

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY
USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT
POLICY

Required Report - public distribution

Date: 2/15/2019

GAIN Report Number: BU1913

Bulgaria

Food and Agricultural Import Regulations and Standards Report

FAIRS Annual Country Report

Approved By:

Jonn Slette

Prepared By:

Mila Boshnakova

Report Highlights:

Bulgaria acceded to the European Union (EU) in 2007 and follows all EU food safety, quality, and standards directives and regulations. The following updates the 2017 Bulgaria [Food and Agricultural Import Regulations and Standards \(FAIRS\)](#) report about applicable Bulgarian regulations for U.S. food-product exports, particularly those which differ from EU legislation. This report should be read in conjunction with the U.S. Mission to the EU's (USEU) Office of Agricultural Affairs' (OAA) most recent EU [FAIRS](#) report. Additional updates and other relevant information can also be found on the FAS Europe's [website](#).

DISCLAIMER: This report was prepared by OAA Sofia for exporters of U.S.-origin food and agricultural products. While every possible care was taken in the preparation of this report, information provided may not be completely accurate because of policy changes since its preparation, or because clear and consistent information regarding 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.

Section I. Food Laws:

Bulgaria acceded to the EU in 2007 and follows all relevant EU directives, regulations, and obligations. EU directives require Member States to harmonize national laws accordingly. The following report outlines regulations which apply to U.S. food product exports to Bulgaria, particularly those which differ from EU legislation and/or regulations. Exporters should be aware that when EU-wide legislation is incomplete, absent, or open to interpretation, Bulgarian laws are applied and imported products are subjected to existing Bulgarian requirements.

Bulgarian Food Law

EU Regulation (EC) 178/2002 establishes the basic framework vis-à-vis Bulgaria's 2011 [Food Law](#), which establishes Bulgaria's food and feed regulations. It establishes basic definitions, goals, and principles for food safety and defines procedural rules, coordination mechanisms between the different public administrations with responsibilities in official food control. Three minor changes were adopted in 2018, including [changes](#) on December 21, 2018. The Food Law's implementing regulations can be found on the Bulgarian Food Safety Agency's (BFSA) website [here](#).

Other major legislation applicable to imported food products can be found in the [Veterinary Medical Act](#) (English version available upon request), including the latest amendments adopted on November 27, 2018. Imports of raw materials and foods of animal origin are regulated under Chapter V, Art.24b Food Law. Additional legislation which may directly or indirectly affect food imports are the [Plant Protection Law](#) and the [Feed Law](#), both of which were revised February 23, 2018. The following sources have a complete list of applicable EU and national legislation (English version Available upon request): EU and National Legislation, Documents, and Tariffs [here](#), and National Legislation [here](#).

New draft amendments to the Food Law were considered by the Cabinet in December 2017. However, other, more urgent issues, as well as the Bulgarian Presidency of the European Council during the first half of 2018, forced Parliament to focus on other priorities and little progress was made on amending the Food Law. Post expects that Parliament will renew its earlier work on the Food Law amendments soon. Parliament continues to debate another new legislation, including the Agricultural and Food Supply Chain Act. The Food Law amendments and the Agriculture and Food Supply Chain Act would effectively deepen Bulgaria's harmonization with the EU. Post expects that both laws will be voted by the Parliament in the first half of 2019.

At the EU level, a new regulation on harmonized food controls, [Regulation 2017/625](#), will enter into force on December 14, 2019, which will supersede the current [Regulation 882/2004](#). For more information see [here](#). In January 2018, the EC finalized a "fitness check" of General Food Law via regulation 178/2002 and then [proposed](#) to revise it the following April. This proposal continues to go through the legislative procedure and is expected to be adopted by mid-2019.

In 2017, Hungary, Slovakia, and the Czech Republic, followed by Bulgaria in 2018, reported that many 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, the European Commission (EC) has proposed an amendment to [Directive 2005/29/EC](#) concerning unfair business-to-consumer commercial practices. For detailed information see [GAIN report "EC Tackles Dual Quality of Foodstuff in the EU."](#) In

Bulgaria, a political party sponsored an amendment to the Food Law on the “dual quality” products issue during fall 2018, but it remains unclear if this proposal will formally be added as part of the Food Law.

Section II. Labeling Requirements:

On December 13, 2014, the general rules on labeling, displaying, and advertising of food products were established by Food Information to Consumers (FIC) [Regulation \(EC\) 1169/2011](#). U.S. standard labeling does not fully comply with EU labeling requirements. Bulgaria’s [Regulation](#) of Food Labeling and Food Presentation (December 13, 2014) introduced [Regulation \(EC\) 1169/2011](#) regarding specific local labeling requirements.

For detailed information on the EU-harmonized labeling legislation, please see the following links:

- EC: [Notice on questions and answers on the application of Regulation 1169/2011 on the Provision of Food Information to Consumers](#) (June 2018) and [Infographic on New Labeling Rules](#)
- FoodDrink Europe (EU Food and Drink Industry Confederation): [Guidance on the Provision of Food Information to Consumers](#)
- USDA Attaché Reports: ‘[New EU Food Labeling Rules Published](#)’, ‘[How to Comply with the EU’s New Food Labeling Rules](#)’, and ‘[EU Labeling Requirements](#)’.

Bulgaria applies EU-harmonized legislation to:

- General Labeling Requirements
- Nutritional Labeling
- Product-Specific Labeling
- Genetically-engineered (GE) products labeling (Regulation (EC) 1829/2003).

Current draft amendments of the Food Law include new provisions for labeling which would more fully harmonize GOB regulations with the EU. The use of Bulgarian language stickers attached to the original label of imported products and/or use of Bulgarian language on the original label are currently being debated. Another point pertains to Bulgarian labeling for small-sized packaged foods products. The FIC Regulation exempts alcoholic beverages from mandatory nutritional labeling and ingredient listing. At present Bulgaria applies nutritional labeling for alcoholic beverages on a voluntary basis.

General Labeling Requirements

Chapter III of the Bulgarian Food Law covers [requirements](#) for labeling of food products (corresponding to Article 9 of FIC regulation 1169/2011). Mandatory labeling information includes:

- Product name
- List of ingredients and quantity of certain ingredients or category of ingredients
- Allergens listed in Annex II
- Nutrition declaration
- Alcoholic content when it is over 1.2% in volume
- Net weight in packaged products
- Expiration date
- Storage and use conditions
- Use instructions when essential to make a proper use the product

- Company identification: name and address of the manufacturer or packer or seller established
- Within the European Union
- Batch information
- Country of Origin

Annex III to FIC regulation 1169/2011 establishes a list of products that require a special warning on the label. The GOB permits multi-language labeling and stickers; however, one of the languages must be Bulgarian (Art.9/1 Food Law). U.S. food manufacturers and/or exporters are encouraged to reach out their Bulgarian stakeholders and discuss questions about labeling requirements.

Ingredients List

The list of ingredients must be preceded by the word “ingredients.” All ingredients must be designated by their specific name and listed in descending order of weight. 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 specific sources of vegetable oils and fats.

Quantitative Ingredients Declaration (QUID)

Article 22 of the FIC regulation requires the indication of the quantity and category of ingredients. Annex VIII to the FIC regulation sets out the technical rules and exemptions from the QUID requirement. The EC published [updated guidelines](#) on QUID requirements in 2017.

Additives and 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.

Allergen Labeling

Article 21 of the FIC 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 EC published an [update of its guidance document on allergen labeling](#) on July 13, 2017. Also see [EU labeling requirements](#) and [Allergen Labeling – Annex 3 \(FoodDrinkEurope\)](#).

Country of Origin Labeling (COOL)

In the EU, COOL is mandatory for beef, pork, poultry, veal meat, sheep and goat meat, fruit and vegetables, eggs, wine, honey, olive oil, fishery and aquaculture products, and EU-certified organic products. In Bulgaria, COOL, per the current Food Law, is mandatory for all food products.

On May 29, 2018, the EC published [Implementing Regulation 2018/775](#), which introduces 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. This Regulation will enter into force on April 1, 2020. The EC is required to publish a guidance document at least 6 months before this date. See GAIN report ‘[Commission Briefing on New Origin Labeling Rules](#)’.

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.” Bulgarian is the official language in Bulgaria.

The currently debated new amendments to the Food Law in Bulgaria are likely to have more detailed requirements regarding translations of mandatory labeling information and how the labels in Bulgarian (usually as stickers) should be placed on the product in order to make the mandatory original label also visible. Specific rules on the use of stickers to provide mandatory labeling information are not included in FIC regulation 1169/2011. EC refers to [FAQs 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.”

Nutritional Labeling

Food products carrying health claims must comply with the provisions of nutritional labeling [Directive 90/496/EC](#). [Regulation 432/2012](#), which establishes a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children’s development and health became applicable on December 14, 2012.

Nutritional Declaration

Under FIC regulation 1169/2011, the nutrition declaration is mandatory. Annex V to the FIC regulation lists foodstuffs which are exempted from the mandatory nutrition declaration requirement. See [here](#) for more information.

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;

The EU’s Food & Drink Industry Federation “FoodDrinkEurope” has launched a [website](#) explaining “reference intakes” to food business operators and consumers.

Health /Nutritional Claims Labeling

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

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. Food products carrying claims must also comply with the provisions of the EU’s FIC regulation. [Commission Implementing Decision 2013/63](#) establishes guidelines for national control authorities as regards the implementation of specific conditions for permitted health claims. [Regulation 353/2008](#) sets implementing rules for applications for the authorization of health claims as provided for in Article 15 of Regulation 1924/2006. Health claims are only allowed if the importance of a balanced diet and healthy lifestyle is also stated on the label. 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. For more information see [here](#) and [GAIN report “Health Claims – New EU Regulation on Generic Descriptors”](#).

Alcoholic Beverages

Alcoholic beverages containing more than 1.2 percent of alcohol by volume are exempted from a nutritional declaration and a list of ingredients. In March 2018, the alcoholic beverages industry presented a [joint self-regulatory proposal](#) outlining general principles of a labeling scheme. These general principles are accompanied by four sector-specific implementation plans for [wine](#), [spirit drinks](#), [beer](#), and [cider & fruit wine](#). It is likely that the new EC will determine if this is a priority when it takes office in November 2019. More information is available in GAIN report “[EU Alcohol Industry Labeling Proposal – Labeling Apart Together](#)”.

Allergen labeling is compulsory on all alcoholic beverages. The percentage of alcohol by volume must be given in the same field as the product name and the net quantity. For wines, rules indicating the amount of alcohol are set out in specific legislation.

Other Specific Labeling Requirements

The FIC Regulation 1169/2011 sets out horizontal rules applicable to all products. Sectoral or “vertical” legislation exists for a number of products. For labeling rules on meat and fish labeling, gluten free foods, trans-fats, minimum durability, warnings on labels and for minimum front size on labels, see the OAA USEU [FAIRS](#) report.

Meat: In October 2018, the EC published [a roadmap](#) to assess its rules on food information for consumers regarding mandatory origin labeling for pork, lamb, goat meat and poultry and determine whether these rules are effective, efficient, coherent and relevant. This roadmap will be followed by an EC report which will be provided to the European Parliament and Council by April 1, 2020. For detailed information, please see [here](#).

Fish: [Regulation 1379/2013](#) sets out labeling rules for fishery and aquaculture products listed in Annex I to the regulation. For more information see the EC’s [website](#).

Trans-fats: On October 4 2018, the EC published a [draft Commission Regulation](#) amending Annex III to [Regulation 1925/2006](#) on trans-fat. If adopted, the new regulation would set a maximum limit of trans fat, other than trans-fat naturally occurring in animal fat, in food which is intended for the final consumer, of two grams per 100 grams of fat.

Glute-free: EC [Implementing Regulation 828/2014](#), applicable since July 20, 2016, sets out conditions for using “gluten-free” and “very low gluten” statements on food labels.

Minimum durability: 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.

Section III. Packaging and Container Regulations:

Size and Content

Bulgarian's National Law Chapter 3 of the Food Law transposes two EU Directives related to the weight and volume of certain prepackaged products ([Council Directive 76/211/EEC](#)). This law establishes nominal quantities for pre-packed products ([Directive 2007/45/EC](#)).

[Directive 2007/45/EC](#) abolished mandatory pack sizes at both EU and national levels and freed sizes for all prepackaged products except wine, spirits, and coffee. Mandatory quantities for wines and spirits are included in the Annex to Directive 2007/45/EC. See [here](#) for more information.

Packaging Waste Management

Please see previous [OAA Sofia's FAIRS report](#) for more information.

Packaging and Materials Which Contact with Foods

A summary of EU and Bulgarian legislation, as well as guidance documents and Bulgarian contact information with regard to the submission of applications for authorization can be found [here](#).

Also, Please see the previous [OAA Sofia's FAIRS report](#).

In May 2018, the EC 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 in the future. See [here](#) for more information.

Section IV. Food Additives Regulations:

Bulgaria applies EU-harmonized legislation regarding food additives. On the EU-harmonized legislation on food additive regulations, please consult the [USEU website section on additives](#).

The EU's "Package on Food Improvement Agents" includes four Regulations:

[Regulation 1331/2008](#) establishing a common authorization procedure for food additives, food enzymes and food flavorings, [Regulation 1332/2008 on food enzymes](#), [Regulation 1333/2008 on food additives](#) and [Regulation 1334/2008 on flavorings](#). 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).

Additives

Authorized food additives and their conditions of use are listed in Annex II to the [Food Additives Regulation 1333/2008](#). The authorized uses of additives are listed according to the category of food to which they may be added.

Annex III to Regulation 1333/2008 contains a second list of food additives approved for the use in food ingredients such as other food additives, food enzymes, food flavorings and nutrients. Specifications for food additives listed in Annexes II and III are laid down in [Commission Regulation 231/2012](#). The EC's [food additives database](#) together with its [user guide](#) provides [detailed information](#) on the different food additives allowed in the EU.

Flavorings

[Regulation 1334/2008](#) establishes a list of authorized flavoring substances, listed according to the

category of food to which they may be added. An [on-line database](#) allows consumers, food businesses and food control authorities to verify which flavoring substances are authorized in food.

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

Enzymes

[Regulation 1332/2008](#) on food enzymes introduced harmonized rules for their scientific evaluation and authorization in the EU and establishes labeling requirements. For detailed information see the European Commission's [website](#).

Processing Aids

Processing aids are subject to national legislation. Requests should be addressed to the Bulgarian Food Safety Agency. Please see the previous [OAA Sofia's FAIRS report](#).

Section V. Pesticides and Other Contaminants:

Tolerance for pesticide residues were harmonized in the EU in 2008. Bulgaria adheres to EU-harmonized legislation on pesticides and contaminants.

Pesticides

European Parliament and Council Regulation 1107/2009 established the rules for approvals of plant protection products (PPPs). PPPs (also referred to as 'pesticides') must contain at least one approved active substance. Only PPPs containing approved active substances as per the list 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 by Bulgarian authorities. According to Annex I of Regulation 1107/2009, the EU is divided in three different zones. Once Bulgaria approves the PPP, it can be mutually recognized and thus authorized within the EU. Bulgaria is included in the Zone C (South) along with Spain, Cyprus, France, Greece, Italy, Malta and Portugal). [Directive 2009/128](#) on the sustainable use of pesticides is also part of the so-called Pesticides Package. For more information see [here](#). For application for pesticide registration in Bulgaria the contact is the BFSA (see below for contact information).

Endocrine Disruptors

Endocrine disruptors refer to substances with the potential to alter and cause unintentional adverse health effects to the endocrine systems of humans and wildlife. In June 2018, the European Chemicals Agency (ECHA) and EFSA published a [technical guidance document](#) to implement the criteria for both biocides and pesticides.

Maximum Residue Levels (MRL)

[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.

See and the [list](#) of authorized active substances or pesticide-MRL combinations [online database](#). The Bulgarian National Pesticides Plan can be found [here](#).

In February 2018, Bulgaria amended its [Feed Law](#) introducing the latest changes from the EU legislation. In December, MinAg published a [draft](#) of amended implementing regulation Decree #10 (Official Gazette #29 of 2009) regarding MRLs in feed (lead, mercury, melamine and decoquinate MRL). The goal is to introduction of [Directive 2002/32/EC](#) and [Regulation EC 2017/2229](#). The draft is released for public comments and is expected to be approved in the first half of 2019.

Import Tolerance

The EC is currently undergoing a regulatory fitness and performance check ([REFIT](#)) of the [EU legislation on pesticides and pesticides residues](#). The external evaluation study was published on [October 18, 2018](#), including an [executive summary](#). The final report concluding the REFIT of the EU pesticide legislation is expected in the first half of 2019. In addition, the European Parliament formed a special Committee on Pesticides that has to investigate glyphosate and other pesticide products and had to report its findings and recommendations by December 12, 2018. Official controls on pesticides can be found [here](#).

Contaminants

Bulgaria applies EU-harmonized legislation regarding food contaminants. Please, consult the USEU website [section on contaminants](#) and EU- wide harmonized maximum levels for contaminants are set in the Annex of [Commission Regulation 1881/2006](#).

The EU has started to discuss the expansion of the group of products subject to a maximum level for ochratoxin A. Please, see GAIN report: “[Additional EU Maximum Levels for Ochratoxin A on the Horizon](#)”. The EU is also expected to start discussions on the lowering of the maximum levels of dioxins following the lowering of the tolerable weekly intake (TWI) by the [European Food Safety Authority](#) in November 2018. Please, see OAA USEU’s [FAIRS](#) report for more information.

Official Controls of Maximum Levels in Foodstuffs

The following regulations concern the sampling methods and methods of analysis for the official controls of the levels of the different contaminants:

- Annex I describes the methods of sampling.
- Annex II proscribes the sample preparation and the performance criteria for analytical methods.

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

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

Dioxins: [Commission Regulation 2017/644](#)

Heavy metals, Tin, 3-MCPD and benzo(a)pyrene: [Commission Regulation 333/2007](#)

Erucic acid: [Commission Regulation \(EU\) 2015/705](#)

Private Industry Standards

Please see the previous [OAA Sofia’s FAIRS report](#) for more information.

Aflatoxin in Tree Nuts

Following the publication of [Commission Implementing Regulation \(EU\) 2017/1269](#) on July 14, 2017, the U.S. pre-export program for peanuts was no longer recognized by the EU. There are no restrictions on the export of U.S. peanuts; however, shipments no longer benefit 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 under [Commission Regulation \(EC\) No 669/2009](#). The list was updated in 2017, as Bulgaria now tests 10 percent of all incoming shipments.

For information on aflatoxin testing and certification can be found for [almonds](#) and [peanuts](#) performed in the United States prior to export to the EU, as well additional information from [USDA](#).

Residues in Animals and Animal Product

The monitoring of residues in animals and animal products is addressed in [Council Directive 96/23/EC](#). This directive includes the monitoring of pesticide residues as well as residues of veterinary drugs and a wide range of other contaminants and undesired substances such as residues of growth promotants. The prohibition of the use of hormones in meat production is addressed in [Council Directive 96/22/EC](#). For additional information on how to export food of animal origin to the EU, see: [Imports of food of animal origin from non-EU countries: Provisions of guarantees equivalent to EU requirements on residues of veterinary medicines, pesticides and contaminants](#).

Also see [here](#) for more information.

Section VI. Other Regulations and Requirements:

An overview of all U.S. authorities that issue the legally required certificates for export to the EU is available on [USDA EU website](#). The websites of each of those authorities provide detailed and up-to-date information on the specific product certificates under their legal authority. Additional certification and documentation requirements can be found [here](#).

Composite Products

U.S. exports of “composite products” continue to be challenging due to burdensome certification requirements introduced in 2012. Composite products are defined as food products containing processed animal-origin and plant-origin ingredients. All composite products which contain a processed meat product are subject to a veterinary check. Generally speaking, composite products which contain over 50 percent of animal-origin ingredients also require a certificate, as well as certification requirements for heat-treated dairy products. The components of animal origin (except gelatin and collagen) used for producing a composite product have to originate from a third country with an approved residue control plan for that particular component. [Commission Decision 2007/275/EC](#) establishes a list of animals and products that are subject to controls at BIPs, including certain composite products, as well as a list of composite products not subject to veterinary checks.

For more information see USDA EU’s website [here](#).

Inspections

BFSA is responsible for inspections and enforcement of food and feed regulations. Products can be checked at import or at all further stages of marketing. Violations of EU food and feed legislation are reported through the [RASFF portal](#). Specific detailed inspection requirements exist for animal products

[\(Directive 97/78/EC\)](#). Products of animal origin must be presented at a Community border inspection post (BIP) and submitted to an import control following prior notification of the shipment. [Commission Decision 2009/821/EC](#) establishes a list of EU BIPs approved to carry out veterinary checks on animals and animal products from third countries. A full list of Bulgarian BIPs can be found [here](#). See the previous [OAA Sofia FAIRS](#) and report for more information.

[European Parliament and Council Regulation 882/2004](#) sets general rules for the performance of official controls to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. [Commission Regulation 669/2009](#) implements Regulation 882/2004 as regards the increased level of official controls on imports of certain feed and food of non-animal origin. Regulations 854/2004 and 882/2004 will be repealed by [European Parliament and Council Regulation 2017/625](#) on December 14, 2019.

Section VII. Other Specific Standards:

For detailed information on the EU-harmonized legislation on other specific standards, please consult the [USEU import rules](#) website.

GE Foods and Feeds

Bulgaria has a centralized system for testing and controlling the unauthorized presence of GE products in the feed and food. Please see [OAA Sofia's previous FAIRS report](#) for more information.

The EU register of authorized GE events is available on the EC's [website](#). Labeling requirements do not apply to foods containing 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. See USDA EU's [website](#) for more information.

The Bulgarian Food Law was changed in 2010 to ban GE ingredients and GE products in baby foods regardless of their safety evaluation (Art. 4a/4 for the Food Law). Please see the previous [OAA Sofia FAIRS](#) report for more information.

Novel Foods

A new [EU framework regulation 2015/2283 on Novel Foods](#) became applicable on January 1, 2018. The Novel Food regulation does not apply to GE, additives, enzymes, flavorings, and extraction solvents. See EC [guidance](#) on "human consumption to a significant degree".

EU Positive 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.

Article 23a of the Food Law introduces the procedure for approval and release on the market of new ingredients and substances as novel foods. Please see the previous [OAA Sofia's FAIRS report](#).

For detailed information see [GAIN report "New EU Law on Novel Food Status Determination."](#) For regulatory questions vis-à-vis food products from [cloned animals](#), engineered nanomaterials, [nanotechnology](#), traditional food from non-EU countries, and fortified foods, please, consult with OAA

USEU [FAIRS](#) and [USDA EU's website](#).

Dietetic or Special Use Foods

[Regulation 609/2013](#) regulates infant formula and follow-on formula, processed cereal-based food, baby food, food for special medical purposes, and total diet replacement for weight control. Foods that no longer fall within the scope of Regulation 609/2013 will be regarded as regular foods.

[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. Please see [GAIN report “The Skinny on New EU Rules for Weight Loss 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 will also apply to baby food and processed cereal-based food intended for infants and young children. Please, see OAA USEU [FAIRS](#) for more information.

Organic Foods

[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 labeling](#) was adopted in May 2018 and will enter into force on January 1, 2021, repealing the Council Regulation 834/2007. The Bulgarian Food Law contains special provisions regarding organic foods in Article 6. Please see [here](#) and [GAIN “New EU Organic Regulations for Early 2018”](#). [EC Implementing Regulation 2016/1842](#) published on October 19, 2016, sets new EU rules for certifying imported organic foods. Since October 19, 2017, only certificates initiated through the EU's Trade Control and Expert System (TRACES) are valid.

Since June 1, 2012, the EU and the United States have mutually recognized their respective organic systems. All products traded under this agreement must be accompanied by an organic export certificate. Per new EU Regulation on organic production adopted in May 2018, this arrangement would expire by January 1, 2026, five years after implementation of the new regulation, by which time, the U.S.-EU arrangement would need to be converted to an organic trade agreement. If not, exporters will have fully to comply with the full set of EU organic regulations for export to the EU.

Organic Wine: [Commission Implementing Regulation 508/2012](#) only authorizes imports of U.S. wines that are certified to comply with the EU's organic wine rules.

Wine, Beer and Other Alcoholic Beverages

Wine: [Commission Regulation 607/2009](#), as amended by [Commission Implementing 1185/2012](#), establishes rules on protected designations of origin, GIs, traditional terms and labeling. For detailed information on the EU's wine legislation, including labeling requirements, see [GAIN report “EU Wine Policy”](#) and the EC's [website](#).

US-EU Wine Agreement: In March 2006, the U.S. and the EU and the U.S. signed the [“Agreement between the United States and the European Community on Trade in Wine”](#).

Information on US-EU wine trade can also be obtained from Alcohol and Tobacco Tax and Trade Bureau at <http://www.ttb.gov/importers/importing-exporting.shtml>.

Spirits: [European Parliament and Council Regulation 110/2008](#) lays down general rules on the definition, description and presentation of spirit drinks. [Commission Implementing Regulation 716/2013](#) lays down rules for the application of Regulation 110/2008 as regards the use of compound terms and spirit GIs. An application to register “Tequilla” as a geographical indicator (GI) is currently going through the legislative approval procedure.

In December 2016, the EC presented a [proposal](#) to replace the current spirits regulation 110/2008 with a new one. The proposal is currently undergoing legislative adoption procedures.

[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 beer-specific EU-harmonized legislation. All alcoholic beverages must comply with allergen labeling requirements. Bulgaria’s beer industry lists ingredients on a voluntary basis.

Commission Report on Labeling of Alcoholic Beverages: The EU’s FIC regulation 1169/2011 exempts alcoholic beverages from mandatory nutrition labeling and ingredients listing, but requires the EC to present a report assessing whether such labeling should be introduced. Following the conclusions of the report, presented in March 2017, the EC invited the EU alcoholic beverages industry to present a self-regulatory proposal covering all sectors. In March 2018, EU industry offered a [joint proposal](#) outlining general principles, accompanied by four sector-specific implementation plans: [wine](#), [spirit drinks](#), [beer](#) and [cider](#). See [here](#) and [GAIN report “EU Alcohol Industry Labeling Proposal – Labeling Apart Together”](#) for more information.

Vertical Legislation and Product – Specific Legislation

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/EC amended by [Directive 2012/12/EU](#)), [preserved milk](#) (Directive 2001/114), [coffee extracts and chicory extracts](#) (Directive 1999/4) and [fruit jams and similar products](#) (Directive 2001/113).

Fruit Juices: Please see [GAIN report “New EU Fruit Juice Labeling Rules”](#) .

Honey: On May 15, 2014, the EU adopted [Directive 2014/63/EU](#) amending [Directive 2001/110/EC](#) on honey.

Single Common Market Organization: [European Parliament and Council Regulation 1308/2013](#) establishes a single common market organization (CMO) for all agricultural products. The single CMO provides definitions and marketing rules for rice, sugar, beef and veal, milk and milk products, eggs and poultry meat, olive oil, fruit and vegetables, spreadable fats and wine. In May 2018, the EC

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

Food Supplements

[EU Directive 2002/46/EC](#) sets out EU-harmonized rules on labeling and vitamins and minerals that may be used in food supplements. U.S. exporters of whey protein supplements should work with their importers to determine whether products should be accompanied by a certificate for processed dairy products or one for composite products. For more information see [GAIN “Certification and Labeling of EU Whey Protein Supplements.”](#)

Marketing food supplements in the EU is a complex. In Bulgaria, the new Food Law is likely to contain special provisions regarding food supplement marketing. This also includes a new set of requirements for e-commerce, sales of food supplements which have not been regulated to date, and which are not harmonized at the EU level. See [GAIN report “Exporting Food Supplements to the EU”](#) and USDA EU’s [website](#) for more specific information on marketing food supplements. _

Frozen Foods

EC Directive [89/108/EEC](#) sets rules for quick-frozen foods and related packaging and labeling. It was transposed into national law through the Food Law. For frozen food of animal origin, [Commission Regulation 16/2012](#) amending [Food Hygiene Regulation 853/2004](#), requires food business operators to provide the dates of production and freezing to buyers and, upon request, to competent authorities. The date of freezing must indicate if a product was frozen more than once.

Irradiated Foodstuffs

[Framework Directive 1999/2/EC](#) outlines the marketing, labeling, import and control procedures and technical aspects of food irradiation. Please see the EC’s [website](#). Until the EU positive list is expanded, national authorizations continue to apply. To date, Bulgaria has no authorizations of food and food ingredients which may be treated with ionizing radiation (see [link](#)). Art.22 of the Bulgarian Food Law regulates irradiation in foods.

Special Use Foods

See [GAIN report “New EU Rules on Dietetic Foods”](#), complemented by [GAIN report “New EU Rules on Dietetic Foods – Update”](#) and the EC’s [website](#).

An EC report on food and beverages labeled specifically for sportspeople concluded that there is no need for specific EU-harmonized provisions beyond existing EU food rules for these products. U.S. exporters should check with their importers whether re-notification may be necessary. Please see [GAIN report “New EU Rules for Sports Food”](#).

New EU rules on “total diet replacement for weight control” will become applicable 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 where the product will be marketed. Please 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.”](#)

Seafood

Detailed information on shipping seafood and fishery products to the EU is provided in the U.S. Department of Commerce’s [“Exporting Seafood to the European Union – December 2017 Update”](#). Information on mandatory EU labeling requirements as well as reports on the feasibility of an EU eco-label can be found in the EC’s Fisheries [website](#).

Pet Food

Requirements for exporting pet food to the EU can be found here [Pet food](#). Pet food products containing animal-origin ingredients must be sourced from approved establishments and be accompanied by veterinary certificates. All exports of U.S. pet food to the EU must comply with EU requirements including rules on labeling, hygiene, animal health, certifications, and additives. Please see: [GAIN report “Exporting Pet Food to the European Union”](#) for more information.

[European Parliament and Council Regulation 767/2009](#) sets out new rules for the labeling and marketing of feed and pet food. Conditions for mixing veterinary medicine into feed are set out in [Directive 90/167/EEC](#). In September 2014, the EC presented a proposal to replace the outdated Directive 90/167/EEC on medicated feed. The scope of the proposal explicitly includes medicated pet food. See [here](#) and [here](#) for more information.

Meat and Fish Labeling

See the OAA USEU [FAIRS](#) report for beef, veal, pork, sheep, goat, and poultry meat requirements.

Vegetarian and Vegan Foods

To date, the EC has not adopted an EU-harmonized definition of the terms “vegetarian” and “vegan.” In the absence of EU-harmonized rules, food companies have started using the “European V-label,” a labeling scheme launched by the umbrella organization the European Vegetarian Union (EVU). For more information see EVU’s [website](#).

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 \(EU\) 1308/2013](#), which establishes definitions and designations that may only be used for dairy product marketing. 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 see [GAIN report E17046](#) on the ECJ ruling.

Section VIII. Copyright and/or Trademark Laws:

Trademarks

In the EU, trademarks can be registered at the national, regional or EU level. [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. Trademarks registered at the national level are protected in the respective state. Applications for registering under the Community Trademark Register must be submitted to the Patent Office of Bulgaria (see contact information below under Annex I).

A trade mark can be registered also at the EU-level as a “Community Trade Mark” at the [Office for Harmonization in the Internal Market](#). A Community Trade Mark gives the owner protection in all EU Member States with one single registration. Additional information on EU trade mark criteria can be found on the EC’s [website](#) and the previous [OAA Sofia’s FAIRS report](#).

Designation of Origin and Protected GIs

Some food product names considered as generic terms in the United States (*e.g.* feta, parmesan) are protected under EU law. In July 2018, the EC presented a proposal on EU accession to the “Geneva Act of the Lisbon Agreement on Appellations of Origin and Geographical Indications.” Membership would allow the EU to force protection of all its GIs among all contracting parties to the Lisbon Agreement. For more information see [GAIN report “EU Prepares to Join Lisbon Agreement on Geographical Indications.”](#)

The [EC’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](#). Bulgaria’s lists of protected food names is available [here](#). Bulgaria has five registered TSG products (meat products), one application for PDO Product (honey) and two registered PGI products (rose oil and a meat product).

In July 2018, Bulgaria amended the [Law on Trade Marks and Geographic Indications](#) (Official gazette 61/2018). The amendment aimed complete harmonization of the local legislation with the EU [European Parliament and Council Regulation 1151/2012](#). Before this change, Bulgaria maintained a national protection on certain geographic indications and designations of origin of food products (for example, yogurt) which was not in compliance with the regulation 1151/2012 since such protection is possible only at the EU level. This caused EC’s warning comments in January 2018 sent to the Bulgarian Patent Office, MinAg and the Ministry of Economy. This triggered the process for full harmonization in July 2018.

Section IX. Import Procedures:

Other Certification and Testing Requirements

An up-to-date overview of all U.S. authorities that issue the legally required certificates for export to the EU is available on our [website](#). Also see the USDA EU [website](#) for additional information.

Sanitary and phytosanitary (SPS) requirements are available on the EC’s websites: DG Health and Consumers [“International Affairs – Import Conditions”](#) and DG Trade [“Trade Helpdesk”](#).

Union Customs Code

Bulgaria follows EU directives, regulations, and obligations when available. Since the EU is a customs

union, all Member States apply the same import duties on goods from outside the EU based on tariff classification of goods and the customs value. Once goods are cleared, they can be moved freely throughout the EU. The UCC along with the implementing provisions became applicable on May 1, 2016, but further changes will be phased in up to December 31, 2020.

A [guide on “Customs formalities on entry and import into the European Union”](#) is available on DG Taxud’s website. A [complete overview of the EU’s UCC](#) is available on the EC’s DG for Taxation and Customs Union (TAXUD) website. Further changes to the EU’s new UCC will be phased in up to December 2020. In the case of Bulgaria, Customs Agency ascribed to the Ministry of Finance, is the responsible entity. Contact information for the Customs Agency can be found in Appendix I.

On October 2, 2017, the EC launched the “[Customs Decisions System](#)”, a new pan-EU electronic system to facilitate permission to import goods into the EU. Importers in Bulgaria are able to use the same portal and exchange applications between all the relevant customs authorities.

The EU uses the Combined Nomenclature (CN) for the customs classification of goods.

The [EU’s 2018 Tariff Schedule](#) was published on October 31, 2017 in Official Journal L 282.

The EU’s [on-line “TARIC” customs database](#) can be consulted to look up commodity codes and relevant import duties. Duties payable on goods imported into the EU/Bulgaria 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.
- Excise duties (alcohol and tobacco) - not harmonized. A list of excise duties applicable on alcoholic beverages and tobacco can be found [here](#).

For detailed information [see European Parliament Briefing “Excise duty on alcohol.”](#) In May 2018, the EC proposed a [new text amending Directive 92/83/EEC](#). If adopted, it would *inter alia* change the definition of “cider” and apply reduced rates to some independent makers of alcoholic drinks.

- Inspection fees – not harmonized
- Value Added Tax – not harmonized. Bulgaria standard VAT rate is 20% percent. The reduced rate applicable to hotel and tourist services is set at 10 percent.

Customs Clearance

The EC’s “[Trade Helpdesk](#)” offers a complete overview of documents needed for customs clearance.

Import Documentation and Process

Agricultural products are examined when they enter Bulgaria by the Bulgarian BIP. TRACES software has been applied since 2014. All BIPs can execute both veterinary and phytosanitary control and inspect all products for human consumption. Please see [OAA Sofia’s previous FAIRS report](#) for more information.

[Regulation #8 for phytosanitary](#) inspections at BIPs (February, 2015) provides basic EU principles for phytosanitary border controls. In April 2018, MinAg amended [Regulation #8](#) in order to achieve full harmonization and adoption of [Directive EU 2017/1279](#) and [Directive EU 2017/1920](#).

U.S. exporters interested in introducing a product into the Bulgarian market should obtain local representation and/or a local importer/distributor to gain knowledge of the market, up-to-date information, and guidance on trade laws and business practices, sales contacts, and market development expertise. Please, contact FAS Sofia for comprehensive information about the local market entry and specifics, regulations and practices.

Inspections, Temporary Entry and Samples

Please see OAA Sofia's previous [FAIRS report](#) for more information.

Appendix I. Government Regulatory Agency Contacts:

Ministry of Agriculture and Food

Blvd. Hristo Botev 55 Sofia 1040

Tel.: (+359) 2-985-11858;

Fax: (+359) 2-981-7955

Website: <http://www.mzh.government.bg>

Ministry of Health

Sqr. Sveta Nedelya 5, Sofia 1000

Tel.: (+359) 2-981-0111

E-mail: press@mh.government.bg

Website: <http://mh.government.bg>

Direction Public Health

Tel.: (+359) 2-9301-252

<http://www.mh.government.bg/bg/kontakti/>

Bulgarian Food Safety Agency

Bul. Pencho Slaveikov 15A, Sofia 1606

Tel.: (+359) 2-915-98-20

Fax: (+359) 2-954-9593

E-mail: bfsa@bfsa.gov

Website: <http://www.babh.government.bg/en/>

Bulgaria Customs Agency, Ministry of Finance

Str. Rakovski 47, Sofia 1202

Tel.: (+359) 2-9594-210

Fax: (+359) 2-9859-4528

E-mail: pr@customs.bg

Website: <http://customs.bg>

Ministry of Economy

Str. Slavyanska 8, Sofia 1000

Tel.: (+359) 2-940-71

Fax: (+359) 2-987-2190

E-mail: e-docs@mi.government.bg

Website: <http://www.mi.government.bg>

National Drug Agency

8 Damyan Gruev Str., Sofia 1303

Tel.: (+359) 2-8903-555

Fax: (+359) 2-8903-434;

E-mail: bda@bda.bg

Website: <http://en.bda.bg/>

National Center of Public Health and Analyses

Acad. Ivan Evst. Geshov 15 blvd Sofia 1431

Tel.: (+359) 2-8056-444

Fax: (+359) 2-9541-211

E-mail: ncpha@ncpha.government.bg

Website: <http://ncpha.government.bg>

Bulgarian Institute for Standardization

1797 Sofia, Lachezar Stanchev" Str. Nr 13

"Izgreve" Complex

Tel.: (+359) 2-8174-504

Fax: (+359) 2-8174-535

Website: <http://www.bds-bg.org/en/contact/index.php>

Executive Agency Bulgarian Accreditation Services

52 A "Dr. G. M. Dimitrov" Blvd. 1797 Sofia Bulgaria,

Tel/Fax: (+359) 2-8735-303

E-mail: ea_bas@abv.bg; office@nab-bas.bg

Website: <http://www.nab-bas.bg/bg/>

Republic of Bulgarian Patent Office

Sofia 1040, 52 b

Dr. G.M. Dimitrov Blvd.

Tel. (359-2) 9701 + extension number,

Fax: *(359-2) 870 83 25

E-mail: bpo@bpo.bg; <http://www.bpo.bg/>

Major Bulgarian Trade Associations

American Chamber of Commerce in Bulgaria

Business Park Sofia, bld. 2, fl. 6. Sofia 1766 Bulgaria

Tel.: (+359) 2-9742

Fax: (+359) 2-9742-741

E-mail: amcham@amcham.bg

Website: <http://amcham.bg>

Bulgarian Chamber of Commerce and Industry

1058 Sofia, 9 Iskar Street

Tel.: (+359) 2-811-740

Fax: (+359) 2-987-3209

E-mail: bcci@bcci.bg

Website: <http://www.bcci.bg>

Bulgarian Industrial Association

1000 Sofia, 16-20 Alabin Street

Tel.: (+359) 2-932-0911

Fax: (+359) 2-987-2604

E-mail: office@bia-bg.com

Website: <http://www.bia-bg.bg>

Bulgarian Association of Food and Beverage Industries

1606 Sofia, 29 Vladaiska Street

Tel.: (+359) 2-952-0989

Fax: (+359) 2-952-0989

E-mail: bafdi@mb.bia-bg.com

Website: <http://www.bia-bg.com/member/26>

Food and Drink Bulgaria

1113 Sofia, 23 A Bl 56 Lulyakova Gradina Street

Tel: (+359) 889 202 265

E-mail: iana.ivanova@fooddrink.bg

Website: <https://www.fooddrinkeurope.eu/member/food-drink-bulgaria/>

Spirits Bulgaria

1618 Sofia, 40 Bratia Bukston Street, floor 5

Tel: (+359) 2 9566090

E-mail: office@spirits.bg

Website: <http://www.spirits.bg/>

Bulgarian Retail Association

1000 Sofia, 150 Kliment Ochridski Blvd

Tel.: (+359) 2-962-4055; (+359) 8-9702-0733

Fax: (+359) 2-962-0162

E-mail: upr.savetbra@gmail.com

Website: <http://bra-bg.org/>

Bulgarian Association for Modern Trade

Sofia 1756, Iztok area, 5“Lachezar Stanchev“ Street

Sofarma Business Towers, Tower B, fl. 4, office 1

Tel.: (+359) 8-957-7746 and (+359) 2-4433-444.

E-mail: office@moderntrade.bg

Website: <http://www.modertrade.bg/>

Appendix II. Other Import Specialist Contacts:**European Union – Delegation of the European Union to the United States**

2300 M Street

NW, Washington, DC 20037

Tel.: (+1) 202-862-9500

Fax: (+1) 202-429-1766

United States Mission to the European Union

Office of Agricultural Affairs

27 Boulevard du Regent

1000 Brussels, Belgium

Tel.: (+32) 2-508-2760

Fax: (+32) 2-511-0918

E-mail: AgUSEUBrussels@fas.usda.gov

Website: <http://www.usda-eu.org>

European Commission Mission to Bulgaria

24, Rakovsky St., 1000 Sofia

Tel.: (+359) 2-933-5252

Fax: (+359) 2-933-5233

E-mail: COMM-REP-SOF@ec.europa.eu

