9
Mool	art 57-59	Louisiana Maritime Chamber of Commerce	Certificate of Origin is required to import under the TRQ of Reg 2020/1988
Tariff Code	22-14		Louisiana Maritime Chamber of Commerce cooperates with
	special non- preferential import arrangement s		Corn Refiners Association (<u>https://corn.org/about-cra/staff/</u>)
Food Suppleme nts Classified under EU Tariff Code 2106 90 98		None	Implementing Regulation 2017/1329 removed the certificate of origin requirement issued by a U.S. Chamber of Commerce for goods shipped within the U.S. specific Tariff Rate Quota for food supplements under CN code 2106 90 98.

Fresh	543/2011	None	Certificate of conformity with the community marketing
fruits and	Annex III		standards for fresh fruit and vegetables. No U.S. agency
vegetables			issues this certificate. Imports to the EU can be certified at
			the border.
Wine, grape juice (*) or grape must		the Treasury - Alcohol and Tobacco Tax and Trade Bureau) is the competent authority	Commercial Document to accompany wine products originating in the United States. Imports of wine into the EU must be accompanied by a "VI1" document, published in <u>Commission Delegated Regulation</u> (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 <u>website</u> . 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 use 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.
Frach			
Fresh 'Emporor'	EU Tariff	USDA/AMS or	Certificate of Authenticity for Fresh 'Emperor' Table Grapes
Table	Schedule <u>2658/87</u>	-Arizona Department of Agriculture, or	For tariff calculation purposes
Grapes	<u>Annex 9</u>	- California Department of Food	
L	l		

		and Agriculture	
		and Agriculture	
		Certificate of	
		Authenticity for	
		Fresh 'Emperor'	
		Table Grapes.	
Tobacco	EU Tariff	Tobacco Assoc. of	Certificate of Authenticity for Tobacco
	Schedule	U.S	For tariff calculation purposes
	<u>2658/87</u>		2019/1776 amends 2658/87
	<u>Annex 9</u>		
Peanuts	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, but the
			EU is doing increased testing for aflatoxin on U.S. peanuts.
Almonds	2015/949	USDA/AMS is the	Use of this certificate not mandatory but regulation
	Annex II	competent authority	mandates that consignments with this certificate are
		for the PEC program.	controlled at less than 1%.
		Shipping Point	
		Inspection Within the	
		Camornia	The USDA Agricultural Marketing Service started to issue PEC
		Department of Food	almond certificates on August 1, 2015. The almond PEC
		and Agriculture is	program builds on and replaces the Voluntary Aflatoxin
		responsible for	Sampling Plan (VASP) program, which stopped being
		signing the PEC	required in September 2014 when the EU voted to remove
		certificate as the	California Almonds from Special Measures (removal from
		local competent	1152/2009). A PEC certificate is only issued if aflatoxin
		authority	testing is done according to EU protocol in USDA approved
			laboratory See also <u>http://www.ams.usda.gov/services/lab-</u>
			testing/aflatoxin
			For further information see <u>Almond Board of California</u>
Orregular	2010/0012		
Organics	<u>2016/1842</u>	USDA/AMS	The EU has implemented a new system of electronic
			Certificates of Inspection (COI) for imports of organic
			products in the EU as of October 19, 2017. The electronic
			certificates replace the paper-based certificates of

			inspection. The COI has to be issued by the relevant control authority or control body before a consignment leaves a third country of export or origin, but <u>2020/479</u> allows that the information contained in the transport document is checked and included in the certificate of inspection by the relevant control authority or control body within maximum 10 days from the issuance of the certificate, as long as it is before the endorsement of the certificate by Member State's authorities.
			The electronic certificates are accessible through the EU's Trade Control & Expert System (<u>TRACES</u>).
			More information here:
			https://ec.europa.eu/agriculture/organic/sites/orgfarming/fi les/quick_reference_guide.pdf
Hop Cones Hop Powders Saps and	1295/2008	Washington Department of Agriculture State Chemical and	Attestation of Equivalence
Extracts of Hops		Hop Lab	
		Idaho Department of Agriculture	
		Division of Plant Industries	
		Hop Inspection Lab	
		Oregon 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	

Appendix II: Related FAS Reports

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/

FAIRS export certificate reports prepared by the FAS offices in the different Member States: <u>https://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/fairs-export-certificate-report/</u>

Attachments:

No Attachments