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**Report Highlights:**

This report is intended to supplement the FAS U.S. Mission to the EU's Food and Agricultural Import Regulations and Standards (FAIRS) Certificate report with Italy-specific information. The U.S. export certification requirements for most products of animal and plant origin destined for the EU and Italy have been harmonized. The few products not yet harmonized are subject to Italian regulations which can be found in this report.

**Disclaimer:** This report was prepared by the USDA/Foreign Agricultural Service in Rome, Italy 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.

## TABLE OF CONTENTS

<b>EXECUTIVE SUMMARY</b> .....	2
<b>SECTION I: EXPORT CERTIFICATES REQUIRED BY ITALY</b> .....	3
<b>SECTION II: SPECIFIC ATTESTATIONS REQUIRED ON EXPORT CERTIFICATES</b> .....	4
<b>SECTION III: GOVERNMENT CERTIFICATE LEGAL ENTRY REQUIREMENTS</b> .....	5
<b>SECTION IV: OTHER CERTIFICATION/ACCREDITATION REQUIREMENTS TO ENSURE MARKET ENTRY</b> .....	5
<b>APPENDIX I: ELECTRONIC COPY OR OUTLINE OF EACH EXPORT CERTIFICATE</b> .....	6
<b>APPENDIX II: INSTRUCTIONS FOR EXPORTERS OF FDA REGULATED PRODUCTS CERTIFIED BY OTHER AGENCIES</b> .....	8

## EXECUTIVE SUMMARY

This report supplements the [FAS U.S. Mission to the EU’s Food and Agricultural Import Regulations and Standards \(FAIRS\) Certificate report](#) with Italy-specific information. Import requirements for food and feed, animals, and plants are harmonized between the EU Member States, including Italy. Most of the certificates required by the EU and Italy 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). U.S. exporters should be aware that in the limited number of cases where certification of a particular product is not harmonized at the EU level, such products would be subject to Italy’s rules.

## SECTION I: EXPORT CERTIFICATES REQUIRED BY ITALY

As a member of the EU, Italy applies the “*Community Acquis*”, i.e., the entire body of EU laws and regulations 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 the EU Member States. It is therefore recommended that this report be read in conjunction with the Food and Agricultural Import Regulations and Standards (FAIRS) Certificate [report](#) produced by the U.S. Mission to the EU in Brussels, Belgium (hereafter referred to as the EU FAIRS Certificate report). You may also want to review Italy FAIRS report, which can be found at: <https://gain.fas.usda.gov/#/>.

Imported products to Italy must meet existing Member State requirements and must be accompanied by the proper certification at the Port of Entry. In general, health certificates are required for all imported products of animal origin, while phytosanitary certificates are needed for all plant products that could introduce pests into Italy. Export certificates must be in the official language of Italy, which is Italian. Unlike veterinary 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 (FAO) of the United Nations. For more information, see the IPPC’s [export certification guide](#).

In the limited number of cases where certification of a particular product is not harmonized, such products would be subject to Italy’s rules (see [section IV](#) of this report). It should be noted that the U.S. regulatory agencies issuing export certificates (see [section II](#) of this report) usually make mention of any Member State specific requirements in their export libraries and guides.

Following an update of the EU’s Animal Health Law ([EU Regulation 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 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 2020/2235 \(consolidated version of September 3, 2024\)](#). 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.

In Italy, the primary responsibility for food safety rests with the Ministry of Health, while food production is the primary responsibility of the Ministry of Agriculture, Food Sovereignty, and Forests. In some instances, other Italian ministries may have responsibilities, such as the Ministry of Economic Development on standards, labeling, and trade promotion, or the Ministry of Economy and Finance on customs and duties.

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## **Purpose of Specific Export Certificates**

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 imported products of animal origin imported in Italy, while phytosanitary certificates are needed for all plant products that could introduce pests into Italy. For detailed information on import requirements for animals and animal products, plants and plant products, and composite products, please see Section II of the [EU FAIRS Certificate report](#).

## **SECTION II: SPECIFIC ATTESTATIONS REQUIRED ON EXPORT CERTIFICATES**

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:

- **AMS: Agricultural Marketing Service, USDA**
  - AMS Dairy Program – EU Dairy and Composite Product Certification Programs  
<https://www.ams.usda.gov/services/imports-exports/dairy-exports/eu-dairy-exports>
  - Certification for Eggs and Egg Products  
<http://www.ams.usda.gov/services/imports-exports/eggs-egg-products>
  - Certification for Honey  
<https://www.ams.usda.gov/services/imports-exports/honey>
  - Certification for Seeds for Sprouting  
<https://www.ams.usda.gov/content/usda-announces-seed-sprouting-export-certification-program>
  
- **APHIS: Animal and Plant Health Inspection Service, USDA**
  - International Animal Export Regulations  
<https://www.aphis.usda.gov/live-animal-export>
  - International Animal Products Export Regulations  
<https://www.aphis.usda.gov/animal-product-export>
  - Plant Export Services  
<https://www.aphis.usda.gov/plant-exports>

- **FDA: U.S. 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: <https://www.fsis.usda.gov/inspection/import-export/import-export-library/european-union>
- **NOAA: National Oceanic and Atmospheric Administration**
  - <https://www.fisheries.noaa.gov/content/export-certification>

### **SECTION III: 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 (including Italian) 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.

Italy applies the [EU Official Controls Regulation \(OCR\)](#), 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 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 general principles of certification as defined in [Regulation 2020/2235](#).

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. For more information, see Section III of the [EU FAIRS Certificate report](#).

### **SECTION IV: OTHER CERTIFICATION/ACCREDITATION REQUIREMENTS TO ENSURE MARKET ENTRY**

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.

## **Non-human primates**

Italy does not require any certification for samples from non-human primates that are:

- Embedded on microscope slides; or
- Suspended in formalin; or
- Suspended in alcohol.

For other samples, Italy requires the health certificate for export of samples (other than processed DNA samples, and those embedded completely on micro slides, or preserved in alcohol or formaldehyde) from non-human primates intended for scientific research. Prior to endorsement of the above referenced health certificate, APHIS must inspect the collection facility to verify the pertinent criteria. In addition, lab reports as referenced in the certificate will be required for each source animal. More information can be viewed on the APHIS website at: <https://www.aphis.usda.gov/animal-product-export>.

## **Quick-frozen vegetables**

Italy requires that all third country establishments that intend to export quick-frozen vegetables register with the Ministry of Health - [Office II](#) of the Directorate-General for Hygiene and Food Safety (in Italian), as per Legislative Decree 27/1/1992, n. 110, art.10 (Implementation of Directive 89/108). The Ministry defines such items as foodstuffs which have undergone a suitable freezing process known as 'quick-freezing' whereby the zone of maximum crystallization is crossed as rapidly as possible (depending on the type of product), and the resulting temperature of the product (after thermal stabilization) is continuously maintained at a level of -18 °C or lower at all points.

## **U.S. Radiation Monitoring**

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

## **APPENDIX I: ELECTRONIC COPY OR OUTLINE OF EACH EXPORT CERTIFICATE**

All EU harmonized certificates must be in both English and Italian. Bilingual certificates (English/Italian) are available for some species/commodities. It is the responsibility of the exporter to obtain a bilingual certificate if it is not available. Exporters should not present these certificates to U.S. agencies for endorsement unless they are prepared with all text in both English and Italian. Exporters should work with their importers to create the bilingual versions. Note: if a consignment is entering the EU through Italy, but is destined to a different EU country, that country may also require a third language to be included. For more information, see Appendix I of the [EU FAIRS Certificate report](#).

#### **A. APHIS CERTIFICATES FOR ANIMALS AND GENETICS**

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

For available bilingual (English/Italian) health certificates, please refer to the following link: [https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/international-standard-setting-activities-oie/regionalization/sa\\_by\\_country/sa\\_i/ct\\_animal\\_italy](https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/international-standard-setting-activities-oie/regionalization/sa_by_country/sa_i/ct_animal_italy).

The APHIS website also provides information on the animal health requirements that must be met by travelers taking their pet to a Member State of the European Union (see <https://www.aphis.usda.gov/aphis/pet-travel>).

#### **B. APHIS CERTIFICATES FOR ANIMAL PRODUCTS**

For available bilingual (English/Italian) health certificates, please refer to the following link: [https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/iregs-for-animal-product-exports/sa\\_international\\_regulations/sa\\_by\\_country/sa\\_i/ct\\_product\\_italy](https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/export/iregs-for-animal-product-exports/sa_international_regulations/sa_by_country/sa_i/ct_product_italy).

#### **C. FSIS CERTIFICATES FOR MEAT, POULTRY, EGG PRODUCTS**

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

Advisory - 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 Italy.

#### **D. AMS CERTIFICATION FOR DAIRY PRODUCTS**

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

And ‘Appendix II: Instructions for Exporters of FDA Regulated Products Certified by Other Agencies’ of the [EU FAIRS Certificate report](#).

#### **E. AMS CERTIFICATION FOR EGGS AND EGG PRODUCTS**

See: <http://www.ams.usda.gov/services/imports-exports/eggs-egg-products>

And ‘Appendix II: Instructions for Exporters of FDA Regulated Products Certified by Other Agencies’ of the [EU FAIRS Certificate report](#).

#### **F. AMS CERTIFICATION FOR HONEY**

See: <https://www.ams.usda.gov/services/imports-exports/honey>

And ‘Appendix II: Instructions for Exporters of FDA Regulated Products Certified by Other Agencies’ of the [EU FAIRS Certificate report](#).

#### **G. AMS CERTIFICATION FOR SEEDS FOR SPROUTING**

See: <https://www.ams.usda.gov/content/usda-announces-seed-sprouting-export-certification-program>

And ‘Appendix II: Instructions for Exporters of FDA Regulated Products Certified by Other Agencies’ of the [EU FAIRS Certificate report](#).

#### **H. NOAA CERTIFICATES FOR SEAFOOD**

See: <https://www.fisheries.noaa.gov/content/export-certification>



And ‘Appendix II: Instructions for Exporters of FDA Regulated Products Certified by Other Agencies’ of the [EU FAIRS Certificate report](#).

**I. FSIS or AMS Certification for Composite Products**

See: <https://www.fsis.usda.gov/inspection/import-export/import-export-library/european-union> <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](#)

**J. FDA CERTIFICATES**

See: <https://www.fda.gov/food/exporting-food-products-united-states/food-export-certificates>

**K. PEDIGREE AND ZOOTECHNICAL CERTIFICATES**

See [Commission Implementing Regulation 2020/602](#) amending Implementing Regulation 2017/717 as regards the model forms of zootechnical certificates for breeding animals and their germinal products.

**L. APHIS PLANT HEALTH CERTIFICATES**

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

**M. OTHER PLANT CERTIFICATES**

See Appendix I of the [EU FAIRS Certificate report](#).

**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 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 [Online Applications for Export Lists](#) for a link to this electronic system and step-by-step instructions.

## **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 [obtained through this website](#). 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 [obtained through this website](#).

## **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 European Commission 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](#).

## **Honey to the EU**

The European Union (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 an 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 (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](#)).

## **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