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Italy

Food and Agricultural Import Regulations and Standards - Narrative

FAIRS Country Report

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Report Highlights:
This report provides updated contact information for Italy and gives an overview of Italian food laws in the EU context. Information on EU Member State specific requirements can be found in the FAIRS reports prepared by the Offices of Agricultural Affairs in the individual EU Member States: http://www.fas.usda.gov/posthome/useu/fairs.html.

Section I. Food Laws:

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

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

To the extent that European Union food laws have been harmonized, Italy's food laws and regulations follow European Union rules. However, in the event that the EU law may be incomplete or absent, the law of each member state applies. The main principle of the single market concept is to ensure that all food products, whether produced in the EU or imported from a third country, can move freely throughout the EU if they comply with uniform requirements. In reality, certain directives allow Member States to make exceptions i.e. in cases where a country can identify unique concerns about a product intended for import. Free movement can only be guaranteed when all aspects are covered by harmonized legislation: e.g. a foodstuff may comply with the general labeling directive but may carry a health claim for which harmonized rules do not yet exist.

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

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

U.S. food and beverage products require no special permits nor are they subject to special rules or regulations regarding their retail sale in Italy. The products must comply with the generally applied rules and regulations, as would any other product sold in the EU market. US exporters should also be aware that any food or agricultural product transshipped through Italian territory must meet Italian requirements, even if the product is transported in a sealed and bonded container and is not expected to enter Italian commerce.

Please note that imports of red meat, meat products, pet food, farmed and wild game meat, ratites, milk and milk products, seafood, bovine embryos and semen, porcine and equine semen, gelatin and animal casings to the EU from the U.S. may only originate from EU approved U.S. establishments.

Section II. Labeling Requirements:

Food labeling and ingredient regulations for the most part have been harmonized within the EU.
General provisions on the labeling, presentation and advertising of foodstuffs marketed in the EU are laid down in European Parliament and Council Directive 2000/13/EC. It applies not only to foodstuffs intended for sale to the ultimate consumer but also for supply to restaurants, hospitals and other mass caterers. Italy sets its own national requirements where EU standards are not yet established.

Note that the standard U.S. label does not comply with EU labeling requirements.
http://useu.usmission.gov/agri/label.html

U.S. food products can generally be uniformly packaged for sale in all EU Member States based on the condition that they conform to the national law set forth in at least one member state. Italy requires that labels also be in the Italian language. Many international companies provide multi-language labels to ensure the possibility of sale throughout the European Union.

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

As previously noted, the standard U.S. label fails to comply with Italian rules and regulations, therefore a sticker with the translation of the U.S. label in Italian and with all the mandatory EU information listed below needs to be placed on the packaging above or in addition to the U.S. label when the product is sold in Italy. As a general rule, labeling has to be in a language easily understood by consumers. Multi-language labeling is allowed throughout the EU.

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

a. Name of the product as commonly used in the trade.
The name established by law or, if this is lacking, a brief description of the product.

b. List of ingredients and food additives in descending order by weight.
The following ingredients require a specific statement on the label: GMOs, packaging gases, sweeteners, aspartame, poly oils, quinine, caffeine, phytosterols and phyostanols and licorice.

c. Food allergen labeling rules were introduced by Directive 2003/89/EC that became effective on November 25, 2005.
The following potential allergenic ingredients must be indicated on food labels: cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk and dairy products (including lactose), nuts and nut products, sesame seeds, lupine and products thereof, mollusks and products thereof and sulphite at concentrations of at least 10 mg per kg or 10 mg/l, celery, and mustard. Allergen labeling also applies to alcoholic beverages.

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

d. Quantitative ingredient declaration (QUID).
The quantity of certain ingredients or categories of ingredients is mandatory in the following cases:

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

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

e. Metric units for all measurements.
The nominal net content or weight expressed in metric units: (weight in grams, liters, kilograms, centiliters, etc.). A small "e" on the label may be used to guarantee that the actual content corresponds to the quantity indicated.

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

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

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

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

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

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

l. Instructions for intended use.

m. Treatments undergone, with specific indications for irradiate or deep-frozen foods.

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

Additives

- Annex II to the labeling directive lists the categories of additives, which must be designated by the name of their category followed by their specific name or EEC number. The categories are the following: color, preservative, anti-oxidant, emulsifier, thickener, gelling agent, stabilizer, flavor enhancer, acid, acidity regulator, anti-caking agent, modified starch, sweetener, raising agent, anti-foaming agent, glazing agent, emulsifying salts, flour treatment agent, firming agent, humectants, bulking agent, propellant gas.

- Flavorings: Annex III to the labeling directive describes the way of designating flavorings in the list of ingredients.

Quinine and Caffeine

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

Phytosterols & Phytostanols

Commission Regulation 608/2004 lays down labeling requirements for foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and phytostanol esters (used to reduce cholesterol levels). For labeling purposes, they must be designated respectively by the terms “plant sterols”, “plant sterol esters”, “plant stanols” and “plant stanol esters”.

Warnings on Labels

Commission Directive 2008/5/EC establishes a list of foodstuffs that require a warning on the label:

- foodstuffs whose durability has been extended by means of packaging gases
- foodstuffs containing (a) sweetener(s)
- foodstuffs containing added sugar(s) and sweetener(s)
- foodstuffs containing aspartame
- foodstuffs containing more than 10% added polyols
- confectionery or beverages containing liquorices

As of July 20, 2010, Regulation 1333/2008 requires foodstuffs containing the food colors sunset yellow (E110), quinoline yellow (E104), carmoisine (E122), allura red (E129) and ponceau 4R (E124) to be labeled “may have an adverse effect on activity and attention in children”. Food placed on the market or labeled before July 20, 2010, which do not comply with this provision may be marketed until their date of minimum durability or use-by-date.

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 the warning symbol established by Annex I of Regulation 450/2009.

Language Requirements

As a general rule, labeling has to be in a language easily understood by consumers. However, as an exception to the general rule, it is also allowed to use:

- Another language provided it can easily be understood by consumers.
- Other means depicting the content (e.g. pictures).

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

Stick-on Labels

While EU legislation does not contain any reference to the use of stick-on labels, Italy accepts them.

Labeling of Genetically Modified Foods

Section VII of this report is entirely dedicated to the regulatory review and commercialization of genetically modified foods in the EU and provides information on EU labeling requirements for genetically modified foods and their derivatives. All foods and ingredients that are produced in whole or in part from genetically modified organisms should indicate this on their labels. The same rules apply to flavors and additives. For detailed information see Section VII.

B. Medical / Health / Nutrition Claims

Medical claims that expressly or implicitly affirm or suggest that a food product has a healing (curative) or preventive effect are prohibited in the EU/Italian labeling directive. Only rather bland references that the product has general beneficial effects are allowed as long as these are not misleading to consumers. U.S. exporters of "health" foods, weight loss/diet foods, baby foods and vitamins should work closely with an Italian importer, since Italian labeling laws regarding health claims can be particularly stringent. Italian legislation sets forth orders, obligations and criminal sanctions for violations.

On July 1, 2007, a new EU regulation on nutrition and health claims entered into force. Regulation 1924/2006 sets EU-wide conditions for the use of nutrition claims such as "low fat" or "high in vitamin C" and health claims such as "helps lower cholesterol". The regulation applies to any food or drink product produced for human consumption that is marketed in the EU. The development of nutrient profiles, originally scheduled for January 2009, has not been finalized yet. The European Commission is working on a proposal but a timeline is not yet available. Once the nutrient profiles, based on scientific evaluations by the European Food Safety Authority (EFSA), have been set, there will be another two-year period before the nutrient profiles begin to apply to allow food operators time to comply with the new rules. Nutrition claims can fail one criterion, i.e. if only one nutrient (salt, sugar or fat) exceeds the limit of the profile, a claim can still be made provided the high level of that particular nutrient is clearly marked on the label. For example, a yogurt can make a low-fat claim even if it has high sugar content but only if the label clearly states "high sugar content". Health claims cannot fail any criteria.

Regulation 353/2008 as amended by Commission Regulation 1169/2009 sets out implementing rules for applications for the authorization of health claims as provided for in Article 15 of Regulation 1924/2006.

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/EFSA/ScientificPanels/NDA/efsa_locale-1178620753812_1178684448831.htm.

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.

Nutritional Value Labeling Ordinance

Nutrition labeling is not mandatory in the EU unless a nutrition claim is made on the label or in advertising messages. Nutrition labeling rules are laid down in Council Directive 90/496/EEC. The presence of a U.S. nutritional label (Nutrition Facts) may be considered to be equivalent to a nutritional claim and consequently its presence on the label requires drawing up the nutritional table according to European (and thus, Italian) standards as well. To avoid this problem, many U.S. products place their Italian language label over the portion of the U.S. label containing nutritional information.

The energy value and the proportion of nutrients must be declared in specific units per 100 grams or per 100 milliliters. Information on vitamins and minerals must be expressed as a percentage of the recommended daily allowance (RDA). The information on the label must be presented in tabular form with the numbers aligned or if space does not permit, in linear form in a language easily understood by the purchaser.

Commission Directive 2008/100/EC update the list of vitamins and minerals and their Recommended Daily Allowances (RDAs) and provide an EU definition of "fiber". The conditions for the use of nutrition claims such as "source of fiber" or

"high fiber" are laid down in Regulation 1924/2006 (see nutrition and health claims).

C. Product-Specific Labeling

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

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

D. Country of Origin Labeling

In the EU, country of origin labeling is mandatory for beef and veal, fruit and vegetables, eggs, poultry meat, wine, honey, olive oil, aquaculture products and for organic products carrying the EU logo. For other products, the indication of the place of origin or provenance is mandatory only if the omission of such information might mislead the consumer.

Section III. Packaging and Container Regulations:

A. Consumer Packaging Ordinance and Laws on Weight and Measures

Council Directive 76/211/EEC (amended by Commission Directive 78/891/EEC) specifies the maximum tolerable error between the actual content and the quantity indicated on the label of prepackaged products.

New Directive 2007/45/EC abolishes regulations on mandatory pack sizes at both EU and national levels. The Directive frees sizes for all prepackaged products except wine and spirits, coffee and white sugar. Member States in which mandatory nominal quantities are prescribed for milk, butter, dried pasta and coffee may maintain their restrictive rules until October 2012. The rules for white sugar may be maintained until October 2013. Mandatory nominal quantities for wines and spirits are set out in the Annex to Directive 2007/45/EC.

B. Materials in Contact with Foodstuffs

Regulations for materials in contact with food are EU-harmonized (see www.useu.be/agri/packaging.html). European Parliament and Council Regulation 1935/2004 specifies the main requirements for materials that come into contact with foodstuffs, including active and intelligent packaging. This regulation entered into force on November 16, 2004 (except for the provisions on traceability which went into effect on October 27, 2006) and repeals and replaces Directives 80/590/EEC

and 89/109/EEC. It also sets out labeling & traceability requirements and the procedure for the authorization of substances through the European Food Safety Authority (EFSA).

C. Packaging Disposal Regulations

In Italy, issues concerning the production, recycling and disposal of packaging materials and waste are governed by articles 34 to 43 of the Ronchi Decree, Legal Decree n. 22/97, which put into force harmonized EU rules of the 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 during a period of five years from the date of effectiveness of the provisions relative to packaging (i.e., by 1 May 2002). These objectives are listed in Attachment E to the Ronchi Decree as follows:

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

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

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

National Packaging Consortium - CONAI (Consorzio Nazionale Imballaggi) is responsible primarily for the preparation of a general packaging waste management and recycling program (the "General Program") that is designed to meet the reuse and recycling objectives listed in article 37 and Attachment E of the Ronchi Decree (please refer to table above).
The web site of the European Food Service and Packaging Association: www.efpa.com/laws.html provides information on EU packaging directives and food laws.

Section IV. Food Additives Regulations:

Food additive use is fully harmonized within the EU (see www.useu.be/agri/additive.html). The Italian food additive sector is governed by Council Directive 89/107/EEC which provides for the establishment of EU harmonized positive lists --lists of what is permitted-- of a wide range of food additives.

All food additives not included in the positive lists are prohibited except for new food additives that receive a temporary two-year authorization by Member States. Most food additives may be used only in limited quantities in certain foodstuffs. Food additives for which no quantitative limits have been established (maximum level established at “quantum satis”) must be used according to good manufacturing practice. This means using only as much as necessary to achieve the desired technological effect. Processing aids and flavorings fall outside of the scope of this directive. An important difference from U.S. legislation is the use of flour bleaching agents: chlorine, bromides and peroxides that are not allowed in the EU.

Regulation 1333/2008 on food additives brings the current miscellaneous additives directive and the directives on colors and

sweeteners into one regulation and became applicable as of January 20, 2010, except for the transitional provisions. It provides for the establishment of an EU positive list, conditions of use and rules on the labeling of additives sold as such.

All food additives, colors and sweeteners that will be entered in Annex II and Annex III to Regulation 1333/2008 are currently being reviewed by the Commission. The review should be completed by January 2011 after which the annexes will enter into force. Food additives are being reviewed based on their compliance with the new provisions, meaning technological need, safety and use, as well as advantages and benefits. A food additive or the specific use of a food additive that is no longer needed will not be transferred to the new Annexes. For colors and sweeteners some specific conditions exist as well. The review is conducted by the Commission and will not require a new risk assessment. Until the completion of the review food additives under the old directives will continue to be permitted. An important difference from U.S. legislation is the use of flour bleaching agents: chlorine, bromides and peroxides are not allowed in the EU.

Additionally, Regulation 1333/2008 also provides for an evaluation program, set up by Commission Regulation 257/2010, for food additives permitted before January 2009. Those food additives shall be subject to a new risk assessment carried out by EFSA and the re-evaluation of approved food additives shall be completed by the end of:

- - 2015 for food colors (currently listed in Directive 94/36/EC)
- - 2018 for all additives other than colors and sweeteners (currently in Directive 95/2/EC)
- - 2020 for all sweeteners (currently listed Directive 94/35/EC)

Annex I of Regulation 1333/2008 lists the approved food additives for which the re-evaluation by EFSA was already completed at the time of adoption of Regulation 257/2010.
Foods containing any of the six food colors Quinoline Yellow (E104), Sunset Yellow (E110), Ponceau 4R (E124), Tartrazine (E102), Azorubine/Carmoisine (E122) and Allura Red AC (E129), will have to be labeled with the phrase, 'may have an adverse effect on activity and attention in children' (Annex V to Regulation 1333/200).

Annex II to the labeling directive lists the categories of additives, which must be designated by the name of their category followed by their specific name or EEC number. The categories are the following: color, preservative, anti-oxidant, emulsifier, thickener, gelling agent, stabilizer, flavor enhancer, acid, acidity regulator, anti-caking agent, modified starch, sweetener, raising agent, anti-foaming agent, glazing agent, emulsifying salts, flour treatment agent, firming agent, bulking agent, and propellant gas.

- Flavorings: Annex III to the labeling directive describes the way of designating flavorings in the list of ingredients.

- The presence of sweeteners/aspartame/polyols and licorice requires standardized statements on the label; packaging gases are not considered as additive but also require a standardized statement (Commission Directive 2008/5/EC).

The lists of authorized food additives and their conditions for use are published in three directives:

1) European Parliament and Council Directive 94/35/EC on sweeteners for use in foodstuffs. The annex to this directive lists maximum usable doses for sweeteners in selected foodstuffs.

2) European Parliament and Council Directive 94/36/EC on colors for use in foodstuffs.
Annex I: list of permitted food colors. Only substances listed in this annex may be used
Annex II: foodstuffs that may not contain added colors
Annex III: foodstuffs to which only certain permitted colors may be added
Annex IV: colors permitted for certain uses only
Annex V: colors permitted in general and the conditions of use therefore.

3) European Parliament and Council Directive 95/2/EC, as amended, the so-called miscellaneous additives directive on food additives other than colors and sweeteners.

Annex I: list of food additives permitted for use in foodstuffs (excl. those listed in Annex II) following the "quantum satis" principle.

Annex II: list of foodstuffs in which only a limited number of additives of Annex I may be used. These include cocoa and chocolate products, fruit juices and nectars, jam and jelly, dehydrated milk and cream, fruits and vegetables, rice, oils and fats, certain cheeses, minced meat, bread and pasta, wines and beer
Annex III: list of conditionally permitted preservatives and antioxidants
Annex IV: list of other permitted additives
Annex V: list of permitted carriers and carrier solvents
Annex VI: list of additives permitted in foods for infants and young children

These lists can be downloaded from the following web page: http://useu.usmission.gov/agri/additive.html

Flavorings

Regulation 1334/2008 on flavorings and certain food ingredients with flavoring properties sets specific rules for the use of the term "natural". The new rules will apply as of January 20, 2011. The positive EU list or Community List of flavoring substances and source materials listed in Annex I of the Regulation should be adopted before the end of 2010.

The register of all flavoring substances, as last amended by Commission Decision 2009/163/EC, authorized in the EU is being reviewed before inclusion in Annex I of the new Regulation as the community list of authorized substances. The adoption of the Community list is scheduled for the end of 2010 and Regulation 2232/96, currently in force, will be repealed when the new list is published. Substances that are subject to restrictive or prohibitive measures in certain member states have been marked.

A Community procedure for the safety assessment and the authorization of smoke flavorings intended for use in or on foods is established in Regulation 2065/2003.

Enzymes

Regulation 1332/2008 on food enzymes introduces harmonized rules for their scientific evaluation and authorization in the EU and establishes labeling requirements. Until the adoption of an EU positive list of authorized enzymes, the existing national provisions on the marketing of food enzymes will continue to apply.

Section V. Pesticides and Other Contaminants:

Current EU pesticide legislation has not been fully harmonized within member states. Regulation 1107/2009 sets out new rules for the authorization of plant protection products (PPPs) and replaces Directive 91/414/EEC. It entered into force at the end of December 2009 and it will become fully applicable June 14, 2011. This Regulation establishes a list of approved active substances. Only PPPs containing active substances included in the list may be authorized for use in the EU. Member States can approve PPPs containing the active substances. According to the new Regulation, the EU is divided in three different zones. Once a Member State approves the PPP it can be mutually recognized and thus authorized within the same EU zone as set out in Annex I of the Regulation. In Italy, the type and maximum quantities of pesticide residues that may be legally present in food products are regulated by art. 5 of the 283/62 decree (general hygiene regulations). All pesticides listed on the positive list are permitted and decrees for their use are issued and updated by the Italian Ministry of Health.

The Maximum Residue Levels (MRLs) for substances not on the list will be set at default level of 0.01 mg/kg.
The legislation allows exporters to request an "import tolerance" for active substances not yet evaluated or in use in the EU.

MRLs: Regulation 396/2005

Since September 2008 all MRLs in the EU have been harmonized by Regulation 396/2005 on food or feed of plant and animal origin. Pesticide MRLs for processed or composite products are based on the MRLs of the raw agricultural ingredients.

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 Regulation 915/2010 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 2012, 2013 and 2014 for samples tested in 2011, 2012 and 2013 respectively.

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 en 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
- heavy metals (section 3):
- lead in milk, infant food, meat, offal, seafood, vegetables, fruit, wine and food supplements
- cadmium in meat, seafood, cereals, soybeans, vegetables, fruit, fungi and food supplements
- 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, infant foods, (smoked) meat, fish and infant food (section 6)

Import Conditions for U.S. Almonds

In September 2007, the EU implemented special import conditions which called for mandatory testing of U.S. almonds imported into the EU. USDA and The California almond industry have developed a "Voluntary Aflatoxin Sampling Plan (VASP)" comparable to the EU sampling procedures so that almonds can be uniformly tested before they are shipped to the EU. Per Commission Regulation 1152/2009, these procedures are considered to provide sufficient assurances which means that almonds shipped under VASP are subject to random controls. Almonds not controlled under VASP continue to be subject to 100% border controls. The Regulation covers almonds in shell or shelled, roasted almonds and mixtures of nuts or dried fruits containing almonds, and foodstuffs containing a significant amount of almonds (at least 20%).

Italy is one of the two EU countries that apply this rule to imports of plant materials. That is, following a (domestic) rapid alert, Italy requires that the next 10 consignments (from that shipper) test within tolerance in order to lift the rapid alert. The almond industry has had a lot of problems with the inconsistent application of this regulation. Although testing is mandatory, at the moment there are only a very limited number of labs that can perform the procedure causing delays in clearing the shipment. The Italian Ministry of Health has taken positive steps to address these problems and although the situation has improved, it still bears monitoring.

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

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 the 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 (amended by Directive 2008/97/EC).

Section VI. Other Regulations and Requirements:

Product Inspection and Registration

Member States are responsible for carrying out inspections on a regular basis and in cases where non-compliance is suspected. Products can be checked at import or at all further stages of marketing. Infringements of EU food and feed legislation are reported through the Rapid Alert System on Food and Feeds (RASFF). The rapid alert system is a network of Member State authorities managed by the European Commission. The weekly reports of the notifications under the rapid alert are available on the European Commission's website (http://ec.europa.eu/food/food/rapidalert/index_en.htm). The information published on the website is limited to the notifying country, the reason for notifying and the country of origin. Repeated non-compliance may lead to suspension of imports or special import conditions for products from the third country concerned, applicable on the entire EU territory.

The criteria for laboratories conducting food controls have been EU harmonized but it is the responsibility of each Member State to designate laboratories authorized to perform analyses (Council Directives 89/397/EEC and 93/99/EEC).

Specific detailed inspection requirements exist for animal products (Directive 97/78/EC). Inspections are carried out under the supervision of a veterinarian at a limited list of ports and border inspection posts (BIP`s – Border Inspection Post.) In Italy they are called PIF - Posti d`Ispezione Frontaliera. Products of animal origin must be presented at a Community border inspection post and submitted to import control following prior notification of the shipment's arrival. Fresh fruits and vegetables are subject to phytosanitary controls and are checked for compliance with EU-harmonized marketing standards, which are controlled by Italian Inspection Posts, which in turn are controlled by the Ministry of Health (USMA- Uffici di Sanita` Marittima, Aerea e di Confine).

Product samples have to comply with EU food regulations. Waivers may be obtained from the Italian Ministry of Health based on Art. 16 of EU directive 97/78/CE and Italian legislative decree 80/2000, which state:

Products from non-EU authorized plants can only be authorized entry to the EU as long as they do not have any commercial value. Authorization must FIRST be obtained from the Italian Ministry of Health.

The exporter must provide the Italian MOH with the following:

1. Total Weight of the shipment
2. Italian Port of Entry and expected date of arrival
3. Intended use for the product
4. Authorization and waiver from U.S. Health/Veterinary inspection authorities
5. Name of Italian Receiving agent with complete contact information and statement that the product will be DESTROYED or shipped back to the States if any is left over.

There is no EU requirement to register imported foods except for the introduction of novel foods, whereby the person/company introducing the novel food must submit a request to the authorities in the Member States where the product will be marketed, and a copy of this request has to be sent to the European Commission's Health and Consumer Protection Directorate. Importers of organic products are required to notify the competent regulatory authority of the Member State of their activity. The introduction of foodstuffs with particular nutritional uses needs to be notified to the Member State where the food is sold.

All product samples have to comply with the food regulations applicable in Italy and the EU.

B. Certification and Documentation Requirements
http://www.fas.usda.gov/posthome/useu/Certification_Guide.html

An overview of legally required certificates in the EU and references to the U.S. authority issuing these certificates is available in USEU Brussels FAS Office GAIN report E49057. An update of this report will be published in January 2011. Detailed information on certification is also available on the website:
http://www.fas.usda/posthome/useu/Certification_Guide.html

Section VII. Other Specific Standards:

A. Genetically Modified Food and Feed

Labeling regulations for GM food products are established by EU 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 (i.e. rennet in cheese production, yeast in wine production). Meat, milk or eggs obtained from animals fed with GM feed or treated with GM medicinal products do not require GM labeling. The trace-ability 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.

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 allowable adventitious presence level for EU-approved varieties of GMOs is set at 0.9 percent. Above this level all products must be labeled. For GM varieties that received a positive EU risk assessment but are not yet formally approved, the adventitious presence level is set at 0.5 percent. A list of these varieties is available at http://ec.europa.eu/food/food/biotechnology/gmfood/events_en.pdf.

The wording to be used on GM food labels is as follows:

- 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 on ingredients, the words "genetically modified" or "produced from genetically modified [name of ingredient]" must appear clearly in the labeling.

B. Novel Foods

(http://www.fas.usda.gov/posthome/useu/novelfood.html)

The Novel Food Regulation 258/97 lays down detailed rules for the authorization of novel foods and novel food ingredients, including foods derived from or containing or consisting of GMOs. It defines novel foods as foods and food ingredients that were not used to a significant degree in the EU before May 15, 1997. The new regulations on GM food provide for a separate regime to deal with the authorization and traceability of novel foods and novel food ingredients that consist of or contain or are derived from GMOs. Pre-market approval of non-GM novel foods will continue under European Parliament and Council Regulation 258/97.

Non-GM categories of novel foods 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

The full list of novel food applications and authorizations/rejections/withdrawals is available from http://ec.europa.eu/food/food/biotechnology/novelfood/app_list_en.pdf.

C. Fortified Foods

Regulation 1925/2006 establishes 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. Although originally scheduled for January 2009, the Commission is still working on a proposal to set maximum permitted levels of vitamins and minerals in foods and food supplements. Minimum amounts are linked to the notion of "significant amount" as defined in the Annex to Council Directive 90/496/EEC on nutrition labeling. The use of vitamins and minerals not included in the annexes to Regulation 1925/2006 is not allowed.

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

D. Dietetic or Special Use Foods

New framework Directive 2009/39/EC consolidates Directive 89/398/EEC and all its amendments into a single text and lays down rules for foodstuffs intended for particular nutritional uses. These are foodstuffs, which due to their special composition or manufacturing process can clearly be distinguished from foodstuffs for normal consumption. Commission Regulation 953/2009 lists the substances (vitamins, minerals and amino acids) that may be added for specific nutritional purposes in foodstuffs for particular nutritional uses.

Provisions regarding compositional and hygiene requirements, quality of raw materials, a list of additives/substances, specific labeling requirements, sampling procedures and analysis methods have been laid down in specific directives for four product categories:

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

- Commission Directive 1999/21/EC on dietary foods for special medical purposes.

Commission Regulation 41/2009 lays down new EU harmonized rules for the composition and labeling of foodstuffs suitable for people who are intolerant to gluten. This regulation, applicable as of January 1, 2012, sets conditions for the use of the terms "very low gluten" and "gluten-free". For more information see GAIN report E49009 "New EU labeling rules for "gluten free" foods".

E. Single Common Market Organization (CMO)

Council Regulation 1234/2007 establishes a single common market organization (CMO) for all agricultural products and replaced the 21 existing specific CMOs for different agricultural sectors. 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.

Animal Products

Veal

Annex XIa to Council Regulation 1234/2007 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 XIa lists the sales descriptions in the different Member States languages and the mandatory labeling requirements.

Fruit and Vegetables
(http:/www.fas.usda.gov/posthome/useu/Fruit-Veg.html)

Commission Regulation 1221/2008 introduced new implementing rules regarding marketing standards and associated checks in the fruit and vegetables sector. Part B of Annex I to this regulation sets out specific marketing standards for 10 products: apples, citrus fruit, kiwi fruit, lettuces, peaches and nectarines, pears, strawberries, sweet peppers, table grapes and tomatoes. Fruits and vegetables not covered by a specific marketing standard must comply with the general marketing standard established by Article 113a (1) of Council Regulation 1234/2007 (Single CMO). The following products are not required to conform to the general marketing standard: mushrooms (other than cultivated mushrooms), capers, bitter and shelled almonds, shelled hazelnuts, shelled walnuts, pine nuts and saffron. UNECE standards can be used only for products covered by the general marketing standard. Marketing standards apply at all marketing stages including import.

Fruit and vegetables destined for the processing industry are not required to conform to the marketing standards provided they are clearly marked "intended for processing" or "for animal feed or other non-food use".

Fresh fruits, vegetables and nuts are subject to phytosanitary controls and are checked for compliance with the quality standards and labeling requirements. A conformity certificate or a certificate of industrial use, to be obtained by the importer at the point of entry, is required for all shipments of fresh produce.

F. Wine, Beer and Other Alcoholic Beverages

Wine

Council Regulation 479/2008 establishes general rules on oenological practices, designations of origin and labeling. The provisions of this regulation as well as the implementing rules have been incorporated into Council Regulation 1234/2007

(Single CMO). Framework Regulation 479/22008 provided for the implementing rules to enter into force on August 1, 2009. As the implementing rules were only published on July 24, 2009, a transitional period was provided in order to ease the transition to the new requirements. Wines placed on the market or labeled before December 31, 2010, that comply with the provisions applicable before August 1, 2009 (rules laid down in Council Regulation 1493/1999), may be marketed until stocks are exhausted. Commission Regulation 607/2009 lays down detailed EU labeling rules.

Ingredients which may trigger an allergic reaction must be included on the label preceded by the word "contains". Alcoholic beverages with sulphite concentrations of more than 10 mg/liter must use one of the following terms: "sulphites", "sulfites", "sulphur dioxide" or "sulfur dioxide". The indication of sulphites may be accompanied by the pictogram included in Annex X to Regulation 607/2009. Replacing the word "sulphites" by "SO2" or the E-number (E220) is not allowed.

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.

Specific rules for organic wines have not yet been adopted. Terms referring to the organic production of grapes are established by Council Regulation 834/2007.

U.S.-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". This Agreement is the first phase and addresses a number of issues, such as labeling and certification. Other important issues such as geographical indications will be addressed in a second phase of the negotiations. 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/industry_circulars/archives/2007/07-02.html. The Agreement's "Protocol on Wine Labeling" sets conditions for the use of optional particulars on wine labels. Information on the US-EU Wine Agreement can also be obtained from the U.S. Dept. of the Treasury - Alcohol and Tobacco Tax and Trade Bureau (http://www.ttb.gov/agreements/us_ec_wine_agreement.shtml).

G. Organic Foods

Council Regulation 834/2007 lays down a new legal framework for organic production and the labeling of organic products. This regulation covers living and unprocessed products including aquaculture, processed products, animal feed, seeds and propagating material. Title IV of this new regulation lays down general rules for the labeling of organic products; Title VI covers trade with third countries. Processed food products can be labeled as organic only if at least 95% of the ingredients are organic. Food products containing less than 95% organic ingredients may refer to the organic production method in the ingredients list only. The Annex to Regulation 834/2007 lists the term "organic" in all the official EU languages. Derivatives or diminutives such as "bio" and "eco" may used only to label products that comply with the EU organic production rules.

Commission Regulation 889/2008 lays down detailed rules for the implementation of Regulation 834/2007 with regard to production, labeling and control. On July 1, 2010, the use of the new EU organic logo became mandatory for all pre-packaged organic products produced in the EU (with a 2-year transitional period) and optional for products from third countries complying with EU organic standards. The model logo is published in Annex XI-A of Regulation 889/2008. Annex XI-B sets out the format of the code number of the control body or authority. This code number together with an indication of the place of farming of the agricultural raw materials must be placed below the EU organic logo. More information on organic food labeling is available in GAIN report E48106.

Commission Regulation 1235/2008 lays down rules for the implementation of Regulation 834/2007 as regards the arrangements for imports of organic products from third countries. In order to export organic products to the EU, third countries must prove that their production standards are equivalent to the EU standards. For third countries currently not included in the EU's equivalency list, such as the U.S., the Commission will compile a list of recognized control bodies and control authorities. To be included in the EU list, U.S. control bodies/authorities must submit a technical dossier. The Commission will only consider complete dossiers submitted before October 31, 2011. A first list of recognized certifiers will be published in the first half of 2011. To avoid trade disruptions, Regulation 1235/2008 establishes transitional rules allowing Member States, until January 1, 2013, to continue to grant authorizations to importers of U.S. organic products on a case-by-case basis. Authorizations will expire at the latest 24 months after the publication of the first list of control bodies/authorities. Shipments of organic products must be accompanied by the model certificate established by Regulation 1235/2008. The European Commission has published guidelines on imports of organic products into the EU on its website.

H. Beef & Meat Labeling

Beef

A compulsory beef labeling scheme has been in place since September 2000. Full implementation of the beef labeling scheme went into effect on January 1, 2002 (Regulations 1760/2000 and 1825/2000). Under this 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

Meat

Commission Directive 2001/101/EC, amending general labeling directive 2000/13/EC, sets out the definition of "meat" for labeling purposes. This definition does not cover mechanically separated meat as it is still subject to Member State legislation. The Commission may propose legislation to harmonize the definition of mechanically separated meat.

I. Health & 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.

More information on the EU health mark is available on USDA'S Food Safety Inspection Service's website at http://www.fsis.usda.gov/regulations_&_policies/European_Union_Requirements/index.asp.

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. More information on the EU's identification mark is available on USDA's Agricultural Marketing Service's website at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5061042.

J. 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".

K. Seafood

Council Regulation 2406/96 lays down common marketing standards for certain fishery products.

Fishery and aquaculture products offered for retail sale in the EU must be properly labeled providing the following information:

Commercial name of the species (each member state has established a list of commercial designations).
Product method: "caught in…", "caught in freshwater", "farmed" or "cultivated".
Catch area: for products caught at sea, a reference to one of the areas listed in the annex. For products caught in freshwater: a reference to the country of origin; for farmed products: a reference to the country in which the product undergoes the final development stage. Operators may indicate a more precise catch area. To improve the traceability and control at all marketing stages - from the ship to the shop - the information concerning the commercial designation, the production method and the catch area for all fishery and aquaculture products must be provided either on the label, on the packaging or by means of a commercial document accompanying the goods (e.g. the invoice).

Detailed information on exporting U.S. seafood to the EU is available in the 2010 update of the "How to export seafood to the European Union" guide which can be downloaded from http://www.fas.usda.gov/posthome/useu/NOAA-Export-to-the-EU-Guide.pdf.

L. Pet Food

Regulation 767/2009 sets out new rules for the labeling and marketing of feed and pet food. Feed and pet food not complying with Regulation 767/2009 and with the provisions on feed additives laid down in Regulation 1831/2003 and Directive 90/167/EC will not be allowed on the EU market. However, for pet food Commission Regulation 454/2010 provides for a 1-year transitional period (until August 31, 2011) to comply with the new labeling requirements. New requirements relate to the indication in descending order of weight of feed materials in compound feed, claims, the establishment of a non-exhaustive "Catalog of Feed Materials" and "Codes of Good Labeling". Regulation 767/2009 covers feed materials, compound feed and medicated or dietetic feed for both food and non-food producing animals.

At the moment Italy still applies additional import requirements for U.S. pet food and feed manufacturers.
For Italy, all U.S. pet food production facilities and pet food ingredient facilities must be APHIS (Animal Plant and Health Inspection Service) inspected and approved. Once a facility is APHIS approved it is included in a list that is transmitted to the Italian Ministry of Health.

There are currently two separate lists of authorized U.S. pet food exporters for Italy:

- Approved Pet Food Facilities list
- Approved Pet Food Ingredients list

APHIS and the Italian Ministry of Health work with FAS Rome to update and maintain these lists.
Therefore, in order for a U.S. company to be authorized to export pet food containing animal by-products to Italy, the first

step is to contact your local APHIS office in the United States to start the process.

Please note all U.S. manufacturers must be on this list PRIOR to shipping their products to Italy.
This requirement will probably change after 3 March 2011 when Italy is expected to adopt in full the new EU requirements which do not require the need for approved facility lists.

U.S. pet food can be shipped to Italy for "trade show purposes only" on a case-by-case basis, and necessitates that FAS Rome request a specific waiver/derogation for importation of samples from the Italian Ministry of Health.
This process can be lengthy and at times complicated; therefore, U.S. exporters are encouraged to contact FAS Rome well in advance of the show.

Once the product is authorized by the Italian Ministry of Health the product is imported to Italy but cannot be sold and must be destroyed or otherwise disposed of after the show. Italian law is very strict on the matter, and sets severe legal sanctions for import and distribution of pet food containing animal products without the required authorization.

Pet food imported for commercial sale that contains product of animal origin must be accompanied by a health certificate signed by APHIS officials. APHIS veterinary services will endorse certificates after facilities have been officially approved as compliant with Regulation 1774/2002.
A statement guaranteeing that SRM's (specified risk materials) have been removed needs to be added to the certificate.

The APHIS website can be viewed at www.aphis.usda.gov

Section VIII. Copyright and/or Trademark Laws:

Trademarks

Community trademark policy was created by Council Regulation 40/94 and implemented by Commission Regulation 2868/95. This regulation creates a single, unitary registration system covering the whole Community territory. The Italian authority with jurisdiction over copyright and/or trademark registration is the Italian Trademark and Patent Office in Rome.

In practice, a Community trademark must meet two conditions: it must be a sign which can be represented in graphic form, and it must make it possible to distinguish goods and services from those of another company. It is valid for a period of 10 years. On completion of the registration procedure, the trademark is registered in the Register of Community trademarks.

Protected Geographical Indications

Geographical indications (GIs) are "indications which identify a good where a given quality, reputation or characteristic of the good is essentially attributable to its geographic origin". Council Regulation 510/2006 on the protection of geographical indications/designations of origin for listed European agricultural products and foodstuffs repealed Regulation 2081/92 to bring its rules in line with a WTO ruling. The new regulation allows third country operators to submit registration applications directly to the Commission rather than through their governments and deletes reciprocity requirements. It also allows third countries to object directly to new registrations. Guidelines for the registration of GIs by third country producers have been published on the Commission's website at
http://ec.europa.eu/agriculture/foodqual/protec/thirdcountries/proced_en.pdf.

The complete list of registered product names that receive protection in the EU can be found at
http://ec.europa.eu/agriculture/qual/en/1bbaa_en.htm.

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.

Section IX. Import Procedures:

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

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

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

The EU uses the Combined Nomenclature (CN) for the customs classification of goods. The CN eight digit code numbers are based on the Harmonized System (HS) nomenclature: the first six digits refer to the HS headings; the two following digits represent the CN subheadings. The EU's on-line customs database can be consulted to look up commodity codes and relevant import duties (http://ec.europa.eu/taxation_customs/dds/en/tarhome.htm).

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

More detailed information is available on the DG Taxation & Customs website:
http://ec.europa.eu/ecip/security_amendment/index_en.htm.

It is also possible to obtain Binding Tariff Information (BTI) from a member state's customs authority to get the proper product classification. Through this system, traders know in advance the tariff classification of the goods they intend to import. BTI is legally binding in all the member states. Information on how to obtain a BTI can be downloaded from the European Commission's Taxation & Custom's website at
http://ec.europa.eu/taxation_customs/customs/customs_duties/tariff_aspects/classification_goods/index_en.htm.

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)
- additional duties on flour and sugar (processed products)
- entry price (fruit and vegetables)
- 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/taxation/vat/consumers/vat_rates/index_en.htm.

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

Appendix I. Government Regulatory Agency Contacts:

MAJOR ITALIAN AND EUROPEAN REGULATORY AGENCIES

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 della Salute
(Ministry of Health)
Direzione Generale per l'Igiene Alimenti e la Nutrizione
Divisione VI. A
Piazza Marconi, Palazzo Italia
00144 Roma
Tel: +39 06 5994
http://www.ministerosalute.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

ICE
Istituto per il Commercio Estero
(Italian Foreign Trade Commission)
Via Liszt, 21

00144 Roma
Tel: +39 06 59921
http://www.ice.it

European Communities Commission
Rue de la Loi 200
1049 Brussels
Belgium
Tel: +32 2 299 11 11

Office for Harmonization in the Internal Market
Avenida de Aguilera, 20
03080 Alicante
Spain
Tel. +34 96 513 92 43
Fax. (34-96) 513 91 73

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 2 508-2760
Fax: +32 2 511-0918
e-mail: AgUSEUBrussels@fas.usda.gov

Appendix II. Other Import Specialist Contacts:

POST CONTACT INFORMATION FOR OFFICE OF AGRICULTURAL AFFAIRS, ROME, ITALY

Street address:
American Embassy
Foreign Agricultural Service
Via Vittorio Veneto 119/A
Rome, 00187
Italy

Tel: +011 39 06 4674 2396
Fax: +011 39 06 4788 7008
E-mail: agrome@usda.gov
Webpage: http://italy.usembassy.gov/agtrade/default.asp

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