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Food and Agricultural Import Regulations and Standards

European Union Report

2007

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Report Highlights:
This report gives a complete overview of food laws currently in force in the EU-27. The following sections were updated: food laws, allergen labeling, language requirements, health claims, packaging, additives, pesticides, contaminants, residues in animal products, inspections, novel foods, fortified foods, special use foods, alcoholic beverages, organic foods, beef labeling, egg marking. NEW: European Commission proposals which may have an impact on U.S.exports are now also included.

Includes PSD Changes: No
Includes Trade Matrix: No
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DISCLAIMER: This report was prepared by the Office of Agricultural Affairs, 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 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 1. 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 advise 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/foodsafe.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.eu.int) 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 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 2. 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 phyostanols and licorice.

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 therof" 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 new 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. Directive 2005/26/EC establishes a list of allergen derivatives that, based on the European Food Safety Authority's risk assessments, are temporarily exempted (until November 25, 2007) from mandatory labeling. A decision to permanently exempt these allergen derivatives from labeling will be taken in October 2007. For more information on the implementation of the allergen labeling rules see GAIN report E35196.

- 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 requires standardized statements on the label; packaging gases are not considered as additive but also require a standardized statement.

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.

Licorice

Commission Directive 2004/77/EC lays down specific rules for the labeling of confectionery and beverages containing glycyrrhizinic acid and its ammonium salt (licorice).

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 is available on our website at http://useu.usmission.gov/agri/label.html.

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

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 within two years of the regulation entering into force, 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 use of nutrition claims which 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.

A list of well-established health function claims such as “calcium is good for your bones” will be established within three years of the regulation entering into force, 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. EFSA has published a first set of "pre-submission" guidelines addressing a number of questions related to applications for health claims authorizations. The guidelines provide information on health claim authorizations falling under the scope of article 14 of Regulation 1924/2006 (disease risk reduction claims and children's development and health) and article 18 (claims that are not included in the EU positive list, based on newly developed science). EFSA guidelines can be downloaded at http://www.efsa.europa.eu/en/science/nda/Pre_submission_guidance.html.

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.

Proposal: On June 28, 2007, the European Commission published a proposal to amend Regulation 1924/2006. As claims referring to children's development and health were already used before the adoption of Regulation 1924/2006, the proposal provides for a three-year transitional period to allow industry to adapt to the new rules, either by phasing out products which do not meet the new criteria or by applying for claim authorization. The proposal has to be adopted under the co-decision procedure.

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, eggs, dairy products, spreadable fats
- seafood

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

SECTION 3. PACKAGING AND CONTAINER REQUIREMENTS

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

A. Container Contents

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.

Currently, consumer products are sold in quantities that were determined by the EU in the 1970's. Council Directive 75/106/EEC prescribes container sizes for liquid products: wine, beer, spirits, vinegar, edible oils, milk and milk based beverages, waters and fruit juices. Council Directive 80/323/EEC prescribes pack sizes for butter, fresh cheeses, salt, sugar, breakfast cereals, pasta, rice, dried fruits and vegetables, coffee, frozen fruits and vegetables, fish fillets, fish fingers, ice cream, preserved fruits and vegetables and products sold in metal containers.

Proposal: In 2004, the European Commission presented a proposal to repeal the existing rules on pack sizes. This proposal will free sizes for all pre-packed products (except wine and spirits, soluble coffee and white sugar) by repealing Directives 75/106/EEC and 80/232/EEC and extend the scope of Directive 76/211/EEC to all pre-packed products. Adoption of the proposal is expected by the end of 2007.

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 (except for the provisions on traceability which will apply from 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. 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 4. FOOD ADDITIVE REGULATIONS

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

Council Directive 89/107/EEC 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 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. This register has been updated by Commission Decisions 2004/357/EC and 2005/389/EC.

*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**. Adoption under the co-decision procedure is expected by the end of 2007.*

SECTION 5. 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

Council Directive 91/414/EEC on the placing of plant protection products on the market sets out rules for the registration of a new pesticide active substance, including the establishment of maximum residue levels (MRLs). Pesticides that were already on the EU market when Directive 91/414 was adopted are undergoing a review. For each active substance, the status of the EU review process can be checked online. The currently ongoing legislative initiatives in the area of pesticides are resulting in a drastic reduction of the number of active substances and MRL's are being harmonized throughout the EU.

Current EU pesticide MRL legislation is based on the following directives: Council Directive 86/362/EEC establishing MRLs for pesticides in cereals and cereal products, Council Directive 86/363/EEC establishing MRLs for pesticides in products of animal origin and Council Directive 90/642/EEC establishing MRLs for pesticides in products of plant origin, including fruits and vegetables. 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).

EU pesticide legislation has not been fully harmonized yet and is still under review. Community MRLs take into account the work done by Codex Alimentarius and by the OECD but exceptions exist. Certain pesticides for which no harmonized MRL has been established are covered by Member State legislation. A list of contact points in the Member States, the European Commission and the European Food Safety Authority (EFSA) is available at http://ec.europa.eu/food/plant/protection/evaluation/contact_points.xls. If there is no EU legislation in place but there is a national MRL for a specific pesticide/commodity combination in the importing Member State and the product being imported into that country conforms with it, then the product can be marketed in that country. Importers wishing to market the product in other Community Member States may face problems.

If there is no EC legislation in place and there is no national MRL in force in the importing Member State, then the exporter needs to obtain an "import tolerance". Application dossiers are first submitted to a Rapporteur Member State (RMS). Information on import tolerances can be obtained from http://www.pesticides.gov.uk/applicant_guide.asp?id=1239

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.

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. The new regulation entered into force on March 1, 2007 and repeals Commission Regulation 466/2001. Annex I of Regulation 1881/2006 includes maximum levels for nitrates, mycotoxins, heavy metals, dioxin, 3-MCPD and polycyclic aromatic hydrocarbons (PAH) in foodstuffs (see Table 1).

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
- Fumonisins 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
- 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, 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.	

Proposal: Special measures for testing U.S. almonds on aflatoxin are anticipated to go into effect on September 1, 2007. These special measures imply that product which has not been tested for aflatoxin under the U.S. Voluntary Aflatoxin Program (VASP) will become subject to 100 percent mandatory testing upon import into the EU, while product that was tested in the U.S. under the VASP will be subject to approximately five percent testing at EU border. The most recent information on the VASP is available from the Almond Board's website at http://www.almondboard.com (Almond Board Programs – Food Quality & Safety). The proposal has been adopted but not yet published in the Official Journal.

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 6. 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 E36071. 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 7. 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. 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. 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.

The European Commission is preparing a "Novel Food Catalogue" that will provide orientation/information about whether foods and food ingredients require authorization under the Novel Food Regulation. The document will be a "living database" updated with information provided to and by the Member States. The catalogue is expected to be published by the end of 2007.

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, the Commission must submit a proposal on minimum and maximum levels. The use of vitamins and minerals not included in the annexes to the new regulation will not be allowed. 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 regulati0n).

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)

Wine labeling rules are laid down in Annex VII to Council Regulation 1493/1999, the EU's basic wine regulation. Commission Regulation 753/2002 lays down rules for applying the provisions contained in regulation 1493/1999, which relate to the description, designation, presentation and protection of certain wine sector products.

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 a certification document using the format specified in Annex III(a) to the Agreement. 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).

Council Regulation 1576/89, as amended, lays down the general rules on the definition, description and presentation of spirit drinks. 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 "SO_2" or the E-number (E220) is not allowed. The list of authorized languages for allergen labeling can be consulted in GAIN report E36066.

Proposal: In December 2005, the European Commission tabled a proposal on the definition, description, presentation and labeling of spirit drinks. The final text of the controversial proposal was published on April 7, 2007, and establishes two categories of vodka: 1) vodka made from potatoes and/or cereals and 2) vodka made from other agricultural raw materials. The raw material used to produce any vodka that is not made from potatoes and/or cereals must be clearly indicated on the label using the expression "produced from …". The proposal was notified to the WTO on June 5, 2007(Notification G/TBT/N/EEC/157). The proposal has to be adopted under the co-decision procedure.

F. Organic Foods

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

Council Regulation 2092/91, as amended, on organic products covers the following requirements and definitions: production and processing methods, labeling and marketing, inspection and imports from third countries. It was supplemented by Regulation 1804/99 to include livestock production. The term "organic" on the label may only be used for product complying with these regulations.

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' Agriculture Marketing Service (AMS) has been designated as the competent authority to accredit U.S. organic certifiers for compliance with ISO 65. To date, Austria, Netherlands, Denmark, Spain, Sweden, United Kingdom and certain German states have officially recognized AMS' ISO 65 accreditation.

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 extends this possibility until a new import regime is being adopted.

Commission Regulation 1788/2001 lays down detailed rules for a certificate of inspection for imports from third countries. 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: 1) In December 2005, the European Commission tabled a proposal for a new regulation on organic production and labeling of organic products. Organic products imported from third countries would be allowed to carry the EU-logo if the

country of origin is indicated on the label. The proposal also creates a basis for adding rules on organic aquaculture, wine, seaweed and yeasts. The proposal is adopted but not yet published in the Official Journal.

2) 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

Council Regulation 700/2007, which will enter into force on July 1, 2008, lays down rules for the marketing of meat of bovine animals aged 12 months or less.

Egg Marking

Commission Regulation 557/2007, which entered into force on July 1, 2007, lays down rules for implementing Council Regulation 1028/2006 on 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 557/2007, 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".

Other

- Council Regulation 1029/2006 of 26 June 1990 on certain marketing standards for poultry
- Council Regulation 1898/87 limits the use of the word “milk” or other dairy products to actual dairy products
- Council Regulation 2991/94 establishes standards for spreadable fats (implementing rules are laid down in Commission Regulation 445/2007)
- 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

(hhtp://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.

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 2007 update of the “How to export seafood to the European Union” guide which can be downloaded from http://www.nmfs.noaa.gov/sfa/PartnershipsCommunications/tradecommercial/documents/eucontents.pdf.

SECTION 8. 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 9. 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 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/en/tarhome.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. A list of customs authorities can be found on the Internet 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.

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

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
- Novel foods
- Nutrition labeling
- Organic food
- Pack sizes
- Pesticides
- Review of labeling rules
- Spirit drinks
- 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 bi-weekly e-newsletter "What's new on the USEU Agric Website" by sending an e-mail to Hilde.Brans@fas.usda.gov.