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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, 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 447 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, Turkey, Albania, Serbia, Ukraine, and Moldova 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 foods of animal origin were published by the EU and implemented by U.S. agencies. Several amendments to the new certificates were made since their first publication. They are available from <u>Commission Implementing Regulation (EU) 2020/2235</u> (consolidated version July 14, 2022) and U.S. Government agencies are making use of the transitional periods foreseen in EU legislation to switch to updated certificate versions. 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 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 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: <u>https://ec.europa.eu/info/relations-united-kingdom/new-normal/consequences-brexit\_en</u>

The European Commission published a notice to stakeholders on the withdrawal of the United Kingdom and EU food law, which is available here: <a href="https://ec.europa.eu/info/sites/info/files/brexit\_files/info\_site/notice\_for\_stakeholders\_food\_law.pdf">https://ec.europa.eu/info/sites/info/files/brexit\_files/info\_site/notice\_for\_stakeholders\_food\_law.pdf</a>

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) 2019/625 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/.

## 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.

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 FAIRS export certificate reports referenced at the end of this report or by contacting the local FAS Post. Post contact information is available from <a href="https://apps.fas.usda.gov/overseas\_post\_directory/">https://apps.fas.usda.gov/overseas\_post\_directory/</a>. 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. These approvals and related restrictions are reflected in the lists published in three EU regulations.
  - <u>Commission Implementing Regulation (EU) 2021/404</u> 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.</u>

These restrictions are frequently updated based on the development of the animal health status in the affected areas.

- <u>Commission Implementing Regulation (EU) 2021/405</u> 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.
- <u>Commission Decision 2011/163/EU</u> of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC: 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 also delisted by the EU for the export of casings. At the time of writing this report, the re-listing process for casings had not been finalized.
- 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: <a href="https://webgate.ec.europa.eu/tracesnt/directory/publication/establishment/index#!/search">https://webgate.ec.europa.eu/tracesnt/directory/publication/establishment/index#!/search</a>. 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> guide 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 sometimes 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 current 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 in Annex V of <u>Commission</u> <u>Implementing Regulation (EU) 2020/2235</u>. Specifically, the EU importer has to provide the list of ingredients and the establishment approval numbers for the animal origin ingredients in the product.

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</u> <u>Implementing Regulation (EU) 2021/632</u>. Composite products listed in <u>Commission Delegated</u> <u>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 Commission Implementing Regulation (EU) 2020/2235 still has to be presented by the importer. 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. 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 natural 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. 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
  - AMS Dairy Program-EU Dairy and Composite Product Certification Programs <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
  - http://www.aphis.usda.gov/regulations/vs/iregs/animals/
  - 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 https://www.fda.gov/food/food-imports-exports/exporting-food-products-united-states
- FSIS: Food Safety and Inspection Service, USDA Export Requirements for the European Union: <u>https://www.fsis.usda.gov/inspection/import-export/import-export-library/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 (http://eur-lex.europa.eu/en/index.htm) 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 Government 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:
  - $\circ$  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@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 (http://www.aphis.usda.gov/regulations/vs/iregs/animals/).

- 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 <a href="https://www.aphis.usda.gov/aphis/pet-travel">https://www.aphis.usda.gov/aphis/pet-travel</a>).

## **B. APHIS Certificates for Animal Products**

IMPORTANT: The list of APHIS health certificates for the EU provided below should be seen in conjunction with the additional information on EU import requirements (for instance on establishment registration) provided on the APHIS website. The APHIS website is updated on a regular basis to incorporate all developments in EU import requirements for all products under APHIS jurisdiction (https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/iregs-for-animal-product-exports/ct\_iregs\_animal\_product\_exports\_home).

#### Materials for human consumption

- 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 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**

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 "<u>Official Listing for Eligible Suppliers for the USDA Export Verification Program for Products</u> <u>Transiting the EU</u>". AMS has developed instructions on general policies and procedures for providing services under the <u>EV Program for Product Transiting the EU</u> in <u>QAD Procedure 1015</u>, <u>QAD Procedure 1000</u>, <u>LP 109 Application Process</u>, and <u>LP-109 Form</u>.

# 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</u> under <u>Commission</u> <u>Implementing Regulation (EU) 2020/761</u> or the <u>FSIS Letterhead Certificate of Authenticity for Beef and Veal</u> under <u>Commission</u> <u>Implementing Regulation (EU) 2020/761</u> or the <u>FSIS Letterhead Certificate of Authenticity for Beef and Veal</u> under <u>Commission Implementing Regulation (EU) No 2020/1988</u>.

# **D. AMS Certification for Dairy**

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

USDA's Agricultural Marketing Service (AMS) is the certifying agency for EU export certificates for dairy products regulated by FDA.

In order to obtain an EU Health Certificate, the manufacturers must have their final production, blending, and/or packing facility listed on the List of EU approved facilities maintained on the European <u>Commission website</u>. Exporters should check whether they have been included in this list. Exporters may apply for inclusion on these lists through the FDA 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.

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.

In the egg sector, USDA's Agriculture Marketing Service (AMS) is the certifying agency for EU export certificates for egg products regulated by FDA. The AMS Livestock, Poultry and Seed Division is responsible for the EU 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 (Exhibit 3-1).

To be eligible for the EU certificates for food products containing eggs or egg products that are regulated by FDA, manufacturers must participate in the <u>AMS Processed Egg and Egg Products</u> <u>Verification Program</u> and appear on the <u>List of EU approved facilities maintained on the European</u> <u>Commission website</u>. FDA-regulated exporters may to apply for inclusion on these lists through the FDA 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.

## 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

The U.S. Department of Commerce National Oceanic and Atmospheric Administration (NOAA) is the certifying agency for EU export certificates for fish and fishery products and molluscan shellfish. However, establishments wishing to export these products must be included on the relevant <u>list of EU</u> approved establishments. Establishments may apply for inclusion on these lists via the FDA 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 offers four documents required for export to the European Union.

They are:

- EU export health certificate;
- Export Health EU Bivalve Mollusc, Echinoderms, Tunicates, and Marine Gastropods
- Legal Harvest U.S. document for fisheries products harvested in the United States, to prevent, deter, and eliminate illegal, unregulated and unreported (IUU) fishing; and,
- The EU "Annex IV" Legal Harvest 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 Legal Harvest documents.

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. FSIS or AMS Certification for Composite Products

See: <u>https://www.fsis.usda.gov/inspection/import-export/import-export-library/european-union</u>

https://www.ams.usda.gov/services/imports-exports/dairy-exports/eu-dairy-exports, and specifically Dairy Program Reference Document on European Union (EU) Composite Product Certificates

The EU defines a composite product as a food product containing both processed products of animal origin (dairy, egg, fishery products, or meat products) and products of plant origin. Exporters of products with ingredients of plant and animal origin will first have to assess whether their product would actually be classified by the EU as a composite product. If it is not classified as such, any of the animal product certificates described above may have to be requested.

If the product fulfills the definition of a composite product, either a private attestation or a composite product certificate will have to be presented to the EU border control inspectors upon import. In both cases, the applicable establishment listing requirements will have to be met.

For shelf stable products not containing meat, a certificate signed by the U.S. Government is not required, but 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 <u>Commission Implementing</u> <u>Regulation (EU) 2020/2235</u>. Specifically, the EU importer has to provide the list of ingredients and the EU approval numbers of the ingredient suppliers in the United States or elsewhere as listed on the <u>EU</u> <u>Approved Establishment list</u> for the animal origin ingredients in the product.

For all other composite products, a certificate issued by FSIS or AMS will be required. Composite product manufacturers are not required to be on an EU approved list; however, composite product manufacturers are required to be <u>registered</u> by the competent authority in the United States, which will either be FSIS or FDA. The animal derived ingredient in a composite product has to be sourced from an establishment on the <u>EU Approved Establishment list</u>, which may be in a different country than the country where the composite product is manufactured.

FSIS will issue the composite product certificate for composite products containing dairy, egg and meat if the composite product is manufactured in a FSIS regulated facility and bears the <u>USDA mark of inspection</u>. Note: Certain products containing small amounts of meat, poultry, or egg products as an ingredient are exempt from FSIS inspection. As an example, composite products containing 3% or less raw meat, or less than 2% cooked meat or poultry are regulated by the FDA.

The AMS Dairy Program will issue the composite product certificate for products containing dairy, egg, fishery, or small amounts of meat when composite products are NOT produced in an FSIS regulated facility and do not bear the USDA mark of inspection, regardless of whether dairy is an ingredient in the composite product.

In order to obtain the required certificate for a composite product containing a dairy ingredient from the United States, a Certificate of Conformance as described in the <u>AMS Dairy Program's Export</u> <u>Verification Program</u> must be provided. Composite product manufacturers utilizing egg products as an ingredient must participate in the <u>AMS Processed Egg and Egg Products Verification Program</u> to be eligible for an EU Composite Product Certificate.

## 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 EU approved list of <u>collagen</u> and <u>gelatin</u> establishments. More information on the product definitions, the documentary requirements, and the process for establishment listing for collagen and gelatin is available from <u>Collagen</u> and <u>Gelatin Export Lists | FDA</u>.

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

For shelf-stable composite products containing only gelatin, collagen or highly refined products of meat origin as processed meat ingredient (such as chondroitin sulphate, hyaluronic acid, other hydrolyzed cartilage products, chitosan, glucosamine, rennet, isinglass and amino acids), the EU now requires a private attestation as set out in Annex V to <u>Commission Implementing Regulation 2020/2235</u>.

Non-shelf stable composite products that contain gelatin, collagen, or highly refined products must be accompanied by an official certificate. Certification required by the EU for these products may not be available to exporters. Contact <u>CFSANExportCertification@fda.hhs.gov</u> (240-402-2307).

## 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

<u>https://pcit.aphis.usda.gov/pcit/faces/signIn.jsf</u>) 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.

## **M.** Other Plant Certificates

Product	Official	U.S. Issuing Agency/	Title/
	Journal Reference/ Model from the Official Journal	U.S. Agency Form	Comments
Rice	<u>2020/761</u>	AARQ	Certificate of EU Quotas Allocation (Annex XIV.2 Part C of <u>2020/761</u>
Wheat (other than Durum)	<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. Federal Grain Inspection Service (FGIS) contact information: https://www.ams.usda.gov/resources/fgis-field-offices
Malting barley	<u>2020/1988</u>	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: <u>https://www.ams.usda.gov/resources/fgis-field-offices</u>
Corn gluten feed	2007/1375	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 Code 23031011		Commerce	Certificate of Origin is required to import under the TRQ of Reg 2020/1988 Louisiana Maritime Chamber of Commerce cooperates with Corn Refiners Association ( <u>https://corn.org/about-cra/staff/</u> )
Fresh fruits and vegetables	<u>543/2011</u> Annex III	None	Certificate of conformity with the community marketing standards for fresh fruit and vegetables. No U.S. agency issues this certificate. Imports to the EU can be certified at the border.
Wine, grape juice (*) or grape must	Agreement between the European Community	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: List 6 – third countries' competent bodies (*) 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 'Emperor' Table Grapes	EU Tariff Schedule <u>2658/87</u> <u>Annex 9</u>	USDA/AMS or -Arizona Department of Agriculture, or - California Department of Food and Agriculture Certificate of Authenticity for Fresh 'Emperor' Table Grapes.	Certificate of Authenticity for Fresh 'Emperor' Table Grapes For tariff calculation purposes
Tobacco Peanuts	EU Tariff Schedule <u>2658/87</u> <u>Annex 9</u> None	Tobacco Assoc. of U.S.	Certificate of Authenticity for Tobacco For tariff calculation purposes 2019/1776 amends 2658/87 <u>Regulation 2017/1269</u> 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 Annex II	for the PEC program. Shipping Point Inspection Within the California Department of Food and Agriculture is responsible for signing the PEC	Use of this certificate not mandatory but regulation mandates that consignments with this certificate are controlled at less than 1%. The USDA Agricultural Marketing Service started to issue PEC almond certificates on August 1, 2015. The almond PEC program builds on and replaces the Voluntary Aflatoxin Sampling Plan (VASP) program, which stopped being required in September 2014 when the EU voted to remove California Almonds from Special Measures (removal from 1152/2009). A PEC certificate is only issued if aflatoxin testing is done according to EU protocol in USDA approved laboratory See also <u>http://www.ams.usda.gov/services/lab- testing/aflatoxin</u> For further information see <u>Almond Board of California</u>

Organics	<u>2021/2306</u>	USDA/AMS	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 application of EU rules on import controls on products from third countries intended to be placed on the EU market as organic products or in-conversion products
Hop Cones Hop Powders Saps and Extracts of		Washington Department of Agriculture State Chemical and Hop Lab	Attestation of Equivalence
Hops		Idaho Department of Agriculture	
		Division of Plant Industries	
		Hop Inspection Lab	
		Oregon Department of Agriculture	
		Commodity Inspection Division	
		California Department of Food	

Division of Inspection Services Analytical Chemistry Laboratory USDA, GIPSA, FGIS - OR USDA, GIPSA, TSD, Tech Service Division, Technical Testing Laboratory –	and Agriculture	
Inspection Services Analytical Chemistry Laboratory USDA, GIPSA, FGIS - OR USDA, GIPSA, TSD, Tech Service Division, Technical Testing Laboratory –	(CDFA-CAC)	
Analytical Chemistry Laboratory USDA, GIPSA, FGIS - OR USDA, GIPSA, TSD, Tech Service Division, Technical Testing Laboratory –		
Laboratory USDA, GIPSA, FGIS - OR USDA, GIPSA, TSD, Tech Service Division, Technical Testing Laboratory –	Inspection Services	8
USDA, GIPSA, FGIS - OR USDA, GIPSA, TSD, Tech Service Division, Technical Testing Laboratory –	-	try
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## **Appendix II: Related FAS Reports**

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

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

## Attachments:

No Attachments