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Prepared By: Mila Boshnakova-Petrova

Approved By: Jonn Slette

Report Highlights:

Bulgaria acceded to the European Union (EU) in 2007 and follows EU food directives, standards, and regulations. This report outlines applicable legislation regarding U.S. food-product exports to Bulgaria, particularly those rules 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) EU FAIRS 2020 report.

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This report should be read in conjunction with the U.S. Mission to the EU’s (USEU) Office of Agricultural Affairs’ (OAA) [EU FAIRS 2020 report](#). Additional updates and other relevant information can be found on the FAS Europe’s [website](#).

DISCLAIMER: This report was prepared by U.S. Embassy Sofia’s OAA 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. Post recommends 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.**

Executive Summary

Bulgaria is a small but growing market for the U.S.-origin food and beverage exports. It shares borders and international points of entry with non-EU countries, including Turkey, Serbia, and North Macedonia. Bulgaria uses international Black Sea seaports, as well as ports for of entry in neighboring Greece and Romania to import food and agricultural products. Significant U.S. food and agricultural trade to Bulgaria is also shipped overland from western EU ports of entry, notably the Netherlands and Germany.

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 legislation applicable to U.S. food exports to Bulgaria, particularly those requirements which differ from EU regulations. Exporters should note that when EU-wide legislation is incomplete, absent, or open for interpretation, Bulgarian national laws may apply.

In mid-2020, Bulgaria completed a major update of its Food Act. The updates were primarily designed to better harmonize Bulgarian food regulations with EU standards. Bulgarian officials are still drafting implementing regulations of the new Food Act, many of these are currently scheduled to enter into force in early 2021. Bulgarian parliamentary elections at the end of March may slow that process.

Bulgarian Food Law

In June 2020, Bulgaria passed the [Food Act](#) (English version available upon request), a major

regulatory update regarding the food industry and trade. Passage of the 2020 Food Act followed years of extensive consultations with numerous stakeholders. The Act's main objective was to harmonize with EU legislation more fully, as well as to achieve better food traceability and consumer protection. The Act introduced regulations for online trade which was previously unregulated. It also levied new taxes on business operators, including vehicle registrations for transporting certain food categories. It also enforced new production and trade requirements for baby food, food supplements, and therapeutic foods. Authorities continue to develop the Food Act's implementing regulations. Most of the new implementing regulations under the [Food Act](#) are expected to be available by the spring-summer of 2021. Until then, see FAS Sofia's [GAIN](#) report and the Bulgarian Food Safety Agency's (BFSA) website [here](#) for more information.

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 August 11, 2020. Imports of raw materials and foods of animal origin are regulated by this legislation.

Additional legislation which may have direct or indirect effect on food imports includes the [Plant Protection Law](#) (last revised July 21, 2020) and the [Feed Law](#) (last revised July 21, 2020). The following sources have a complete list of applicable EU and national legislation (English version available upon request): EU legislation [here](#), and national legislation [here](#).

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. To address this issue, in April 2018 the European Commission (EC) proposed to amend [Directive 2005/29/EC](#) concerning unfair commercial practices. In November 2019, the EU adopted [Directive \(EU\) 2019/2161](#) amending previous rules on EU consumer protection rules. The new Directive includes 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. In Bulgaria, a political decision was taken to move this topic from the Ministry of Agriculture's portfolio to the Ministry of Economy. The Ministry of Economy intends to transpose these changes into the national legislation in 2021.

Relevant Competent Authorities

The Ministry of Agriculture and Foods (MinAg) controls imports of food products for human consumption, animal feed/ingredients and live animals not intended for direct human consumption through the BFSA. Food safety is the responsibility of BFSA, which coordinates the food and feed chain control. BFSA remains the competent regulatory authority on all food imports, exports, and manufacturing except for bottled water (mineral, spring, and table water). The [BFSA website](#) lists all relevant regulations, documents, certificates, tariffs, registers, and any other information, including links to the EU regulations.

Since 2016, the [Risk Assessment Center](#) has operated as an independent agency under the direct supervision of MinAg. It is responsible for risk assessment and management and works directly with the European Food Safety Authority (EFSA).

Section II. Labeling Requirements

On December 13, 2014, the EC's general rules on labeling, displaying, and advertising of food products were established by Food Information to Consumers (FIC) [Regulation \(EC\) 1169/2011](#). Details can be found [here](#).

Bulgaria's [Regulation](#) of Food Labeling and Food Presentation (December 13, 2014) introduced [Regulation \(EC\) 1169/2011](#) regarding specific local labeling requirements. Currently, Bulgarian authorities are drafting a new implementing regulation about labeling under the [Food Act](#) which will fully harmonize Bulgarian government regulations with the EU. Chapter I, Section IV in the law covers packaging, labeling, presentation, and advertising of foods. Current labeling regulation is silent regarding at what stage of the supply chain the label or the sticker in Bulgarian should be placed on the product. Official sources, however, have indicated to the Post that the products should bear original labeling (not necessarily in Bulgarian) allowing proper identity and food safety checks prior to Customs clearing. The products must be properly labeled in Bulgarian (by a sticker or by translation of the original label) when placed for retail sale.

Bulgaria applies EU-harmonized legislation to:

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

General Labeling Requirements

As per Article 9 of FIC regulation 1169/2011 and Chapter I, Section IV of the Food Act, 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 over 1.2 percent 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 EU
- Batch information
- Country of origin

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 defines 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.

For information on Minimum Durability and Quantitative Ingredients Declaration (QUID), see the [EU FAIRS 2020 report](#).

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. Please, see EC published [update of its guidance document on allergen labeling](#) on July 13, 2017, [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 is mandatory for almost all food products. Additional details will be available soon, pending the publication of an implementing regulation under the Food Act.

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. Detailed information on COOL is provided on FAS/USEU's [website](#) and on FoodDrink Europe (EU Food and Drink Industry Confederation) [Guidance on the Origin Indication of the Primary Ingredient](#) (2019).

The Bulgarian [Food Act](#) introduced two new labels for local foods (see [GAIN](#)). The first is “Produced in Bulgaria” and it means primary produced farm products produced in the country, namely crops, livestock products, and wild-caught fish and game products. The second term is “Product from Bulgaria”. It relates to products whose main ingredient is produced in Bulgaria and all stages of the production process take place in the country.

Language Requirements

Article 15 of FIC Regulation 1169/2011 stipulates that the mandatory information 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 Government of Bulgaria (GOB) permits multi-language labeling and stickers, although one of the languages must be Bulgarian.

Specific rules on stickers to provide mandatory labeling information are not included in FIC regulation 1169/2011. The 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.” U.S. manufacturers or exporters are encouraged to contact potential importer to learn the labeling requirements applicable.

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, a 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 nutritional declaration:

- Energy value: expressed in kilojoules (kj) and kilocalories (kcal)
- In this 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 EC published a [guidance document](#) and a simplified [summary table](#) for nutrient values declared on labels. Annex V of the FIC regulation establishes a list of products exempted from the mandatory nutrition declaration requirement. FoodDrinkEurope launched a [website](#) explaining details to food business operators and consumers.

Under the May 2020 Farm to Fork Strategy, the EC proposed harmonizing mandatory front-of-pack nutrition labeling before the end of 2022. This decision is supported by [a report](#) regarding the use of additional forms of expression and presentation of the nutrition declaration.

Health /Nutritional Claims Labeling

Nutritional Claims

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

Health Claims

Rules on health claims are set out in [Nutrition & Health Claims Regulation 1924/2006](#). On May 20, 2020, the EC announced nutrient profiles to restrict promotion of food high in salt, sugars and/or fat as required by Regulation 1924/2006 would be established before the end of 2022.

[Regulation 432/2012](#) establishes the EU positive list of functional health claims and their conditions for use. Food product labels with health-related claims must also comply with the provisions of the EU's FIC regulation. [Commission Implementing Decision 2013/63](#) establishes guidelines for national authorities to determine 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](#).

Alcoholic Beverages

Alcoholic beverages containing more than 1.2 percent of alcohol by volume are exempt from mandatory nutritional declarations and ingredient lists. In March 2018, the alcoholic beverage industry presented a [joint self-regulatory proposal](#) outlining general principles of a voluntary labeling scheme. These general principles are accompanied by four sector-specific implementation plans for wine, [spirit drinks](#), [beer](#), and [cider & fruit wine](#).

On June 4, 2019, the European spirits sector signed a [Memorandum of Understanding](#) (MOU) and committed to *voluntarily* include caloric information on labels and online ingredient and nutritional information. On September 5, 2019, the European beer industry also signed an [MOU](#) and committed to *voluntarily* inform consumers on ingredient and nutrition information. Please, see details on the Brewers of Europe's [website](#). Under the MOU, Bulgarian brewers follow voluntary nutritional labeling for beer. Reportedly, the Bulgarian distilled spirits industry may join the voluntary EU-industry MOU in early 2021.

In 2019, the European Parliament added specific requirements on nutrition declaration for wine. The [proposed amendment](#) would introduce mandatory wine nutritional labeling, which may only be limited to caloric information and the list of ingredients. A final decision is expected in early 2021.

Allergen labeling is compulsory on all alcoholic beverages. The percentage of alcohol by volume must be provided 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 various products. For labeling rules on minimum durability, warnings on labels, and for minimum front sizes on labels see the [EU FAIRS 2020 report](#).

Genetically Engineered (GE) Foods: Labeling regulations for GE 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 products that are not food ingredients, such as processing aids. Meat, milk, or eggs obtained from animals fed with GE feed or treated with GE pharmaceutical products do not require GE labeling. Traceability rules require all business operators to transmit and retain information on GE products to identify the supplier and the buyer of the GE product. Each individual GE event must be approved before it can be used in food and feed. The list of approved events can be found [here](#).

The GE labeling requirements do not apply to foods containing a proportion equal to or less than 0.9 percent of individual food ingredients, provided the presence is adventitious or technically unavoidable. Above this level, all products must be labeled. EU-harmonized legislation defining “non-GE,” “GE-free” or similar labeling terms does not exist. More details can be found [here](#) and in the [EU FAIRS 2020 report](#). The Bulgarian [Food Act](#) transposed all EU requirements for GE food labeling (see [Food Act](#), Chapter III, Section IV and [GAIN](#)) and introduced stricter labeling rules regarding the font size and label size for such foods.

Bulgaria has a centralized system for testing and controlling the unauthorized presence of GE products in the feed and food. The Food Act bans GE ingredients and GE products in baby foods

regardless of their safety evaluation.

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](#) establishes regulations for its implementation. A new [EU Regulation](#) on organic production and labeling was adopted in May 2018 and it will enter into force on January 1, 2022. For more information see [GAIN report](#) “New EU Organic Regulations for Early 2018” and the [EU FAIRS 2020 report](#).
US-EU Equivalence Arrangement: The [US-EU Organic Equivalence Arrangement](#) took effect on June 1, 2012. The U.S. and EU recognize each other’s organic production rules and control systems as equivalent under their respective rules. In May 2018, the EU adopted a new Organic Regulation that will enter into force in 2021. Under this new regulation, the EU-U.S. equivalence arrangement would expire five years after the entry into force on January 1, 2026. By this date, the U.S.-EU arrangement has to be converted to an organic trade agreement. Please, see details [here](#). Since October 19, 2017, only certificates initiated through the EU’s Trade Control and Expert System (TRACES) are valid. For more information see [here](#).

Organic Wine: [Commission Implementing Regulation 203/2012](#), applicable since August 1, 2012, sets out specific rules for the production and labeling of organic wine. 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 exported to the EU. [Commission Implementing Regulation 508/2012](#) only authorizes imports of U.S. organic wines that are certified to comply with the EU’s organic wine rules.

Meat: Please, see here regarding [beef](#) labeling rules. [Commission Implementing Regulation 1337/2013](#) sets rules for labeling of fresh, chilled, and frozen meat of swine, sheep, goats, and poultry. 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.

Fish and Seafood: [Regulation 1379/2013](#) sets out labeling rules for fishery and aquaculture products listed in Annex I to the regulation. On May 20, 2020, the EC 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. 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](#). Detailed information on shipping seafood and fishery products to the EU is provided in the U.S. Department of Commerce’s [here](#).

Trans Fats and Gluten-free Labeling: In April 2019, [Regulation 2019/649](#) amending Annex III to [Regulation 1925/2006](#) on trans fats was published and entered into force in May 2019. The regulation sets a maximum limit of trans fat, other than trans fat naturally occurring in animal fat, at 2 grams per 100 grams of fat. Food which does not comply with this regulation may continue to be placed on the market until April 1, 2021. EC [Implementing Regulation 828/2014](#), applicable since July 20, 2016, sets out conditions for using “gluten-free” and “low gluten” statements on food labels.

Wine: The EU’s [Single Common Market Organization \(CMO\) Regulation 1308/2013](#) establishes framework rules for wine. [Commission Regulation 2019/33](#) and [Commission Regulation 2019/34](#) lays down detailed rules on protected designations of origin and geographical indications, traditional

terms and labeling. The new EU database for wines and spirits “[eAmbrosia](#)” lists the traditional terms that are protected in the EU. For detailed information on the EU’s wine legislation, including labeling requirements, see USEU GAIN [report](#) “EU Wine Policy” and the EC’s [website](#).

U.S.-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 seven 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 [here](#).
Distilled Spirits: [European Parliament and Council Regulation 110/2008](#) established general rules on the definition, description, and presentation of spirit drinks. Regulation 110/2008 will be repealed on May 25, 2021 and replaced by [Regulation 2019/787](#) which was adopted in May 2019. This Regulation will lay down general rules on the definition, description, presentation, and labeling of spirit drinks, as well as on the protection of geographical indicators (GI). The public database [eAmbrosia](#) lists the registered GIs for distilled spirits registered in the EU. In February 2019, a GI for “tequila” was approved 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 whiskey” and “bourbon whiskey” are protected product designations.

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.

Special Use 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. Foods that no longer fall within the scope of Regulation 609/2013 are regarded as regular foods. Given the specific nature of the products covered, regulation 609/2013 introduces additional labeling requirements and derogations from the FIC regulation. For details, please see GAIN reports [here](#) and [here](#), and the EC’s [website](#).

Functional foods for athletes do not fall within the scope of regulation 609/2013. An EC report on food and beverages labeled specifically for athletes concluded that there is no need for specific EU-harmonized provisions as existing horizontal EU food rules already provide an adequate legal framework for these products. U.S. exporters should check with their importers whether re-notification may be necessary.

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 of each Member State where the product will be marketed. More information can be found [here](#) and in [EU FAIRS 2020 report](#). Chapter III, Section II of the Bulgarian [Food Act](#) transposes current EU norms regarding dietetic foods, food for special medical purposes, and infant and baby foods.

For information on frozen foodstuffs, fruit juice, and honey, see [EU FAIRS 2020 report](#).

Section III. Packaging and Container Regulations

Size and Content

The Bulgarian Food Act 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

See [here](#) and [EU FAIRS 2020 report](#) for specific information.

Materials in Contact with Foodstuffs

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](#). Chapter II, Section II of the Bulgarian [Food Act](#) transposes current EU legislation about packaging, and materials in contact with foodstuffs.

[Directive \(EU\) 2019/904](#) to reduce the environmental impact of certain plastic products was published on June 5, 2019. Bulgaria has until July 3, 2021 to transpose this directive into national laws, regulations, and administrative provisions to comply with it. See [here](#) for more information.

Section IV. Food Additives Regulations

Bulgaria applies EU-harmonized legislation regarding food additives, please see [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](#).

Additives

Authorized food additives and their conditions of use are listed in Annex II to the [Food Additives Regulation 1333/2008](#). Only additives listed on the EU's positive list are authorized under specific conditions. Inclusion in the EU positive list is based on a risk assessment by EFSA.

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 established 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. 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 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. For more information see FoodDrink Europe's [Guidelines on Flavorings](#) (2019).

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. The EU list of authorized smoke flavorings for use in and/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 EC's [website](#).

Chapter III, Section III of the [Food Act](#) about food additives, enzymes, flavorings and foods for sports people introduced EU legislation into the national law.

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. 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](#). Once Bulgaria approves a PPP, it can become mutually recognized and authorized within the EU.

Endocrine Disruptors

Endocrine disruptors refer to substances with the potential to alter and cause unintentional adverse health effects to human and animal endocrine systems. The EC published [Regulation 2018/605](#), identifying endocrine disrupting properties under [Regulation 1107/2009](#) on plant protection products. 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. A general default MRL of 0.01 mg/kg applies where a pesticide is not specifically mentioned. See and the [list](#) of authorized active substances or pesticide-MRL combinations [online database](#). Official controls on pesticides can be found [here](#).

The Bulgarian National Pesticides Plan can be found [here](#). In February 2019, Bulgaria approved [amended legislation](#) (Decree 310, Official Gazette#12 of 2019) regarding MRLs in feed (lead, mercury, melamine, and decoquinate MRL) transposing [Directive 2002/32/EC](#) and [Regulation EC 2017/2229](#).

Import Tolerance

If there is no EU legislation in place in the importing Member State, then the exporter can seek to obtain an "import tolerance" for active substances that have not been evaluated or used in Europe before. Applications for import tolerances must be submitted to the "Rapporteur Member State". Information on import tolerances is available in "[Pesticide Use and Food Safety](#)" [guide](#) published by the European Crop Protection Association (ECPA). All MRLs, including import tolerances, apply EU wide since September 2008. The application form for an import tolerance can be found [here](#). On Official Controls of MRLs, please, see [here](#) and [EU FAIRS 2020 report](#).

Contaminants

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

Official Controls

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

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](#)

Aflatoxin in Tree Nuts

Following the publication of [Commission Implementing Regulation \(EU\) 2017/1269](#) on July 14, 2017, the EU no longer recognized the U.S. peanut pre-export program. While there are no restrictions on U.S. peanut exports per se, shipments no longer benefit from the reduced testing level for aflatoxin upon entry. On April 1, 2015, U.S. the list of products/origins subject to increased import controls under [Commission Regulation \(EC\) No 669/2009](#) included U.S. pistachios. The list was updated in 2017 and Bulgaria now tests 10 percent of all incoming shipments.

Residues in Animals and Animal Product

Residue monitoring for animals and animal products is addressed in [Council Directive 96/23/EC](#). This directive includes 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 promoters. 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 [here](#).

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” remain subject to burdensome certification requirements introduced in 2012. Composite products are defined by [Decision 2007/275/EC](#) 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. Composite products which contain over 50 percent of animal-origin ingredients also currently 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 must originate from a third country with an approved residue control plan for that component.

The current certification requirements for composite products will continue to apply until April 21, 2021. Following changes in several related pieces of EU legislation, after that date, entry requirements will no longer be based on the percentage of animal-origin ingredients, but rather on the animal health or public health risk linked to the composite product itself.

Until April 21, 2021, all composite products containing processed meat are subject to veterinary inspection. The new system that is scheduled to go 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. Entry requirements will be different for each of these three categories but have not been published yet. All processed products of animal origin must be sourced from EU-approved establishments. The EU will continue to require composite product certificates for all non-shelf stable products and for shelf stable composite products with a meat ingredient. A company’s private attestation will be required for shelf stable products not containing meat.

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. The main elements of this regulation became effective on Dec 14, 2019. 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 list of products subject to official controls at border posts was updated with effect from Dec 14, 2019 in [Commission Implementing Regulation \(EU\) 2019/2007](#).

The BFSa is responsible for national-level inspections and enforcement of food and feed

regulations. Products can be checked upon entry or at all further stages of marketing. There are no known pre-shipment testing requirements to be met or inspections to be conducted prior to shipment. Violations of EU food and feed legislation are reported through the [RASFF portal](#). Products of animal origin must be presented at EU 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](#). For facility and product registrations, see the [EU FAIRS 2020 report](#).

Section VII. Other Specific Standards

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

Novel Foods

A new [EU framework regulation 2015/2283 on Novel Foods](#) became applicable on January 1, 2018 (see [here](#)). The Novel Food regulation does not apply to GE, additives, enzymes, flavorings, and extraction solvents. Novel foods require a pre-market authorization. Applications for authorization must be submitted to the EC via an [e-submission system](#). An overview of the different steps of the authorization procedure is available [here](#). [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. The latest consolidated version of the text is available [here](#).

Chapter III, Section VII of the Bulgarian [Food Act](#) introduces the procedure for approval and release on the market of new ingredients and substances as novel foods. The Minister of Health is the competent authority in charge of novel foods. An Implementing regulation on the novel foods is expected in early 2021.

For regulatory questions vis-à-vis food products from [cloned animals](#), engineered nanomaterials, [nanotechnology](#), and [fortified foods](#), please, consult with [USDA EU's website](#).

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. [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.

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, please, see [here](#) and GAIN [report](#). Marketing food supplements in the EU is a complex issue, see details [here](#). The Bulgarian [Food Act](#) (Chapter III, Section III) transposes EU legislation and contains special

provisions regarding food supplements marketing. This includes a new set of requirements for e-commerce, sales of food supplements which have not been regulated to date. The BFSA requires registration and approval of each food supplement before its release to the market. A detailed implementing regulation about food supplements is expected in early 2021.

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.

Chapter III, Section V of the Bulgarian [Food Act](#) regulates irradiated foodstuffs and transposes the EU legislation. To date, Bulgaria has no authorizations of food and food ingredients which may be treated with ionizing radiation (see [link](#)).

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 USEU GAIN [report](#) “Exporting Pet Food to the European Union” and [EU FAIRS 2020 report](#) for more information.

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](#).

Section VIII. Trademarks, Brand Names, and Intellectual Property Rights

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 trademark can be registered also at the EU-level as a “Community Trademark” at the [Office for Harmonization in the Internal Market](#). A Community Trademark gives the owner protection in all Member States with one single registration. Additional information on EU trade mark criteria can be found on the EC's [website](#) and in [EU FAIRS 2020 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. 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 Database of Origin and Registration \(DOOR\)](#). 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). The country submitted four more applications for TSG status, all for meat products.

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.

Optional Quality Terms

Regulation 1151/2012 sets out criteria for the use of optional quality terms. The EC is empowered to reserve new terms or amend the conditions of use of existing terms. In 2019, the EC launched [an evaluation](#) of GIs and protected Traditional Specialties Guaranteed (TSG) programs. The purpose of this evaluation is to provide an in-depth assessment of the overall functioning of the GIs and TSGs quality schemes of the EU with a focus on GIs registered at EU level (from EU and third countries) and placed on the EU internal market. This evaluation should be completed by 2021.

Section IX. Import Procedures

Union Customs Code (UCC)

The EU is a customs union and all Member States uniformly apply import duties on goods from outside the EU based on the 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. 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.

[Regulation 2019/515](#) on the mutual recognition of goods lawfully marketed in another EU country applied on April 19, 2020. It introduced 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 new rules can be found on the EC's [website](#).

Import Duties

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

The [EU's 2020 Tariff Schedule](#) was published on October 31, 2019 in the Official Journal.

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."](#)
- Inspection fees – not harmonized
- Value Added Tax (VAT) – not harmonized. Bulgaria's standard VAT rate is 20 percent. The reduced rate applicable to hotel and tourist services is set at 10 percent. Since July 1, 2020, Bulgaria temporarily reduced its VAT to nine percent until the end of 2021 for some products and services to assist sectors hit hard by the COVID-19 outbreak, including restaurant service and food delivered by restaurants, books, baby food, and diapers.

Import Documentation and Process

Agricultural products are examined when they enter Bulgaria by the Bulgarian BIP. The TRACES NT system was applied in December 2019 with the new EU import rule and official control regulations. All BIPs can execute both veterinary and phytosanitary control and inspect all products for human consumption. The EC's [Trade Helpdesk](#) offers a complete overview of documents needed for customs clearance.

In Bulgaria, there is no official requirement for import documentation to be translated in Bulgarian. The most commonly used language by border inspectors is English. Translation in Bulgarian, though, can speed up the safety and customs clearing process. Product samples for trade shows and/or not for commercial distribution are subject to the same import regulations as all other food products.

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.

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.

Section X. Trade Facilitation

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](#) system was introduced to ensure legal certainty for business operators when calculating import duties. For more information on the Pre-Clearance Program, see the [EU FAIRS 2020 report](#).

Electronic Certificates

The Official Controls Regulation ([Regulation \(EU\) 2017/625](#)) provides the legal basis for the acceptance of electronic certificates using the EU's Integrated Management System for Official Controls (IMSOC). For plant products, Bulgaria is able to receive U.S. electronic phytosanitary certificates sent via the Hub created by the International Plant Protection Convention (IPPC). For other commodities, currently no connection exists between IMSOC and the respective U.S. systems the U.S. Government Agencies uses to issue electronic certificates. In absence of such a connection, paper certificates will satisfy the EU requirement for an original certificate with an ink signature.

Import Control Fees

The Official Controls Regulation 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 byproducts, 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](#). Specific fee information can be found [here](#).

Average Release Time for Products – Common Delays

Bulgaria ports are organized efficiently to perform customs formalities as well as the necessary animal and plant health inspections. Incomplete or incorrect certification generally leads to delays.

Duplicative Inspections

Inspections on imported foods are concentrated at the EU external borders. Once goods have passed inspection and customs duties are paid, they can move freely throughout the EU. However, official controls remain at any stage of distribution in the EU. Due to its geographic location, Bulgaria is an external EU border with eight BIPs at the border with Turkey, Serbia, and North Macedonia. Bulgaria is often used as a door for commercial overland traffic from the Turkey and the Middle East, and for international ocean freight from the Black Sea ports of Varna and Bourgas.

Appendix I. Government Regulatory Key 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

E-mail: bfsa@bfsa.gov

Fax: (+359) 2-954-9593

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

Customs Agency, Ministry of Finance

Str. Rakovski 47, Sofia 1202

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

E-mail: pr@customs.bg

Fax: (+359) 2-9859-4528

Website: <http://customs.bg>

National Drug Agency

8 Damyan Gruev Str., Sofia 1303

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

E-mail: bda@bda.bg;

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

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

E-mail: ncpha@ncpha.government.bg

Fax: (+359) 2-9541-211

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

Bulgarian Institute for Standardization

1797 Sofia, Lachezar Stanchev" Str. Nr 13

"Izgrev" Complex

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

Website: <https://bds-bg.org/bg/>

Fax: (+359) 2-8174-535

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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: <https://www.bia-bg.com/> **Error! Hyperlink reference not valid.**

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 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.moderntrade.bg/>

Appendix II. Other Import Specialist Contacts:

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

Attachments:

No Attachments