



USDA Foreign Agricultural Service

GAIN Report

Global Agriculture Information Network

Template Version 2.09

Required Report - public distribution

Date: 7/10/2008

GAIN Report Number: E48078

EU-27

FAIRS Country Report

Annual European Union Report

2008

Approved by:

Kurt Seifarth

U.S. Mission to the EU

Prepared by:

Hilde Brans

Report Highlights:

This report gives a complete overview of food laws currently in force in the EU-27. The following sections were updated: labeling requirements (allergen labeling, nutrition and health claims), packaging (pack sizes), pesticides, contaminants, specific standards (GMOs, novel foods, wine and spirit drinks, organic foods, beef labeling, egg marking, other), import procedures. European Commission proposals which may have an impact on U.S. exports are also included. NEW: Annex IV (website links and guidance documents).

Includes PSD Changes: No
Includes Trade Matrix: No
Annual Report
Brussels USEU [BE2]
[E4]

SECTION I. FOOD LAWS.....	4
SECTION II. LABELING REQUIREMENTS	6
A. General Requirements	6
Compulsory Information:	6
Quinine and Caffeine	8
Phytosterols & Phytostanols	8
Quantitative Ingredients Declaration (QUID)	8
Language Requirements.....	9
Stick-on Labels.....	9
Samples	10
Labeling of Genetically Modified Foods and Novel Foods	10
B. Medical / Health / Nutrition Claims	10
Requirements Specific to Nutritional Labeling	11
C. Product-Specific Labeling	11
SECTION III. PACKAGING AND CONTAINER REQUIREMENTS	13
A. Pack Sizes	13
B. Packaging Waste Management	13
C. Materials in Contact with Foodstuffs	13
SECTION IV. FOOD ADDITIVE REGULATIONS	15
Processing Aids	16
Flavorings	16
SECTION V. PESTICIDES AND CONTAMINANTS	17
Pesticides.....	17
Contaminants	18
Official Controls of Maximum Levels in Foodstuffs	19
Residues in Animals and Animal Product.....	20
SECTION VI. OTHER REGULATIONS AND REQUIREMENTS	21
A. Product Inspection and Registration.....	21
B. Certification and Documentation Requirements.....	21
SECTION VII. OTHER SPECIFIC STANDARDS	23
A. Genetically Modified Foods (GMOs)	23
B. Novel Foods	23
C. Fortified Foods.....	24
D. Dietetic or Special Use Foods	24
E. Wine, Beer and Other Alcoholic Beverages	25
F. Organic Foods.....	26
G. Vertical Legislation (Breakfast Directives).....	27
H. Animal Products	27
I. Frozen Foodstuffs	28
J. Irradiated Foodstuffs.....	28
K. Fruits and Vegetables	29
L. Seafood.....	29
SECTION VIII. COPYRIGHT AND/OR TRADEMARK LAWS	30
Trademarks	30
Protected Geographical Indications.....	30
SECTION IX. IMPORT PROCEDURES.....	31
APPENDIX I. GOVERNMENT REGULATORY AGENCY CONTACTS.....	33
APPENDIX II. HOW TO OBTAIN LEGISLATION	34
APPENDIX III. EU INITIATIVES	35
APPENDIX IV. WEBSITE LINKS & GUIDANCE DOCUMENTS.....	36

DISCLAIMER: This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service, U.S. Mission to the European Union in Brussels, Belgium for U.S. exporters of domestic food and agricultural products. While every possible care was taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. FINAL APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

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://useu.usmission.gov/agri/fairsh.html>

SECTION I. FOOD LAWS

The European Union (EU), formerly known as the European Economic Community (EEC), was created by the Treaty of Rome on March 25, 1957. Through several accessions, the EU has gradually expanded to become the world's largest multi-nation trading bloc. Since January 1, 2007, the European Union comprises 27 member states with approximately 490 million consumers.

EU member states: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom.

All EU Member countries accept the entire body of EU laws and obligations associated with the treaties and agreements to which the EU is a party, including the EU laws and rules pertaining to processed foods.

Originally created as a customs union, the process of harmonizing existing Member State legislation has been long and cumbersome and is still ongoing. While the vast majority of food laws and regulations have been harmonized throughout the EU, the single EU market is still not a "done deal". It is important to note that when EU-wide legislation is incomplete or absent, the laws of Member States apply, often resulting in different rules in different Member States. The FAIRS reports prepared by the Offices of Agricultural Affairs in the EU Member States are excellent sources of information on Member State specific requirements (<http://useu.usmission.gov/agri/fairs.html>).

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 the requirements. In reality, certain directives allow Member States to make exceptions e.g. in cases where a country can prove health 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.

EU legislation is made up of Directives and Regulations which must be translated into the 23 official languages in use in the EU-27. **Directives** define the result that must be achieved but leave to each Member State the choice of form and methods to transpose the directive into national laws (usually within 2-3 years after adoption). **Regulations** are binding in their entirety and automatically enter into force on a set date in all Member States. Amendments to EU legislation are usually published in new and separate Directives and Regulations, making it difficult to be sure of all possible amendments when doing research. When legislation is referenced in this guide, it is implied that all further amendments also apply. Where possible, this guide links directly to referenced pieces of EU legislation. However, as legislative acts in pdf-format are only available as of 1995, links are not being established to legislation that was published before 1995. The Eurlex website (<http://eur-lex.europa.eu/en/index.htm>) provides free access to European Union law.

The EU has followed a dual approach in harmonizing food laws: "horizontal" legislation that covers aspects which are common to all foodstuffs (such as additives, labeling, hygiene, etc.) and "vertical" legislation on specific products (e.g., cocoa and chocolate products, sugars, honey, fruit juices, fruit jams, novel foods, etc.).

In the aftermath of the BSE crisis and several other food scandals in the late 1990s, the EU published in Jan 2000 its White Paper on Food Safety setting out a legislative action plan for a pro-active new food policy. The EU developed a "Farm to Fork" approach covering all sectors of the food and feed chain, with traceability as basic concept. The application of the "precautionary principle" as described in the February 2000 [Commission Communication on the Precautionary Principle](#) is also an important concept in the EU's approach. Key elements in the new approach were the establishment of a framework laying down the general principles and requirements of EU food law, the establishment of the European Food Safety Authority (EFSA) which is an independent body providing scientific advice to the legislators, the development of specific food and feed safety legislation including a major overhaul of the existing hygiene legislation, and the creation of a framework for harmonized food controls. The new regulations on general food law, food and feed controls, food hygiene and feed hygiene are the framework regulations for the new EU food safety system. Revisions of existing EU food regulations or new regulations all implement the principles contained in the new framework regulations. Information on the EU's food safety approach is available on our website at <http://useu.usmission.gov/agri/foodsafety.html>.

EU political structures include the permanent bureaucracy of the Commission, the Council of Member State representatives, and the European Parliament. All are involved in creating and passing legislation. For more information on how the EU works, see our website at <http://useu.usmission.gov/agri/institutions.html> and the website of the European Commission at http://europa.eu/index_en.htm. It is the task of the European Food Safety Agency (<http://www.efsa.europa.eu>) to provide scientific advice to the legislators on matters related to food safety.

Enforcement of EU food legislation is done by Member State officials. Auditing oversight of Member State performance is done by European Commission officials. The European Commission has the power to initiate legal action in the European Court of Justice against Member States who are not complying with EU Directives and Regulations.

Exporters should be aware that there may be some variation among Member States in applying EU harmonized legislation. This may result from the lack of harmonized guidelines for the enforcement of rules; it may be due to variations in the transitional period needed to adjust to EU rules; there may be temporary waivers or exemptions –usually called derogations; in certain cases there may be room for interpretation of EU harmonized legislation; certain aspects which are not regulated in detail at EU level may be handled differently in different Member States, e.g. acceptability of stick-on labels varies among Member States. Also, there is a wide variation in inspection fees, in registration fees and in the time required to evaluate dossiers on products used in the course of the food production process.

Up to date information on EU food import rules as well as general information on EU import duties and quotas can be found on our website at <http://useu.usmission.gov/agri/usda.html>. This website also links to additional sources of useful information.

AS A REMINDER: Imports of red meat, meat products, 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

<http://useu.usmission.gov/agri/label.html>

A. General Requirements

The standard U.S. label fails to comply with EU labeling requirements.

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. Section 7 covers labeling requirements for specific products, including genetically modified and novel foods.

Compulsory Information:

- The name under which the product is sold.
- The list of ingredients, in descending order of weight. Important exceptions include added water in foods reconstituted from concentrates, and cheese, which is covered by special rules. The following ingredients require a specific statement on the label: GMO's, packaging gases, sweeteners, aspartame and polyols, quinine and caffeine, phytosterols and phyosteranols and licorice.
- Allergens: Food allergen labeling rules were introduced by [Directive 2003/89/EC](#) and entered into force on November 25, 2005. 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](#) which will 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. [GAIN report E36066](#) lists the different languages that the EU member states will accept for the purpose of allergen labeling of wine. 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 (for more information see [GAIN report E47105](#)).
- Certain ingredients may be designated by the name of the category rather than the specific name (Annex I to Directive 2000/13/EC). These include fats, oils (note that peanut oil is also subject to the new allergen rules), starch, fish, cheese, spices, herbs, gum bases, crumbs, sugar, dextrose, glucose syrup, milk proteins, cocoa butter, crystallized fruit, vegetables and wine. Directive 2001/101/EC adds meat as a category and defines the term "meat" for the labeling of pre-packed meat-based products (for more information see [GAIN report E23004](#)).
- The quantity of certain ingredients or categories of ingredients (QUID) – see below.
- The net quantity of prepackaged foodstuffs expressed in metric units (liter, centiliter, milliliter, kilogram or gram).

- The date of minimum durability: the shelf life is indicated by the words "Best before..." when the date includes an indication of the day, or by "Best before end of..." in other cases. The date has to be given in order of day- month-year. However, for foodstuffs with a shelf life of less than three months, the day and month of expiry are adequate; for a shelf life of three to eighteen months the month and year are sufficient; for more than eighteen months shelf life the year is sufficient indication. In the case of highly perishable foodstuffs the date consisting of the day, the month and possibly the year has to be preceded by the words "use by."
- Any special storage conditions or conditions of use.
- The name or business name and address of the manufacturer, packager or vendor established within the Community.
- Particulars of the place of origin or provenance in case absence of such information might mislead the consumer.
- Instructions for use.
- The actual alcoholic strength for beverages containing more than 1.2 percent alcohol by volume.
- A mark to identify the lot to which a foodstuff belongs, determined by the producer, manufacturer or packager or by the first seller in the EU. The marking must be preceded by the letter "L", except in cases when it is clearly distinguishable from other indications on the label. The lot identification is not necessary if the date (day and month) of minimum durability or "use by" date, appears in un-coded form on the label.
- Treatments undergone, with specific indications for irradiated foods and deep-frozen foods (see section 7).

Note: the use of the EAN (European Article Numbering) product coding system is not regulated by EU law. However, this bar code system is commonly used in the EU to fulfill the traceability requirement, which became mandatory on January 1, 2005 (See also [GAIN 35112](#)).

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, 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](#)).

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".

Quantitative Ingredients Declaration (QUID)

Quantitative ingredients declaration (QUID) is compulsory in the following cases:

- Where the ingredient or category of ingredients appears in the name under which the foodstuff is sold:
e.g. "15% strawberries" on strawberry ice cream - QUID for strawberries
"35% fruit" on fruit pie - QUID for total fruit content
- Where the ingredient or category of ingredients is usually associated with that name by the consumer: e.g. goulash soup - QUID for beef
- Where the ingredient or category of ingredients is emphasized on the labeling in words (e.g. "made with butter"), pictures (e.g. of a cow to emphasize dairy ingredients) or graphics (different size, color and/or style of print).
- 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.

The QUID requirement DOES NOT apply to constituents naturally present in foods and which have not been added as ingredients e.g. caffeine (in coffee) and vitamins and minerals (in fruit juices). QUID declarations are not needed in a number of cases, e.g. when products state the drained net weight or where an ingredient is used for purposes of flavoring. QUID declarations CANNOT replace nutrition labeling.

[Commission Directive 1999/10/EC](#) provides for exemptions from the QUID requirement:

- When the wording "with sweeteners" or "with sugar(s) and sweetener(s) accompanies the name under which a foodstuff is sold.
- When the addition of vitamins and minerals is subject to nutrition labeling.
- When foodstuffs are concentrated or dehydrated.

General guidelines have been drawn up to help Member States and industry organizations implement the principle of QUID. A copy of these guidelines can be downloaded from the European Commission's website at http://ec.europa.eu/food/fs/fl/fl02_en.pdf.

Language Requirements

As a general rule, labeling has to be in a language easily understood by consumers; this is in practice the official language(s) of the member state. 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.

Language labeling requirements in practice:

EU Member State	Language
Austria	
Belgium	French AND Dutch, German also recommended
Bulgaria	Bulgarian
Czech Republic	Czech
Denmark	Danish
Estonia	Estonian
Finland	Finnish
France	French
Germany	German
Greece	Greek
Hungary	Hungarian
Ireland	British English
Italy	Italian
Latvia	Latvian
Lithuania	Lithuanian
Luxembourg	French or German
Malta	Maltese or English or Italian
Netherlands	Dutch
Poland	Polish
Portugal	Portuguese
Romania	Romanian
Slovakia	Slovak
Slovenia	Slovene
Spain	Spanish
Sweden	Swedish
United Kingdom	British English

Stick-on Labels

EU legislation does not contain any reference to the use of stick-on labels. It is up to individual Member States whether to accept stick-on labels.

Samples

EU legislation covers all foods destined for consumption. It does not contain any specific labeling requirements or exceptions for samples. Exporters are advised to consult the member state FAIRS reports for specific information (<http://useu.usmission.gov/agri/fairs.html>).

Labeling of Genetically Modified Foods and Novel Foods

Section 7.A 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. The words "produced from genetically modified ..." or "genetically modified" as a footnote or specification following the ingredient have to be used to indicate the presence of the GM soy and corn proteins and all GM additives and flavorings that are currently on the market.

B. Medical / Health / Nutrition Claims

<http://useu.usmission.gov/agri/claims.html>

On July 1, 2007, a new 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 on the EU market. Only foods that fit a certain nutrient profile (below certain salt, sugar and/or fat levels) will be allowed to carry claims. Nutrition and health claims will only be allowed on food labels if they are included in one of the EU positive lists. Food products carrying claims must comply with the provisions of [nutritional labeling directive 90/496/EC](#).

Nutrient profiles will be developed January 2009, based on scientific evaluations by the European Food Safety Authority (EFSA). Once they 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 a high sugar content but only if the label clearly states "high sugar content". Health claims cannot fail any criteria.

New products on the EU market must respect the conditions for using nutrition claims 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.

A list of well-established health function claims such as "calcium is good for your bones" will be established by January 2010, based on Member States' lists of health claims already approved at national level. This three-year period should allow food operators sufficient time to adjust. As disease risk reduction claims were previously not allowed in the EU, there is no transitional period for such claims. Disease risk reduction claims and claims referring to the health and development of children will require an authorization on a case-by-case basis, following the submission of a scientific dossier to EFSA. Health claims based on new scientific data will have to be submitted to EFSA for evaluation but a simplified authorization procedure has been established. [GAIN Report E48055](#) describes how application dossiers for authorization of health claims should be prepared and presented. A guidance document on how companies can apply for health claim authorizations can be downloaded from EFSA's

website at http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178623592471.htm

Trade marks 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 within 15 years.

Requirements Specific to Nutritional Labeling

Nutrition labeling is not mandatory in the EU unless a nutrition claim is made on the label or in advertising messages. "Nutrition labeling" means any information on the label that relates to energy value and to the following nutrients: protein, carbohydrate, fat, fiber, sodium, vitamins and minerals present in significant amounts. Nutrition labeling rules are laid down in Council Directive 90/496/EEC.

Where nutritional labeling is provided, the information to be given should consist of either group 1 or group 2 in the following order:

Group 1	Group 2
- the energy value	- the energy value
- the amount of protein, carbohydrate and fat	- the amount of protein, carbohydrate, sugar, fat, saturates, fiber and sodium

When a nutrition claim is made for sugars, saturates, fiber and sodium, the information under Group 2 must be given.

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.

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
- 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

More details on above products can be found in Section 7.

Proposal: On January 30, 2008, the European presented a proposal to revise the EU's general food labeling requirements. New requirements would include the mandatory declaration of nutrition information on the front label of pre-packaged foods, a minimum font size of 3 mm for printing mandatory information and an ingredients list on the label of alcopops. For more information on the labeling proposal see [GAIN Report E48020](#).

SECTION III. PACKAGING AND CONTAINER REQUIREMENTS

<http://useu.usmission.gov/agri/packaging.html>

A. Pack Sizes

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

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

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. Packaging Waste Management

Member States are required to take measures to reduce packaging waste and must introduce systems for reuse, recovery and recycling of packaging materials (Council Directive 94/62/EC). To facilitate collection, reuse and recovery including recycling, an identification system for packaging has been drawn up (Commission Decision 97/129/EC). Its use is voluntary. A well-known and widely used recycling program is the German "green dot" system. More information can be found on the Packaging Recovery Organization Europe website which provides easy access to all Green Dot systems in Europe (www.pro-e.org).

C. Materials in Contact with Foodstuffs

[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 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. Additional requirements will be proposed in specific measures and will include positive lists of authorized substances and/or materials. Annex I to regulation 1935/2004 lists the group of materials for which specific measures may be adopted. To date, [specific directives](#) have been developed for plastics, regenerated cellulose film, ceramics. In the case of ceramics, migration limits have been established for two of their constituents, namely lead and cadmium. Materials must bear an indication "for food contact" or the symbol reproduced in Annex II to Regulation 1935/2004.

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

Exporters are advised to verify if a Member State follows EU provisions as Member States are allowed to authorize provisionally the use of certain substances not listed in one of the specific directives. They may also restrict or temporarily prohibit the use of certain materials authorized by the specific directives for reasons of public health. A summary of national legislation can be downloaded from the European Commission website at http://ec.europa.eu/food/food/chemicalsafety/foodcontact/sum_nat_legis_en.pdf.

SECTION IV. FOOD ADDITIVE REGULATIONS

<http://useu.usmission.gov/agri/additive.html>

Council Directive 89/107/EEC provides for the establishment of EU harmonized positive lists of a wide range of food additives. All food additives not included in the positive lists are prohibited except for those 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.

Substances added to foodstuffs as nutrients such as minerals, trace elements, vitamins do not fall under the scope of this directive and continue to be subject to Member States legislation.

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 which 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 our additives webpage (<http://useu.usmission.gov/agri/additive.html>).

An important difference from U.S. legislation is the use of flour bleaching agents: chlorine, bromates and peroxides are not allowed in the EU.

Specific information on authorized additives can be obtained from our office. Upon request, our office can also provide a multilingual list of all food additives.

Labeling requirements for additives and flavorings are laid down in directive 2001/13/EC (general labeling directive) and directive 89/107/EEC. The addition of a new food additive to the EU positive list is a lengthy process. However, any Member State can allow the domestic

use of a new food additive on their territory for a two-year period. Companies are advised to submit an application to the Member State where they want to start using a new additive and simultaneously to the Commission. Procedures on obtaining the 2-year waiver differ from one Member State to another, and the time necessary to obtain approval also can vary significantly. The procedure for inclusion of an additive in the positive list requires that a dossier be sent to the European Food Safety Agency (EFSA) and to the Commission. EFSA reviews a substance and has to give a positive opinion before the Commission can propose the addition to the positive list.

Processing Aids

A list of extraction solvents allowed in the production of foodstuffs and food ingredients, along with their conditions of use has been established in Council [Directive 88/344/EC](#).

Flavorings

In an initial step to harmonize the use of flavorings in the EU, the European Commission compiled a [register of all flavoring substances](#) authorized in the different EU member states. Substances that are subject to restrictive or prohibitive measures in certain member states have been marked.

Proposal: In July 2006, the European Commission tabled a [package of four legislative proposals](#) which would upgrade the current rules for additives and flavorings, introduce harmonized EU legislation on food enzymes and introduce a single common procedure for the approval of food additives, flavorings and enzymes. The proposal on food additives would bring the current directives (framework, colors, sweeteners and miscellaneous) into one regulation. For more information see [GAIN report E36113](#). The proposals have to be adopted under the co-decision procedure.

SECTION V. PESTICIDES AND CONTAMINANTS

The legislation on pesticides and contaminants is partially harmonized in the EU. Enforcement of both EU and remaining Member State rules is done at the Member State level.

Pesticides

<http://useu.usmission.gov/agri/pesticides.html>

The marketing and use of plant protection products is regulated by [Council Directive 91/414/EEC](#). This Directive provides for the establishment of an EU positive list of active substances. Active substances are being reviewed under this Directive and may only be used in plant protection products when they are included in the positive list. Only products containing substances included in the positive list may be authorized for use in the EU. **The currently ongoing legislative initiatives in the area of pesticides are resulting in a drastic reduction of the number of active substances and maximum residue levels (MRLs) are being harmonized throughout the EU.**

Proposal: The European Commission has tabled a [proposal](#) establishing new rules for the authorization of Plant Protection Products (PPPs) which will replace Council Directive 91/414/EEC. The main aim of the proposal is to facilitate the current approval and authorization procedures and to increase harmonization while maintaining a high level of protection for humans, animals and the environment. The proposal has to be adopted under the co-decision procedure.

The existing legislation that establishes MRLs for pesticides in food is currently in a transitional phase. The current situation in the EU is still characterized by a dual system where EU and national MRLs for pesticides coexist. However, as of September 2, 2008 all MRLs will be harmonized at the EU level. Framework [Regulation 396/2005](#) will then become fully applicable and will replace the currently applicable Directives 86/362/EEC, 86/363/EEC and 90/642/EEC.

Regulation 396/2005 becomes fully applicable six months after publication of the first four Annexes in the Official Journal. Annex I was published in 2006; Annexes II, III and IV were published at the beginning of March 2008 which means that Regulation 396/2005 will become fully applicable at the beginning of September 2008.

Annex I simply **lists** the **commodities** to which MRLs apply.

Annex II contains **existing MRLs** that were already harmonized at EU level and will replace the EU's current MRL Directives. They may be higher than the default limit.

Annex III contains **temporary MRLs** and consists of two parts:

-**Part A** contains MRLS which have not yet been harmonized at EU level, including those for active substances awaiting a decision for inclusion in Annex I of Directive 91/414 and some import tolerances.

-**Part B** contains all draft temporary MRLs for active substances already harmonized at the EU level (and therefore included in Annex II) but in and on new commodities (for example tropical products) established in Annex I (= new pesticide/crop combinations). These MRLs will eventually be shifted to Annex II of Regulation 396/2005.

Annex IV will contain the substances for which **no MRLs are required** (exempt from tolerance products).

For all substances not included in these four Annexes, the MRL will be set at EU default level of 0.01 ppm (**Annex V**).

Pesticide MRLs for processed or composite products are based on the MRLs for the raw agricultural ingredients. Harmonized sampling plans have been developed for the official control of residues ([Commission Directive 2002/63/EC](#)).

If there is no EC legislation in place in force in the importing Member State, then the exporter needs to obtain an "import tolerance". It is still possible to obtain an import tolerance, even for active substances that have not been evaluated or used in Europe before. Applications for import tolerances must be submitted to the "Rapporteur Member State" (RMS). The Commission assigns a Member State, if no RMS exists. The RMS reviewed dossiers are evaluated by the European Food Safety Authority (EFSA) before being forwarded to the Commission for consideration. Information on import tolerances can be obtained from http://www.pesticides.gov.uk/applicant_guide.asp?id=1239

When fully implemented, all MRLs, including import tolerances, will apply EU wide, removing possible trade problems that were the result of the previous/current situation whereby Member States can set their own national MRLs in the absence of harmonized EU MRLs.

Contaminants

<http://useu.usmission.gov/agri/contaminants.html>

Maximum Levels

EU wide harmonized maximum levels for contaminants are set in the Annex of [Commission Regulation 1881/2006](#). Annex I of Regulation 1881/2006 includes maximum levels for nitrates, mycotoxins, heavy metals, 3-MCPD, dioxin and polycyclic aromatic hydrocarbons (PAH) in foodstuffs (see Table 1).

Commission Decision 2007/563/EC sets special conditions for the import of U.S. almonds into the EU. The decision applies to 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 10 percent). Official Member States controls are carried out on approximately 5 percent of consignments of foodstuffs which are covered by the "Voluntary Aflatoxin Sampling Plan" (VASP) and to each consignment of foodstuffs not covered by the VASP. More information is available on the [Almond Board of California's website](#).

Table 1: Commission Regulation 1881/2006 sets maximum levels for the following contaminants in foodstuffs:**Section 1: Nitrates**

- Nitrate in lettuce and spinach and infant food

Section 2: Mycotoxins

- Aflatoxins in nuts, dried fruit, cereals, maize, spices, milk, infant food

[Guidance document for competent authorities for the control of compliance with EU legislation on aflatoxin \(European Commission Document\)](#)

- Ochratoxin A in cereals, cereal products, dried vine fruit, infant food
- Patulin in apple juice, apple juice ingredients, infant food
- Deoxynivalenol in cereals, cereal products, infant food
- Zearalenone in cereals, cereal products, infant food
- Fumonisin in maize and maize based products
- T-2 and HT-2 toxin in cereals and cereal products

Section 3: Heavy metals

- Heavy metals lead, cadmium, mercury in meat, fish, vegetables and fruit, food supplements
- Tin in canned foods and beverages and baby foods

Section 4: 3-monochloropropane-1,2-diol (3-MCPD)

- 3-MCPD in vegetable protein, soy sauce

Section 5: Dioxin and dioxin-like PCBs

- Dioxins in meat, fish, fish liver and derived products, milk, eggs and oils & fats

Section 6: PAH

- Polycyclic Aromatic Hydrocarbons (PAH) in oils and fats, infant foods, meat and fish

Official Controls of Maximum Levels in Foodstuffs

The Directives in Table 2 concern the sampling methods and methods of analysis for the official controls of the levels of the different contaminants. Annex I describes the methods of sampling; Annex II concerns the sample preparation and the performance criteria for the methods of analysis.

Table 2: Sampling & Analysis Methods for Official Controls

Nitrates	Commission Regulation 1882/2006
Mycotoxins: Aflatoxins, Ochratoxin A, Patulin and Fusarium toxins	Commission Regulation 401/2006
Dioxins	Commission Regulation 1883/2006
Heavy metals, Tin, 3-MCPD and PAH (benzo(a)pyrene)	Commission Regulation 333/2007
Action levels for dioxins and dioxin-like PCBs in foodstuffs are set by Commission Recommendation 2006/88/EC as part of a pro-active approach to reduce the presence of dioxins and dioxin-like PCBs in food and feed. The action levels for dioxins and furans are generally set at around 2/3 of the new maximum levels and an investigation into the cause of the contamination is required if the action levels are exceeded.	

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 above-mentioned pesticide residues but includes also the monitoring of 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](#).

Proposal: On June 4, 2007, the European Commission tabled a [proposal](#) to amend Council Directive 96/22/EC concerning the prohibition of certain substances having a hormonal thyreostatic action and of beta-agonists. The proposal has to be adopted under the co-decision procedure.

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 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.

Criteria for laboratories conducting food controls have been harmonized but it is the Member States' responsibility to designate laboratories that are allowed to perform analyses.

Specific detailed inspection requirements exist for animal products ([Directive 97/78/EC](#)). Products of animal origin must be presented at a Community border inspection post and submitted to an import control following prior notification of the shipment. The list of border inspection posts agreed for veterinary checks on animals and animal products from third countries and the list of animals and animal products that are subject to controls at border inspection posts can be accessed through our website at <http://useu.usmission.gov/agri/borderposts.html>. Fresh fruits and vegetables are subject to phytosanitary controls and are checked for compliance with EU-harmonized marketing standards (see section 7.J).

Product samples have to comply with the food regulations applicable in the EU. Exemptions exist for meat and meat products, for which a waiver may be obtained from the listing requirement described on <http://useu.usmission.gov/agri/certification.html>.

Inspection fees for non-animal origin products differ from one Member State to another. Measures in case of non-compliance also vary widely, ranging from non-admittance of a product to forced destruction. This may be a decisive factor in choosing a port of entry for products where problems are more likely.

Generally, there is no EU requirement to register imported foods except for the introduction of novel foods (see section 7.B). The person/company introducing a novel food has to 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 Commission's Health and Consumer Protection Directorate. Importers of organic products (see section 7.E) are required to notify the competent regulatory authority of the Member State of their activity. The introduction of foodstuffs with particular nutritional uses (see section 7.C) needs to be notified to the Member State where the food is sold. Exporters of vitamin-enriched foods or nutritional supplements are especially advised to check for the existence of specific Member State registration or notification requirements.

B. Certification and Documentation Requirements

http://useu.usmission.gov/agri/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 [GAIN report E47088](#). An update of this report will be

published in September 2007. Detailed information on certification is also available on our website at http://useu.usmission.gov/agri/Certification_Guide.html

SECTION VII. OTHER SPECIFIC STANDARDS

A. Genetically Modified Foods (GMOs)

<http://useu.usmission.gov/agri/GMOs.html>

Labeling regulations for GM food products are established by Regulation 1829/2003 (articles 12-13). These rules apply to products that have undergone varying degrees of processing. The regulation does not require labeling of food products that are not food ingredients, such as processing aids. Meat, milk or eggs obtained from animals fed with GM feed or treated with GM medicinal products do not require GM labeling.

The traceability rules require all business operators to transmit and retain information on GM products in order to identify both the supplier and the buyer of the GM product.

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. The transitional provision that allowed an adventitious presence level of 0.5 percent for GM varieties that received a positive EU risk assessment but are not yet formally approved expired in April 2007.

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

For more information see the 2007 Annual Agricultural Biotechnology Report ([GAIN report E47044](#)).

B. Novel Foods

<http://useu.usmission.gov/agri/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.

Proposal: On January 14, 2008, the European Commission presented a proposal to revise the current rules on novel foods. The proposal covers foods that have been produced using new techniques (such as animal cloning) and new technologies (such as nanotechnology) and foods which have a safe history of use in third countries (such as noni juice). Only foods included in the "Community list of novel foods" will be allowed on the EU market. For detailed information on the Novel Foods proposal see [GAIN Report E48014](#).

C. Fortified Foods

(<http://useu.usmission.gov/agri/foodsupplements.html>)

[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. Within two years of the regulation entering into force (by January 19, 2009), the Commission must submit a proposal on minimum and maximum levels. The use of vitamins and minerals not included in the annexes to Regulation 1925/2006 is not allowed. However, Member States may under certain conditions provide for a temporary derogation (until January 19, 2014) for vitamins and minerals not included in the annexes. Foods not complying with the new rules may be marketed until December 31, 2009, if they were put on the market or labeled before July 1, 2007 (date of entry into force of the regulation).

D. Dietetic or Special Use Foods

(<http://useu.usmission.gov/agri/partnutr.html>)

[Council Directive 89/398/EEC](#) is a framework directive laying 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 Directive 2001/15/EC](#) lists the chemical substances in

each category of nutritional substances (vitamins, minerals and amino acids) that may be added for specific nutritional purposes in foodstuffs for particular nutritional uses.

Provisions including compositional and hygiene requirements, provisions regarding the 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 (amended by [Commission Directive 2007/29/EC](#)).
- [Commission Directive 2006/141/EC](#) on infant formula and follow-on formula.
- [Commission Directive 1999/21/EC](#) on dietary foods for special medical purposes.

To take advantage of technological developments, the Commission may authorize the marketing of products, which do not comply with the requirements of the specific directives for a two-year period.

Specific directives on foods and beverages for sports people or on foods intended for diabetics are still subject to Member State legislation. The introduction of foodstuffs intended for particular nutritional uses for which no specific rules are set must be notified to the Member State where the food is sold. A list of competent Member State authorities can be downloaded at

http://ec.europa.eu/food/food/labellingnutrition/nutritional/list_auth_art9_en.pdf.

E. Wine, Beer and Other Alcoholic Beverages

(<http://useu.usmission.gov/agri/wine.html>)

On June 6, 2008, [Council Regulation 479/2008](#) reforming the Common Market Organization for Wine was published. Chapter VI of the new regulation lays down rules for the labeling and presentation of wine which will apply as of August 1, 2009. Measures necessary for the implementation of Chapter VI will be adopted at a later date. Until August 1, 2009, the date the new rules enter into force, rules laid down in [Council Regulation 1493/1999](#) will continue to apply.

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/2007/2007_02.html. The Agreement's "Protocol on Wine Labeling" sets conditions for the use of optional particulars on wine labels.

[GAIN report E36067](#) gives an overview of the mandatory information required on wine labels and lists the conditions for supplementing the mandatory information with optional information. 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/international_trade/us_ec_wine_agreement.htm).

[European Parliament and Council Regulation 110/2008](#) was published in February 2008 and entered into force on May 20, 2008. This new regulation lays down general rules on the definition, description and presentation of spirit drinks. Spirit drinks not meeting the requirements of the new regulation may continue to be marketed until May 20, 2009. There is no Community legislation for beer, although some member states have adopted national provisions to make the list of ingredients compulsory.

Alcoholic beverages containing sulphur dioxide and sulphites at concentrations of more than 10 mg/liter must be labeled "contains sulphites" or "contains sulphur dioxide". Replacing the word "sulphites" by "SO₂" or the E-number (E220) is not allowed. The list of authorized languages for allergen labeling can be consulted in [GAIN report E36066](#).

F. Organic Foods

(<http://useu.usmission.gov/agri/organic.html>)

[Council Regulation 834/2007](#) lays down a new legal framework for organic production and the labeling of organic products. Title IV of this new regulation lays down general rules for the labeling of organic products; Title VI covers trade with third countries. The use of an EU organic logo will become mandatory for products produced in the EU but will be optional for organic products from third countries. However, due to "technical" problems with the design, the use of a new EU organic logo will be delayed until July 2010. Detailed rules for the implementation of the new regulation will be adopted at a later stage. Regulation 834/2007 will enter into force on January 1, 2009 and repeal Council Regulation 2092/91. Until that date, [Council Regulation 2092/91](#) will continue to apply.

While organic standards have been set at the EU level, implementation and enforcement of the regulation is the responsibility of the individual member states. This Member State responsibility also extends to imports of organic products. In order to import U.S. organic products, EU importers must work through their designated member state authority to obtain an import authorization. These authorizations are granted on a case-by-case basis, subject to the member state's review of two main elements: the organic standards and inspection measures applied by the certifier of the product and the certifier's compliance with EN 45011 or ISO Guide 65.

The importer must demonstrate that the product was produced according to standards equivalent to the EU standards. In addition, the importer must provide evidence that the certifier of the product has been accredited to EN 45011/ISO 65 by an authority recognized by the member state. Individual member states may have different criteria for judging compliance with these requirements. In the U.S., USDA's Agriculture Marketing Service (AMS) has been designated as the competent authority to accredit U.S. organic certifiers for compliance with ISO 65.

Regulation 2092/91 provided for the possibility for Member States to grant import authorizations on a case-by-case basis until December 31, 2006. [Council Regulation 1991/2006](#) extended this possibility until the adoption of a new import regime.

Detailed rules for implementing the provisions concerning the certificate of inspection for import from third countries are laid down in [Commission Regulation 605/2008](#). Certifiers of U.S. organic products must use the EU certificate format for products to be exported to the EU. An original certificate must accompany the good and is verified at the border by the member state authorities. Goods are not released until the authorities have verified that a valid import authorization has been granted for the consignment. Member states have

several options for implementing the regulation, which means that procedures may differ from member state to member state.

Proposal: A proposal to replace the current national import authorization system with a new permanent import regime is being discussed. The new system would use technical equivalency evaluations to authorize imports from third countries. This proposal has not yet been published.

G. Vertical Legislation (Breakfast Directives)

(<http://useu.usmission.gov/agri/vertic.html>)

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

H. Animal Products

Beef Labeling (<http://useu.usmission.gov/agri/label>)

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

Labeling requirements for meat of bovine animals aged 12 months or less are laid down in [Council Regulation 361/2008](#) (an amendment to Regulation 1234/2007 – see "Other – Single CMO"). Bovine animals aged less than 12 months are classified in two categories: 1) bovine animals aged 8 months or less and 2) bovine animals aged more than 8 months but less than 12 months. Regulation 361/2008 lists the different sales descriptions for the two categories. [Commission Regulation 566/2008](#) lays down detailed rules (compulsory information on labels and trade with third countries) for the marketing of the meat of bovine animals aged 12 months or less.

Egg Marking

[Commission Regulation 589/2008](#) lays down detailed rules for implementing Council Regulation 1234/2007 (see "Other – Single CMO") as regards marketing standards for eggs. The U.S. currently only exports shell eggs to the EU for breaking and further processing in food processing facilities. Such eggs are graded as "class B" eggs under EU standards. According to EU interpretation of Article 30 of Regulation 589/2008, eggs imported from third countries, including eggs for processing, must be clearly and legibly marked in the country of origin in accordance with the ISO 3166 country code. In practice, this means

that each egg individually has to be marked "USA". [Commission Regulation 598/2008](#) provides, under strict conditions, for an exemption from the marking requirement. [Commission Regulation 617/2008](#) lays down rules for the marking of eggs for hatching.

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>.

Other (milk, milk products, spreadable fats, poultry meat and fishery products)

- Single CMO: [Council Regulation 1234/2007](#) replaces a number of specific commodity regulations and establishes a "Single Common Organization" of agricultural markets. As of July 1, 2008, Council Regulation 1898/87 on the protection of designations used in the marketing of milk and milk products and Council Regulation 2991/94 laying down standards for spreadable fats will be repealed and replaced by the provisions laid down by Council Regulation 1234/2007.

- [Commission Regulation 543/2008](#) lays down detailed rules for implementing Council Regulation 1234/2007 (single CMO) as regards the marketing standards for poultry meat.

- [Council Regulation 2406/96](#) of 26 November 1996 laying down common marketing standards for certain fishery products

Product briefs on seafood and pet food can be found on our website at <http://useu.usmission.gov/agri/seafood2.html> and <http://useu.usmission.gov/agri/petfood.html>.

I. Frozen Foodstuffs

(<http://useu.usmission.gov/agri/frozen.html>)

[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".

J. Irradiated Foodstuffs

(<http://useu.usmission.gov/agri/irradiation.html>)

Harmonization of EU rules on food irradiation has been slow and only a few products have so far received EU-wide approval.

[Framework Directive 1999/2/EC](#) outlines the marketing, labeling, import and control procedures and technical aspects of food irradiation. Irradiated foods must be labeled "irradiated" or "treated with ionizing radiation".

[Implementing Directive 1999/3/EC](#) establishes a Community list of foods and food ingredients authorized for irradiation treatment. The list contains only one food category: "dried aromatic herbs, spices and vegetable seasonings". Until the positive list is expanded, the national authorizations listed on our website continue to apply.

K. Fruits and Vegetables

(<http://useu.usmission.gov/agri/Fruit-Veg.html>)

Fresh fruits, vegetables and nuts are 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 our 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.

Proposal: A European Commission proposal to simplify EU rules on marketing standards for fruits and vegetables is current being discussed. The Commission wants to replace a number of specific regulations with one basic rule and keep specific rules for apples, citrus fruit, kiwifruit, lettuce and endives, peaches, pears, strawberries, sweet peppers, table grapes and tomatoes.

L. Seafood

(<http://useu.usmission.gov/agri/seafood2.html>)

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 February 2008 update of the "How to export seafood to the European Union" guide which can be downloaded from

<http://useu.usmission.gov/agri/How%20to%20export%20seafood2008.pdf>.

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.

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. Applications for registering Community trademarks under these regulations may be filed with the Alicante, Spain, based Office of Harmonization for the Internal Market, subject to the fees set out in Commission Regulation 2869/95, or at a national industrial property office in a Member State of the European Union.

On completion of the registration procedure, the trademark is registered in the Register of Community trademarks.

The Community Trademark did not replace the existing trademark laws of the member states, for which a need will continue to exist, but co-exists alongside national trademarks. [Council Directive 89/104/EEC](#) approximates national trademark rules as regards what can and cannot be registered, the exclusivity of rights and conditions under which trademark rights can be forfeited.

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. [Commission Regulation 2454/93](#) lays down provisions for the implementation of the 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 which means that all the Member States apply the same tariff on goods imported from outside the EU. Once an imported good is cleared in one Member State, it can move freely throughout the EU.

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/tarhome_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. A list of customs authorities can be found at http://ec.europa.eu/taxation_customs/common/links/customs/index_en.htm. The customs value of a good is the CIF price at the European border derived from the product price found on the invoice and the transportation costs reflected in the airway bill or the bill of lading.

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.

Other customs procedures described in detail in the Code include entry into free zones, situations where no import duty is payable: e.g. the inward processing regime, under which goods can be imported for processing but the finished product must be exported from the Community market. The Code also provides for a two-stage right of appeal lodged in the

Member State where a decision has been taken or applied for: in the first instance to the customs authority, then to the national courts.

Proposal: A proposal establishing rules for the implementation of a "Modernized Customs Code" (MCCC) is expected to be finalized and adopted by the beginning of 2009. The MCCC would simplify existing legislation through promoting the concept of "centralized clearance" and the development of "Single Window" and "One-Stop-Shop" concepts.

APPENDIX I. GOVERNMENT REGULATORY AGENCY CONTACTS**Commission of the European Communities**

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
Organization chart: <http://useu.usmission.gov/agri/staff.html>
Mailing address:
27 Boulevard du Regent
1000 Brussels
Belgium
Tel: (32-2)508-2760
Fax: (32) (2) 511-0918
e-mail: AgUSEUBrussels@fas.usda.gov

Other FAS Offices in the European Union <http://useu.usmission.gov/agri/FAS-in-EU-27.html>

USDA/FDA contacts for certification of animal products

<http://useu.usmission.gov/agri/certification.html>

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

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

APPENDIX II. HOW TO OBTAIN LEGISLATION

<http://useu.usmission.gov/agri/legis.html>

The Official Journal (<http://europa.eu.int/eur-lex/lex/JOIndex.do?ihmlang=en>)

The Official Journal is the EU equivalent to the U.S. Government's "Federal Register". The L (Legislation) and C (Information and Notices) series of the Official Journal are published daily in all the official languages of the EU.

Legislation in force (<http://eur-lex.europa.eu/en/legis/index.htm>)

The texts are arranged under twenty main chapter headings. Legislation relating to agriculture, biotechnology, organic farming, foodstuffs, etc. can be found under heading 03 "Agriculture" and heading 15 "Environment, Consumers and Health Protection". On this site you can find the initial legislation and all the amendments as published in the Official Journal. The Directory also gives access to **consolidated texts**, which have no legal value but which integrate a basic instrument of Community legislation with its subsequent amendments and corrections in a single text.

APPENDIX III. EU INITIATIVES

This report gives an overview of EU food laws currently in force. However, below follows a list of EU proposals / initiatives that may possibly affect U.S. food exports to the EU:

- Acrylamide
- Additives
- Animal welfare labeling
- Enzymes
- Food contact materials
- Functional foods
- Geographical Indications
- Novel foods
- Nutrition labeling
- Organic food
- Pesticides
- Pet food
- Review of labeling rules
- Sweeteners

Please check our website (<http://useu.usmission.gov/agri/usda.html>) for updates and report on legislative developments. You can also subscribe to our e-newsletter "What's new on the USEU Agric Website" by sending an e-mail to Hilde.Brans@fas.usda.gov.

APPENDIX IV. WEBSITE LINKS & GUIDANCE DOCUMENTS

EUROPEAN COMMISSION:

- DG Health & Consumers: http://ec.europa.eu/dgs/health_consumer/index_en.htm
- DG Agriculture: http://ec.europa.eu/agriculture/index_en.htm
- DG Taxation & Customs Union: http://ec.europa.eu/taxation_customs/index_en.htm

EU Decision-Making Procedures:

- http://eur-lex.europa.eu/en/droit_communaute/droit_communaute.htm

European Food Safety Authority (EFSA):

- http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_home.htm

U.S. Mission to the EU:

- Foreign Agricultural Service: <http://useu.usmission.gov/agri/usda.html>
- Foreign Commercial Service: <http://www.buyusa.gov/europeanunion/>

FAIRS Reports:

- <http://useu.usmission.gov/agri/fairs.html>

GUIDANCE DOCUMENTS:

- EU general food law – implementation guidelines:
http://ec.europa.eu/food/food/foodlaw/guidance/guidance_rev_7_en.pdf
- How to read a food label:
http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/publications/leaflet_EN6_1211_2007_web.pdf
- Food traceability factsheet:
http://ec.europa.eu/food/food/foodlaw/traceability/factsheet_trace_2007_en.pdf
- Pesticide residues:
http://ec.europa.eu/food/plant/protection/resources/publications_en.htm
- EU rules on wood packaging material:
http://ec.europa.eu/food/plant/organisms/imports/overview_eu_rules.pdf
- Food contact materials - a practical guide:
http://ec.europa.eu/food/food/chemicalsafety/foodcontact/practical_guide_en.pdf
- Questions and answers on the regulation of GMOs in the EU:
http://ec.europa.eu/food/food/biotechnology/gmfood/qanda_en.pdf
- GM guidelines for the European Food & Drink Industries:
<http://www.ciaa.eu/documents/brochures/GM%20guidelines.pdf>
- EFSA guidance document on health claims:
http://www.efsa.europa.eu/EFSA/KeyTopics/efsa_locale-1178620753812_NutritionAndHealthClaims.htm
- Vitamins & minerals – guidance on submissions for safety evaluations:
http://ec.europa.eu/food/food/labellingnutrition/nutritional/adm_guidance_safety_substances_en.pdf