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Report Highlights:

This report provides an overview of EU food and feed legislation currently in force for the EU. USDA Foreign Agricultural Service (FAS) staff reviewed and updated all sections of this annual report. Special attention should be given to the upcoming changes stemming from the EU's new Farm to Fork Strategy. For ongoing updates on developments in EU food and feed legislation, check the USEU FAS website at www.usda-eu.org.

Table of Contents

Executive Summary	6
Disclaimer:.....	7
Section I. General Food Laws	8
Brexid.....	8
EU-Harmonized Legislation.....	8
Mutual Recognition.....	9
Regulations and Directives	9
Food Safety Legislation	9
EU Institutions	10
Transparency.....	10
“Dual Quality” Products	10
Section II. Labeling Requirements	11
A. General Requirements.....	11
1. Compulsory Information	12
2. Warnings on Labels.....	13
3. Minimum Font Size	13
4. Language Requirements	14
5. Ingredients List.....	15
6. Allergen Labeling	15
7. Minimum Durability	16
8. Quantitative Ingredients Declaration (QUID)	16
9. Additives & Flavorings	17
10. Origin Labeling.....	17
11. Alcoholic Beverages.....	18
12. Nutrition Declaration	20
13. Gluten-Free	22
14. Trans Fats.....	22
15. Use of Stickers.....	22
16. Samples.....	22
17. Checklist for Compliance with new FIC Rules.....	23
B. Other Specific Labeling Requirements	25

1. Nutrition Claims.....	25
2. Health Claims.....	25
3. Genetically Modified Foods Labeling.....	26
4. Organic Food Labeling.....	27
5. Wine, Beer and Other Alcoholic Beverages.....	29
6. Special Use Foods.....	30
7. Meat Labeling.....	31
8. Health and Identification Marks	33
9. Fish Labeling	33
10. Frozen Foodstuffs.....	34
11. Vertical & Product-Specific Legislation	34
12. Plant-based Meat and Dairy Alternatives.....	35
Section III. Packaging and Container Regulations	35
A. Size & Content.....	35
B. Packaging Waste Management	36
C. Reducing Packaging Related Waste	36
D. Materials in Contact with Foodstuffs.....	36
Section IV. Food Additive Regulations	38
A. Additives (including colors and sweeteners).....	38
B. Flavorings.....	39
D. Processing Aids.....	39
Section V. Pesticides and Contaminants	40
A. Pesticides	40
Maximum Residue Limits (MRLs): Regulation 396/2005.....	40
Early Alert System For Active Substances and MRLs Under Review.....	41
Import Tolerances.....	41
Ongoing Review.....	41
Official Controls.....	42
B. Contaminants.....	42
Maximum Levels	42
Official Controls of Maximum Levels in Foodstuffs.....	44

Official Aflatoxin Controls on U.S. Products	44
Residues in Animals and Animal Products	45
Section VI. Other Requirements, Regulations, and Registration Measures	45
A. Certification and Documentation Requirements	45
B. Inspections	46
C. Facility Registration	47
D. Product Registration	47
Section VII. Other Specific Standards	48
A. Novel Foods	48
B. Food from Animal Clones	49
C. Nanotechnology	50
D. Fortified Foods	50
E. Dietetic Foods	51
F. Food Supplements	52
G. Irradiated Foodstuffs	53
H. Seafood	53
I. Pet Food	53
J. Vegetarian and Vegan Foods, and Plant-Based Meat and/or Dairy Alternatives	54
Section VIII. Trademarks, Brand Names and Intellectual Property Rights	54
A. Trademarks	54
B. Protected Geographical Indications	55
Section IX. Import Procedures	57
A. Union Customs Code	57
B. Customs Clearance	57
C. Import Duties	58
Section X: Trade Facilitation	59
A. Advance Rulings	59
B. Pre-Clearance Program	59
C. Electronic Certificates	59
D. Import Control Fee	60
E. Average Release Time for Products –Common Delays	60

F. Duplicative Inspections 60
Appendix I. Government Regulatory Agency Contacts 60
Appendix II. Other Import Specialist Contacts 62

Executive Summary

This report provides an overview of food and feed legislation currently in force for the European Union (EU). The “Food Information to Consumers (FIC)” Regulation is the main food labeling piece of legislation in force in the EU. It is applicable to all pre-packaged food and drink products marketed in the EU, including those imported from third countries. However, the FIC regulation allows the 27 EU Member States to deviate from European rules. Information on Member State specific rules can be found in the FAIRS reports prepared by the Foreign Agriculture Service (FAS) offices in the different Member States.

EU requirements for food differ from the ones in the United States and the standard U.S. label fails to comply with EU labeling requirements. This report looks at general requirements for food and feed labels, food hygiene, contaminants, food packaging, food additives and flavorings and import procedures. The European Union also has some specific rules for novel foods, genetically modified foods, geographical indications, and food for specific nutritional purposes.

On May 20, 2020, the European Commission published its ‘Farm to Fork Strategy’ which foresees regulatory changes that will impact EU food labeling legislation in the next five years. New requirements are expected to be adopted by the European Union including food sustainability labeling, animal welfare labeling, additional origin labeling, marketing standards for fishery and aquaculture products, nutrient profiles and mandatory front-of-pack nutrition labeling.

Disclaimer:

This report was prepared by the staff of FAS Brussels for U.S. exporters of domestic food and agricultural products. While every possible care has been taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped.

FINAL IMPORT APPROVAL OF ANY PRODUCTS IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

Section I. General Food Laws

The European Union (EU) currently consists of 27 Member States with approximately 445 million consumers. EU Member States are: 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 and Sweden. The United Kingdom (U.K.) left the European Union on January 31, 2020. Montenegro, North Macedonia, Turkey, Albania and Serbia are candidates to join the EU.

All EU Member States 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.

Brexit

The United Kingdom withdrew from the European Union as of February 1, 2020. The Agreement on the withdrawal of the UK from the EU entered into force on the same date. This Agreement provided for a transition period, which ended on December 31, 2020. During the transition period, EU law was applicable to and in the United Kingdom. On December 24, 2020, the EU and UK negotiators reached [an agreement](#) that sets out the rules on the new partnership between the EU and UK which started to apply from January 1, 2021. More information: https://ec.europa.eu/info/relations-united-kingdom/new-normal/consequences-brexit_en

The European Commission published a notice to stakeholders on the withdrawal of the United Kingdom and EU food law, which is available here:

https://ec.europa.eu/info/sites/info/files/brexit_files/info_site/notice_for_stakeholders_food_law.pdf

EU-Harmonized Legislation

Most but not all 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 <https://gain.fas.usda.gov/>. Regulatory and marketing information, by Member State, is available on the [Foreign Agricultural Service Europe website](#).

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.

Mutual Recognition

Where legislation has not been harmonized at the 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 in cases where a country can prove public safety, health or environmental concerns about a product intended for import. [Regulation 2019/515](#) on the mutual recognition of goods lawfully marketed in another Member State 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. It also introduces a voluntary ‘mutual recognition declaration’, which businesses can use to demonstrate that their products are lawfully marketed in another EU country. Detailed information about the rules can be found on the European Commission’s website: https://ec.europa.eu/growth/single-market/goods/free-movement-sectors/mutual-recognition_en

Regulations and Directives

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 Eurlex website. EU laws are translated into the 24 official languages in use in the EU-27 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.

Food Safety Legislation

The EU’s approach to food safety includes all sectors of the food and feed chain. [General Food Law Regulation 178/2002](#) lays down the general principles, including the [precautionary principle](#), and sets out requirements and procedures related to food safety and crisis management. The Member States are responsible for carrying out food controls in order to check that food business operators comply with EU food law requirements. A new regulation on harmonized food controls, [Regulation 2017/625](#), became applicable on December 14, 2019, repealing [Regulation 882/2004](#). A “rapid alert system” for food and feed (RASSF) is in place to share cross-border information when risks to public health are detected in the food chain. The Standing Committee on Food and Feed (PAFF), composed of Member State technical experts, assists the Commission in the preparation of food and feed safety measures. The General Food Law regulation also provided for the establishment of the European Food Safety Authority (EFSA), an independent body that provides scientific advice to the European Commission. 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/>.

In January 2018, the Commission finalized a “[fitness check](#)” of General Food Law regulation 178/2002. It found that ineffective risk communication has a negative impact on consumers’ trust and on the acceptability of risk management decisions. In June 2019, [Regulation 2019/1381](#) on the transparency and sustainability of the EU risk assessment in the food chain and amending the General Food law was published in the EU’s Official Journal. The main elements of the regulation aim at ensuring more transparency, increasing the independence of studies, strengthening the governance of EFSA as well as developing comprehensive risk communication. The new text regulates eight sectoral legislative acts across the agri-food industry including food additives; smoke flavoring; food contact materials; feed additives, food enzymes and flavorings, and novel foods. For more information, please see GAIN Report E18037 on “[Proposed New Rules on Transparency and Risk Communication](#)”.

EU Institutions

There are three main institutions involved in developing policies and passing legislation that applies throughout the EU: the European Commission, the Council of the European Union and the European Parliament. In principle, the Commission proposes new laws and the Council and European Parliament adopt them under the “Ordinary Legislative Procedure”. EU legislators often invoke the precautionary principle to the detriment of innovation. Detailed information on the EU procedures can be found in [GAIN report “How the EU works –guide to EU decision-making”](#) and on our website at <http://www.usda-eu.org/eu-basics-questions/>.

Transparency

In March 2017, the Commission launched a [single web portal](#) where citizens and stakeholders can provide feedback on all initiatives throughout the law-making process. 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 https://ec.europa.eu/info/law/law-making-process/better-regulation-why-and-how_en.

“Dual Quality” Products

In 2017, three EU Member States - Hungary, Slovakia and Czech Republic - reported that many products, including food products, sold in their countries are of lower quality than the same brands and packaging sold in “older” Member States. In order to tackle this issue, in April 2018, the European Commission proposed to amend [Directive 2005/29/EC](#) concerning unfair business-to-consumer commercial practices. In November 2019, the EU adopted [Directive \(EU\) 2019/2161](#) amending the rules on better enforcement and modernization of EU consumer protection rules. The new Directive introduces an article stating that “any marketing of a good, in one Member State, as being identical to a good marketed in other Member States, while that good has significantly different composition or

characteristics, unless justified by legitimate and objective factors” shall be regarded as misleading. For detailed information see [GAIN report “EC Tackles Dual Quality of Foodstuff in the EU”](#).

Advisory Bodies

EFSA is responsible for providing scientific advice to the legislators on matters related to food safety. EFSA’s “Applications Helpdesk” assists with the submission and monitoring of applications for regulated products in the following 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 <https://www.efsa.europa.eu/en/applications>

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 Center website <https://ec.europa.eu/research/ege/index.cfm>.

Enforcement

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. For more information, see the Commission’s website https://ec.europa.eu/info/law/law-making-process/overview-law-making-process/applying-eu-law/monitoring-implementation-eu-directives/infringement-procedure_en.

[See our website
www.usda-eu.org](http://www.usda-eu.org)
for updates on EU food laws and policies

Section II. Labeling Requirements

A. General Requirements

The standard U.S. label fails to comply with EU labeling requirements. On December 13, 2014, the EU’s “[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 FIC regulation became 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: [Notice on questions and answers on the application of Regulation 1169/2011 on the Provision of Food Information to Consumers](#) (June 2018)
- 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](#)

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.

In December 2020, the European Commission published a roadmap outlining its intention to advance a legislative proposal to revise Regulation (EU) 1169/2011. This revision will include:

- Harmonized mandatory front-of-pack nutrition labelling
- The setting of ‘nutrient profiles’ restricting the promotion (via nutrition and health claims) of foods that are high in fats, sugars and/or salt
- The extension of mandatory origin or provenance indications to certain products
- A revision of the EU rules on date marking (‘use by’ and ‘best before’)

A legislative proposal is expected in the fourth quarter of 2022. For more information, please see [GAIN Report Commission Publishes Roadmap on the Upcoming Revision of Food Labeling Requirements](#).

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 or “use by date”
- Any special storage conditions and/or conditions of use
- Name of business 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, phytostanols or phytostanol 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 that are smaller than 10 cm² do not need to bear a nutrition declaration nor a list of ingredients.

x-HEIGHT



Legend

1	Ascender line
2	Cap line
3	Mean line
4	Baseline
5	Descender line
6	x-height
7	Font size

The minimum font size does not apply to mandatory labeling requirements set out in other EU legislation, such as the font size requirements set out in Directive 76/2011 to indicate the nominal quantity (see Section III 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 word “ingredients” must precede the list of 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/>

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 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.

Following a public consultation launched in November 2014, the Commission published an [update of its guidance document on allergen labeling](#) in July 2017.

Other guidance documents:

- FoodDrink Europe (EU Food and Drink Industry Confederation): [Guidelines on precautionary allergen labelling](#)
- [Allergen Labeling – Food Safety Authority Ireland](#)

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.

Guidance documents:

- European Food Safety Authority: [Guidance on date marking and related food information: part 1 \(date marking\)](#) (2021)
- European Food Safety Authority: [Guidance on date marking and related food information: part 2 \(food information\)](#) (2021)

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.

In November 2017, the European Commission published [updated guidelines](#) on the QUID requirement. The guidelines explain when QUID is mandatory and which products are exempt from QUID.

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.” [Regulation 1334/2008](#) lays down additional rules on the use of the term “natural”.

Guidance documents:

- FoodDrink Europe (EU Food and Drink Industry Confederation): [Guidelines on Flavourings](#) (2019)

10. Origin Labeling

<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 origin labeling was already mandatory for honey, fruit and vegetables, olive oil, fishery and aquaculture products and beef. The FIC Regulation extends the mandatory origin labeling requirement to fresh, chilled and frozen pork, sheep and goat meat and poultry. Under Article 26 of the FIC Regulation, mandatory origin labeling 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”)

The FIC Regulation required the European Commission to prepare reports on the feasibility of introducing mandatory origin labeling for dairy products, “minor” meats, unprocessed products and single ingredient products. The reports are available on DG SANTE’s website:

https://ec.europa.eu/food/safety/labelling-and-nutrition/food-information-consumers-legislation/origin-labelling_en.

On May 29, 2018, the European Commission published [Implementing Regulation 2018/775](#), which introduced mandatory dual origin labeling when a country of origin is given or visually implied on the label of a food product but the origin is not the same as that of its primary ingredient. The country of

origin or the place of provenance of a primary ingredient which is not the same as the given country of origin or the given place of provenance of the food shall be given with reference to one geographical areas as listed in article 2 of Regulation 2018/775 or by means of a statement as follows: ‘(name of the primary ingredient) do/does not originate from (the country of origin or the place of provenance of the food)’ or any similar wording likely to have the same meaning for the consumer. This Regulation entered into force on April 1, 2020.

On January 30, 2020, the Commission adopted [Notice C/2020/428](#) that aims to help actors of the food chain as well as the competent national authorities better understand and correctly apply the provisions of Regulation (EU) No 1169/2011 related to the origin indication of the primary ingredient.

Example: A jar of peanut butter with a statement such as “made in the USA” or carrying an American flag would trigger this regulation if the peanuts were sourced from another country.

Detailed information on COOL is provided on the FAS/USEU website <http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/eu-labeling-requirements/country-of-origin-labeling/>.

On May 20, 2020, the Commission published the [EU Farm to Fork Strategy](#) (F2F). Part of this Strategy aims to ensure that EU consumers are able to make informed decision when buying food. As part of the F2F, the Commission announced that it will “consider proposing the extension of mandatory origin or provenance indications to certain products, while fully taking into account impacts on the single market” before the end of 2022.

Guidance documents:

- Primary Food Processor (PFP) – FoodDrinkEurope - EuroCommerce: [Guidance on Commission Implementing Regulation \(EU\) 2018/775](#) (May 2020)
- Food Supplements Europe: [Guidance on the obligation of origin labelling with regard to “primary ingredients of different origin” for food supplements](#) (December 2020)
- GAIN report [Commission Briefing on New Origin Labeling Rules](#)

COOL is mandatory for honey, fruits and vegetables, olive oil, fishery and aquaculture products, beef, pork, sheep and goat meat and poultry

11. Alcoholic Beverages

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”).

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 the end of 2014 examining whether the exemption for alcoholic beverages should be maintained. In March 2017, the Commission finally published its long-awaited report. Following the conclusions of the report, the Commission gave the EU alcoholic beverages industry one year to present a self-regulatory proposal covering all beverages (beer, wines and spirits). In March 2018, the industry presented a [joint self-regulatory proposal](#) outlining general principles of a labeling scheme shared by the alcoholic beverage industry. These general principles were accompanied by four sector-specific implementation plans for [wine](#), [spirit drinks](#), [beer](#) and [cider & fruit wine](#). More information is available in GAIN report “[EU Alcohol Industry Labeling Proposal – Labeling Apart Together](#)”.

Spirits:

On June 4, 2019, the European spirits sector signed a [Memorandum of Understanding](#) and committed to voluntarily include energy information on-label while comprehensive ingredients and nutritional information will be available online. The declaration of ingredients will follow the definition provided in the FIC Regulation:

- There is no obligation to declare processing aids (if used)
- Calorie information will be provided per 100ml and per consumption unit, provided that the unit used and the number of units contained in the package is stated. The proposed consumption unit by default is 30ml.

Illustrative examples of how on-label energy information can be provided for spirits (Source: SpiritsEurope):



Beers:

On September 5, 2019, the European beer industry also signed a [Memorandum of Understanding](#) and committed to voluntarily inform consumers on ingredient and nutrition information. In conformity with the provisions of the FIC Regulation:

- Ingredients must be listed in descending order of weight as recorded at the time of their use in the manufacture of the beverage
- Nutrition information must be provided per 100 ml
- Beers over 1.2% of alcohol by volume shall either solely list the energy values or list all seven nutritional values

More information can be found on the Brewers of Europe’s dedicated website: <https://beerwisdom.eu>

Wine:

In 2019, during discussions on the reform of the Common Agricultural Policy (CAP), the European Parliament amended the proposal of the European Commission and added specific requirements on nutrition declarations for wine. Unlike for spirits and beers, the [proposed amendment](#) to the CAP would introduce *mandatory* wine labeling for the nutrition declaration, the content of which may be limited to the energy value only, and the list of ingredients. The energy value would be expressed per 100ml. In addition, it may be expressed per consumption unit and easily recognizable by the consumer, provided that the unit used is quantified on the label and that the number of units contained in the package is stated. While an agreement on the CAP was reached in June 2021, at the time of writing, the final text of the amendment on the new nutrition declaration for wine was not publicly available.

On June 24, 2021, the European Commission published a roadmap outlining its intention to revise the labeling rules on alcoholic beverages as part of its upcoming revision of Regulation (EU) 1169/2011. The revision will introduce a mandatory list of ingredients and nutrition information for all alcoholic beverages placed on the EU market. The legislative proposal is expected in 2022. For more information, please see GAIN Report: [European Commission Publishes Roadmap on Revision of Labeling Rules for Alcoholic Beverages](#).

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 became mandatory on December 13, 2016. Annex V to the FIC Regulation lists foodstuffs that 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. The European Commission also published a [guidance document](#) and a simplified [summary table](#) for tolerances of nutrient values declared on a label with EU legislation.

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

FoodDrinkEurope 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 Member States to recommend the use of additional forms of expression or presentation of the nutrition declaration.

So far, eight Member States have adopted additional front-of-pack nutritional labeling schemes: Sweden and Denmark with the [Keyhole system](#), and France, Belgium, Spain, The Netherlands, Luxembourg and Germany with [the Nutri-Score](#). The latter has also been adopted by leading food manufacturers such as Nestlé and Danone. However, some Member States, such as Italy, are not in favor of mandatory front-of-pack labeling. Italy is worried that front-of-pack labeling unfairly discriminates against traditional Mediterranean food such as olive oil, ham and cheeses. Italy presented an alternative plan for a new nutrition-labeling scheme in January 2020: the [NutrInform](#). Romania and the Czech Republic support the NutrInform scheme.

As part of the Farm to Fork Strategy, the Commission announced that it would propose harmonized mandatory front-of-pack nutrition labeling before the end of 2022 as part of the revision of the FIC Regulation. This decision is supported by [a Commission’s report](#) regarding the use of additional forms of expression and presentation of the nutrition declaration, published on the same day as the F2F. This report notes that front-of-pack labeling has the potential to help consumers make health-conscious food choices and that it seems appropriate to introduce a harmonized mandatory front-of-pack nutrition labeling at EU-level.

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 (Regulation 41/2009). With the adoption of the [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

In April 2019, [Regulation 2019/649](#) amending Annex III to [Regulation 1925/2006](#) on trans fat was published in the Official Journal.

This new Regulation sets a maximum limit of 2 grams of trans fat per 100 grams of fat in food intended for the final consumer, other than trans fat naturally occurring in animal fat.

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

In December 2020, the European Commission launched the **Food Labelling Information System** (FLIS), which enables users to select a food and then automatically retrieve the mandatory EU labeling indications in 24 EU languages. The system also provides links to the relevant legal provisions and existing guidance documents. In all, 87 different categories of food are covered. You can access the FLIS here:

https://ec.europa.eu/food/safety/labelling_nutrition/labelling_legislation_en/food_labelling_information_system/start/select-countries

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 ingredients 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 COOL for primary ingredient when its omission could mislead the consumers

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

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

Fiber

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)

B. Other Specific Labeling Requirements

The EU's "Food Information to Consumers" Regulation 1169/2011 sets out horizontal rules applicable to all products. Sectorial or "vertical" legislation exists for a number of products. Labeling requirements outlined 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 overlapping 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 regarding 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 EU's Traditional Herbal Medicinal Products Directive.

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 was 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. Please see GAIN Report: [Health Claims - EU Authorization Procedure](#) for a description of 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 health effect, 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.

On May 20, 2020, the Commission announced that it would set nutrient profiles to restrict promotion of food high in salt, sugars and/or fat as required by [Regulation 1924/2006](#) before the end of 2022. Currently, the implementation of Regulation 1924/2006 on nutrition and health claims made on foods remains incomplete since the Commission did not establish nutrient profiles that had to be set by January 2009. In that context, nutrient profiles are thresholds of nutrients such as fat, sugars and salt above which nutrition and health claims are restricted or prohibited. This proposal builds on the results of the [REFIT evaluation](#) of the EU legislation on nutrition and health claims launched in 2015.

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 https://webgate.ec.europa.eu/dyna/gm_register/index_en.cfm. 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:

https://ec.europa.eu/food/plant/gmo/traceability_labelling_en and in the annual GAIN reports on agricultural biotechnology. The latest report is available [here](#).

Non-GMO: EU-harmonized legislation defining “non-GM,” “GM-free” or similar labeling terms does not 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. A new [EU Regulation on organic production and labelling of organic products](#) was adopted in May of 2018 and it will enter into force on January 1, 2022. The entry into force of the Regulation, initially scheduled for 2021, was postponed due to the COVID-19 crisis and to give economic operators more time to prepare for the new rules. For more information about the new Organic Regulation, please see GAIN report “[New EU Organic Regulation Entering Into Force in 2021 - Regulatory Update.](#)” (Please note that this report was published before the postponement and the dates included in the report were all postponed by a year.)

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 Equivalence 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. In May 2018, the European Union adopted a new Organic Regulation that will enter into force in 2022. Under this new Regulation, the U.S.-EU Equivalence Arrangement would expire five years after the entry into force of the new regulation. By this date, the U.S.-EU Arrangement must be converted to an organic trade agreement. If not, exporters will have fully to comply with the exact same standards as the EU organic regulations to export to the EU.

[Commission Implementing Regulation 2016/1842](#), published on October 19, 2016, sets new rules for the certification of EU organic food imports. Since October 19, 2017, only certificates initiated through the EU’s Trade Control and Expert System (TRACES) are valid. For more information see [GAIN report “Electronic Certificate of Inspection Required for EU Organics Trade”](#).

Organic Wine: [Commission Implementing Regulation 203/2012](#), applicable since August 1, 2012, sets out specific rules for the production and labeling of organic wine. Only wines produced in accordance with this regulation qualify as “organic wine” and can carry the EU organic logo. Labeling wine as “made from organic grapes” is no longer allowed in the EU, which means that U.S. wines labeled as such cannot be imported into the EU. Sorbic acid and desulfuration are not allowed and the maximum sulfite content may not exceed 100 mg per liter for red wine (150 mg per liter for conventional) and 150

mg per liter for white/rosé wines (200 mg per liter for conventional). In the United States, the addition of sulfites is not allowed in organic wines. [Commission Implementing Regulation 508/2012](#) only authorizes imports of U.S. wines that are certified to comply with the EU's organic wine rules.

New EU rules on organic food will apply from January 1, 2022

5. Wine, Beer and Other Alcoholic Beverages

Wine: The EU's [Single Common Market Organization \(CMO\) Regulation 1308/2013](#) establishes framework rules for wine.

[Commission Regulation 2019/33](#), [Commission Regulation 2019/34](#), [Commission Regulation 2021/1235](#) and [Commission Regulation 2021/1236](#) outline detailed rules on protected designations of origin and geographical indications, traditional terms and labeling. Chapters III of Regulation 2019/33 and 2019/34 set out rules on the use of traditional terms. The new EU database for wines and spirits "[eAmbrosia](#)" lists the traditional terms that are protected in the EU.

Non-EU countries need to obtain authorization from the European Commission in order to use EU-protected traditional terms. To date, the Commission has not made any progress on the U.S. applications, submitted in 2010, to use 11 traditional terms (Chateau, Clos, Ruby, Tawny, Crusted, Crusting, Noble, Solera, Sur lie, Vintage and Vintage character).

In addition to the rules set out in the Single CMO, wine must also comply with the allergen labeling rules established by the [EU's general labeling regulation 1169/2011](#). For detailed information on the EU's wine legislation, including labeling requirements, see [GAIN report "EU Wine Policy"](#) and the European Commission's website https://ec.europa.eu/agriculture/wine/legislation_en.

US-EU Wine Agreement: In March 2006, the U.S. and the EU 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 percent and not more than 22 percent. 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 <https://www.ttb.gov/wine/us-ec-wine-agreement-faqs>. 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 US-EU wine trade can also be obtained from the U.S. Dept. of the Treasury - Alcohol and Tobacco Tax and Trade Bureau <https://www.ttb.gov/itd/international-imports-exports-requirements/>.

Spirit Drinks: [Regulation 2019/787](#) entered into force in May 2021. This Regulation outlines general rules on the definition, description, presentation and labeling of spirits, as well as on the protection of geographical indications of spirits. It also establishes rules on the use of legal names of spirits in the

presentation and labeling of foodstuffs other than spirits drinks and provide for provisions on the use of compound terms for the presentation of spirit drinks.

The public database [eAmbrosia](#) lists the geographical indications of spirit drinks registered in the European Union. In February 2019, “Tequila” was approved as a geographical indication in the EU ([Implementing Regulation 2019/335](#)).

[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.

**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 revised “foods for specific groups” rules set out in [European Parliament and Council Regulation 609/2013](#) became applicable. Its scope 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. Pictures of infants are not allowed on the packaging of formula and no text or pictures may idealize its use.

[Commission Delegated Regulation 2016/127](#) lays down the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding.

Commission [Delegated Regulation 2016/128](#) lays down the specific compositional and information requirements for food for special medical purposes.

Foods that no longer fall within the scope of Regulation 609/2013, such as meal replacements and low-calorie cereal bars, are regarded as “normal” foods and must comply with the EU’s horizontal food labeling rules. For more information see Section VI-E “Dietetic Foods”.

As a 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.

Food for sportspeople does not fall within the scope of Regulation 609/2013. A Commission report on food and beverages labeled specifically for sportspeople concluded there is no need for specific EU-harmonized provisions as existing horizontal EU food rules already provide an adequate legal framework for these products. Before the adoption of Regulation 609/2013, certain Member States required the notification of sports food as a special use food. U.S. exporters should check with their importers whether re-notification may be necessary. For more information see [GAIN report “New EU Rules for Sports Food”](#).

New EU rules on “total diet replacement for weight control” will come into effect on October 27, 2022. [Commission Delegated Regulation 2017/1798](#) sets out specific compositional and labeling requirements as well as a notification procedure under which food business operators are required to send copies of their product labels to the competent authority of each Member State where the product will be marketed. For more information see [GAIN report “The Skinny on New EU Rules for Weight Loss Products.”](#)

Artificial sweeteners are not allowed in dietetic bakery products. For detailed information see [GAIN report “EU bans use of artificial sweeteners in dietetic bakery products.”](#)

The use of artificial sweeteners is no longer allowed in dietetic bakery products.

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 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 [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 State 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 became applicable on April 1, 2015:

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

For swine:

- If the animal slaughtered is older than 6 months, the Member State or third country in which the last rearing period of at least 4 months took place
- If the animal slaughtered is younger than 6 months and has a live weight of at least 80 kg, the Member State or third country in which the rearing period after the animal reached 30 kg took place
- If the animal slaughtered is younger than 6 months and has 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 where the animal slaughtered is 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 slaughtered is 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 single Member State 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.”

In October 2018, the European Commission published [a roadmap](#) to assess whether the rules on food information to consumers regarding the mandatory origin labeling for pork, sheep, goats and poultry are effective, efficient, coherent and relevant. The Commission published [its final](#) report on August 10, 2021. The evaluation concluded that the objectives of the Regulation have been met and remained relevant despite a changing context, in particular the increasing consumer demand for more extensive information on food labels.

On May 20, 2020, the European Commission announced that one of objectives of the Farm to Fork Strategy is to improve animal welfare, improve animal health and reduce the need for medication. In that regard, the Commission said that it will consider “options for animal welfare labeling to better transmit value through the food chain.”

8. Health and Identification Marks

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 establishments in third countries.

More information on the EU health mark is available on USDA’s Food Safety and 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>.

9. Fish Labeling

[Regulation 1379/2013](#) sets out labeling rules for fishery and aquaculture products listed in Annex I to the regulation. Mandatory labeling information includes:

- Commercial designation of the species and its scientific name
- Production method
- Area where the products were caught or farmed
- Whether the product has been defrosted
- Date of minimum durability

For more information see the European Commission’s website https://ec.europa.eu/fisheries/cfp/market/consumer-information_en.

On May 20, 2020, the European Commission [announced](#) that it will propose a revision of the EU marketing standards for agricultural, fishery and aquaculture products. The proposal is expected by the end of 2022.

10. 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 for 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 foods of animal origin, [Commission Regulation 16/2012](#), which amended [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

11. 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](#) (Directive 2001/111), [cocoa and chocolate products](#) (Directive 2000/36), [honey](#) (Directive 2001/110), [fruit juices and similar products](#) (Directive 2001/112), [preserved milk](#) (Directive 2001/114), [coffee extracts and chicory extracts](#) (Directive 1999/4) and [fruit jams and similar products](#) (Directive 2001/113). These Directives are often referred to as the “breakfast directives.”

Fruit Juices: Detailed information can be found in [GAIN report “New EU Fruit Juice Labeling Rules”](#) published in May 2012.

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 that should not be considered 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, fruits and vegetables, spreadable fats and wine.

In May 2018, the European Commission published [Delegated Regulation 2018/1096](#) on the requirements for certain indications on the labeling of olive oil regarding the maximum acidity and year of harvesting.

In June 2021, the Commission launched a [public consultation](#) period before revising EU marketing standards for agricultural products. This review follows an overall evaluation process of the EU marketing standards in the common market organization, the ‘breakfast directives’ and other legislation.

12. Plant-based Meat and Dairy Alternatives

To date, there is no EU-harmonized definition of the terms “vegetarian” and “vegan” and no specific requirements for the labeling of plant-based meat and dairy alternatives.

In July 2017, the European Court of Justice (ECJ) ruled that plant-based products cannot be labeled with dairy names such as “cheese,” “butter” or “milk”. The ECJ based [its ruling](#) on [Regulation 1308/2013](#), which defines definitions and designations that may only be used for the marketing of dairy products. A list of exceptions for non-dairy products that may be labeled with reserved dairy names was established by [Commission Decision 2010/791](#). For more information, please see GAIN Report “[European Court Prohibits Use of Dairy Names for Non-Dairy Products](#).”

Section III. Packaging and Container Regulations

A. Size & Content

The maximum tolerable error between the actual content weight 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. Under this Directive, only wine and spirits have defined package sizes, with the exception of *shochu* bottled in Japan. 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](#) provides for measures aimed at limiting the production of packaging waste and promoting recycling, re-use and other forms of waste recovery. 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://ec.europa.eu/environment/waste/packaging/legis.htm>.

C. Reducing Packaging Related Waste

In May 2018, the European Commission proposed new rules to target the ten single use plastic products most often found on Europe’s beaches and seas, as well as lost fishing gear. The ban of certain products could also affect food packaging. Some provisions of [Directive \(EU\) 2019/904](#) to reduce the impact of certain plastic products on the environment, such as the ban on single-use plastics, went into effect on July 3, 2021. This was the deadline for Member States to transpose the directive into national laws, regulations and administrative provisions. Other provisions in the Directive, such as the extended producer responsibility, will take effect by the end of 2024.

On March 11, 2020, the European Commission published its [Circular Economy Action Plan](#). The Action Plan lists 35 actions that focus on the design and production for a circular economy, with the aim to ensure that the resources used are kept in the EU economy for as long as possible. As part of this Action Plan, the Commission announced that it will propose new legislation on packaging, packaging waste, bioplastics and food contact materials. For more information about the upcoming legislative changes, please see GAIN Report [European Union Single Use Plastics Directive Enters into Force](#).

D. 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.

Regulation 1935/2004 was last amended by [Regulation \(EU\) 2019/1381](#) on the transparency and sustainability of the EU risk assessment in the food chain, which went into effect on March 27, 2021.

The European Commission did a regulatory fitness and performance check (REFIT) of the [EU’s Food Contact Material’s \(FCM\) legislation](#). The evaluation process consisted of different steps and the [final report](#) was published on July 3, 2020.

[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.

Specific measures set out additional requirements and include lists of authorized substances and materials. To date, [specific directives](#) have been developed for [plastic materials \(Commission Regulation 10/2011\)](#), including a union list of authorized substances. There is an EU guidance document available on its [implementation](#). [Commission Implementing Regulation 321/2011](#), amending Regulation 10/2011 on plastic materials, bans the use of Bisphenol A in plastic infant feeding bottles, while [Commission Regulation \(EU\) 2018/213](#) limits the use of bisphenol A in varnishes and coatings intended to come into contact with food.

Another specific measure in [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.

There are also the [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.

Member States are allowed to provisionally authorize 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. When there is no specific EU legislation, Member States may establish national measures. U.S. exporters are advised to verify if Member State specific measures apply. 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.

In May 2018, the European Commission proposed new rules to target the ten single use plastic products most often found on Europe's beaches and seas, as well as lost fishing gear. The ban of certain products could also affect food packaging. Some provisions of [Directive \(EU\) 2019/904](#) to reduce the impact of certain plastic products on the environment, such as the ban on single-use plastics, went into effect on July 3, 2021. This was the deadline for Member States to transpose the directive into national laws, regulations and administrative provisions. Other provisions in the Directive, such as the extended producer responsibility, will take effect by the end of 2024.

For more information, see the European Commission's [Brochures on Food Contact Materials](#)

Section IV. 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](#) (amended by [Regulation \(EU\) 2019/1381](#) on the transparency and sustainability of the EU risk assessment in the food chain) establishes 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](#). Only additives included in the EU's positive list may be used in food products marketed in the EU. Inclusion in the EU positive list is based on a risk assessment 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. It has also been adjusted by [Commission Implementing Regulation \(EU\) 2020/1823 to](#) accommodate the changes linked to [Regulation \(EU\) 2019/1381](#) on the transparency and sustainability of the EU risk assessment in the food chain. These new provisions went into effect on March 27, 2021.

A. Additives (including colors and sweeteners)

Annex II to [Food Additives Regulation 1333/2008](#) lists all additives approved for use in foods and their conditions for use. 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 EU does not allow the use of flour bleaching agents chlorine, bromates and peroxides.

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

Member States may continue to prohibit the use of certain categories of food additives in traditional foods listed in Annex IV to regulation 1333/2008.

In 2016, EFSA completed a re-evaluation of EU-approved food colors. As a result, Annex V to Regulation 1333/2008 was amended to introduce mandatory 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 must be labeled "may have an adverse effect on activity and attention in children" (see also Section V – Labeling Requirements). [Commission Regulation 232/2012](#) lowered the limits for food colors Quinoline Yellow (E104), Sunset Yellow (E110) and Ponceau 4R (E124). Food color Red 2G (E 128) was removed from the EU's positive list.

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 https://ec.europa.eu/food/safety/food_improvement_agents/additives_en.

Re-Evaluation Program

[Commission Regulation 257/2010](#) sets out a re-evaluation program for EFSA to assess food additives that were approved before Food Additives Regulation 1333/2008 entered into force. It was amended by [Commission Implementing Regulation \(EU\) 2021/148](#) to provide levels of transparency and confidentiality similar to procedures to update the Union List of Approved Food Additives.

The re-evaluation of approved food additives was scheduled to be completed by the end of 2020. Please find a link to the [summary table](#) of permitted food additives and status of their re-evaluation by EFSA (status as of December 17, 2020). The re-evaluation is still ongoing as of September 2021.

For more information on the re-evaluation of food additives:

https://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation_en

B. Flavorings

[Regulation 1334/2008](#) establishes a list of authorized flavoring substances, listed according to the category of food to which they may be added. It also sets specific rules for the use of the term “natural.” An [on-line database](#) allows 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.

[Regulation 2065/2003](#) establishes a safety assessment and authorization procedure for smoke flavorings intended for use in or on foods. [Commission implementing Regulation 1321/2013](#) establishes the EU positive list of authorized smoke flavoring primary products for use in or on foods and/or for the production of derived smoke flavorings.

C. Enzymes

[Regulation 1332/2008](#) on food enzymes introduced harmonized rules for their scientific evaluation and authorization in the EU. Articles 10-13 of Regulation 1332/2008 set out specific labeling requirements. EFSA is currently evaluating industry applications for authorization of existing and new food enzymes. Until the Commission draws up an EU-list of authorized food enzymes, national rules will continue to apply. For detailed information see the European Commission's website https://ec.europa.eu/food/safety/food_improvement_agents/enzymes/eu_rules_en

D. Processing Aids

Processing aids are subject to Member States' national legislation. EU harmonized rules exist only for

extraction solvents used in the production of foodstuffs and food ingredients ([Council Directive 2009/32/EC](#)).

Section V. Pesticides and Contaminants

A. Pesticides

<https://www.usda-eu.org/eu-early-alert/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. Exporters can look up specific details on PPPs approved for use in a certain Member State in the [EU pesticide database](#) or check the relevant Member State FAIRS report. Maximum Residue Levels (MRLs) for substances that are not on the EU positive list will be set at a 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 (SUD) is also part of the so-called Pesticides Package, which is currently under revision. For more information see the European Commission website: https://ec.europa.eu/food/plants/pesticides_en

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. 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](#).

In 2016, the European Commission notified a document to the WTO explaining its [on-going review of MRLs \(last updated July 2, 2021\)](#) in the EU to non-EU countries. The information submitted by the EU provided details about, explaining the on-going process in the European Union to review the of current maximum residue levels (MRLs) for pesticides under Article 12 of Regulation (EC) No. 396/2005 and how non-EU countries can actively contribute to the reviewing process. Article 12 of Regulation (EC) 396/2005 provides for a mechanism to review the existing maximum residue levels (MRLs) of all approved and certain non-approved pesticides. This review process has been on-going since 2008. It also

includes references to the EFSA progress report for the Article 12 review of MRLs ([last updated July 20, 2021](#)).

Note:

On January 20, 2021, the European Commission's Directorate General for Health and Food Safety (DG SANTE) held an information session with third countries to discuss adding environmental factors into the MRL-setting process ([presentations available here](#)) although it is not yet clear how or when this would take effect, but this would make the MRL-setting process more burdensome.

Early Alert System For Active Substances and MRLs Under Review

The EU early alert system provides information on ongoing and upcoming reviews for active substances and MRLs that are of interest to U.S. stakeholders. The information presented in this document provides interested stakeholders with advance notice of which active ingredients are under review for renewal of approval in the EU and highlights which substances may be restricted or not renewed for approval. This list is not all-inclusive and other substances and MRLs may be undergoing review as well. For more information, please see: <https://www.usda-eu.org/eu-early-alert/>

Import Tolerances

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 EFSA before being forwarded to the Commission. Information on import tolerances is available in the "[Pesticide Use and Food Safety](#)" [guide](#) published by the [Croplife Europe](#). All MRLs, including import tolerances, have applied EU-wide since September 2008. The application form for an import tolerance can be found [here](#).

Ongoing Review

A key commitment of the European Commission's F2F and Biodiversity Strategies is a 50 percent reduction of the use and risk of pesticides by 2030. The Strategies aim to protect and restore biodiversity and make the European agrifood sector more sustainable through pesticide reduction targets and wider adoption of integrated pest management (IPM) practices. As part of the F2F Strategy, the Commission proposed several initiatives that link to EU pesticide regulations. The pesticide initiatives outlined in the F2F and Biodiversity Strategies will also be supported by recommendations from the completed reevaluation of the functioning and effectiveness of the EU legislation on plant protection products and pesticide residues, known as REFIT (see also section below). Please find here a link to the GAIN report on the [Pesticide Initiatives in the Farm to Fork Strategy](#).

The European Commission did a regulatory fitness and performance check (REFIT) on the [EU legislation on pesticides and pesticides residues](#). The evaluation process consisted of different steps, such as a roadmap, an external study, as well as a consultation strategy with an online public consultation, focus groups, in-depth interviews, and case studies to collect data and information. The

European Commission adopted the [final report](#), which outlines the main findings, on May 20, 2020, concluding the REFIT of the EU pesticide legislation.

In addition to the Commission's evaluation, the European Parliament formed a special Committee on Pesticides that investigated glyphosate and other pesticide products. Some of the recommendations from the [PEST Committee's final report](#) were also used in the final REFIT report.

The F2F Strategy outlines the draft proposal revising the Sustainable Use of Pesticides Directive (SUD). The revision aims to “significantly reduce use and risk and dependency on pesticides and enhance integrated pest management” and should be available by early 2022. The goal of introducing these specific pesticide reduction targets is for the Commission and the individual Member States, through their National Action Plans, to promote the sustainable use of PPPs, and to make progress in measuring, as well as reducing, the risks related to PPP use. In order to achieve the pesticide reduction targets, the Commission also plans to present provisions under the SUD to enhance the implementation of IPM. IPM is a means to reduce PPP dependency: farmers will only be able to use chemical PPPs after exhausting preventive, physical, biological or other non-chemical methods of pest control.

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 2020/585 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 August 31, 2022, 2023 and 2024 for samples tested in 2021, 2022 and 2023 respectively. For more information see the European Commission website: https://ec.europa.eu/food/plants/pesticides/maximum-residue-levels/enforcement_en

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 in cereals and cereal products
- Heavy metals (section 3):
 - lead in milk, baby and infant food, meat, offal, fish and seafood, vegetables, fruit, wine, food supplements, honey, spices and salt
 - cadmium in fruit and nuts, meat and meat products, fish and seafood, cereals, oilseeds (including soybeans and peanuts), vegetables, fungi, pulses, baby formula and infant food, cereals, cocoa and chocolate products, food supplements
 - mercury in fish and seafood and food supplements
 - tin in canned foods, canned beverages and canned baby foods
 - inorganic arsenic in rice and rice products
- 3-monochloropropanediol (3-MCPD), 3-MCPD fatty acid esters and glycidyl fatty acid esters (section 4)
 - 3-MCPD in vegetable protein and soy sauce
 - Glycidyl fatty acid esters expressed as glycidol in fats and oils and infant formula
 - Sum of 3-MCPD and 3-MCPD fatty acid esters in oils and fats, infant food and formula
- 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, cocoa products, banana chips, dried herbs and spices, food supplements, powders of food of plant origin for the preparation of beverages and infant food (section 6)
- Melamine in infant food (section 7)
- Inherent plant toxins (section 8):
 - erucic acid in fats and oils, foods containing these ingredients and infant formula
 - tropane alkaloids in processed cereal-based foods
 - hydrocyanic acid in apricot kernels
 - pyrrolizidine alkaloids in tea and infusions, food supplements, dried herbs
- perchlorate in fruit and vegetables, tea and infusions, infant/young children formula, baby food and processed cereal based foods (section 9)

The currently applicable consolidated Annex of [Commission Regulation 1881/2006](#) will be updated in the near future to reflect the new maximum levels for ergot sclerotia published in [Commission Regulation 1399/2021](#) and the new maximum levels for tropane alkaloids published in [Commission](#)

[Regulation 1408/2021](#). Please note that the EU has also finished discussions on the revision of maximum levels of ochratoxin A OTA. Based on the outcome of these discussions, a maximum level for OTA in pistachios for direct consumption and for further processing will be published in the near future.

In 2017, the EU adopted [Regulation 2017/2158](#) establishing benchmark levels to reduce the presence of acrylamide in food. This regulation requires that food business operators apply mandatory measures to reduce the presence of acrylamide, proportionate to the size and nature of their establishment. In November 2019, the Commission adopted [Recommendation 2019/1888](#) recommending that competent authorities in the Member States regularly monitor the presence of acrylamide and its levels in food, in particular in the food listed in the Annex of this Recommendation. In recent years, the Commission has consulted with stakeholders about the acrylamide issue with the view of initiating discussions on additional measures. The EU is currently finalizing the process on the establishment of maximum levels of acrylamide in foods for infants and young children.

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 different contaminants. These regulations concern the methods of sampling and the sample preparation as well as the performance criteria for the methods of analysis:

- Nitrates: [Commission Regulation 1882/2006](#)
- Mycotoxins: [Commission Regulation 401/2006](#)
- Dioxins: [Commission Regulation 2017/644](#)
- Trace elements and Processing Contaminants: [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 73 of [Regulation \(EU\) 2017/625 of the European Parliament and of the Council](#) (the Official Controls Regulation-OCR). This recognition is still sometimes referred to as "Article 24 recognition", which was the relevant article in Regulation 882/2004 that was superseded by the OCR. The USDA Agricultural Marketing Service began issuing PEC almond certificates on August 1, 2015.

Following the publication of [Commission Implementing Regulation \(EU\) 2017/1269](#) on July 14, 2017, the U.S. pre-export program for peanuts is no longer recognized by the EU. There is no **restriction on the export of U.S. peanuts; however, shipments are no longer benefitting from the reduced testing level for aflatoxin** upon entry in the EU.

On April 1, 2015, U.S. pistachios were included in the list of products/origins subject to increased import controls. On July 25, 2019, U.S. peanuts were also included in this EU list. The mandatory

testing levels for U.S. pistachios and peanuts are laid out in [Commission Implementing Regulation \(EU\) 2019/1793](#). Member States must now test 10 percent of all incoming shipments for both products. The regulation does not impose any requirements on U.S. exporters.

For additional information on aflatoxin testing and certification performed in the United States prior to export to the EU, see:

- [PEC Program Manual](#)
- [Pistachio Export Aflatoxin Reporting \(PEAR\) Program](#)
- <http://www.ams.usda.gov/services/lab-testing/aflatoxin>

Residues in Animals and Animal Products

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

[Regulation \(EU\) 2017/625 of the European Parliament and of the Council](#) provides the currently applicable framework for official controls on foods, and includes transitional provisions applicable until December 14, 2022, continuing the application of [Directive 96/23/EC](#) on the monitoring of residues in animals and animal products. This directive 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. The prohibition of the use of hormones in meat production itself is addressed in [Council Directive 96/22/EC](#).

For additional information on how to export food of animal origin to the EU, please see the EU's report on [Residues and Food Safety Imports of Food of Animal Origin from non-EU Countries](#).

Section VI. Other Requirements, Regulations, and Registration Measures

A. Certification and Documentation Requirements

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

An overview of all U.S. authorities that issue the legally required certificates for export to the EU is available on our website at <https://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/u-s-agencies-providing-eu-certificates/>. The websites of each of those authorities provide detailed and up-to-date information on the specific product certificates under their legal authority.

Following an update of the EU's Animal Health Law, which entered into force on April 21, 2021, the EU has updated all required certificates for products of animal origin. Models of the new certificates for foods of animal origin were published in [Commission Implementing Regulation \(EU\) No 2020/2235](#), as amended by [Commission Implementing Regulation \(EU\) 2021/1471](#). The transitional provisions of Regulation 2020/2235 allow for the continued use of the old certificates until March 15, 2022, provided that the certificates are signed before Jan 15, 2022. At the time of writing, U.S. Government agencies have not yet switched to any of the new certificates. This is also the case for the composite product certificates issued by the Agricultural Marketing Service and Food Safety and Inspection Service (see below).

Composite Products:

[Regulation \(EU\) 2019/625](#) defines composite products 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. U.S. exports of “composite products” continue to be restricted by burdensome certification requirements. While the U.S. is eligible to ship hormone-free meat, dairy products, egg products, and fishery products separately, it is often not possible to ship the composite products that combine these eligible ingredients.

Exporters should be aware that in parallel with the aforementioned changes to the composite product certificate, the EU also made changes to the categories of composite products that require U.S. Government-issued health certificates. The new system is no longer based on the percentage of ingredients of animal product in the final product, as was the case until April 21, 2021. The new system that went into effect on April 21, 2021 establishes three categories of composite products: (1) non-shelf stable composite products, (2) shelf stable composite products that contain meat products and (3) shelf stable composite products that do not contain meat products. All processed products of animal origin have to be sourced from EU approved establishments. The EU continues to require composite product certificates for all non-shelf stable products and for shelf stable composite products with a meat ingredient. A private company attestation will be required for shelf stable products not containing meat. It should be noted that this attestation is not issued by the U.S. Government, but has to be signed by the representative of the importing company.

More information on the import conditions for composite products is available on the European Commission’s [website](#). This website also includes a compilation of [Questions & Answers](#) intended to clarify a multitude of practical questions that have been raised on the new rules.

B. Inspections

The [Official Controls Regulation \(EU\) 2017/625](#) sets common rules for official controls to ensure the correct application of food and feed law, rules on animal health and welfare, plant health and plant protection products (Official Controls Regulation - OCR). The main elements of this regulation went into effect on Dec 14, 2019.

The list of animal origin products subject to official controls at border posts was updated in [Commission Implementing Regulation \(EU\) 2021/632](#). Composite products listed in [Commission Delegated Regulation 2021/630](#) are exempted from checks at the border because of the low risk the present. The list includes products such as biscuits, confectionary and food supplements. All consignments to be presented at the border control posts have to undergo documentary checks. Identity and physical checks are carried out at a frequency depending on the risk linked to the specific animals or goods. The criteria to determine and modify the frequency of rates are established by the Commission.

The EU also maintains a list of food and feed of non-animal origin from certain third countries subject to a specified level of physical controls for certain contaminants. This list is published in [Commission](#)

[Implementing Regulation \(EU\) 2019/1793](#) and is regularly reviewed to account for the latest non-compliance information.

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.

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.

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 contact the FAS office in the Member State where the trade show will take place. Please also contact our Member State FAS office or the EU APHIS office (Xavier.Mennig@usda.gov) for export of food samples for technical or research purposes.

C. 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. 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.

Detailed information on certification of products from approved U.S. establishments is available on our website at <http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/>.

D. 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 VII "Other Specific Standards."

Certain foods, such as total diet replacements for weight control, fall within the scope of the EU's [Foods for Specific Groups Regulation 609/2013](#) and must be notified to the competent authority of the Member State where the food is marketed.

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. More information is also available at https://ec.europa.eu/food/safety/labelling_nutrition/vitamins_minerals_en.

Section VII. Other Specific Standards

A. Novel Foods

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

The EU's new [framework regulation 2015/2283 on Novel Food](#) became applicable on January 1, 2018. It defines novel food as food that has not been 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 regulation (e.g. [cranberry extract powder](#)). It can be a newly developed, innovative food resulting from new production techniques (e.g. nanotechnology) as well as a traditional - but unknown to EU consumers - food from a non-EU country (e.g. noni juice). The Novel Food regulation does not apply to GMO's, additives, enzymes, flavorings and extraction solvents. A [guidance document](#) on "human consumption to a significant degree" is available on the European Commission's website.

Authorization procedure: Novel foods require a pre-market authorization. Applications for authorization must be submitted to the European Commission via an [e-submission system](#). The Commission may request the European Food Safety Authority (EFSA) to carry out a risk assessment. An [overview of the different steps](#) of the authorization procedure is available on EFSA's website. [Commission Implementing Regulation 2017/2469](#) sets out administrative and scientific requirements for novel food applications. Authorizations are generic and no longer applicant-linked as was the case under the previous rules.

EU Novel Food List: [Commission Implementing Regulation 2017/2470](#) establishes a list of novel foods authorized in the EU. Entries in the list include specifications, conditions of use, additional labeling requirements and post-monitoring requirements. This Implementing Regulation is amended every time a new novel food is authorized.

Novel Food Status: Food business operators are responsible for verifying whether the food they intend to market in the EU is novel or not. Novel Food regulation 2015/2283 provides for a consultation process when the status of a food or food ingredient is unsure. [Commission Implementing Regulation 2018/456](#) lists the procedural steps that food business operators must follow to consult with the competent authority of the Member State where they first intend to market their product. A [list of the competent Member State authorities](#) is available on the Commission's website. For detailed information see [GAIN report "New EU Law on Novel Food Status Determination."](#)

Engineered nanomaterials: Engineered nanomaterials require a novel food authorization before being used in food.

Food from clones: Until separate legislation on cloning is adopted, food from clones but not offspring falls within the scope of the Novel Food regulation.

Traditional food from non-EU countries: Novel Food regulation 2015/2283 introduces a faster notification and simplified assessment procedure for traditional foods with a demonstrated history of safe food use from non-EU countries. Foods from non-EU countries which are considered novel foods will only qualify as “traditional foods” if they are derived from primary production. For example, juice derived from an exotic fruit not consumed in the EU before May 15, 1997 but part of a regular diet in a non-EU country, would qualify as a ‘traditional food.’ [Commission Implementing Regulation 2017/2468](#) sets out administrative and scientific requirements for the notification of traditional foods falling within the scope of the Novel Food regulation.

The Commission also published guidance documents about the new authorization procedures for business operators:

- [e-submission user guide](#)
- [Administrative guidance on the submission of applications for authorization of a novel food pursuant to Article 10 of the Novel Food Regulation](#) (updated in 2021)
- [Guidance on the preparation and presentation of an application for authorization of a novel food in the context of the Novel Food Regulation](#)
- [Guidance on the preparation and presentation of the notification and application for authorization of traditional foods from third countries in the context of the Novel Food Regulation](#)
- [European Commission: Questions and Answers: Novel Food Regulation](#)
- [FoodDrinkEurope, EU Specialty Food Ingredients, and FoodSupplementsEurope: Guidance For Food Business Operators On The Verification Of The Status Of A New Food Under The New Novel Foods Regulation 2015/2283](#)

U.S. Exporters are advised to verify 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 2015/2283](#). 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:

- A [proposal](#) on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes
- A [proposal](#) to prohibit the placing on the market of food from animal clones.

In September 2020, the Commission decided to withdraw these two 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): 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).

Novel Food Regulation: Novel Food Regulation 2015/2283 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” (Article 3.2.f).

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:

- European Food Safety Authority: [New guidance on nanotechnologies in food and feed](#) (published July 2018)
- EU Science Hub: <https://ec.europa.eu/jrc/en/research-topic/nanotechnology>

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 ten 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/system/files/2021-01/labelling_nutrition-vitamins_minerals-comm_reg_en.pdf

More information can be found on the European Commission’s website: https://ec.europa.eu/food/safety/labelling_nutrition/vitamins_minerals_en

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/>

[Regulation 609/2013](#) sets out compositional and labeling rules for foods for specific nutritional uses. Its scope 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. Dietetic foods, e.g. gluten-free foods, not covered by Regulation 609/2013 are considered regular foods and must comply with the rules set out [in Food Information to Consumers regulation 1169/2011](#), [Regulation 1925/2006](#) on the addition of vitamins and minerals to food, and with [Regulation 1924/2006](#) on nutrition and health claims.

[Commission Delegated Regulation 2016/128](#) sets out specific requirements for food for special medical purposes (FSMPs).

[Commission Delegated Regulation 2016/127](#) sets out specific compositional and information requirements for infant-formula and follow-on formula.

[Commission Delegated Regulation 2018/561](#) details the protein requirements for follow-on formula.

[Commission Delegated Regulation 2019/828](#) sets out vitamin D requirements for infant formula and erucic acid requirements for infant formula and follow-on formula.

[Commission Regulation 2020/685](#) sets maximum levels of perchlorate in fresh produce, teas, infant formula and baby food. Perchlorate levels in infant formula, follow-on formula, foods for special medical purposes intended for infants and young children and young child formula as well as processed cereal based food cannot exceed 0.01 mg/kg limit while other baby food are subject to a 0.02 mg/kg limit.

[Commission Delegated Regulation 2017/1798](#) sets out new rules for “total diet replacements for weight control”. The new rules will become applicable on October 27, 2022. For detailed information see [GAIN report “The Skinny on New EU Rules for Weight Loss Products.”](#)

[Commission Regulation 2018/97](#) bans the use of artificial sweeteners in fine bakery products. For more information see [GAIN report “EU bans use of artificial sweeteners in dietetic bakery products.”](#)

New rules on the reduction of acrylamide levels in food, set out in [Commission Regulation 2017/2158](#), became applicable on April 11, 2018. The new rules also apply to baby food and processed cereal-based food intended for infants and young children.

U.S. Exporters of dietetic products should verify whether the products fall within the scope of Regulation 609/2013

F. Food Supplements

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

[EU Directive 2002/46/EC](#) only sets out EU-harmonized rules on labeling and vitamins and minerals that may be used in food supplements. Key aspects in the marketing of food supplements such as minimum and maximum levels of vitamins and minerals or the use of other substances such as botanical extracts remain the competence of the Member States. Directive 2002/46 defines food supplements as food which means that all exports of food supplements must not only comply with Directive 2002/46 but also with horizontal rules applicable to all foods including rules on additives, novel foods, hygiene, contaminants and GMOs.

On June 28, 2021, the Council published [a report](#) on the state of play of the rules applying to the placing of food supplements on the EU market. In the report, the Portuguese Presidency of the Council calls on the Commission to propose a revision of the Directive to update the definition of food supplements, harmonize the conditions of access to the market and increase awareness among consumers.

U.S. exporters of whey protein supplements should work with their importers to determine whether their product should be accompanied by a certificate for processed dairy products or one for composite products. For more information see [GAIN report “Certification and Labeling of EU Whey Protein Supplements.”](#) Marketing food supplements in the EU is a very complex issue. [GAIN report “Exporting Food Supplements to the EU”](#) provides detailed information on marketing food supplements in the EU.

Guidance documents:

- [European Commission: The application of the Mutual Recognition Regulation to food supplements](#)
- [FoodSupplementsEurope: Guidelines on How to Apply the New Mutual Recognition Regulation \(EU\) 2019/515 to Food Supplements in the EU](#)

G. Irradiated Foodstuffs

Harmonization of EU rules on food irradiation has been slow and only a few products have so far received EU-wide approval. [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: https://ec.europa.eu/food/safety/biological-safety/food-irradiation_en

H. Seafood

Detailed information on shipping seafood and fishery products to the EU is provided in the U.S. Department of Commerce's [website](#). Information on mandatory EU labeling requirements as well as reports on the feasibility of an EU eco-label can be found in the European Commission's Fisheries website https://ec.europa.eu/fisheries/cfp/market/consumer-information_en.

I. Pet Food

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

In the EU, pet food is subject to feed marketing legislation and veterinary legislation. The EU's feed marketing legislation covers food for pets as well as feed for food-producing animals. The veterinary legislation covers products of animal origin and hay/straw as these products present a risk for spreading animal diseases. Pet food products containing an animal origin ingredient must be sourced from approved establishments and have to be accompanied by a veterinary certificate. All exports of U.S. pet food to the EU must comply with EU requirements including rules on labeling, hygiene, animal health, certification and the use of additives. [GAIN report "Exporting Pet Food to the European Union"](#) provides a detailed overview of EU legislation relating to imports of pet food.

[European Parliament and Council Regulation 767/2009](#) sets out rules for the labeling and marketing of feed and pet food. It covers feed materials, compound feed and medicated or dietetic feed for both food and non-food producing animals. Feed and pet food not complying with Regulation 767/2009 and with the provisions on feed additives laid down in [Regulation 1831/2003](#) will not be allowed on the EU market.

Conditions for mixing veterinary medicine into feed are set out in [Directive 90/167/EEC](#). In January 2019, the European Union published [Regulation 2019/4 on the manufacture, placing on the market and use of medicated feed](#) in the EU's Official Journal which will replace Directive 90/167/EEC as of January 28, 2022. The new Regulation explicitly includes the manufacturing of medicated feed for pets in the scope of the legislation. More information is available on the Commission's website: https://ec.europa.eu/food/animals/health/veterinary-medicines-and-medicated-feed/medicated-feed-safe-and-controlled-oral_en

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](#) establishes guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products.

[Commission Regulation 2020/354](#) establishes a list of intended uses of feed intended for particular nutritional purposes. It repeals Directive 2008/38/EC. The new Regulation updates the general conditions for feed intended for particular nutritional purposes and the list of intended uses. Amendments include essential nutritional characteristics and the labelling declarations. Feed that has been labelled before March 25, 2022 in accordance with the rules applicable before March 25, 2020 may continue to be placed on the EU market and used until the existing stocks are exhausted.

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

J. Vegetarian and Vegan Foods, and Plant-Based Meat and/or Dairy Alternatives

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, many 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>.

In July 2017, the European Court of Justice (ECJ) ruled that plant-based products cannot be labeled with dairy names such as “cheese,” “butter” or “milk”. The ECJ based [its ruling](#) on [Regulation 1308/2013](#) setting out definitions and designations that may only be used for the marketing of dairy products. A list of exceptions for non-dairy products that may be labeled with reserved dairy names was established by [Commission Decision 2010/791](#). For more information, please see GAIN Report “[European Court Prohibits Use of Dairy Names for Non-Dairy Products](#).”

Section VIII. Trademarks, Brand Names and Intellectual Property Rights

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 intellectual property (IP) office ([full list of national offices](#)). Currently, the only regional-level IP office in the EU is 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](#). [Commission Implementing Regulation 2018/626](#) sets out detailed rules on application procedures. [Commission Delegated Regulation 2018/625](#) sets out procedural rules on opposition and revocation of EU trademarks.

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 feta, parmesan and Parma ham, are protected under EU law. [European Parliament and Council Regulation 1151/2012](#), applicable since January 4, 2016, 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 also open to non-EU countries. Wines and spirits are covered by specific legislation ([Commission Regulation 2019/33](#) and [Commission Regulation 2019/34](#)) and do not fall within the scope of Regulation 1151/2012.

In October 2019, the Council of the EU adopted [Council Decision \(EU\) 2019/1754](#) approving the EU’s accession to the “Geneva Act of the Lisbon Agreement on Appellations of Origin and Geographical Indications.” This membership enables the EU to obtain protection for its GI’s in all [30 contracting parties](#) to the Lisbon Agreement. Practical details on the implementation of the Lisbon Agreement in the EU are laid in Regulation [2019/1753](#). For more information see [GAIN report “EU Prepares to Join Lisbon Agreement on Geographical Indications.”](#)

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)

“Protected Geographical Indication” (PGI) is defined as follows:

- 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 in 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 “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

In 2019, the European Commission launched an [evaluation](#) of Geographical Indications and Traditional Specialties Guaranteed protected in the European Union. The purpose of this evaluation was to provide an in-depth assessment of the overall functioning of the GIs and TSGs quality schemes with a focus on GIs registered at EU level (from EU and third countries) and placed on the EU internal market. This study was completed in March 2021 and highlights that the EU framework on GIs and TSGs is effective and provides a clear EU added value. They conclude that the schemes are relevant and broadly coherent with other EU and national policies, but there is room for further integration. The study identified some limits, such as the low awareness and understanding of GIs and TSGs by consumers in some Member States as well as weaknesses of the controls at the downstream stages of the value chain.

Registration of GIs for Spirit Beverages

Regulation (EU) [2019/787](#) updates the definitions of various spirits beverage categories. It also clarifies and changes the rules on the protection of GIs, including registration.

On July 29, 2021, the European Commission published Delegated Regulation (EU) [2021/1235](#) and Implementing Regulation (EU) [2021/1236](#) concerning GIs applications for registration for spirits beverages. Both regulations ensure implementation of EU law is consistent with the new Regulation 2019/787.

Section IX. Import Procedures

A. Union Customs Code

The “Union Customs Code” (UCC) established in [European Parliament and Council Regulation 952/2013](#) is the framework regulation on rules and procedures for customs throughout the EU. Implementing provisions were published on December 29, 2015. [Commission Delegated Regulation 2015/2446](#) and [Commission Implementing Regulation 2015/2447](#) outline detailed rules for the implementation of certain provision of the new UCC, including Binding Tariff Information and origin of goods. The UCC along with the implementing provisions became applicable on May 1, 2016.

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 [series of guidance documents on the UCC](#) is available on DG Taxud’s website.

On October 2, 2017, the European Commission launched the “[Customs Decisions System](#)”, a new pan-EU electronic system that makes it easier for traders to get permission to import goods into the EU. Importers in all the Member States are able to use the same portal and exchange applications between all the relevant customs authorities.

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

B. Customs Clearance

The European Commission’s “Trade Helpdesk” provides a complete overview of documents needed for customs clearance: <http://trade.ec.europa.eu/tradehelp/>.

In October 2020, the European Commission launched the “[Access2Markets](#)” database. This new portal provides information on:

- Tariffs
- Rules of origin
- Taxes and additional duties
- Import procedures and formalities
- Product requirements
- Trade barriers
- Trade flow statistics

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 2021 Tariff Schedule](#) was published on January 1, 2021 in the Official Journal. 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 is valid for three years. U.S. exporters should be aware that the UCC makes the declaration of a BTI decision mandatory when completing customs formalities. All BTI decisions issued by the Member States' customs authorities are entered into an [EBTI-database](#). [Administrative guidelines on the BTI process](#) are published on DG Taxud's website. All business operators must submit all new applications electronically. More information is available on the [EC'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 at:

https://europa.eu/youreurope/business/taxation/vat/vat-rules-rates/index_en.htm

A list of excise duties applicable on alcoholic beverages and tobacco can be found at:

https://ec.europa.eu/taxation_customs/sites/taxation/files/resources/documents/taxation/excise_duties/alcoholic_beverages/rates/excise_duties-part_i_alcohol_en.pdf

[Council Directive 92/83/EEC](#) sets out common definitions of alcoholic products that are subject to excise duty and ensure that all Member States treat the same products in the same way. The Directive also specifies the method to calculate excise duty on alcoholic products and the criteria for products to

benefit from reduced rates or exemptions. The excise legislation also sets down the minimum rates of tax that must be applied for each category. However, Member States have the freedom to set rates at a higher level.

[Directive 2020/1151](#) amends Directive 92/83/EEC and will apply from January 1, 2022. The new Directive increases the threshold for lower strength beer that can benefit from reduced excise duty rates. It extends the special regime of reduced excise duty rates for small beer and ethyl alcohol producers to producers of other fermented beverages, such as cider. Directive 2020/1151 also sets out the conditions for application of the exemption from excise duty rules for denatured alcohol, used for example in cleaning products.

Section X: Trade Facilitation

A. Advance Rulings

The customs duties that must be paid upon import of a product depend on the tariff classification applicable to the product. The Binding Tariff Information (BTI) system was introduced to ensure legal certainty for business operators when calculating import duties. All currently valid BTI decisions are accessible in the [public BTI database](#). Detailed information on the BTI system can be found at the European Commission's website: https://ec.europa.eu/taxation_customs/business/calculation-customs-duties/what-is-common-customs-tariff/binding-tariff-information-bti_en

B. Pre-Clearance Program

The Official Controls Regulation (OCR - [Regulation \(EU\) 2017/625](#)) provides the legal basis for the recognition of official controls in the country of origin of the goods. The OCR does not provide any legal basis for pre-clearance programs similar to the preclearance inspections conducted in foreign countries by APHIS personnel and funded by the exporters. Rather, Article 73 of the OCR provides for the approval of pre-export controls performed by third countries. Under this system, the EU approval specifies the competent authorities of the third country under the responsibility of which pre-export controls must be performed, the certificates to be used for export of these goods and the maximum frequency of official controls to be performed by the competent authorities of Member States at the entry of the consignments into the Union.

C. Electronic Certificates

The Official Controls Regulation (OCR - [Regulation \(EU\) 2017/625](#)) provides the legal basis for the general EU acceptance of electronic certificates using the EU's Integrated Management System for Official Controls (IMSOC). For plant products, all EU Member States are able to receive U.S. e-Phytos sent via the Hub created by the International Plant Protection Convention (IPPC). For other commodities, currently no connection exists between IMSOC and the respective systems U.S. Government agencies use to issue electronic certificates. In absence of such a connection, paper

certificates are required to satisfy the EU requirement for an original certificate with an ink signature.

D. Import Control Fee

The Official Controls Regulation (OCR - [Regulation \(EU\) 2017/625](#)) provides the legal basis for the financing of import controls. Mandatory fees are charged to operators for certain official controls, including on import controls of animals, products of animal origin, germinal products, animal by-products, composite products, hay and straw, plants and plant products. Operators also have to pay for the border controls performed on food and feed of non-animal origin listed in [Commission Implementing Regulation \(EU\) 2019/1793](#). This regulation mandates specific frequencies of controls for certain hazards in products depending on their origin. Several products have to be tested for aflatoxins under this regulation. In addition, fees are also charged to operators for official controls that were not originally planned because they are necessary to follow-up non-compliance.

E. Average Release Time for Products –Common Delays

The average release time for products depends on the Member State and port of import. The main ports in the European Union are organized in an efficient way to perform customs formalities as well as the necessary veterinary and plant inspections. Incomplete or incorrect certification generally leads to delays in the clearance of goods throughout the EU.

F. Duplicative Inspections

Inspections on imported foods are concentrated at the external borders of the European Union. Once goods have passed inspection and customs duties are paid, they can move freely throughout the EU. However, official controls remain possible at any stage of distribution in the EU.

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

E-mail: delegation-usa-info@eeas.europa.eu

Website: https://eeas.europa.eu/delegations/united-states-america_en

United States Mission to the European Union

Office of Agricultural Affairs

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

Animal and Plant Health Inspection Service (EU office)

27 Boulevard du Regent

1000 Brussels

Belgium

Listing of APHIS-Brussels Staff:

https://www.aphis.usda.gov/aphis/ourfocus/internationalservices/offices/contact_us_pages/contact_us_b_russels_belgium

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:

<https://fas-europe.org/>

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

There are no other import specialist contacts.

Attachments:

No Attachments