



Required Report: Required - Public Distribution

Date: December 20, 2022

Report Number: BU2022-0028

Report Name: Food and Agricultural Import Regulations and Standards **Export Certificate Report**

Country: Bulgaria

Post: Sofia

Report Category: FAIRS Export Certificate Report

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Report Highlights:

As a European Union (EU) Member State, Bulgaria applies EU regulatory requirements for all animaland plant-origin food and agricultural imports. Bulgarian regulatory authorities may be consulted, on a case-by-case basis, regarding import requirements for some categories of non-harmonized products.

DISCLAIMER: This report was prepared by the Office of Agricultural Affairs (OAA) at the U.S. Embassy in Sofia, Bulgaria for U.S. exporters of domestically produced food and agricultural products. While every possible care has been 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 PRODUCTS IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

NOTE: The page of the Bulgarian Food Safety Agency was under construction at time of publishing of this report.

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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

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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, can be found here. The Bulgarian officials will respond to the importer in writing
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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
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• Live animals and animal genetics (APHIS); 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 here)
• APHIS certificates for animal products; At present, the most frequently used are the certificates for exports of beef, collagen, and gelatin (for human consumption), pet food, and trade samples
• FSIS certificates for meat, poultry, and egg products; FSIS website/Export Library (here) is updated on a regular basis to incorporate all developments in EU import requirements for all products under FSIS jurisdiction. 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

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
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 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
• Dairy Products (AMS): Dairy products fall under FDA jurisdiction, however FDA has delegated authority to sign health certificates to USDA/Agricultural Marketing Service (AMS). U.S. exporters should have their production facility listed in the list of EU approved establishments
• APHIS plant health certificates;
For additional information concerning market entry, other import requirements, and a current importer list, U.S. exporters of agricultural products and commodities should contact:
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Appendix II. Bulgarian Competent Authorities

Executive Summary

Bulgaria follows EU regulations and model certificates. Please, refer the FAS USEU report about model certificates for 2022, <u>FAIRS Export Certificate Report Annual</u>.

Bulgarian food safety inspectors at border points of entry are generally helpful 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 OAA if there are issues with U.S.-origin shipments. U.S. exporters are encouraged to consult with FAS/Sofia (Post) 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).

In April 2021 the EU updated its Animal Health Law (<u>Regulation (EU) 2016/429</u>) and all required certificates for products of animal origin. Models of the certificates for food of animal origin were published in <u>Commission Implementing Regulation (EU) No 2020/2235</u>, as amended by <u>Commission Implementing Regulation (EU) 2021/1471</u>. FAS cooperates closely with the regulatory agencies to ensure that their export libraries are up-to-date, and the applicable certificate versions are made available to exporters. Post recommends that U.S. exporters consult with the OAA in Sofia for any questions related to import requirements, import certificates, or issues about Bulgaria-specific import regulations.

Product(s)	Title of Certificate	Attestation Required on Certificate	Purpose	Requesting Ministry
Products of Animal Origin	Health Certificate	Attestation is dependent on the product. Detailed attestation can be found in the model certificates available atEURhttp://eur- lex.europa.eu/homepage.htmlLex under the relevant regulations (e.g. dairy products, pork, beef, etc.) –Models of the new certificates for food of animal origin were published in Commission Implementing Regulation (EU) No 2020/235, as amended by Commission Implementing Regulation (EU) 2021/1471.	Food Safety	BFSA (Veterinary Service/Border Control)
Composite Products	Health Certificate	Regulation (EU) 2019/625 defines 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	Plant Health	BFSA (Phytosanitary Service/Border Control)

		export.		
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. <u>Directive 2002/99/EC</u>, 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.

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 <u>Regulation (EU) 2016/429</u> and <u>Delegated Regulation (EU) 2020/692</u> (please refer to the English versions <u>here</u>). Supplementary information regarding the export certificates is available in the <u>FAIRS</u> <u>Export Certificate Report Annual</u> and at the FAS USEU <u>website</u>.

B. Export Certificates/Requirements for Animal Products

In general, the EU requires health certificates for all imported animal-origin products. There are three main requirements:

- EU recognition of a country as eligible to export a particular product. <u>Commission Implementing Regulation (EU) 2021/404 of 24 March 2021</u> 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 in accordance with <u>Regulation (EU) 2016/429 of the European Parliament and the Council. 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;
- 2. Recognition of approved production establishments, which may be subject to EU audits (see the EU-approved list <u>here</u> and <u>here</u>); and
- 3. Animal or public health certificates based on the EC's published model. Models of the new certificates for food of animal origin were published in <u>Commission Implementing Regulation</u> (EU) No 2020/2235, as amended by <u>Commission Implementing Regulation (EU) 2021/1471</u>.

The EU requires veterinary and/or general health certificates with each meat and meat product shipment to be signed and dated prior to export. The competent U.S. certifying agent will delete any statement appearing on the EU model certificate that is not applicable.

C. Export Certificates/Requirements for Plant and Plant Products

Import requirements for plants and plant products are harmonized at the EU level. The <u>International</u> <u>Plant Protection Convention</u> (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 the United States, APHIS issues the required phytosanitary certificate with the requisite attestations to specific EU requirements.

D. Composite Products – Products Subject/Not Subject to Veterinary Checks and Certification

Regulation (EU) 2019/625 defines composite products as foodstuffs intended for human consumption that contain processed products of animal origin and ingredients of plant origin. U.S. exports of "composite products" continue to be restricted due to burdensome certification requirements. While the U.S. is eligible to ship hormone-free meat, dairy products, egg products, and fishery products separately, it is often not possible to ship the composite products that combine these eligible ingredients. Exporters should be aware that in parallel with the aforementioned changes to the composite product certificate that was triggered by an update of the EU's Animal Health Law, the EU also made changes to the categories of composite products that require U.S. Government-issued health certificates. The current system, which went into effect on April 21, 2021, is no longer based on the percentage of ingredients of animal product in the final. It establishes three categories of composite products, (2) shelf stable composite products. All processed products of animal origin must be sourced from EU-approved establishments. The EU continues to require composite products with a meat ingredient.

E. 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 <u>Commission Delegated Regulation (EU) 2019/2122</u> applies to these products. See <u>FAIRS Export Certificate Report Annual</u> for more information.

F. 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 <u>Bulgarian Food Safety Agency</u> (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. In general, 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.

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.

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).

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 <u>Regulation (EU) 884/2014</u>, can be found <u>here</u>. 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 <u>website</u> 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 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. Please, see more details <u>here</u>.

Appendix I. Electronic Copy or Outline of Each Export Certificate

See FAS USEU's website here, as well as USEU's FAIRS Export Certificate Report 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.

- Live animals and animal genetics (APHIS); 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 <u>here</u>).
- <u>APHIS certificates for animal products</u>; At present, the most frequently used are the certificates for exports of beef, collagen, and gelatin (for human consumption), pet food, and trade samples.
- FSIS certificates for meat, poultry, and egg products; FSIS website/Export Library (here) is updated on a regular basis to incorporate all developments in EU import requirements for all products under FSIS jurisdiction. 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.

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

- <u>Dairy Products (AMS)</u>: Dairy products fall under FDA jurisdiction, however FDA has delegated authority to sign health certificates to USDA/Agricultural Marketing Service (AMS). U.S. exporters should have their production facility listed in the <u>list of EU approved</u> <u>establishments</u>.
- AMS Certification 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 (see details here). To be eligible for EU certificates, U.S. manufacturers should participate in <u>AMS</u> <u>Processed Eggs and Egg Products Verification Program</u> and be included in <u>the List of EU</u> <u>approved facilities</u>. The <u>AMS Livestock, Poultry and Seed Division</u> issues the certificates based on exporter request in the form of a worksheet: <u>Processed Egg and Processed Egg Products</u> <u>Worksheet (</u>EU only). Please see details <u>here</u> about certificates of honey and <u>here</u> for seeds for sprouting.
- <u>FSIS</u> and <u>AMS</u> Certification for Composite Products: The EU defines a composite product as a food product containing both processed products of animal and plant origin. Such 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 <u>Commission Implementing Regulation (EU) No 2020/2235.</u> The EU importer should provide a list of ingredients and EU approval numbers of the ingredient suppliers as listed in the <u>EU list of approved establishments.</u> 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 <u>FAIRS Export Certificate Report Annual</u>.

- <u>Certificates for Seafood (NOAA)</u>: 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 <u>Procedures to request EU Health Certification to the EU</u> available from the NOAA website and consult the U.S. Commercial Service Guide for How to Export to the EU.
- FDA Certificates. Please, see <u>Certificates issued by FDA for gelatin and collages for human</u> <u>consumption</u>, as well as the EU approved lists for <u>collagen</u> and <u>gelatin</u> establishments. (also see FAS USEU's <u>FAIRS Export Certificate Report Annual</u>);
- <u>APHIS plant health certificates;</u>
- Pedigree and Zootechnical Certificates <u>Commission Implementing Regulation (EU) 2020/602</u> 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.
- TTB <u>Wine Export Certificate</u>: Alcohol and Tobacco Tax and Trade Bureau (<u>TTB</u>) is the U.S. body issuing VI1 certificate for exports of wine to the EU. <u>VI1 form</u> 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 VI1, which does not require TTB approval. The self-certifying export certificate is a simplified version of previous certificates (VI1s) required by the EU. <u>TTB Industry Circular 2007-2</u> provides more information on the self-certifying certificate and includes an attachment containing the form. Exporters may also refer to <u>instructions</u> for processing the two prior VI1 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

16 Koziak Street Sofia 1407, Bulgaria Tel: (+3592) 939 5720 E-mail: <u>agsofia@fas.usda.gov</u>

Appendix II. Bulgarian Competent Authorities

Ministry of Agriculture Blvd. Hristo Botev 55 Sofia 1040 Tel.: (+359) 2-985-11858 Fax: (+359) 2-981-7955 Website: <u>http://www.mzh.government.bg</u>

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Attachments:

No Attachments