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**Report Highlights:**

This report provides an overview of health certificates needed for exporting plants, animals, foods, and other animal origin products to Bulgaria.

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## DISCLAIMER

This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service in Bulgaria, 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**

Bulgaria follows European Union (EU) regulations and model certificates. Please, refer the FAS USEU report about model certificates for 2024, [EU FAIRS Export Certificate Report Annual \(E42024-0034\)](#).

Bulgarian food safety inspectors at border points of entry are generally approachable and can be consulted in advance when U.S. exporters and Bulgarian importers have questions regarding appropriate certificates for specific products. Border inspectors consult with the European Commission (EC) when questions arise. They also regularly contact the FAS/Sofia if there are issues with U.S.-origin shipments. U.S. exporters are encouraged to consult with FAS/Sofia prior to shipping consignments to Bulgaria.

**Section I. List of All Export Certificates Required by Government (Matrix)**

Bulgaria closely follows EU legislation and requires the same export certificates for U.S. products as other EU member states. The purpose of these required certificates is food safety. Health certificates are required for all products of animal origin, and phytosanitary certificates are needed for all plant products that could introduce pests into the EU. The Bulgarian Food Safety Agency ([BFSA](#)), under the Ministry of Agriculture, is tasked with Bulgarian border control. The specific products with the respective titles of certificates and attestations are listed below (see Appendix I). FAS/Sofia recommends that U.S. exporters consult with the FAS/Sofia for any questions related to import requirements, import certificates, or issues about Bulgaria-specific import regulations.

In 2017, the EU adopted a new framework regulation for official controls ([Regulation \(EU\) 2017/625](#)). The major regulation was supplemented by several other regulations including [Commission Delegated Regulation \(EU\) 2022/2292](#) with regard to requirements for the entry into the EU 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. The regulations provide the legal basis for the verification by EU officials of most of the certification information and are strictly followed by Bulgarian border inspectors.

<b>Product(s)</b>	<b>Title of Certificate</b>	<b>Attestation Required on Certificate</b>	<b>Purpose</b>	<b>Requesting Ministry</b>
Products of Animal Origin	Health Certificate	Attestation is dependent on the product. Detailed attestation can be found in the model certificates available under the relevant regulations (e.g. dairy products, pork, beef, etc.) – The most recent updated models of the certificates for food of animal origin were published in	Food Safety	BFSA (Veterinary Service/Border Control)

		<a href="#"><u>Commission Implementing Regulation (EU) 2020/2235 (consolidated version July 29, 2024)</u></a>		
Composite Products	Health Certificate	<a href="#"><u>Commission Delegated Regulation (EU) 2022/2292</u></a> establishes specific entry conditions for composite products.	Food Safety	BFSA (Veterinary Service/Border Control)
Plant Products which can introduce pests	Phytosanitary Certificate	APHIS inspectors attest to specific requirements of EU legislation by making additional declarations in the relevant phytosanitary certificate boxes. These declarations are specific for different plant species, and they are subject to change. Thus, the shipper needs to check for the most recent language before export.	Plant Health	BFSA (Phytosanitary Service/Border Control)
Various Plant Products	Other than Phytosanitary Certificate	e.g., aflatoxin levels in almonds: Use of the Pre-Export Certification (PEC) program is not mandatory, but EU regulation mandates that consignments with this certificate are controlled for aflatoxin levels at less than 1%. USDA/AMS is the competent authority for the PEC program.	Food Safety and Quality	BFSA (Veterinary Service/Border Control)

**A. Export Certificates/Requirements for Live Animals and Animal Genetics**

The EU imposes general requirements for all veterinary health certificates. [Directive 2002/99/EC](#), Annex IV.6, stipulates that certificates must be issued before consignments leave the control of the competent authority. Non-compliance will lead to rejection of the shipment at the EU border entry point.

[APHIS](#) issues the following certificates for exports to the EU: 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 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>. 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 EU (see <https://www.aphis.usda.gov/aphis/pet-travel>).

Bulgaria is an importer mainly of bovine genetics and live breeding poultry (ducks) from the United States. The U.S. exporters of these products are advised to consult with the FAS/Sofia for any questions related to the relevant import requirements.

Prior to April 2021 bilingual Bulgarian/English health certificates were available for some commodities/species on the Animal and Plant Health Inspection Service's (APHIS) website (bovine semen and equine semen). Since April 20, 2021, English-only certificates are accepted in accordance with [Regulation \(EU\) 2016/429](#) and [Delegated Regulation \(EU\) 2020/692](#) (please refer to the English versions).

Supplementary information regarding the export certificates is available in the [EU FAIRS Export Certificate Report Annual \(E42024-0034\)](#) and at the FAS USEU [website](#).

## **B. Export Certificates/Requirements for Animal Products**

[Commission Delegated Regulation \(EU\) 2022/2292](#) establishes the requirements for entry into the EU of consignments of food-producing animals and certain goods intended for human consumption. These entry requirements are harmonized across the EU in a three-level process:

1. Country Approval: EU recognition of a country as eligible to export a particular product. [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 EU of animals, germinal products, and products of animal origin is permitted. [Commission Implementing Regulation \(EU\) 2021/405](#) outlines the list of third countries or regions thereof authorized for the entry into the EU 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 Bulgaria (and 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.
2. Establishment Approval: Recognition of approved production establishments, which may be subject to EU audits (see the EU-approved [list](#)). Only those products processed at approved establishments may enter the EU.
3. Product Certification: Animal or public health certificates based on the model certificates published by the EU in [Commission Implementing Regulation \(EU\) 2020/2235](#) 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.

In April 2021 the EU updated its Animal Health Law ([Regulation \(EU\) 2016/429](#)) and 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 [Commission Implementing Regulation \(EU\) 2020/2235 \(consolidated version July 29, 2024\)](#) 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.

Certificates 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 requires veterinary and/or general health certificates with each meat and meat product shipment to be signed and dated prior to export. In accordance with [Commission Implementing Regulation \(EU\) 2020/2235](#) certificates must be issued before the consignments to which they relate leave the control of the competent authority.

[APHIS](#) issues a number of certificates for animal products, including materials for human consumption and materials not for human consumption. 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>).

Please, refer to [EU FAIRS Export Certificate Report Annual \(E42024-0034\)](#) for more information.

The lists of [FSIS](#) health certificates for the EU should be seen in conjunction with the additional information on EU import requirements provided on the FSIS website. The FSIS website is updated on a regular basis to incorporate all developments in [EU import requirements for all products](#) under FSIS jurisdiction.

FSIS issues health certificates for the following products shipped to the EU with the intention to be sold on the EU market: fresh meat: beef and bison, pork, poultry and wild boar; further processed products from fresh meat that is eligible for certification to the EU, whether the fresh product is sourced inside or outside the U.S.; and egg products under FSIS authority: egg products under the authority of FSIS are liquid, frozen, or dried eggs, with or without ingredients.

The EU 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 EU 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](#).

The [FSIS](#) website (export library) is updated on a regular basis to incorporate all developments in EU import requirements for all products under FSIS jurisdiction.

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.

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 [FSIS export library](#) provides details on how to obtain the [FSIS Letterhead Certificate of Authenticity for Beef and Veal](#) under [Commission Implementing Regulation \(EU\) 2020/761](#) or the [FSIS Letterhead Certificate of Authenticity for Beef and Veal](#) under [Commission Implementing Regulation \(EU\) No 2020/1988](#).

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 Bulgaria (and the EU).

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.

### **C. Export Certificates/Requirements for Plant and Plant Products**

Import requirements for plants and plant products are harmonized at the EU level.

The [International Plant Protection Convention](#) (IPPC) provides model certificates recognized by the EU. Unlike veterinary products, IPPC provides only one model export certificate and one re-export certificate for all plant products. For more information, see the [IPPC ePhyto Solution](#) at the website of the IPPC.

For the United States, [APHIS](#) issues the required plant health/phytosanitary certificate with the attestations to specific EU requirements. The attestation to the specific requirements of EU legislation with the necessary declarations is included in the space provided on the phytosanitary certificate.

The [APHIS Plant Health Export Information site](#) provides also additional information on [Wood Packaging Materials](#) and on certification programs such as the [European Union Ash Systems Approach Program](#) for lumber. See [EU FAIRS Export Certificate Report Annual \(E42024-0034\)](#) for more information.

### **D. 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 processed products of animal origin and ingredients of plant origin. While the United States is eligible to ship hormone-free meat, dairy products, egg products, and fishery products separately, it is often not possible to ship the composite products that combine these eligible ingredients.



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.

FSIS will issue [EU composite product certificates 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 [EU FAIRS Export Certificate Report Annual \(E42024-0034\)](#) for more information and the EC’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 new rules.

## **E. FDA 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 collagen and gelatin establishments](#). The collagen and gelatin certificates of [Commission Decision 2003/863](#) continue to be valid for bovine and porcine material. More information on the product definitions, the documentary requirements, and the process for establishment listing for collagen and gelatin is available from [Collagen and Gelatin Export Lists | FDA](#).

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 requires a private attestation as set out in Annex V to [Commission Implementing Regulation 2020/2235](#). However, the EU will start to require a certificate for exports of shelf-stable composite products containing bovine gelatin and collagen as of 29 January 2025.

Non-shelf stable composite products that contain gelatin, collagen, or highly refined products must be accompanied by an official certificate. Bulgaria imports such products from the United States and border officials strictly follow the above regulations.

## **F. Pedigree and Zootechnical Certificates**

EC [Implementing Regulation \(EU\) 2020/602 of 15 April 2020](#) amending Implementing Regulation (EU) 2017/717 contains the model forms of zootechnical certificates for breeding animals and their germinal products.



## **J. 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 [Commission Implementing Regulation \(EU\) 2021/632](#). 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 EC.

Composite products listed in [Commission Delegated Regulation 2021/630](#) 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. Checks on products and accompanying private attestation may be carried out by [BFSA](#) at the point of destination, point of release for free circulation, warehouses or operators premises.

## **G. Products Outside of Regular Commercial Channels**

Products outside of regular commercial channels are often for research activities, samples for trade shows, and/or for personal consumption, and [Commission Delegated Regulation \(EU\) 2019/2122](#) applies to these products. The regulation 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.

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/Sofia if the trade show will take place in Bulgaria to obtain more details on the specific animal health conditions and traceability requirements under which goods can be brought in. Please also contact our EU APHIS office ([Xavier.Mennig@usda.gov](mailto:Xavier.Mennig@usda.gov)) 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.

See the [EU FAIRS Export Certificate Report Annual \(E42024-0034\)](#) for more information.

## **H. Export Certificates/Requirements for Non-harmonized Products**

Only a few products/by-products or exotic animals are not harmonized under EU legislation. In such cases, the National Bulgarian Food Safety Agency ([BFSA](#)) is the competent authority for providing the specific import conditions on non-harmonized products. Interested U.S. exporters should request additional guidance from FAS/Sofia.

## **Section II. Purpose of Specific Export Certificate(s)**

Imported products must meet existing Bulgarian (as an EU member) requirements, and products must be accompanied by the proper certification at the port of arrival. Health certificates are required for all imported products of animal origin and phytosanitary certificates are needed for all plant products that could introduce pests into the EU.

Transit certificates issued by the competent U.S. Government agency must accompany food shipments that physically enter the EU 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 [Commission Delegated Regulation \(EU\) 2019/2124](#). These cover the entry of goods into EU territory that are further transported: to a border control post in order to leave the EU territory; to an approved warehouse; to a NATO or U.S. military base located in the EU territory; to a vessel leaving the EU, 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 (for example the aflatoxin certificate for almonds).

The EU imposes a number of general requirements for all veterinary certificates. In accordance with [Commission Implementing Regulation \(EU\) 2020/2235](#), 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.

Prior to shipment, U.S. exporters should confirm with their Bulgarian importers that the consignment will be allowed to enter with the documentation accompanying the consignment. If there is any doubt regarding or lack of clarity, or if EU requirements are not listed, the Bulgarian importer may contact the pertinent border inspection points (BIP) with a description of the proposed import, including any animal-origin contents, and the intended use in Bulgaria. The approved BIPs for non-animal origin food and feed imports, as per [Regulation \(EU\) 884/2014](#) are available upon request at the BFSa. The Bulgarian officials will respond to the importer in writing.

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

BFSa requires the seal number of the container to be printed on the veterinary certificate. If no seal number is present on the certificate, border inspectors will make efforts to do identity checks based on other supporting documents. However, a physical inspection may be necessary to verify the identity of the shipment. For some veterinary certificates, additional statements (declaration of BSE/TSE) need to be included.

### Section IV. Government Certificate's Legal Entry Requirements

Bulgarian (and EU) food legislation changes frequently. All new changes and amendments are published in the EU Official Journal. The EUR-Lex [website](#) provides free access to EU laws.

Since 2017 the EU has allowed electronic certification in the EU's Integrated management System for Official Control. However, U.S. regulatory agencies do not issue electronic certificates in this system and continue to use paper certificates. Please, see FAS USEU's [FAIRS Export Certificate Report 2024 Annual](#) for specific requirements regarding paper certificates.

## Section V. Other Certification/Accreditation Requirements

Health certificates are mandatory for animal product imports, as are phytosanitary certificates for most plant product imports. In some cases, there are additional certificates (e.g., organic products) or voluntary certificates (e.g., almonds) that may expedite the import process.

For all veterinary health certificates that are provided in paper format, the EU applies certain general principles of certification as defined in [Commission Implementing Regulation \(EU\) 2020/2235](#). Please, see more details about certification at FAS USEU [website](#).

### U.S. Radiation Monitoring

Harmonization of EU rules on food irradiation has been slow and only a few products have so far received EU-wide approval. 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.

### Transit Certificates

Transit certificates issued by the competent U.S. Government agency must accompany food shipments that physically enter the EU 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](#).

## Appendix I. Electronic Copy or Outline of Each Export Certificate

See FAS USEU's [website](#), as well as USEU's [FAIRS Export Certificate Report 2024 Annual](#). The following links on USDA/FSIS/AMS/APHIS websites contain important samples of import certificates (in English or in English/Bulgarian) required for various products.

### [Certificates for live animals and animal genetics:](#)

Currently, the most frequently used certificates used for Bulgaria are APHIS animal health certificates for bovine semen/embryos, equine semen, hatching eggs, day-old chicks, and pet dogs and cats. APHIS also provides information on the animal health requirements that must be met by travelers taking their pet to Bulgaria (see details about [per travel at APHIS page](#)).

### [APHIS Certificates for animal products:](#)

At present, the most frequently used are the [APHIS certificates for exports](#) of animal products such as beef, collagen, and gelatin (for human consumption), pet food, and trade samples.

### [FSIS Certificates for meat, poultry, and egg products:](#)

The FSIS website is updated on a regular basis to incorporate all developments in [EU import requirements for all products](#) under FSIS jurisdiction, as follows: 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 meat and poultry should be slaughtered, processed, and stored at EU approved establishments. 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 EU. 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. Beef exports require the FSIS 9060-5 Export Certificate for Wholesomeness and animal health/official certificate for fresh meat from bovine animals; please, see the respective certificates for pork, poultry, meat preparations, and eggs and egg products.

#### [Certificates for dairy products:](#)

Dairy products fall under FDA jurisdiction, however FDA has delegated authority to sign health certificates to USDA/Agricultural Marketing Service (AMS). Information on these certificates can be [obtained through this website](#). U.S. exporters should have their production facility listed in the list of EU approved establishments.

#### [AMS Certificates for Eggs and Egg products, Honey, and Seeds for Sprouting:](#)

AMS is the certifying agency for EU export certificates for egg products regulated by FDA. To be eligible for EU certificates, U.S. manufacturers should participate in [AMS Processed Eggs and Egg Products Verification Program](#) and be included in the [List of EU approved facilities](#). 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.

The AMS Livestock, Poultry and Seed Division issues the certificates based on exporter request in the form of a worksheet: [Processed Egg and Processed Egg Products Worksheet](#) (EU only).

#### [Certificates for Composite Products:](#)

[FSIS](#) and [AMS](#) both issue certificates for composite products. These products should be accompanied either by a private attestation or a composite product certificate. For shelf stable products not containing meat, no certificate signed by the U.S. Government is 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 \(EU\) No 2020/2235](#). The EU importer should provide a list of ingredients and EU approval numbers of the ingredient suppliers as listed in the [EU list of approved establishments](#). For all other composite products, a certificate issued by FSIS or AMS is required. Product manufacturers should be registered by the U.S. competent authorities. Please see more details in FAS USEU’s [FAIRS Export Certificate Report 2024 Annual](#).

[Certificates for Seafood \(NOAA\)](#): FDA has delegated authority for export certification of fish and fishery products to Department of Commerce National Oceanic and Atmospheric Administration (NOAA). For additional information on exporting seafood, please see [Procedures to request EU Health Certification to the EU](#) available from the NOAA website and consult the U.S. Commercial Service [Guide for How to Export to the EU](#).

[FDA Certificates](#): Please, see [Certificates issued by FDA for gelatin and collages for human consumption](#), as well as the EU approved lists for [collagen](#) and [gelatin](#) establishments. (also see FAS USEU's [FAIRS Export Certificate Report 2024 Annual](#));

[Certificates for Plant Health](#): Please, see APHIS plant health certificates;

[Pedigree and Zootechnical Certificates](#): [Commission Implementing Regulation \(EU\) 2020/602 of 15 April 2020](#) amending Implementing Regulation (EU) 2017/717 contains the model forms of zootechnical certificates for breeding animals and their germinal products.

TTB [Wine Export Certificate](#): Alcohol and Tobacco Tax and Trade Bureau ([TTB](#)) is the U.S. body issuing VII certificate for exports of wine to the EU. [VII form](#) certifies that the wine exported complies with the conditions governing the production and entry into circulation applicable in the U.S., has been produced using oenological practices in accordance with the terms of the EC-U.S. Agreement on Trade in Wine, and has been produced by a winery licensed by TTB for the production of grape wine. Exporters of U.S. wines may also use a self-certified version of the VII, which does not require TTB approval. The self-certifying export certificate is a simplified version of previous certificates (VIIs) required by the EU. [TTB Industry Circular 2007-2](#) provides more information on the self-certifying certificate and includes an attachment containing the form. Exporters may also refer to [instructions](#) for processing the two prior VII forms and attachments, which are still valid for use in exporting wine to EU countries.

For additional information concerning market entry, other import requirements, and a current importer list, U.S. exporters of agricultural products and commodities should contact:

**Office of Agricultural Affairs**

6 Koziak Street Sofia 1407, Bulgaria

Tel: (+3592) 939 5720

E-mail: [agsofia@fas.usda.gov](mailto:agsofia@fas.usda.gov)

## Appendix II. Instructions for Exporters of FDA Regulated Products Certified by Other Agencies

### Composite Products to the EU

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. USDA's Food Safety Inspection Service ([FSIS](#)) will issue EU composite product certificates 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.

The new EU requirements for composite products will impact stakeholders who have not been required to obtain an export certificate from AMS Dairy Program in the past. 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 [How to Apply for an AMS Dairy or Composite Product Export Certificate](#) for more information.

### Dairy to the EU

USDA's Agricultural Marketing Service (AMS) is the certifying agency for [EU export certificates for dairy products](#) regulated by FDA. For more information, contact [DairyExportsQuestions@usda.gov](mailto:DairyExportsQuestions@usda.gov). 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 EC's website. 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 [Online Applications for Export Lists](#) for a link to this electronic system and step-by-step instructions.

### 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 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).

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 Online Applications for Export Lists for a link to this electronic system and step-by-step instructions. [List of EU approved facilities](#) maintained on the EC's website.

### Seafood

The EU export health certificate is required by the EU Directorate-General for Health and Consumer Protection and attests to the safety of fish and fishery -- both wild and aquaculture -- products shipped to the EU. 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 Online Applications for Export Lists for a link to this electronic system and step-by-step instructions. Please note that the EU will only accept export certificates signed after an establishment has been added to the list published on the [EC website](#) and the list has entered into force. Once listed, U.S. establishments may contact National Oceanic and Atmospheric Administration (NOAA) Seafood Inspection Program to request export certificates for U.S. seafood exports to the EU. Prior to exporting, industry should consult the EC's EU List of Approved Establishments External Link Disclaimer to verify that the establishment from which they intend to export is listed. These certificates must be requested and issued prior to shipment of the product. [Follow this link to submit a request online.](#)



For additional information on exporting seafood to the EU, consult the [U.S. Commercial Service Guide for How to Export to the EU](#) or contact [stephane.vrignaud@trade.gov](mailto:stephane.vrignaud@trade.gov).

#### Honey to the EU

The EU has listed the United States as a country eligible to export honey to the EU provided honey producers meet their program requirements. Under the program, domestic U.S. companies must adhere to specific requirements for each shipment destined to a EU member country. The [USDA Agricultural Marketing Service outlines specific requirements for U.S. honey shipped to EU markets](#) related to Hazardous Analysis and Critical Control Point (HACCP) planning, recordkeeping, testing, sampling, as well as labeling requirements in accordance with Regulation (EC) No 852/2004 and that the product(s) have been handled and where appropriate, prepared, packaged, and stored in a hygienic manner in accordance with the requirements of Annex II to Regulation (EC) No 852/2004 ([these regulations can be downloaded from the following link](#)).

#### Seeds for Sprouting to the EU

USDA's Agriculture Marketing Service (AMS) is the certifying agency for seeds for sprouting regulated by FDA. See: <https://www.ams.usda.gov/content/usda-announces-seed-sprouting-export-certification-program>.

#### **Attachments:**

No Attachments