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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 certificate changes that have occurred in the past months and have updated their export manuals to reflect those changes. Sections updated: All sections.

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT POLICY

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DISCLAIMER

This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service in Brussels, Belgium for U.S. exporters of domestic food and agricultural products to the European Union. It is important to note that the information provided may no longer be completely accurate because policies have changed since its publishing 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 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:

Most 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, 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.

A. 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 450 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 (UK) left the European Union on January 31, 2020. Montenegro, North Macedonia, Türkiye, Albania, Serbia, Ukraine, and Moldova are candidates to join the EU.

All EU Member States 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.

In December 2018, the EU published Regulation (EU) 2019/6 on veterinary medicinal products that seeks to address antimicrobial resistance (AMR) by more strictly defining the criteria for use of antimicrobial products in animal medicine. Article 118 of the regulation expands these restrictions to operators in third countries, who will be required to ensure that animal products exported to the EU and intended for human consumption do not originate from animals that have been treated with specified antimicrobial medicines reserved for human use or utilized for growth promotion.

When the new AMR requirements are applied to products exported to the EU, the EU will only accept products of animal origin from countries that have submitted appropriate evidence and guarantees that the imported products will comply with the new rules. A third country list was published in Commission Implementing Regulation (EU) 2024/2598 includes the United States for all exported products.

In addition to the country listing, the new AMR requirements are also leading to changes in the model health certificates for all products affected by the legislation. The updates to the model health certificates were published in February 2024 in Implementing Regulation (EU) 2024/399. Beginning September 3, 2024, two additional animal health attestations are required to be listed on official health certificates, but exporting countries are not required to make the attestations until the regulation is implemented on September 3, 2026.

The United States Department of Agriculture's Foreign Agricultural Service (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.

Brexit:

The United Kingdom withdrew from the European Union on January 31, 2020. The Agreement on the withdrawal of the UK from the EU entered into force on the same date. This Agreement provided a transition period, which ended on December 31, 2020. On December 24, 2020, the EU and UK negotiators reached an agreement that sets out the rules on the new partnership between the EU and UK which started to apply from January 1, 2021. More information can be found here. The European Commission published a notice to stakeholders on the withdrawal of the United Kingdom and EU food law, which is available here: https://commission.europa.eu/document/download/fdb2fe1e-d767-4386-8dbd-8edfb45b4e7a_en.

On May 19, 2025, the EU and the UK announced their intention to establish a Common Sanitary and Phytosanitary Area. Details of this agreement will have to be worked out. The EU has stated that it will propose a mandate and seek the authorization of the European Council to launch negotiations with the UK on an SPS Agreement. The specific certificates that were developed for export to the U.K. following Brexit remain in place until further notice.

In 2017, the European Union adopted a new framework regulation for official controls (Regulation (EU) 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 Commission Delegated Regulation (EU) 2022/2292 with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption and Commission Delegated Regulation (EU) 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 (AGUSEUBrussels@usda.gov) or one of the FAS offices in the Member State of import. Post contact information is available from https://apps.fas.usda.gov/overseas_post_directory/

B. 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. 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 authorizing the 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 GAIN FAIRS export certificate reports 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.

SECTION II. SPECIFIC ATTESTATIONS REQUIRED ON EXPORT CERTIFICATES

Products of Animal Origin:

<u>Commission Delegated Regulation (EU) 2022/2292</u> establishes the requirements of consignments of food-producing animals and certain goods intended for human consumption for entry into the European Union. These entry requirements 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. These approvals and related restrictions are reflected in the lists published in two EU regulations.

- Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 outlines the list 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. Restrictions currently apply to the export of poultry products from several areas in the United States. These restrictions are frequently updated based on the development of the animal health status in the affected areas.
- Commission Implementing Regulation (EU) 2021/405 outlines the list of third countries or regions thereof authorized for the entry into the Union of certain animals and goods intended for human consumption. Shellfish is restricted from all U.S. states except Washington State and Massachusetts. The list of third countries with approved control plans for pharmacologically active substances, pesticides and contaminants in certain food-producing animals and products of animal origin intended for human consumption is now integrated in Annex I of Commission Implementing Regulation (EU) 2021/405. U.S. lamb and mutton are currently not eligible for export to the EU. In the 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. In 2021, the United States was delisted by the EU for the export of casings but was relisted in March 2023.

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: https://webgate.ec.europa.eu/tracesnt/directory/listing/establishment/publication/index#!/search?country Code=US.

 In November 2024, a listing requirement was also introduced for honey and other apiculture products. Product entering the EU must now come from establishments listed on the list of Honey and Other Apiculture Products Establishments (HON). 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 Commission Implementing Regulation (EU) 2020/2235 certificates must be issued before the consignments 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.

Composite Products:

Commission Delegated Regulation (EU) 2022/2292 establishes specific entry conditions for composite products. These are defined as foodstuffs intended for human consumption that contain <u>processed</u> products of animal origin and ingredients of plant origin. Composite products include a wide variety of products, including but not limited to 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 United States is eligible to ship hormone-free meat, dairy products, egg products, and fishery products separately, it is sometimes not possible to ship the composite products that combine these eligible ingredients.

Three categories of composite products are distinguished: (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 requires 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 in Annex V of Commission Implementing Regulation (EU) 2020/2235. Specifically, the EU importer has to provide the list of ingredients and the establishment approval numbers for the animal origin ingredients in the product.

If a product with multiple ingredients contains an unprocessed animal origin product, it will not be considered a composite product. Obtaining certification from U.S. Government agencies for multiple animal origin ingredients in a final product that is not a composite product is usually not possible. More information on the import conditions for composite products is available on the European Commission's website. This website also includes a compilation of Questions & Answers intended to clarify a multitude of practical questions that have been raised on the 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>. 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.

Composite products listed in <u>Commission 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. For these products, a private attestation in accordance with the model laid down in Annex V to <u>Commission Implementing Regulation (EU) 2020/2235</u> still has to be presented by the importer. Checks on products and accompanying private attestation may be carried out by the Member State's competent authorities at the point of destination, point of release for free circulation, warehouses or operators' premises.

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 animal 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 IPPC ePhyto Solution at the website of the IPPC. Phytosanitary certificates are issued by APHIS inspectors, who can attest to the specific requirements of EU legislation.

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 animals and goods that could enter the EU outside of regular commercial channels. 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 and samples of products of animal origin, or composite products for product analysis and quality testing, including organoleptic analysis
- 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 persons which are not intended to be placed on the market
- Pet animals

In order to send product samples to commercial trade shows in cases where the harmonized EU commercial health certificates allowing the product to be sold freely in the EU cannot be obtained, it is

advised to make contact with the FAS office in the Member State where the trade show will take place to obtain more details on the specific animal health conditions and traceability requirements under which goods can be brought in. Please also contact our <u>Member State FAS office</u> or the EU APHIS office (<u>Xavier.Mennig@usda.gov</u>) for the 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. GOVERNMENT CERTIFICATE LEGAL ENTRY REQUIREMENTS

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
 - AMS Dairy Program-EU Dairy and Composite Product Certification Programs https://www.ams.usda.gov/services/imports-exports/dairy-exports/eu-dairy-exports
 - Eggs and Egg Products Export Information
 http://www.ams.usda.gov/services/imports-exports/eggs-egg-products European Union (EU) (pdf)
 - Mandatory Procedures for Domestic Honey Exported to the European Union and Great Britain
 - https://www.ams.usda.gov/services/imports-exports/honey
 - Seeds for Sprouting Certification Program
 Please contact SClinspectionoperations@usda.gov
- APHIS: Animal and Plant Health Inspection Service, USDA
 - International Animal Export Regulations <u>https://www.aphis.usda.gov/live-animal-export</u>
 - International Animal Products Export Regulations https://www.aphis.usda.gov/animal-product-export
 - Plant Export Services
 https://www.aphis.usda.gov/aphis/ourfocus/planthealth/SA_Export
- 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: https://www.fsis.usda.gov/inspection/import-export/import-export-library/european-union
- NOAA: National Oceanic and Atmospheric Administration https://www.fisheries.noaa.gov/content/export-certification

Exporters of FDA regulated products that are certified by other agencies should refer to Appendix II for specific guidance on how to meet EU product certification and establishment listing requirements.

SECTION IV

A. Other Certification/Accreditation Requirements to Ensure Market Entry:

EU food legislation is characterized by a constant flow of new regulations. EU regulations are available in the 24 official languages in use in the EU-27 and published chronologically in the Official Journal of the European Union, which is the official publication for EU legal acts and other official information from EU institutions. The Eur-lex website provides free access to the electronic versions of 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. 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. Consolidated texts (i.e. the consolidation of a basic legal act and subsequent amendments into one text) are also available on the European Commission's Eur-lex website.

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. Paper and electronic certificates issued in accordance with the applicable EU standards have the same legal value.

Commission Implementing Regulation (EU) 2019/1715 (IMSOC Regulation) lays out the rules on the issuance of electronic certificates and the use of electronic signatures, in or in exchange with TRACES, which is the European Commission's online platform for sanitary and phytosanitary certification and border clearance formalities. The U.S. Government does not issue certificates in TRACES. U.S. agencies continue to issue paper documents for the exports of all animal origin products. The IPPC ephyto solution allows for the transfer of ePhytos between APHIS and the EU's TRACES system.

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

- In addition to the signature of the official veterinarian/certifying officer, the certificate shall bear an official stamp. The color of the 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
 - o 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.

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.

B. U.S. Radiation Monitoring:

The European Union does not require attestation of radioactivity for imports. Harmonization of EU rules on food irradiation has been slow and only a few products have received EU-wide approval so far. The import of irradiated food from the United States is not authorized as no U.S. establishments are included in the list of approved facilities in third countries for the irradiation of foods. EU regulations do not require certification related to the non-application of irradiation treatment as a condition for entry of food.

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 https://www.aphis.usda.gov/live-animal-export.

- Horses/Equine (Live and Germplasm)
- Cattle/Bovine (Germplasm)
- Sheep and Goats/Ovine and Caprine (Germplasm)
- Swine/Porcine (Live and Germplasm)
- Poultry
- Birds (Non-Poultry)
- Aquatic Animals
- Research/Laboratory 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/animal-product-export).

Materials 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)
- Dicalcium Phosphate
- 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
- 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)
- Tricalcium Phosphate
- 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/inspection/import-export/import-export-library/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 United States.
- 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 FSIS Form 9060-5 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

Transit certificates 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 for poultry and meat even though they relate to animal health. While establishments of origin do not need to be EU approved, establishments that produce products that include meat and poultry ingredients that transit or are stored in the EU need to be registered on the "Official Listing for Eligible Suppliers for the USDA Export Verification Program for Products Transiting the EU". AMS has developed instructions on general policies and procedures for providing services under the EV Program for Product Transiting the EU in QAD Procedure 1015, QAD Procedure 1000, LP 109 Application Process, and LP-109 Form.

Ineligible Products - Highly Pathogenic Avian Influenza (HPAI)

FSIS will not issue export or transit certificates for fresh poultry from areas that are subject to EU animal health restrictions following outbreaks of Highly Pathogenic Avian Influenza (HPAI) in the

United States. When an area becomes subject to restrictions, a map of the areas is posted on the FSIS website. For each of the affected areas, the start date as well as the end date of the restrictions is mentioned. 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. The <u>FSIS export library</u> provides details on how to obtain the <u>FSIS Letterhead Certificate of Authenticity for Beef and Veal under Commission Implementing Regulation (EU) 2020/761</u> or the <u>FSIS Letterhead Certificate of Authenticity for Beef and Veal under Commission Implementing Regulation (EU) No 2020/1988</u>.

D. AMS Certification for Dairy

See: Appendix II: Instructions for Exporters of FDA Regulated Products Certified by Other Agencies

E. AMS Certification for Eggs and Egg Products

See: Appendix II: Instructions for Exporters of FDA Regulated Products Certified by Other Agencies

F. AMS Certification for Honey

See: Appendix II: Instructions for Exporters of FDA Regulated Products Certified by Other Agencies

G. AMS Certification for Seeds for Sprouting

See: Appendix II: Instructions for Exporters of FDA Regulated Products Certified by Other Agencies

H. NOAA Certificates for Seafood

See:Appendix II: Instructions for Exporters of FDA Regulated Products Certified by Other Agencies 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 stephane.vrignaud@trade.gov.

I. FSIS or AMS Certification for Composite Products

The EU defines a composite product as a food product containing both <u>processed</u> products of animal origin (dairy, egg, fishery products, or meat products) and products of plant origin. <u>USDA's Food Safety Inspection Service (FSIS) will issue EU composite product certificates</u> for composite products produced at FSIS-regulated facilities and bearing the USDA mark of inspection. AMS Dairy Program will issue the EU composite product certificates for composite products NOT produced in an FSIS-regulated facility and not bearing the USDA mark of inspection, regardless of whether dairy is an ingredient in the composite product. (See Appendix II: Instructions for Exporters of FDA Regulated Products Certified by Other Agencies)

J. FDA Certificates

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

The U.S. Food and Drug Administration issues all EU export certificates for collagen and gelatin for human consumption. FDA will only issue certificates to exporters that have been included in the <u>EU approved list of collagen and gelatin establishments</u>. More information on the product definitions, the documentary requirements, and the process for establishment listing for collagen and gelatin is available from <u>Collagen and Gelatin Export Lists | FDA</u>.

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.

The EU also requires certificates for highly refined products described in Section XVI of Annex II to Regulation 853/2004 including chondroitin sulphate, hyaluronic acid, other hydrolyzed cartilage products, chitosan, glucosamine, rennet, isinglass, and amino acids. Certification required by the EU for these products may not be available to exporters. Contact CFSANExportCertification@fda.hhs.gov (+1-240-402-2307).

Readers are referred to Appendix II for additional information on FDA regulated product certified by other agencies.

K. Pedigree and Zootechnical Certificates

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

L. 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/signIn.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 Packaging Materials</u> and on certification programs such as the <u>European Union Ash Systems Approach Program</u> for lumber.

M. Other Plant Certificates

Product	Official Journal Reference/ Model from the Official Journal	U.S. Issuing Agency/ U.S. Agency Form	Title/ Comments
Rice	2020/761 Annex XIV.2 Part C	AARQ	Certificate of EU Quotas Allocation
Wheat (other than Durum)		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. Federal Grain Inspection Service (FGIS) contact information: https://www.ams.usda.gov/resources/fgis-field-offices
Malting barley	2020/1988 Annex II	FGIS	Certificate of conformity: Quality Certificate providing access to the 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 gluten feed	2023/2834 Annex XIV	FGIS	Commodity Inspection Certificate 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-content/uploads/2018/10/Feed2006.pdf pp.8-9
Corn Gluten Meal Tariff	2015/2447 art 57-59 and Annex 22-14 special non-		Certificate of Origin is required to import under the TRQ of Reg 2020/1988 Louisiana Maritime Chamber of Commerce cooperates with

Code	preferential		Corn Refiners Association (https://corn.org/about-cra/staff/)
	import		(======================================
	arrangements		
Fresh fruits		None	Certificate of conformity with the community marketing
	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,	2006/232/EC	TTB (Department of	Commercial Document to accompany wine products
grape juice	Agreement	the Treasury -	originating in the United States.
(*) or		Alcohol and Tobacco	Imports of wine into the EU must be accompanied by a
grape must	European	Tax and Trade	"VI1" document, published in Commission Delegated
	Community	Bureau) is the	Regulation (EU) 2018/273. This is a certificate of origin and
	and the	competent authority	analysis issued in the country of origin. As a result of the
	United States		U.SEU wine agreement, the U.S. can follow a simplified
	of America		procedure and use the Commercial Document to accompany
	on trade on		wine products originating in the United States in Annex III
	wine		of the Agreement. Wine producers that have received
	Annex III		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
	2018/273		website. The list of approved U.S. wine producers and
	VI1 Form,		laboratories delegated to draw up the document is published
			on the European Commission's website:
			<u>List 6 – third countries' competent bodies</u>
			(*) 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.
Fresh		USDA/AMS or	Certificate of Authenticity for Fresh 'Emperor' Table Grapes
'Emperor'	Schedule		For tariff calculation purposes
Table	<u> 2658/87</u>	of Agriculture, or	
Grapes	Annex 9	- California	
		Department of Food	
		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>		
	Annex 9		

Almonds	Annex II	Within the California Department of Food and Agriculture is	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. A PEC certificate is only issued if aflatoxin testing is done according to EU protocol in USDA approved laboratory See also http://www.ams.usda.gov/services/lab-testing/aflatoxin For further information see Almond Board of California
Peanuts	No EU regulation with standard model certificate		At the request of the American Peanut Council (APC), AMS administers a program for aflatoxin testing of peanuts destined for export to the EU. The Peanut Export Program (PEP) was developed to meet European Union (EU) expectations for a formal aflatoxin control program for U.S. peanut exports to EU Member States. An aflatoxin certificate is not required by the EU but certification according to Peanut Export Program (PEP) is commonly provided by exporters.
Pistachios	No EU regulation with standard model certificate		At the request of the Administrative Committee for Pistachios (ACP), AMS administers a program for aflatoxins and ochratoxin A testing of pistachios destined for EU through the Pistachio Export Aflatoxin Reporting (PEAR) Program. An aflatoxin certificate is not required by the EU but certification according to the PEAR program is commonly provided by exporters.
Organics	2021/2306		The EU has implemented a system of electronic Certificates of Inspection (COI) for imports of organic products in the EU. 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 2021/2306 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. More information here: https://agriculture.ec.europa.eu/farming/organic-farming/trade_en Commission Notice Questions and answers on the

		lamplication of EII myles on import controls on madvets from
		application of EU rules on import controls on products from
		third countries intended to be placed on the EU market as
2022/2024	TILL I C	organic products or in-conversion products
		Attestation of Equivalence
Annex XIV		
	The state of the s	
	Agriculture	
	State Chemical and	
	Hop Lab	
	Idaho Department of	
	_	
	Division of Plant	
	Industries	
	Hop Inspection Lab	
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	•	
	California	
	Department of Food	
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	2023/2834 Annex XIV	Annex XIV Agencies authorized to issue an attestation of equivalence for products of the hop sector imported into the EU Washington Department of Agriculture State Chemical and Hop Lab Idaho Department of Agriculture Division of Plant Industries Hop Inspection Lab Oregon Department of Agriculture Commodity Inspection Division

APPENDIX II: INSTRUCTIONS FOR EXPORTERS OF FDA REGULATED PRODUCTS CERTIFIED BY OTHER AGENCIES

FDA regulated products covered by this section include seafood, dairy products, honey and other apiculture products, egg and egg products regulated by the FDA, and composite products regulated by the FDA.

For each of these products, the exporter needs to assess whether they must obtain a health certificate to accompany shipments sent to the EU. Exporters should be aware that NOAA issues the health certificates required by the EU for seafood. AMS issues the health certificates required by the EU for the other product groups.

In addition, the exporter will have to check whether the animal origin ingredient or product supplier is listed on the appropriate EU approved establishment list in TRACES. The handling of the listing process, whereby companies are included in the list of EU approved establishments, remains under the responsibility of FDA.

Products not needing controlled temperatures during transport may not require a U.S. Government-issued certificate. Most animal origin ingredients must be sourced from EU approved establishments listed in TRACES. Animal ingredient suppliers in the United States will have to work with the FDA to be listed. Consignments shipped to the EU must rely on a private declaration from the importer to convey information regarding the establishment where the animal product ingredient is sourced. This will not be conveyed as part of a U.S. government certificate.

Seafood

The EU export health certificate attests to the safety of fish and fishery - both wild and aquaculture and is required by the EU Directorate-General for Health and Consumer Protection. U.S. exports of seafood products to the EU are subject to establishment listing requirements as a precondition for market access. Establishments may apply for inclusion on these lists via the Export Listing Module (ELM). Please visit the Online Applications for Export Lists for a link to this electronic system and for step-by-step instructions. Please note, the EU will only accept export certificates signed after an establishment has been added to the list published on the European Commission website and only when the list has entered into force. Once listed, U.S. establishments may contact the National Oceanic and Atmospheric Administration (NOAA) Seafood Inspection Program to request export certificates for U.S. seafood exports to the EU. These certificates must be requested and issued prior to shipment of the product. Follow this link to submit a request online.

Dairy Products

USDA's Agricultural Marketing Service (AMS) is the certifying agency for EU export certificates for dairy products regulated by the FDA. For more information, contact DairyExportsQuestions@usda.gov.

In order to obtain an EU Health Certificate, manufacturers must have their final production, blending, and/or packing facility listed on the directory of EU approved facilities on the <u>European Commission</u> <u>website</u>. Exporters should check whether the manufacturing facility for exported products has been

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

Honey and Other Apiculture Products

The EU requires a Chapter 45 certificate with public health attestations for imports of the following apiculture products intended for human consumption: honey, beeswax, royal jelly, propolis, or pollen imported under the Harmonized System (HS) code headings 0409, 0410, 1212, 1521, and 1702. Exporters of these products should contact SCIinspectionoperations@usda.gov to obtain a Chapter 45 certificate.

In order to obtain an EU Health Certificate, establishments that produce (process, bottle, or pack) honey or other apiculture products must be listed on the directory of EU approved facilities on the European Commission website. Exporters should check whether the establishment for exported products has been included on this list. Exporters may apply for inclusion on these lists through the FDA Export Listing Module (ELM). Please visit the Online Applications for Export Lists for a link to this electronic system and step- by-step instructions.

Composite products (see below) containing apiculture products as an ingredient fall outside the scope of the Chapter 45 certificate.

Eggs and Egg Products

In the egg sector, USDA's Agriculture Marketing Service (AMS) is the certifying agency for export certificates for egg products regulated by FDA. The AMS Livestock, Poultry, and Seed Division is responsible for the EU export certificates for 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, noodles, cake mixes, dietary foods, dried nobake 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 following website: https://www.fda.gov/media/172542/download.

U.S. exports of eggs and egg products to the EU are subject to establishment listing requirements as a precondition for market access. Establishments may apply for inclusion on these lists via the Export Listing Module (ELM). Please visit the Online Applications for Export Lists for a link to this electronic system and step- by-step instructions. When plant ingredients are added to egg products, exporters should consult the below section on composite products.

Composite Products

The EU defines a composite product as a food product containing both processed products of animal origin and products of plant origin. This section only concerns composite products regulated by FDA; it

does not concern composite products produced at FSIS-regulated facilities bearing the USDA mark of inspection.

EU legislation distinguishes three categories of composite products: (1) non-shelf stable composite products, (2) shelf stable composite products that contain meat products, and (3) shelf stable products that do not contain meat products. These three products have different entry requirements. The EU requires composite product certificates for all non-shelf stable products and for shelf stable products with a meat ingredient.

All composite product certificates are available from <u>ATLAS</u> and managed by the AMS Dairy Program, irrespective of the ingredients in the final product. Prior to requesting a certificate from AMS Dairy Program, a new customer will need to establish a USDA level 2 e-authentication account. Go to AMS Dairy Program – EU Dairy and Composite Product Certification Programs | Agricultural Marketing Service for additional information.

In 2025, changes are being implemented to the certificates for composite products that contain a processed honey or apiculture product ingredient and for composite products that contain gelatin or collagen derived from ruminant bones. For composite products containing gelatin or collagen derived from ruminant bones, the approval number of the establishment on TRACES gelatin or TRACES collagen list must be indicated in the certificate. Composite product certificates for products containing processed honey or apiculture products must also indicate the establishment registration number from the appropriate TRACES list. All certificates issued after November 19, 2025 must include this information. Please visit the Online Applications for Export Lists for a link to this electronic system and step- by-step instructions. For further information from FDA, please see FDA's website: https://www.fda.gov/food/exporting-food-products-united-states/food-export-lists, or contact FDA at: hfpexportcertification@fda.hhs.gov.

Shelf-stable composite products that do not contain meat and do not contain collagen or gelatin derived from bovine bones do not require an export certificate. If the product contains animal ingredients of animal origin, the EU importer will have to complete and sign a private attestation. In the attestation, they must provide the TRACES establishment number for the ingredient of animal origin. Since the introduction of the establishment listing for honey and apiculture products, Member States have also requested this information in the private attestation for the processed honey ingredient.

Attachments:

No Attachments