

USDA Foreign Agricultural Service

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. Developments in EU food legislation and initiatives that may have an impact on U.S. exports of food and agricultural products are highlighted on a blue background. Information provided in this report is also available on the new USEU/FAS website <http://www.usda-eu.org>.

SUMMARY

WHAT IS NEW FOR 2012?

All sections of this report were updated. The main developments in EU food legislation and other key updates are highlighted on a blue background.

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DISCLAIMER: This report was prepared by the Office of Agricultural Affairs, U.S. Mission to the European Union in Brussels, Belgium for U.S. exporters of domestically produced food and agricultural products. While every possible care was taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. Final approval of any product is subject to the importing country's rules and regulations as interpreted by border officials at the time of product entry.

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 "Community acquis", i.e. the entire body of EU laws and obligations associated with the treaties and international agreements to which the EU is a party. Since the EU was originally created as a Customs Union, EU common rules extend to all aspects of trade policy including preferential trade, health and environmental controls, and the common agricultural and fisheries policies, and all MS must comply with them.

The process of harmonizing existing Member State legislation has been long and cumbersome and is still ongoing. According to a European Commission memo published in December 2012, around 98% of food legislation is harmonized at the EU level. 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. National measures still exist, for example, for certain food contact materials, the addition of nutrients to food and food supplements, maximum levels for vitamins and minerals, and for fees for official controls. 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. More information is available on the European Commission's "Better Regulation" website http://ec.europa.eu/governance/better_regulation/index_en.htm.

The EU has developed an integrated "Farm to Fork" approach covering all sectors of the food and feed chain, based on the precautionary principle and including traceability as described in the [Commission Communication on the Precautionary Principle](#). Key elements of this approach include the establishment of a framework regulation laying down the general principles and requirements of EU food law ([Regulation 178/2002](#)); 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 ([Regulation 882/2004](#)). The regulations on general food law, food and feed controls, food and feed hygiene make up the body of the EU's food safety laws. Revisions of existing EU food regulations or new regulations all apply the principles contained in the framework regulations. For more information see <http://www.usda-eu.org/topics/food-safety/>.

For ethical issues, the Commission has given a mandate to the "European Group" (EGE) to provide advice on ethical questions relating to sciences and new technologies. The EGE delivers opinions on the ethical implications of modern developments in agriculture technologies. Its mandate is renewed every five years. For more information see http://ec.europa.eu/bepa/european-group-ethics/index_en.htm.

There are three main institutions involved in developing policies and passing legislation that applies throughout the EU: the European Commission, the Council of the European Union 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. EFSA is responsible for providing scientific advice to the legislators on matters related to food safety.

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.

VISIT OUR NEW WEBSITE [HTTP://WWW.USDA-EU.ORG](http://www.usda-eu.org)! An overview of EU food laws currently in force can be found in the section "Trade with the EU."

AS A REMINDER: Exports 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 originate only from EU approved U.S. establishments.

For more information see <http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/approved-u-s-establishments/>.

SECTION II. LABELING REQUIREMENTS

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/eu-labeling-requirements/>

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.

Directive 2000/13/EC will be repealed by [European Parliament and Council Regulation 1169/2011](#). This new EU Regulation, adopted in November 2011, establishes new horizontal food labeling requirements which will apply from December 13, 2014, except for the new mandatory nutrition declaration requirement which will apply from December 13, 2016, and Part B of Annex VI (specific requirements concerning the designation of minced meat) which will apply from January 1, 2014. Detailed information on the EU's new food labeling requirements is available in [GAIN Report E70002 "New EU Food Labeling Rules Published"](#).

Section VII of this report 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 phyostanols 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 sulfite at concentrations of at least 10 mg per kg or 10 mg/l, celery, and mustard. Allergen labeling also applies to alcoholic beverages. A temporary derogation for wines fined with egg and milk derivatives expired on June 30, 2012. For more information see Section VII-G "Wine, Beer and Other 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](#) established a list of ingredients and substances which are permanently exempted from the mandatory allergen labeling requirement.

- 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 – in that order - are exempt from the lot marking requirement. Detailed information on indications or marks identifying the lot to which a foodstuff belongs is provided in [Directive 2011/91/EU](#).
- 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.

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](#). For more information see Section IV "Food Additive Regulations".

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.

This Directive will be repealed on December 13, 2014, when the EU's new labeling Regulation 1169/2011 becomes applicable.

Phytosterols & Phytosterols

[Commission Regulation 608/2004](#) lays down labeling requirements for foods and food ingredients with added phytosterols, phytosterol esters, phytosterols and phytosterol 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”.

This Directive will be repealed on December 13, 2014, when the EU’s new labeling Regulation 1169/2011 becomes applicable.

Quantitative Ingredients Declaration (QUID)

Quantitative ingredients declaration (QUID) is compulsory in the following cases (Article 7 of Directive 2000/13/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/food/labellingnutrition/resources/fl02_en.pdf.

This Directive will be repealed on December 13, 2014, when the EU's new labeling Regulation 1169/2011 becomes applicable.

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

This Directive will be repealed on December 13, 2014, when the EU's new labeling Regulation 1169/2011 becomes applicable.

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

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
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.usda-eu.org/trade-with-the-eu/eu-import-rules/fairs-reports/>.

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-A.

B. Medical / Health / Nutrition Claims

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/nutrition-health-claims/>

[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 with a high sugar content but only if the label clearly states “high sugar content”. Health claims cannot fail any criteria.

Health Claims

In December 2011, the European Commission proposed a list of 222 functional health claims for substances other than botanicals. More than two years after the due date set by Regulation 1924/2006, the list of EU-approved functional health claims and their conditions of use was finally adopted on May 25, 2012. [Regulation 432/2012](#) establishing the EU positive list becomes applicable on December 14, 2012. Anyone will be able to use the permitted health claims provided the conditions set out in Regulation 432/2012 are met. The EU’s [online “Register of Nutrition and Health Claims”](#) has been updated not only with the 222 authorized health claims but also with the more than 1600 rejected claims and the reasons for their non-authorization. Health claims referring to botanical substances have been put on hold because the Commission and the Member States are discussing the potential conflict of the Health Claims Regulation with the Traditional Herbal Medicinal Products Directive. All claims that are not authorized and not on hold or under consideration are prohibited as of December 14, 2012. Food products carrying claims must comply with the provisions of [nutritional labeling directive 90/496/EC](#).

The list of permitted health claims is different from the individual applications for health claims relating to disease risk reduction and claims referring to the health and development of children which require an

authorization on a case-by-case basis, following the submission of a scientific dossier to EFSA. A simplified authorization procedure has been established for health claims based on new scientific data.

[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.

Nutrition Claims

The Annex to Regulation 1924/2006 lists the EU authorized nutrition claims and their conditions of use. [Commission Regulation 1047/2012](#) published in November 2012 adds a new "No Added Sodium/Salt" claim to the EU positive list and amends the conditions of use of the "Reduced [Name of the Nutrient]" claim.

Requirements Specific to Nutrition Labeling

Under the current rules, 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).

The EU's new labeling regulation 1169/2011 which will apply from December 13, 2014, introduces the mandatory declaration of the energy value and the amounts of fat, saturates, carbohydrates, sugars, protein and salt expressed per 100 grams or per 100 milliliters in the same field of vision on food labels. The salt content must be expressed as "salt" not "sodium" but where appropriate, a statement indicating that the salt content is exclusively due to the presence of naturally occurring sodium may appear in close proximity to the nutrition declaration. The nutrition declaration may additionally be given on a per portion basis and expressed as a percentage of daily reference intakes set out in Part B of Annex XIII.

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.

The EU's new labeling regulation 1169/2011 which will apply from December 13, 2014, extends the mandatory country of origin labeling to meat listed in Annex XI (swine, sheep and goat, poultry) and when the country of origin of a food is not the same as its primary ingredient. The European Commission has until December 13, 2013, to carry out a feasibility study on the possible extension of mandatory country of origin labeling to meat used as an ingredient. It has until December 13, 2014, to assess the impact of country of origin labeling of other types of meat, milk, milk used as an ingredient in dairy products, unprocessed foods, single-ingredient products, and ingredients that represent more than 50% of a food.

SECTION III. PACKAGING AND CONTAINER REQUIREMENTS

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/food-contact-materials/>

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 white sugar may maintain these rules 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 EU and national legislation as well as guidance documents and contact information with regard to the submission of applications for authorization can be downloaded from the European Commission website at http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents_en.htm.

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

SECTION IV. FOOD ADDITIVE REGULATIONS

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/food-additives/>

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](#).

The common authorization procedure for food additives, food enzymes and food flavorings, established by [Regulation 1331/2008](#) is introducing a single common procedure for the approval of food additives, flavorings and enzymes. The benefits of this common approach include simplified legislation and more consistency in the procedures used to approve additives, flavorings and enzymes with an emphasis on the safety evaluations by EFSA on which the approval procedure is based.

The implementing rules are laid down in Commission [Regulation 234/2011](#), [Commission implementing Regulation 562/2012](#), explaining the content of an application and all the data both administrative and technical that have to be submitted to the Commission. The Commission will then request EFSA to verify the suitability of the data. An application consists of a letter, a technical dossier and a summary of the dossier.

Additives (including colors and sweeteners)

[European Parliament and Council Regulation 1333/2008](#) setting out the rules for the use of food additives, applies 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. Annex I to this Regulation contains definitions of 26 different categories of food additives.

[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.

Specifications for food additives listed in Annexes II and III are laid down in [Commission Regulation 231/2012](#). 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 in Directive 94/35/EC)

[Annex I](#) of Regulation 257/2010 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 1333/2008). The limits for these food colors have recently been lowered by [Commission Regulation 232/2012](#).

For an overview of the rules in force until the new regulation becomes fully 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.

[Commission Directive 2009/163/EU](#) sets conditions for the use of neotame as a sweetener.

Detailed information on the use of food additives can be obtained from the European Commission's website at http://ec.europa.eu/food/food/chemicalsafety/additives/new_regul_en.htm.

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 apply since January 20, 2011.

The new union list on flavoring substances, which was finally published in the Official Journal on October 2, 2012, will be introduced in Annex I of [Regulation 1334/2008](#) on flavorings and certain food ingredients with flavoring properties. It contains more than 2500 substances that are authorized for use in the EU. The two new pieces of legislation clarify and harmonize the use of flavoring substances within the single market list and will be introduced in Annex I of framework [Regulation 1334/2008](#) on flavorings.

[Commission Implementing Regulation \(EU\) No 872/2012](#) provides for a new EU wide list of flavoring substances which can be used in food and will apply from April 22, 2013, giving time for the EU food industry to adapt to the new rules. All flavoring substances not in the list will be prohibited after a phasing out period of 18 months. The current [Regulation 2232/96](#) is repealed by this new legislation and will no longer be in force as of April 21, 2013.

[Commission Regulation \(EU\) No 873/2012](#) concerns transitional measures for other flavorings such as flavorings made from non-food sources and apply since October 22, 2012.

The authorized uses of flavoring substances are listed according to the category of food to which they may be added and are also available in an [on-line database](#) allowing consumers, food businesses and food control authorities to easily identify which flavoring substances are authorized in food.

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. Food enzymes have not been regulated before or are regulated similar to processing aids under the legislation of the Member States. [Regulation 234/2011](#), last amended by [Commission Implementing Regulation 562/2012](#), 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. 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.

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.usda-eu.org/trade-with-the-eu/eu-import-rules/pesticides/>

[Regulation 1107/2009](#) sets out new rules for the authorization of plant protection products (PPPs) and replaces Directive 91/414/EEC and fully applies since June 14, 2011. Rules cover pesticides currently or formerly used in agriculture in or outside the EU (around 1100).

[Commission implementing Regulation 540/2011](#), 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.

Besides the framework Regulation above, the so called pesticide package also contains a [Directive for the sustainable use of pesticides](#).

Maximum Residue Limits (MRLs): Regulation 396/2005

Since September 2008 all MRLs in the EU have been harmonized by [Regulation 396/2005](#) on food or feed of plant and animal origin. Pesticide MRLs for processed or composite products are based on the MRLs of the raw agricultural ingredients. MRLs apply to 315 fresh products and to the same products after processing. 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.

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 VII 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 788/2012](#) 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 2014, 2015 and 2016 for samples tested in 2013, 2014 and 2015 respectively.

CONTAMINANTS

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/contaminants/>

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)
- Melamine in infant food (section 7)

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 252/2012](#)
- Heavy metals, Tin, 3-MCPD and benzo(a)pyrene: [Commission Regulation 333/2007](#) as amended by [Commission Regulation 836/2011](#)

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. 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%). While almonds shipped without a VASP certificate used to be subject to 100 pct border controls in the original Commission Regulation 1152/2009, the regulation has been amended in March 2012 to no longer authorize imports without a VASP ([Commission Regulation 274/2012](#)).

Regulation 1152/2009 also introduced 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

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/residue-plans/>

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 State authorities 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.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/>.

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. 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. See Section VII for detailed information.

B. Certification and Documentation Requirements

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/>

An overview of legally required certificates in the EU and references to the U.S. authority issuing these certificates is available on our website at <http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/>.

SECTION VII. OTHER SPECIFIC STANDARDS

A. Genetically Modified Foods

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/agricultural-biotechnology/>

Labeling Requirements

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.

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”.

GM-Free Labeling

EU-harmonized legislation defining “non-GM”, ‘GM-free’ or similar labeling terms does not (yet) exist. National provisions and operator-specific “GM-free” and similar labeling schemes have been developed in several Member States. The European Commission is studying the existing GM-free labeling initiatives in the EU to assess the need for regulatory harmonization. The results of this study will be published on the European Commission’s website.

“Low Level Presence” (LLP)

On June 24 2011, the EU adopted [Commission Regulation 619/2011](#) setting 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 the [Annual EU-27 Agricultural Biotechnology Report](#), released in August 2012.

Proposal

In September 2012, the European Commission published a [proposal](#) to amend the existing rules on honey established by [Council Directive 2001/110/EC](#). The proposal clarifies that pollen is a natural constituent and not an ingredient of honey. This proposal was presented following a Court of Justice preliminary ruling on GM pollen in honey. The Commission’s proposal does not affect the Court’s conclusion that GM pollen in food are subject to the EU’s GMO legislation.

B. Novel Foods

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/novel-foods/>

The [Novel Food Regulation 258/97](#) lays down detailed rules for the authorization of novel foods and novel food ingredients. 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 Novel Foods Regulation does not cover foods and food ingredients for which a specific approval procedure exists, including GMO’s, food additives, flavorings and extraction solvents.

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 (last updated June 2012).

Proposal

In 2011, a revision of the EU Novel Foods Regulation proposed by the European Commission failed to win the required consensus from the European Parliament and Council. The Commission will restart the process and present a new novel foods proposal in the first half of 2013.

C. Nanotechnology

<http://www.usda-eu.org/topics/nanotechnology/>

The Commission introduced an overarching working definition last year, by its [Commission Recommendation](#). The definition is based on the size of the particles of a material, rather than hazard or risk. It is designed to be used for regulatory purposes and will cover all uses, but more specific definitions are being developed and will exist alongside. 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>. The definition will be reviewed in 2014 in the light of technical and scientific progress.

On October 3, 2012, the Commission adopted the Communication on [the Second Regulatory Review on Nanomaterials](#) explaining how the Commission plans to improve EU law to ensure the safe use of nanomaterials. It is accompanied by a Staff Working Paper on nanomaterial types and uses, including safety aspects giving a detailed overview of available information on nanomaterials on the market, including their benefits and risks. Therefore, the Commission favors the application of a case-by-case approach regarding the risk assessment of nanomaterials, using indications of potential risks in terms of exposure or hazard.

Regulating nanotechnology in food in the EU – The current EU legislative framework covers in principle the potential health, safety and environmental risks in relation to nanomaterials but may have to be modified in the light of new information becoming available. DG Sanco has always proposed the use of the existing EU food legislation wherever possible, since it provides a good framework to cover all new applications in the food area as well as existing applications. The present legislation on food additives and novel foods already requires risk evaluation and pre-marketing notification. The ongoing revision of specific food legislation addresses explicitly the use of nanomaterials in all foods.

D. Fortified Foods

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/eu-labeling-requirements/fortified-foods/>

[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](#) (list updated August 20, 2012). A “Community Register” on the addition of vitamins and minerals and of certain other substances is available on the European Commission’s website at http://ec.europa.eu/food/food/labellingnutrition/vitamins/comm_reg_en.pdf.

E. Dietetic or Special Use Foods

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/eu-labeling-requirements/dietetic-foods/>

Framework [Directive 2009/39/EC](#) consolidated 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 marketing of dietetic foods for which no specific rules have been

established 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. The proposal will probably be adopted in 2013 and become applicable in 2016. 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.usda-eu.org/trade-with-the-eu/eu-import-rules/marketing-standards/>

[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

Olive Oil: [Regulation 29/2012](#)

G. Wine, Beer and Other Alcoholic Beverages

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/eu-labeling-requirements/wine-labeling/>

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](#) 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 sulfur dioxide contents: 150 mg per liter for red wines, 200 mg per liter for white and rosé wines.

Labeling

[Commission Regulation 607/2009](#), as amended by [Commission Implementing 1185/2012](#), 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. Since Regulation 607/2009 became applicable, the European Commission received 15 applications from third countries –13 of which came from the United States - to use EU protected traditional terms. [Commission Implementing Regulation 723/2012](#) allows the use of the traditional term “Cream” on U.S. grapevine products. Allowing the use of the traditional term “Chateau” on U.S. grapevine products is still under consideration by the European Commission.

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”](#).

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. The use of the term “alcohol free wine” is not allowed in several Member States.

Allergen Labeling

Under the [EU’s general labeling directive 2000/13/EC](#), the indication of allergens listed in Annex III is mandatory on all food and beverage labels. A temporary derogation from this rule for wines fined with egg and milk derivatives expired on June 30, 2012. [Commission Implementing Regulation 579/2012](#) sets out the modalities for the labeling of allergens on wine. Starting July 1, 2012, a wine label must state that it “contains” one or more of the following allergens: “sulphites”, “sulfites”, “sulphur dioxide”, “sulfur dioxide”, “egg”, “egg protein”, “egg product”, “egg lysozyme”, “egg albumin”, “milk”, “milk product”, “milk casein” or “milk protein”. The translation of these terms in all the official EU languages is available in Part A of the Annex to Regulation 579/2012. Information on the authorized languages to label allergens in the different EU Member States is available on the European Commission’s website at http://ec.europa.eu/agriculture/markets/wine/labelling_allergens.pdf. The terms designating the allergenic ingredient may be supplemented by the pictograms laid down in Part B of the Annex to Regulation 579/2012.

Allergen labeling is mandatory for alcoholic beverages with sulfite concentrations of more than 10 mg/liter. Wine products in which the milk/egg proteins cannot be detected are exempt from the mandatory labeling rules.

Organic Wine

EU organic legislation now also covers wine. [Commission Implementing Regulation 203/2012](#), applicable since August 1, 2012, allows the use of the term “organic wine” where before the label could only mention “wine made from organic grapes.” Regulation 203/2012 sets out the conditions to label wine as organic. Sorbic acid and desulfuration are not allowed and the level of sulfites must be at least 30-50 mg per liter lower than their conventional equivalent. For more information see Section VII-H “Organic Foods.”

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](#) 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.usda-eu.org/trade-with-the-eu/eu-import-rules/organic-production/>

[Council Regulation 834/2007](#) establishes the legal framework for organic production and the labeling of organic products. This regulation covers living and unprocessed products including aquaculture, processed agricultural products, animal feed, seeds and vegetative propagating material. Products from hunting and fishing of wild animals are excluded from the scope of the regulation. Title IV of Regulation 834/2007 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. Labeling a food product as “100% organic” is not accepted in the EU. 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](#) and <http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/eu-labeling-requirements/organic-labeling-requirements/>.

Information on the EU’s organic products market is available in [GAIN Report NL2006](#).

US-EU Equivalency Arrangement

[Commission Regulation 1235/2008](#) lays down rules for the implementation of Regulation 834/2007 regarding 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. In February 2012, the United States and the EU agreed to a new historic partnership on organic trade. The “US-EU Organic Equivalency Arrangement,” which entered into force on June 1, 2012, ensures that both parties operate in conformity with each other’s respective organic programs. All products traded under the Arrangement must be accompanied by an organic import certificate issued by a USDA-AMS accredited certifying agent. The list of USDA accredited certifying agents and the model EU certificate can be downloaded from the USDA-AMS website at <http://www.ams.usda.gov/AMSV1.0/noprotradeeuropeanunion>. The Agreement is effective for three years, until June 1, 2015, and will then be re-examined by both parties for areas of improvement. For more information on the US-EU Organic Equivalency Arrangement see <http://www.usda-eu.org/trade-with-the-eu/trade-agreements/us-eu-organic-arrangement/>.

Organic Wine

EU organic legislation now also covers wine. [Commission Implementing Regulation 203/2012](#), applicable since August 1, 2012, allows the use of the term “organic wine” where before the label could only mention “wine made from organic grapes”. Regulation 203/2012 sets out the conditions to label wine as organic. Sorbic acid and desulfuration are not allowed and the level of sulfites must be at least 30-50 mg per liter lower than their conventional equivalent. As Regulation 203/2012 was only published in March 2012, a month after the U.S. and the EU signed the Equivalency Arrangement, organic wine was not included in the deal. [Commission Implementing Regulation 508/2012](#), published in June 2012, includes U.S. organic wines in Annex III to Regulation 1235/2008. Until a joint US-EU working group concludes its examination of the equivalence of organic wine making rules, U.S. organic wine certified to comply with the EU’s organic wine making rules can be imported into the EU.

Proposal

The adoption of a legislative proposal to review the organic framework regulation is included in the European Commission’s 2013 Work Program. In September 2012, the Commission published a “Roadmap” outlining several policy options as part of an “Impact Assessment” initiative. The Roadmap can be downloaded from the Commission’s website at http://ec.europa.eu/governance/impact/planned_ia/docs/2012_agri_014_organic_farming_en.pdf.

I. Vertical Legislation (Breakfast Directives)

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/eu-labeling-requirements/>

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](#).

[Directive 2012/12/EU](#), published in April 2012, sets out new labeling rules for fruit juices and fruit nectars. This directive amends [framework Directive 2001/112/EC](#) relating to fruit juices and certain similar products intended for human consumption. Member States have until October 28, 2013, to transpose the provisions of the new directive into national law. Products which are placed on the market or labeled before October 28, 2013, may continue to be marketed until April 28, 2015. Detailed information on key changes introduced by the new directive can be found in [GAIN report “New EU Fruit Juice Labeling Rules.”](#)

Proposal

In September 2012, the European Commission published a [proposal](#) to amend the existing rules on honey established by [Council Directive 2001/110/EC](#). The proposal clarifies that pollen is a natural constituent and not an ingredient of honey. This proposal was presented following a Court of Justice preliminary ruling on GM pollen in honey. The Commission’s proposal does not affect the Court’s conclusion that GM pollen in food are subject to the EU’s GMO legislation.

J. Beef & Meat Labeling

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/eu-labeling-requirements/beef-labeling/>

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

Proposal

In September 2011, the European Commission published a [proposal](#) to delete the voluntary beef labeling schemes established by Regulation 1760/2000. The proposal did not include any amendments to the mandatory labeling requirements. The proposal is currently going through the first reading phase of the ordinary legislative procedure (co-decision) and is expected to be adopted in the second half of 2013.

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_&_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

[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".

Until the stage at which frozen food of animal origin intended for human consumption is labeled in accordance with the [current Food Labeling Directive 2000/13](#) (for more information see Section II) or used for further processing, [Commission Regulation 16/2012](#) requires food business operators to provide the date of production AND the date of freezing to the buyers and upon request, to the competent authorities. Where a food is made from a batch of raw materials with different dates of production and freezing, the older dates of production and/or freezing must be made available.

The EU's [new Food Labeling Regulation 1169/2011](#) (for more information see Section II) requires that, starting December 13 2014, labels on frozen meat, frozen meat preparations and frozen unprocessed fishery products indicate the date of freezing or the date of first freezing in cases where the product has been frozen more than once.

M. Irradiated Foodstuffs

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 or foods containing irradiated ingredients must be labeled "irradiated" or "treated with ionizing radiation". This directive requires the European Commission to publish an [annual report on food irradiation in the EU](#). To enforce correct labeling or to detect non-authorized products, several analytical methods have been standardized by the European Committee for Standardization (CEN).

[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. The list of national authorizations is available on the European Commission's website at http://ec.europa.eu/food/food/biosafety/irradiation/comm_legisl_en.htm.

N. Seafood

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

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

- Commercial name of the species (each member state has established a list of commercial designations).
- Product method: “caught in...”, “caught in freshwater”, “farmed” or “cultivated”.
- Catch area: for products caught at sea, a reference to one of the areas listed in the annex.
 - 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 March 2012 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/Howtoexportseafood2012%20.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. Discussions between the European Parliament and the Council on the adoption of the proposal are still on-going in the context of the ordinary legislative procedure (co-decision). More information on the status of the Fisheries Reform proposal can be found on the Commission’s website at http://ec.europa.eu/fisheries/reform/index_en.htm.

O. Pet Food

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/pet-food/>

In the EU, pet food is subject to feed marketing legislation and veterinary legislation. The EU’s feed marketing legislation covers food for pets as well as feed for food-producing animals. The veterinary legislation covers products of animal origin and hay/straw as these products present a risk for spreading animal diseases. Pet food products containing an animal origin ingredient must be sourced from approved establishments and have to be accompanied by a veterinary certificate. All exports of U.S. pet

food to the EU must comply with EU requirements including rules on labeling, hygiene, animal health, certification and the use of additives. [GAIN report “Exporting Pet Food to the European Union”](#) provides a detailed overview of EU legislation relating to imports of pet food.

[European Parliament and Council Regulation 767/2009](#) sets out 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. For more information see [GAIN report E50060 “EU Feed and Pet Food Labeling Requirements”](#). EU border inspection officials will verify the labels on imported pet food for compliance with EU requirements. Annex 4 to the [“Code of Good Labeling Practice for Pet Food”](#), drafted by the European Pet Food Industry (FEDIAF) establishes a “check-list” that pet food manufacturers can use to verify compliance with EU labeling rules.

[Commission Regulation 575/2011](#) establishes a 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.

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.usda-eu.org/topics/geographical-indications/>

[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](#).

On December 10, 2010, the European Commission presented a proposal on "Agricultural Product Quality Schemes" introducing a harmonized, simplified and shorter registration procedure for PDO's and PGI's and providing clarifications on intellectual property rights. After two years of negotiations, the proposal was adopted in November 2012, and consequently published as [European Parliament and Council Regulation 1151/2012](#). The new rules enter into force on January 3, 2013, and cover agricultural products and foodstuffs but not wines and spirits which are covered by specific legislation. The new regulation consolidates four different quality schemes (Protected Designations of Origin, Protected Geographical Indications, Traditional Specialties Guaranteed, and Optional Quality Terms) into a single legal framework. The provisions on labeling and the use of EU logos for PDO's, PGI's and TSG's will apply from January 4, 2016.

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.

[Regulation 450/2008](#) establishing the “Modernized Customs Code” was adopted in 2008 but is not yet applicable. It is due to become applicable once its implementing provisions are in force, at the latest June 24, 2013. However, as the European Commission decided to amend the Modernized Customs Code before it becomes applicable, a [proposal to recast the Modernized Customs Code](#) was published in February 2012.

[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 “Taric” customs database](#) can be consulted to look up commodity codes and relevant import duties. Taric is a multilingual database covering all measures relating to tariff and trade legislation. The [EU’s 2013 Tariff Schedule](#) was published on October 31, 2012 in Official Journal L 304. A list of customs authorities can be found at http://ec.europa.eu/taxation_customs/common/links/customs/index_en.htm.

It is also possible to obtain Binding Tariff Information (BTI) from a member state’s customs authority to get the proper product classification. Through this system, traders know in advance the tariff classification of the goods they intend to import. BTI, generally valid for six years, 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 designated for the purpose of issuing binding tariff information](#) was published in Official Journal C 144 of May 14, 2011. All BTIs issued by the national customs authorities have been entered into the European Commission’s [EBTI-database](#). 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/how_vat_works/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
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Belgium
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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
Website: www.usda-eu.org

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

Food and Drug Administration (FDA)
Mailing address:
27 Boulevard du Regent
1000 Brussels
Belgium
Tel: (32-2)8114518

E-mail: PraterD@state.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		

For updates see <http://www.usda-eu.org/ask-the-expert/>.

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”](#)
- Eco-labeling ([EU Eco-label Work Plan 2011-2015](#))
- Food from cloned animals
- Footprinting
- GMO’s Low Level Presence for food imports
- Halal / Meat obtained from animals slaughtered in religious rites
- 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
- Pesticides
- Seafood labeling
- Smoke flavorings
- Sustainability ([Sustainable Consumption & Production \(SCP\) Round Table](#))

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.usda-eu.org>
- 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
- **Food labeling**: guidance documents
http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/index_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

- Guidance on the implementation of **Nutrition and Health Claims** Regulation 1924/2006

http://ec.europa.eu/food/food/labellingnutrition/claims/guidance_claim_14-12-07.pdf

- Guidance for applicants on **health claims**: <http://www.efsa.europa.eu/en/nda/ndaguidelines.htm>

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

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:0704:FIN:EN:PDF](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/Howtoexportseafood2012%20.pdf>