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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 U.S. 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. In June 2016, the U.K. voted in a referendum to leave the EU. Until negotiations on an exit agreement between the U.K. and the other 27 Member States are concluded, the U.K. remains a member of the EU.

This report is designed to be read in conjunction with the Italy FAIRS Certificate report which can be found at https://it.usembassy.gov/embassy-consulates/embassy/sections-offices/fas/
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://www.usda-eu.org/trade-with-the-eu/eu-import-rules/fairs-reports/

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 Ministry of Health, while food production is the primary responsibility of the 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.
The Ministry of Health is organized as a General Secretariat with 12 Directorates-General.
The following three Directorates deal with hygiene and food safety, nutrition and veterinary public health:

• Directorate-General for animal health and veterinary medicinal products (DGSAF);
• Directorate-General for hygiene, food safety and nutrition (DGISAN);
• Directorate-General for collegial bodies for health protection (DGOCTS).

DGSAF is responsible for drawing up national programs for the eradication of animal diseases and guidelines for the control of animal welfare on farms by ensuring effective controls on imported animals, food of animal origin and feeding stuffs at the Border Inspection Posts (BIPs). It also provides general guidelines for feedstuffs and animal nutrition, issues marketing authorizations for veterinary medicinal products aimed at licensing of manufacturing, import permits And compliance with GMP (Good Manufacturing Practices).

DGISAN is concerned with: health and safety of food production and marketing, primary products included; oversight of the food chain and operational guidelines for official controls on imported food; management of the RASFF system and the food, feed, and animal by-products division; nutrition and products for use in special diets; functional foods; food supplements; herbal products for food; nutritional labeling; nutritional education; health aspects related to food technology and novel foods; genetically modified organisms; additives, food flavorings, contaminants and food contact materials; plant protection products; hygiene and safety of food for export; investigations, audits and inspections in the areas of competence**.**

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

Peripheral offices of the MOH (BIPs, USMAF,UVAC)
The following local ministerial offices are responsible for import controls and intra-Union trade:
• 23 Border Inspection Posts (BIPs) for import controls on animals, food of animal origin and feedstuffs;
• 37 local offices at the main ports and airports, responsible for import controls on food of non-animal origin, which depend on 12 main Maritime, Aviation and Border Health Offices (USMAF);
• 17 Veterinary Offices for Compliance with EU Requirements (UVAC), responsible for intra Community trade of animals, food of animal origin and feed.

The Nucleo Anti Sofisticazioni (NAS – the Food Law Enforcement Department) is a special unit of the Italian Corps of Carabinieri, which operates under the supervision and direction of the Ministry of Health. It is organized into a central command, 3 main local units and 38 regional inspection units. It carries out investigations and controls on illegal adulteration of foodstuffs, fraud, and trafficking of medicines, both on its own initiative and upon request from MOH offices. This includes hygiene inspections, verification of control systems, sampling and analysis of products and examination of authorization documents.

The National Health Institute (ISS) is the leading technical and scientific public body of the Italian National Health Service. The ISS (which falls under MoH) supervises all laboratories in charge of food and feed controls and carries out confirmatory analysis at the national level. Its activities include research, control, training and consultation in the interest of public health protection. The ISS is also a community reference laboratory for escherichia coli (including Vero toxigenic E. coli), parasites (i.e. Trichinella) and the residues listed in annex I, group B 3 (c) of Directive 96/23/EC.

The Istituti Zooprofilattici Sperimentali - National Reference Centers (IZS) are located in most Italian regions. The IZS's are veterinary public health institutes which form a network of public laboratories at the national and regional level. The centers are organized in 10 central laboratories and 85 field diagnostic units at the regional level. All IZS laboratories for the official control of feed and foodstuffs are accredited to perform analyses on food of animal origin and on animal health.

Tests on contaminants, pesticides and food of plant origin are performed by 27 Environment Protection Agencies (ARPA) with 54 local laboratories at the regional level. ARPA comprises laboratories that are responsible for both environmental monitoring and food controls. The laboratories report to the local LHU-ASL, and they may perform analyses for more than one LHU-ASL in a particular region. Official analyses are also carried out by the Public Health Laboratories (PHL-LSP) operating within the ASL's Prevention Departments. The tested matrixes include food of animal and non-animal origin, water and food contact materials.

U.S. food and beverage products must comply with the generally applied rules and regulations, as would any other product sold in the EU market. U.S. exporters should also be aware that any food or agricultural product trans-shipped through Italian territory will be 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:

General Requirements

The standard U.S. label fails to comply with EU and Italian 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 becomes applicable on December 13, 2016. Italy requires that labels be in Italian. There are several international companies that provide multi-language labels to ensure the possibility of sale throughout the European Union.
The objective of a "regulation" is to set harmonized rules that apply throughout the EU. However, the FIC regulation allows EU Member States to deviate from EU rules. Article 39 of the FIC regulation sets conditions for Member States to adopt additional mandatory national measures, including measures for country of origin labeling. The FIC regulation exempts alcoholic beverages from mandatory nutrition labeling and ingredient listing but Article 41 allows Member States to maintain national rules on the listing of ingredients until EU-harmonized provisions are adopted. U.S. exporters are strongly advised to check for additional national requirements with their importers.

Compulsory Information

Article 9 of FIC regulation 1169/2011 sets out the list of mandatory declarations on food and drink labels:

- Name of the food
- List of ingredients
- Allergens listed in Annex II
- Quantity of certain ingredients or category of ingredients
- Net quantity of the food
- Date of minimum durability of "use by date"
- Any special storage conditions and/or conditions of use
- Name of business name and address of the food business operator under whose name the food is marketed. If that operator is not established in the EU, the name and address of the importer
- Country of origin or place of provenance in accordance with the provisions of Article 26
- Instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions
- Alcoholic strength by volume for beverages containing more than 1.2% by volume of alcohol
- Nutrition declaration

Warnings on Labels

Annex III to FIC regulation 1169/2011 establishes a list of products that require a special warning on the label:

- Foods whose durability has been extended by means of packaging gases
- Foods containing sweeteners authorized under Food Additives Regulation 1333/2008

- Foods containing added sugar and sweeteners authorized under Food Additives Regulation 1333/2008
- Foods containing aspartame authorized under Food Additives Regulation 1333/2008
- Foods containing more than 10% added polyols authorized under Food Additives Regulation 1333/2008
- Confectionery and beverages containing licorice (glycyrrhizin acid or its ammonium salt)
- Beverages containing more than 150mg/l of caffeine and foods with added caffeine
- Foods or food ingredients with added phytosterols, phytosterol esters, phytostanols or phytostanol esters

Annex V to Food Additives Regulation 1333/2008 requires foodstuffs containing the food colors sunset yellow (E110), quinolone yellow (E104), carmoisine (E122), allura red (E129), tartrazine (E102) and ponceau 4R (E124) to be labeled "may have an adverse effect on activity and attention in children."

Any non-edible parts of a packaging system that consumers could mistake for food must be labeled with the words "DO NOT EAT" and where technically possible carry a warning symbol.

Minimum Font Size

Article 13 of FIC regulation 1169/2011 introduces a minimum font size for printing the mandatory information on food and drink labels. As a general rule, the information must be printed in characters using of minimum font size of 1.2 mm for the "x-height" as defined in Annex IV. If the largest surface of a food package or container is less than 80 cm^2 the minimum font size is reduced to 0.9 mm. On packages with a printable surface smaller than 25 cm^2, the nutrition declaration is not required. Packages which are smaller than 10 cm^2 do not need to bear a nutrition declaration nor a list of ingredients. The minimum font size does not apply to mandatory labeling requirements set out in other EU legislation such as for example the font size requirements set out in Directive 76/2011 to indicate the nominal quantity (see Section IV Packaging and Container Requirements).

Language Requirements

Article 15 of FIC regulation 1169/2011 stipulates that the mandatory information should be provided in "a language easily understood by the consumers of the Member States where the food is marketed." For Italy, the label must be in Italian. In order to avoid non-compliance with the new labeling rules, translations of mandatory information must be accurate. Automated online translation tools may generate incorrect translations and should not be used unless edited.

Ingredients List

The list of ingredients must be preceded by the word "ingredients." All ingredients must be designated by their specific name and listed in descending order of weight. Ingredients present in the form of engineered nanomaterials must be indicated in the list of ingredients followed by the word "nano" in brackets. Annex VII to FIC regulation 1169/2011 sets out specific provisions concerning the indication of ingredients and categories of ingredients in the list of ingredients. This Annex requires

the mandatory indication of the source of vegetable oils and fats.

Allergen Labeling

FIC regulation 1169/2011 introduced 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.

Example: "tofu**" (soya)** – "whey" **(milk)**

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.

Minimum Durability

Annex X to FIC regulation 1169/2011 sets out rules for the indication of the date of minimum durability, use-by date and date of freezing. The use-by date must be indicated on individual pre-packed portions. The durability date and the date of (first) freezing preceded by the words "frozen on" is required on labels of frozen meat, frozen meat preparations and frozen unprocessed fishery products.

Quantitative Ingredients Declaration (QUID)

Article 22 of the FIC regulation requires the indication of the quantity of an ingredient or category of ingredients in the following cases:

- Where the ingredient or category of ingredients appears in the name of the food or 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, expressed as a percentage, must appear either in or immediately next to the name of the food or in the list of ingredients. Annex VIII to the FIC regulation sets out the technical rules and exemptions from the QUID requirement.

European Commission guidelines on QUID can be downloaded from their website at http://ec.europa.eu/food/safety/docs/labelling_legislation_guidance_quid_en.pdf. The Commission is currently working on an update of the QUID guidelines.

Additives & Flavorings

Annex VII, Part C to FIC regulation 1169/2011 lists the categories of additives which must be designated by the name of their category, followed by their specific name or E-number. Part D of the same Annex sets out rules for the indication of flavorings, smoke flavorings and the use of the term "natural."

Country of Origin Labeling (COOL)

Before the adoption of FIC regulation 1169/2011 COOL was already mandatory for honey, fruit 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 applies 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 case, the label must indicate that the country of origin of the primary ingredient is different from that of the food product.

Detailed information on COOL is provided in GAIN report "The EU's Country of Origin Labeling Policy". The FIC regulation required the European Commission to prepare reports on the feasibility of introducing mandatory COOL for dairy products, "minor" meats, unprocessed products and single ingredient products. The reports are available on DG SANTE's website http://ec.europa.eu/food/safety/labelling_nutrition/labelling_legislation/index_en.htm.

Alcoholic Beverages

Alcoholic beverages containing more than 1.2% of alcohol by volume are still exempted from the obligation to bear a nutrition declaration and a list of ingredients. The FIC regulation required the European Commission to prepare a report by end 2014 examining whether the exemption for alcoholic beverages should be maintained. To date, the Commission has not released the report but is expected

to do so early 2017. Allergen labeling is compulsory on all alcoholic beverages (see "Allergen Labeling"). On beverages containing more than 1.2% of alcohol by volume (excluding wines), the actual alcoholic strength by volume must be indicated in accordance with Annex XII to FIC regulation 1169/2011. The alcoholic strength must be indicated by a figure with maximum one decimal place followed by the symbol "% vol." The alcoholic strength must be given in the same field of vision as the product name and the net quantity. For wines, rules for the indication of the alcoholic strength are set out in specific legislation (see Chapter B.5 "Other Specific Labeling Requirements - Wine").

Nutrition Declaration

Under FIC regulation 1169/2011, the nutrition declaration becomes mandatory on December 13, 2016. Annex V to the FIC regulation lists foodstuffs which are exempted from the mandatory nutrition declaration requirement. The nutrition declaration must be presented, if space permits, in tabular format with the numbers aligned and where space does not permit, in linear format. All elements of the mandatory nutrition declaration should be in the same field of vision on the food label or package.

Mandatory content of the nutrition declaration:

- Energy value: expressed in kilojoules (kj) and kilocalories (kcal)
- In this particular order: amounts of fat, saturates, carbohydrate, sugars, protein and salt, expressed in grams (g), milligrams (mg) or micrograms (µg) per 100 grams or per 100 milliliters

Nutrition declarations per portion or per consumption unit, in addition to the declaration per 100 grams or milliliters are allowed provided that the number of portions/consumption units is clearly indicated on the package. The salt content must be expressed as "salt" not "sodium" but where appropriate, a statement indicating that the salt content is exclusively due to the presence of naturally occurring sodium may appear in close proximity to the nutrition declaration.

The following elements may, on a voluntary basis, be repeated on the front label:

- Energy value
- Energy value together with the amounts of fat, saturates, sugars and salt

The content of the mandatory nutrition declaration may be supplemented with the indication of the amounts of one or more of the following:

- Monounsaturated
- Polyunsaturated
- Polyols
- Starch
- Fiber
- Vitamins and minerals listed in Part A of Annex III to the FIC regulation (incl. percentage of reference intakes)

Detailed rules on the presentation of the nutrition declaration are set out in Annex XV to the FIC

regulation.

Annex V to the FIC regulation establishes a list of products that are exempted from the mandatory nutrition declaration requirement.

The EU's Food & Drink Industry Federation "FoodDrinkEurope" has launched a website explaining "reference intakes" to food business operators and consumers: http://referenceintakes.eu/reference-templates.html. For detailed information on the nutrition panel see the guidance documents listed in "General Requirements" (Chapter A).

Article 35 of the FIC regulation allows voluntary national labeling schemes, such as for example the U.K. traffic light labeling scheme, to provide nutrition information to consumers. The FIC regulation requires the Commission to prepare a report by December 13, 2017, on experience gained with the national schemes and their impact on the internal market. The Commission may accompany this report with proposals to modify the current rules.

Gluten-Free

Harmonized compositional and labeling rules for foods for persons with gluten intolerance were previously set out in the EU's directive on foods for particular nutritional uses (Directive 41/2009). With the adoption of the new dietetic foods regulation 609/2013, it was decided that gluten-free foods would be regulated under the FIC regulation. Commission Implementing Regulation 828/2014, applicable since July 20, 2016, sets out conditions for using "gluten-free" and "very low gluten" statements on food labels.

Trans Fats

Rules to limit and label the content of trans fats in food products are not yet EU-harmonized. Certain Member States such as Denmark, Austria, Hungary and Latvia have set national legal limits on industrially produced trans fats in foods. The FIC regulation required the European Commission to prepare a report by end 2014 on the presence of trans fats in foods. On October 11, 2016, the Commission published a roadmap to assess several policy options for limiting industrial trans-fat intakes in the EU. Based on the outcome of the impact assessment, the Commission may come forward with a legal proposal.

Use of Stickers

Specific rules on the use of stickers to provide mandatory labeling information are not included in FIC regulation 1169/2011. On this issue, the European Commission refers to point 2.1.1 of their Questions and Answers on the Application of Regulation 1169/2011 document which says that "labels should not be easily removable so as to jeopardize the availability or the accessibility of the mandatory food information to the consumer." As previously noted, the standard U.S. label fails to comply with 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. 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.

Samples

FIC Regulation 1169/2011 does not include any provisions on samples.

Other Specific Labeling Requirements

The EU's "Food Information to Consumers" regulation 1169/2011 sets out horizontal rules applicable to all products. Sectorial or "vertical" legislation exists for a number of products. Labeling requirements set out in product-specific legislation complement the horizontal rules set out in regulation 1169/2011. For example, EU wine regulations do not include provisions on allergen labeling. This means that wine labels not only have to comply with the requirements set out in wine regulation 607/2009 but also with the allergen labeling requirement set out in FIC regulation 1169/2011.

1. Nutrition Claims

The Annex to Nutrition & Health Claims Regulation 1924/2006 lists the EU authorized nutrition claims and their conditions of use. The use of nutrition claims not included in the annex is not allowed.

2. Health Claims

Rules on the use of health claims are set out in Nutrition & Health Claims Regulation 1924/2006. 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 rejected claims and the reasons for their non-authorization. Since December 14, 2012, all claims that are not authorized and not on hold or under consideration are prohibited. Food products carrying claims must also comply with the provisions of the EU's "Food Information to Consumers (FIC)" regulation 1169/2011. Commission Implementing Decision 2013/63 sets out guidelines for national control authorities as regards the implementation of specific conditions for permitted health claims.

The authorization of health claims referring to botanical substances was put on hold because of the potential conflict with the Traditional Herbal Medicinal Products Directive. In October 2015, the European commission published a "roadmap" to evaluate Regulation 1924/2006. The evaluation will focus on two specific elements: the authorization of health claims referring to botanical ingredients and the establishment of nutrient profiles. Regulation 1924/2006 required the Commission to establish nutrient profiles, thresholds for salt, fat and sugar above which nutrition and health claims would be restricted. To date, nutrient profiles have not yet been adopted and the Commission will now assess whether they are necessary to ensure adequate implementation of the regulation. The evaluation should be completed by June 2017 and will be used to decide whether the nutrition and health claims regulation should be amended.

The list of permitted functional health claims is different from the individual applications for health claims relating to disease risk reduction and claims referring to the health and development of children which require an authorization on a case-by-case basis, following the submission of a scientific dossier to EFSA. A simplified authorization procedure has been established for health claims based on new scientific data.

Regulation 353/2008 sets out implementing rules for applications for the authorization of health claims as provided for in Article 15 of Regulation 1924/2006. GAIN Report E48055 describes how application dossiers for authorization of health claims should be prepared and presented. A guidance document on how companies can apply for health claim authorizations can be downloaded from EFSA's website at http://www.efsa.europa.eu/en/nda/ndaclaims.htm.

Commission Regulation 907/2013 establishes rules for the use of "generic descriptors" which could be interpreted by consumers as health claims. Generic descriptors such as "digestive biscuits" and "cough drop" would normally be banned under Regulation 1924/2006 because they suggest a beneficial effect on health but the implied health benefit has not been evaluated scientifically by the European Food Safety Authority (EFSA). For more information see GAIN report "Health Claims – New EU Regulation on Generic Descriptors".

Trademarks and brand names that suggest health and/or nutritional benefits but do not comply with the new rules must be entirely removed from the EU market by January 19, 2022.

3. Genetically Modified Foods Labeling

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]."

Example: a biscuit containing soy flour derived from GM-soy must be labeled "contains soy flour from genetically modified soy."

- 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.

Example: for vegetable oils containing rapeseed oil produced from genetically modified rapeseed, the reference "contains rapeseed oil from genetically modified rapeseed" must appear in the list of ingredients.

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.

Example 1: "a spirit containing caramel produced from genetically modified corn."
Example 2: "genetically modified sweet corn."

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.

4. Organic Food Labeling

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. Commission Implementing Regulation 2016/1842 published on October 19, 2016, sets new rules for the certification of EU organic food imports. Starting October 19, 2017, the EU will require electronic certification through the EU's Trade Control and Expert System (TRACES).

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.

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.

US-EU Equivalency Arrangement: The US-EU Organic Equivalence Arrangement took effect on June 1, 2012. The U.S. and EU have recognized each other's organic production rules and control systems as equivalent under their respective rules. Organic products certified to the USDA organic standards may be sold and labeled as organic in the EU. Both the USDA organic seal and the EU organic logo may be used on products traded under this Arrangement. When using the EU organic logo, exporters must meet all the EU labeling requirements.

Organic Wine: Commission Implementing Regulation 203/2012, applicable since August 1, 2012, sets out the conditions to label wine as organic. It allows the use of the term "organic wine" but NOT the term "wine made from organic grapes." Sorbic acid and desulfurization are not allowed and the level of sulfites must be at least 30-50 mg per liter lower than their conventional equivalent. As Regulation 203/2012 was only published in March 2012, a month after the U.S. and the EU signed the Equivalency Arrangement, organic wine was not included in the deal. Commission Implementing Regulation 508/2012, published in June 2012, includes U.S. organic wines in Annex III to Regulation 1235/2008 on import arrangements with third countries. Only U.S. organic wines certified to comply with the EU's

organic wine making rules can be imported into the EU.

5. Wine, Beer and Other Alcoholic Beverages

Wine: The EU's Single Common Market Organization Regulation 1308/2013 establishes framework rules for wine. Commission Regulation 607/2009, as amended by Commission Implementing 1185/2012, lays down detailed rules on protected designations of origin and geographical indications, traditional terms and labeling. For detailed information on the EU's wine legislation see the European Commission's website http://ec.europa.eu/agriculture/wine/legislation/index_en.htm.

Chapter II of Regulation 607/2009 establishes the application procedure for a designation of origin or a geographical indication. Designation of origin or geographical indications which have been accepted are entered in a "Register of protected designations of origin and protected geographical indications" maintained by the European Commission. The register lists geographical indications protected in the EU as well as third countries' geographical indications and names of origin protected under bilateral wine trade agreements. The register is available through the Commission's online "E-Bacchus" database.

Chapter III of Regulation 607/2009 sets out rules on the use of traditional terms. The "E-Bacchus" database lists the traditional terms that are protected in the EU. The use of expressions such as "style," "type," "method`', "as produced in," "imitation," "flavor," "like" or similar, accompanied by a traditional term included in the E-Bacchus database is not allowed. Third countries may use traditional terms not listed in the database. Since Regulation 607/2009 became applicable, the European Commission received several applications from third countries – most of which came from the United States - to use EU protected traditional terms. Commission Implementing Regulation 723/2012 allows the use of the traditional term "Cream" on U.S. grapevine products. Six years after receiving the applications, the European Commission has not made any progress on allowing the use of other traditional terms such as "Chateau" on U.S. grapevine products.

Chapter IV of Regulation 607/2009 sets out rules for the indication of compulsory and optional information on wine labels. The mandatory information must appear in the same field of vision on the container, in such a way that all the information (except the lot number) is readable without having to turn the container. The mandatory information must be clearly distinguishable from surrounding text or graphics.

The indication of the wine grape variety on the label is optional. For third country wines, the wine grape variety must be included in at least one of the lists established by the "international Organization of Vine and Wine (OIV), the "Union for the Protection of Plant Varieties (UPOV)" or the "International Board for Plant Genetic Resources (IBPGR)." Terms such as "barrel matured," "barrel aged" (listed in Annex XVI to Regulation 607/2009) may not be used on wines produced with the aid of oak chips. The use of the term "alcohol free wine" is not allowed in several Member States. Examples of compliant wine labels can be found in the U.K. Food Standards Agency's "Wine Labeling Guidance."

Allergen Labeling: The indication of allergens listed in Annex II to "Food Information to Consumers (FIC)" regulation 1169/2011 is mandatory on all food and beverage labels. Commission Implementing

Regulation 579/2012 sets out the modalities for the labeling of allergens on wine. A wine label must state that it "contains" one or more of the following allergens: "sulphites," "sulfites," "sulphur dioxide," "sulfur dioxide," "egg," "egg protein," "egg product," "egg lysozyme," "egg albumin," "milk," "milk product," "milk casein" or "milk protein." The translation of these terms in all the official EU languages is available in Part A of the Annex to Regulation 579/2012. The terms designating the allergenic ingredient may be supplemented by the pictograms laid down in Part B of the Annex to Regulation 579/2012. Allergen labeling must respect the minimum font size requirement (1.2 mm) established by FIC regulation 1169/2011.

US-EU Wine Agreement: In March 2006, the U.S. and the EU and the U.S. signed the "Agreement between the United States and the European Community on Trade in Wine". The Agreement covers wine with an actual alcohol content of not less than 7% and not more than 22%. All U.S. wine imports must be accompanied by certification and analysis documentation using the format specified in Annex III (a) to the Agreement. More information on the simplified EU import certificate form can be obtained from the Alcohol and Tobacco Tax and Trade Bureau at http://www.ttb.gov/agreements/us_ec_wine_agreement.shtml and in their guidance document "Procedures for exporting wine to the EU." The Agreement's "Protocol on Wine Labeling" sets conditions for the use of optional particulars on wine labels. Commission Regulation 1416/2006 concerns the protection of U.S. names of origin in the EU.

Spirit Drinks: European Parliament and Council Regulation 110/2008 lays down general rules on the definition, description and presentation of spirit drinks. Commission Implementing Regulation 716/2013 lays down rules for the application of Regulation 110/2008 as regards the use of compound terms and geographical indications of the spirit drinks. This regulation prohibits the use of the term "spirit drink" as part of a compound term.
Commission Regulation 936/2009 applies the agreements between the EU and third countries on the mutual recognition of certain spirit drinks. Under this regulation, "Tennessee Whisky" and "Bourbon Whisky" are protected product designations.

Nominal Quantity: Mandatory nominal quantities for wines and spirits are set out in the Annex to Directive 2007/45/EC.

Beer: While there is no specific EU-harmonized legislation for beer labeling, Italy has adopted national provisions to make the list of ingredients and nutritional value compulsory. All alcoholic beverages must comply with the allergen labeling requirements (see "Wine").

6. Special Use Foods

On July 20, 2016, the EU's new "foods for specific groups" rules set out in European Parliament and Council Regulation 609/2013 became applicable. This regulation repeals all the directives on "foodstuffs intended for particular nutritional uses" (PARNUTS). The scope of the new regulation is limited to infant formula, follow-on formula, processed cereal-based food and baby food, food for special medical purposes and total diet replacement for weight control. Under the new rules, pictures of infants are no longer allowed on the packaging and no text or pictures may idealize the use of

formula. Foods that no longer fall within the scope of Regulation 609/2013, such as for example low calorie cereal bars will be regarded as "normal" foods and must comply with the Food Information to Consumers Regulation 1169/2011, Nutrition and Health Claims Regulation 1924/2006 and Fortified Foods Regulation 1925/2006. Rules on gluten-free foods were transferred from the PARNUTS directive to the Food Information to Consumers (FIC) regulation 1169/2011 (see Chapter A.13).

As a general rule, labeling requirements set out in the FIC regulation also apply to food categories covered under regulation 609/2013. However, given the specific nature of the products covered, regulation 609/2013 introduces additional labeling requirements and derogations from the FIC regulation. In June 2016, the European Commission issued a report on food and beverages labeled specifically for sportspeople. The report concluded that sportspeople can hardly be characterized as a specific vulnerable group of consumers as sport has become a mainstream activity. The report identified three broad categories of sports food on the EU market: (1) sport drinks, (2) protein-based muscle strengthening, building and post exercise recovery products and (3) energy and performance boosting products. According to the Commission report, there is no need for specific provisions for food intended for sportspeople as existing horizontal EU food rules already provide an adequate framework for these products in terms of food safety, food composition, consumer information and legal certainty.

7. Meat Labeling

Beef

Regulation 1760/2000 sets out rules for compulsory and voluntary beef labeling. Detailed rules for the implementation of Regulation 1760/2000 are set out in Regulation 1825/2000. Under the compulsory beef labeling scheme, labels for all bovine meat must indicate the following information:

- "Born in: name of third country"
- "Reared in: name of third country or third countries"
- For beef derived from animals born, raised and slaughtered in the same third country, the above indications may be combined as "Origin: name of third country"
- A reference number ensuring the link between the meat and the animal or animals
- "Slaughtered in: third country / approval number of slaughterhouse"
- "Cutting in: third country / approval number of cutting plant"
- A traceability code linking the meat to the animal or a group of animals representing the production of maximum one day

Regulation 653/2014, an amendment to Regulation 1760/2000, changed the rules for voluntary labeling. Voluntary beef labeling has to comply with the rules set out in the "Food Information to Consumers" Regulation 1169/2011. Definitions and requirements applicable to terms and or categories of terms that may be put on labels of pre-packed fresh and frozen beef and veal will be adopted at a later date.

Veal

Annex VII to European Parliament and Council Regulation 1308/2013 classifies bovine animals aged less than 12 months in two categories: 1) "category V" - bovine animals aged 8 months or less and 2) "category Z" - bovine animals aged more than 8 months but less than 12 months. For both categories, Annex VII lists the sales descriptions in the different Member States languages and the mandatory labeling requirements.

Pork, Sheep, Goats and Poultry

Commission Implementing Regulation 1337/2013 sets out new rules for the indication of the country or place of provenance for fresh, chilled and frozen meat of swine, sheep, goats and poultry. The following new labeling requirements will apply as of April 1, 2015:

1) The indication **"Reared in: name of the Member State of third country"** in accordance with the following criteria:

For swine:

- In case the animal is slaughtered older than 6 months, the Member State or third country in which the last rearing period of at least 4 months took place
- In case the animal is slaughtered younger than 6 months and with a live weight of at least 80 kg, the Member State or third country in which the rearing period after the animal has reached 30 kg took place
- In case the animal is slaughtered younger than 6 months and with a live weight less than 80 kg, the Member State or third country in which the whole rearing took place

For sheep and goats:

- The Member State or third country in which the last rearing period of at least 6 months took place, or in cases the animal is slaughtered younger than 6 months, the Member State or third country in which the whole rearing period took place

For poultry:

- The Member State or third country in which the last rearing period of at least one month took place or, in case the animal is slaughtered younger than one month, the Member State or third country in which the whole rearing period after the animal was placed for fattening took place

In cases where any of the above rearing periods are not attained in any of the Member States or third countries, the place of rearing must be indicated as "Reared in: several Member States of the EU" or "Reared in: several non-EU countries" or "Reared in several EU and non-EU countries." As an alternative the place of rearing may also be indicated as "Reared in: list of the Member States or third countries where the animal was reared."

The indication "Origin: name of Member State or third country" may be used in cases where the meat

has been obtained from animals born, reared AND slaughtered in one single Member State or third country.

2) The indication "Slaughtered in: name of the Member State or third country." By way of derogation for meat imported from third countries, in cases where information on the rearing periods is not available, the meat must be labeled as "Reared in: non-EU" and "Slaughtered in: name of the third country where the animal was slaughtered."

8. Health and Identification Marks

The EU's "Food Hygiene Package" introduced new rules concerning the application of health and identification marks. Chapter III of European Parliament and Council Regulation 854/2004 lays down rules for applying a health mark to fresh meat. Annex II to European Parliament and Council Regulation 853/2004 lays down rules for applying an identification mark to products of animal origin. Linear presentation of the required information is allowed only for imports from EU-approved establishment in third countries.

9. Frozen Foodstuffs

Council Directive 89/108/EEC sets rules for quick-frozen foodstuffs and for their packaging and labeling. Quick-frozen foodstuffs sold to the final consumer should carry the following additional labeling indications: the product name with the indication "quick-frozen," the date of minimum shelf life, the period during which the purchaser may store the product, the storage temperature and/or type of storage equipment required, batch identification and a clear indication of the type "do not re-freeze after defrosting." Annex VI, Part A, to FIC regulation 1169/2011 stipulates that foods that have been frozen before sale and which are sold defrosted, the name of the food must be accompanied by the designation "defrosted."

For food of animal origin, Commission Regulation 16/2012 amending Food Hygiene Regulation 853/2004, requires food business operators to provide the date of production AND the date of freezing to the buyers and upon request, to the competent authorities. Where a food is made from a batch of raw materials with different dates of production and freezing, the older dates of production and/or freezing must be made available.

Annex III to FIC regulation 1169/2011 requires that labels on frozen meat, frozen meat preparations and frozen unprocessed fishery products indicate the date of freezing or the date of first freezing in cases where the product has been frozen more than once.

Italy requires, through Legislative Decree 27/1/1992, n. 110, art. 10, "Implementation of directive 89/108/CEE that all third country establishments that intend to export quick-frozen vegetables register with the Italian Ministry of Health. The ministry defines such items as foodstuffs which have undergone a suitable freezing process known as 'quick-freezing' whereby the zone of maximum crystallization is crossed as rapidly as possible, depending on the type of product, and the resulting temperature of the product (after thermal stabilization) is continuously maintained at a level of -18 °C or lower at all points. Italy gives the following EU regulations as the basis for its regulation: Regulation (EC) No 852/2004 of the European Parliament and of the Council of April 29, 2004 on the hygiene of

foodstuffs; Commission Regulation (EC) No 37/2005 of January 12, 2005 on the monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption; and Council Directive 89/108/EEC of December 21, 1988 on the approximation of the laws of the Member States relating to quick-frozen foodstuffs for human consumption.."

In order to notify Italian authorities, the establishment must complete an application (available at http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=1154&area=sicurezzaAlimentare&menu=controlli) with specific attachments, and addressed to the following office:

Ufficio II della DG SAN
Ministero della Salute
Viale G. Ribotta, 5
00144 Rome
Italy

The application should be sent through the Italian Embassy in Washington, with the following requested documentation:

- Application form completed by the exporting Food Business Operator (FBO)
- Technical report concerning the main features of the production plant
- Statement from the local competent authority of the country of origin that the quick-frozen vegetables exported to Italy are produced in compliance with Council Directive 89/108/EEC, and that the legislation in force in the country of origin is equivalent to the EU legislation

The Italian Ministry of Health reviews all of the documentation and has the right to ask for additional documents or call a meeting with the applicants. Once the third country establishment is approved by the Italian authorities, the list is updated and posted on the website of the Ministry of Health, and the company is allowed to export quick frozen vegetables to Italy.

10. Vertical & Product-Specific Legislation

Vertical legislation on the manufacture and marketing of specific products has been developed for sugars, cocoa and chocolate products, honey, fruit juices and similar products, preserved milk, coffee extracts and chicory extracts and fruit jams and similar products.

Fruit Juices: Directive 2012/12/EU, published in April 2012, set out new labeling rules for fruit juices and fruit nectars. This directive amended framework Directive 2001/112/EC relating to fruit juices and certain similar products intended for human consumption. Products placed on the market or labeled before October 28, 2013, could continue to be marketed until April 28, 2015. Detailed information on key changes introduced by the new directive can be found in GAIN report "New EU Fruit Juice Labeling Rules."

Honey: On May 15, 2014, the EU adopted Directive 2014/63/EU amending Directive 2001/110/EC relating to honey. It defines pollen as a natural constituent of honey and should not be considered to be an ingredient of honey. This means that GM pollen present as a quantity of more than 0.9% of the honey (not the pollen) would need to be labeled as such. Since pollen only forms around 0.5% of any batch of honey, it will never exceed the GM labeling threshold.

Single Common Market Organization: European Parliament and Council Regulation 1308/2013 establish a single common market organization (CMO) for all agricultural products. The single CMO provides definitions and marketing rules for rice, sugar, beef and veal, milk and milk products, eggs and poultry meat, olive oil, fruit and vegetables, spreadable fats and wine.

Section III. Packaging and Container Regulations:

A. Size & Content

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.

B. Packaging Waste Management

Member States are required to take measures to reduce packaging waste and must introduce systems for reuse, recovery and recycling of packaging materials. Council Directive 94/62/EC harmonizes national measures concerning the management of packaging and packaging waste and its impact on the environment. To facilitate collection, reuse and recovery including recycling, an identification system for packaging has been drawn up (Commission Decision 97/129/EC). Its use is voluntary. A well-known and widely used recycling program is the German “green dot” system. More information can be found on the Packaging Recovery Organization Europe website which provides easy access to all Green Dot systems in Europe (www.pro-e.org). An overview of current EU legislation applicable to packaging and packaging waste is available on the European Commission’s website http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01994L0062-20150526&qid=1446639081652&from=EN.

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:

- Organize 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).

C. Materials in Contact with Foodstuffs

European Parliament and Council Regulation 1935/2004 specify the main requirements for all materials that come into contact with foodstuffs. It also sets out labeling and traceability requirements and the procedure for the authorization of substances through the European Food Safety Authority (EFSA). Annex I to regulation 1935/2004 lists the group of materials which may be covered by specific measures. Specific measures set out additional requirements and include lists of authorized substances and materials. To date, specific directives have been developed for plastic materials (Commission Regulation 10/2011), recycled plastic materials (Commission Regulation 282/2008), regenerated cellulose film (Commission Directive 2007/42/EC) and ceramics (Council Directive 84/500/EC). In the case of ceramics, migration limits have been established for lead and cadmium. Materials must bear an indication "for food contact" or the symbol reproduced in Annex II to Regulation 1935/2004.

Commission Implementing Regulation 321/2011, amending Regulation 10/2011 on plastic materials, bans the use of Bisphenol A in plastic infant feeding bottles.

Commission Regulation 450/2009 sets out definitions and authorization procedures for the use of

active and intelligent materials and articles intended to come into contact with food. An EU guidance document on active and intelligent food contact materials is available on the European Commission's website.

Commission Regulation 2023/2006 lays down rules on good manufacturing practice (GMP) for the groups of materials and articles intended to come into contact with food listed in annex I to Regulation 1935/2004.

Section IV. Food Additives Regulations:

Italy applies 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). Commission Implementing Regulation 234/2011 explains in detail how applications to update the EU positive lists should be drafted (content, data requirements and presentation). EFSA then verifies the suitability of the data.

A. Additives (including colors and sweeteners)

Additives that are authorized in food and their conditions of use are listed in Annex II to the Food Additives Regulation 1333/2008. The authorized uses of additives are listed according to the category of food to which they may be added. Annex I to regulation 1333/2088 lists the definitions of 26 different categories of food additives. Only additives included in the EU's positive list are authorized under specific conditions. An important difference from U.S. legislation is that the use of flour beaching agents' chlorine, bromates and peroxides is not allowed in the EU.

Annex III to Regulation 1333/2008 contains a second list of food additives approved for the use in food ingredients such as other food additives, food enzymes, food flavorings and nutrients. Specifications for food additives listed in Annexes II and III are laid down in Commission Regulation 231/2012.

Annex IV lists traditional foods for which certain Member States may continue to prohibit the use of certain categories of food additives.

Annex V to Regulation 1333/2008 contains labeling information for six food colors: Quinoline Yellow (E104), Sunset Yellow (E110), and Ponceau 4R (E124), Tartrazine (E102), Azorubine/Carmoisine (E122) and Allura Red AC (E129). Foods containing these colors have to be labeled "may have an adverse effect on activity and attention in children" (see also Section V – Labeling Requirements). The limits for these food colors were lowered by Commission Regulation 232/2012.

Re-Evaluation Program

A re-evaluation program set up by Commission Regulation 257/2010 requires a new risk assessment

carried out by EFSA for additives which were approved before Food Additives Regulation 1333/2008 entered into force.

The re-evaluation of approved food additives is/was to be completed by the end of:

- 2015 for food colors (currently listed in Directive 94/36/EC)
- 2015-2016 for preservatives, antioxidants, glutamates, silicon dioxide
- 2018 for all additives other than colors and sweeteners (currently in Directive 95/2/EC)
- 2020 for all sweeteners (currently listed in Directive 94/35/EC)

On October 13, 2015, EFSA published a list of food additives under re-evaluation. EFSA has launched a call for analytical data on concentration levels in food and beverages to re-assess the safety of a fifth batch of food additives. Data can be submitted until January 31, 2017. For more information see EFSA's website at http://www.efsa.europa.eu/en/data/call/160524.

EFSA was accepting data on usage level and/or concentration data in food and beverages intended for human consumption until May 31, 2016.

The Commission's food additives database together with its user guide provides detailed information on the different food additives allowed in the EU. More information on the use of food additives can be obtained from the European Commission's website at http://ec.europa.eu/food/safety/food_improvement_agents/index_en.htm.

B. Flavorings

Regulation 1334/2008 on flavorings and certain food ingredients with flavoring properties sets specific rules for the use of the term "natural." Annex I of Regulation 1334/2008 establishes a list of substances that are authorized for use in the EU. The authorized uses of flavoring substances are listed according to the category of food to which they may be added and are also available in an on-line database allowing consumers, food businesses and food control authorities to verify which flavoring substances are authorized in food.

Commission Regulation 873/2012 concerns transitional measures for other flavorings such as flavorings made from non-food sources.

The procedure for the safety assessment and the authorization of smoke flavorings intended for use in or on foods is established in Regulation 2065/2003. The Union list of authorized smoke flavoring primary products for use as such in or on foods and/or for the production of derived smoke flavorings is established by Commission implementing Regulation1321/2013.

C. Enzymes

Regulation 1332/2008 on food enzymes introduced harmonized rules for their scientific evaluation and authorization in the EU and establishes labeling requirements. Specific labeling requirements are set in Articles 10-13 of Regulation 1332/2008.

Regulation 234/2011 on the implementation of the common authorization procedure, last amended

by Commission Implementing Regulation 562/2012 regarding specific data required for the risk assessment of food enzymes, set out a 2 year-deadline starting from September 11, 2011 to submit applications on existing and new enzymes. However, the initial deadline for submitting applications was extended to 42 months by Commission Regulation1056/2012. Information for the risk assessment of food enzymes submitted by industry is in the process of being evaluated by EFSA. Based on EFSA's risk assessment, the Commission will establish an EU positive list of authorized enzymes. Until the adoption of such a list, the existing national provisions on the marketing of food enzymes will continue to apply.

D. Processing Aids

Processing aids are subject to Member States national legislation. EU harmonized rules exist only for certain categories of processing aids: a list of extraction solvents allowed in the production of foodstuffs and food ingredients, along with their conditions of use has been established in Council Directive 2009/32/EC.

Section V. Pesticides and Other Contaminants:

A. PESTICIDES

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

European Parliament and Council Regulation 1107/2009 sets out rules for the authorization of plant protection products (PPPs). PPPs (also referred to as 'pesticides') contain at least one approved active substance. Only PPPs containing active substances included in the list of approved active substances as established in Commission implementing Regulation 540/2011 may be authorized for use in the EU. Before any PPP can be placed on the market or used, it must be authorized in the relevant Member State(s). According to Annex I of Regulation 1107/2009, 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 EU. Maximum Residue Levels (MRLs) for substances that are not on the EU positive 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 also 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.

Endocrine Disruptors

Endocrine disruptors (EDs) refer to substances with the potential to alter and cause unintentional adverse health effects to the endocrine systems of humans and wildlife. Both the Plant Protection Products Regulation 1107/2009 (Pesticides) and the Biocidal Products Regulation 528/2012 (Biocides) introduced "endocrine disrupting properties" as one of the categories of hazard-based cut-off criteria. This would allow the EU to ban certain products from the market based on hazard identification rather than risk assessment without taking exposure into account. On June 15, 2016, the European Commission presented draft measures outlining scientific criteria to identify EDs under the Plant

Protection Products Regulation (1107/2009) and Biocidal Products Regulation (528/2012), using the World Health Organization (WHO) definition for EDs as a basis. The new measures, which will apply immediately for the approval of new substances and re-approval of currently authorized products once adopted, could enter into force as early as mid-2017.

Maximum Residue Limits (MRLs): Regulation 396/2005

European Parliament and Council Regulation 396/2005 harmonize all MRLs in the EU 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. A general default MRL of 0.01 mg/kg applies where a pesticide is not specifically mentioned. For a list of authorized active substances or pesticide-MRL combinations, see the European Commission's online database.
On June 17, 2016, the European Commission notified a document to the WTO explaining the on-going review of MRLs in the EU to non-EU countries, highlighting the active substances and relevant MRLs that are scheduled to be reviewed in the near future.

Import Tolerance

If there is no EU legislation in place in the importing Member State, then the exporter can seek to obtain an "import tolerance" for active substances that have not been evaluated or used in Europe before. Applications for import tolerances must be submitted to the "Rapporteur Member State" (RMS). The Commission assigns a Member State, if no RMS exists. The RMS reviewed dossiers are evaluated by the European Food Safety Authority before being forwarded to the Commission. Information on import tolerances is available in "Pesticide Use and Food Safety" guide published by the European Crop Protection Association (ECPA). Since September 2, 2008 all MRLs, including import tolerances, apply EU wide. The application form for an import tolerance can be found here.

Upcoming Review

Both Regulation 1107/2009 and Regulation 396/2005 are scheduled to be reviewed in the next coming years. More background information on the upcoming review can be found in the ECPA's position paper.

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 2016/662 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 2018, 2019 and 2020 for samples tested in 2017, 2018 and 2019 respectively.

B. CONTAMINANTS

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

Maximum Levels

EU- wide harmonized maximum levels for contaminants are set in the Annex of Commission Regulation 1881/2006. The Annex to Regulation 1881/2006 includes maximum levels for:

- Nitrates in lettuce, spinach and infant food (section 1)
- Mycotoxins (section 2):
- aflatoxins in nuts, dried fruit, cereals, maize, spices, milk and infant food
- ochratoxin A in cereals, cereal products, dried vine fruit, roasted coffee, soluble coffee, wine, grape juice, spices, infant food and licorice
- patulin in fruit juices, spirit drinks, solid apple products, apple juice and infant food
- deoxynivalenol in cereals, cereal products, maize, pasta and infant food
- zearelenone in cereals, cereal products, maize, refined maize oil, bread and small bakery wares and infant food
- fumonisins in maize and maize based products
- T-2 and HT-2 toxin in cereals and cereal products
- citrinin in rice/yeast fermented food supplements
- ergot sclerotia and ergot alkaloids
- Heavy metals (section 3):
- lead in milk, baby and infant food, meat, offal, seafood, vegetables, fruit, wine and food supplements
- cadmium in meat, fish and seafood, cereals, soybeans, vegetables, fruit, fungi and food supplements, baby formula and infant food, cereals and soybeans, cocoa
- mercury in seafood and food supplements
- tin in canned foods, canned beverages and canned baby foods
- 3-MCPD in vegetable protein and soy sauce (section 4)
- Dioxin and PCBs in meat, liver, fishery products, milk, eggs and oils & fats (section 5)
- Polycyclic aromatic hydrocarbons (PAH) in oils & fats, cocoa, infant foods, (smoked) meat, bivalve molluscs, fish and infant food (section 6)
- Melamine in infant food (section 7)
- Inherent plant toxins (section 8):
- erucic acid
- fats and oils and foods containing these ingredients
- infant formula
- tropane alkaloids

Official Controls of Maximum Levels in Foodstuffs

The following regulations concern the sampling methods and methods of analysis for the official controls of the levels of the different contaminants. Annex I describes the methods of sampling; Annex II concerns the sample preparation and the performance criteria for the methods of analysis:

- Nitrates: Commission Regulation 1882/2006
- Mycotoxins: Commission Regulation 401/2006
- Dioxins: Commission Regulation 589/2014
- Heavy metals, Tin, 3-MCPD and benzo(a)pyrene: Commission Regulation 333/2007

- Erucic acid: Commission Regulation (EU) 2015/705
-

Official Aflatoxin Controls on U.S. Products

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 began issuing PEC almond certificates on August 1, 2015. The almond PEC program builds on and replaces the Voluntary Aflatoxin Sampling Plan (VASP) program, which was no longer required after 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 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 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 must 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.

Residues in Animals and Animal Product

The monitoring of residues in animals and animal products is addressed separately in Council Directive 96/23/EC. This directive includes the monitoring of pesticide residues as well as residues of veterinary drugs and a wide range of other contaminants and undesired substances such as residues of growth promotants. The prohibition of the use of hormones in meat production is addressed in Council Directive 96/22/EEC. Directive 96/23/EC states that any third country exporting to the EU must submit a plan setting out its guarantees on the monitoring of the groups of residues and substances referred to in Annex I to Council Directive 96/23/EC. Furthermore, a split system has to be in place guaranteeing that animals have not been treated with growth promotants if their products will be exported to the EU.

Section VI. Other Regulations and Requirements:

A. Novel Foods

http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/novel-foods/

Current Rules

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

An Information and Guidance Document on "human consumption to a significant degree" is published on the European Commission's website: 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 2018

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. On November 10, 2016, EFSA published guidance documents on novel foods and traditional food from third countries explaining in detail what kind of information applicants need to provide and how it should be presented.

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. The Commission is expected to update the definition early 2017.

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. The Commission is expected to clarify what a "reasoned safety objection" entails.

B. Food from Animal Clones

Food derived from cloned animals currently falls within the scope of the Novel Food Regulation 258/97. Under this regulation, food produced by "new breeding practices" needs a pre-market approval based on a risk assessment. In December 2013, under pressure of the European Parliament and the Council of the EU, the European Commission proposed two pieces of specific legislation on food from cloned animals: 1) a proposal on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes and 2) a proposal to prohibit the placing on the market of food from animal clones. To date, the European Parliament and the Council of the EU have not made any progress on the cloning proposals. Until separate legislation is adopted, food from clones falls within the scope of the Novel Foods regulation.

C. Nanotechnology

Currently, EU legislation that explicitly addresses nanomaterials in food includes the following regulations:

Food Information to Consumers (FIC): Regulation 1169/2011 defines engineered nanomaterials as "any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are

characteristic of the nanoscale." The current definition uses size as the only defining criterion and does not include a threshold value. The presence of engineered nanomaterials in food products must be clearly indicated on the label. The name of such ingredients must be followed by the word "nano" in brackets (Art. 18 of Regulation 1169/2011).

New Novel Foods Regulation: The definition of engineered nanomaterials is set out in the new Novel Foods Regulation (see point A) and will be deleted from the FIC Regulation (applicable end 2017).

Food Additives:- Regulation 1333/2008 states that when "there is a significant change in the production methods or in the starting materials used" for food additives already on the Community list of approved food additives, "or there is a change in particle size, for example through nanotechnology, the food additive prepared by those new methods or materials shall be considered as a different additive and a new entry in the Community lists or a change in the specifications shall be required before it can be placed on the market."

Food Contact materials – Regulation 450/2009 on active and intelligent packaging states that "new technologies to engineer substances with different chemical and physical properties than the same substances at a larger scale, for example nanoparticles, should be assessed at a case-by-case basis as regards their risk until more information is known about such new technology."

D. 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 eight 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: https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_nutrition-vitamins_minerals-comm_reg_en.pdf.

E. Dietetic Foods

In June 2013, the EU adopted Regulation 609/2013 which completely overhauled the dietetic food rules (for detailed information see Section V "Special Use Foods"). The scope of this regulation is limited to infant formula and follow-on formula, processed cereal-based food and baby food, food for special medical purposes and total diet replacement for weight control. Regulation 609/2013 became applicable on July 20, 2016. Under the new rules, pictures of infants are no longer allowed on labels. Foods that no longer fall within the scope of Regulation 609/2013 will be regarded as regular foods.

Commission Delegated Regulation 2016/128 sets out specific requirements for food for special medical

purposes (FSMPs). The European Food Safety Authority (EFSA) has published scientific and technical guidance to help the European Commission apply new rules on foods for special medical purposes (FSMPs). Commission Delegated Regulation 2016/217 sets out specific compositional and information requirements for infant-formula and follow-on formula.

F. Irradiated Foodstuffs

Harmonization of EU rules on food irradiation has been slow and only a few products have so far received EU-wide approval. Framework Directive 1999/2/EC outlines the marketing, labeling, import and control procedures and technical aspects of food irradiation. Irradiated foods or foods containing irradiated ingredients must be labeled "irradiated" or "treated with ionizing radiation."

G. Seafood

Detailed information on shipping seafood and fishery products to the EU is provided in the exporter guide "Exporting Seafood to the European Union – October 2016 Update" which can be downloaded from the Department of Commerce – NOAA Fisheries' website at http://www.seafood.nmfs.noaa.gov/pdfs/howtoexportseafood2016.pdf. In May 2016, the Commission released a report on the feasibility of an EU eco-label scheme for fishery and aquaculture products.

H. 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. GAIN report "Exporting Pet Food to the European Union" provides a detailed overview of EU legislation relating to imports of pet food.

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. For more information see GAIN report E50060 "EU Feed and Pet Food Labeling Requirements." 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. 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 established guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products.

I. Vegetarian & Vegan Foods

The Food Information to Consumers (FIC) regulation 1169/2011 requires the European Commission to set out rules for the voluntary labeling of foods as "suitable for vegetarians and vegans." To date, the Commission has not adopted an EU-harmonized definition of the terms "vegetarian" and "vegan." In the absence of EU-harmonized rules, food companies have started using the "European V-label," a labeling scheme launched by umbrella organization the European Vegetarian Union (EVU).

Section VII. Other Specific Standards:

Facility Registration

The EU approves establishments to ship products of animal origin based on submissions from U.S. government agencies. Only products processed in approved establishments may enter the EU. Third country lists per sector and per country are published on the European Commission's website https://webgate.ec.europa.eu/sanco/traces/output/non_eu_listsPerCountry_en.htm.

Product Registration

U.S. exporters should be aware that certain products and ingredients may fall within the scope of the Novel Foods Regulation and need a pre-market authorization. Detailed information is provided in Section VI "Other Specific Standards." The introduction of foodstuffs with particular nutritional uses needs to be notified to the Member State where the food is sold. Exporters of vitamin-enriched foods or nutritional supplements are especially advised to check for the existence of specific Member State registration or notification requirements. A list of the competent Member State authorities is available on the European Commission's website at https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_nutrition-supplements-food_supplements_authorities_en.pdf.

Section VIII. Copyright and/or Trademark Laws:

A. Trademarks

In the EU, trademarks can be registered at the national, regional or EU level. Trademarks registered at the national level are protected in one EU Member State. Applications must be submitted directly to the relevant national IP-office (full list of national offices). Currently, there is only one regional-level IP office in the EU, i.e. the Benelux Office which registers trademarks for three Member States: Belgium, the Netherlands and Luxembourg. Applications for the protection of a trademark in all EU Member

States must be submitted to the European Union Intellectual Property Office (EUIPO). An online application costs 850 EUR. Full details on the registration process are available on the EUIPO website. Rules on the protection of trademarks in the EU are set in EU Directive 2015/2436.

B. 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 became 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

Example of a PDO: Prosciutto di Parma (Parma ham)

"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

Example of a PGI: Gouda Holland

"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.

Example of a TSG: Mozzarella

Detailed information on the TSG scheme is available in GAIN report E80061 "The EU's Traditional Specialties Guaranteed" Scheme Explained".

Optional Quality Terms:

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.

Example of an optional quality term: Mountain Product

Section IX. Import Procedures:

A. Union Customs Code

The "Union Customs Code" (UCC) established in European Parliament and Council Regulation 952/2013 is the new framework regulation on rules and procedures for customs throughout the EU. Implementing provisions were published in Official Journal L 343 on December 29, 2015; Commission Delegated Regulation 2015/2466 and Commission Implementing Regulation 2015/2447 lay down detailed rules for the implementation of certain provision of the new UCC including Binding Tariff Information and origin of goods. The new UCC along with the implementing provisions became applicable on May 1, 2016, but further changes will be phased in up to December 31, 2020.

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.

B. Customs Clearance

The European Commission's DG Trade "Export Helpdesk" provides a complete overview of documents needed for customs clearance:
http://exporthelp.europa.eu/thdapp/display.htm?page=rt%2frt_Requirements.html&docType=main&languageId=en

C. Import Duties

The EU uses the Combined Nomenclature (CN) for the customs classification of goods. The CN eight digit code numbers are based on the Harmonized System (HS) nomenclature: the first six digits refer to the HS headings; the two following digits represent the CN subheadings. The EU's on-line "Taric" customs database can be consulted to look up commodity codes and relevant import duties. Taric is a multilingual database covering all measures relating to tariff and trade legislation. The EU's 2017 Tariff Schedule was published on October 28, 2016 in Official Journal L 294. A list of Member State customs authorities can be found at https://ec.europa.eu/taxation_customs/national-customs-websites_en.

Commission Regulation 900/2008 lays down analytical methods and other technical provisions to calculate the starch/glucose and sucrose/invert sugar/isoglucose content in processed products. These calculations are used to determine the additional duties on flour and sugar in processed products.

Goods are only released after payment of the import duty and other taxes that may be due.

Duties payable on goods imported into the EU may include:

- import duty (expressed as ad valorem tariffs or specific tariffs per unit weight/volume/number of pieces) – EU harmonized
- additional duties on flour and sugar (processed products) – EU harmonized
- entry price (fruit and vegetables) – EU harmonized
- environmental taxes - not harmonized
- inspection fees - not harmonized
- Value Added Tax (VAT) - not harmonized
- excise duties (alcohol and tobacco) - not harmonized

A list of VAT rates applicable in the different Member States can be found on the Internet at http://ec.europa.eu/taxation_customs/resources/documents/taxation/vat/how_vat_works/rates/vat_rates_en.pdf.

A list of excise duties applicable on alcoholic beverages and tobacco can be found at http://ec.europa.eu/taxation_customs/taxation/excise_duties/index_en.htm.

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.

Appendix I. Government Regulatory Agency Contacts:

Ministero della Salute (Ministry of Health)
Direzione Generale per l'Igiene Alimenti e la Nutrizione
Via Giorgio Ribotta 5,
00144 Roma
Tel: +39 06 5994
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

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

European Commission
Rue de la Loi 200
1049 Brussels
Belgium
Tel: (32-2) 299 1111

European Union Intellectual Property Office (EUIPO)
Avenida de Europa, 4
E-03009 Alicante
Spain
Tel: (34-96)513 91 00
E-mail: information@euipo.europea.eu
Website: https://euipo.europa.eu

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
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:
27 Boulevard du Regent
1000 Brussels
Belgium
Tel: (32-2)811-5831
E-mail: Stephane.Vrignaud@trade.gov

Food and Drug Administration (FDA)
27 Boulevard du Regent
1000 Brussels
Belgium
Tel: (32-2)8114518

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

Other FAS Offices in the European Union:
http://apps.fas.usda.gov/overseas_post_directory/index.asp

FDA contacts for certification of animal products:
http://www.fda.gov/AnimalVeterinary/Products/ImportExports/default.htm

Food Safety & Inspection Service (FSIS) Export Requirements for the EU:
http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products

Animal & Plant Health Inspection Service (APHIS) – Import & Export:
http://www.aphis.usda.gov/import_export/index.shtml

Appendix II. Other Import Specialist 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: https://it.usembassy.gov/embassy-consulates/embassy/sections-offices/fas/

United States Mission to the European Union
Office of Agricultural Affairs
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

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Rue de la Loi 200
1049 Brussels
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