

USDA Foreign Agricultural Service

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Global Agricultural Information Network

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Italy

Food and Agricultural Import Regulations and Standards - Narrative

FAIRS Country Report

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Report Highlights:

This report is intended to supplement the FAS USEU European Food & Agricultural Import Regulations (FAIRS) Report with Italy-specific information. The Italy FAIRS provides contact information for the competent authorities that are responsible for the import of animal products, plant products, forestry products, fishery products and general food products into the Italian market.

DISCLAIMER: The Office of Agricultural Affairs of the USDA/Foreign Agricultural Service in Rome, Italy prepared this report for U.S. exporters of domestic food and agricultural products. While every possible care was taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped.

FINAL APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

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Section I. Food Laws:

The European Union (EU) has gradually expanded to become the world's largest multi-nation trading bloc. Since July 1, 2013, the European Union comprises 28 member states with approximately 500 million consumers. EU member states: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom. Iceland, Montenegro, the Former Yugoslav Republic of Macedonia and Turkey are candidates to join the EU.

This report is designed to 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. This is available at: <http://gain.fas.usda.gov/Pages/Default.aspx>

To the extent that European Union food laws are harmonized, Italy's food laws and regulations follow European Union rules. However, in the event that the EU rules are only framework legislation or there is no guidance, the regulations of each member state apply. The main principle of the single market concept is to ensure that all food products, whether produced in the EU or imported from a third country, can move freely throughout the EU if they comply with uniform requirements. In reality, certain directives allow Member States to make exceptions i.e. in cases where a country can identify unique concerns about a product intended for import. Free movement can only be guaranteed when all aspects are covered by harmonized legislation: e.g. a foodstuff may comply with the general labeling directive but may carry a health claim for which harmonized rules do not yet exist.

Imported products must meet existing Member State requirements in cases where EU regulatory harmonization is not yet complete. Italian authorities implement EU rules (directives and regulations) for food and agriculture through country specific laws and decrees. Up to date information on EU food import rules as well as general information on EU import duties and quotas can be found on the USEU website: <http://www.usda-eu.org/reports/>

In Italy Food Safety is the primary responsibility of the Italian Ministry of Health, while food production is the primary responsibility of the Italian Ministry of Agriculture. In some instances, other Italian Ministries may have responsibilities, such as the Ministry for Productive Activities on standards, labeling and trade promotion, or the Ministry of Economy and Finance on customs and duties.

Ministero della Salute (Ministry of Health)

Direzione Generale per l'Igiene Alimenti e la Nutrizione

Via Giorgio Ribotta 5,

00144 Roma

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<http://www.ministerosalute.it>

Ministero delle Politiche Agricole e Forestali (Ministry of Agriculture)

Via XX Settembre 20

00187 Roma

Tel: +39 06 46651

<http://www.politicheagricole.it>

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 reviewed by Italian authorities, even if the product is transported in a sealed and bonded container and is not expected to enter the Italian market.

Please note that imports of red meat and meat products; pet food; farmed and wild game meats; ratites; milk and milk products; seafood; bovine embryos, porcine and equine embryos and semen; gelatin; and animal casings from the United States must come from an EU approved U.S. establishment. Up to date information can be found at the following EU website:

https://webgate.ec.europa.eu/sanco/traces/output/non_eu_listsPerCountry_en.htm#

An overview of EU food laws currently in force can be found on the FAS USEU website

<http://www.usda.-eu.org>

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

Section II. Labeling Requirements:

As of December 13, 2014, Directive 2000/13/EC will be repealed by European Parliament and Council Regulation 1169/2011 on the “Provision of Food Information to Consumers”. This regulation establishes new horizontal food labeling requirements which will become applicable on December 13, 2014, except for the new mandatory nutrition declaration requirement which will apply from December 13, 2016. Part B of Annex VI to Regulation 1169/2011 setting out specific requirements for the designation of minced meat will apply from January 1, 2014. Detailed information on the EU’s new food labeling requirements is available in FAS USEU GAIN Report E70002 “New EU Food Labeling Rules Published”.

The European Commission has published a “Questions and Answers on the Application of Regulation 1169/2011 on the Provision of Food Information to Consumers” document on its website at

http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/docs/qanda_application_reg1169-2011_en.pdf

The European Commission still needs to adopt a series of “delegated” and “implementing” acts for the application of Regulation 1169/2011. Updates will be published on the www.usda-eu.org website and in GAIN reports during the course of 2014.

The EU’s Food and Drink Industry Confederation has published a guidance document “Guidance on the Provision of Food Information to Consumers”. Several Member States have also published guides to

compliance with Regulation 1169/2011, including the U.K. “The Food Information Regulations 2013 – Guide to compliance” and Ireland “Overview of changes to food labeling introduced under the new Food Information Regulation”.

Food labeling and ingredient regulations for the most part have been harmonized within the EU.

General provisions on the labeling, presentation and advertising of foodstuffs marketed in the EU are laid down by Regulation (EC) 1169/2011. This regulation consolidates general labeling requirements in a single text.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN:PDF>

U.S. food products can generally be uniformly packaged for sale in all EU Member States based on the condition that they conform to the national law set forth in the first point of entry into the European Union. Please note, though, that Italy requires that labels also be Italian. Many international companies provide multi-language labels to ensure the possibility of sale throughout the European Union. Note that the standard U.S. label does not comply with EU labeling requirements.

In Italy, there are two laws that regulate food product labeling, both of which simply implement EU directives. One decree concerns the mandatory specifications (Legal Decree 2003/181 putting into effect Directive 13/2000/EC, providing guidance on the detailed information that must be displayed on labels, requirements, and allowed exceptions) and the other concerning nutritional labeling specifications.

As previously noted, the standard U.S. label fails to comply with Italian rules and regulations, therefore a sticker with the translation of the U.S. label in Italian and with all the mandatory EU information listed below 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 has to be in a language easily understood by consumers. Multi-language labeling is allowed throughout the EU.

All food and beverage products imported into Italy (as part of the EU) for sale must make the following information available:

- a. The name of the product as commonly used in the trade.
The name established by law or, if this is lacking, a brief description of the product.
- b. A list of ingredients and food additives in descending order by weight.
The following ingredients require a specific statement on the label: GMOs, packaging gases, sweeteners, aspartame, poly oils, quinine, caffeine, phytosterols and phyostanols and licorice.
- c. An Indication on the label of the following potential allergenic ingredients per Directive 2003/89/EC: cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk and dairy products (including lactose), nuts and nut products, sesame seeds, lupine and products thereof, mollusks and products thereof and sulfites at concentrations of at least 10 mg per kg or 10 mg/l, celery, and mustard. Allergen labeling also applies to alcoholic beverages.

Guidelines for the implementation of the allergen labeling rules are available on the Commission's website: http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/guidelines_6_10.pdf

d. A Quantitative Ingredients Declaration (QUID).

The quantity of certain ingredients or categories of ingredients are mandatory in the following cases:

- Where the ingredient or category of ingredients appears in the name under which the foodstuff is sold.
- Where the ingredients or category of ingredients is usually associated with that name by the consumer.
- Where the ingredient or category of ingredients is emphasized on the labeling in words, pictures or graphics.
- Where the ingredient or category of ingredients is essential to characterize a foodstuff and to distinguish it from similar products.

The QUID declaration must be indicated in or immediately next to the name under which the product is sold, unless a list of ingredients is voluntarily indicated on the label in which case the quantity may appear in the list. The quantity of the ingredient, expressed as a percentage, must correspond to the quantity of the ingredient(s) actually used in the preparation of the product.

e. Metric units for all measurements.

The nominal net content or weight expressed in metric units: (weight in grams, liters, kilograms, centiliters, etc.).

f. An expiration date.

Every package must have listed the minimum shelf-life period. The preferred language is "Best before end of DD/MM/YY." It is also possible to state the time limit of consumption if the food is stored and prepared properly.

g. The storage conditions.

Any special storage conditions or conditions of use should be stated. Instructions for use should be given as necessary.

h. Alcoholic content.

This is required for drinks with alcoholic content equal or greater than 1.2 percent alcohol in volume.

i. The name or business name and address of manufacturer, packager, vendor, and importer established within the European Union.

j. The country of origin.

Particulars of the place of origin or provenance in case absence of such information might mislead the consumer.

k. A lot marking.

Council Directive 89/396/EEC requires that foodstuffs carry a mark identifying the lot to which a foodstuff belongs.

l. Instructions for intended use.

m. Treatments the product may have undergone, with specific indications for irradiate or deep-frozen foods.

n. The actual alcoholic strength for beverages containing more than 1.2 percent alcohol by volume.

Allergen labeling rules will change considerably when the EU's new labeling regulation 1169/2011 becomes applicable on December 13, 2014. The presence of allergens will have to be indicated, in bold, in the list of ingredients. "Contains x allergen" statements will no longer be allowed. The EU Food and Drink Industry Confederation has published a guidance document "Food Allergen Management for Food Manufacturers". The British Retail Consortium also published a guidance document "Allergen Labeling and the Requirements in Regulation 1169/2011". For detailed information on the EU-harmonized labeling legislation, please consult the EU-28 FAIRS Report: <http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Food%20and%20Agricultural%20Import%20Regulations%20and%20Standards%20-%20Narrative%20Brussels%20USEU%20EU-27%2012-30-2013.pdf>

For additional information on labeling that will apply from December 13, 2014, please see USEU GAIN report "New EU food labeling rules":

<http://gain.fas.usda.gov/Recent%20GAIN%20Publications/NEW%20EU%20FOOD%20LABELING%20RULES%20PUBLISHED%20Brussels%20USEU%20EU-27%201-12-2012.pdf>

Quinine and Caffeine

Commission Directive 2002/67/EC requires the compulsory labeling of quinine and caffeine used in the production or preparation of foodstuffs (usually tonic waters and energy drinks). Quinine and caffeine must be mentioned in the ingredients list, preceded by the term "flavoring". Beverages containing more than 150 mg of caffeine per liter will have to be labeled with "high caffeine content" followed by the caffeine content expressed in mg/100 ml.

This Directive will be repealed on December 13, 2014, when the EU's new labeling Regulation 1169/2011 becomes applicable.

Phytosterols & Phytostanols

Commission Regulation 608/2004 lays down labeling requirements for foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and phytostanol esters (used to reduce cholesterol levels). For labeling purposes, they must be designated respectively by the terms "plant sterols", "plant sterol esters", "plant stanols" and "plant stanol esters". Article 2 of this regulation lists the warning statements that have to be indicated on the label.

This Directive will be repealed on December 13, 2014, when the EU's new labeling Regulation 1169/2011 becomes applicable.

Quantitative

Food Additives

Italy applies EU-harmonized legislation regarding food additives. For detailed information on the EU-harmonized legislation on food additive regulations, please consult the EU-27 FAIRS Report as well as the USEU website section on additives:

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

Language Requirements

Multi-language labeling is allowed throughout the EU, but for Italy, the language requirement requires that the label also be in Italian.

Stick-on Labels

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 Italy.

Medical / Health / Nutrition Claims

Food products carrying health claims must comply with the provisions of nutritional labeling Directive 90/496/EC. Regulation 432/2012 establishes a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health. It became applicable on December 14, 2012. U.S. exporters of "health" foods, weight loss/diet foods, baby foods and vitamins should work closely with an Italian importer, since Italian labeling laws regarding health claims can be particularly stringent. Italian legislation sets forth orders, obligations, and criminal sanctions for violations.

Regulation 432/2012 establishes the EU positive list of functional health claims and their conditions of use. Any producer can use the permitted health claims provided the conditions set out in Regulation 432/2012 are met. The EU's online "Register of Nutrition and Health Claims" lists the authorized health claims as well as the more the rejected claims and the reasons for their non-authorization. Health claims referring to botanical substances have been put on hold because the Commission and the Member States are still discussing the potential conflict of the Health Claims Regulation with the Traditional Herbal Medicinal Products Directive.

Since December 14, 2012, all claims that are not authorized and not on hold or under consideration are prohibited. Food products carrying claims must comply with the provisions of nutritional labeling directive 90/496/EC. Commission Implementing Decision 2013/63 sets out guidelines for national control authorities as regards the implementation of specific conditions for permitted health claims.

Nutritional Labeling

Food products carrying health claims must comply with the provisions of nutritional labeling Directive 90/496/EC. Regulation 432/2012 establishes a list of permitted health claims for foods, other than those referring to the reduction of disease risk and to children's development and health. It became

applicable on December 14, 2012.

Product-Specific Labeling

For a number of products, specific labeling requirements have been established in addition to the general requirements described above. These include:

- genetically modified foods
- novel foods
- fortified foods
- foodstuffs for particular nutritional uses including dietetic and baby/infant foods
- beef
- wine
- spirit drinks
- olive oil
- organic foods
- cocoa and chocolate products, sugars, honey, fruit juices, and similar products, preserved milk
- coffee extracts and chicory extracts, fruit jam, jellies, marmalades and chestnut puree
- fresh fruits and vegetables
- meat, poultry, eggs, dairy products, spreadable fats
- seafood
- pet food

Country of Origin Labeling

In the EU, country of origin labeling is mandatory for beef and veal, fruit and vegetables, eggs, poultry meat, wine, honey, olive oil, aquaculture products and for organic products carrying the EU logo. For other products, the indication of the place of origin or provenance is mandatory only if the omission of such information might mislead the consumer. On October 25, 2011, a new EU regulation on the provision of food information to consumers was adopted. The new regulation (European Parliament and Council Regulation 1169/2011) was published in Official Journal L 304 on November 22, 2011. The new EU labeling requirements will apply from December 13, 2014, except for the mandatory nutrition declaration which will apply from December 13, 2016.

Section III. Packaging and Container Regulations:

Italy applies EU-harmonized legislation to packaging and containers. There are two EU Directives related to the making-up by weight or by volume of certain prepackaged products. See Council Directive 76/211/EEC:

<http://eur-lex.europa.eu/LexUriServ/site/en/consleg/1976/L/01976L0211-19780929-en.pdf>

and the laying down of rules on nominal quantities for pre-packed products Council Directive 2007/45/EC:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:247:0017:0020:EN:PDF>

For more detailed information on the EU's harmonized legislation on packaging and container regulations, please consult the EU-27 FAIRS report as well as the USEU website section on packaging:

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

Packaging Disposal Regulations

In Italy, issues concerning the production, recycling and disposal of packaging materials and waste are governed by Articles 34-43 of the Ronchi Decree, Legal Decree n. 22/97, which put into force the harmonized EU rules of Council Directive 94/62/EC. The provisions contained in these articles apply to a broad range of packaging issues including: prime materials utilized for packaging; finished packaging for retail/unit sales of products and for wholesale or warehousing use (multiple or secondary packaging); packaging for transportation; waste or by-products from packaging; management of packaging waste; and the reuse, recycling and disposal of packaging, its waste or by-products.

The principal scope of the Ronchi Decree is to encourage the reuse and recycling of packaging. To this end, Article 37 of the Ronchi Decree sets forth certain objectives which must be met by producers and users of packaging. The objectives per Attachment E of the Ronchi Decree are as follows:

	Minimum	Maximum
a) Packaging waste to be reused as material or components for energy: by weight at least	50%	65%
b) Packaging waste to be recycled: by weight at least	25%	45%
c) Any packaging material to be recycled: by weight at least	15%	15%

Producers and users of packaging may perform their obligations for reuse, recycling and collection by one of the following means:

- Organizing independently the collection, reuse, recycling and recuperation of packaging waste;
- Join the National Packaging Consortium (described below);
- Establish a return system to repurchase used packaging.

National Packaging Consortium - CONAI (Consorzio Nazionale Imballaggi) is responsible primarily for the preparation of a general packaging waste management and recycling program (the "General Program") that is designed to meet the reuse and recycling objectives listed in Article 37 and Attachment E of the Ronchi Decree (see table above).

The web site of the European Food Service and Packaging Association:

<http://www.efpa.com/laws.html> provides information on EU packaging directives and food laws.

Section IV. Food Additives Regulations:

Italy applies EU-harmonized legislation regarding food additives. For detailed information on the EU-harmonized legislation on food additive regulations, please consult the EU-27 FAIRS report as well as the USEU website section on additives:

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

Section V. Pesticides and Other Contaminants:

Tolerance for pesticide residues were harmonized in the EU in 2008. Italy adheres to EU-harmonized legislation on pesticides and contaminants. The complete list of MRLs and commodity combinations allowed in the EU can be obtained from the Commission's webpage:

http://ec.europa.eu/food/plant/plant_protection_products/pesticides_database/index_en.htm

For detailed information on EU-harmonized legislation on pesticide and contaminant regulations, please consult the EU-27 FAIRS report as well as the USEU website section on pesticides:

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

Import Conditions for U.S. Almonds

In September 2007, the EU implemented special import conditions which called for mandatory testing of U.S. almonds imported into the EU. USDA and The California almond industry have developed a "Voluntary Aflatoxin Sampling Plan" (VASP) comparable to the EU sampling procedures so that almonds can be uniformly tested before they are shipped to the EU. Per Commission Regulation 1152/2009, these procedures are considered to provide sufficient assurances which means that almonds shipped under VASP are subject to random controls. The Regulation covers almonds in shell or shelled, roasted almonds and mixtures of nuts or dried fruits containing almonds, and foodstuffs containing a significant amount of almonds (at least 20%).

While almonds shipped without a VASP certificate used to be subject to 100 percent border controls in the original Commission Regulation 1152/2009, the regulation has been amended in March 2012 to no longer authorize imports without a VASP (Commission Regulation 274/2012).

Regulation 1152/2009 also introduced the use of a Common Entry Document (CED). Importers have to provide prior notification to the competent authorities at the designated port of entry for the goods covered by the regulation at least 1 working day prior to the arrival of the goods, using the CED. The CED was published as Annex II to Regulation 669/2009. Provisions for methods of sampling and analysis for the official control of mycotoxins including aflatoxins are laid down in Commission Regulation 401/2006.

For additional information on the VASP program check the Almond Board of California website at:

<http://www.almondboard.com/English/Pages/default.aspx>

Section VI. Other Regulations and Requirements:

Council Directive 2000/29/EC, harmonizes the importation requirements of plants and plant products into the EU. Phytosanitary certificates, issued by an APHIS inspector, are required to accompany all plant and plant products entering the EU. Please contact your nearest APHIS Export Certification Specialist:

http://www.aphis.usda.gov/import_export/plants/plant_exports/ecs/index.shtml

For detailed information on certification, please see the USEU certification site:

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

Member States are responsible for carrying out inspections on a regular basis and in cases where non-compliance is suspected. Products can be checked at import or at all further stages of marketing. Infringements of EU food and feed legislation are reported through the Rapid Alert System on Food and Feeds (RASFF). The rapid alert system is a network of Member State authorities managed by the European Commission. The weekly reports of the notifications under the rapid alert are available on

the European Commission's website: http://ec.europa.eu/food/food/rapidalert/index_en.htm

The information published on the website is limited to the notifying country, the reason for notifying and the country of origin. Repeated non-compliance may lead to suspension of imports or special import conditions for products from the third country concerned, applicable for the entire EU territory.

For detailed information about other specific EU-harmonized import requirements, please consult the EU-27 FAIRS report or the USEU import rules website:

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

Genetically Engineered Foods

Labeling regulations for genetically modified (GM) food products are established by Regulation 1829/2003 (articles 12-13). 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 or 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.

Each individual genetically modified organism (GMO) must be approved before it can be used in food and feed. 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. Above this level, all products must be labeled using the following wording:

- Where the food consists of more than one ingredient, the words "genetically modified" or "produced from genetically modified [name of ingredient]" must follow in brackets immediately after the ingredient concerned. A compound ingredient with a GM component should be labeled "contains [name of ingredient] produced from genetically modified [name of organism]". The designations may appear in a footnote to the ingredients list, provided they are printed in a font at least the same size as that of the list of ingredients or, where there is no list of ingredients, clearly on the labeling.

For more information, please see the Annual Biotechnology GAIN report for Italy:

[http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Biotechnology%20in%20Italy%20Annual%202013 Rome Italy 10-2-2013.pdf](http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Biotechnology%20in%20Italy%20Annual%202013%20Rome%20Italy%2010-2-2013.pdf)

Novel Foods

The Novel Food Regulation 258/97:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1997:043:0001:0006:EN:PDF>

lays down detailed rules for the authorization of novel foods and novel food ingredients, including foods derived from, containing, or consisting of GE ingredients. It defines novel foods as foods and food ingredients that were not used to a significant degree in the EU before May 15, 1997.

The EU catalogue on Novel Foods can be consulted on the EU Commission's website:

<http://ec.europa.eu/food/food/biotechnology/novelfood/nfnetweb/index.cfm>

This catalogue provides information on whether or not a product would require authorization under the Novel Food Regulation. The list of novel food applications, authorizations, rejections and withdrawals also can be found on the Commission's website:

http://ec.europa.eu/food/food/biotechnology/novelfood/app_list_en.pdf

Fortified Foods

European Parliament and Council Regulation 1925/2006:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:404:0026:0038:EN:PDF>

amended by Regulation (EC) 1170/2009:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:314:0036:0042:En:PDF>

establishes an EU-wide regulatory framework for the addition to foods of vitamins and minerals and certain other substances such as herbal extracts. It lists the vitamins and minerals that may be added to foods and sets criteria for setting maximum and minimum levels.

Only vitamins and minerals included in the annexes to Regulation 1925/2006 may be used. Member States may under certain conditions provide for a temporary derogation (until January 19, 2014) for vitamins and minerals not included in the annexes. Such derogations should be obtained from the Italian Ministry of Health.

Section VII. Other Specific Standards:

Organic Foods

Effective June 1, 2012, the European Union and the United States began recognizing the other countries' certified organic products. Under the Partnership, the EU recognizes the USDA National Organic Program (NOP) as equivalent to the EU Organic Program (under applicable EU regulations) and allows U.S. organic products to be marketed as "organic" in the EU using the EU organic logo and vice versa.

The Partnership is limited to organic products certified under the NOP program of U.S. origin, either produced within the U.S. or where the final processing or packaging occurs within the United States. All products traded under the Partnership must be accompanied by an organic export certificate. This document states the production location, identifies the organization that certified the organic product, verifies that prohibited substances and methods were not used, certifies that the terms of the Partnership were met, and allows the traded products to be tracked. More information about this partnership can be found on the USDA Organics Home Page for International Agreements:

<http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateJ&leftNav=NationalOrganicProgram&page=NOPInternationalAgreements&description=International%20Agreements&act=nopgeninfo>

Fruit Juices

Directive 2001/112/EC:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:010:0058:0066:EN:PDF>

amended by Directive 2012/12/EU:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:115:0001:0011:EN:PDF>

regulates fruit juices and certain similar products intended for human consumption. Key amendments relate to fruit juice labeling rules on orange juice, nutrition claims, mixed juices and sugars and sweeteners. More information about EU fruit juice labeling requirements can be found in the USEU GAIN Report E70022:

<http://gain.fas.usda.gov/Recent%20GAIN%20Publications/NEW%20EU%20FRUIT%20JUICE%20LABELING%20RULES%20Brussels%20USEU%20EU-27%205-31-2012.pdf>

Seafood

Council Regulation 2406/96:

<http://eur-lex.europa.eu/LexUriServ/site/en/consleg/1996/R/01996R2406-20050602-en.pdf>

lays down common marketing standards for fishery products. Fishery and aquaculture products offered for retail sale in the EU must be properly labeled providing the following information:

- the commercial name of the species (each member state has established a list of commercial designations).
- the production method: “caught in...,” “caught in freshwater”, “farmed,” or “cultivated.”
- the catch area: for products caught at sea, a reference to one of the areas listed in the annex; for products caught in freshwater, a reference to the country of origin; for farmed products a reference to the country in which the product undergoes the final development stage. Operators may indicate a more precise catch area.

To improve the traceability and control at all marketing stages - from the ship to the shop - the information concerning the commercial designation, the production method and the catch area for all fishery and aquaculture products must be provided either on the label, on the packaging or by means of a commercial document accompanying the goods (e.g. the invoice).

Detailed information on exporting U.S. seafood to the EU is available in the 2010 update of the “How to Export Seafood to the European Union” guide which can be downloaded from

<http://www.fas.usda.gov/posthome/useu/NOAA-Export-to-the-EU-Guide.pdf>

On October 17, 2013, the European Council of Ministers agreed to the EC proposal to re-shape the Common Organization of the Market (CMO), which in turn will affect the U.S. seafood industry as there will be changes to the consumer information chapter. Specifically, the text clarifies what mandatory consumer information must be included on product marking and labeling. Mandatory information now includes the gear type used in wild capture fisheries and the requirement of a more detailed indication of the catch area. Text on the Common Organization of the Markets can be found here:

<http://register.consilium.europa.eu/pdf/en/13/st12/st12005.en13.pdf>

These new labeling requirements will apply as of December 13, 2014. Fishery and aquaculture products and their packages which were labeled or marked prior to that date and which do not comply

with these requirements may be marketed until such stocks have been used up. All seafood sold at the retail level will need to have nutritional information on the package. Regulation 1169/2011: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:008:0029:0030:EN:PDF>

describes the minimum information for labels intended for retail or mass caterers. Exporters should pay specific attention to Article 9 and subsequent articles as well as all of the Annexes.

Pet Food

[European Parliament and Council Regulation 767/2009](#) sets out new rules for the labeling and marketing of feed and pet food. It covers feed materials, compound feed and medicated or dietetic feed for both food and non-food producing animals. Feed and pet food not complying with Regulation 767/2009 and with the provisions on feed additives laid down in [Regulation 1831/2003](#) and Directive 90/167/EC will not be allowed on the EU market. New requirements relate to: the indication in descending order of weight of feed materials in compound feed; claims; and the establishment of a non-exhaustive “Catalog of Feed Materials” and “Codes of Good Labeling”. For more information see [GAIN report E50060 “EU Feed and Pet Food Labeling Requirements”](#).

[Commission Regulation 575/2011](#) establishes a new catalogue of feed materials. It enables operators to use more precise names and expressions for the feed they place on the market. The Annex to the Catalogue contains three parts: A) general provision, B) a glossary of processes and C) a list of feed materials. The use of the Catalog is voluntary, but where it is used all relevant provisions must be met. [Commission Recommendation 2011/25/EU](#) establish guidelines for the distinction between feed materials, feed additives, biocidal products, and veterinary medicinal products. A [“Code of Good Labeling Practices for Pet Food”](#) drafted by the European Pet Food Industry (FEDIAF) was published on October 20, 2011.

More information about EU pet food labeling requirements can be found in the USEU GAIN report E50060:

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

For more information about the Italian pet food sector, please see FAS Rome’s GAIN report IT1455 - Italy Pet Food Sector Overview 2014.

<http://photos.state.gov/libraries/italy/217417/pdf/Italy%20Pet%20Food%20Sector%20Overview%20014-10-20-2014.pdf>

Section VIII. Copyright and/or Trademark Laws:

[Council Regulation 207/2009](#):

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:078:0001:0042:EN:PDF>

lays down the rules for registering trademarks. It creates a single, unitary registration system covering the whole European Community. In practice, a Community trademark must meet two conditions: it must be a sign, which can be represented in graphic form, and it must make it possible to distinguish goods and services from those of another company. It is valid for a period of 10 years. On completion of the registration procedure, the trademark is registered in the Register of Community trademarks. The Community Trademark did not replace the existing trademark laws of the member states but co-

exists alongside national trademarks. [Directive 2008/95/EC](#) approximates the laws of the Member States relating to trade marks. For detailed information on the EU-harmonized legislation on copyright and/or trademark laws, please consult the EU-27 FAIRS report as well as the USEU website: <http://www.usda-eu.org/>

Geographical Indications

Geographical indications (GIs) are “indications which identify a good where a given quality, reputation or characteristic of the good is essentially attributable to its geographic origin”.

In November 2012, Regulation 1151/2012:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:343:0001:0029:EN:PDF>

on quality schemes for agricultural products and foodstuffs repealing Council Regulation 510/2006:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R0510:20080529:EN:PDF>

was published and came into force on January 3, 2013. Regulation 1151/2012 lays down detailed rules on protected designations of origin and geographical indications, traditional terms and labeling.

The European Commission’s website:

http://ec.europa.eu/agriculture/quality/schemes/index_en.htm

provides guidance on how to register a GI. Lists of protected names by country, product type, registered name, and name applied for are available through the Commission’s online “DOOR” (Database of Origin and Registration) database. There are also guidelines for the registration of GIs by third country producers at the following website:

http://ec.europa.eu/agriculture/foodqual/protec/thirdcountries/proced_en.pdf

Section IX. Import Procedures:

Council Regulation 2913/92 establishes the Community Customs Code. The Code lists all the customs procedures applicable to the trade in goods with third countries. Import duties are determined by the tariff classification of goods and by the customs value. With the implementation of the Code, the Member States of the European Union form a customs union that means that all the Member States apply the same tariff on goods imported from outside the EU. Once an imported good is cleared in one Member State, it can move freely throughout the EU, and therefore also to Italy.

Products are examined when they enter Italy by border inspection posts (BIP’s – Border Inspection Post - In Italy called P.I.F. Posti d’Ispezione Frontaliera). Health authorities or laboratories perform tests and relative analysis of samples. Import operations can be completed and the product may enter commerce within 48 hours from the time of arrival at port if no specific problems arise from the import document inspection or sample testing.

It is important to work with experienced importers, i.e. have the import agent work with Italian regulatory authorities to ensure acceptability of the specific product. It is also advisable for the agent to contact health authorities at the port of entry as interpretation of health directives may vary from port to port.

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 customs database can be consulted to look up commodity codes

(http://ec.europa.eu/taxation_customs/dds/en/tarhome.htm) and applicable duties

(http://ec.europa.eu/taxation_customs/dds2/taric/taric_consultation.jsp?Lang=en)

[European Parliament and Council Regulation 648/2005](#), a "security amendment" to Regulation 2913/92, introduces a number of measures to tighten security for goods crossing international borders. The provisions to implement the security amendment to the Customs Code are established by [Council Regulation 1875/2006](#). Starting January 1, 2011, all traders involved in customs transactions have to provide EU customs authorities with security data on goods before they are imported into the EU. The type of security data requested varies according to the means of transport and can include a description of the goods, information on the consignor or exporter, the route of the goods and any potential hazards. The time limits for submitting advance security data also vary according to the means of transport: 24 hours for maritime cargo to 1 hour for road traffic and air transport. The European Commission's DG for Taxation and Customs Union has created a "[European Customs Information Portal](#)" to communicate information for traders on the safety and security amendment to the Community Customs Code.

Appendix I. Government Regulatory Agency Contacts:

Ministero delle Politiche Agricole e Forestali

(Ministry of Agriculture)

Via XX Settembre 20

00187 Roma

Tel: +39 06 46651

<http://www.politicheagricole.it>

Ministero delle Attivita' Produttive

(Ministry of Productive Activities)

(Bureau of Foreign Trade)

Viale America 341

00144 Roma

Tel: +39 06 59931

<http://www.sviluppoeconomico.gov.it/>

Ministero delle Economie e Finanze

(Ministry of Finance)

Uff. Relazioni Internazionali (International Bureau)

Viale dell'Aeronautica, 122

00144 Roma

Tel: +39 06 5925967

<http://www.tesoro.it>

<http://www.finanze.gov.it/export/>

Agenzia delle Dogane

(Customs Agency)

Via M. Carucci 71

00143 Roma

Tel: +39-06-50241

<http://www.agenziadogane.it>

Appendix II. European Located Regulatory Agency Contacts:**European Commission**

Rue de la Loi 200

1049 Brussels

Belgium

Tel: (32-2) 299 1111

Office for Harmonization in the Internal Market

Avenida de Aguilera, 20

03080 Alicante

Spain

Tel: (34-96) 513 9243

Fax: (34-96) 513 9173

European Union - Delegation of the European Commission to the United States

2300 M Street

NW, Washington, DC 20037 Tel: (202) 862-9500

Fax: (202) 429-1766

United States Mission to the European Union

Office of Agricultural Affairs

Mailing address:

27 Boulevard du Regent

1000 Brussels

Belgium

Tel: (32-2)811-5793

Fax: (32) (2) 811-5560

E-mail: AgUSEUBrussels@fas.usda.gov

Website: www.usda-eu.org

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

Mailing address:

27 Boulevard du Regent

1000 Brussels

Belgium

Tel: (32-2)811-5831

E-mail: Stephane.Vrignaud@trade.gov

Food and Drug Administration (FDA)

Mailing address:

27 Boulevard du Regent

1000 Brussels

Belgium

Tel: (32-2)8114518

E-mail: PraterD@state.gov

Other FAS Offices in the European Union:

http://www.fas.usda.gov/ofso/overseas_post_directory/ovs_directory_search.asp

USDA/FDA contacts for certification of animal products:

<http://www.fas.usda.gov/posthome/useu/certification.html>

USDA/FDA contacts for U.S. export requirements and documentation

http://www.fas.usda.gov/agx/ship_doc_req/food_ag_us_req.asp

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

<http://www.fsis.usda.gov/Regulations & Policies/European Union Requirements/index.asp>

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

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

Appendix II. Other Import Specialist Contacts:

Office of Agricultural Affairs,

American Embassy,

Via Vittorio Veneto 119/A, Rome, 00187, Italy

Tel: +011 39 06 4674 2396

Fax: +011 39 06 4788 7008

E-mail: agrome@fas.usda.gov

Webpage: <http://www.usembassy.it/agtrade/>