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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 US Mission to the EU's Food & Agricultural Import Regulations and Standards (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.

Section I. Food Laws:

The European Union (EU) has 28 Member States with approximately 500 million consumers. The EU Member States are Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom.

This report is designed to be read in conjunction with the Italy FAIRS Certificate report which can be found at http://italy.usembassy.gov/agtrade.html. You may also want to review the FAIRS report produced by the U.S. Mission to the EU in Brussels, Belgium that is available at: http://gain.fas.usda.gov/Pages/Default.aspx

All EU Member States (including Italy) accept the "*Community Acquis*", i.e. the entire body of EU laws and obligations 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. 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 Mission 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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Via XX Settembre 20
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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.

EU food legislation is characterized by a constant flow of new regulations and directives, amendments to existing legislation and implementation rules. EU laws are translated into the 24 official languages in use in the EU-28 and published in the Official Journal as soon as they are translated. Directives define the result that must be achieved but leave to each Member State the choice of form and methods to transpose the directive into national laws (usually within 2-3 years after adoption). Regulations are binding in their entirety and automatically enter into force on a set date in all Member States. Amendments to EU legislation are usually published in new and separate Directives and 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 but come with a warning that they are not legally binding. 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.
The Eurlex website is http://eur-lex.europa.eu/en/index.htm and provides free access to European Union law.

Section II. Labeling Requirements:

The standard U.S. label fails to comply with EU labeling requirements. On December 13, 2014, the EU's new "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 new FIC regulation will apply as of December 13, 2016. However, if nutrition information is provided on a voluntary basis before this date, it must comply with the new rules.

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 in Italian. Many international companies provide multi-language labels to ensure the possibility of sale throughout the European Union.

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 concerns nutrition 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 EU Commission's website: http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/guidelines_6_10.pdf

FIC regulation 1169/2011 introduced some important changes for allergen labeling. Article 21 of the FIC regulation stipulates that each product or substance capable of inducing an allergic reaction must be indicated in the list of ingredients with reference to the name of the substance or product as listed in Annex II to the FIC regulation. The name of the substance or product must be highlighted through a typeset that clearly distinguishes it from the other ingredients, for example in bold or with a background color.

Where an ingredients list is provided, the voluntary use of warning boxes or statements such as "contains X" to repeat the presence of the allergenic ingredients is no longer allowed. On products that do not require an ingredients list, such as for example wine, the presence of allergens must be indicated using the word "contains" followed by the name of the substance or product as listed in Annex II to the FIC regulation. Allergen labeling is mandatory on all alcoholic beverages and must respect the minimum font size requirement. Member States may decide in which language(s) allergens should be indicated on the label.

In November 2014, the European Commission launched a public consultation on a Guidance Document on Allergen Labeling. The consultation closed on January 4, 2015. For more information please consult DG SANTE's website: http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/food/consult_20150104_allergy-intolerance_en.htm

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.

Quantitative

Food Additives
Italy applies EU-harmonized legislation regarding food additives. The EU's "Package on Food Improvement Agents" includes four regulations: Regulation 1331/2008 establishing a common authorization procedure for food additives, food enzymes and food flavorings, Regulation 1332/2008 on food enzymes, Regulation 1333/2008 on food additives and Regulation 1334/2008 on flavorings. Regulation 1331/2008 establishes a common authorization procedure for food additives, food enzymes and food flavorings based on safety evaluations carried out by the European Food Safety Authority (EFSA). The implementing rules are laid down in Commission Regulation 234/2011, explaining the content of an application and all the data both administrative and technical that have to be submitted to the Commission. The Commission then requests EFSA verify the suitability of the data. An application consists of a letter, a technical dossier and a summary of the dossier.

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
On July 20, 2016, the EU's new rules on dietetic foods set out in European Parliament and Council Regulation 609/2013 will become applicable and repeal the existing rules on "foodstuffs intended for particular nutritional uses". The scope of this regulation is limited to infant formula and follow-on formula, processed cereal-based foods and baby foods, food for special medical purposes and total diet replacement for weight control. Foods that no longer fall within the scope of Regulation 609/2013, such as low calorie cereal bars and slimming products, will be regarded as "normal foods" and must comply with the Food Information to Consumers Regulation 1169/2011 and the Nutrition

and Health Claims Regulation 1924/2006.

Until July 2016 when Regulation 609/2013 becomes applicable, the current rules in framework Directive 2009/39/EC still apply. Foodstuffs for particular nutritional uses are defined as foodstuffs, which due to their special composition or manufacturing process can clearly be distinguished from foodstuffs for normal consumption. Commission Regulation 953/2009 lists the substances (vitamins, minerals and amino acids) that may be added for specific nutritional purposes in foodstuffs for particular nutritional uses. There are provisions regarding compositional and hygiene requirements, quality of raw materials, a list of additives/substances, specific labeling requirements, sampling procedures and analysis methods stipulated for four product categories:

- Commission Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children.
- Commission Directive 96/8/EC on foods intended for use in energy-restricted diets for weight reduction.
- Commission Directive 2006/141/EC on infant formula and follow-on formula, amended by Commission Regulation 1243/2008 as regards compositional requirements for certain infant formulae.
- Commission Directive 1999/21/EC on dietary foods for special medical purposes.

Commission Regulation 41/2009 lays down new EU harmonized rules for the composition and labeling of foodstuffs suitable for people who are intolerant to gluten. This regulation sets conditions for the use of the terms "very low gluten" and "gluten-free". Effective July 20, 2016, the provisions relating to "gluten-free" and "lower gluten" food under the Food Information to Consumers Regulation 1169/2011 will apply. For more information see GAIN report "New EU Rules on Dietetic Foods". Specific directives on foods and beverages for athletes or on foods intended for diabetics are still subject to Member State legislation. The marketing of dietetic foods for which no specific rules have been established must be notified to the Member State where the food is sold.

A list of competent Member State authorities can be downloaded at http://ec.europa.eu/food/food/labellingnutrition/nutritional/list_auth_art11_en.pdf.

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 (COOL)

Before the adoption of FIC regulation 1169/2011 country of origin labeling was already mandatory for honey, fruits and vegetables, olive oil, fishery and aquaculture products and beef. The FIC regulation extends the mandatory COOL requirement to fresh, chilled and frozen pork, sheep and goat meat and poultry. Under Article 26 of the FIC regulation, mandatory COOL provisions apply in the following cases:

- Where failure to indicate the country of origin or place of provenance might mislead the consumer
- For fresh, chilled and frozen pork, sheep and goat meat and poultry (see "Meat Labeling")
- When the country of origin is given voluntarily, i.e. on products for which COOL is not mandatory, but the origin of the primary ingredient is not the same as that of the food product. In such cases, the label must indicate that the country of origin of the primary ingredient is different from that of the food product.

For more information on the status of required Commission reports see DG SANTE's website http://ec.europa.eu/food/safety/labelling_nutrition/labelling_legislation/index_en.htm.

Section III. Packaging and Container Regulations:

Italy applies EU-harmonized legislation to packaging and containers. There are two EU Directives related to the make-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

The maximum tolerable error between the actual content and the quantity indicated on the label, and methods to check this are fixed in Council Directive 76/211/EEC, as amended. A small "e" of at least 3 mm on the label guarantees that the actual content corresponds to the quantity indicated. The size of the figures indicating the quantity depends on the nominal quantity:

- nominal quantity greater than 1000 g or 100 cl: at least 6 mm high
- greater than 200 g/20 cl but less than 1000 g/100 cl: at least 4 mm
- greater than 50 g/5 cl but less than 200 g/20 cl: at least 3 mm
- less than 50 g/2 cl: 2 mm. The quantity must be followed by the unit of measurement.

Directive 2007/45/EC abolished regulations on mandatory pack sizes at both EU and national levels. The Directive frees sizes for all prepackaged products except wine and spirits, and coffee. Mandatory

nominal quantities for wines and spirits are set out in the Annex to Directive 2007/45/EC. Detailed information on "Legal Metrology" is available on the European Commission's website http://ec.europa.eu/growth/single-market/goods/building-blocks/legal-metrology/.

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. The EU's "Package on Food Improvement Agents" includes four regulations: Regulation 1331/2008 establishing a common authorization procedure for food additives, food enzymes and food flavorings, Regulation 1332/2008 on food enzymes, Regulation 1333/2008 on food additives and Regulation 1334/2008 on flavorings.

Regulation 1331/2008 establishes a common authorization procedure for food additives, food enzymes and food flavorings based on safety evaluations carried out by the European Food Safety Authority (EFSA). The implementing rules are laid down in Commission Regulation 234/2011,

explaining the content of an application and all the data both administrative and technical that have to be submitted to the Commission. The Commission then requests EFSA verify the suitability of the data. An application consists of a letter, a technical dossier and a summary of the dossier.

Section V. Pesticides and Other Contaminants:

European Parliament and Council Regulation 1107/2009 sets out rules for the authorization of plant protection products (PPPs). Commission implementing Regulation 540/2011, establishes a list of approved active substances. Only PPPs containing active substances included in the list may be authorized for use in the EU. Member States can approve PPPs containing the active substances. According to the new Regulation, the EU is divided in three different zones. Once a Member State approves the PPP it can be mutually recognized and thus authorized within the same EU zone as set out in Annex I of the Regulation. The Maximum Residue Levels (MRLs) for substances not on the list will be set at default level of 0.01 mg/kg. The legislation allows exporters to request an "import tolerance" for active substances not yet evaluated or in use in the EU.

Directive 2009/128 on the sustainable use of pesticides is part of the so-called Pesticides Package. For more information see the European Commission website http://ec.europa.eu/food/plant/pesticides/sustainable_use_pesticides/index_en.htm.

Maximum Residue Limits (MRLs): Regulation 396/2005

Since September 2008 all MRLs in the EU have been harmonized by European Parliament and Council Regulation 396/2005 on food or feed of plant and animal origin. Pesticide MRLs for processed or composite products are based on the MRLs of the raw agricultural ingredients. MRLs apply to 315 fresh products and to the same products after processing. See the European Commission's website at http://ec.europa.eu/food/plant/pesticides/index_en.htm for the latest updates.

- Annex I lists the commodities to which MRLs apply.
- Annex II contains existing MRLs that were already harmonized at EU level and replaces the EU's old MRL Directives.
- Annex III lists EU "temporary" MRLs or pesticides for which, before September 1, 2008, MRLs were only set at national level.
- Annex IV lists the substances for which no MRLs are required and so are exempt from tolerance products.
- Annex V will contain the list of pesticides for which a default limit other than 0.01 mg/kg will apply. Pesticide MRLs for processed or composite products are based on the MRLs for the raw agricultural ingredients.
- Annex VI will contain the list of conversion factors of MRLs for processed commodities. This Annex has not been published yet.
- Annex VII contains a list of pesticides used as fumigants for which the Member States are allowed to apply special derogations before the products are placed on the market.

For a list of authorized active substances or pesticide-MRL combinations, see the European Commission's online database at http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN.

Official Controls

Harmonized sampling methods are established for the official control of residues in and on products of plant and animal origin by Commission Directive 2002/63/EC. Commission Implementing Regulation 2015/595 outlines the latest version of the coordinated multi annual control program of the EU for pesticides residues, which requires Member States to take and analyze samples for product and pesticide residue combinations in food of plant and animal origin. Annex I to the Regulation sets out the pesticide and product combinations to be monitored. Annex II sets out the number of samples that need to be taken for each combination. The Member States must submit results of the sample tests to the EU by 31 August 2017, 2018 and 2019 for samples tested in 2016, 2017 and 2018 respectively. For more information see the European Commission website http://ec.europa.eu/food/plant/pesticides/max_residue_levels/enforcement/index_en.htm.

Import Conditions for U.S. Almonds

In April 2015, the EU approved the pre-export checks (PEC) program for U.S. almonds. U.S. almonds were included in the Annex to Commission Implementing Regulation (EU) 2015/949 which lists all EU approved Pre-export Check programs. The acceptance of the U.S. program reflects the EU's recognition of aflatoxin controls performed at U.S. origin in line with Article 23 of the EU Regulation on Official Food and Feed Controls (Regulation (EC) No 882/2004). The USDA Agricultural Marketing Service started to issue PEC almond certificates on August 1, 2015. The almond PEC program builds on and replaces the Voluntary Aflatoxin Sampling Plan (VASP) program, which stopped being required in September 2014, when the EU voted to remove California Almonds from Special Measures.

With the publication of Commission Implementing Regulation (EU) 2015/949, all EU accepted programs have been combined in the one regulation. The U.S. peanut program which was approved in 2009 is now also covered by the general provisions of Commission Implementing Regulation (EU) 2015/949. Under the regulation, import authorities are directed to subject consignments of U.S. almonds and peanuts with a PEC certificate to a less than 1% control level at the border. The PEC program is voluntary; a PEC certificate is not a requirement for import into the EU. Shipments without a PEC certificate do not benefit from the reduced inspection levels upon import in the EU.
On April 1, 2015, U.S. pistachios were included in the list of products/origins subject to increased import controls under Commission Regulation (EC) No 669/2009. Member States have to test 20 percent of all incoming shipments until the list in the Annex of the regulation is amended. This regulation does not impose any requirements on exporters.

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.

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. The EU register of authorized GMOs can be consulted on the European Commission's website at http://ec.europa.eu/food/plant/gmo/eu_register/index_en.htm. 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]".
- Where the ingredient is designated by the name of a category (e.g. vegetable oil), the words "contains genetically modified [name of organism]" or "contains [name of ingredient] produced from genetically modified [name of organism]" must be used.
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.

- Where there is no list of ingredients, the words “genetically modified” or “produced from genetically modified [name of ingredient]” must appear clearly in the labeling.
More information can be found on the European Commission’s website: http://ec.europa.eu/food/plant/gmo/traceability_labelling/index_en.htm and in the Italy Biotechnology GAIN report from the Post website at http://italy.usembassy.gov/agtrade.html.

Controls of GE food: Office VI of the Directorate General for Food Hygiene, Food Safety, and Nutrition (DGFHFSN) at the Italian Ministry of Health is responsible for controls on GE food, including applications for authorization of GE food. Office II of DGFHFSN is responsible for controls on GE food of non-animal origin (both raw materials and processed food). The Port, Airport, and Border Health Offices (USMAFs) perform controls of GE food and GE food of non-animal origin at the point of entry. Standard controls involve documentary, identity and physical checks, and sampling. Samples are taken from approximately 5-10 percent of consignments focusing largely on those declared ‘GE-free’. Accredited laboratories upload the analysis’ results directly to the information system of the Experimental Zoo-prophylaxis Institute of Lazio and Tuscany. The National GE Food Control Plan for 2015-2018 is available at: http://www.salute.gov.it/imgs/C_17_pubblicazioni_2257_allegato.pdf

Controls of GE feed: Office VII of the Directorate General for Animal Health and Veterinary Medicine (DGAHVM) at the Italian Ministry of Health is responsible for controls on GE feed, including applications for authorization of GE feed. GE feed controls at the point of entry are performed by the veterinary services of the Border Airports and Ports (BIPs). Standard controls involve documentary, identity and physical checks, and sampling. Accredited laboratories upload the analysis’ results directly to the information system of the Experimental Zoo-prophylaxis Institute of Lazio and Tuscany (IZSLT). The National GE Feed Control Plan (PNAA) for 2015-2017 is available at: http://www.salute.gov.it/imgs/C_17_pubblicazioni_2269_allegato.pdf

Controls of GE seed: The Italian Ministry of Agricultural and Forestry Policies (MIPAAF) is responsible for controls on GE seed. The Central Inspectorate for Quality Control of Foodstuff and Agricultural Products (ICQRF) and the Agricultural Research Council-Center for Seed Testing and Certification (CRA-SCS), in cooperation with Customs perform GE seed controls. MIPAAF controls registration of seed varieties through the National Register and regulates the tolerances for the adventitious presence of genetically modified seeds in conventional seed lots. Italy applies a “zero tolerance” for adventitious presence of GE seeds in conventional lots. For technical purposes, the tolerance level is 0.049 percent, or the minimum detectable level.

Novel Foods

The Novel Food Regulation 258/97 lays down detailed rules for the authorization of novel foods and novel food ingredients. It defines novel foods as foods and food ingredients that were not used to a significant degree in the Novel food categories consist of food and food ingredients:

- with a new intentionally modified primary molecular structure, or
- consisting of, or isolated from, micro-organisms, fungi or algae, or
- consisting of, or isolated from plants or animals, except for foods and food ingredients obtained by traditional propagating or breeding practices with a history of safe use, or

- to which a production process not currently used has been applied, where that process changes the composition or structure of the food or food ingredient significantly

For additional information please see the European Commission's website at http://ec.europa.eu/food/safety/docs/novel-food_guidance_human-consumption_en.pdf.

Unlike food additives and vitamins and minerals, a positive list of novel foods and ingredients does not yet exist. A Novel Foods Catalog is available on the website of the European Commission but has no legal value. U.S. exporters are advised to check the legal status of novel food ingredients before exporting to the EU. For more information see the European Commission's website at http://ec.europa.eu/food/safety/novel_food/index_en.htm and GAIN report "Negative List for Novel Foods and Ingredients".

New Rules as of 2017

A new EU framework regulation 2015/2283 on Novel Foods was adopted in November 2015 and published in Official Journal L 327 on December 11, 2015. Most provisions of the new Novel Foods Regulation will become applicable on January 1, 2018. Main elements of the new Novel Foods Regulation include:
Definition: A novel food is defined as food that has been not 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 new regulation. The definition also covers food produced with "non-traditional breeding techniques".

Authorization procedure: Under the new centralized authorization procedure authorizations would take up to 18 months compared to 42 months under the current rules. Applications for authorizations must be submitted to the European Commission and the European Food Safety Authority (EFSA) will carry out the risk assessments. Under the current rules, the Member States' competent authorities carry out risk assessments and if an objection is raised by a Member State or group of Member States, the Commission asks EFSA for a second evaluation.
EFSA Risk Assessments: The new regulation sets out the risk assessment process by EFSA and introduces deadlines.

EU Positive List: The new regulation provides for the establishment of Union list of novel foods. Authorizations will be granted through "implementing acts" which means that the European Parliament will not be able to veto them. Authorizations will be generic and no longer applicant-linked. Member States will be able to suspend or temporarily restrict the marketing and use of any novel food in case of an alleged health risk. The Commission will then examine the Member State's protective measure and take a decision.
Status: The new regulation provides for a consultation process when the status of a food or food ingredient is unsure. Procedural steps for the consultation process will be adopted by an implementing act.

Food from clones: Until separate legislation on cloning is adopted, food from clones but not offspring will fall within the scope of the Novel Foods Regulation.

Engineered nanomaterials: Engineered nanomaterials require a novel food authorization before being used in food. The definition currently set out in the Food Information to Consumers Regulation 1169/2011 is transferred to the new Novel Foods Regulation.
Traditional food from third countries: Traditional foods from third countries with a demonstrated safe history of use of at least 25 years would only need to be notified if no safety concerns are raised by Member States or EFSA.

Fortified Foods

European Parliament and Council Regulation 1925/2006 established an EU-wide regulatory framework for the addition of vitamins and mineral and of certain other substances such as herbal extracts to foods. It lists the vitamins and minerals that may be added to foods and sets criteria for setting maximum and minimum levels. A European Commission proposal setting harmonized maximum and minimum permitted levels of vitamins and minerals in foods and food supplements is already seven years overdue (original deadline set by Regulation 1925/2006 was January 2009). Vitamins and minerals must be expressed as a percentage of the "Reference Intakes" listed in Annex III to the "Food Information to Consumers" regulation 1169/2011 (see also Section V "Nutrition Declaration". The use of vitamins and minerals not included in the annexes to Regulation 1925/2006 is not allowed. A "Community Register" on the addition of vitamins and minerals and of certain other substances is available on the European Commission's website at
http://ec.europa.eu/food/food/labellingnutrition/vitamins/comm_reg_en.pdf

Section VII. Other Specific Standards:

Organic Foods

Council Regulation 834/2007 is the EU's general framework regulation that sets out rules for organic production and labeling. Commission Regulation 889/2008 sets out detailed rules for the implementation of Regulation 834/2007. The term "organic" and all its derivatives or diminutives such as "bio" and "eco" may be used only to label products that comply with EU organic production rules and if at least 95% of the ingredients of agricultural origin are organic. For products containing less than 95% organic ingredients, the term "organic" may be used only to indicate individual organic ingredients in the list of ingredients. When reference is made to the organic production method in the ingredients list, the total percentage of organic ingredients must be indicated. The Annex to Regulation 834/2007 lists the term "organic" in all the official EU languages. For more information see the European Commission's website at http://ec.europa.eu/agriculture/organic/eu-policy/legislation_en#regulation.

On July 1, 2012, the use of the EU organic logo became mandatory on all pre-packaged organic products produced in the EU. Organic products imported from third countries may carry the EU organic logo if they comply with the EU production rules. When the EU organic logo appears on the label, the indication of the place of farming is required.

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.

Seafood

Detailed information on shipping seafood and fishery products to the EU is provided in the exporter guide "Exporting Seafood to the European Union – August 2015 Update" which can be downloaded from the Department of Commerce – NOAA Fisheries' website at http://www.seafood.nmfs.noaa.gov/pdfs/howtoexportseafood2015.pdf. Information on labeling can also be found in the European Commission's "Pocket Guide to the EU's new fish and aquaculture consumer labels", published in December 2014.

Pet Food

In the EU, pet food is subject to feed marketing legislation and veterinary legislation. The EU's feed marketing legislation covers food for pets as well as feed for food-producing animals. The veterinary legislation covers products of animal origin and hay/straw as these products present a risk for spreading animal diseases. Pet food products containing an animal origin ingredient must be sourced from approved establishments and have to be accompanied by a veterinary certificate. All exports of U.S. pet food to the EU must comply with EU requirements including rules on labeling, hygiene, animal health, certification and the use of additives.

European Parliament and Council Regulation 767/2009 sets out 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 will not be allowed on the EU market. Conditions for mixing veterinary medicine into feed are set out in Directive 90/167/EEC. In September 2014, the European Commission presented a proposal to replace the outdated Directive 90/167/EEC on medicated feed. The scope of the proposal explicitly includes medicated feed for pets. Adoption of this proposal is expected in the first half of 2016. EU border inspection officials will verify the labels on imported pet food for compliance with EU requirements. Annex 4 to the "Code of Good Labeling Practice for Pet Food", drafted by the European Pet Food Industry (FEDIAF) establishes a "check-list" that pet food manufacturers can use to verify compliance

with EU labeling rules.
Commission Regulation 68/2013 establishes a 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) glossary of processes and C) list of feed materials. The use of the Catalog is voluntary but where it is used all relevant provisions have to be complied with. Commission Recommendation 2011/25/EU lays out the guidelines with the distinctions between feed materials, feed additives, biocidal products and veterinary medicinal products.

Additional information in the Italy Pet Food Sector report which can be found at http://gain.fas.usda.gov/Pages/Default.aspx

Section VIII. Copyright and/or Trademark Laws:

There are two ways to register a trade mark in the EU. A trade mark can either be registered at national level at the industrial property office of EU Member States or at EU-level as a "Community trade mark" at the Office for Harmonization in the Internal Market. A Community Trade Mark gives the owner protection in all EU Member States with one single registration. The website of the Office for Harmonization in the Internal Market provides detailed information on the definition, registration process and ownership of trademarks: https://oami.europa.eu/ohimportal/en/trade-marks.

Information on EU trade mark protection criteria can be found on the European Commission's website at http://ec.europa.eu/growth/industry/intellectual-property/trade-mark-protection/index_en.htm.

Protected Geographical Indications

Several food product names considered as generic in the U.S. such as for example feta, parmesan and Parma ham, are protected under EU law. European Parliament and Council Regulation 1151/2012 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 open to third countries. Wines and spirits are covered by specific legislation and do not fall within the scope of the regulation.

The provisions on labeling and the use of EU logos for PDOs, PGIs and TSGs set out in Regulation 1151/2012 become applicable on January 4, 2016. 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 "DOOR" (Database of Origin and Registration) database.

"Protected Designation of Origin" (PDO) is defined as follows:

- Originating in a specific place, region or in exceptional cases, a country
- Quality and characteristics of the product are essentially or exclusively due to a particular geographical environment with its inherent natural and human factors
- ALL of the production steps take place in the defined geographical area

"Protected Geographical Indication" (PGI) is defined as follows:

- Originating in a specific place, region or country
- Quality, reputation or other characteristics are essentially attributable to the geographical origin
- At least one of the production steps takes place in the defined geographical area

"Traditional Specialties Guaranteed" (TSG):
The TSG quality label is used to communicate the value-added characteristics of traditional recipes and traditional production methods to consumers. "Traditional" is defined as a proven usage of at least 30 years. Unlike the PDO and PGI schemes, the geographical origin of a product is irrelevant under the TSG scheme. Under the new rules, TSGs are included a Community Register with name reservation. Only products complying with the TSG specifications can use the registered name.

Regulation 1151/2012 sets out criteria for the use of optional quality terms. The European Commission is empowered to reserve new terms or amend the conditions of use of existing terms. Regulation 1151/2012 on EU Quality Schemes becomes applicable on January 4, 2016.

Italy is particularly vigorous in its enforcement of geographical indications, including raising concerns about packaging and labeling they deem may be misleading to consumers even if the terms used are not officially protected.

Section IX. Import Procedures:

On May 1, 2016, the new "Union Customs Code" established in European Parliament and Council Regulation 952/2013 becomes applicable. Until then, the current Community Customs Code (Council Regulation 2913/92) and its implementing provisions continue to apply.
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 which 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.

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.

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)

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. Other Import Specialist 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 III. 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/

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SECTION I: FOOD LAWS