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Food and Agricultural Import Regulations and Standards - Narrative

FAIRS Country Report

Approved By:

Karisha Kuypers

Prepared By:

Hilde Brans

Report Highlights:

This report provides an overview of EU food and feed legislation currently in force. All sections of the report were updated but special attention should be given to the EU's new dietetic food rules applicable since July 20, 2016 (Section V-VI). For updated on developments in EU food and feed legislation check the FAS USEU website www.usda-eu.org.

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.

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Section I. General Food Laws

The European Union (EU) has gradually expanded to become the world's largest multi-nation trading bloc. Since July 1, 2013, the European Union comprises 28 member states with approximately 500 million consumers. EU member states: Austria, Belgium, Bulgaria, Croatia, 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 (U.K.). Iceland, Montenegro, the Former Yugoslav Republic of Macedonia, Turkey, Albania and Serbia are candidates to join the EU. In June 2016, the U.K. voted in a referendum to leave the EU. Until negotiations on an exit agreement between the U.K. and the other 27 Member States are concluded, the U.K. remains a member of 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. EU Member States share a customs union, a single market in which goods can move freely, a common trade policy and a common agricultural and fisheries policy.

Reportedly, around 98% of food legislation is harmonized at the EU level. Imported products must meet existing Member State requirements in cases where EU regulatory harmonization is not yet complete or absent. U.S. exporters should be aware that products not covered by EU-harmonized food law may be subject to different national rules. 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>.

Where legislation has not been harmonized at EU-level, "mutual recognition" should guarantee the free movement of goods in the EU. Under the principle of mutual recognition, products lawfully produced and/or marketed in one Member State should, in theory, be allowed to be marketed in any other Member State. 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. In June 2016, the European Commission launched a [public consultation](#) on the possible revision of the Mutual Recognition Regulation.

The EU has followed a dual approach in harmonizing food laws: "horizontal" legislation covering aspects common to all foodstuffs (such as additives, labeling, hygiene, etc.) and "vertical" legislation on specific products (e.g., wine, cocoa and chocolate products, sugars, honey, fruit juices, fruit jams, novel foods, etc.). U.S. exporters should be aware that products may have to comply with several pieces of legislation. For example, wine labeling rules are set out in specific (vertical) legislation but allergen labeling rules which also apply to wine are set out in the EU's general food labeling (horizontal) regulation.

EU food legislation consists of “regulations” and “directives” and rules for their implementation. Directives lay down results that must be achieved but each Member State is free to decide how to transpose directives into national law (usually within 2-3 years after adoption). Regulations do not require transposition. They are binding in their entirety and automatically enter into force on a set date in all Member States. Amendments to EU legislation are published in separate directives and regulations. 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. EU laws are translated into the 24 official languages in use in the EU-28 and published in the Official Journal as soon as they are translated. 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.

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](#)). An [EFSA “infographic”](#) explains the difference between “risk assessment” and “risk management.” 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 these framework regulations. For more information see <http://www.usda-eu.org/topics/food-safety/>.

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. A [new Interinstitutional Agreement](#) between the three institutions was published in the Official Journal in May 2016. In principle, the Commission proposes new laws and the Council and European Parliament adopt them under the “Ordinary Legislative Procedure” (ex co-decision). The precautionary principle is often invoked by the EU legislators to the detriment of innovation. Detailed information on the EU procedures can be found in [GAIN report “How the EU works – A guide to EU decision-making”](#) (updated April 2016) and on our website at <http://www.usda-eu.org/eu-basics-questions/>.

In May 2015, the European Commission presented its “Better Regulation Package,” a so-called update of its own law-making practices in order to meet EU legislators’ and citizens’ expectations in terms of impact assessment, transparency, stakeholder consultation and implementation. In July 2016, the European Commission launched a new consultation tool offering stakeholders the opportunity to provide online feedback on draft EU secondary legislation. Detailed information on the new feedback tool can be found in [GAIN report “New Online Feedback Tool to Comment on Draft EU Legislation”](#). The “REFIT” program, launched in 2013, evaluates whether existing legislation is still fit for purpose and makes changes where needed. Information on the Better Regulation Package and the REFIT program is available on the European Commission’s website http://ec.europa.eu/smart-regulation/index_en.htm.

The “European Group on Ethics in Science and New Technologies” (EGE) is an independent and multi-disciplinary advisory body tasked to advise the European Commission on ethical aspects of science and new technologies in preparation of new EU legislation and policies. For more information see the European Political Strategy Centers’ website <https://ec.europa.eu/research/ege/index.cfm>.

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.

See our website

www.usda-eu.org

for updates on EU food laws and policies

Section II. Food Additive Regulations

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

The EU's "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](#).

[Regulation 1331/2008](#) establishes a common authorization procedure for food additives, food enzymes and food flavorings based on safety evaluations carried out by the European Food Safety Authority (EFSA). [Commission Implementing Regulation 234/2011](#) explains in detail how applications to update the EU positive lists should be drafted (content, data requirements and presentation). EFSA then verifies the suitability of the data.

A. Additives (including colors and sweeteners)

Additives that are authorized in food and their conditions of use are listed in Annex II to the [Food Additives Regulation 1333/2008](#). The authorized uses of additives are listed according to the category of food to which they may be added. Annex I to regulation 1333/2008 lists the definitions of 26 different categories of food additives. Only additives included in the EU's positive list are authorized under specific conditions. An important difference from U.S. legislation is that the use of flour bleaching agents chlorine, bromates and peroxides is not allowed in the EU.

Annex III to Regulation 1333/2008 contains a second list of food additives approved for the use in food ingredients such as other food additives, food enzymes, food flavorings and nutrients. Specifications for food additives listed in Annexes II and III are laid down in [Commission Regulation 231/2012](#).

Annex IV lists traditional foods for which certain Member States may continue to prohibit the use of certain categories of food additives.

Annex V to Regulation 1333/2008 contains labeling information for six food colors: Quinoline Yellow (E104), Sunset Yellow (E110), Ponceau 4R (E124), Tartrazine (E102), Azorubine/Carmoisine (E122) and Allura Red AC (E129). Foods containing these colors have to be labeled "may have an adverse effect on activity and attention in children" (see also Section V – Labeling Requirements). The limits for these food colors were lowered by [Commission Regulation 232/2012](#).

Re-Evaluation Program

A re-evaluation program set up by [Commission Regulation 257/2010](#) requires a new risk assessment carried out by EFSA for additives which were approved before Food Additives Regulation 1333/2008 entered into force.

The re-evaluation of approved food additives is/was to be completed by the end of:

- 2015 for food colors (currently listed in Directive 94/36/EC)
- 2015-2016 for preservatives, antioxidants, glutamates, silicon dioxide
- 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)

On October 13, 2015, EFSA published a [list of food additives under re-evaluation](#). EFSA has launched a call for analytical data on concentration levels in food and beverages to re-assess the safety of a 5th batch of food additives. Data can be submitted until January 31, 2017. For more information see EFSA's website at <http://www.efsa.europa.eu/en/data/call/160524>.

Data on usage level and/or concentration data in food and beverages intended for human consumption could be submitted to EFSA until May 31, 2016.

The Commission's [food additives database](#) together with its [user guide](#) provides detailed information on the different food additives allowed in the EU. More information on the use of food additives can be obtained from the European Commission's website at http://ec.europa.eu/food/safety/food_improvement_agents/index_en.htm.

B. Flavorings

[Regulation 1334/2008](#) on flavorings and certain food ingredients with flavoring properties sets specific rules for the use of the term "natural." Annex I of [Regulation 1334/2008](#) establishes a list of substances that are authorized for use in the EU. 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 verify which flavoring substances are authorized in food.

[Commission Regulation 873/2012](#) concerns transitional measures for other flavorings such as flavorings made from non-food sources.

The procedure for the safety assessment and the authorization of smoke flavorings intended for use in or on foods is established in [Regulation 2065/2003](#). The Union list of authorized smoke flavoring primary products for use as such in or on foods and/or for the production of derived smoke flavorings is established by [Commission implementing Regulation 1321/2013](#).

C. Enzymes

[Regulation 1332/2008](#) on food enzymes introduced harmonized rules for their scientific evaluation and authorization in the EU and establishes labeling requirements. Specific labeling requirements are set in Articles 10-13 of Regulation 1332/2008.

[Regulation 234/2011](#) on the implementation of the common authorization procedure, last amended by [Commission Implementing Regulation 562/2012](#) regarding specific data required for the risk assessment of food enzymes, set out a 2 year-deadline starting from September 11, 2011 to submit applications on

existing and new enzymes. However, the initial deadline for submitting applications was extended to 42 months by [Commission Regulation 1056/2012](#). Information for the risk assessment of food enzymes submitted by industry is in the process of being evaluated by EFSA. Based on EFSA's risk assessment, the Commission will establish an EU positive list of authorize enzymes. Until the adoption of such a list, the existing national provisions on the marketing of food enzymes will continue to apply.

D. 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](#).

Section III. Pesticides and Contaminants

A. PESTICIDES

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

[European Parliament and Council Regulation 1107/2009](#) sets out rules for the authorization of plant protection products (PPPs). PPPs (also referred to as 'pesticides') contain at least one approved active substance. Only PPPs containing active substances included in the list of approved active substances as established in [Commission implementing Regulation 540/2011](#) may be authorized for use in the EU. Before any PPP can be placed on the market or used, it must be authorized in the relevant Member State(s). According to Annex I of Regulation 1107/2009, 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 EU. Maximum Residue Levels (MRLs) for substances that are not on the EU positive 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.

[Directive 2009/128](#) on the sustainable use of pesticides is also part of the so-called Pesticides Package. For more information see the European Commission website http://ec.europa.eu/food/plant/pesticides/sustainable_use_pesticides/index_en.htm.

Endocrine Disruptors

“Endocrine disruptors” (EDs) refer to substances with the potential to alter and cause unintentional adverse health effects to the endocrine systems of humans and wildlife. Both the Plant Protection Products Regulation 1107/2009 (Pesticides) and the Biocidal Products Regulation 528/2012 (Biocides) introduced “endocrine disrupting properties” as one of the categories of hazard-based cut-off criteria. This would allow the EU to ban certain products from the market based on hazard identification rather than risk assessment without taking exposure into account. On June 15, 2016, the European Commission presented two draft measures outlining scientific criteria to identify EDs under the Plant Protection Products Regulation (1107/2009) and Biocidal Products Regulation (528/2012), using the World Health Organization (WHO) definition for EDs as a basis. The new measures, which will apply immediately for the approval of new substances and re-approval of currently authorized products once adopted, could enter into force as early as mid-2017.

Maximum Residue Limits (MRLs): Regulation 396/2005

[European Parliament and Council Regulation 396/2005](#) harmonizes all MRLs in the EU 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. A general default MRL of 0.01 mg/kg applies where a pesticide is not specifically mentioned.

See the European Commission's website at http://ec.europa.eu/food/plant/pesticides/max_residue_levels_en for the latest updates.

For a list of authorized active substances or pesticide-MRL combinations, see the European Commission's [online database](#).

On June 17, 2016, the European Commission notified a document to the WTO explaining the [on-going review of MRLs](#) in the EU to non-EU countries, highlighting the active substances and relevant MRLs that are scheduled to be reviewed in the near future.

Import Tolerance

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 is available in "[Pesticide Use and Food Safety](#)" guide published by the European Crop Protection Association (ECPA). Since September 2, 2008 all MRLs, including import tolerances, apply EU wide. The application form for an import tolerance can be found [here](#).

Upcoming Review

Both Regulation 1107/2009 and Regulation 396/2005 are scheduled to be reviewed in the next coming years. More background information on the upcoming review can be found in the [ECPA's position paper](#).

Official Controls

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 Implementing Regulation 2016/662 outlines the latest version of the coordinated multi annual control program of the EU for pesticides residues, which](#) 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 2018, 2019 and 2020 for samples tested in 2017, 2018 and 2019 respectively. For more information see the European Commission website http://ec.europa.eu/food/plant/pesticides/max_residue_levels/enforcement/index_en.htm.

B. 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
 - citrinin in rice/yeast fermented food supplements
 - ergot sclerotia and ergot alkaloids
- Heavy metals (section 3):
 - lead in milk, baby and infant food, meat, offal, seafood, vegetables, fruit, wine and food supplements
 - cadmium in meat, fish and seafood, cereals, soybeans, vegetables, fruit, fungi and food supplements, baby formula and infant food, cereals and soybeans, cocoa
 - 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, cocoa, infant foods, (smoked) meat, bivalve molluscs, fish and infant food (section 6)
- Melamine in infant food (section 7)
- Inherent plant toxins (section 8):
 - erucic acid
 - fats and oils and foods containing these ingredients
 - infant formula
 - tropane alkaloids

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 589/2014](#)
- Heavy metals, Tin, 3-MCPD and benzo(a)pyrene: [Commission Regulation 333/2007](#)
- [Erucic acid: Commission Regulation \(EU\) 2015/705](#)

Official Aflatoxin Controls on U.S. Products

In April 2015, the EU approved the pre-export checks (PEC) program for U.S. almonds. U.S. almonds were included in the Annex to [Commission Implementing Regulation \(EU\) 2015/949](#) which lists all EU-approved Pre-export Check programs. The acceptance of the U.S. program reflects the EU's recognition of aflatoxin controls performed at U.S. origin in line with Article 23 of the EU Regulation on Official Food and Feed Controls ([Regulation \(EC\) No 882/2004](#)). The USDA Agricultural Marketing Service began issuing PEC almond certificates on August 1, 2015. The almond PEC program builds on and replaces the Voluntary Aflatoxin Sampling Plan (VASP) program, which was no longer required after September 2014 when the EU voted to remove California Almonds from Special Measures.

With the publication of Commission Implementing Regulation (EU) 2015/949, all EU accepted programs have been combined in one regulation. The U.S. peanut program which was approved in 2009 is now also covered by the general provisions of [Commission Implementing Regulation \(EU\) 2015/949](#). Under the regulation, import authorities subject consignments of U.S. almonds and peanuts with a PEC certificate to a **less than 1% control level** at the border. The PEC program is voluntary; a PEC certificate is not a requirement for import into the EU. Shipments without a PEC certificate do not benefit from the reduced inspection levels upon import in the EU.

For additional information on aflatoxin PEC certification, see:

- <http://www.almonds.com/processors/newsletters/handle/gearing-pec-program>
- <http://www.peanutsusa.org.uk/eu-food-aflatoxin-legislation>
- <http://www.ams.usda.gov/services/lab-testing/aflatoxin>

On April 1, 2015, U.S. pistachios were included in the list of products/origins subject to increased import controls under [Commission Regulation \(EC\) No 669/2009](#). Member States must test 20 percent of all incoming shipments until the list in the Annex of the regulation is amended. This regulation does not impose any requirements on exporters.

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 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 its guarantees on 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 IV. Packaging and Container Requirements

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](#) abolished regulations on mandatory pack sizes at both EU and national levels. The Directive frees sizes for all prepackaged products except wine and spirits, and coffee. Mandatory nominal quantities for wines and spirits are set out in the Annex to Directive 2007/45/EC.

Detailed information on "Legal Metrology" is available on the European Commission's website <http://ec.europa.eu/growth/single-market/goods/building-blocks/legal-metrology/>.

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](#) harmonizes national measures concerning the management of packaging and packaging waste and its impact on the environment. 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). An overview of current EU legislation applicable to packaging and packaging waste is available on the European Commission's website <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01994L0062-20150526&qid=1446639081652&from=EN>.

C. Materials in Contact with Foodstuffs

[European Parliament and Council Regulation 1935/2004](#) specifies the main requirements for all 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 (EFSA). Annex I to regulation 1935/2004 lists the group of materials which may be covered by specific measures. Specific measures set out additional requirements and include lists of authorized substances and materials. 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](#), amending Regulation 10/2011 on plastic materials, bans 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 the European Commission'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/safety/chemical_safety/food_contact_materials_en.

Check out the [European Commission's website](#) for information on specific substances.

Section V. Labeling Requirements

A. General Requirements

The standard U.S. label fails to comply with EU labeling requirements. On December 13, 2014, the EU's new "[Food Information to Consumers \(FIC\) regulation 1169/2011](#)" became applicable to all pre-packaged food and drink products marketed in the EU, including those imported from third countries. The mandatory nutrition declaration requirement introduced by the new FIC regulation becomes applicable on December 13, 2016.

Detailed information on food labeling requirements set out in the FIC regulation is available in [GAIN report "New EU Food Labeling Rules Published"](#), supplemented by [GAIN report "How to Comply with the EU's New Food Labeling Rules"](#). These reports as well as updates on EU labeling rules can be found on FAS USEU's website at <http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/eu-labeling-requirements/>.

In order to assist food business operators complying with the EU's food labeling rules, the European Commission as well as several Member State authorities and EU food federations have published guidance documents.

- European Commission: [Questions and Answers on the Application of Regulation 1169/2011 on the Provisions of Food Information to Consumers](#)
- [European Commission: Infographic on the new labeling rules](#)
- FoodDrink Europe (EU Food and Drink Industry Confederation): [Guidance on the Provision of Food Information to Consumers](#)
- U.K.: [The Food Information Regulations 2013 – Guide to compliance](#)
- Ireland: [Food and Drink Labeling – A Practical Guide for Industry](#)

The objective of a "regulation" is to set harmonized rules that apply throughout the EU. However, the FIC regulation allows EU Member States to deviate from EU rules. Article 39 of the FIC regulation sets conditions for Member States to adopt additional mandatory national measures, including measures for country of origin labeling. The FIC regulation exempts alcoholic beverages from mandatory nutrition labeling and ingredient listing but Article 41 allows Member States to maintain national rules on the listing of ingredients until EU-harmonized provisions are adopted. U.S. exporters are strongly advised to check for additional national requirements with their importers.

1. Compulsory Information

Article 9 of FIC regulation 1169/2011 sets out the list of mandatory declarations on food and drink labels:

- Name of the food
- List of ingredients
- Allergens listed in Annex II
- Quantity of certain ingredients or category of ingredients
- Net quantity of the food
- Date of minimum durability of “use by date”
- Any special storage conditions and/or conditions of use
- Name of business name and address of the food business operator under whose name the food is marketed. If that operator is not established in the EU, the name and address of the importer
- Country of origin or place of provenance in accordance with the provisions of Article 26
- Instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions
- Alcoholic strength by volume for beverages containing more than 1.2% by volume of alcohol
- Nutrition declaration

2. Warnings on Labels

Annex III to FIC regulation 1169/2011 establishes a list of products that require a special warning on the label:

- Foods whose durability has been extended by means of packaging gases
- Foods containing sweeteners authorized under [Food Additives Regulation 1333/2008](#)
- Foods containing added sugar and sweeteners authorized under [Food Additives Regulation 1333/2008](#)
- [Foods containing aspartame authorized under Food Additives Regulation 1333/2008](#)
- [Foods containing more than 10% added polyols authorized under Food Additives Regulation 1333/2008](#)
- Confectionery and beverages containing licorice (glycyrrhizinic acid or its ammonium salt)
- Beverages containing more than 150mg/l of caffeine and foods with added caffeine
- Foods or food ingredients with added phytosterols, phytosterol esters, phytosterols or phytosterol esters

Annex V to [Food Additives Regulation 1333/2008](#) requires foodstuffs containing the food colors sunset yellow (E110), quinoline yellow (E104), carmoisine (E122), allura red (E129), tartrazine (E102) and ponceau 4R (E124) to be labeled “may have an adverse effect on activity and attention in children.”

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

3. Minimum Font Size

Article 13 of FIC regulation 1169/2011 introduces a minimum font size for printing the mandatory information on food and drink labels. As a general rule, the information must be printed in characters using of minimum font size of 1.2 mm for the “x-height” as defined in Annex IV. If the largest surface of a food package or container is less than 80 cm² the minimum font size is reduced to 0.9 mm. On packages with a printable surface smaller than 25 cm², the nutrition declaration is not required. Packages which are smaller than 10 cm² do not need to bear a nutrition declaration nor a list of ingredients.

The minimum font size does not apply to mandatory labeling requirements set out in other EU legislation such as for example the font size requirements set out in Directive 76/2011 to indicate the nominal quantity (see Section IV Packaging and Container Requirements).

Minimum Font Size for printing mandatory information is 1.2 mm

4. Language Requirements

Article 15 of FIC regulation 1169/2011 stipulates that the mandatory information should be provided in “a language easily understood by the consumers of the Member States where the food is marketed.” In practice, this means the official language(s) of that Member State. Member States may specify which information needs to be provided in one or more official EU languages. In order to avoid non-compliance with the new labeling rules, translations of mandatory information must be accurate. Automated online translation tools may generate incorrect translations and should not be used unless edited. Please consult the [Member State FAIRS reports](#) for information on specific Member State language requirements.

U.S. Exporters should verify with their importers about additional Member State language requirements

5. Ingredients List

The list of ingredients must be preceded by the word “ingredients.” All ingredients must be designated by their specific name and listed in descending order of weight. Ingredients present in the form of engineered nanomaterials must be indicated in the list of ingredients followed by the word “nano” in brackets. Annex VII to FIC regulation 1169/2011 sets out specific provisions concerning the indication

of ingredients and categories of ingredients in the list of ingredients. This Annex requires the mandatory indication of the source of vegetable oils and fats.

In the list of ingredients “Vegetable oils” and “vegetable fats” must be followed by a list of the specific vegetable sources

6. Allergen Labeling

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

FIC regulation 1169/2011 introduced important changes for allergen labeling. Article 21 of the FIC regulation stipulates that each product or substance capable of inducing an allergic reaction must be indicated in the list of ingredients with reference to the name of the substance or product as listed in Annex II to the FIC regulation. The name of the substance or product must be highlighted through a typeset that clearly distinguishes it from the other ingredients, for example in bold or with a background color.

Example: “tofu” (soya) – “whey” (milk)

Where an ingredients list is provided, the voluntary use of warning boxes or statements such as “contains X” to repeat the presence of the allergenic ingredients is no longer allowed.

On products that do not require an ingredients list, such as for example wine, the presence of allergens must be indicated using the word “contains” followed by the name of the substance or product as listed in Annex II to the FIC regulation. Allergen labeling is mandatory on all alcoholic beverages and must respect the minimum font size requirement. Member States may decide in which language(s) allergens should be indicated on the label.

In November 2014, the European Commission launched a public consultation on a [Guidance Document on Allergen Labeling](#). The consultation closed on January 4, 2015. For more information please consult DG SANTE’s website: http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/food/consult_20150104_allergy-intolerance_en.htm.

Other guidance documents:

- [Allergen Labeling – Annex 3 \(FoodDrinkEurope\)](#)
- [Advice on Food Allergen Labeling \(U.K. Food Standards Agency\)](#)
- [Food allergen labeling – technical guidance \(U.K. Food Standards Agency\)](#)

Allergens must be highlighted in the list of ingredients

7. Minimum Durability

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

Annex X to FIC regulation 1169/2011 sets out rules for the indication of the date of minimum durability, use-by date and date of freezing. The use-by date must be indicated on individual pre-packed portions. The durability date **AND** the date of (first) freezing preceded by the words “frozen on” is required on labels of frozen meat, frozen meat preparations and frozen unprocessed fishery products.

Dates must be given in the following order: day/month/(if required) year

8. Quantitative Ingredients Declaration (QUID)

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

Article 22 of the FIC regulation requires the indication of the quantity of an ingredient or category of ingredients in the following cases:

- Where the ingredient or category of ingredients appears in the name of the food or is usually associated with that name by the consumer
- Where the ingredient or category of ingredients is emphasized on the labeling in words, pictures or graphics
- Where the ingredient or category of ingredients is essential to characterize a foodstuff and to distinguish it from similar products

The QUID declaration, expressed as a percentage, must appear either in or immediately next to the name of the food or in the list of ingredients. Annex VIII to the FIC regulation sets out the technical rules and exemptions from the QUID requirement.

European Commission guidelines on QUID can be downloaded from their website at http://ec.europa.eu/food/safety/docs/labelling_legislation_guidance_quid_en.pdf. The Commission is currently working on an update of the QUID guidelines.

If an ingredient is emphasized on the label, the quantity (%) must be indicated in the list of ingredients

Example: “made with butter” – QUID for butter

9. Additives & Flavorings

Annex VII, Part C to FIC regulation 1169/2011 lists the categories of additives which must be designated by the name of their category, followed by their specific name or E-number. Part D of the same Annex sets out rules for the indication of flavorings, smoke flavorings and the use of the term “natural.”

10. Country of Origin Labeling (COOL)

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

Before the adoption of FIC regulation 1169/2011 COOL was already mandatory for honey, fruit and vegetables, olive oil, fishery and aquaculture products and beef. The FIC regulation extends the mandatory COOL requirement to fresh, chilled and frozen pork, sheep and goat meat and poultry. Under Article 26 of the FIC regulation, mandatory COOL applies in the following cases:

- Where failure to indicate the country of origin or place of provenance might mislead the consumer
- For fresh, chilled and frozen pork, sheep and goat meat and poultry (see “Meat Labeling”)
- When the country of origin is given voluntarily, i.e. on products for which COOL is not mandatory, but the origin of the primary ingredient is not the same as that of the food product. In such case, the label must indicate that the country of origin of the primary ingredient is different from that of the food product.

Detailed information on COOL is provided [in GAIN report “The EU’s Country of Origin Labeling Policy”](#). The FIC regulation required the European Commission to prepare reports on the feasibility of introducing mandatory COOL for dairy products, “minor” meats, unprocessed products and single ingredient products. The reports are available on DG SANTE’s website http://ec.europa.eu/food/safety/labelling_nutrition/labelling_legislation/index_en.htm.

Regulation 1169/2011 extends mandatory COOL to fresh, chilled and frozen pork, sheep and goat meat and poultry

11. Alcoholic Beverages

Alcoholic beverages containing more than 1.2% of alcohol by volume are still exempted from the obligation to bear a nutrition declaration and a list of ingredients. The FIC regulation required the

European Commission to prepare a report by end 2014 examining whether the exemption for alcoholic beverages should be maintained. To date, the Commission has not released the report but is expected to do so early 2017. Allergen labeling is compulsory on all alcoholic beverages (see “Allergen Labeling”). On beverages containing more than 1.2% of alcohol by volume (excluding wines), the actual alcoholic strength by volume must be indicated in accordance with Annex XII to FIC regulation 1169/2011. The alcoholic strength must be indicated by a figure with maximum one decimal place followed by the symbol “% vol..” The alcoholic strength must be given in the same field of vision as the product name and the net quantity. For wines, rules for the indication of the alcoholic strength are set out in specific legislation (see Chapter B.5 “Other Specific Labeling Requirements - Wine”).

The alcoholic strength must be given in the same field of vision as the product name and the net quantity

12. Nutrition Declaration

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

Under FIC regulation 1169/2011, the nutrition declaration becomes mandatory on December 13, 2016. Annex V to the FIC regulation lists foodstuffs which are exempted from the mandatory nutrition declaration requirement. The nutrition declaration must be presented, if space permits, in tabular format with the numbers aligned and where space does not permit, in linear format. All elements of the mandatory nutrition declaration should be in the same field of vision on the food label or package.

Mandatory content of the nutrition declaration:

- Energy value: expressed in kilojoules (kj) and kilocalories (kcal)
- **In this particular order:** amounts of fat, saturates, carbohydrate, sugars, protein and salt, expressed in grams (g), milligrams (mg) or micrograms (µg) per 100 grams or per 100 milliliters

Nutrition declarations per portion or per consumption unit, in addition to the declaration per 100 grams or milliliters are allowed provided that the number of portions/consumption units is clearly indicated on the package. 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 following elements may, on a voluntary basis, be repeated on the front label:

- Energy value
- Energy value together with the amounts of fat, saturates, sugars and salt

The content of the mandatory nutrition declaration may be supplemented with the indication of the amounts of one or more of the following:

- Monounsaturates
- Polyunsaturates
- Polyols
- Starch
- Fiber
- Vitamins and minerals listed in Part A of Annex III to the FIC regulation (incl. percentage of reference intakes)

Detailed rules on the presentation of the nutrition declaration are set out in Annex XV to the FIC regulation.

Annex V to the FIC regulation establishes a list of products that are exempted from the mandatory nutrition declaration requirement.

The EU's Food & Drink Industry Federation "FoodDrinkEurope" has launched a website explaining "reference intakes" to food business operators and consumers: <http://referenceintakes.eu/reference-templates.html>. For detailed information on the nutrition panel see the guidance documents listed in "General Requirements" (Chapter A).

Article 35 of the FIC regulation allows voluntary national labeling schemes, such as for example the U.K. traffic light labeling scheme, to provide nutrition information to consumers. The FIC regulation requires the Commission to prepare a report by December 13, 2017, on experience gained with the national schemes and their impact on the internal market. The Commission may accompany this report with proposals to modify the current rules.

Nutrition information must be presented in tabular format and in a specific order expressed per 100 grams/milliliters

13. Gluten-Free

Harmonized compositional and labeling rules for foods for persons with gluten intolerance were previously set out in the EU's directive on foods for particular nutritional uses (Directive 41/2009). With the adoption of the [new dietetic foods regulation 609/2013](#), it was decided that gluten-free foods would be regulated under the FIC regulation. Commission Implementing Regulation 828/2014, applicable since July 20, 2016, sets out conditions for using "gluten-free" and "very low gluten" statements on food labels.

14. Trans Fats

Rules to limit and label the content of trans fats in food products are not yet EU-harmonized. Certain Member States such as Denmark, Austria, Hungary and Latvia have set national legal limits on industrially produced trans fats in foods. The FIC regulation required the European Commission to prepare a report by end 2014 on the presence of trans fats in foods. On October 11, 2016, the Commission published a [roadmap](#) to assess several policy options for limiting industrial trans fat intakes in the EU. Based on the outcome of the impact assessment, the Commission may come forward with a legal proposal.

15. Use of Stickers

Specific rules on the use of stickers to provide mandatory labeling information are not included in FIC regulation 1169/2011. On this issue, the European Commission refers to point 2.1.1 of [their Questions and Answers on the Application of Regulation 1169/2011](#) document which says that “labels should not be easily removable so as to jeopardize the availability or the accessibility of the mandatory food information to the consumer.” Some Member States may allow the use of stickers while other may not. Please consult the [Member State FAIRS reports](#) for more information.

U.S. Exporters should check with their importers whether the destination Member State allows the use of stickers

16. Samples

FIC Regulation 1169/2011 does not include any provisions on samples.

17. Checklist for Compliance with new FIC Rules

FOOD LABELS	
Language / Specific Member State requirements	
Minimum font size	
Name of food (must include specific treatments such as “refrozen,” “smoked,” “powdered,” percentage of added water to meat and fishery products	
Warnings (Annex III to FIC regulation lists products that require a warning label)	
Instructions for use (symbols are allowed IN ADDITION to text)	

ALLERGEN LABELING

Allergens listed in Annex II to FIC regulation must be indicated	
Allergen boxes are no longer allowed when an ingredients list is provided	
Each allergen must be highlighted (bold, background color) in the list of ingredients	
“Contains + name of allergen” where no ingredients list is provided	

INGREDIENTS LIST

Heading must include the word “Ingredients” (do not highlight)	
All ingredient must be listed in descending order of weight	
“Nano” in brackets to indicate presence of engineered nanomaterials	
Quantitative Ingredients Declaration (QUID) for ingredients given special emphasis	
Source of vegetable oil or fat must be indicated	
Proteins added to meat products must be indicated	

DATE OF MINIMUM DURABILITY

Instructions listed in Annex X to FIC regulation	
“Use by” date on highly perishable foods / on each individual pre-packed portion / storage instructions	
“Best before” / “Best before end” on other foods	
Durability AND “frozen on” date on frozen products	
Reference to where the date is given on the label	

ALCOHOLIC STRENGTH

Instructions listed in Annex XII to FIC regulation	
Actual alcoholic strength by volume of alcohol of beverages containing more than 1.2% by volume of alcohol must be indicated as “alcohol” or the abbreviation “alc.” X% vol.	
Product name, net quantity and alcohol strength must be indicated in the same field of vision	

COUNTRY OF ORIGIN (COOL)

Mandatory COOL where failure to indicate this would mislead consumer	
Mandatory COOL for meat from sheep, goats, poultry and pigs	
Mandatory COOL for other products may be adopted in near future	

Mandatory Nutrition Declaration (applicable as of December 13, 2016 – nutrition panels provided before this date must comply with FIC regulation)

Instructions listed in Annex XV to FIC regulation	
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Tabular format (linear format where space does not permit tabular format)	
Expressed per 100g/ml	
Energy in KJ and kcal	
In this particular order, amounts of:	
Fat	
Saturates	
Carbohydrate	
Sugars	
Protein	
Salt (not sodium)	

Voluntary Nutrition Declaration (may complement Mandatory Nutrition Declaration)	
Mono saturates	
Polyunsaturates	
Polyols	
Starch	
Fibre	
Vitamins and minerals listed in Annex XIII to FIC regulation	
Energy value or Energy Value together with Fats, Saturates, Sugars, Salt may be repeated	
Reference Intake (RI) set out in Annex XIII per portion or consumption unit (must include energy value per 100g/ml and per portion)	

See also Commission [infographic “New EU food labeling rules.”](#)

B. Other Specific Labeling Requirements

The EU’s “Food Information to Consumers” regulation 1169/2011 sets out horizontal rules applicable to all products. Sectoral or “vertical” legislation exists for a number of products. Labeling requirements set out in product-specific legislation complement the horizontal rules set out in regulation 1169/2011. For example, EU wine regulations do not include provisions on allergen labeling. This means that wine labels not only have to comply with the requirements set out in wine regulation 607/2009 but also with the allergen labeling requirement set out in FIC regulation 1169/2011.

U.S. Exporters should be aware that different pieces of legislation may apply to single products

1. Nutrition Claims

The Annex to [Nutrition & Health Claims Regulation 1924/2006](#) lists the EU authorized nutrition claims and their conditions of use. The use of nutrition claims not included in the annex is not allowed.

2. Health Claims

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

Rules on the use of health claims are set out in [Nutrition & Health Claims Regulation 1924/2006](#). [Regulation 432/2012](#) establishes the EU positive list of functional health claims and their conditions of use. Any producer can 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"](#) lists the authorized health claims as well as the rejected claims and the reasons for their non-authorization. Since December 14, 2012, all claims that are not authorized and not on hold or under consideration are prohibited. Food products carrying claims must also comply with the provisions of the EU's ["Food Information to Consumers \(FIC\)" regulation 1169/2011](#). [Commission Implementing Decision 2013/63](#) sets out guidelines for national control authorities as regards the implementation of specific conditions for permitted health claims.

The authorization of health claims referring to botanical substances was put on hold because of the potential conflict with the Traditional Herbal Medicinal Products Directive. In October 2015, the European commission published a ["roadmap"](#) to evaluate Regulation 1924/2006. The evaluation will focus on two specific elements: the authorization of health claims referring to botanical ingredients and the establishment of nutrient profiles. Regulation 1924/2006 required the Commission to establish nutrient profiles, thresholds for salt, fat and sugar above which nutrition and health claims would be restricted. To date, nutrient profiles have not yet been adopted and the Commission will now assess whether they are necessary to ensure adequate implementation of the regulation. The evaluation should be completed by June 2017 and will be used to decide whether the nutrition and health claims regulation should be amended.

The list of permitted functional 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>.

[Commission Regulation 907/2013](#) establishes rules for the use of "generic descriptors" which could be interpreted by consumers as health claims. Generic descriptors such as "digestive biscuits" and "cough drop" would normally be banned under Regulation 1924/2006 because they suggest a beneficial effect on health but the implied health benefit has not been evaluated scientifically by the European Food

Safety Authority (EFSA). For more information see [GAIN report “Health Claims – New EU Regulation on Generic Descriptors”](#).

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.

Health Claims are only allowed if the importance of a balanced diet and healthy lifestyle is also stated on the label

3. Genetically Modified Foods Labeling

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

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. The EU register of authorized GMOs can be consulted on the European Commission’s website at http://ec.europa.eu/food/plant/gmo/eu_register/index_en.htm. 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.”

More information can be found on the European Commission’s website:

http://ec.europa.eu/food/plant/gmo/traceability_labelling/index_en.htm and in the [annual GAIN reports on agricultural biotechnology](#).

Non-GMO: 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.

4. Organic Food Labeling

[Council Regulation 834/2007](#) is the EU’s general framework regulation that sets out rules for organic production and labeling. [Commission Regulation 889/2008](#) sets out detailed rules for the implementation of Regulation 834/2007. [Commission Implementing Regulation 2016/1842](#) published on October 19, 2016, sets new rules for the certification of EU organic food imports. Starting October 19, 2017, the EU will require electronic certification through the EU’s Trade Control and Expert System (TRACES).

The term “organic” and all its derivatives or diminutives such as “bio” and “eco” may be used only to label products that comply with EU organic production rules and if at least 95% of the ingredients of agricultural origin are organic. For products containing less than 95% organic ingredients, the term “organic” may be used only to indicate individual organic ingredients in the list of ingredients. When reference is made to the organic production method in the ingredients list, the total percentage of organic ingredients must be indicated. The Annex to Regulation 834/2007 lists the term “organic” in all the official EU languages.

For more information see the European Commission’s website at http://ec.europa.eu/agriculture/organic/index_en.

On July 1, 2012, the use of the EU organic logo became mandatory on all pre-packaged organic products produced in the EU. Organic products imported from third countries may carry the EU organic logo if they comply with the EU production rules. When the EU organic logo appears on the label, the indication of the place of farming is required.

US-EU Equivalency Arrangement: The US-EU Organic Equivalence Arrangement took effect on June 1, 2012. The U.S. and EU have recognized each other's organic production rules and control systems as equivalent under their respective rules. Organic products certified to the USDA organic standards may be sold and labeled as organic in the EU. Both the USDA organic seal and the EU organic logo may be used on products traded under this Arrangement. When using the EU organic logo, exporters must meet all the EU labeling requirements.

For more information please see [USDA Agricultural Marketing Service: National Organic Program \(International Trade Policies: European Union\)](#)

Organic Wine: [Commission Implementing Regulation 203/2012](#), applicable since August 1, 2012, sets out the conditions to label wine as organic. It allows the use of the term “organic wine” but NOT the term “wine made from organic grapes.” 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](#) on import arrangements with third countries. Only U.S. organic wines certified to comply with the EU's organic wine making rules can be imported into the EU.

5. Wine, Beer and Other Alcoholic Beverages

Wine: The EU's [Single Common Market Organization Regulation 1308/2013](#) establishes framework rules for wine. [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. For detailed information on the EU's wine legislation see the European Commission's website http://ec.europa.eu/agriculture/wine/legislation/index_en.htm.

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 lists geographical indications protected in the EU as well as third countries' geographical indications and names of origin protected under bilateral wine trade agreements. 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 several applications from third countries – most 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. Six years after receiving the applications, the European Commission has not made any progress on allowing the use of other traditional terms such as “Chateau” on U.S. grapevine products.

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.

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. Examples of compliant wine labels can be found in the [U.K. Food Standards Agency’s “Wine Labeling Guidance.”](#)

Allergen Labeling: The indication of allergens listed in Annex II to [“Food Information to Consumers \(FIC\)” regulation 1169/2011](#) is mandatory on all food and beverage labels. [Commission Implementing Regulation 579/2012](#) sets out the modalities for the labeling of allergens on wine. 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. 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 must respect the minimum font size requirement (1.2 mm) established by FIC regulation 1169/2011. Member States may decide in which language(s) allergens should be indicated on the label.

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 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/agreements/us_ec_wine_agreement.shtml and in their guidance document “Procedures for exporting wine to the EU.” 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 at <http://www.ttb.gov/importers/importing-exporting.shtml>.

Spirit Drinks: [European Parliament and Council Regulation 110/2008](#) lays down general rules on the definition, description and presentation of spirit drinks. [Commission Implementing Regulation 716/2013](#) lays down rules for the application of Regulation 110/2008 as regards the use of compound terms and geographical indications of the spirit drinks. This regulation prohibits the use of the term “spirit drink” as part of a compound term.

[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.

Nominal Quantity: Mandatory nominal quantities for wines and spirits are set out in the Annex to [Directive 2007/45/EC](#).

Beer: There is no specific EU-harmonized legislation for beer. 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”).

Alcoholic beverages must comply with the EU’s allergen labeling rules set out in FIC Regulation 1169/2011

6. Special Use Foods

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

On July 20, 2016, the EU’s new “foods for specific groups” rules set out in [European Parliament and Council Regulation 609/2013](#) became applicable. This regulation repeals all the directives on “foodstuffs intended for particular nutritional uses” (PARNUTS). The scope of the new regulation is limited to infant formula, follow-on formula, processed cereal-based food and baby food, food for special medical purposes and total diet replacement for weight control. Under the new rules, pictures of infants are no longer allowed on the packaging and no text or pictures may idealize the use of formula. Foods that no longer fall within the scope of Regulation 609/2013, such as for example low calorie cereal bars will be regarded as “normal” foods and must comply with the Food Information to Consumers Regulation 1169/2011, Nutrition and Health Claims Regulation 1924/2006 and Fortified Foods Regulation 1925/2006. Rules on gluten-free foods were transferred from the PARNUTS directive to the Food Information to Consumers (FIC) regulation 1169/2011 (see Chapter A.13).

As a general rule, labeling requirements set out in the FIC regulation also apply to food categories covered under regulation 609/2013. However, given the specific nature of the products covered, regulation 609/2013 introduces additional labeling requirements and derogations from the FIC regulation. For detailed information on the new dietetic food rules see [GAIN report “New EU Rules on Dietetic Foods”](#), complemented by [GAIN report “New EU Rules on Dietetic Foods – Update”](#) and the Commission’s website at http://ec.europa.eu/food/safety/labelling_nutrition/special_groups_food_en.

In June 2016, the European Commission issued a report on food and beverages labeled specifically for sportspeople. The report concluded that sportspeople can hardly be characterized as a specific vulnerable group of consumers as sport has become a mainstream activity. The report identified three broad categories of sports food on the EU market: (1) sport drinks, (2) protein-based muscle strengthening, building and post exercise recovery products and (3) energy and performance boosting products. According to the Commission report, there is no need for specific provisions for food

intended for sportspeople as existing horizontal EU food rules already provide an adequate framework for these products in terms of food safety, food composition, consumer information and legal certainty. Before the adoption of regulation 609/2013, certain Member States required the notification of sports food as a food intended for particular nutritional uses while others did not. Whether a possible re-notification is needed will depend on the decision of the Member State. For more information see [GAIN report “New EU Rules for Sports Food”](#).

On July 20, 2016, the EU’s new “foods for specific groups” regulation 609/2013 became applicable

7. 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

[Regulation 653/2014](#), an amendment to Regulation 1760/2000, changed the rules for voluntary labeling. Voluntary beef labeling has to comply with the rules set out in the [“Food Information to Consumers” Regulation 1169/2011](#). Definitions and requirements applicable to terms and or categories of terms that may be put on labels of pre-packed fresh and frozen beef and veal will be adopted at a later date.

Veal

Annex VII to [European Parliament and Council Regulation 1308/2013](#) 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 VII lists the sales descriptions in the different Member States languages and the mandatory labeling requirements.

Pork, Sheep, Goats and Poultry

[Commission Implementing Regulation 1337/2013](#) sets out new rules for the indication of the country or place of provenance for fresh, chilled and frozen meat of swine, sheep, goats and poultry. The following new labeling requirements will apply as of April 1, 2015:

1) The indication **“Reared in: name of the Member State of third country”** in accordance with the following criteria:

For swine:

- In case the animal is slaughtered older than 6 months, the Member State or third country in which the last rearing period of at least 4 months took place
- In case the animal is slaughtered younger than 6 months and with a live weight of at least 80 kg, the Member State or third country in which the rearing period after the animal has reached 30 kg took place
- In case the animal is slaughtered younger than 6 months and with a live weight less than 80 kg, the Member State or third country in which the whole rearing took place

For sheep and goats:

- The Member State or third country in which the last rearing period of at least 6 months took place, or in cases the animal is slaughtered younger than 6 months, the Member State or third country in which the whole rearing period took place

For poultry:

- The Member State or third country in which the last rearing period of at least one month took place or, in case the animal is slaughtered younger than one month, the Member State or third country in which the whole rearing period after the animal was placed for fattening took place

In cases where any of the above rearing periods are not attained in any of the Member States or third countries, the place of rearing must be indicated as “Reared in: several Member States of the EU” or “Reared in: several non-EU countries” or “Reared in several EU and non-EU countries.” As an alternative the place of rearing may also be indicated as “Reared in: list of the Member States or third countries where the animal was reared.”

The indication “Origin: name of Member State or third country” may be used in cases where the meat has been obtained from animals born, reared AND slaughtered in one single Member State or third country.

2) The indication **“Slaughtered in: name of the Member State or third country.”** By way of derogation for meat imported from third countries, in cases where information on the rearing periods is not available, the meat must be labeled as “Reared in: non-EU” and “Slaughtered in: name of the third country where the animal was slaughtered.”

8. Health and 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/wps/portal/fsis/topics/international-affairs/exporting-products/export-library-requirements-by-country/European-Union>. 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.

9. 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." Annex VI, Part A, [to FIC regulation 1169/2011](#) stipulates that foods that have been frozen before sale and which are sold defrosted, the name of the food must be accompanied by the designation "defrosted."

For food of animal origin, [Commission Regulation 16/2012](#) amending [Food Hygiene Regulation 853/2004](#), 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.

Annex III to FIC regulation 1169/2011 requires that 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.

Date of first freezing must be indicated when a product has been frozen more than once

10. Vertical & Product-Specific Legislation

<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](#).

Fruit Juices: [Directive 2012/12/EU](#), published in April 2012, set out new labeling rules for fruit juices and fruit nectars. This directive amended [framework Directive 2001/112/EC](#) relating to fruit juices and certain similar products intended for human consumption. Products placed on the market or labeled before October 28, 2013, could 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.”](#)

Honey: On May 15, 2014, the EU adopted [Directive 2014/63/EU](#) amending [Directive 2001/110/EC](#) relating to honey. It defines pollen as a natural constituent of honey and should not be considered to be an ingredient of honey. This means that GM pollen present as a quantity of more than 0.9% of the honey (not the pollen) would need to be labeled as such. Since pollen only forms around 0.5% of any batch of honey, it will never exceed the GM labeling threshold.

Single Common Market Organization: [European Parliament and Council Regulation 1308/2013](#) establishes a single common market organization (CMO) 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.

Section VI. Other Specific Standards

A. Novel Foods

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

Current Rules

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 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

An Information and Guidance Document on “human consumption to a significant degree” is published on the European Commission’s website: http://ec.europa.eu/food/safety/docs/novel-food_guidance_human-consumption_en.pdf.

Unlike food additives and vitamins and minerals, a positive list of novel foods and ingredients does not yet exist. A Novel Foods Catalog is available on the website of the European Commission but has no legal value. U.S. exporters are advised to check the legal status of novel food ingredients before exporting to the EU. For more information see the European Commission’s website at http://ec.europa.eu/food/safety/novel_food/index_en.htm and [GAIN report “Negative List for Novel Foods and Ingredients”](#).

New Rules as of 2018

A new [EU framework regulation 2015/2283 on Novel Foods](#) was adopted in November 2015 and published in Official Journal L 327 on December 11, 2015. Most provisions of the new Novel Foods Regulation will become applicable on January 1, 2018. Main elements of the new Novel Foods Regulation include:

Definition: A novel food is defined as food that has been not consumed to a significant degree in the EU before May 15, 1997 AND falling within at least one of the categories listed in Article 3 of the new regulation. The definition also covers food produced with “non-traditional breeding techniques.”

Authorization procedure: Under the new centralized authorization procedure authorizations would take up to 18 months compared to 42 months under the current rules. Applications for authorizations

must be submitted to the European Commission and the European Food Safety Authority (EFSA) will carry out the risk assessments. Under the current rules, the Member States' competent authorities carry out risk assessments and if an objection is raised by a Member State or group of Member States, the Commission asks EFSA for a second evaluation.

EFSA Risk Assessments: The new regulation sets out the risk assessment process by EFSA and introduces deadlines. On November 10, 2016, EFSA published guidance documents on [novel foods](#) and [traditional food from third countries](#) explaining in detail what kind of information applicants need to provide and how it should be presented.

EU Positive List: The new regulation provides for the establishment of Union list of novel foods. Authorizations will be granted through “implementing acts” which means that the European Parliament will not be able to veto them. Authorizations will be generic and no longer applicant-linked. Member States will be able to suspend or temporarily restrict the marketing and use of any novel food in case of an alleged health risk. The Commission will then examine the Member State's protective measure and take a decision.

Status: The new regulation provides for a consultation process when the status of a food or food ingredient is unsure. Procedural steps for the consultation process will be adopted by an implementing act.

Food from clones: Until separate legislation on cloning is adopted, food from clones but not offspring will fall within the scope of the Novel Foods Regulation.

Engineered nanomaterials: Engineered nanomaterials require a novel food authorization before being used in food. The definition currently set out in the Food Information to Consumers Regulation 1169/2011 is transferred to the new Novel Foods Regulation. The Commission is expected to update the definition early 2017.

Traditional food from third countries: Traditional foods from third countries with a demonstrated safe history of use of at least 25 years would only need to be notified if no safety concerns are raised by Member States or EFSA. The Commission is expected to clarify what a “reasoned safety objection” entails.

U.S. Exporters are advised to check the legal status of novel food ingredients

B. Food from Animal Clones

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

Food derived from cloned animals currently falls within the scope of the [Novel Food Regulation 258/97](#). Under this regulation, food produced by “new breeding practices” needs a pre-market approval based on a risk assessment. In December 2013, under pressure of the European Parliament and the Council of the EU, the European Commission proposed two pieces of specific legislation on food from cloned animals: 1) [a proposal on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes](#) and 2) [a proposal to prohibit the placing on the market of food](#)

[from animal clones.](#) To date, the European Parliament and the Council of the EU have not made any progress on the cloning proposals. Until separate legislation is adopted, food from clones falls within the scope of the Novel Foods regulation.

C. Nanotechnology

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

Currently, EU legislation that explicitly addresses nanomaterials in food includes the following regulations:

Food Information to Consumers (FIC): [Regulation 1169/2011](#) defines engineered nanomaterials as “any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale.” The current definition uses size as the only defining criterion and does not include a threshold value. The presence of engineered nanomaterials in food products must be clearly indicated on the label. The name of such ingredients must be followed by the word “nano” in brackets (Art. 18 of Regulation 1169/2011).

New Novel Foods Regulation: The definition of engineered nanomaterials is set out in the new Novel Foods Regulation (see point A) and will be deleted from the FIC Regulation (applicable end 2017).

Food Additives:- [Regulation 1333/2008](#) states that when “there is a significant change in the production methods or in the starting materials used” for food additives already on the Community list of approved food additives, “or there is a change in particle size, for example through nanotechnology, the food additive prepared by those new methods or materials shall be considered as a different additive and a new entry in the Community lists or a change in the specifications shall be required before it can be placed on the market.”

Food Contact materials – [Regulation 450/2009](#) on active and intelligent packaging states that “new technologies to engineer substances with different chemical and physical properties than the same substances at a larger scale, for example nanoparticles, should be assessed at a case-by-case basis as regards their risk until more information is known about such new technology.”

For more information on nanotechnology in the EU see:

- FoodDrinkEurope: <http://www.fooddrinkEurope.eu/our-actions/topic/nanotechnology/eu-projects/>
- European Food Safety Authority: <http://www.efsa.europa.eu/en/supporting/pub/762e>
- [European Commission Joint Research Center](#)

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](#) established 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. A European Commission proposal setting harmonized maximum and minimum permitted levels of vitamins and minerals in foods and food supplements is already eight years overdue (original deadline set by Regulation 1925/2006 was January 2009). Vitamins and minerals must be expressed as a percentage of the “Reference Intakes” listed in Annex III to the [“Food Information to Consumers” regulation 1169/2011](#) (see also Section V “Nutrition Declaration.” The use of vitamins and minerals not included in the annexes to Regulation 1925/2006 is not allowed. A “Community Register” on the addition of vitamins and minerals and of certain other substances is available on the European Commission’s website at https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_nutrition-vitamins_minerals-comm_reg_en.pdf.

Maximum permitted levels of vitamins and minerals in foods and food supplements are not yet EU harmonized

E. Dietetic Foods

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

In June 2013, the EU adopted [Regulation 609/2013](#) which completely overhauled the dietetic food rules (for detailed information see Section V “Special Use Foods”). The scope of this regulation is limited to infant formula and follow-on formula, processed cereal-based food and baby food, food for special medical purposes and total diet replacement for weight control. Regulation 609/2013 became applicable on July 20, 2016. Under the new rules, pictures of infants are no longer allowed on labels. Foods that no longer fall within the scope of Regulation 609/2013 will be regarded as regular foods.

[Commission Delegated Regulation 2016/128](#) sets out specific requirements for food for special medical purposes (FSMPs). The European Food Safety Authority (EFSA) has published scientific and technical guidance to help the European Commission apply new rules on foods for special medical purposes (FSMPs). For more information see [EFSA’S FAQ document on FSMPs](#).

[Commission Delegated Regulation 2016/217](#) sets out specific compositional and information requirements for infant-formula and follow-on formula.

F. 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." For more information see the European Commission’s website at http://ec.europa.eu/food/safety/biosafety/irradiation_en.

G. Seafood

Detailed information on shipping seafood and fishery products to the EU is provided in the exporter guide “Exporting Seafood to the European Union – October 2016 Update” which can be downloaded from the Department of Commerce – NOAA Fisheries’ website at <http://www.seafood.nmfs.noaa.gov/pdfs/howtoexportseafood2016.pdf>. Information on labeling can also be found in the European Commission’s “[Pocket Guide to the EU’s new fish and aquaculture consumer labels](#)”, published in December 2014.

In May 2016, the Commission released a [report on the feasibility of an EU eco-label scheme](#) for fishery and aquaculture products.

H. 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. For more information see [GAIN report E50060 “EU Feed and Pet Food Labeling Requirements.”](#) Feed and pet food not complying with Regulation 767/2009 and with the provisions on feed additives laid down in [Regulation 1831/2003](#) will not be allowed on the EU market. Conditions for mixing veterinary medicine into feed are set out in [Directive 90/167/EEC](#). In September 2014, the European Commission presented a proposal to replace the outdated Directive 90/167/EEC on medicated feed. The scope of the proposal explicitly includes medicated feed for pets. [Click here](#) for an update on the status of the proposal. 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 68/2013](#) 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](#) established guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products.

For more information on animal nutrition, see the European Commission website at http://ec.europa.eu/food/safety/animal-feed_en.

I. Vegetarian & Vegan Foods

The Food Information to Consumers (FIC) regulation 1169/2011 requires the European Commission to set out rules for the voluntary labeling of foods as “suitable for vegetarians and vegans.” To date, the Commission has not adopted an EU-harmonized definition of the terms “vegetarian” and “vegan.” In the absence of EU-harmonized rules, food companies have started using the “European V-label,” a labeling scheme launched by umbrella organization the European Vegetarian Union (EVU). For more information see EVU’s website at <http://v-label.eu/about-v-label>.

Section VII. Facility and Product Registration

A. Facility Registration

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

The EU approves establishments to ship products of animal origin based on submissions from U.S. government agencies. Only products processed in approved establishments may enter the EU. Detailed information on approved U.S. establishments is available on our website at <http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/>. Third country lists per sector and per country are published on the European Commission’s website https://webgate.ec.europa.eu/sanco/traces/output/non_eu_listsPerCountry_en.htm.

B. Product Registration

U.S. exporters should be aware that certain products and ingredients may fall within the scope of the Novel Foods Regulation and need a pre-market authorization. Detailed information is provided in Section VI “Other Specific Standards.”

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. A list of the competent Member State authorities is available on the European Commission’s website at https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_nutrition-supplements-food_supplements_authorities_en.pdf.

Section VIII. Other Certification and Testing Requirements

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. authorities issuing these certificates is available on our website at <http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/>.

Composite Products: U.S. exports of “composite products” are continuing to be restricted due to burdensome certification requirements introduced in a 2012 European Commission Regulation. Composite products are defined as foodstuffs intended for human consumption that contain processed products of animal origin and ingredients of plant origin. Composite products include a wide variety of products, including cheesecakes, high protein food supplements, pizza, and lasagnas. While the U.S. is eligible to ship hormone-free meat, dairy products, egg products, and fishery products separately, it is often no longer possible to ship the composite products that combine these eligible ingredients.

All composite products containing a processed meat product are subject to a veterinary check.

Generally speaking, composite products that contain more than 50 percent of animal origin products also require a certificate, and there are certification requirements concerning the heat treatment for all dairy products. The EU has created a model health certificate for imports of composite products, which was implemented in 2012. A detailed “Product Decision Tree” to clarify the scope of the legislation was made available by the European Commission in 2013. This guidance greatly expanded the number and types of products affected by the legislation. The decision tree is included in [the further guidance](#) that was developed and published in 2015 to address a wide range of implementation questions related to the import and transit of composite products. For more information see <http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/>.

Inspections

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 database with RASFF notifications is accessible via the [RASFF portal](#). Information published on this website provides several notification details such as the reason for the non-compliance and the origin of the product but does not include company information. 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. [Commission Implementing Decision \(EU\) 2016/1196](#) amends Commission Decision 2007/275/EC by updating the list of products that are subject to veterinary checks as well as the list of exempted products from January 1, 2017 onwards.

[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 destined for human consumption have to comply with the food regulations applicable in the EU. In order to send product samples to commercial trade shows, it is advised to take contact with the FAS office in the Member State where the trade shows takes place. Please also contact our Member State FAS office or the EU APHIS office (Xavier.Mennig@aphis.usda.gov) for export of food samples for technical or research purposes.

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.

An overview of sanitary and phytosanitary requirements is also available on the European Commission websites: DG Health and Consumers "[International Affairs – Import Conditions](#)" and DG Trade "[Export Helpdesk](#)".

Section IX. Import Procedures

A. Union Customs Code

The “Union Customs Code” (UCC) established in [European Parliament and Council Regulation 952/2013](#) is the new framework regulation on rules and procedures for customs throughout the EU. Implementing provisions were published in Official Journal L 343 on December 29, 2015: [Commission Delegated Regulation 2015/2466](#) and [Commission Implementing Regulation 2015/2447](#) lay down detailed rules for the implementation of certain provision of the new UCC including Binding Tariff Information and origin of goods. The new UCC along with the implementing provisions became applicable on May 1, 2016, but further changes will be phased in up to December 31, 2020.

A [complete overview of the EU’s new UCC](#) is available on the European Commission’s DG for Taxation and Customs Union (TAXUD) website.

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. 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. A [guidance document on “Customs formalities on entry and import into the European Union”](#) is available on DG Taxud’s website.

B. Customs Clearance

The European Commission’s DG Trade “Export Helpdesk” provides a complete overview of documents needed for customs clearance:

http://exporthelp.europa.eu/thdapp/display.htm?page=rt%2ft_Requirements.html&docType=main&languageId=en

C. Import Duties

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 2017 Tariff Schedule](#) was published on October 28, 2016 in Official Journal L 294. A list of Member State customs authorities can be found at https://ec.europa.eu/taxation_customs/national-customs-websites_en.

Business operators can obtain Binding Tariff Information (BTI) from a member state's customs authority in order to get the proper product classification and relevant import duty. A BTI decision is legally binding in all the Member States. A BTI used to be valid for six years but the new UCC reduces the validity from six to three years. U.S. exporters should be aware that the new UCC makes the declaration of a BTI decision mandatory when completing customs formalities where before the BTI declaration was not legally required. All BTI decisions issued by the Member States' customs authorities are entered into an [EBTI-database](#). [Administrative guidelines on the new BTI-system](#) are published on DG Taxud's website. 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/resources/documents/taxation/vat/how_vat_works/rates/vat_rates_en.pdf.

A list of excise duties applicable on alcoholic beverages and tobacco can be found at http://ec.europa.eu/taxation_customs/taxation/excise_duties/index_en.htm.

The EU's new Union Customs Code became applicable on May 1, 2016

Section X. Copyright and/or Trademark Laws

A. Trademarks

In the EU, trademarks can be registered at the national, regional or EU level. Trademarks registered at the national level are protected in one EU Member State. Applications must be submitted directly to the relevant national IP-office ([full list of national offices](#)). Currently, there is only one regional-level IP office in the EU, i.e. the Benelux Office which registers trademarks for three Member States: Belgium, the Netherlands and Luxembourg. Applications for the protection of a trademark in all EU Member States must be submitted to the European Union Intellectual Property Office (EUIPO). An online application costs 850 EUR. Full details on the registration process are available on the [EUIPO website](#). Rules on the protection of trademarks in the EU are set in EU [Directive 2015/2436](#).

B. Protected Geographical Indications

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

Several food product names considered as generic in the U.S. such as for example feta, parmesan and Parma ham, are protected under EU law. [European Parliament and Council Regulation 1151/2012](#) sets out rules on optional quality terms such as “mountain product” and regulates three EU-wide quality labeling schemes. It covers the “Protected Designation of Origin” (PDO) scheme, the “Protected Geographical Indication” (PGI) scheme and the “Traditional Specialties Guaranteed” (TSG) scheme. Registration under the different schemes is open to third countries. Wines and spirits are covered by specific legislation and do not fall within the scope of the regulation.

The provisions on labeling and the use of EU logos for PDOs, PGIs and TSGs set out in Regulation 1151/2012 became applicable on January 4, 2016. 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](#).

“Protected Designation of Origin” (PDO) is defined as follows:

- Originating in a specific place, region or in exceptional cases, a country
- Quality and characteristics of the product are essentially or exclusively due to a particular geographical environment with its inherent natural and human factors
- ALL of the production steps take place in the defined geographical area
- Example of a PDO: Prosciutto di Parma (Parma ham) Originating in a specific place, region or country
- Quality, reputation or other characteristics are essentially attributable to the geographical origin
- At least one of the production steps takes place in the defined geographical area

Example of a PGI: Gouda Holland

“Traditional Specialties Guaranteed” (TSG):

The TSG quality label is used to communicate the value-added characteristics of traditional recipes and traditional production methods to consumers. “Traditional” is defined as a proven usage of at least 30 years. Unlike the PDO and PGI schemes, the geographical origin of a product is irrelevant under the TSG scheme. Under the new rules, TSGs are included a Community Register with name reservation. Only products complying with the TSG specifications can use the registered name.

Example of a TSG: Mozzarella

Detailed information on the TSG scheme is available in [GAIN report E80061 “The EU’s Traditional Specialties Guaranteed” Scheme Explained](#)”.

Optional Quality Terms:

Regulation 1151/2012 sets out criteria for the use of optional quality terms. The European Commission is empowered to reserve new terms or amend the conditions of use of existing terms.

Example of an optional quality term: Mountain Product

**Regulation 1151/2012 on EU Quality Schemes became applicable on
January 4, 2016**

APPENDIX I. GOVERNMENT REGULATORY AGENCY CONTACTS

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

European Union Intellectual Property Office (EUIPO)
Avenida de Europa, 4
E-03009 Alicante
Spain
Tel: (34-96)513 91 00
E-mail: information@euipo.europa.eu
Website: <https://euipo.europa.eu>

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: US-FDA-EUR@fda.hhs.gov

Other FAS Offices in the European Union:

http://apps.fas.usda.gov/overseas_post_directory/index.asp

FDA contacts for certification of animal products:

<http://www.fda.gov/AnimalVeterinary/Products/ImportExports/default.htm>

Food Safety & Inspection Service (FSIS) Export Requirements for the EU:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products>

Animal & Plant Health Inspection Service (APHIS) – Import & Export:

http://www.aphis.usda.gov/import_export/index.shtml

APPENDIX II. OTHER IMPORT SPECIALIST CONTACTS

U.S. MISSION TO THE EU – FAS ORGANIZATIONAL CHART

Email: firstname.lastname@fas.usda.gov

<http://www.usda-eu.org/contact-fas/>

James Higgiston, Minister-Counselor for Agricultural Affairs		
Mary Ellen Smith Senior Agricultural Attache	Marcela Rondon Agricultural Attache	Karisha Kuypers Agricultural Attache
T-TIP EU Food & Agriculture Policies CSS Budget & Administration ICASS CSSF	Biotechnology New Breeding Techniques Grains & Feed Oilseeds & Products Organic Products Biofuels Sugar Forest Products Food & Feed Additives Packaging Materials Sustainability / Climate Change Wines & Spirits WTO Bilateral Coverage (Belgium)	Dairy, Livestock & Poultry Veterinary Equivalency Agreement Animal Health Animal Cloning GE Animals Animal Products Novel Foods Nanotechnology Pet Food Food & Drink Labeling Geographical Indications Fish & Seafood Horticultural Products Endocrine Disruptors Pesticides/Contaminants
Gerda Vandercammen Agricultural Specialist	Antonella Rossetti 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 Analysis CODEX Belgium Coverage: Bilateral Port Issues	European Parliament Relations Oilseeds & Products Policy Biofuels Policy / Market Analysis Sustainability Criteria Climate / Change / Environment Organic Products Rural Development Forest Products Belgium Coverage: Sustainability Criteria Climate Change / Environment Wood Pellets / Market Situation	Dairy, Livestock & Poultry Veterinary Equivalency Agreement Animal Welfare Animal Health Animal Cloning GE Animals Animal Products / By-Products Sugar WTO (Market Access, Domestic Support, Export Competition) Belgium Coverage: Agricultural Policy & Commodity Analysis Market Inquiries for Dairy, Livestock and Poultry, Sugar, Grains and Feed, Oilseeds and Products and Biofuels

Barrie Williams Agricultural Specialist	Tania De Belder Agricultural Specialist	Hilde Brans Agricultural Specialist
<p>European Parliament Relations PermRep Relations Biotechnology Common Agricultural Policy (CAP) Grains & Feed Policy EU Budget Risk Analysis</p>	<p>Pesticides (MRLs) Endocrine Disruptors New Breeding Techniques (NBTs) Food & Feed Additives Nanotechnology / New Technologies Packaging Materials Horticultural Products Policy WTO SPS & TBT Notifications Belgium Coverage: Biotechnology NBTs Fruits and Vegetables: market situation, analysis, policy reporting and market access inquiries</p>	<p>EU Decision-Making Procedures Agriculture Council / EU Presidency Food & Drink (Incl. Wine & Spirits) Labeling Nutrition & Health Claims Novel Foods Animal Cloning Dietetic Foods & Food Supplements EU Food Quality Schemes Pet Food Wine & Spirits Policy Belgium Coverage: Food and Drink Labeling Processed Products: market situation, analysis, policy reporting and market access inquiries</p>