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Report Highlights:

Romania applies European Union (EU) regulations on imports of animal and non-animal products from the United States. The legislation on export certification is generally harmonized at the EU level. Romanian legislation applies to the minor categories on which requirements are not harmonized. This report contains updated links when necessary. This report should be read in conjunction with the EU FAIRS Export Certificate Report, as it provides comprehensive information about export certificates.

Table of Contents	
Executive Summary	2
Section I. List All the Export Certificates Required by Government (Matrix)	2
Section II. Specific Attestation Required on Export Certificates	3
Section III. Government Certificate Legal Entry Requirements	4
Section IV. Other Certification/Accreditation Requirements to Ensure Market Entry	4
Appendix I. Direct Hyperlink, Electronic Copy, Scanned Copy, or Outline of Each Export Certificate	4
Appendix II: Instructions for Exporters of FDA Regulated Products Certified by Other Agencies	4

DISCLAIMER: This report was prepared by the U.S. Embassy Bucharest's Office of Agricultural Affairs, for U.S exporters of domestic 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.

Executive Summary

Romania harmonized its national sanitary-veterinary requirements and export certificates with the legislation developed at the EU level. As a member of the EU since 2007, Romania requires that U.S. certifying agents use these EU standard formats. Export certificates must be drawn up in English or the official language of Romania, which is Romanian. The certificates must be issued before the consignment leaves the control of the competent authority of the United States.

Romanian authorities are responsible for enforcing EU and national legislation through inspection of imported goods and the accompanying certificates. The competence on health certificates for live animals and animal and non-animal origin food products laws belongs to the <u>National Sanitary</u> <u>Veterinary and Food Safety Authority (ANSVSA)</u>, while the competence on phytosanitary certificates belongs to the <u>National Phytosanitary Authority (ANF)</u>. The list of border inspection points authorized to conduct verification on the goods intended for import is <u>here</u>.

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

Romania's national sanitary-veterinary requirements and export certificates are aligned with the legislation developed at the EU level. The export certificates include a series of health and safety requirements that are meant to guarantee that imports meet the standards of production in Romania.

Similar to the other EU member states, Romania requires health certificates for the imported live animals and products of animal origin and phytosanitary certificates for the imported plant products. Please check the <u>EU FAIRS Export Certificate Report</u> for further details in this section.

Section II. Specific Attestation Required on Export Certificates

Animal-Origin Products and Live Animals

In case of animal-origin products, following an update of the EU's Animal Health Law (<u>Regulation</u> (EU) 2016/429), which entered into force on April 21, 2021, the EU has updated all required certificates for products of animal origin. Models of the new certificates for food of animal origin were published by the EU and implemented by U.S. agencies. Several amendments to the new certificates were made since their first publication (<u>Commission Implementing Regulation (EU) No 2020/2235</u> its consolidated version in 2023).

The requirements for animal products exports to Romania are provided by <u>USDA' Food Safety and</u> <u>inspection Service (FSIS)</u> under the EU requirements section, which includes the export certificate models. The import requirements for live animals (including embryos) into Romania are available on the <u>APHIS</u> website. If a bilingual (English/Romanian) certificate for a particular species or commodity does not exist, please refer to the English version, if acceptance was confirmed by the Romanian authority. Please check the <u>EU FAIRS Export Certificate Report</u> for further details regarding the import requirements for animal products and live animals.

Romania does not maintain a full public database with the model certificates for importing goods into the country. Therefore, prior to shipment, exporters should always confirm with their importers that the consignment will be allowed to enter with the documentation accompanying the consignment. If there is any doubt about which documents are required, or if any requirements are not listed, U.S. exporters should ask their importer to email the appropriate Romanian officials at <u>office@ansvsa.ro</u> with a full product description, including any animal-origin contents, and the intended use in Romania. Romanian officials will respond to the importer in writing. U.S. exporters should then obtain that response from their importer and provide it, along with a full translation (including the original email question) to their local Veterinary Services service center. Alternatively, U.S. exporters may contact directly <u>ANSVSA</u> at <u>office@ansvsa.ro</u> to inquire about the certificate model and import requirements.

Plant-Origin Products

Import requirements for plants and plant products are harmonized at the EU level. The international body regulating the international trade with plants and plant products who lays down the models of certificates is the <u>International Plant Protection Convention of the Food and Agriculture Organization of the United Nations</u> (IPPC). Unlike veterinary products, there is only one model certificate for all plant products in accordance with IPPC's conventions. For more information, see the <u>export certification</u> guide on the <u>IPPC website</u>. Phytosanitary certificates are issued by APHIS inspectors, who can attest to specific requirements of EU legislation by making additional declarations in the relevant box.

There are only a few products/by-products for which EU legislation is not harmonized. In such cases, import of these products is subject to Romanian national legislation and import requests are assessed by

the competent authorities on a case-by-case basis. <u>ANSVSA</u> is the competent authority for providing the specific import conditions on non-harmonized products, thus the U.S. exporters are advised to seek guidance before shipping those goods.

Section III. Government Certificate Legal Entry Requirements

Below is a list of U.S. competent authorities providing detailed export certificate information:

- AMS: Agricultural Marketing Service, USDA <u>Export Verification</u>
- APHIS: Animal and Plant Health Inspection Service, USDA
 International Animal Export Regulations
 International Animal Products Export Regulations
 Plant Export Services
- FSIS: Food Safety and Inspection Service, USDA Export Requirements for the European Union
- FDA: Food and Drug Administration Exporting Food Products from the United States
- FGIS: Federal Grain Inspection Service; Grain Inspection, Packers and Stockyards Administration, USDA Official Certificates | Agricultural Marketing Service
- NOAA: National Oceanic and Atmospheric Administration Export Certification to the European Union | NOAA Fisheries

Exporters of FDA regulated products that are certified by other agencies should refer to Appendix II for specific guidance on how to meet EU product certification and establishment listing requirements. For further details, please read the <u>EU FAIRS Export Certificate Report</u>.

Section IV. Other Certification/Accreditation Requirements to Ensure Market Entry Please read the <u>EU FAIRS Export Certificate Report</u>.

Appendix I. Direct Hyperlink, Electronic Copy, Scanned Copy, or Outline of Each Export Certificate

Please read the EU FAIRS Export Certificate Report.

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

a. Composite Products

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. <u>USDA's Food Safety</u>

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 <u>How to Apply for an AMS Dairy or Composite Product Export Certificate</u> for more information.

b. Dairy to the EU

USDA's Agricultural Marketing Service (AMS) is the certifying agency for <u>EU export certificates for</u> <u>dairy products</u> regulated by FDA. For more information, contact <u>DairyExportsQuestions@usda.gov</u>. In order to obtain an EU Health Certificate, the manufacturers must have their final production, blending, and/or packing facility listed on the <u>List of EU approved facilities</u> maintained on the European Commission 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 <u>Online Applications for Export Lists</u> for a link to this electronic system and step-by-step instructions.

c. Dairy to Other Export Markets

The Agricultural Marketing Service's Dairy Program is responsible for issuing dairy export certificates accepted by most countries. Information on these certificates can be <u>obtained through this website</u>. The Animal Plant Health Inspection Service (APHIS) issues export certificates for a limited number of countries including Albania, Australia, Georgia, Japan, Mexico, New Zealand, South Africa, Suriname, and Ukraine. Information regarding APHIS export certificates can be <u>obtained through this website</u>.

d. Eggs and Egg Products

In the egg sector, USDA's 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, eggnog 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 European Commission website.

e. 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 <u>Export Listing Module (ELM)</u>. 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 <u>EC website</u> 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. <u>Follow</u> this link to submit a request online.

f. Honey to the EU

The EU has listed the United States as a country eligible to export honey to the European Union 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 <u>USDA Agricultural Marketing Service outlines specific requirements for U.S. honey shipped to EU markets</u> related to Hazardous Analysis and Critical Control Point (HAACP) 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).

g. Seeds for Sprouting

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

For questions or additional information regarding this report, please contact USDA's Foreign Agricultural Service (FAS) office in Bucharest at the address below: 4-6 Dr. Liviu Librescu Boulevard, Sector 1, Bucharest, Romania Phone: +40 21 2003374 E-mail: <u>agbucharest@fas.usda.gov</u>

Attachments:

No Attachments