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GAIN Report

Global Agricultural Information Network

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EU-27

Food and Agricultural Import Regulations and Standards - Narrative

FAIRS Country Report

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Report Highlights:

This report updates each of the nine sections and provides an overview of food laws currently in force in the EU-27. In order to facilitate the reading of this report, updates specific to 2011 have been highlighted. European Commission proposals/initiatives which may have an impact on U.S. exporters are also included. Information published on the USEU/FAS website will be transferred to a new website in the first half of 2012.

SUMMARY

In order to facilitate the reading of this report, updates and legislative proposals which may affect U.S. exports are being presented as follows:

- Regulations that were published in 2011 and measures that went into force in 2011 have been **highlighted in blue**

- Legislative proposals and initiatives are presented in text boxes with a yellow background

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SECTION I. FOOD LAWS

The European Union (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 500 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. Croatia will become the 28th EU Member State on July 1, 2013. Iceland, the Former Yugoslav Republic of Macedonia and Turkey are candidates to join the EU.

All EU Member countries accept the "acquis", i.e. 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. These reports can be downloaded from the FAS website at <http://gain.fas.usda.gov/Pages/Default.aspx>.

The main principle of the single market concept is the "principle of mutual recognition" 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. There is one exception to this principle: certain directives allow Member States to make exceptions e.g. in cases where a country can prove public safety, health or environmental concerns about a product intended for import. [Regulation 764/2008](#), adopted in July 2008, sets out the procedural requirements for denying mutual recognition and defines the rights and obligations of national authorities on the one hand and enterprises on the other. 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 have not yet been finalized. Imported products must meet existing Member State requirements in cases where EU regulatory harmonization is not yet complete.

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.). EU food legislation is characterized by a constant flow of new regulations and directives, amendments to existing legislation and implementation rules. EU laws are translated into the 23 official languages in use in the EU-27 and published chronologically in the Official Journal. Directives define the result that must be achieved but leave to each Member State the choice of form and methods to transpose the directive into national laws (usually within 2-3 years after adoption). Regulations are binding in their entirety and automatically enter into force on a set date in all Member States. Amendments to EU legislation are usually published in new and separate Directives and Regulations, making it difficult to be sure of all possible amendments when doing research. Consolidated texts, i.e. the consolidation of a basic legal act and subsequent amendments into one text, are available on the European Commission's website but come with a warning that they are not legally binding. When legislation is referenced in this guide, it is implied that all further amendments also apply. Where possible, this guide links directly

to the consolidated versions of referenced EU legislation. The Eurlex website (<http://eur-lex.europa.eu/en/index.htm>) provides free access to European Union law.

In the context of "Better Regulation" the EU is in the process of carrying out a "rolling simplification program." The main objectives of this program are the simplification of existing EU law and the introduction of a new regulatory approach. One of the main simplification tools consists in substituting directives with regulations. Under this new approach, the use of regulations instead of directives should help eliminate the diverging interpretations by the different Member States and as regulations are directly applicable, Member States no longer need to go through the lengthy process of transposing into national laws. Another simplification tool is the codification and consolidation of legal acts and their amendments into a single text which is legally binding once published in the Official Journal.

In the aftermath of the BSE crisis and several other food scandals in the late 1990s, 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 this 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 and the creation of a framework for harmonized food controls. The regulations on general food law, food and feed controls, food and feed hygiene are the framework regulations for the EU's food safety system. Revisions of existing EU food regulations or new regulations all implement the principles contained in the framework regulations.

For ethical issues, the Commission has given a mandate to the "European Group on Ethics" (EGE) to provide advice on ethical questions relating to sciences and new technologies. EGE delivers opinions on the ethical implications of modern developments in agriculture technologies. Its mandate is renewed every five years.

There are three main institutions involved in developing policies and passing legislation that applies throughout the EU: the European Commission, the Council of Member State representatives and the European Parliament. In principle, the Commission proposes new laws and the Council and European Parliament adopt them under the "Ordinary Legislative Procedure" (ex co-decision). The Member States then implement them and the Commission ensures that EU laws are properly applied and implemented. The European Food Safety Authority (EFSA) is responsible for providing scientific advice to the legislators on matters related to food safety. As of November 2011, EFSA's "Applications Helpdesk" acts as a front office and support desk for applicants who have questions regarding applications in the following scientific areas: animal by-products, decontamination substances, feed additives, food contact materials, food ingredients, food processing, agricultural biotechnology products, nutrition and pesticides. For more information see <http://www.efsa.europa.eu/en/applicationshelpdesk.htm>.

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 may be variations 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.

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, animal casings and animal by-products to the EU from the U.S. may only originate from EU approved U.S. establishments.

For more information see

http://ec.europa.eu/food/food/biosafety/establishments/third_country/index_en.htm.

SECTION II. LABELING REQUIREMENTS

<http://www.fas.usda.gov/posthome/useu/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 pre-packaged 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 VII covers labeling requirements for specific products, including genetically modified and novel foods.

Compulsory Information:

The compulsory information must appear on the pre-packaging or on a label attached to it. The information must be marked in such a way that it is easily visible, clearly legible and indelible. The following information is mandatory on labels:

- 1) The name under which the product is sold.
- 2) The list of ingredients, in descending order of weight. A) Important exceptions include added water in foods reconstituted from concentrates, and cheese, which is covered by special rules. B) The following ingredients require a specific statement on the label: GMO's, packaging gases, sweeteners, certain food colorings, aspartame and polyols, quinine and caffeine, phytosterols and phyosteranols and licorice.
- 3) Allergens: Annex IIIa to Directive 2000/13/EC lists the groups of potential allergenic ingredients which 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, lupin and products thereof, mollusks and products thereof and sulphite at concentrations of at least 10 mg per kg or 10 mg/l, celery, and mustard. Allergen labeling also applies to alcoholic beverages. [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.

A temporary derogation from the EU requirement that wines fined with egg and milk derivatives must be labeled for allergens was set to expire on December 31, 2010 but has been extended until June 30, 2012.

- 4) 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, wine and meat preceded by the name(s) of the animal species from which it comes.
- 5) The quantity of certain ingredients or categories of ingredients (QUID) – see below.
- 6) The net quantity of prepackaged foodstuffs expressed in metric units (liter, centiliter, milliliter, kilogram or gram).
- 7) 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 minimum durability date is replaced by the "use by" date consisting of the day, the month and possibly the year (articles 9-10 of Directive 2000/13/EC). Detailed information can be found in the ["Guidance on the application of date labels to food"](#) published by the U.K.'s Department for Environment, Food and Rural Affairs (defra).
- 8) Any special storage conditions or conditions of use.
- 9) The name or business name and address of the manufacturer or packager, or of the seller established within the Community.
- 10) Particulars of the place of origin or provenance in case absence of such information might mislead the consumer.
- 11) Instructions for use.
- 12) The actual alcoholic strength for beverages containing more than 1.2 percent alcohol by volume.
- 13) 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. Foods marked with a "Best Before" or "Use By" date that consists of at least the Day and Month are exempt from the lot marking requirement. Food marked with a "Best before End" date with Month and Year only does not qualify for exemption. (Directive 89/396/EEC)
- 14) 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 Report 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. Specific requirements for the use of the term "natural" to describe a flavoring are set out in Article 16 of [European Parliament and Council Regulation 1334/2008](#).

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 (Article 7 of Directive 200/13/EC):

- 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.

Warnings on Labels

[Commission Directive 2008/5/EC](#) establishes a list of foodstuffs that require a warning on the label:

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

Starting July 20, 2010, [Regulation 1333/2008](#) (see section IV) requires foodstuffs containing the food colors sunset yellow (E110), quinoline yellow (E104), carmoisine (E122), allura red (E129) and ponceau 4R (E124) to be labeled "may have an adverse effect on activity and attention in children".

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



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
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Austria	German
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://www.fas.usda.gov/posthome/useu/fairs.html>).

Labeling of Genetically Modified Foods

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

B. Medical / Health / Nutrition Claims

<http://www.fas.usda.gov/posthome/useu/claims.html>

[European Parliament and Council 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. In order to carry a claim, foods must fit a certain “nutrient profile” (below certain salt, sugar and/or fat levels).

The development of nutrient profiles, originally scheduled for January 2009, has not been finalized yet. The European Commission is still working on a proposal but a timeline is not yet available. Once the nutrient profiles, based on scientific evaluations by the European Food Safety Authority (EFSA), have been set, there will be another two-year period before the nutrient profiles begin to apply to allow food operators time to comply with the new rules. Nutrition claims can fail one criterion, i.e. if only one nutrient (salt, sugar or fat) exceeds the limit of the profile, a claim can still be made provided the high level of that particular nutrient is clearly marked on the label. For example, a yogurt can make a low-fat claim even if it has a high sugar content but only if the label clearly states “high sugar content”. Health claims cannot fail any criteria.

In December 2011, the European Commission proposed a list of 222 functional health claims. The proposed list includes generic claims for substances other than botanicals and will be submitted to the European Parliament and Council for scrutiny. If no objections are raised within three months, the list will be published in the Official Journal and included in the online EU Register. Botanical claims are being placed on hold and will be assessed at a later stage. Disease risk reduction claims and claims referring to the health and development of children 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.

Only nutrition and health claims included in one of the EU positive lists may be used on food labels. The EU Register of nutrition and health claims on foods can be consulted online at http://ec.europa.eu/food/food/labellingnutrition/claims/community_register/index_en.htm. Some sections of the Register are missing but will be completed as appropriate. Food products carrying claims must comply with the provisions of [nutritional labeling directive 90/496/EC](#).

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

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

Proposal: The European Commission is proposing to add two new nutrition claims to the EU positive list: 1) “now contains X% less of [energy, fat, saturated fat, sodium/salt and/or sugars] to allow for commercial communication of reformulation initiatives 2) “no added salt” if the natural content of sodium is low. The proposal will likely be adopted in January 2012.

Requirements Specific to Nutrition Labeling

Nutrition labeling is not mandatory in the EU unless a nutrition claim is made on the label or in advertising messages. Nutrition labeling rules are laid down in [Council Directive 90/496/EEC](#). "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 as defined in the Annex to Directive 90/496/EC. The nutrition labeling rules do not apply to food supplements and natural mineral waters.

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. Nutritional information may also include the amounts of starch, polyols, mono-unsaturates, poly-unsaturates, cholesterol and any of the vitamins listed in the Annex to Directive 90/496/EC. Information on vitamins and minerals must be expressed in units specified in the Annex and 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. Examples of the nutrition information panel can be found in a [leaflet](#) published by the EU's Food & Drink Industry Confederation.

In October 2008, Council Directive 90/496/EEC was amended by [Commission Directive 2008/100/EC](#). Commission Directive 2008/100/EC updates the list of vitamins and minerals and their Recommended Daily Allowances (RDAs) and provides an EU definition of "fiber". The conditions for the use of nutrition claims such as "source of fiber" or "high fiber" are laid down in Regulation 1924/2006 (see nutrition and health claims).

C. Product-Specific Labeling

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

- genetically modified foods
- novel foods
- fortified foods
- foodstuffs for particular nutritional uses including dietetic and baby/infant foods
- beef
- wine
- spirit drinks
- olive oil
- organic foods

- cocoa and chocolate products, sugars, honey, fruit juices and similar products, preserved milk
- coffee extracts and chicory extracts, fruit jam, jellies, marmalades and chestnut puree
- fresh fruits and vegetables
- meat, poultry, eggs, dairy products, spreadable fats
- seafood
- pet food

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

D. Country of Origin Labeling

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

NEW! On October 25, 2011, a new EU regulation on the provision of **food information to consumers** was adopted. The new regulation, [European Parliament and Council Regulation 1169/2011](#), was published in Official Journal L 304 on November 22, 2011. The new EU labeling requirements will apply from December 13, 2014 except for the mandatory nutrition declaration which will apply from December 13, 2016. Detailed information on the new labeling rules will be provided in a separate GAIN report.

SECTION III. PACKAGING AND CONTAINER REQUIREMENTS

<http://www.fas.usda.gov/posthome/useu/packaging.html>

A. Size & Content

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

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

[Directive 2007/45/EC](#) 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. It also sets out labeling and 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 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 [plastic materials \(Commission Regulation 10/2011\)](#), [recycled plastic materials \(Commission Regulation 282/2008\)](#), [regenerated cellulose film \(Commission Directive 2007/42/EC\)](#) and [ceramics \(Council Directive 84/500/EC\)](#). In the case of ceramics, migration limits have been established for lead and cadmium. Materials must bear an indication "for food contact" or the

symbol reproduced in Annex II to Regulation 1935/2004. [Commission Implementing Regulation 321/2011](#) restricts the use of Bisphenol A in plastic infant feeding bottles.

[Commission Regulation 450/2009](#) sets out definitions and authorization procedures for the use of active and intelligent materials and articles intended to come into contact with food. An [EU guidance document](#) on active and intelligent food contact materials is available on DG Sanco's website.

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

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.

For more information on specific substances, check out the [Food contact materials database](#).

DG Sanco's webpage on food contact materials also provides guidance documents and contact information with regard to the submission of applications for authorization: http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents_en.htm

SECTION IV. FOOD ADDITIVE REGULATIONS

<http://www.fas.usda.gov/posthome/useu/additive.html>

The “Package on Food Improvement Agents” includes four regulations: [Regulation 1331/2008](#) establishing a common authorization procedure for food additives, food enzymes and food flavorings, [Regulation 1332/2008 on food enzymes](#), [Regulation 1333/2008 on food additives](#) and [Regulation 1334/2008 on flavorings](#).

Additives (including colors and sweeteners)

[European Parliament and Council Regulation 1333/2008](#) setting out the rules for the use of food additives, has been in effect since January 20, 2010. This regulation provided for a revision of the food additives approved under the old directives in order to establish an EU positive list of food additives including colors and sweeteners.

[Commission Regulation 1129/2011](#) establishes a list of all authorized food additives in foodstuffs as well as the conditions of use and amends Annex II to Regulation 1333/2008. Only additives placed in Annex II will be authorized for use in food products sold on the EU market. Regulation 1129/2011 will apply as of June 2013 in order to allow the Union's food industry to adapt to the new rules. [Commission Regulation 1130/2011](#) establishes a second list of food additives and amends Annex III to Regulation 1333/2008. This list concerns additives approved for the use in food ingredients such as other food additives, food enzymes, food flavorings and nutrients. Regulation 1130/2011 applies since December 2, 2011 but a transitional period of 24 months applies to preparations not complying with Parts 2, 3 and/or Section A of Part 5 of Annex III and until May 31, 2013 for preparations not complying with Parts 1 and 4 of Annex III. Until Annexes II and III become fully applicable, food additives approved under the old directives will continue to be permitted. The authorized uses of additives are from now on listed according to the category of food to which they may be added. The new legislation also provides for clear conditions under which additives may be added to food.

[Commission Regulation 1131/2011](#) approves the sweetener steviol glycosides, commonly known as [stevia](#), which is extracted from the leaves of the Stevia Rebaudiana Bertoni plant. Stevia's approval for its use in several food categories will allow industry to innovate and to develop new products. Annex II to Regulation 1333/2008 is amended accordingly.

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

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

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

For an overview of the rules in force until the new regulation becomes applicable see the [2008 FAIRS report](#) (GAIN report E48078). An important difference from U.S. legislation is the use of flour bleaching agents: chlorine, bromates and peroxides are not allowed in the EU.

See also the Commission's [food additives database](#) which contains all necessary information on the different food additives allowed in the EU.

Flavorings

[Regulation 1334/2008](#) on flavorings and certain food ingredients with flavoring properties sets specific rules for the use of the term "natural". [The new rules went into force on January 20, 2011](#). The [register of all flavoring substances](#), as last amended by [Commission Decision 2009/163/EC](#), authorized in the EU is being reviewed before inclusion in Annex I of the new Regulation as the community list of authorized substances. [Regulation 2232/96](#), currently still in force, will be repealed when the new list is published. Substances that are subject to restrictive or prohibitive measures in certain member states have been marked.

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

Enzymes

[Regulation 1332/2008](#) on food enzymes introduces harmonized rules for their scientific evaluation and authorization in the EU and establishes labeling requirements. Until the adoption of an EU positive list of authorized enzymes, the existing national provisions on the marketing of food enzymes will continue to apply. [Regulation EC 234/2011 regarding the implementation of the common authorization procedure](#) sets out a deadline of two years starting from September 11, 2011, to submit applications on existing and new enzymes and for industry to provide the information for the risk assessment.

Processing Aids

Processing aids are subject to Member States national legislation. EU harmonized rules exist only for certain categories of processing aids: a list of extraction solvents allowed in the production of foodstuffs and food ingredients, along with their conditions of use has been established in Council [Directive 2009/32/EC](#) (last amended by [Directive 2010/59/EC](#)).

SECTION V. PESTICIDES AND CONTAMINANTS

Pesticides

<http://www.fas.usda.gov/posthome/useu/pesticides.html>

[European Parliament and Council Regulation 1107/2009](#) sets out new rules for the authorization of plant protection products (PPPs) and replaces Directive 91/414/EEC. It entered into force at the end of December 2009 and became fully applicable on June 14, 2011. This Regulation establishes a list of approved active substances. Only PPPs containing active substances included in the list may be authorized for use in the EU. Member States can approve PPPs containing the active substances. According to the new Regulation, the EU is divided in three different zones. Once a Member State approves the PPP it can be mutually recognized and thus authorized within the same EU zone as set out in Annex I of the Regulation.

The Maximum Residue Levels (MRLs) for substances not on the list will be set at default level of 0.01 mg/kg.

The legislation allows exporters to request an "import tolerance" for active substances not yet evaluated or in use in the EU.

Maximum Residue Limits

Since September 2008 all MRLs in the EU have been harmonized by [European Parliament and Council Regulation 396/2005](#) on food or feed of plant and animal origin. Pesticide MRLs for processed or composite products are based on the MRLs of the raw agricultural ingredients. See [DG SANCO's webpage](#) for the latest updates.

Annex I lists the commodities to which MRLs apply.

Annex II contains existing MRLs that were already harmonized at EU level and replaces the EU's old MRL Directives.

Annex III lists EU "temporary" MRLs or pesticides for which, before September 1, 2008, MRLs were only set at national level. It specifies MRLs for 471 pesticides.

Annex IV lists the substances for which no MRLs are required and so are exempt from tolerance products.

Annex V will contain the list of pesticides for which a default limit other than 0.01 mg/kg will apply. This Annex has not been published yet. Pesticide MRLs for processed or composite products are based on the MRLs for the raw agricultural ingredients.

Annex VI will contain the list of conversion factors of MRLs for processed commodities. This Annex has not been published yet.

Annex VII contains a list of pesticides used as fumigants for which the Member States are allowed to apply special derogations before the products are placed on the market.

Annex VIII contains active substance and product combinations for which Member States may authorize residue levels that exceed the limits set in Annex II and III.

For a list of authorized active substances or pesticide-MRL combinations, see: [DG Sanco's pesticides-MRL database](#).

If there is no EU legislation in place in the importing Member State, then the exporter can seek to obtain an "import tolerance" for active substances that have not been evaluated or used in Europe before. Applications for import tolerances must be submitted to the "Rapporteur Member State" (RMS). The Commission assigns a Member State, if no RMS exists. The RMS reviewed dossiers are evaluated by the European Food Safety Authority before being forwarded to the Commission. Information on import tolerances can be obtained from http://www.pesticides.gov.uk/applicant_guide.asp?id=1239. Since September 2, 2008 all MRLs, including import tolerances, apply EU wide.

Harmonized sampling methods are established for the official control of residues in and on products of plant and animal origin by [Commission Directive 2002/63/EC](#). [Commission Regulation 1274/2011](#) requires Member States to take and analyze samples for product and pesticide residue combinations in food of plant and animal origin. Annex I to the Regulation sets out the pesticide and product combinations to be monitored. Annex II sets out the number of samples that need to be taken for each combination. The Member States must submit results of the sample tests to the EU by 31 August 2013, 2014 and 2015 for samples tested in 2012, 2013 and 2014 respectively.

Contaminants

<http://www.fas.usda.gov/posthome/useu/contaminants.html>

Maximum Levels

EU wide harmonized maximum levels for contaminants are set in the Annex of [Commission Regulation 1881/2006](#). The Annex to Regulation 1881/2006 includes maximum levels for:

- nitrates in lettuce, spinach and infant food (section 1)
- mycotoxins (section 2):
 - aflatoxins in nuts, dried fruit, cereals, maize, spices, milk and infant food
 - ochratoxin A in cereals, cereal products, dried vine fruit, roasted coffee, soluble coffee, wine, grape juice, spices, infant food and licorice
 - patulin in fruit juices, spirit drinks, solid apple products, apple juice and infant food
 - deoxynivalenol in cereals, cereal products, maize, pasta and infant food
 - zearalenone in cereals, cereal products, maize, refined maize oil, bread and small bakery wares and infant food
 - fumonisins in maize and maize based products
 - T-2 and HT-2 toxin in cereals and cereal products
- heavy metals (section 3):
 - lead in milk, infant food, meat, offal, seafood, vegetables, fruit, wine and food supplements
 - cadmium in meat, seafood, cereals, soybeans, vegetables, fruit, fungi and food supplements
 - mercury in seafood and food supplements
 - tin in canned foods, canned beverages and canned baby foods
- 3-MCPD in vegetable protein and soy sauce (section 4)
- dioxin and PCBs in meat, liver, fishery products, milk, eggs and oils & fats (section 5)
- polycyclic aromatic hydrocarbons (PAH) in oils & fats, infant foods, (smoked) meat, fish and infant food (section 6)

Official Controls of Maximum Levels in Foodstuffs

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

Nitrates: [Commission Regulation 1882/2006](#)

Mycotoxins: [Commission Regulation 401/2006](#)

Dioxins: [Commission Regulation 1883/2006](#)

Heavy metals: [Commission Regulation 333/2007](#)

Heavy metals, 3-MCPD and benzo(a)pyrene: [Commission Regulation 836/2011](#) will apply as of September 1, 2012.

Import Conditions for U.S. Almonds

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

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

More information is available in the [European Commission's Guidance Document](#) and on the [Almond Board of California's website](#).

Residues in Animals and Animal Product

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

SECTION VI. OTHER REGULATIONS AND REQUIREMENTS

A. 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. Commission Decision 2009/821/EC establishes a list of EU border inspection posts approved to carry out veterinary checks on animals and animal products from third countries. [Commission Decision 2007/275/EC](#) establishes a list of animals and products that are subject to controls at border inspection posts, including certain composite products as well as a list of composite products that are not subject to veterinary checks.

[European Parliament and Council Regulation 854/2004](#) lays down specific rules for the organization of official controls on products of animal origin. [European Parliament and Council Regulation 882/2004](#) lays down general rules for the performance of official controls to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. [Commission Regulation 669/2009](#) implements Regulation 882/2004 as regards the increased level of official controls on imports of certain feed and food of non-animal origin.

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://www.fas.usda.gov/posthome/useu/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**. 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** are required to notify the competent regulatory authority of the Member State of their activity. The introduction of **foodstuffs with particular nutritional uses** needs to be notified to the Member State where the food is sold. 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://www.fas.usda.gov/posthome/useu/Certification_Guide.html

An overview of legally required certificates in the EU and references to the U.S. authority issuing these certificates is available in [GAIN Report E60015](#). An update of this report will be published in 2012. Detailed information on certification is also available on our website at

http://www.fas.usda.gov/posthome/useu/Certification_Guide.html

SECTION VII. OTHER SPECIFIC STANDARDS

A. Genetically Modified Foods

<http://www.fas.usda.gov/agri/GMOs.html>

Labeling regulations for genetically modified (GM) food products are established by [Regulation 1829/2003](#) (articles 12-13). These rules apply to products that have undergone varying degrees of processing. The regulation does not require labeling of food products that are not food ingredients, such as processing aids. Meat, milk or eggs obtained from animals fed with GM feed or treated with GM medicinal products do not require GM labeling. EU-harmonized legislation defining "non-GM", "GM-free" or similar labeling terms does not (yet) exist.

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

Each individual genetically modified organism (GMO) must be approved before it can be used in food and feed. All food products containing or consisting of GMOs, produced from GMOs or containing ingredients produced from GMOs must be labeled even if they no longer contain detectable traces of GMOs. The labeling requirement does not apply to foods containing GMOs in a proportion equal to or less than 0.9 percent of the food ingredients considered individually, provided their presence is adventitious or technically unavoidable. Above this level, all products must be labeled using the following wording:

- Where the food consists of more than one ingredient, the words "genetically modified" or "produced from genetically modified [name of ingredient]" must follow in brackets immediately after the ingredient concerned. A compound ingredient with a GM component should be labeled "contains [name of ingredient] produced from genetically modified [name of organism]".
Example: a biscuit containing soy flour derived from GM-soy must be labeled "contains soy flour from genetically modified soy".

- Where the ingredient is designated by the name of a category (e.g. vegetable oil), the words "contains genetically modified [name of organism]" or "contains [name of ingredient] produced from genetically modified [name of organism]" must be used.
Example: for vegetable oils containing rapeseed oil produced from genetically modified rapeseed, the reference "contains rapeseed oil from genetically modified rapeseed" must appear in the list of ingredients.

The designations may appear in a footnote to the ingredients list, provided they are printed in a font at least the same size as that of the list of ingredients or, where there is no list of ingredients, clearly on the labeling.

- Where there is no list of ingredients, the words "genetically modified" or "produced from genetically modified [name of ingredient]" must appear clearly in the labeling.
Example 1: "a spirit containing caramel produced from genetically modified corn".
Example 2: "genetically modified sweet corn".

[Commission Regulation 619/2011](#) sets a tolerance of 0.1 percent - "Low Level Presence" (LLP) - for adventitious traces of non EU-authorized GMOs in feed imports. For more information see the [European Commission press release "Questions and Answers on the low level presence \(LLP\) of GMOs in feed imports"](#). The Commission may come forward with proposals dealing with LLP in food imports.

For more information on biotechnology and biotech products see [2011 Agricultural Biotechnology Report \(GAIN report FR9074\)](#) and [2010 Agricultural Biotechnology Report \(GAIN report FR9043\)](#).

B. Novel Foods

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

The [Novel Food Regulation 258/97](#) lays down detailed rules for the authorization of novel foods and novel food ingredients, including foods derived from or containing or consisting of GMOs. It defines novel foods as foods and food ingredients that were not used to a significant degree in the EU before May 15, 1997. The new regulations on GM food provide for a separate regime to deal with the authorization and traceability of novel foods and novel food ingredients that consist of or contain or are derived from GMOs.

Novel food categories consist of food and food ingredients:

- with a new intentionally modified primary molecular structure, or
- consisting of, or isolated from, micro-organisms, fungi or algae, or
- consisting of, or isolated from plants or animals, except for foods and food ingredients obtained by traditional propagating or breeding practices with a history of safe use, or
- to which a production process not currently used has been applied, where that process changes the composition or structure of the food or food ingredient significantly

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

C. Nanotechnology

A [European Commission Recommendation on the definition of a nanomaterial](#) was published in Official Journal L 275 of October 20, 2011. This recommendation provides EU legislators with a legal coherent cross-cutting reference for nanomaterials when proposing new legislation. It defines nanomaterials as materials whose main constituents have a dimension of between 1 and 100 billionth of a meter. For more information see [GAIN report E60060 "Commission sets out working definition for nanomaterials"](#) and the European Commission's website at <http://ec.europa.eu/environment/chemicals/nanotech/index.htm>.

D. Fortified Foods

(<http://www.fas.usda.gov/posthome/useu/foodsupplements.html>)

[European Parliament and Council Regulation 1925/2006](#) establishes an EU-wide regulatory framework for the addition of vitamins and mineral and of certain other substances such as herbal extracts to foods. It lists the vitamins and minerals that may be added to foods and sets criteria for setting maximum and minimum levels. Although originally scheduled for January 2009, the Commission is still working on a proposal to set maximum permitted levels of vitamins and minerals in foods and food supplements. Minimum amounts are linked to the notion of "significant amount" as defined in the Annex to [Council Directive 90/496/EEC](#) on nutrition labeling. The use of vitamins and minerals not included in the annexes to Regulation 1925/2006 is not allowed. 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. Such derogations should be obtained from the [competent authorities in the individual Member States](#).

E. Dietetic or Special Use Foods

(<http://www.fas.usda.gov/posthome/useu/partnutr.html>)

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

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

- [Commission Directive 2006/125/EC](#) on processed cereal-based foods and baby foods for infants and young children.
- [Commission Directive 96/8/EC](#) on foods intended for use in energy-restricted diets for weight reduction.
- [Commission Directive 2006/141/EC](#) on infant formula and follow-on formula, amended by [Commission Regulation 1243/2008](#) as regards compositional requirements for certain infant formulae.
- [Commission Directive 1999/21/EC](#) on dietary foods for special medical purposes.

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

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

Specific directives on foods and beverages for athletes 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_art11_en.pdf.

Proposal: In June 2011, the European Commission presented a proposal to revise the current legislative framework for dietetic foods. The draft regulation proposes to abolish the concept of dietetic foods. Foods other than infant-formula, follow-on formula and foods for special medical purposes will be treated as "normal" foods unless they make a nutrition or health claim in which case they will have to comply with the requirements set out in the Nutrition & Health Claims Regulation (see Section II.B). Although the proposal does not ban any products, products will need to be re-labeled or reformulated. For more information see [GAIN report E60045 "Commission proposes to abolish concept of dietetic foods"](#).

F. Single Common Market Organization (CMO)

In 2006, the European Commission proposed to replace 21 specific common market organization (CMO) regulations for different agricultural sectors with a new Single CMO regulation. The objective was to streamline and simplify the Common Agricultural Policy (CAP) for the benefit of farmers, administrations and companies handling agricultural commodities. [Council Regulation 1234/2007](#) establishes a single common market organization for all agricultural products. The single CMO provides definitions and marketing rules for rice, sugar, beef and veal, milk and milk products, eggs and poultry meat, olive oil, fruit and vegetables, spreadable fats and wine.

Marketing Standards

Fruit and Vegetables (Article 113 Single CMO)

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

[Commission Regulation 543/2011](#) lays down detailed rules for the implementation of Article 113 of the Single CMO. This regulation sets out specific marketing standards for 10 products: apples, citrus fruit, kiwi fruit, lettuces, peaches and nectarines, pears, strawberries, sweet peppers, table grapes and tomatoes. Fruits and vegetables not covered by a specific marketing standard must comply with the general marketing standard. The details of the general marketing standard are set out in Part A of Annex I to Regulation 543/2011. The following products are not required to conform to the general marketing standard: mushrooms (other than cultivated mushrooms), capers, bitter and shelled almonds, shelled hazelnuts, shelled walnuts, pine nuts, pistachios, macadamia, pecans and saffron. Products conforming to UNECE standards are considered as conforming to the general marketing standard. Marketing standards apply at all marketing stages including import. For more information see the European Commission's ["Fruit and Vegetables Marketing Standards" webpage](#).

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

Fresh fruits, vegetables and nuts are subject to phytosanitary controls and are checked for compliance with the quality standards and labeling requirements. A conformity certificate (Annex III to Regulation 543/2011) - to be obtained by the importer at the point of entry - is required for all shipments of fresh produce.

Veal

Annex XIa to Council Regulation 1234/2007 classifies bovine animals aged less than 12 months in two categories: 1) "category V" - bovine animals aged 8 months or less and 2) "category Z" - bovine animals aged more than 8 months but less than 12 months. For both categories, Annex XIa lists the sales descriptions in the different Member States languages and the mandatory labeling requirements.

Milk and milk products: Annexes XII and XIII to Regulation 1234/2007

Eggs and poultry meat: Annex XIV to Regulation 1234/2007

Eggs for hatching and farmyard poultry chicks: [Regulation 617/2008](#)

Spreadable fats: Annex XV to Regulation 1234/2007

G. Wine, Beer and Other Alcoholic Beverages

(<http://www.fas.usda.gov/posthome/useu/wine.html>)

Wine

Rules on oenological practices, designations of origin and labeling, originally established by [Council Regulation 479/2008](#), have been incorporated into the Single CMO ([Council Regulation 1234/2007](#)).

Oenological Practices

[Commission Regulation 606/2009](#), amended by [Commission Regulation 53/2011](#), lays down detailed rules for permitted oenological practices. Annex I A sets out the oenological practices authorized in the EU and the conditions for their use. For experimental purposes, Member States may authorize the use of certain oenological practices not provided for in the relevant EU regulations for a maximum of three years. Annex I B sets out the maximum allowed sulphur dioxide contents: 150 mg per liter for red wines, 200 mg per liter for white and rosé wines.

Labeling

[Commission Regulation 607/2009](#) lays down detailed rules on protected designations of origin and geographical indications, traditional terms and labeling.

Chapter II of Regulation 607/2009 establishes the application procedure for a designation of origin or a geographical indication. Designation of origin or geographical indications which have been accepted are entered in a "Register of protected designations of origin and protected geographical indications" maintained by the European Commission. The register is available through the Commission's [online "E-Bacchus" database](#).

Chapter III of Regulation 607/2009 sets out rules on the use of traditional terms. The ["E-Bacchus" database](#) lists the traditional terms that are protected in the EU. The use of expressions such as "style", "type", "method", "as produced in", "imitation", "flavor", "like" or similar, accompanied by a traditional term included in the E-Bacchus database is not allowed. Third countries may use traditional terms not listed in the database.

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

For detailed information see GAIN [REPORT E49061 "New EU wine labeling rules"](#).

Ingredients which may trigger an allergic reaction (see Annex IIIa to [European Parliament and Council Directive 2000/13/EC](#)) must be indicated on the label preceded by the word "contains". Alcoholic beverages with sulphite concentrations of more than 10 mg/liter must use one of the following terms: "sulphites", "sulfites", "sulphur dioxide" or "sulfur dioxide". The indication of sulphites may be accompanied by the pictogram included in Annex X to Regulation 607/2009. Replacing the word "sulphites" by "SO₂" or the E-number (E220) is not allowed. The list of authorized languages for allergen labeling can be consulted in [GAIN report E36066](#). A temporary derogation from the EU requirement that wines fined with egg and milk derivatives must be labeled for allergens was set to expire on December 31, 2010 but has been extended until June 30, 2012. As of July 1, 2012 wines fined with casein and ovalbumin must be labeled for allergens ([Commission Regulation 1266/2010](#)).

The indication of the wine grape variety on the label is optional. For third country wines, the wine grape variety must be included in at least one of the lists established by the "international Organization of Vine and Wine (OIV), the "Union for the Protection of Plant Varieties (UPOV)" or the "International Board for Plant Genetic Resources (IBPGR)". Terms such as "barrel matured", "barrel aged" (listed in Annex XVI to Regulation 607/2009) may not be used on wines produced with the aid of oak chips.

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

US-EU Wine Agreement

In March 2006, the U.S. and the EU and the U.S. signed the "[Agreement between the United States and the European Community on Trade in Wine](#)". The first phase of this agreement addresses a number of issues, such as labeling and certification. Other important issues such as geographical indications and the use of traditional terms will be addressed in a second phase of the negotiations. The Agreement covers wine with an actual alcohol content of not less than 7% and not more than 22%. All U.S. wine imports must be accompanied by certification and analysis documentation using the format specified in Annex III (a) to the Agreement. More information on the simplified EU import certificate form can be obtained from the Alcohol and Tobacco Tax and Trade Bureau at http://www.ttb.gov/industry_circulars/archives/2007/07-02.html. The Agreement's "Protocol on Wine Labeling" sets conditions for the use of optional particulars on wine labels. [Commission Regulation 1416/2006](#), as amended by [Commission Implementing Regulation 1212/2011](#), concerns the protection of U.S. names of origin in the EU. 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/itd/index.shtml>).

Spirit Drinks & Beer

[European Parliament and Council Regulation 110/2008](#) lays down 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. All alcoholic beverages must comply with the allergen labeling requirements (see "Wine").

[Commission Regulation 936/2009](#) applies the agreements between the EU and third countries on the mutual recognition of certain spirit drinks. Under this regulation, "Tennessee Whisky" and "Bourbon Whisky" are protected product designations.

H. Organic Foods

(<http://www.fas.usda.gov/posthome/useu/organic.html>)

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

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

[Commission Regulation 1235/2008](#) lays down rules for the implementation of Regulation 834/2007 as regards the arrangements for imports of organic products from third countries. In order to export organic products to the EU, third countries must prove that their production standards are equivalent to the EU standards. For third countries currently not included in the EU's equivalency list, the Commission will compile a list of recognized control bodies and control authorities. To be included in the EU list, U.S. control bodies/authorities must submit a technical dossier. In December 2011 [Implementing Regulation 1267/2011 amending regulation 1235/2008](#) was published in Official Journal L 324. This Regulation contains the first list of recognized certifiers, including seven U.S. certifiers; Washington State Department of Agriculture, Organic crop improvement association, Oregon Tilth, Quality Assurance International, International Certification Services Inc., Organic Certifiers and California Certified Organic Farmers. To avoid trade interruptions, Member States can, until January 1, 2013, continue to grant authorizations to importers of U.S. organic products on a case-by-case basis. Shipments of organic products must be accompanied by the model certificate established by Regulation 1235/2008. The European Commission has published [guidelines on imports of organic products](#) into the EU on its website.

NEW! The U.S. and EU are in the process of finalizing an "Organic Equivalence Cooperation Arrangement." On December 20, 2011, the EU's Standing Committee on Organic Farming voted to add USDA's National Organic Program as an equivalent third country program. The final step is for the EU to amend Commission Regulation 1235/2008 to add the United States as an equivalent country. Equivalence will expand market access for U.S. organic products and reduce duplicative requirements and certification costs, while protecting organic integrity. Both sides hope to implement the equivalence arrangement early 2012.

Proposal: There is currently no EU definition of organic wine. Wine cannot be labeled as "organic wine" but only as wine "made from organically grown grapes." There are no specific requirements for the production of such wines or which substances may be added. On August 12, 2011 the Commission notified a [draft regulation on organic wines](#) to the WTO (G/TBT/N/EEC/395). The Commission is hoping that the proposed legislation will be adopted in the first half of 2012 and be applicable starting August 1, 2012.

Information on the EU's organic products market is available in [GAIN report NL0022](#).

I. Vertical Legislation (Breakfast Directives)

(<http://www.fas.usda.gov/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.

New! On December 14, 2011 the European Parliament (EP) voted on the Commission's proposal to amend Directive 2001/112/EC relating to **fruit juices** and certain similar products intended for human consumption. Key amendments approved by the EP mainly relate to the labeling of fruit juices and nectars. The EP and Council already agreed on these amendments in informal trilogue meetings. The Council now only needs to formally adopt the amendments before the proposal becomes law (expected early 2012).

Key amendments to the fruit juice labeling rules include:

- **Orange Juice:** Product sold as "orange juice" may contain up to 10% mandarin juice. The addition of mandarin juice must be indicated in the list of ingredients.
- **Nutrition claim:** As sugar is not included in the list of authorized ingredients for the production of fresh and concentrated fruit juices, labels on such products may no longer carry the nutrition claim "with no added sugar". During a transitional period the statement "no fruit juices contain added sugars" may appear on the label to enable the industry to properly inform the consumers.
- **Mixed Juices:** Products composed from two or more fruits must have a product name that reflects the actual fruit content, in descending order of the volume of the juices or purees used, as indicated in the list of ingredients. For example, a mixture of 90% apple and 10% raspberry juice should be labeled as "apple and raspberry juice" and not as "raspberry juice" as currently allowed. A generic name such as "mixed juice" or a similar wording may be used when there are three or more fruits sources.
- **Sugars and sweeteners:** Fruit juices will by definition not contain any sugars or sweeteners. "Nectars" made from fruit puree with added water may contain added sugar or sweeteners. The nutrition claim "no added sugar" will not be allowed on the labels of nectars containing artificial sweeteners.

Once adopted, products not complying with the new rules may be marketed until three years from the date of entry into force of the new rules. Directives must be transposed into national legislation. Member States will have a transposition period of 18 months to update their national legislation accordingly. A detailed GAIN report will follow after publication of the new rules in the Official Journal.

J. Beef & Meat Labeling

(<http://www.fas.usda.gov/posthome/useu/label>)

Beef

[Regulation 1760/2000](#) sets out rules for compulsory and voluntary beef labeling. Detailed rules for the implementation of Regulation 1760/2000 are set out in [Regulation 1825/2000](#). Under the

compulsory beef labeling scheme, labels for all bovine meat must indicate the following information:

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

Meat

General labeling directive 2000/13/EC sets out the definition of "meat" for labeling purposes. This definition does not cover mechanically separated meat (MSM) as it is still subject to Member State legislation. The European Commission is considering working on a guidance document to better identify which products should be considered as MSM and if appropriate, propose legislative amendments.

K. 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_and_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>.

L. Frozen Foodstuffs

(<http://www.fas.usda.gov/posthome/useu/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".

M. Irradiated Foodstuffs

(<http://www.fasu.usda.gov/posthome/useu/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 EU positive list is expanded, national authorizations continue to apply.

N. Seafood

(<http://www.fas.usda.gov/posthome/useu/seafood2.html>)

[Council Regulation 2406/96](#) lays down common marketing standards for certain fishery products.

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

- Commercial name of the species (each member state has established a list of commercial designations).
- Product method: "caught in...", "caught in freshwater", "farmed" or "cultivated".
- Catch area: for products caught at sea, a reference to one of the areas listed in the annex.
 - o For products caught in freshwater: a reference to the country of origin;
 - o 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 July 2011 update of the "How to export seafood to the European Union" guide which can be downloaded from NOAA's website at <http://www.seafood.nmfs.noaa.gov/Howtoexportseafood2011.pdf>.

Proposal: In July 2011 the European Commission presented a [proposal for a new regulation on the common organization of the markets in fishery and aquaculture products](#). The draft regulation includes mandatory labeling requirements. The proposal has to be adopted by the Council and the European Parliament following the ordinary legislative procedure (co-decision).

O. Pet Food

(<http://www.fas.usda.gov/posthome/useu/index.htm>)

[European Parliament and Council Regulation 767/2009](#) sets out new rules for the labeling and marketing of feed and pet food. It covers feed materials, compound feed and medicated or dietetic feed for both food and non-food producing animals. Feed and pet food not complying with Regulation 767/2009 and with the provisions on feed additives laid down in [Regulation 1831/2003](#) and Directive 90/167/EC will not be allowed on the EU market. New requirements relate to the indication in descending order of weight of feed materials in compound feed, claims, the

establishment of a non-exhaustive "Catalog of Feed Materials" and "Codes of Good Labeling". For more information see [GAIN report E50060 "EU Feed and Pet Food Labeling Requirements"](#).

[Commission Regulation 575/2011](#) establishes a new catalogue of feed materials. It enables operators to use more precise names and expressions for the feed they place on the market. The annex to the Catalogue contains three parts: A) general provision, B) glossary of processes and C) list of feed materials. The use of the Catalog is voluntary but where it is used all relevant provisions have to be complied with. [Commission Recommendation 2011/25/EU](#) establishes guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products. A "[Code of Good Labeling Practice for Pet Food](#)" drafted by the European Pet Food Industry (FEDIAF) was published on October 20, 2011.

SECTION VIII. COPYRIGHT AND/OR TRADEMARK LAWS

Trademarks

[Council Regulation 207/2009](#) lays down rules for the registration of Community trademarks. It creates a single, unitary registration system covering the whole Community.

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 but co-exists alongside national trademarks. [Directive 2008/95/EC](#) approximates the laws of the Member States relating to trade marks.

Protected Geographical Indications

(<http://www.fas.usda.gov/posthome/useu/GI.html>)

[Council Regulation 510/2006](#) lays down rules on the protection of designation of origin (PDO) and geographical indications (PGI) for agricultural products intended for human consumption (except wine and spirit drinks which are covered by separate legislation). [Commission Regulation 1898/2006](#) lays down detailed rules for the implementation of Regulation 510/2006. Under these regulations, third country operators can submit registration applications directly to the Commission and object directly to new registrations. The [European Commission's website](#) provides guidance on how to register a PDO/PGI or how to object to a PDO/PGI proposed for registration. Lists of protected names by country, product type, registered name and name applied for are available through the Commission's [online "DOOR" \(Database of Origin and Registration\) database](#).

Proposal: On December 10, 2010 the European Commission presented a proposal on "Agricultural Product Quality Schemes". The proposal introduces a harmonized, simplified and shorter registration procedure for PDO's and PGI's and provides clarifications on intellectual property rights. The proposal covers agricultural products and foodstuffs but not wines and spirits which are covered by specific legislation. The proposal is currently going through the legislative adoption procedure.

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.

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

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/dds2/taric/taric_consultation.jsp?Lang=en&redirectionDate=20101215. [The EU's 2012 Tariff Schedule](#) was published on October 28, 2011 in Official Journal L 282.

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. [A list of customs authorities designated for the purpose of issuing binding tariff information](#) was published in Official Journal C 144 of May 14, 2011. 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.

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

Goods are only released after payment of the import duty and other taxes that may be due. Duties payable on goods imported into the EU may include:

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

A list of VAT rates applicable in the different Member States can be found on the Internet at http://ec.europa.eu/taxation_customs/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 EU Customs 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

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

Office for Harmonization in the Internal Market
Avenida de Aguilera, 20
03080 Alicante
Spain
Tel: (34-96) 513 9243
Fax: (34-96) 513 9173

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
Mailing address:
27 Boulevard du Regent
1000 Brussels
Belgium
Tel: (32-2)811-5793
Fax: (32) (2) 811-5560
E-mail: AgUSEUBrussels@fas.usda.gov

National Oceanic & Atmospheric Administration (NOAA) Representative to the EU:
Mailing address:
27 Boulevard du Regent
1000 Brussels
Belgium
Tel: (32-2)811-5831
E-mail: Stephane.Vrignaud@trade.gov

Other FAS Offices in the European Union:
http://www.fas.usda.gov/ofso/overseas_post_directory/ovs_directory_search.asp

USDA/FDA contacts for certification of animal products:
<http://www.fas.usda.gov/posthome/useu/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

Food Safety & Inspection Service (FSIS) Export Requirements for the EU:
http://www.fsis.usda.gov/Regulations_&Policies/European_Union_Requirements/index.asp

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

APPENDIX II. OTHER IMPORT SPECIALIST CONTACTS

- Please see [Member States FAIRS reports](#).
- **U.S. MISSION TO THE EU – FAS ORGANIZATIONAL CHART**

Maurice House, Minister-Counselor for Agricultural Affairs		
Cynthia Guven Senior Agricultural Attache	Elisa Wagner Agricultural Attache	Valerie Ralph Agricultural Attache
EU Food & Agriculture Policies Climate Change/Environment Third Country Agreements Food Aid CODEX TEC	Biotechnology Grains & Feed Oilseeds & Products Organic Products Biofuels Horticultural Products & Sugar Forest Products	Dairy, Livestock & Poultry Veterinary Equivalency Agreement PRT's Animal Cloning Novel Foods Nanotechnology
Gerda Vandercammen Agricultural Specialist	Karin Bendz Agricultural Specialist	Yvan Polet Agricultural Specialist
EU Food & Feed Import Controls EU General Food Law / Food Hygiene EU Food Safety Policies Contaminants Certification/TRACES Risk Assessment/Risk Management	Oilseeds & Products Biofuels Climate Change/Environment Organic Products Rural Development Forest Products Wines & Spirits	Dairy, Livestock & Poultry Animal Welfare GE Animals WTO (Market Access, Domestic Support, Export Competition) Sugar
Barrie Williams Agricultural Specialist	Tania De Belder Agricultural Specialist	Hilde Brans Agricultural Specialist
Biotechnology CAP Grains & Feed Agriculture & Fisheries Council EU Budget	Pesticides Food & Feed Additives Nanotechnology Packaging Materials Horticultural Products WTO SPS & TBT Notifications	EU Decision-Making Procedures Food & Drink (Incl. Wine) Labeling Nutrition & Health Claims Novel Foods Dietetic Foods & Food Supplements EU Food Quality Schemes
Email: Firstname.Lastname@fas.usda.gov		

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 in the coming years:

- Animal welfare labeling: for more information see [GAIN report E49084 "Animal Welfare Labeling – European Commission Report"](#)
- Dietetic foods
- Eco-labeling
- Food from cloned animals
- Fruit juice labeling
- Geographical Indications
- GMO's Low Level Presence for food imports
- Marketing Standards for products not covered by a specific standard
- Maximum levels for vitamins and minerals in fortified foods and food supplements
- Nanotechnology
- Nutrient profiles
- Novel foods
- Organic wine
- Pesticides
- Seafood labeling
- Smoke flavorings

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
- Other Directorates General: http://ec.europa.eu/about/ds_en.htm

ABC of European Union Law:

- http://eur-lex.europa.eu/en/editorial/abc_toc_r1.htm

European Food Safety Authority (EFSA):

- <http://www.efsa.europa.eu>

U.S. Mission to the EU:

- Foreign Agricultural Service: <http://www.fas.usda.gov/posthome/useu/index.html>
- Foreign Commercial Service: <http://www.buyusa.gov/europeanunion/>

FAIRS Reports:

- <http://gain.fas.usda.gov/Pages/Default.aspx>

GUIDANCE DOCUMENTS:

- EU **general food law** – implementation guidelines:
http://ec.europa.eu/food/food/foodlaw/guidance/guidance_rev_8_en.pdf
- **Food hygiene** regulations:
http://ec.europa.eu/food/food/biosafety/hygienelegislation/guide_en.htm

- Guidance document for competent authorities for the control of compliance with EU legislation on **aflatoxins**:

<http://ec.europa.eu/food/food/chemicalsafety/contaminants/guidance-2010.pdf>

- **Plant protection**:

http://ec.europa.eu/food/plant/protection/resources/publications_en.htm#council

- **Pesticide residues**: http://ec.europa.eu/food/plant/protection/pesticides/publications_en.htm

- Guidance documents on **animal by-products**:

http://ec.europa.eu/food/food/biosafety/animalbyproducts/faq_en.htm

- How to read a **food label**:

http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/publications/leaflet_EN6_12112007_web.pdf

- Food **traceability** factsheet:

http://ec.europa.eu/food/food/foodlaw/traceability/factsheet_trace_2007_en.pdf

- Guidelines on imports of **organic** products:

http://ec.europa.eu/agriculture/organic/files/news/download-material/guidelines_for_imports_en.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

- **Vitamins** & minerals – guidance on submissions for safety evaluations:

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

- Commission Communication on the future necessity and use of **mechanically separated meat** in the EU, including the information policy towards consumers: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:0704:FIN:EN:PDF>.

- How to export **seafood** to the EU:

<http://www.seafood.nmfs.noaa.gov/Howtoexportseafood2011.pdf>