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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 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 2019 report. Additional updates and other relevant information can be found on the FAS Europe's website.

Table of Contents

Section I. Food Laws:

Bulgaria acceded to the EU in 2007 and follows all relevant EU directives, regulations, and obligations. EU directives require Member States to harmonize national laws accordingly. The following report outlines legislation applicable to U.S. food exports to Bulgaria, particularly those requirements which differ from EU regulations. Exporters should note that whenever EU-wide legislation is incomplete, absent, or open for interpretation, Bulgarian national laws may apply.

In January 2018, the European Commission (EC) finalized a 'fitness check' of the General Food Law, Regulation 178/2002. In June 2019, the General Food Law was amended under Regulation 2019/1381 regarding the transparency and sustainability of EU risk assessment procedures and was published in the EU's Official Journal. The main objective of the amendment was to ensure more transparency, to increase the independence of research, strengthen the governance of European Food Safety Agency (EFSA), and develop comprehensive risk communication measures. The regulation has an influence on eight sectoral legislative acts across food production sectors, including food additive, smoke flavoring, food contact materials, food additive, food enzymes, flavoring, and novel foods.

Bulgarian Food Law

Regulation (EC) 178/2002 establishes general principles and objectives vis-à-vis Bulgaria's 2011 Food Law. The Food Law establishes the Bulgaria's basic food and feed regulations, is based on EU regulations, and applies to domestic and imported products. It establishes basic definitions, goals, and principles for food safety and defines procedural rules, coordination mechanisms between the different public administrations with responsibilities in official food control. Three minor changes were adopted in 2018, including changes in December 21, 2018. The Food Law's implementing regulations can be found on the Bulgarian Food Safety Agency's (BFSA) website here. Other major legislation which applies to imported food products can be found in the Veterinary Medical Act (English version available upon request), including the latest amendments adopted on March 22, 2019. Imports of raw materials and foods of animal origin are regulated by this legislation (Chapter V, Art.24b Food Law). Additional legislation which may have direct or indirect effect on food imports including the Plant Protection Law (last revised February 26, 2019) and the Feed Law (last revised February 23, 2018). The following sources have a complete list of applicable EU and national legislation (English version available upon request): EU and national legislation and tariffs here, and national legislation here.

New amendments to the Food Law have been considered by the Cabinet since December 2017. For political and other reasons, this legislation was delayed until the middle of 2019. Post expects that the Parliament will renew its work on the Food Law amendments after January 2020. It is likely that the revised Food Law will be discussed in the Parliament along with another new legislation, the Agricultural and Food Supply Chain Act. The Food Law amendments and the Agriculture and Food Supply Chain Act would effectively deepen Bulgaria's harmonization with the EU. Post expects that both laws will be voted by the Parliament by March 2020.

At the EU level, a new regulation on harmonized food controls, Regulation 2017/625, enters into force on December 14, 2019, repealing current Regulation 882/2004. For more information see 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. In order to address this issue, in April 2018, the EC proposed to amend Directive 2005/29/EC concerning unfair business-to-consumer commercial practices. In April 2019, the European Parliament and EC agreed on final text amending the rules on better enforcement and modernization of 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, attempts to amend the Food Law on the "dual quality" products in 2018 failed. The issue was debated in the middle of 2019 and a political decision was taken to move this topic from the Ministry of Agriculture portfolio to the Ministry of Economy. Reportedly, the Ministry of Economy intends to follow the EU directive on this issue and to transpose it into the national legislation by late 2020.

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 authority on official control on all food imports, exports, and manufacturing with the exception of 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 direct supervision of the MinAg. It is responsible for risk assessment and management and works directly with the European Food Safety Agency.

Section II. Labeling Requirements:

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

For detailed information on the EU-harmonized labeling legislation, please see the following links: EC: Notice on questions and answers on the application of Regulation 1169/2011 on the Provision of Food Information to Consumers (June 2018); FoodDrink Europe (EU Food and Drink Industry Confederation): Guidance on the Provision of Food Information to Consumers; USEU report "New EU Food Labeling Rules Published", supplemented by the report "How to comply with the EU's New Food Labeling Rules", and EU Labeling Requirements.

Bulgaria applies EU-harmonized legislation to:

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

Current draft amendments of the Food Law include new provisions for labeling which would more fully harmonize Bulgarian government regulations with the EU. The FIC Regulation exempts alcoholic beverages from mandatory nutritional labeling and ingredient listing. At present Bulgaria applies nutritional labeling for alcoholic beverages on a voluntary basis.

General Labeling Requirements

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

- Product name

- List of ingredients and quantity of certain ingredients or category of ingredients
- Allergens listed in Annex II
- Nutrition declaration
- Alcoholic content when 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

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

Ingredients List

The list of ingredients must be preceded by the word "ingredients." All ingredients must be designated by their specific name and listed in descending order of weight. Annex VII to FIC regulation 1169/2011 sets out specific provisions concerning the indication of ingredients and categories of ingredients in the list of ingredients. This Annex requires the mandatory indication of the specific sources of vegetable oils and fats.

Quantitative Ingredients Declaration (QUID)

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

Additives and Flavorings

Annex VII, Part C to FIC regulation 1169/2011 lists the categories of additives which must be designated by the name of their category, followed by their specific name or E-number.

Allergen Labeling

Article 21 of the FIC stipulates that each product or substance capable of inducing an allergic reaction must be indicated in the list of ingredients with reference to the name of the substance or product as listed in Annex II to the FIC regulation. The EC published an update of its guidance document on allergen labeling on July 13, 2017. Also see EU labeling requirements and Allergen Labeling – Annex 3 (FoodDrinkEurope).

Country of Origin Labeling (COOL)

In the EU, COOL is mandatory for beef, pork, poultry, veal meat, sheep and goat meat, fruit and vegetables, eggs, wine, honey, olive oil, fishery and aquaculture products, and EU-certified organic products. In Bulgaria, COOL, per the current Food Law, is mandatory for almost all food products. On May 29, 2018, the EC published Implementing Regulation 2018/775, which introduces mandatory dual-origin labeling when a country of origin is given or visually implied on the label of a food product but the origin is not the same as that of its primary ingredient. See USEU GAIN report "Commission Briefing on New Origin Labeling Rules". Detailed information on COOL is provided in the USEU GAIN report "The EU's Country of Origin Labeling Policy" and on the FAS/USEU website as well as on FoodDrink Europe (EU Food and d Drink Industry Confederation) Guidance on the Origin Indication of the Primary Ingredient (2019).

Language Requirements

Article 15 of FIC regulation 1169/2011 stipulates that the mandatory information should be provided in "a language easily understood by the consumers of the Member States where the food is marketed." Bulgarian is the official language in Bulgaria.

The currently debated Food Law in Bulgaria is likely to have more detailed requirements regarding translations of mandatory labeling information and how the labels in Bulgarian (usually as stickers) should be placed on the product in order to make the mandatory original label visible. Specific rules on the use of stickers to provide mandatory labeling information are not included in FIC regulation 1169/2011. According to the EC's FAQs on the Application of Regulation 1169/2011 document, "labels should not be easily removable so as to jeopardize the availability or the accessibility of the mandatory food information to the consumer."

Nutritional Labeling

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

Nutritional Declaration

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

Mandatory content of the nutrition declaration:

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

Detailed rules on the presentation of the nutrition declaration are set out in Annex XV to the FIC regulation. The EC published a guidance document and a simplified summary table for tolerance values for the control of compliance of nutrient values declared on a label with EU legislation. Annex V to the FIC regulation establishes a list of products that are exempted from the mandatory nutrition

declaration requirement. The EU's Food & Drink Industry Federation "FoodDrinkEurope" has launched a website explaining "reference intakes" to food business operators and consumers.

Article 35 of the FIC regulation allows Member States to recommend the use of additional forms of expression or presentation of the nutrition declaration. So far, Bulgaria, unlike some other Member States, has not adopted any additional front of pack nutritional labeling schemes.

Health/Nutritional Claims Labeling

Nutritional Claims

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

Health Claims

Rules on the use of health claims are set out in Nutrition & Health Claims Regulation 1924/2006. Regulation 432/2012 establishes the EU positive list of functional health claims and their conditions of use. Food products carrying claims must also comply with the provisions of the EU's FIC regulation. Commission Implementing Decision 2013/63 establishes guidelines for national control authorities as regards the implementation of specific conditions for permitted health claims. Regulation 353/2008 sets implementing rules for applications for the authorization of health claims as provided for in Article 15 of Regulation 1924/2006. Health claims are only allowed if the importance of a balanced diet and healthy lifestyle is also stated on the label. Trademarks and brand names that suggest health and/or nutritional benefits but do not comply with the new rules must be entirely removed from the EU market by January 19, 2022. For more information see here and USEU report "Health Claims – New EU Regulation on Generic Descriptors".

Alcoholic Beverages

Alcoholic beverages containing more than 1.2 percent of alcohol by volume are exempted from a nutritional declaration and a list of ingredients. In March 2018, the alcoholic beverages industry presented a joint self-regulatory proposal outlining general principles of a labeling scheme. These general principles are accompanied by four sector 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 and committed to *voluntarily* include energy information on-label while comprehensive ingredients and nutritional information will be available online. The declaration of ingredients will follow the definition provided in the FIC Regulation:

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

- Ingredients must be listed in descending order of weight as recorded at the time of their use in the manufacture of the beverage;
- Nutrition information must be provided per 100 ml;

- With regard to nutrition information, beers over 1.2 percent of alcohol by volume shall either solely list the energy values or list all seven nutritional values;

More information can be found on the Brewers of Europe's dedicated website.

In 2019, the European Parliament amended the proposal of the EC and added specific requirements on nutrition declaration for *wine*. The proposed amendment to the Common Agricultural Policy would introduce mandatory wine labeling for the nutrition declaration, the content of which may be limited to the energy value only, and the list of ingredients. The energy value would be expressed per 100ml. In addition, it may be expressed per consumption unit, easily recognizable by the consumer, provided that the unit used is quantified on the label and that the number of units contained in the package is stated. This amendment is going through the EU legislative process. A final decision is expected late 2020 or early 2021.

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

Other Specific Labeling Requirements

The FIC Regulation 1169/2011 sets out horizontal rules applicable to all products. Sectoral or "vertical" legislation exists for a number of products. For labeling rules on meat and fish labeling, gluten free foods, trans-fats, minimum durability, warnings on labels and for minimum front size on labels, see the OAA USEU FAIRS report from 2018.

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

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

Trans-fats: In April 2019, Regulation 2019/649 amending Annex III to Regulation 1925/2006 on trans-fats was published in the Official Journal. This new Regulation sets a maximum limit of trans fat, other than trans-fat naturally occurring in animal fat, in food, which is intended for the final consumer, of 2 grams per 100 grams of fat. The Regulation entered into force in May 2019. However, food which does not comply with this Regulation may continue to be placed on the market until April 1, 2021.
Glute-free: EC Implementing Regulation 828/2014, applicable since July 20, 2016, sets out conditions for using "gluten-free" and "very low gluten" statements on food labels.

Minimum durability: Annex X to FIC regulation 1169/2011 sets out rules for the indication of the date of minimum durability, use-by date and date of freezing. The use-by date must be indicated on individual pre-packed portions. The durability date and the date of (first) freezing preceded by the

words “frozen on” is required on labels of frozen meat, frozen meat preparations and frozen unprocessed fishery products.

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. 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.

U.S.-EU Wine Agreement: In March 2006, the U.S. and the EU and the U.S. signed the “Agreement between the United States and the European Community on Trade in Wine”. The Agreement covers wine with an actual alcohol content of not less than 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. The Agreement’s “Protocol on Wine Labeling” sets conditions for the use of optional particulars on wine labels. Commission Regulation 1416/2006 concerns the protection of U.S. names of origin in the EU.

Distilled Spirits: European Parliament and Council Regulation 110/2008 provides general rules on the definition, description and presentation of distilled spirits. This regulation prohibits the use of the term “spirit drink” as part of a compound term describing an alcoholic beverage. 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 labelling of spirit drinks, as well as on the protection of geographical indications of spirit drinks. It will also lay down rules on the use of legal names of spirit drinks in the presentation and labeling of foodstuffs other than spirit drinks and provide for provisions on the use of compound terms for the presentation of spirit drinks.

Commission Implementing Regulation 716/2013 lays down rules for the application of Regulation 110/2008 as regards the use of compound terms and geographical indications of the spirit drinks. The public database eAmbrosia lists the geographical indications of spirit drinks registered in the EU. In February 2019, “Tequila” was approved as a geographical indication in the EU (Implementing Regulation 2019/335).

Commission Regulation 936/2009 applies the agreements between the EU and third countries on the mutual recognition of certain spirit drinks. Under this regulation, “Tennessee whiskey” and “bourbon whiskey” are protected product designations.

Section III. Packaging and Container Regulations:

Size and Content

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

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

Packaging Waste Management

Please see previous OAA Sofia's 2018 FAIRS Country report for more information.

Packaging and Materials Which Contact with Foods

A summary of EU and Bulgarian legislation, as well as guidance documents and Bulgarian contact information with regard to the submission of applications for authorization can be found here. Also, please see the previous OAA Sofia's 2018 FAIRS Country report for more information.

In May 2018, the EC proposed new rules to target the ten single use plastic products most often found on Europe's beaches and seas, as well as lost fishing gear. The ban of certain products could also affect food packaging in the future. See here for more information.

Directive 2007/45/EC abolished regulations on mandatory pack sizes at both EU and national levels. Under this Directive, only wine and spirits have defined package sizes, with the exception of *shochu* bottled in Japan. Mandatory nominal quantities for wines and spirits are set out in the Annex to Directive 2007/45/EC.

Section IV. Food Additives Regulations:

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

The EU's "Package on Food Improvement Agents" includes four Regulations: Regulation 1331/2008 establishing a common authorization procedure for food additives, food enzymes and food flavorings, Regulation 1332/2008 on food enzymes, Regulation 1333/2008 on food additives and Regulation 1334/2008 on flavorings. Only additives included in the EU's positive list may be used in food products marketed in the EU. Inclusion in the EU positive list is based on a risk assessment by the European Food Safety Authority (EFSA).

Additives

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

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

FIC regulation 1169/2011 lists the categories of additives, which must be designated by the name of their category, followed by their specific name or E-number. Part D of the same Annex sets out rules for the indication of flavorings, smoke flavorings and the use of the term "natural." Regulation 1334/2008 lays down additional rules on the use of the term "natural". Please, see also FoodDrink Europe Guidelines on Flavorings (2019).

Re-Evaluation Program

Commission Regulation 257/2010 sets out a re-evaluation program for EFSA to assess food additives that were approved before Food Additives Regulation 1333/2008 entered into force.
The re-evaluation of approved food additives is scheduled to be completed by the end-2020. Please find a link to the summary table of permitted food additives and status of their re-evaluation by EFSA (status as of September 9, 2019). For more information on the re-evaluation of food additives see here.

Flavorings

Regulation 1334/2008 establishes a list of authorized flavoring substances, listed according to the category of food to which they may be added. An on-line database allows consumers, food businesses and food control authorities to verify which flavoring substances are authorized in food.

The EU list of authorized smoke flavoring primary products for use as such in or on foods and/or for the production of derived smoke flavorings is established by Commission implementing Regulation1321/2013.

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.

Processing Aids

Processing aids are subject to national legislation. Requests should be addressed to the Bulgarian Food Safety Agency. Please see OAA Sofia's 2018 FAIRS Country report for more information.

Section V. Pesticides and Other Contaminants:

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

Pesticides

European Parliament and Council Regulation 1107/2009 established the rules for approvals of plant protection products (PPPs). PPPs (also referred to as 'pesticides') must contain at least one approved active substance. Only PPPs containing approved active substances as per the list established in Commission implementing Regulation 540/2011 may be authorized for use in the EU. Before any PPP can be placed on the market or used, it must be authorized by Bulgarian authorities. According to Annex I of Regulation 1107/2009, the EU is divided in three different zones. Once Bulgaria approves

the PPP, it can be mutually recognized and thus authorized within the EU. Bulgaria is included in the Zone C (South) along with Spain, Cyprus, France, Greece, Italy, Malta and Portugal). Directive 2009/128 on the sustainable use of pesticides is also part of the so-called Pesticides Package. For more information see here. For application for pesticide registration in Bulgaria the contact is the BFSA (see below for contact information).

Endocrine Disruptors

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

Maximum Residue Levels (MRL)

European Parliament and Council Regulation 396/2005 harmonizes all MRLs in the EU on food or feed of plant and animal origin. Pesticide MRLs for processed or composite products are based on the MRLs of the raw agricultural ingredients. See and the list of authorized active substances or pesticide-MRL combinations online database. The Bulgarian National Pesticides Plan can be found here.

In February 2018, Bulgaria amended its Feed Law introducing the latest changes from the EU legislation. In December 2018, MinAg published a draft of amended implementing regulation Decree #10 (Official Gazette #29 of 2009) regarding MRLs in feed (lead, mercury, melamine and decoquinate MRL) with the goal to introduce Directive 2002/32/EC and Regulation EC 2017/2229. The amended legislation was approved on February 8, 2019 (Official Gazette#12 of 2019).

Import Tolerance

The EC is currently undergoing a regulatory fitness and performance check (REFIT) of the EU legislation on pesticides and pesticides residues. The external evaluation study was published on October 18, 2018, including an executive summary. Official controls on pesticides can be found here.

Upcoming Review

The EC did a regulatory fitness and performance check (REFIT) on the EU legislation on pesticides and pesticides residues. The evaluation process consisted of different steps, such as a roadmap, an external study, as well as a consultation strategy with an online public consultation, focus groups, in-depth interview, case studies etc. in order to collect data and information. The final report concluding the REFIT was finalized in the first half of 2019 but has not yet been released.
In addition to the EC's evaluation, the European Parliament formed a special Committee on Pesticides that investigated glyphosate and other pesticide products. Some of the recommendations from the PEST Committee's final report were also used for the final REFIT report.

Contaminants

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

The EU has started to discuss the expansion of the group of products subject to a maximum level for ochratoxin A. Please, see USEU GAIN report: "Additional EU Maximum Levels for Ochratoxin A on the Horizon". Please, see OAA USEU FAIRS 2019 report for more information.

Official Controls of Maximum Levels in Food Products

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

- Annex I describes the methods of sampling.

Annex II proscribes the sample preparation and the performance criteria for analytical methods.

Nitrates: Commission Regulation 1882/2006
Mycotoxins: Commission Regulation 401/2006
Dioxins: Commission Regulation 2017/644
Heavy metals, Tin, 3-MCPD and benzo(a)pyrene: Commission Regulation 333/2007
Erucic acid: Commission Regulation (EU) 2015/705

In November 2019, the Commission adopted Recommendation 2019/1888 recommending that competent authorities in the Member States monitor regularly the presence of acrylamide and its levels in food, in particular in the food listed in the Annex of the Recommendation.

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 2019/533 outlines the latest version of the coordinated multi annual control program of the EU for pesticides residues, which requires Member States to take and analyze samples for product and pesticide residue combinations in food of plant and animal origin. Annex I to the Regulation sets out the pesticide and product combinations to be monitored. Annex II sets out the number of samples that need to be taken for each combination. The Member States must submit results of the sample tests to the EU by August 31, 2021, 2022 and 2023 for samples tested in 2020, 2021 and 2022 respectively. For more information see the EC website here.

Private Industry Standards

Please see the previous OAA Sofia's FAIRS Narrative 2018 report for more information.

Aflatoxin in Tree Nuts

Following the publication of Commission Implementing Regulation (EU) 2017/1269 on July 14, 2017, the U.S. pre-export program for peanuts was no longer recognized by the EU. There are no restrictions on the export of U.S. peanuts; however, shipments no longer benefit from the reduced testing level for aflatoxin upon entry in the EU. On April 1, 2015, U.S. pistachios were included in the list of products/origins subject to increased import controls under Commission Regulation (EC) No 669/2009. The list was updated in 2017, as Bulgaria now tests 10 percent of all incoming shipments.

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

Residues in Animals and Animal Product

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

Section VI. Other Regulations and Requirements:

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

Composite Products

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

Inspections

BFSA is responsible for inspections and enforcement of food and feed regulations. Products can be checked at import or at all further stages of marketing. Violations of EU food and feed legislation are reported through the RASFF portal. Specific detailed inspection requirements exist for animal products (Directive 97/78/EC). Products of animal origin must be presented at a Community border inspection post (BIP) and submitted to an import control following prior notification of the shipment. Commission Decision 2009/821/EC establishes a list of EU BIPs approved to carry out veterinary checks on animals and animal products from third countries. A full list of Bulgarian BIPs can be found here. See OAA Sofia's FAIRS Narrative 2018 report for more information.

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

Section VII. Other Specific Standards:

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

A new Regulation on the mutual recognition of goods will apply as of April 19, 2020. Regulation 2019/515 on the mutual recognition of goods lawfully marketed in another Member State will replace Regulation 764/2008. It introduces a voluntary 'mutual recognition declaration', which businesses can use to demonstrate that their products are lawfully marketed in another EU country. Detailed information about the new rules can be found on the EC'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. For example, juice derived from an exotic fruit not consumed in the EU before May 15, 1997 but part of a regular diet in a non-EU country, would qualify as a 'traditional food." Commission Implementing Regulation 2017/2468 sets out administrative and scientific requirements for the notification of traditional foods falling within the scope of the Novel Food regulation.

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

- e-submission user guide
- Administrative guidance on the submission of applications for authorization of a novel food pursuant to Article 10 of the Novel Food Regulation
- Guidance on the preparation and presentation of an application for authorization of a novel food in the context of the Novel Food Regulation
- Guidance on the preparation and presentation of the notification and application for authorization of traditional foods from third countries in the context of the Novel Food Regulation

GE Foods and Feeds

Bulgaria has a centralized system for testing and controlling the unauthorized presence of GE products in the feed and food. Please see previous OAA Sofia's FAIRS Narrative 2018 report for more information. The EU register of authorized GE events is available on the EC's website. Labeling requirements do not apply to foods containing a proportion equal to/or less than 0.9 percent of the food ingredients considered individually, provided their presence is adventitious or technically

unavoidable. Above this level, all products must be labeled. See USDA EU's website for more information.

The Bulgarian Food Law was changed in 2010 to ban GE ingredients and GE products in baby foods regardless of their safety evaluation (Art. 4a/4 for the Food Law). Please see the previous OAA Sofia's FAIRS Narrative 2018 report for more information

Foods from Cloned Animals

Food derived from cloned animals currently falls within the scope of the Novel Food Regulation 2015/2283. Under this regulation, food produced by "new breeding practices" needs a pre-market approval based on a risk assessment. In December 2013, under pressure of the European Parliament and the Council of the EU, the EC proposed two pieces of specific legislation on food from cloned animals:

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

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

Novel Foods

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

EU Positive List: Commission Implementing Regulation 2017 2470 establishes a list of novel foods authorized in the EU. Entries in the list include specifications, conditions of use, additional labeling requirements and post-monitoring requirements.

Article 23a of the Food Law introduces the procedure for approval and release on the market of new ingredients and substances as novel foods. Please see OAA Sofia's previous 2018 FAIRS Country report for more information.

For detailed information see USEU GAIN report "New EU Law on Novel Food Status Determination". For regulatory questions vis-à-vis food products from cloned animals, engineered nanomaterials, nanotechnology, traditional food from non-EU countries, and fortified foods, please, consult with USDA EU's website.

Dietetic or Special Use Foods

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

Commission Delegated Regulation 2017/1798 sets out the rules for "total diet replacements for weight control". These rules will become applicable on October 27, 2022. Please see USEU GAIN report "The skinny on New EU Rules for Eight Loss Products". New rules on the reduction of acrylamide levels in food, set out in Commission Regulation 2017/2158, became applicable on April 11, 2018. These rules also apply to baby food and processed cereal-based food intended for infants and young children. Please, see EU FAIRS 2019 report for more information.

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

In 2019, the European Parliament amended the proposal of the EC so that names that fall under Article 17 of Regulation (EU) 1169/2011 that are currently used for meat products and meat preparations shall be reserved exclusively for products containing meat. These designations include, for example, steak, sausage, escalope, burger, and hamburger. This amendment (Amd 165) is still going through the EU legislative process. A final decision is expected late 2020 or beginning of 2021.

Organic Foods

Council Regulation 834/2007 is the EU's general framework regulation that sets out rules for organic production and labeling. Commission Regulation 889/2008 sets out detailed rules for the implementation of Regulation 834/2007. A new EU Regulation on organic production and labeling was adopted in May 2018 and will enter into force on January 1, 2021, repealing the Council Regulation 834/2007. The Bulgarian Food Law contains special provisions regarding organic foods in Article 6. Please see here and USEU GAIN report "New EU Organic Regulations for Early 2018". EC Implementing Regulation 2016/1842 published on October 19, 2016, sets EU rules for certifying imported organic foods. Since October 19, 2017, only certificates initiated through the EU's Trade Control and Expert System (TRACES) are valid.

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

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

Wine, Beer and Other Alcoholic Beverages

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

US-EU Wine Agreement: In March 2006, the U.S. and the EU signed the "Agreement between the United States and the European Community on Trade in Wine". Information on US-EU wine trade can also be obtained from Alcohol and Tobacco Tax and Trade Bureau here.

Spirits: European Parliament and Council Regulation 110/2008 lays down general rules on the definition, description and presentation of spirit drinks. Commission Implementing Regulation 716/2013 lays down rules for the application of Regulation 110/2008 as regards the use of compound terms and spirit GIs. "Tequila" was registered as a geographical indicator (GI) in the EU as of March 20, 2019.

Commission Regulation 936/2009 applies the agreements between the EU and third countries on the mutual recognition of certain spirit drinks. Under this regulation, "Tennessee Whisky" and "Bourbon Whisky" are protected product designations.

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

Beer: There is no beer-specific EU-harmonized legislation. All alcoholic beverages must comply with allergen labeling requirements. Bulgaria's beer industry lists ingredients on a voluntary basis.

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

Vertical Legislation and Product – Specific Legislation

Vertical legislation on the manufacture and marketing of specific products has been developed for sugars (Directive 2001/111), cocoa and chocolate products (Directive 2000/36), honey (Directive 2001/110), fruit juices and similar products (Directive 2001/112/EC amended by Directive 2012/12/EU), preserved milk (Directive 2001/114), coffee extracts and chicory extracts (Directive 1999/4) and fruit jams and similar products (Directive 2001/113).

Fruit Juices: Please see USEU GAIN report "New EU Fruit Juice Labeling Rules".

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

Single Common Market Organization: European Parliament and Council Regulation 1308/2013 establishes a single common market organization (CMO) for all agricultural products. The single CMO provides definitions and marketing rules for rice, sugar, beef and veal, milk and milk products,

eggs and poultry meat, olive oil, fruit and vegetables, spreadable fats and wine. In May 2018, the EC published Delegated Regulation 2018/1096 on the requirements for certain indications on the olive oil labeling regarding the maximum acidity and year of harvesting.

Food Supplements

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

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

Frozen Foods

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

Irradiated Foodstuffs

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

Special Use Foods

See USEU GAIN reports " New Rules on Dietetic Foods" and "New EU Rules on Dietetic Foods – Update" and the EC's website.

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

New EU rules on "total diet replacement for weight control" will become applicable on October 27, 2022. Commission Delegated Regulation 2017/1798 sets out specific compositional and labeling requirements as well as a notification procedure under which food business operators are required to send copies of their product labels to the competent authority where the product will be

marketed. Please see USEU GAIN report "The Skinny on New Rules for Weight Loss Products". Artificial sweeteners are not allowed in dietetic bakery products. For detailed information see USEU GAIN report "EU bans use of artificial sweeteners in dietetic bakery products".

Seafood

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

Pet Food

Requirements for exporting pet food to the EU can be found here Pet food. Pet food products containing animal-origin ingredients must be sourced from approved establishments and be accompanied by veterinary certificates. All exports of U.S. pet food to the EU must comply with EU requirements including rules on labeling, hygiene, animal health, certifications, and additives. Please see USEU GAIN report "Exporting Pet Food to the European Union" for more information. European Parliament and Council Regulation 767/2009 sets out new rules for the labeling and marketing of feed and pet food. Conditions for mixing veterinary medicine into feed are set out in Directive 90/167/EEC.

In September 2014, the EC presented a proposal to replace the outdated Directive 90/167/EEC on medicated feed. The scope of the proposal explicitly includes medicated pet food. See here and here for more information. In January 2019, the EU published Regulation 2019/4 in the EU's Official Journal which will replace Directive 90/167/EEC as of January 28, 2022. The new Regulation explicitly includes the manufacturing of medicated feed for pets in the scope of the legislation. More information is available on the EC's website.

Meat and Fish Labeling

See the EU FAIRS 2019 report for beef, veal, pork, sheep, goat, and poultry meat requirements.

Vegetarian and Vegan Foods

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

In July 2017, the European Court of Justice (ECJ) ruled that plant-based products cannot be labeled with dairy names such as "cheese", "butter" or "milk". The ECJ based its ruling on Regulation (EU) 1308/2013, which establishes definitions and designations that may only be used for dairy product marketing. A list of exceptions for non-dairy products that may be labeled with reserved dairy names was established by Commission Decision 2010/791.

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 Geographical Indications and Traditional Specialties Guaranteed protected in the EU. 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 the end of 2020.

Wines and spirits are covered by specific legislation (Commission Regulation 2019/33 and Commission Regulation 2019/34) and do not fall within the scope of Regulation 1151/2012.

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

Section VIII. Copyright and/or Trademark Laws:

Trademarks

In the EU, trademarks can be registered at the national, regional or EU level. Commission Implementing Regulation 2018/626 sets out detailed rules on application procedures. Commission Delegated Regulation 2018/625 sets out procedural rules on opposition and revocation of EU trademarks. Trademarks registered at the national level are protected in the respective state. Applications for registering under the Community Trademark Register must be submitted to the Patent Office of Bulgaria (see contact information below under Annex I).
A trade mark can be registered also at the EU-level as a "Community Trade Mark" at the

Office for Harmonization in the Internal Market. A Community Trade Mark gives the owner protection in all EU Member States with one single registration. Additional information on EU trade mark criteria can be found on the EC's website and the previous OAA Sofia's FAIRS Narrative 2018 report for more information

Designation of Origin and Protected GIs

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

The EC's website provides guidance on how to register a PDO/PGI, or how to object to a PDO/PGI proposed for registration. Lists of protected names by country, product type, registered name and name applied for are available through the Commission's online "DOOR" (Database of Origin and Registration) database. Bulgaria's lists of protected food names is available here. Bulgaria has five registered TSG products (meat products), one application for PDO Product (honey) and two registered PGI products (rose oil and a meat product).

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

Section IX. Import Procedures:

Other Certification and Testing Requirements

An up-to-date overview of all U.S. authorities that issue the legally required certificates for export to the EU is available on our website. Also see the USDA EU website for additional information. Sanitary and phytosanitary (SPS) requirements are available on the EC's websites: DG Health and Consumers "International Affairs – Import Conditions" and DG Trade "Trade Helpdesk".

Union Customs Code

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

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

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

The EU uses the Combined Nomenclature (CN) for the customs classification of goods.
The EU's 2018 Tariff Schedule was published on October 31, 2017 in Official Journal L 282.

The EU's on-line "TARIC" customs database can be consulted to look up commodity codes and relevant import duties. Duties payable on goods imported into the EU/Bulgaria may include:

- Import duty (expressed as ad valorem tariffs or specific tariffs per unit weight/volume/number of pieces) – EU harmonized.
- Additional duties on flour and sugar (processed products) – EU harmonized.
- Entry price (fruit and vegetables) – EU harmonized.
- Excise duties (alcohol and tobacco) - not harmonized. A list of excise duties applicable on alcoholic beverages and tobacco can be found here.

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

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

The EU's 2020 Tariff Schedule was published on October 31, 2019 in the Official Journal. A list of Member State customs authorities can be found here.

As of October 1, 2019, business operators shall introduce all new applications electronically. More information is available on the EC's website. The customs value of a good is the CIF price at the European border derived from the product price found on the invoice and the transportation costs reflected in the airway bill or the bill of lading.

Customs Clearance

The EC's "Trade Helpdesk" offers a complete overview of documents needed for customs clearance.

Import Documentation and Process

Agricultural products are examined when they enter Bulgaria by the Bulgarian BIP. TRACES software has been applied since 2014 and a new TRACES NT system is applied starting December 14, 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. Please see the previous OAA Sofia's FAIRS Narrative 2018 report for more information.

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

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

Inspections, Temporary Entry and Samples
Please see OAA Sofia's previous 2018 FAIRS Country report for more information

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. 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.

Appendix I. Government Regulatory Agency Contacts:

Ministry of Agriculture and Food
Blvd. Hristo Botev 55 Sofia 1040
Tel.: (+359) 2-985-11858; Fax: (+359) 2-981-7955
Website: http://www.mzh.government.bg

Ministry of Health
Sqr. Sveta Nedelya 5, Sofia 1000
Tel.: (+359) 2-981-0111
E-mail: press@mh.gevernment.bg Website: http://mh.government.bg
Direction Public Health
Tel.: (+359) 2-9301-252
http://www.mh.government.bg/bg/kontakti/

Bulgarian Food Safety Agency
Bul. Pencho Slaveikov 15A, Sofia 1606
Tel.: (+359) 2-915-98-20 Fax: (+359) 2-954-9593
E-mail: bfsa@bfsa.gov Website: http://www.babh.government.bg/en/

Customs Agency, Ministry of Finance
Str. Rakovski 47, Sofia 1202
Tel.: (+359) 2-9594-210 Fax: (+359) 2-9859-4528
E-mail: pr@customs.bg Website: http://customs.bg

Ministry of Economy
Str. Slavyanska 8, Sofia 1000
Tel.: (+359) 2-940-71 Fax: (+359) 2-987-2190
E-mail: e-docs@mi.government.bg Website: http://www.mi.government.bg

National Drug Agency
8 Damyan Gruev Str., Sofia 1303
Tel.: (+359) 2-8903-555 Fax: (+359) 2-8903-434;
E-mail: bda@bda.bg; Website: http://en.bda.bg/

National Center of Public Health and Analyses
Acad. Ivan Evst. Geshov 15 blvd Sofia 1431
Tel.: (+359) 2-8056-444 Fax: (+359) 2-9541-211
E-mail: ncpha@ncpha.government.bg Website: http://ncpha.government.bg

Bulgarian Institute for Standardization
1797 Sofia, Lachezar Stanchev" Str. Nr 13
"Izgrev" Complex
Tel.: (+359) 2-8174-504 Fax: (+359) 2-8174-535
Website: http://www.bds-bg.org/en/contact/index.php

Executive Agency Bulgarian Accreditation Services
52 A "Dr. G. M. Dimitrov" Blvd. 1797 Sofia Bulgaria,
Tel/Fax: (+359) 2-8735-303
E-mail: ea_bas@abv.bg; office@nab-bas.bg Website: http://www.nab-bas.bg/bg/

Republic of Bulgarian Patent Office
Sofia 1040, 52 b
Dr. G.M. Dimitrov Blvd.
Tel. (359-2) 9701 + extension number,
Fax: *(359-2) 870 83 25
E-mail: bpo@bpo.bg; http://www.bpo.bg/

Major Bulgarian Trade Associations

American Chamber of Commerce in Bulgaria
Business Park Sofia, bld. 2, fl. 6. Sofia 1766 Bulgaria
Tel.: (+359) 2-9742 Fax: (+359) 2-9742-741
E-mail: amcham@amcham.bg Website: http://amcham.bg

Bulgarian Chamber of Commerce and Industry
1058 Sofia, 9 Iskar Street
Tel.: (+359) 2-811-740 Fax: (+359) 2-987-3209
E-mail: bcci@bcci.bg Website: http://www.bcci.bg

Bulgarian Industrial Association
1000 Sofia, 16-20 Alabin Street

Tel.: (+359) 2-932-0911 Fax: (+359) 2-987-2604
E-mail: office@bia-bg.com Website: http://www.bia-bg.bg

Bulgarian Association of Food and Beverage Industries
1606 Sofia, 29 Vladaiska Street
Tel.: (+359) 2-952-0989 Fax: (+359) 2-952-0989
E-mail: bafdi@mb.bia-bg.com Website: http://www.bia-bg.com/member/26

Food and Drink Bulgaria
1113 Sofia, 23 A Bl 56 Lulyakova Gradina Street
Tel: (+359) 889 202 265
E-mail: iana.ivanova@fooddrink.bg
Website: https://www.fooddrinkeurope.eu/member/food-drink-bulgaria/

Spirits Bulgaria
1618 Sofia, 40 Bratia Bukston Street, floor 5
Tel: (+359) 2 9566090
E-mail: office@spirits.bg
Website: http://www.spirits.bg/

Bulgarian 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:

European Union – Delegation of the European Union to the United States
2300 M Street
NW, Washington, DC 20037
Tel.: (+1) 202-862-9500 Fax: (+1) 202-429-1766

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