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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. For more in-depth information at the general EU level, please refer to the USEU website (http://useu.usmission.gov/agri).

Section I. Food Laws:

Table of Contents

B. Medical/Health Claims
Nutritional Value Labeling Ordinance
Health Claims
Dietetic Foods Ordinance
Allergen Labeling

SECTION III. PACKAGING AND CONTAINER REQUIREMENTS

A. Consumer Packaging Ordinance and Laws on Weight and Measures
B. Materials in Contact with Foodstuffs
C. Packaging Disposal Regulations
A. Phytosanitary Requirements
B. Health Requirements for Plant Products

SECTION IV. FOOD ADDITIVE REGULATIONS

A. Food Additives and Flavorings

SECTION V. PESTICIDES AND OTHER CONTAMINANTS

SECTION VI. OTHER REGULATIONS AND REQUIREMENTS

A. Product Inspection and Registration
B. Certification and Documentation Requirements
AGRIM Certificates
Health Certificates
Plant Products
Animal Products
Processed Foods

SECTION VII. OTHER SPECIFIC STANDARDS

A. Genetically Modified Food and Feed
B. Genetically Modified Seeds
C. Novel Foods
D. Dietetic or Special Use Foods
E. Fortified Foods
F. Wine, Beer and Other Alcoholic Beverages
G. Organic Foods
H. Beef Labeling
I. Egg Marking
J. Frozen Foodstuffs
K. Fruits and Vegetables
L. Seafood
M. Pet Food and Animal By-Products
N. Other

SECTION VIII. COPYRIGHT AND/OR TRADEMARK LAWS

A. Trademarks
B. Protected Geographical Indications

SECTION IX. IMPORT PROCEDURES

ANNEX A – MAJOR ITALIAN AND EUROPEAN REGULATORY AGENCIES

ANNEX B – POST CONTACT INFORMATION

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

SECTION I. FOOD LAWS

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 an 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:

A. General 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.

od allergen labeling rules were introduced by Directive 2003/89/EC that became effective on November 25, 2005. The following 12 groups of 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 and sulphite at concentrations of at least 10 mg per kg or 10 mg/l, celery, and mustard.

Directive 2006/142/EC due tol enter into force on December 23, 2008, adds "lupin and products thereof" and "mollusks and products thereof" to the list of allergenic ingredients. Allergen labeling also applies to alcoholic beverages.

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.

ıme 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.

Medical/Health Claims

Nutritional Value Labeling Ordinance

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.

Health 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.

New products on the EU market must respect the conditions for use of nutrition claims that are set out in detail in the Annex of Regulation 1924/2006. Products already labeled or on the market before January 2007 may remain on the market with the old labels until January 2010. From 2010, only nutrition claims included in the Annex will be allowed.

Allergen Labeling

EU food allergen labeling rules were introduced by Directive 2003/89/EC. Under this directive, the following 12 groups of 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 and sulphite at concentrations of at least 10 mg per kg or 10 mg/l, celery, and mustard. Directive 2006/142/EC adds "lupin and products thereof" and "mollusks and products thereof" to the list of allergenic ingredients. Allergen labeling also applies to alcoholic beverages.

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

These guidelines also specify in which cases derogations may be accepted: for foodstuffs for which no ingredients list is required, for sub ingredients of certain compound ingredients, for ingredients which belong to well defined categories and for substances that are not regarded as ingredients. Commission Directive 2007/68/EC establishes a list of ingredients and substances which are permanently exempted from the mandatory allergen labeling requirement.

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.

Phytosanitary Requirements
Health Requirements for Plant Products

Phytosanitary certificates are required under the EU's Plant Health Directive 2002/89/EC implemented by Legislative Decree 214 of August 19, 2005. Imports of fresh fruits and vegetables and unprocessed nuts from the U.S. must be

accompanied by a U.S. Department of Agriculture phytosanitary certificate or PPQ577, issued by an official Animal and Plant Health Inspection Service (APHIS) inspector. The certificate is used to certify that the commodities have been inspected and that they comply with the importing country's phytosanitary regulations.

Fresh fruits, vegetables and nuts are all subject to phytosanitary controls and are checked for compliance with EU marketing standards for quality and labeling. 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. Marketing standards for fruits and vegetables are available on the USEU website. Standards exist for apples and pears, apricots, artichokes, asparagus, aubergines (eggplant), avocados, beans, Brussels sprouts, cabbage, carrots, cauliflowers, celery, cherries, citrus fruit, courgettes (zucchini), cucumbers, garlic, kiwis, leeks, lettuce, curly and escarole chicory, melons, onions, peaches and nectarines, peas for shelling, plums, spinach, strawberries, sweet peppers, table grapes, tomatoes, watermelons, witloof chicory, miniature produce, mixes of fruit and vegetables, walnuts and hazelnuts.

Section IV. Food Additives Regulations:

A. Food Additives and Flavorings

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, bromates and peroxides that are not allowed in the EU.

Labeling requirements for additives and flavorings are laid down in directive 2001/13/EC (general labeling directive) and directive 89/107/EEC.

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, humectant, bulking agent, 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

Section V. Pesticides and Other Contaminants:

Pesticides

(http://useu.usmission.gov/agri/pesticides.html)

Current EU pesticide legislation has not been fully harmonized within member states. A first step towards harmonization of EU legislation on pesticides was made by the introduction of Council Directive 76/895/EC establishing maximum residue levels allowed for free movement throughout the member states. 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 reference law for MRLs is outlined by the Minister of Health Decree dated 19 May 2000 (Decreto del Ministro della Sanità del 19 maggio 2000), which establishes MRLs pertaining to foodstuff for human consumption. It implements EU Directives 97/41/CE and 1999/65/CE and 1999/71/CE. It includes MRLs that are set by implementation of EU Directives as well as those that are set at country level. A consolidated text of the Italian law with all the annexes and the updates on MRLs is available (in Italian) at:

http://www.ministerosalute.it/alimenti/sicurezza/sicApprofondimento.jsp?lang=english&label=pro&id=412&dad=s

In the near future there will be a change to the legislative scenario with regard to maximum residue levels, consequent to publication of the recent Community Regulation No. 396/2005. New framework Regulation 396/2005 on maximum residue levels in or on food and feed of plant and animal origin will complete the harmonization exercise. MRL's for unapproved substances will all automatically revert to the default level of 0.01 mg/kg. The new regulation will become fully applicable when its annexes have been completed and adopted. At that time, the currently applicable Directives 86/362/EEC, 86/363/EEC and 90/642/EEC will become obsolete. When fully implemented, all MRL's, including import tolerances, will apply EU wide, removing the trade problems that were the result of the current situation whereby Member States can set their own national MRL's in the absence of Community MRL's.

Section VI. Other Regulations and Requirements:

A. 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 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.

B. Certification and Documentation Requirements

AGRIM Certificates

http://useu.usmission.gov/agri/Certification_Guide.html

The EU requires import licenses (AGRIM certificates) for most agricultural products for which it provides market support. In order to obtain a license, an application form must be submitted and security fee must be paid to the issuing Member State. Licenses vary in validity with most expiring three months after the month of issuance.

Health Certificates for Plant Products

(http://useu.usmission.gov/agri/plantcertif.html)
(http:// www.aphis.usda.gov/ppq/pim/exports/certificates&forms.htm)

Phytosanitary certificates are required under the EU's Plant Health Directive 2000/29/EC. Imports of fresh fruits and vegetables and unprocessed nuts must be accompanied by a U.S. Department of Agriculture phytosanitary certificate or PPQ577, issued by an official Animal and Plant Health Inspection Service (APHIS) inspector. The certificate is used to certify that the commodities have been inspected and that they comply with the importing country's phytosanitary regulations.

Health Certificates for Animal Products
(http://useu.usmission.gov/agri/certification.html)

Animal products imported into the EU or through the EU must be accompanied by a veterinary certificate. EU harmonized health certificates are mandatory for meat, poultry, dairy, eggs, gelatin and seafood.

The European Union has well developed harmonized legislation for imports of animal products. Approval to export to the EU requires that the exporting country have an effective system to contain animal and human health risks, that the production plants are individually approved, and that the product itself passes inspection on arrival in the EU. The EU recognizes for all animal products that the U.S. has effective veterinary systems. However, as a result of the EU's hormone ban in cattle raising, and the rejection of chlorine as an anti-microbial treatment in poultry slaughter, U.S. exports to the EU of beef and poultry using these processes have been banned.

EU lists of approved establishments are drawn up of approved, recognized countries. Various U.S. agencies, including FSIS, APHIS, AMS, and FDA are involved in the listing process. Establishments are subject to occasional EU audits after listing. Exporters should be aware that getting a plant listed can take several months. At present, the following food products must come from an EU-approved establishment: red meat, meat products, farmed & wild game meat, ratites, animal casings, milk & milk products, fish & fishery products and gelatin. An importer must give at least 24 hours notice of intent to import animal products to the competent Member State authority and to the Border Inspection Post (BIPs) at the port or airport of entry.

Health Certificates for Processed Foods
(http://useu.usmission.gov/agri/foodcertif.html)

All animal products imported into the EU, and therefore also Italy, need animal or public health certification. For processed foods containing animal product, the situation is more complicated because there is no legislation specifying the percentage of dairy, egg, red meat or poultry meat that a foodstuff must contain to necessitate certification. As such, it is best to check the documentation requirements with the importer. In principle, products containing any amount of red meat or poultry meat must be certified. Certification of products containing egg products or dairy products depends on the composition of the product. Generally, any foodstuff containing more than 50 percent egg/dairy products will need the corresponding certificate.

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.

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
(http://useu.usmission.gov/agri/GI.html)

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.

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).

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

Appendix I. Government Regulatory Agency Contacts:

ANNEX A – 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:

ANNEX B –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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