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Report Highlights:

Bulgaria acceded to the European Union (EU) in 2007 and follows EU directives and regulations pertaining to food safety, quality and standards. This report outlines 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 (USEU) Office of Agricultural Affairs'(OAA) 2024 EU FAIRS report. Additional updates and other relevant information can be found on the FAS Europe website.

DISCLAIMER: This report was prepared by the Office of Agricultural Affairs at the U.S. Embassy in Sofia, Bulgaria for U.S. exporters of domestic 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. 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.

Note 1: English translations of hyperlinks with an asterisk may be requested from FAS/Sofia. Note 2: The page of the Bulgarian Food Safety Agency has been upgraded but not yet completed with all necessary content.

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Executive Summary

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

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.

Following the political stalemate over the last three years, Bulgaria had its most recent (the seventh election since April 2021) nationwide Parliamentary elections in October 2024. However, no permanent government is expected to be established soon. Since August, an interim Cabinet appointed by the President has been governing the country. These caretaker Cabinets that have dominated the political stage in the last three years have limited responsibilities on policy issues, especially on longer term decisions, and are usually short-lived for three to four months. The most recent two Parliaments (in 2023 and so far in 2024) also had short mandates of under a year and had a busy agenda aiming to address a number of legislative issues related to higher political priorities such as security, energy, and economic stability. Legislation related to agricultural and food issues remained a lower priority. The current Parliament is in the process of structuring and is expected to start its effective work later this year.

Section I. Food Laws

The EU's approach to food safety includes all sectors of the food and feed chain. General Food Law Regulation 178/2002 establishes the basic regulatory framework, including the precautionary principle, and sets out requirements and procedures related to food safety and crisis management. The regulation on harmonized food control, Regulation 2017/625 became applicable in 2019. In June 2019, Regulation 2019/1381 on transparency and sustainability of the EU risk assessment in the food chain, amending the General Food Law, was published in the EU's Official Journal. This regulation covers food additives, smoke flavoring, food contact materials, food enzymes, flavorings, and novel foods.

The regulations on general food law, food and feed control, and food and feed hygiene make up the body of the EU's food safety laws. Revisions of existing EU food regulations or new regulations apply the principles contained in these framework regulations (see more details on <u>U.S. Mission to the EU</u> website and the 2024 EU FAIRS report).

Bulgarian Food Law

In June 2020 Bulgaria passed the <u>Food Act</u>* (in Bulgarian, please, see Note 1), a major regulatory update regarding the food industry and trade. The Act's main objective was to more closely harmonize

with EU legislation, as well as to achieve better food traceability and consumer protection. The Act introduced regulations for online trade that were previously unregulated. It also levied new taxes on business operators, including vehicle registrations for transporting certain food categories, and 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 implementing regulations under the Food Act were approved in 2022 but new amendments are currently being developed. The Ministry of Agriculture (MinAg) and the Bulgarian Food Safety Agency (in Bulgarian) publish all relevant regulations under the Food Act on their websites, respectively on the MinAg's national legislation platform* (in Bulgarian) and BFSA's national regulations' page* (in Bulgarian).

The latest <u>amendment</u>*(in Bulgarian) to the Food Act was done in September 2023 and addressed the use of nitrous oxide in foods, food establishments and food service outlets. The reason driving this amendment was misuse of this chemical by youngsters for different purposes. The amendment imposed heavy fines for the violation of the proper use of nitrous oxide.

Other major legislation applicable to imported food products can be found in the <u>Veterinary Medical Act*</u> (in Bulgarian), including the latest amendments adopted on December 23, 2022. Imports of raw materials and foods of animal origin are regulated by this legislation. Another relevant law last amended in 2020 is the <u>Animal Husbandry Law</u>* (June 20, 2020) (in Bulgarian) covering new policies in the area of genetic resources. Similar legislation was updated for the beekeeping industry (<u>Beekeeping Law*</u>, last amendment December 8, 2023) (in Bulgarian). Additional legislation which may have direct or indirect effect on food imports includes the <u>Plant Protection Law*</u> (last revised March 12, 2024) (in Bulgarian) and the <u>Feed Law</u>* (last revised March 12, 2024) (in Bulgarian). In November 2021, the Ministry of Health updated the regulation about laboratory control and analysis of foods (<u>Naredba #12</u>* of November 10, 2021) (in Bulgarian) . The following sources have a complete list of applicable EU and national Bulgarian legislation: MinAg's <u>EU legislation</u>* (in Bulgarian) , and MinAg's Bulgarian legislation* (in Bulgarian).

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 2019 the EU adopted <u>Directive (EU) 2019/2161</u> amending the rules on better enforcement of EU consumer protection rules. The new Directive included 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 drafted the respective <u>bill</u> (in Bulgarian) as an amendment to the <u>Consumer Protection Law</u>* (in Bulgarian) to transpose the EU directive. The law was amended in March 2022 (<u>Official Gazette #20</u>*, March 9, 2022) (in Bulgarian).

Relevant Competent Authorities

The Ministry of Agriculture controls imports of food products for human consumption, animal feed/ingredients, and live animals not intended for direct human consumption through the Bulgarian Food Safety Administration (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, with the exception of bottled water (mineral, spring, and table water). The

competent authority for bottled water is the <u>Ministry of Health</u>. The <u>BFSA website</u> lists all relevant regulations, documents, certificates, tariffs, registers, and any other information, including links to the EU regulations.

Since 2016 the <u>Risk Assessment Center</u> 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

In 2014 the European Commission (EC)'s general rules on labeling, displaying, and advertising of food products became applicable by Food Information to Consumers (FIC) Regulation (EC) 1169/2011. The mandatory nutrition declaration requirement introduced by the FIC regulation became applicable in 2016. Details can be found at the FAS/USDA/U.S. Mission to the EU's website and in 2024 EU FAIRS report. The standard U.S. label fails to comply with EU labeling requirements, and U.S. exporters are strongly advised to consult with their importers regarding information on additional Bulgarian requirements.

In March 2021 Bulgarian authorities approved an implementing <u>regulation</u> (in Bulgarian) related to labeling under the Food Act which fully harmonized Bulgarian regulations with the EU (Official Gazette #25 of March 26, 2021). 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.

In 2020 the EC published a roadmap outlining its intention to advance a legislative proposal to revise Regulation (EU) 1169/2011. This revision will include harmonized mandatory front-of-pack nutrition labelling, setting of 'nutrient profiles' restricting the promotion (via nutrition and health claims) of foods that are high in fats, sugars and/or salt, extension of mandatory origin or provenance indications to certain products, and a revision of the EU rules on date marking ('use by' and 'best before'). A legislative proposal has been delayed and it is unclear if the new Commission will propose it for the period 2024-2029. Please, see details about the EU roadmap at FAS/USDA/U.S. Mission to the EU website and GAIN Report Commission Publishes Roadmap on the Upcoming Revision of Food Labeling Requirements.

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 strength by volume for beverages containing more than 1.2% by volume of alcohol
- 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. If that operator is not established in the EU, the name and address of the importer
- Batch information
- Country of origin or place of provenance in accordance with the provisions of Article 26

Warning On Labels

Annex III to FIC Regulation 1169/2011 establishes a list of products that require a special warning on the label. For foods containing added sugar and sweeteners the applicable regulations is <u>Food Additives</u> <u>Regulation 1333/2008</u>, the same regulation applies also for foods containing more than 10 percent added polyols; for food containing aspartame; as well as for confectionery and beverages containing licorice (glycyrrhizinic acid or its ammonium salt), beverages containing more than 150mg/l of caffeine and foods with added caffeine; and foods or food ingredients with added phytosterols, phytosterol esters, phytostanols or phytostanol esters.

Annex V of the regulation requires foodstuffs containing the food colors sunset yellow (E110), quinoline yellow (E104), carmoisine (E122), allura red (E129), tartrazine (E102), and ponceau 4R (E124) to be labeled "may have an adverse effect on activity and attention in children." This does not concern beverages containing more than 1,2 % by volume of alcohol.

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

Ingredients List

For information on ingredient lists, minimum durability and quantitative ingredients declaration (QUID), see the <u>2024 EU FAIRS</u> report. The EC has published <u>guidelines</u> on the QUID requirement which explains when QIUD is mandatory and which products are exempt from QUID. If the ingredient is emphasized on the label, the quantity in percentage must be indicated to the list of ingredients. Annex VII to FIC regulation 1169/2011 sets out specific provisions concerning the indication of ingredients and categories of ingredients in the list of ingredients. This Annex requires the mandatory indication of the source of vegetable oils and fats.

Please note that dates must be given in the following order: day/month/year (if required). In the last three years, several U.S. shipments to Bulgaria were rejected entry due to non-compliant date order.

Additives and Flavorings

For information on additives and flavorings please refer to FoodDrinkEurope (EU Food and Drink Industry Confederation): <u>Guidelines on Flavourings</u> (2019) and the <u>2024 EU FAIRS</u> report.

Allergen Labeling

Allergens must be highlighted in the list of ingredients. Please refer to the <u>2024 EU FAIRS</u> report, as well as the EC's <u>Notice relating to the provision of information on substances or products causing allergies or intolerances</u>, FoodDrink Europe: <u>Guidelines on precautionary allergen labelling</u>, and <u>Allergen Labeling – Food Safety Authority Ireland</u>.

Origin Labeling (Country of Origin Labeling/COOL)

Origin labeling is mandatory for honey, fruit and vegetables, olive oil, fishery and aquaculture products, beef as well as fresh, chilled, and frozen pork, sheep and goat meat, and poultry.

In November 2023, the EC adopted <u>Delegated Regulation (EU) 2023/2429</u> which imposes mandatory origin labeling rules for nuts and dried fruits and ripened bananas. The country, or countries of origin in the case of blends or mixes, will have to appear on the label. Bulgaria is a significant importer of U.S. nuts and U.S. exporters are advised to consult with FAS/Sofia on this issue once the regulation is adopted in the EU. Additionally, under Article 26 of the FIC Regulation, mandatory origin labeling applies when failure to indicate the country of origin or place of provenance might mislead the consumer.

In May 2024, the EU adopted <u>Directive (EU) 2024/1438</u> which changes origin labeling for honey. Now, if the honey originates in more than one country, the countries of origin where the honey was harvested shall be indicated on the label in the principal field of vision, in descending order of their share in weight, together with the percentage that each of those countries of origin represents.

Please refer to the <u>2024 EU FAIRS</u> report, FoodDrink Europe's (EU Food and Drink Industry Confederation) <u>Guidance on Commission Implementing Regulation (EU) 2018/775</u> (May 2020) and GAIN report <u>Commission Briefing on New Origin Labeling Rules.</u>

In 2019, the MinAg issued a <u>regulation</u> (Ordinance 4, May 2019) (in Bulgarian) defining the term of use and control on manufacturers of so called "mountain products" which corresponded and transposed to the EU quality schemes regulation (EC) <u>1151/2012</u> (Article 31). In October 2023, the MinAg published a <u>registry</u> (in Bulgarian) of manufacturers of "mountain products" that bear such labelling. As of November 2024, the register contains 26 products, mainly dairy products, honey and horticulture products.

The Bulgarian Food Act introduced two new labels for local foods. The first is "Produced in Bulgaria," and it means farm products produced in the country, namely crops, livestock products, and wild-caught fish and game. The second term is "Product from Bulgaria," relating 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. U.S.

manufacturers or exporters are encouraged to contact their importer to learn the applicable labeling requirements.

Nutritional Declaration

Under FIC Regulation 1169/2011, the nutrition declaration became mandatory on December 13, 2016. Annex V to the FIC Regulation lists foodstuffs that are exempted from the mandatory nutrition declaration requirement.

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

For additional information on EU nutritional declaration regulations see EC's <u>guidance document</u> and a simplified <u>summary table</u> for tolerances of nutrient values declared on a label with EU legislation. FoodDrinkEurope launched a website explaining "reference intakes" to food business operators and consumers: http://referenceintakes.eu/reference-templates.html. For more information, please see the 2024 EU FAIRS report.

As part of the Farm to Fork Strategy, the EC announced that it would propose harmonized mandatory front-of-pack nutrition labeling as part of the revision of the FIC Regulation. The publication of the proposal has been delayed.

Between 2020 and 2024 Mondelez International, Nestlé, PepsiCo, Coca-Cola, and Unilever in Bulgaria began voluntary labeling of their products using the Evolved Nutrition Label (NutriInform) to test consumer perception. In 2023 and in 2024 FoodDrinks Bulgaria organized several discussions with industry and regulators on available front-of-pack nutritional declaration options. Most food industry groups had a neutral opinion about the EU schemes and stated that such labeling should be voluntary and not mandatory. The conclusion was that "there are no unhealthy foods, there are unhealthy diets." Bulgaria does not officially support any of the currently used schemes in the EU. At the same time, the industry has a strong position in support of <u>digital labeling</u>.

Health / Nutritional Claims Labeling

Nutritional Claims

The Annex to <u>Nutrition & Health Claims Regulation 1924/2006</u> lists the authorized EU nutrition claims and conditions of use. Nutritional claims that are not included in the annex are not allowed.

Health Claims

EU rules on the use of health claims are set out in Nutrition & Health Claims Regulation 1924/2006, and Regulation 432/2012. The EU's online "Register of Nutrition and Health Claims" lists the authorized health claims as well as the rejected claims and the reasons for their non-authorization. All claims that are not authorized and not on hold or under consideration are prohibited. Food products carrying claims must also comply with the provisions of the EU's "Food Information to Consumers (FIC)" Regulation 1169/2011. 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 had to be removed from the EU market by January 19, 2022. Bulgaria follows these regulations.

On May 20, 2020, the EC announced that it would set nutrient profiles to restrict promotion of food high in salt, sugars and/or fat as required by Regulation 1924/2006. The publication of the proposal has been delayed and is not yet scheduled. Currently, the Bulgarian food industry is focused on lowering salt/sodium content in food as a higher priority compared to nutritional labeling. For more information see the 2024 EU FAIRS report.

Alcoholic Beverages

Alcoholic beverages must comply with the EU's allergen labeling rules set out in FIC Regulation 1169/2011. Allergen labeling is compulsory on all alcoholic beverages. Mandatory nominal quantities for wines and spirits are set out in the Annex to <u>Directive 2007/45/EC</u>. Alcoholic beverages containing more than 1.2% of alcohol by volume are exempted from the obligation to bear a nutrition declaration and a list of ingredients. On December 8, 2023, the labeling of a nutrition declaration and a list of ingredients became mandatory for wines.

In June 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. The Bulgarian distilled spirits industry joined the voluntary EU-industry MOU in 2022.

On September 5, 2019, the European beer industry also signed an MOU and committed to *voluntarily* inform consumers on ingredient and nutrition information. Under the MOU, Bulgarian brewers follow voluntary nutritional labeling for beer. For more information on alcoholic beverages please see the 2024 EU FAIRS report.

Wine

Commission Regulation 1308/2013 establishes framework rules for wine. Commission Regulation 2019/33 and Commission Regulation 2019/34 outline detailed rules on protected designations of origin and geographical indications, traditional terms, and labeling. Chapters III of Regulation 2019/33 and 2019/34 set out rules on the use of traditional terms. The new EU database for wines and spirits "eAmbrosia" lists the traditional terms that are protected in the EU.

Mandatory nominal quantities for wines and spirits are set out in the Annex to <u>Directive 2007/45/EC.</u> In 2021, the EU adopted <u>Regulation 2021/2117</u> which introduces a compulsory nutrition declaration and a compulsory list of ingredients for wines, aromatized wines, and dealcoholized and partially dealcoholized wines. These rules on the mandatory nutrition declaration and list of ingredients entered into force on December 8, 2023. In November 2023, the EC published a "<u>Questions and Answers</u>" <u>notice</u> on the implementation of new EU wine labeling provisions. For more information, please see GAIN Report: <u>European Commission Publishes New EU Labeling Rules for Wines – January 2022 and the 2024 EU FAIRS</u> report, as well as and the EC's <u>website</u>.

U.S.-EU Wine Agreement

For information on the U.S.-EU Wine Agreement see the <u>2024 EU FAIRS</u> report.

Spirit Drinks

Regulation 2019/787 entered into force in May 2021. This Regulation outlines general rules on the definition, description, presentation, and labeling of spirits, as well as on the protection of geographical indications of spirits. In February 2022, the EC published <u>Guidelines for the implementation of certain labelling provisions of Regulation (EU) 2019/787</u>. The public database <u>eAmbrosia</u> lists the geographical indications of spirit drinks registered in the European Union. In February 2019, "Tequila" was approved as a geographical indication in the EU (<u>Implementing Regulation 2019/335</u>). This regulation was later replaced and consolidated, and the current version can be found here (<u>Regulation (EU) 2019/787 of April 17, 2019, consolidated version</u>). For information on EU spirit drinks regulations see the <u>2024 EU FAIRS</u> report.

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

Other Specific Labeling Requirements

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, quantitative ingredients declaration, minimum font sizes on labels, gluten-free food, trans-fats, and samples, see the 2024 EU FAIRS report.

Genetically Engineered (GE) Foods

The Bulgarian Food Act (Chapter III, Section IV) transposed all EU requirements for GE food labeling (see 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.

In July 2023, the EC published <u>a proposal</u> for a new Regulation for plants obtained by certain New Genomic Techniques (NGTs). The EC proposes two categories of NGT plants: Category 1 – NGT plants that could also occur naturally or be produced by conventional breeding techniques and Category 2 - NGTs plants that could not occur naturally or be produced by conventional breeding techniques. Category 1 plants and products would be labelled in the same way as conventional plants and products. Food containing products belonging to Category 2 would follow the same requirements as food containing GMOs. The proposal is currently going through the EU legislative process and may still change. Under current regulation, all products obtained via genome editing must adhere to GMO legislation.

Additional information on GE foods can be found at U.S. Mission to the EU's <u>website</u> and in the <u>2024</u> <u>EU FAIRS</u> report.

Organic Foods

The <u>EU Regulation (Regulation (EU) 2018/848</u> on organic production and labeling was adopted in 2018 and entered into force on January 1, 2022. The entry into force of the Regulation, initially scheduled for 2021, was postponed due to the COVID-19 crisis and to give economic operators more time to prepare for the new rules. For more information see the <u>2024 EU FAIRS</u> report, as well as EC <u>website</u>.

Organic Wine

Regulation 2018/848 lays down the rules for the production and labeling of organic wine. Only wines produced in accordance with this regulation qualify as "organic wine" and can carry the EU organic logo. Labeling wine as "made from organic grapes" is no longer allowed in the EU, which means that U.S. wines labeled as such cannot be imported into the EU. For information on the EU's organic wine legislation, including labeling requirements, see EC's website at http://ec.europa.eu/agriculture/organic/index en and the 2024 EU FAIRS report.

Meat

Regulation 1760/2000 sets out rules for compulsory and voluntary beef labeling. Detailed rules for the implementation of Regulation 1760/2000 are set out in Regulation 1825/2000. Commission Implementing Regulation 1337/2013 sets out new rules for the indication of the country or place of provenance for fresh, chilled, and frozen meat of swine, sheep, goats and poultry. As of September 2024, the Commission has not advanced a legislative proposal requiring animal welfare labeling. For information on the EU's meat legislation (beef, veal, pork, sheep, coats and poultry, and minced meat), including labeling requirements, see the 2024 EU FAIRS report.

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 would propose a revision of the EU marketing standards for agricultural, fishery, and aquaculture products. Detailed information on shipping seafood and fishery products to the EU is provided by the U.S. Department of Commerce certification page, and information on EU regulations can be found in the 2024 EU FAIRS report.

Trans Fats and Gluten-free Labeling

In April 2019 <u>Regulation 2019/649</u> amending Annex III to <u>Regulation 1925/2006</u> on trans fats was published and entered into force in May 2019. The regulation sets a maximum limit of 2 grams per 100 grams of fat in food intended for consumers. Commission <u>Implementing Regulation 828/2014</u>, applicable since July 20, 2016, sets out conditions for using "gluten-free" and "very low gluten" statements on food labels.

Special Use Foods

The EU's "foods for specific groups" rules are set out in <u>Regulation (EU) 609/2013</u>. Food for sportspeople does not fall within the scope of Regulation 609/2013. An EC's report on food and beverages labeled specifically for sportspeople concluded there is no need for specific EU-harmonized provisions as existing horizontal EU food rules already provide an adequate legal framework for these products. For more information see GAIN report "New EU Rules for Sports Food."

Artificial sweeteners are not allowed in dietetic bakery products. For detailed information see <u>GAIN</u> report "EU bans use of artificial sweeteners in dietetic bakery products."

For information on special use foods, including fish, frozen foodstuffs, fruit juice, honey, jams, preserved milk and olive oil see the 2024 EU FAIRS report.

Honey

<u>Directive 2014/63/EU</u> defines pollen as a natural constituent of honey that should not be considered an ingredient of honey. This means that GM pollen present as a quantity of more than 0.9% of the honey (not the pollen) would need to be labeled as such. Since pollen only forms around 0.5% of any batch of honey, it is unlikely to exceed the GM labeling threshold. <u>Directive 2024/1438</u> introduces changes to origin labeling for honey: if the honey originates in more than one country, the countries of origin where the honey has been harvested shall be indicated on the label in the principal field of vision, in descending order of their share in weight, together with the percentage that each of those countries of origin represents. The Directive also specifies that in the case of baker's honey, the words "intended for cooking only" shall appear on the label in close proximity to the product name.

In January 2023, Bulgaria adopted a <u>regulation*</u> (Decree #3 of January 6, 2023) (in Bulgarian) about honey for human consumption which harmonized local legislation with <u>Directive 2001/110/EU</u> and <u>Directive 2014/63/EU</u>. The regulation also introduced country-of-origin labeling.

Plant-based Meat and Dairy Alternatives

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

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

Bulgarian consumers are sensitive regarding correct labeling information on dairy products, while the dairy industry is split on this issue. Several manufacturers produce less expensive dairy products, mainly cheese, which contain more plant oils/proteins and less milk and have a good market niche. Due to pressure from industry and consumer protection advocates to regulate the market by clear differentiation of the two types of products, Bulgaria approved a regulation* (Ordinance for specific requirements to dairy products) (in Bulgarian) related to dairy products in August 2021 and updated it with a new regulation* (in Bulgarian) in May 2023. Such dairy products, including cheese, butter, and milk, cannot be labeled, advertised, or presented in any way with dairy names. These products should be sold in retail only packaging, on separate displays or shelves, and under a general category called "imitating products." Imitating products exclude plant-based dairy alternatives that contain up to 10 percent milk.

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) which establishes nominal quantities for prepacked products. Directive 2007/45/EC abolished mandatory pack sizes at both EU and national levels. Mandatory quantities for wines and spirits are included in the Annex to Directive 2007/45/EC. See EC's packaging waste page and 2024 EU FAIRS report for specific information.

Packaging Sustainability Measures

<u>Council Directive 94/62/EC</u> provides for measures aimed at limiting the production of packaging waste and promoting recycling, re-use, and other forms of waste recovery.

In 2024, the EU adopted a new Regulation on Packaging and Packaging Waste. The <u>current text</u> is going through a legal review but is expected to be published in the Official Journal in the second half of 2024. The Regulation introduces waste reduction targets and requires that all packaging placed on the EU market is recyclable and carries recycling labeling. The Regulation also bans single-use plastic grouped packaging, single use plastic packaging for unprocessed fresh fruit and vegetables, and single use plastic packaging for condiments, preserves, sauces, coffee creamer, sugar, and seasoning in the hotel and restaurant sector. For more information, please see GAIN Report: <u>European Union: European Union Finalizes New Rules for Packaging and Packaging Waste Reduction</u>. The Regulation will enter into force in 2026.

Since 2021, <u>Directive (EU) 2019/904</u> bans a list of products that include cutlery, plates, straws, beverage stirrers, food containers made of polystyrene and products made from oxo-degradable plastic. Harmonized marking specifications on single-use plastic product labels are laid down in <u>EU Regulation 2020/2151</u>. For more information, please see GAIN Report <u>European Union Single Use Plastics</u> <u>Directive Enters into Force</u>.

In November 2022 a <u>Communication</u> on an EU policy framework on biobased, biodegradable, and compostable plastics, which, while nonbinding, will guide future EU work on this issue. See EC's packaging waste <u>page</u> and the <u>2024 EU FAIRS</u> report for specific information.

Bulgaria transposed above the EU directive and the respective <u>regulation</u>* (in Bulgarian) was approved in November 2021. Business operators have a detailed time schedule for meeting the mandates of the regulation in stages starting from 2022 until 2030. A specially developed <u>guidance</u> (in Bulgarian) assist business in implementation of the regulation.

In 2023 and 2024, the Bulgarian food and retail industries made a significant progress in developing a deposit system, mainly for beer and soft drink packaging. In February 2024, the Ministry of Environment, as the institution in charge, had a public consultation seeking a solid analysis, impact assessment and a faster introduction of the deposit system for drinks' plastic, metal and glass packages from 0.1 to 3.0 liters. These efforts have enjoyed strong public support. Several retailers introduced pilot projects (Lidl and Kaufland) for PET (plastic) bottles and beer cans. The retail industry, the food/drinks industry, and environmental NGOs are still developing a nationwide system, as the efforts are

coordinated by the Ministry of Environment of Waters and the Ministry of Economy. The introduction of the deposit system has been slow due to political uncertainty, and it is currently expected that it will be fully introduced by 2026. The goal is 77 percent of recycling of PET bottles by 2025 compared to current only 22 percent.

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 at EC <u>food safety page</u>. Chapter II, Section II of the Bulgarian <u>Food Act</u> (in Bulgarian) transposes current EU legislation about packaging and materials in contact with foodstuffs.

European Parliament and Council Regulation 1935/2004 specifies the main requirements for all materials that come into contact with foodstuffs. It also sets out labeling and traceability requirements and the procedure for the authorization of substances through the European Food Safety Authority (EFSA). Annex I to Regulation 1935/2004 lists the group of materials which may be covered by specific measures. More information can be found on EFSA's website. For additional information on materials in contact with foodstuffs see the 2024 EU FAIRS report.

Section IV. Food Additive Regulations

Bulgaria applies EU-harmonized legislation regarding food additives (see <u>USEU website section on additives</u>). The EU's "Package on Food Improvement Agents" includes four regulations: <u>Regulation 1331/2008</u> establishing a common authorization procedure for food additives, food enzymes, and food flavorings, <u>Regulation 1332/2008 on food enzymes</u>, <u>Regulation 1333/2008 on food additives</u> and <u>Regulation 1334/2008 on flavorings</u>. Please refer to the 2024 EU FAIRS report for more details.

Additives (Including Colors and Sweeteners)

Annex II to Regulation 1333/2008 on food additives lists all additives approved for use in foods and their conditions for use. Annex III to Regulation 1333/2008 contains a second list of food additives approved for use in food ingredients such as other food additives, food enzymes, food flavorings and nutrients. The EC's food additives database provides detailed information on the different food additives allowed in the EU. Bulgaria generally adheres to EU-harmonized legislation on additives. For information on additives see the 2024 EU FAIRS report.

Re-Evaluation Program

On July 20, 2023, <u>Regulation (EU) 2023/1329</u> amending the specification for glycerol (E 422), polyglycerol esters of fatty acids (E 475) and polyglycerol polyricinoleate (E 476) entered into force. <u>Regulation (EU) 2023/1428</u> amending the specification for mono- and diglycerides of fatty acids (E 471) entered into force on July 30, 2023. Please see the <u>schematic representation of the transitional measures</u>. Bulgaria generally adheres to EU-harmonized legislation. For information on the reevaluation program see the <u>2024 EU FAIRS</u> report.

Flavorings

<u>Regulation 1334/2008</u> establishes a list of authorized flavoring substances, listed according to the category of food to which they may be added. It also sets specific rules for the use of the term "natural". Bulgaria generally adheres to EU-harmonized legislation on flavorings.

Regulation 2065/2003 establishes a safety assessment and authorization procedure for smoke flavorings intended for use in or on foods. Commission implementing Regulation 1321/2013 establishes the EU positive list of authorized smoke flavoring primary products for use in or on foods and/or to produce derived smoke flavorings. In January 2024, following EFSA's scientific assessments, the EC decided not to renew the authorizations for eight smoke flavorings: SF-001, SF-002, SF-003, SF-004, SF-005, SF-006, SF-007, SF-008, SF-009 and SF-010. Commission Implementing Regulation (EU) 2024/2067 sets out different phase-out periods to give time for producers and operators to adapt to the new rules, following the deletion of eight smoke flavorings from the Union list. After a phase-out period, these flavorings will no longer be permitted for use in the EU:

- When used to replace traditional smoking (e.g. hams, fish, cheeses) the phase-out period is in place until July 1, 2029.
- For uses where the smoke flavoring is added for extra flavor (e.g. soups, crisps, sauces), the phase-out period will be in place until July 1, 2026.

For information on flavorings see the 2024 EU FAIRS report.

Enzymes

Bulgaria generally adheres to EU-harmonized legislation on enzymes. For detailed information see the EC's website https://ec.europa.eu/food/safety/food_improvement_agents/enzymes/eu_rules_en_and the <a href="https://ec.europa.eu/food/safety/food_improvement_agents/enzymes/eu_rules_en_and=agents/enzymes/eu_rules_en_and=agents/enzymes/eu_rules_en_and=agents/enzymes/eu_rules_en_and=agents/enzymes/eu_rules_en_and=agents/enzymes/eu_rules_en_and=agents/enzymes/eu_rules_en_and=agents/enzymes/eu_rules_en_and=agents/enzymes/eu_rules_en_and=agents/enzymes/en_agents/enzymes/en_agents/enzymes/enz

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.

<u>Directive 2009/128</u> on the sustainable use of pesticides (SUD) is also part of the so-called Pesticides Package, which is currently under revision. The EC adopted a proposal in June 2022 for a new Regulation on the Sustainable Use of Plant Protection Products (SUR), including EU wide targets to reduce by 50 percent the use and risk of chemical pesticides by 2030. The SUR was proposed as part of the EU's flagship Farm to Fork strategy but was withdrawn in February 2024. The EC's 2009 directive on the sustainable use of pesticides will remain in place for the foreseeable future.

The EC is also considering adding environmental factors into the MRL and IT setting process in its effort to enhance agricultural sustainability. These non-science-based targets and practices are problematic, and they could potentially lead to additional negative implications for U.S. agricultural trade. For more information see the EC website: <u>Sustainable use of pesticides (europa.eu)</u>, EC <u>food safety/pesticides page</u> and <u>2024 EU FAIRS</u> report.

In August 2023, the MinAg approved a new <u>regulation*</u> (Decree#12 of August 23) (in Bulgarian), about the procedures for use of plant protection chemicals, in accordance with <u>Regulation (EU) 2021/1165</u> and notified EC following <u>Regulation (EU) 2015/1535</u>. Once Bulgaria approves a PPP, it can become mutually recognized and authorized within the EU.

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 the EC's website at

http://ec.europa.eu/food/plant/pesticides/max_residue_levels_en for the latest updates. For a list of authorized active substances or pesticide-MRL combinations, see the EC's online database.

Bulgaria generally adheres to EU-harmonized legislation on MRL. The Bulgarian National Pesticides Plan 2023 can be found at the MinAg <u>website</u> (in Bulgarian) and BFSA <u>strategic documents page</u> (in Bulgarian). In 2019, Bulgaria approved <u>amended legislation*</u> (in Bulgarian) (Decree 310, Official Gazette#12 of 2019) regarding MRLs in feed (lead, mercury, melamine, and decoquinate MRL) transposing <u>Directive 2002/32/EC</u> and <u>Regulation EC 2017/2229</u>.

The EU early alert system provides information on ongoing and upcoming reviews for active substances and MRLs that are of interest to U.S. stakeholders. For more information, please see FAS/USDA/U.S. Mission to the EU page and the 2024 EU FAIRS report.

Import Tolerance

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 guidelines for an import tolerance can be found at EC food safety page.

Official Controls

Harmonized sampling methods are established for the official control of residues in and on products of plant and animal origin by Commission Directive 2002/63/EC. Commission Implementing Regulation 2024/989 outlines the latest version of the coordinated multi annual control program of the EU for pesticides residues, which requires Member States (including Bulgaria) to take and analyze samples for product and pesticide residue combinations in food of plant and animal origin. Annex I to the Regulation sets out the pesticide and product combinations to be monitored. Annex II sets out the number of samples that need to be taken for each combination. Member States (including Bulgaria) must submit results of the sample tests to the EU by August 31, 2026, 2027, and 2028 for samples tested in 2025, 2026, and 2027 respectively.

Implementing Regulation 2024/989 repeals <u>Implementing Regulation (EU) 2023/731</u>, which will continue to apply regarding samples tested in 2024 until September 1, 2025. For more information see the EC website: https://ec.europa.eu/food/plants/pesticides/maximum-residue-levels/enforcement_en. For information on official controls please review the <u>2024 EU FAIRS</u> report.

Contaminants

Bulgaria applies EU-harmonized legislation regarding food contaminants. EU-wide harmonized maximum levels for contaminants are set in the Annex of <u>Commission Regulation (EU) 2023/915</u>. Please see USEU website <u>section on contaminants</u> and <u>2024 EU FAIRS</u> report for more details.

Official Aflatoxin Control on U.S. Products

In April 2015, the EU approved the pre-export checks (PEC) program for U.S. almonds. U.S. almonds were included in the Annex to Commission Implementing Regulation (EU) 2015/949 which lists all EU approved pre-export check programs. The USDA Agricultural Marketing Service began issuing PEC almond certificates on August 1, 2015.

On July 25, 2019, U.S. peanuts were included in the list of products/origins subject to increased import controls. The mandatory testing level for U.S. peanuts is laid out in Commission Implementing Regulation (EU) 2019/1793. Bulgaria must test 20 percent of all incoming peanut shipments. The regulation does not impose any requirements on U.S. exporters. Commission Implementing Regulation (EU) 2019/1793 also requires aflatoxin controls on 30 percent of consignments of pistachios and derived products originating in the United States but transshipped through Türkiye to the EU. The testing rates specified in Commission Implementing Regulation (EU) 2019/1793 are revised semiannually.

For additional information on aflatoxin testing and certification, please see: <u>PEC Program Manual</u>; <u>Pistachio Export Aflatoxin Reporting (PEAR) Program</u> and at USDA/AMS aflatoxins <u>page</u>. Bulgarian imports of U.S. nuts grow every year and U.S. exporters are advised to consult with FAS/Sofia on aflatoxin issues prior to exports.

Residues Control Plans for Animals and Animal Products

Bulgaria adheres to EU-harmonized legislation on residues in animals and animal products. The prohibition on the use of hormones in meat production itself is addressed in <u>Council Directive 96/22/EC</u>. A country is eligible to export food of animal origin to the EU if it has received approval from the EC for the residue plans it submits on a yearly basis to the EC for the various animal species of interest. Approvals are published in Annex 1 to Regulation (EU) 2021/405.

For additional information on how to export food of animal origin to the EU, please see the EU's <u>Guidance on EU requirements for imports of products of animal origin – Monitoring for residues of veterinary medicines, pesticides and contaminants, EC's <u>brochure</u> on this topic and the <u>2024 EU FAIRS</u> report.</u>

Section VI. Other Requirements, Regulations and Registration Measures

Certification and Documentation Requirements

An overview of all U.S. authorities that issue the legally required certificates for export to the EU is available on <u>USDA EU website</u>. 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 at FAS/USDA/U.S. Mission to the EU page.

Following an update of the EU's Animal Health Law, which entered into force on April 21, 2021, the EU has updated all required certificates for products of animal origin and for composite products. Models of the new certificates for foods of animal origin were published by the EU and implemented by U.S. agencies. Several amendments to the new certificates were made since their first publication. They are available from Commission Implementing Regulation (EU) No 2020/2235. For additional information please refer to the 2024 EU FAIRS report.

Composite Products

Regulation (EU) 2022/2292 defines composite products as food containing both products of plant origin and processed products of animal origin. U.S. exports of "composite products" continue to be restricted by burdensome certification requirements. Bulgaria adheres to EU-harmonized legislation on composite products.

USDA's Food Safety Inspection Service (FSIS) will issue EU composite product certificates for composite products produced at FSIS-regulated facilities and bearing the USDA mark of inspection. AMS Dairy Program will issue the EU composite product certificates for composite products not produced in an FSIS-regulated facility and not bearing the USDA mark of inspection, regardless of whether dairy is an ingredient in the composite product. The new EU requirements for composite products will impact stakeholders who have not been required to obtain an export certificate from AMS Dairy Program in the past. Prior to requesting a certificate from AMS Dairy Program, a new customer will need to establish a USDA level 2 e-authentication account. Go to How to Apply for an AMS Dairy or Composite Product Export Certificate for details.

More information on the import conditions for composite products is available on the EC's <u>website</u>. For information on composite products please refer to the <u>2024 EU FAIRS</u> report.

Facility Registration

The EU approves establishments to ship products of animal origin based on submissions from U.S. Government agencies. Detailed information on certification of products from approved U.S. establishments is available at Approved U.S. Establishments - USDA (usda-eu.org).

Inspections

The Official Controls Regulation (EU) 2017/625 sets common rules for official controls to ensure the correct application of food and feed laws, rules on animal health and welfare, plant health, and plant protection products. The list of animal origin products subject to official controls at border posts was updated in Commission Implementing Regulation (EU) 2021/632. Composite products listed in Commission Delegated Regulation 2021/630 are exempted from checks at the border because of the low risk present in these products. The EU also maintains a list of food and feed of non-animal origin from certain third countries subject to a specified level of physical controls for certain contaminants. This list is published in Commission Implementing Regulation (EU) 2019/1793 and is regularly reviewed to account for the latest non-compliance information.

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 <u>RASFF portal</u>. Products of animal origin must be presented at EU border inspection posts (BIP) and submitted to an import control following prior notification of the shipment. <u>Commission Decision 2009/821/EC</u> 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 at BFSA <u>border control page</u> (in Bulgarian). For product registrations such as foods for specific groups, vitamin enriched foods and nutritional supplements, see the <u>2024 EU FAIRS</u> report.

Section VII. Other Specific Standards

Novel Foods

Bulgaria adheres to EU-harmonized legislation on novel foods. The updated Regulation 2015/2283 on Novel Food defines novel food as food that has not been consumed to a significant degree in the EU before May 15, 1997 and falling within at least one of the categories listed in Article 3 of the regulation (e.g. cranberry extract powder). Commission Implementing Regulation 2017/2470 establishes a list of novel foods authorized in the EU. Entries in the list include specifications, conditions of use, additional labeling requirements and post-monitoring requirements. This implementing regulation is amended every time a new novel food is authorized, please make sure to reference the latest version.

U.S. exporters are advised to verify the legal status of novel food ingredients. For information on novel foods please refer to the 2024 EU FAIRS report.

Traditional Food from non-EU countries

For information on traditional food from non-EU countries please refer to the <u>2024 EU FAIRS</u> report.

Food from Animal Clones and Nanotechnology

Food derived from cloned animals currently falls within the scope of the <u>Novel Food Regulation</u> <u>2015/2283</u>. Under this regulation, food produced by "new breeding practices" needs a pre-market approval based on a risk assessment. On nanotechnology, please, refer to the <u>2024 EU FAIRS</u> report

Dietetic Foods

Regulation 609/2013 sets out compositional and labeling rules for foods for specific nutritional uses. Its scope is limited to infant formula and follow-on formula, processed cereal-based food and baby food, food for special medical purposes and total diet replacement for weight control. Bulgaria adheres to EU-harmonized legislation on dietetic foods. U.S. exporters of dietetic products should verify whether the products fall within the scope of the above regulation. For information on dietetic foods please refer to the 2024 EU FAIRS report. The Bulgarian regulation about foods for sportsmen can be found at BFSA regulations' page* (in Bulgarian).

Fortified Foods

European Parliament and Council Regulation 1925/2006 established an EU-wide regulatory framework for the addition of vitamins and mineral and of certain other substances such as herbal extracts to foods. Maximum permitted levels of vitamins and minerals in foods and food supplements are not EU harmonized. More information can be found on the EC's website: https://ec.europa.eu/food/safety/labelling nutrition/vitamins minerals en

Bulgaria adheres to the EU legislation. The <u>Ministry of Health</u> maintains a <u>register</u> (in Bulgarian) of foods enriched with vitamins and minerals. As of November 15, 2024, this register contains 212 such products, mainly soft drinks, energy drinks, drinking milk, and baby food.

Food Supplements

<u>EU Directive 2002/46/EC</u> only sets out EU-harmonized rules on labeling and vitamins and minerals that may be used in food supplements. The Bulgarian <u>Food Act</u> (Chapter III, Section III) (in Bulgarian) 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.

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

The BFSA requires registration and approval of each food supplement (and sportsman) before its release to the market. Bulgaria adopted a <u>regulation</u>* (in Bulgarian) about food supplements in December 2021 which transposed <u>Directive 2002/46/EC</u>.

Irradiated Foodstuffs

Chapter III, Section V of the Bulgarian Food Act (in Bulgarian) 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 <u>link</u>). For additional information on irradiated foodstuffs please refer to the <u>2024 EU FAIRS</u> report.

Seafood

Detailed information on shipping seafood and fishery products to the EU is provided on the U.S. Department of Commerce's <u>website</u> and the <u>2024 EU FAIRS</u> report.

Information on mandatory EU labeling requirements as well as reports on the feasibility of an EU ecolabel can be found in the EC's Fisheries website.

Pet Food

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

In October 2023, the EU adopted <u>Regulation 2023/2419</u> on the labeling of organic pet food. Pet food can be labeled with the EU organic production logo if 95 percent of its agricultural ingredients are organic. The rules made the EU organic production logo mandatory for prepacked organic pet food. Organic pet food labeled in accordance with national rules or private standards accepted by the Member States (including Bulgaria) between January 1, 2022, and October 30, 2023, could be placed on the market until stocks are exhausted. For more information, please see <u>GAIN Report EU Adopts New Rules for Organic Pet Food</u>.

For information on pet food please refer to the <u>2024 EU FAIRS</u> report and <u>GAIN report "Exporting Pet Food to the European Union.</u>

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

The Food Information to Consumers (FIC) regulation 1169/2011 requires the EC to set out rules for the voluntary labelling of foods as "suitable for vegetarians and vegans." To date, the Commission has not adopted an EU-harmonized definition of the terms "vegetarian" and "vegan." In the absence of EU-harmonized rules, many food companies have started using the "European V-label," a labelling scheme launched by umbrella organization the European Vegetarian Union (EVU). For more information see EVU's website at http://v-label.eu/about-v-label and the 2024 EU FAIRS report.

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

In the EU, trademarks can be registered at the national, regional or EU level. Rules on the protection of trademarks in the EU are set in EU <u>Directive 2015/2436</u>. <u>Commission Implementing Regulation 2018/626</u> sets out detailed rules on application procedures. <u>Commission Delegated Regulation 2018/625</u> 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 Community Trademark gives the owner protection in all Member States (including Bulgaria) with one single registration. Additional information on EU trademark criteria can be found on the EC's website and in the 2024 EU FAIRS report.

Protected Designation of Origin (PDO) and Protected Geographic Indications (PGI)

As part of the EU's system of intellectual property rights, names of products registered as geographical indications (GIs) are legally protected against imitation and misuse within the EU and in non-EU countries where a specific protection agreement has been signed.

On May 13, 2024, the new Regulation 2024/1143 on Geographical Indications for Wine, Spirit Drinks, and Agricultural Products, as well as Traditional Specialties Guaranteed and Optional Quality Terms for Agricultural Products entered into force. This regulation establishes rules on optional quality terms such as "mountain product" and regulates three EU-wide quality labeling schemes. It covers the "Protected Designation of Origin" (PDO) scheme, the "Protected Geographical Indication" (PGI) scheme and the "Traditional Specialties Guaranteed" (TSG) scheme. Registration under the different schemes is also open to non-EU countries. The new Regulation improves the protection of GIs used as an ingredient in a

processed product and of GI products sold online. The new regulation also strengthens the protection of GI names in the domain name system. Wines and spirits are also covered by specific legislation:

<u>Commission Regulation 2019/33</u> and <u>Commission Regulation 2019/34</u>.

The <u>European Commission's website</u> provides guidance on how to register a PDO/PGI or how to object to a PDO/PGI proposed for registration. <u>eAmbrosia</u> is the EU's legal register of the names of agricultural products and foodstuffs, wine, and spirit drinks that are registered and protected across the EU.

Bulgaria's lists of protected food names is available at EC's <u>portal</u>. As of November 2024, Bulgaria has seven registered TSG products (meat products), four registered PDO product (white cheese, yogurt, herbal tea and honey), and two registered PGI products (rose oil and a meat product).

In July 2018 Bulgaria amended the <u>Law on Trademarks and Geographic Indications</u> (Official Gazette 61/2018) (in Bulgarian). The amendment aimed to complete harmonization of the local legislation with the EU <u>European Parliament and Council Regulation 1151/2012</u>. 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.

Registration of Geographic Indications for Spirit Beverages

Regulation (EU) <u>2019/787</u> updates the definitions of various spirits beverage categories. It also clarifies and changes the rules on the protection of GIs, including registration. On July 29, 2021, the EC published Delegated Regulation (EU) <u>2021/1235</u> and Implementing Regulation (EU) <u>2021/1236</u> concerning GIs applications for registration of spirits beverages. As of November 2024, Bulgaria has 54 wines registered under PDO scheme and 12 spirit drinks under PGI.

Section IX. Import Procedures

Union Customs Code (UCC)

The "Union Customs Code" (UCC) established in <u>Regulation 952/2013</u> is the framework regulation on rules and procedures for customs throughout the EU. <u>Commission Delegated Regulation 2015/2446</u> and <u>Commission Implementing Regulation 2015/2447</u> outline detailed rules for the implementation of certain provision of the UCC, including Binding Tariff Information and origin of goods. All Member States (including Bulgaria) 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 move freely throughout the EU. The UCC, along with the implementing provisions, became applicable on May 1, 2016. A <u>complete overview of the EU's UCC</u> is available on the EC's DG TAXUD website. In the case of Bulgaria, the Customs Agency under the Ministry of Finance is the responsible entity. Contact information for the Customs Agency can be found in Appendix I.

In 2017, the EC launched the "<u>Customs Decisions System</u>", a new pan-EU electronic system to facilitate permission to import goods into the EU. Importers in Bulgaria can use the same portal and exchange applications between all the relevant customs authorities.

In May 2023, the EC released <u>a proposal</u> to reform the UCC. The reform aims to simplify and rationalize customs reporting requirements for traders. More information about the proposal can be found on the <u>Commission's website</u>.

Customs Clearance

Bulgaria adheres to EU-harmonized legislation on customs clearance. The EC's <u>Access2Markets</u> database provides a complete overview of documents needed for customs clearance such as:

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

On September 29, 2023, the Bulgarian Ministry of Finance adopted a <u>regulation*</u> (in Bulgarian) about fiscal control on movement of products of high fiscal risk on the territory of the country (applicable since October 3, 2023). The regulation is implemented by the National Revenue Agency (NRA) (more details at NRA's <u>page*</u> (in Bulgarian). Most foods and alcohol drinks are subject of this regulation. The industry describes the regulation as burdensome and requiring considerable administrative resources. Although the regulation is applicable to Bulgarian importers/traders, the U.S. exporters may need to provide detailed information about their shipments to their local partner for compliance with this regulation.

Import Duties

Bulgaria adheres to EU-harmonized legislation on import duties. The <u>EU's revised 2024 Tariff</u> <u>Schedule</u> was published on July 1, 2024 in the Official Journal. The EU's <u>on-line "TARIC" customs</u> database can be consulted to look up commodity codes and relevant import duties.

Duties payable on goods imported into the EU may include:

- Import duty (expressed as ad valorem tariffs or specific tariffs per unit weight/volume/number of pieces) – EU harmonized (above)
- Additional duties on flour and sugar (processed products) EU harmonized (above)
- Entry price (fruit and vegetables) EU harmonized (above)
- Environmental taxes not harmonized (Please, see relevant BFSA taxes on the <u>administrative</u> <u>services page</u>*(in Bulgarian)
- Inspection fees not harmonized (Please, see the inspection fees charged by BFSA administrative services page* (in Bulgarian)
- Value Added Tax (VAT) The standard VAT in Bulgaria is set at 20 percent.
- Excise duties (alcohol and tobacco) not harmonized (see below).

Excise Duty for Alcohol Products

Since February 13, 2023, Directive (EU) 2020/262 replaced EU Directive 2008/118. The excise legislation establishes the minimum rates of tax that must be applied for each category, but Member States (including Bulgaria) can decide to set rates at a higher level. As of February 13, 2023, all excise duty transactions in the EU also became fully electronic. The Directive increases the threshold for lower strength beer that can benefit from reduced excise duty rates. It extends the special regime of reduced excise duty rates for small beer and ethyl alcohol producers to producers of other fermented beverages, such as cider. Directive 2020/1151 also sets out the conditions for application of the exemption from excise duty rules for denatured alcohol, used for example in cleaning products. More information on excise duties for alcohol can be found on the Commission's website.

The level of excise duties on alcohol and tobacco products in Bulgaria are the lowest in the EU at 66 percent of the EU average. Please, see the Bulgarian <u>list of excise duties</u>* (last revision on July 12, 2024) and relevant <u>documents</u>* (last revision on September 17, 2024) (in Bulgarian) and rules at the Bulgarian Customs Agency website.

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 <u>Trade Helpdesk</u> offers a complete overview of documents needed for customs clearance.

In Bulgaria there is no official requirement for import documentation to be translated into Bulgarian. The most used language by border inspectors is English. Translation in Bulgarian, though, can speed up the border 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 local market entry and specific regulations and practices.

Other Certification and Testing Requirements

For information on other certification and testing requirements please refer to the <u>2024 EU FAIRS</u> report.

Section X. Trade Facilitation

Advance Rulings

For information on advance rulings and the pre-clearance program please refer to the <u>2024 EU FAIRS</u> 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 can 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 the 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 (Regulation (EU) 2017/625) provides the legal basis for the financing of import controls. Mandatory fees are charged to operators for certain official controls, including on import controls of animals, products of animal origin, germinal products, animal 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. This regulation mandates specific frequencies of controls for certain hazards in products depending on their origin. Several products have to be tested for aflatoxins under this regulation. In addition, fees are also charged to operators for official controls that were not originally planned because they are necessary to follow-up non-compliance. Specific fee information can be found at the BFSA's administrative services page* (in Bulgarian).

Average Release Time for Products – Common Delays

Bulgaria's 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 Türkiye, Serbia, and North Macedonia. Bulgaria is often used as a door for commercial overland traffic from the Türkiye 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

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.gevernment.bg Website: https://www.mh.government.bg/en/

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.bg Website: https://bfsa.egov.bg/wps/portal/bfsa-web/home

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

National Drug Agency

8 Damyan Gruev Str., Sofia 1303

Tel.: (+359) 2-8903-555 Fax: (+359) 2-8903-434; E-mail: <u>bda@bda.bg</u> Website: <u>http://en.bda.bg</u>

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

"Izgrev" Complex

Tel.: (+359) 2-8174-504 Fax: (+359) 2-8174-535

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

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Bulgarian Association of Food and Beverage Industries

1606 Sofia, 29 Vladaiska Street

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

E-mail: <u>bafdi@mb.bia-bg.com</u> Website: <u>http://www.bia-bg.com/member/26</u>

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