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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) report with Italy-specific information. Italy's FAIRS provides contact information for the competent authorities that are responsible for the import of animal, plant, fish, and food products into the Italian market.

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.

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EXECUTIVE SUMMARY

This report supplements the FAS U.S. Mission to the EU’s Food and Agricultural Import Regulations and Standards (FAIRS) report with Italy-specific information. To the extent that EU food laws have been harmonized, Italy’s food laws and regulations follow EU rules. However, the few products not yet harmonized are subject to Italian regulations. EU requirements for food differ from the ones in the

United States and the standard U.S. label fails to comply with EU (and, therefore, Italian) labeling requirements. This report looks at general requirements for food and feed labels, food hygiene, contaminants, food packaging, food additives and flavorings, and import procedures.

SECTION I: FOOD LAWS

As a member of the European Union (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. It is therefore recommended that this report be read in conjunction with the Food and Agricultural Import Regulations and Standards (FAIRS) [report](#) produced by the U.S. Mission to the EU in Brussels, Belgium (hereafter referred to as the EU FAIRS report). You may also want to review Italy FAIRS Certificate report, which can be found at: <https://gain.fas.usda.gov/#/>.

To the extent that EU food laws have been harmonized, Italy’s food laws and regulations follow EU rules. Similarly, Italy employs the same tariffs and border measures as the other EU Member States. Products imported into Italy must meet all Italian and EU food safety and quality standards, as well as labeling and packaging regulations. The few products not yet harmonized are subject to Italian regulations. The national competent authority needs to be consulted on a case-by-case basis to address requirements for non-harmonized products.

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, and Forestry Policies. In some instances, other 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.

The Ministry of Health (MoH) is organized as a General Secretariat with 12 Directorates General. The following three Directorates deal with hygiene and food safety, nutrition, and veterinary public health:

- Directorate-General for Animal Health and Veterinary Medicinal Products (DGSA);
- Directorate-General for Hygiene, Food Safety, and Nutrition (DGSAN);
- Directorate-General for Collegial Bodies for Health Protection (DGOCTS).

DGSA is responsible for drawing up national programs for the eradication of animal diseases and guidelines for the control of animal welfare on farms, by ensuring effective controls on imported animals, food of animal origin, and feedstuffs at the Veterinary Offices for Compliance with EU Requirements (UVAC-PIF). It also provides general guidelines for feedstuffs and animal nutrition, and issues marketing authorizations for veterinary medicinal products aimed at licensing of manufacturing, import permits, and compliance with GMP (Good Manufacturing Practices).

DGSAN is concerned with health and safety of food production and marketing; oversight of the food chain and operational guidelines for official controls on imported food; management of the RASFF

(Rapid Alert System for Food and Feed) system, and of the food, feed, and animal by-products division; nutrition and products for use in special diets; functional foods; food supplements; herbal products for food; nutritional labeling; nutritional education; health aspects related to food technology; novel foods; genetically modified organisms; food additives; food flavorings; contaminants; food contact materials; plant protection products; hygiene and safety of food for export; investigations, audits, and inspections in the areas of competence.

DGOCTS is the national European Food Safety Agency (EFSA)'s contact point. It is responsible for the physical, chemical, and biological risk aspect of food safety. It is also the contact point for the Food Safety National Committee. It is responsible for the coordination and planning of actions aimed at assessing risks in the food chain, as well as activities of the Committee of Consumers and Producers Associations, in collaboration with DGSAN.

Peripheral offices of the MoH include Maritime, Aviation, and Border Health Offices (USMAF-SASN), and Veterinary Offices for Compliance with EU Requirements (UVAC-PIF).

The Nucleo Anti Sofisticazioni (NAS – the Food Law Enforcement Department) is a special unit of the Italian Corps of Carabinieri, which operates under the direction and supervision of the MoH. It carries out investigations and controls on illegal adulteration of foodstuffs, fraud, and trafficking of medicines, both on its own initiative and upon request from MoH offices. This includes hygiene inspections, verification of control systems, sampling and analysis of products, and examination of authorization documents.

The National Health Institute ([ISS](#)) is the leading technical and scientific public body of the Italian health service. The ISS (which falls under MoH) supervises all laboratories in charge of food and feed controls and carries out confirmatory analysis at the national level. Its activities include research, control, training, and consultation in the interest of public health protection.

The Experimental Zooprophyllactic Institutes - National Reference Centers ([IZS](#)) are public veterinary health institutes, organized in 10 central laboratories and 90 field diagnostic units at the regional level. Tests on contaminants, pesticides, and food of plant origin are performed by 27 Environmental Protection Agencies (ARPA) with 54 local laboratories at the regional level. The laboratories report to the Local Health Units (LHU-ASL). The Public Health Laboratories (PHL-LSP) operating within the ASL's Prevention Departments also carry out official analyses. The tested matrixes include food of animal and non-animal origin, water, and food contact materials.

U.S. food and beverage products must comply with the generally applied rules and regulations, as would any other product sold in the EU market. U.S. exporters should also be aware that any food or agricultural product trans-shipped through Italian territory will be inspected by Italian authorities, even if the product is transported in a sealed and bonded container and is not expected to enter the Italian market.

EU food legislation consists of "Regulations" and "Directives", and rules for their implementation. Directives lay down results that must be achieved, but each Member State is free to decide how to transpose directives into national law (usually within 2-3 years after adoption). Regulations do not

require transposition. They are binding in their entirety and automatically enter into force on a set date in all Member States. Amendments to EU legislation are published in separate directives and regulations. Consolidated texts, i.e. the consolidation of a basic legal act and subsequent amendments into one text, are available on the European Commission's [Eurlex website](#). EU laws are translated into the 24 official languages (including Italian) in use in the EU-27 and published in the Official Journal as soon as they are translated. 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.

SECTION II: LABELING REQUIREMENTS

A. General Requirements

Italy applies EU-harmonized legislation on food labeling. The standard U.S. label fails to comply with EU labeling requirements. On December 13, 2014, the EU's "[Food Information to Consumers \(FIC\) Regulation 1169/2011](#)" became applicable to all pre-packaged food and drink products marketed in the EU, including those imported from third countries. The mandatory nutrition declaration requirement introduced by the FIC regulation became applicable on December 13, 2016. For more information, see Section II of the [EU FAIRS report](#).

Origin Labeling

The Italian government introduced Country of Origin Labeling (COOL) measures for milk and milk products, rice, durum wheat, tomato-based products, and pork meat products (e.g., hams and cured meat), in effect until December 31, 2021. These measures have not been notified to the WTO. On April 1, 2020, [EU Implementing Regulation 2018/775](#) entered into force. Such regulation introduces mandatory dual origin labeling when a country of origin is given or visually implied on the label of a food product, but the origin is not the same as that of its primary ingredient. Producers can simply state that the main ingredient does not originate from the country origin if the food or label is as "EU," "non-EU", the name of a third country, or any other option listed in Article 2 of the Regulation. On January 30, 2020, the Commission adopted [Notice C/2020/428](#), aimed at helping actors of the food chain as well as the competent national authorities to better understand and correctly apply the provisions of the FIC Regulation related to the origin indication of the primary ingredient.

Example: A jar of peanut butter with a statement such as "made in the USA" or carrying an American flag would trigger this regulation if the peanuts were sourced from another country.

Detailed information on COOL is provided on the FAS/USEU [website](#).

On May 20, 2020, the Commission published the [EU Farm to Fork Strategy](#) (F2F). Part of this Strategy aims to ensure that EU consumers can make informed decision when buying food. As part of the F2F Strategy, the Commission announced that it will "consider proposing the extension of mandatory origin or provenance indications to certain products, while fully taking into account impacts on the single market" before the end of 2022.

Nutrition Declaration

Article 35 of the FIC regulation allows Member States to recommend the use of additional forms of expression or presentation of the nutrition declaration. On December 8, 2020, Italy's inter-ministerial decree on [NutrInform](#) Battery labeling system entered into force. NutrInform Battery is a voluntary front of pack nutrition labeling that the Italian Ministries of Agriculture, Health, and Economic Development notified to the European Commission. NutrInform Battery uses battery symbols to indicate the percentages of energy, fats, saturated fats, sugars, and salt in a food portion compared to the recommended daily intake. GIs are excluded from the scope of the decree.

As part of the Farm to Fork Strategy, the EU Commission announced that it would propose harmonized mandatory front-of-pack nutrition labeling before the end of 2022 as part of the revision of the FIC Regulation.

Use of Stickers

Specific rules on the use of stickers to provide mandatory labeling information are not included in FIC Regulation. On this issue, the European Commission refers to point 2.1.1 of [Questions and Answers on the Application of Regulation 1169/2011](#), which says, "Labels should not be easily removable so as to jeopardize the availability or the accessibility of the mandatory food information to the consumer." As previously noted, the standard U.S. label fails to comply with EU (and, therefore, Italian) rules and regulations. Thus, a sticker with the translation of the U.S. label in Italian needs to be placed on the packaging above or in addition to the U.S. label when the product is sold in Italy. As a rule, labeling must be in a language easily understood by consumers. While EU legislation does not contain any reference to the use of stick-on labels, Italy accepts them, but they must be applied before the product is imported into the country.

B. Other Specific Labeling Requirements

Genetically Modified Foods Labeling

Italy implemented EU Regulations [2003/1829](#) on genetically modified food and feed, and [2003/1830](#) concerning the traceability and labeling of "GMOs" (Genetically Modified Organisms) and the traceability of food and feed products produced from "GMOs" in April 2004. Labeling regulations for genetically modified (GM) food products are established by Articles 12-13 of EU Regulation 2003/1829. These rules apply to products that have undergone varying degrees of processing. The regulation does not require labeling of food products that are not food ingredients, such as processing aids. Meat, milk, and eggs obtained from animals fed with GM feed or treated with GM medicinal products do not require GM labeling. The traceability rules require all business operators to transmit and retain information on GM products in order to identify both the supplier and the buyer of the GM product.

GMOs must be approved before they can be used in food and feed. The EU register of authorized GMOs can be consulted on the European Commission's [website](#). All food products containing or consisting of GMOs, produced from GMOs, or containing ingredients produced from GMOs must be labeled even if they no longer contain detectable traces of GMOs. The labeling requirement does not apply to foods containing GMOs in a proportion equal to or less than 0.9 percent of the food ingredients considered individually, provided their presence is adventitious or technically unavoidable.

For more information, see Section II of the [EU FAIRS report](#). You may also want to review Italy Biotechnology report, which can be found at: <https://gain.fas.usda.gov/#/>.

Plant-Based Meat/Dairy Alternatives

The FIC Regulation requires the European Commission to set out rules for the voluntary labeling of foods as “suitable for vegetarians and vegans.” To date, the Commission has not adopted an EU-harmonized definition of the terms “vegetarian” and “vegan.” In the absence of EU-harmonized rules, many Italian food companies have started using the “[European V-label](#),” a labeling scheme launched by the European Vegetarian Union (EVU). For more information, please consult the Italian Vegetarian Association’s [website](#) (in Italian).

In July 2017, the European Court of Justice (ECJ) ruled that plant-based products cannot be labeled with dairy names such as “cheese,” “butter” or “milk”. The ECJ based [its ruling](#) on [Regulation 2013/1308](#) setting out definitions and designations that may only be used for the marketing of dairy products. A list of exceptions for non-dairy products that may be labeled with reserved dairy names was established by [Commission Decision 2010/791](#). The Italian-language terms allowed under Decision 2010/791 (Annex I) are: “Latte di mandorla”, “Burro di cacao”, “Latte di cocco”, and “Fagiolini al burro”. For more information, please see GAIN Report “[European Court Prohibits Use of Dairy Names for Non-Dairy Products](#).”

SECTION III: PACKAGING AND CONTAINER REGULATIONS

Italy applies EU-harmonized legislation on packaging and container. For more information, see Section III of the [EU FAIRS report](#).

In Italy, the National Packaging Consortium - [CONAI](#) (Consorzio Nazionale Imballaggi) manages the recycling and recovery of packaging, pursuing the objectives set by the European legislation.

SECTION IV: FOOD ADDITIVE REGULATIONS

Italy applies EU-harmonized legislation on food additives. The EU’s “Package on Food Improvement Agents” includes four Regulations: [Regulation 2008/1331](#) establishing a common authorization procedure for food additives, food enzymes, and food flavorings; [Regulation 2008/1332 on food enzymes](#); [Regulation 2008/1333 on food additives](#); and [Regulation 2008/1334 on food flavorings](#). Only additives included in the EU’s positive list may be used in food products marketed in the EU. Inclusion in the EU positive list is based on a risk assessment by EFSA. [Commission Implementing Regulation 2011/234](#) explains in detail how applications to update the EU positive lists should be drafted (content, data requirements, and presentation). EFSA then verifies the suitability of the data. For more information, see Section IV of the [EU FAIRS report](#).

Additives

DGSAN at the Italian MoH is concerned with health aspects related to food additives. In Italy, production, marketing, and storage of food additives are regulated by the State-Regions-Provinces [Agreement](#) (in Italian) of April 29, 2010, concerning guidelines on the implementation of Regulation

No. 2004/852 on the hygiene of foodstuffs. Only [authorized](#) food business operators can produce, sell, and store food additives.

[Office VI of the DGSAN](#) (in Italian) is responsible for controls on food additives. Border Control Posts (PCF), UVAC, and USMAF-SASN offices perform random controls on food additives at the point of entry. Standard controls involve documentary, identity and physical checks, and sampling. Second instance analytical services are available to food business operators at the ISS. Accredited laboratories upload the analysis' results directly to the National Health Information System ([NSIS](#) – in Italian).

The National Food Additives and Food Flavorings Control Plan for 2020-2024 is available at: http://www.salute.gov.it/imgs/C_17_pubblicazioni_2927_allegato.pdf (in Italian)

Flavorings

DGSAN is concerned with health aspects related to food flavorings. In Italy, production, marketing, and storage of food flavorings are regulated by the State-Regions-Provinces Agreement of April 29, 2010, concerning guidelines on the implementation of Regulation 2004/852 on the hygiene of foodstuffs. Only [authorized](#) food business operators can produce, sell, and store food flavorings.

Office VI of the DGSAN is responsible for controls on food flavorings. PCF, UVAC, and USMAF-SASN perform random controls on food flavorings at the point of entry. Standard controls involve documentary, identity and physical checks, and sampling. Second instance analytical services are available to food business operators at the ISS. Accredited laboratories upload the analysis' results directly to the NSIS.

The National Food Additives and Food Flavorings Control Plan for 2020-2024 is available at: http://www.salute.gov.it/imgs/C_17_pubblicazioni_2927_allegato.pdf (in Italian)

Enzymes

So far, in Italy, the only two enzymes authorized as food additives are invertase and lysozyme. For more information, see the European Commission's website: https://ec.europa.eu/food/safety/food_improvement_agents/enzymes/eu_rules_en.

DGSAN is concerned with health aspects related to food enzymes. In Italy, production, marketing, and storage of food enzymes are regulated by the State-Regions-Provinces Agreement of April 29, 2010, concerning guidelines on the implementation of Regulation No. 2004/852 on the hygiene of foodstuffs. Only [authorized](#) food business operators can produce, sell, and store food enzymes.

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SECTION V: PESTICIDES AND OTHER CONTAMINANTS

Italy applies EU-harmonized legislation on pesticides and other contaminants. For detailed information, see Section V of the [EU FAIRS report](#).

SECTION VI: OTHER REQUIREMENTS, REGULATIONS, AND REGISTRATION

MEASURES

Certification and Documentation Requirements

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/>.

An overview of all U.S. authorities that issue the legally required certificates for export to the EU is available at: <https://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/u-s-agencies-providing-eu-certificates/>. The websites of each of those authorities provide detailed and up-to-date information on the specific product certificates under their legal authority.

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 V of [Italy FAIRS Certificate report](#)). It should be noted that the U.S. regulatory agencies issuing export certificates usually make mention of any Member State specific requirements in their export libraries and guides.

Following an update of the EU's Animal Health Law, 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 in [Commission Implementing Regulation 2020/2235](#), as amended by [Commission Implementing Regulation 2021/1471](#). The transitional provisions of Regulation 2020/2235 allow for the continued use of the old certificates until March 15, 2022, provided that the certificates are signed before Jan 15, 2022. At the time of writing, U.S. Government agencies have not yet switched to any of the new certificates. This is also the case for the composite product certificates issued by the Agricultural Marketing Service (AMS) and Food Safety and Inspection Service (FSIS).

Facility Registration

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/approved-u-s-establishments/>

The EU approves establishments to ship products of animal origin based on submissions from U.S. government agencies. Only products processed in approved establishments may enter the EU. Third country lists per sector and per country are published on the European Commission's website https://webgate.ec.europa.eu/sanco/traces/output/non_eu_listsPerCountry_en.htm. Detailed information on certification of products from approved U.S. establishments is available on the FAS/USEU website at: <http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/>.

Frozen Foodstuffs

Italy requires that all third country establishments that intend to export quick-frozen vegetables register with the Italian MoH ([Office II of the DG SAN](#) – 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.

SECTION VII: OTHER SPECIFIC STANDARDS

Novel Foods

Italy applies EU-harmonized legislation on novel foods. [Office IV of the DG SAN](#) (in Italian) at the MoH is concerned with health aspects related to novel foods. EU Regulation [2015/2283](#) defines novel food as food that has not been consumed to a significant degree in the EU before May 15, 1997, and falling within at least one of the categories listed in Article 3 of the Regulation (e.g. [cranberry extract powder](#)). It can be a newly developed, innovative food resulting from new production techniques (e.g., nanotechnology) as well as a traditional - but unknown to EU consumers - food from a non-EU country (e.g., noni juice). The Novel Food regulation does not apply to GMO's, additives, enzymes, flavorings, and extraction solvents. A [guidance document](#) on "human consumption to a significant degree" is available on the European Commission's website.

Food business operators are responsible for verifying whether the food they intend to market in the EU is novel or not. Novel Food Regulation provides for a consultation process when the status of a food or food ingredient is unsure. Commission Implementing Regulation [No. 2018/456](#) lists the procedural steps that food business operators must follow to consult with the competent authority of the Member State (in Italy, Office IV of the DG SAN) where they first intend to market their product. For more information, see Section VII of the [EU FAIRS report](#).

SECTION VIII: TRADEMARKS, BRAND NAMES, AND INTELLECTUAL PROPERTY RIGHTS

Trademarks

In the EU, trademarks can be registered at the national, regional, or EU level. Trademarks registered at the national level are protected in one EU Member State. Applications must be [submitted](#) directly to the Italian Directorate General for the Protection of Industrial Property - Patent and Trademark Office, Ministry of Economic Development. Applications for the protection of a trademark in all EU Member States must be submitted to the European Union Intellectual Property Office (EUIPO). An online application costs €850. Full details on the registration process are available on the [EUIPO website](#). Rules on the protection of trademarks in the EU are set in EU [Directive 2015/2436](#). [Commission Implementing Regulation 2018/626](#) sets out detailed rules on application procedures. [Commission Delegated Regulation 2018/625](#) sets out procedural rules on opposition and revocation of EU trademarks.

Protected Geographical Indications

Several food product names considered as generic in the U.S. such as for example parmesan and Parma ham are protected under EU law. [European Parliament and Council Regulation 2012/1151](#), applicable since January 4, 2016, sets out rules on optional quality terms such as "mountain product" and regulates

three EU-wide quality-labeling schemes. It covers the “Protected Designation of Origin” (PDO) scheme, the “Protected Geographical Indication” (PGI) scheme, and the “Traditional Specialties Guaranteed” (TSG) scheme. Registration under the different schemes is also open to non-EU countries. Wines and spirits are covered by specific legislation ([Commission Regulation 2019/33](#) and [Commission Regulation 2019/34](#)) and do not fall within the scope of Regulation 2012/1151.

In October 2019, the Council of the EU adopted [Council Decision 2019/1754](#) approving the EU’s accession to the “Geneva Act of the Lisbon Agreement on Appellations of Origin and Geographical Indications.” This membership enables the EU to obtain protection for its GIs in all [30 contracting parties](#) to the Lisbon Agreement. Practical details on the implementation of the Lisbon Agreement in the EU are laid in Regulation [2019/1753](#). For more information, see [GAIN report “EU Prepares to Join Lisbon Agreement on Geographical Indications.”](#)

The [European Commission’s website](#) provides guidance on how to register a PDO/PGI or how to object to a PDO/PGI proposed for registration. Lists of protected names by country, product type, registered name and name applied for are available through the Commission’s online “[eAmbrosia](#)” database. For more information, see Section VIII of the [EU FAIRS report](#).

SECTION IX: IMPORT PROCEDURES

Union Customs Code

Italy applies the “Union Customs Code” (UCC), the framework regulation on rules and procedures for customs throughout the EU, established in the [EU Regulation 2013/952](#). For detailed information, see Section IX of the [EU FAIRS report](#).

Customs Clearance

The European Commission’s Trade Helpdesk provides a complete overview of documents needed for customs clearance: <http://trade.ec.europa.eu/tradehelp/>.

Import Duties

The EU uses the Combined Nomenclature (CN) for the customs classification of goods. The CN eight-digit code numbers are based on the Harmonized System (HS) nomenclature: the first six digits refer to the HS headings; the two following digits represent the CN subheadings. The EU’s [on-line “TARIC” customs database](#) can be consulted to look up commodity codes and relevant import duties. TARIC is a multilingual database (including Italian) covering all measures relating to tariff and trade legislation. The [EU’s 2021 Tariff Schedule](#) was published on January 1, 2021 in the Official Journal.

Business operators can obtain a Binding Tariff Information (BTI) decision from [Italy's Customs Authority](#) in order to get the proper product classification and relevant import duty. A BTI decision is legally binding in all the Member States and is valid for three years. U.S. exporters should be aware that the UCC makes the declaration of a BTI decision mandatory when completing customs formalities. All BTI decisions issued by Italy’s customs authority are entered into the [EBTI-database](#). [Administrative](#)

[guidelines on the BTI process](#) are published on DG Taxud's website. As of October 1, 2019, business operators shall introduce all new applications electronically. More information is available on the [EC's website](#). The customs value of a good is the CIF price at the European border derived from the product price found on the invoice and the transportation costs reflected in the airway bill or the bill of lading. For more information, see Section IX of the [EU FAIRS report](#).

SECTION X: TRADE FACILITATION

Advance Rulings

The customs duties that must be paid upon import of a product depend on the tariff classification applicable to the product. The BTI system was introduced in the EU to ensure legal certainty for business operators when calculating import duties. All currently valid BTI decisions are accessible in the [public BTI database](#). Detailed information on the BTI system can be found at the European Commission's [website](#).

Pre-Clearance Program

Italy applies the Official Controls Regulation (OCR - [Regulation 2017/625](#)), which provides the legal basis for the recognition of official controls in the country of origin of the goods. The OCR does not provide any legal basis for pre-clearance programs like the preclearance inspections conducted in foreign countries by APHIS personnel and funded by the exporters. Rather, Article 73 of the OCR provides for the approval of pre-export controls performed by third countries. Under this system, the EU approval specifies the competent authorities of the third country under the responsibility of which pre-export controls must be performed, the certificates to be used for export of these goods and the maximum frequency of official controls to be performed by Italy's competent authorities at the entry of the consignments into the country.

Electronic Certificates

OCR provides the legal basis for the general EU acceptance of electronic certificates using the EU's Integrated Management System for Official Controls (IMSOC). For plant products, Italy can receive U.S. e-Phytos sent via the Hub created by the International Plant Protection Convention (IPPC). For other commodities, currently no connection exists between IMSOC and the respective systems the U.S. Government Agencies use to issue electronic certificates. In absence of such a connection, paper certificates are required to satisfy Italy's requirement for an original certificate with an ink signature.

Import Control Fees

Italy applies the OCR Regulation, providing the legal basis for the financing of import controls. Mandatory fees are charged to operators for certain official controls, including on import controls of animals, products of animal origin, germinal products, animal by-products, composite products, hay and

straw, plants and plant products. Operators also have to pay for the border controls performed on food and feed of non-animal origin listed in [Commission Implementing Regulation 2019/1793](#). This regulation mandates specific frequencies of controls for certain hazards in products depending on their origin. Several products must be tested for aflatoxin under this regulation. In addition, fees are also charged to operators for official controls that were not originally planned, because they are necessary to follow-up non-compliance.

Average Release Time for Products – Common Delays

Italy's ports of imports are organized in an efficient way to perform customs formalities as well as the necessary veterinary and plant inspections. Incomplete or incorrect certification generally leads to delays in the clearance of goods.

Duplicative Inspections

Once goods have passed inspection and customs duties are paid, they can move freely throughout Italy and the EU. However, official controls remain possible at any stage of distribution.

APPENDIX I: GOVERNMENT REGULATORY KEY AGENCY CONTACTS

Ministry of Health

Directorate General for Food Hygiene, Food Safety, and Nutrition

Address: Via Giorgio Ribotta, 5 - 00144 Rome, Italy

Tel: +39-06-599-41

E-mail: dgsan@postacert.sanita.it

Website: <http://www.salute.gov.it/portale/home.html>

Ministry of Agricultural, Food, and Forestry Policies

Address: Via XX Settembre, 20 - 00187 Rome, Italy

Tel: +39-06-466-51

E-mail: urp@politicheagricole.it

Website: <http://www.politicheagricole.it>

Ministry of Economic Development

Address: Via Molise, 2 - 00187 Rome, Italy

Tel: +39-06-470-51

E-mail: segreteria.ministro@mise.gov.it

Website: <https://www.mise.gov.it/index.php/en/>

Ministry of Economy and Finance

Address: Via XX Settembre, 97 - 00187 Rome, Italy

Tel: +39-06-476-111

E-mail: mef@pec.mef.gov.it

Website: http://www.mef.gov.it/en/index_en.html

Customs Agency

Address: Via Mario Carucci, 71 - 00143 Rome, Italy

Tel: +39-800-257-428

Website: <https://www.adm.gov.it/portale/>

European Commission

Address: Rue de la Loi, 200 - 1049 Brussels, Belgium

Tel: +32-2-299-1111

Website: https://ec.europa.eu/info/index_en

European Union Intellectual Property Office (EUIPO)

Address: Avenida de Europa, 4 - 03009 Alicante, Spain

Tel: +34-965-139-100

E-mail: information@euipo.europa.eu

Website: <https://euipo.europa.eu>

Delegation of the European Commission to the United States

Address: 2175 K Street - NW, Washington, DC 20037

Tel: (202)-862-9500

E-mail: delegation-usa-info@eeas.europa.eu

Website: https://eeas.europa.eu/delegations/united-states-america/27290/about_en

United States Mission to the European Union

Office of Agricultural Affairs

Address: Boulevard du Regent, 27 - 1000 Brussels, Belgium

Tel: +32-2-811-5793

E-mail: AgUSEUBrussels@usda.gov

Website: <https://www.usda-eu.org/>

Animal and Plant Health Inspection Service

Address: Boulevard du Regent, 27 - 1000 Brussels, Belgium

Listing of APHIS-Brussels Staff:

https://www.aphis.usda.gov/aphis/ourfocus/internationalservices/offices/contact_us_pages/contact_us_brussels_belgium

National Oceanic & Atmospheric Administration (NOAA) Representative to the EU:

Address: Boulevard du Regent, 27 - 1000 Brussels, Belgium

Tel: +32-2-811-5831

E-mail: Stephane.Vrignaud@trade.gov

Food and Drug Administration (FDA)

Address: Boulevard du Regent, 27 - 1000 Brussels, Belgium

Tel: +32-2-811-4518

E-mail: US-FDA-EUR@fda.hhs.gov

Other FAS Offices in the European Union:

<https://fas-europe.org/>

FDA contacts for certification of animal products:

<http://www.fda.gov/AnimalVeterinary/Products/ImportExports/default.htm>

Food Safety & Inspection Service (FSIS) Export Requirements for the EU:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products>

Animal & Plant Health Inspection Service (APHIS) – Import & Export:

http://www.aphis.usda.gov/import_export/index.shtml

APPENDIX II: OTHER IMPORT SPECIALIST TECHNICAL CONTACTS

Office of Agricultural Affairs, Foreign Agricultural Service, U.S. Embassy Rome, Italy

Address: Via Veneto, 119a - 00187 Rome, Italy

Tel: (011)-(39)-06-4674-2396

Fax: (011)-(39)-06-4788-7008

E-mail: agrome@usda.gov

Webpage: <https://it.usembassy.gov/embassy-consulates/rome/sections-offices/fas/>

FAS Italy publishes numerous market and commodity reports available through the Global Agricultural Information Network (GAIN) at: <https://gain.fas.usda.gov/#/>.

Attachments:

No Attachments