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# Bulgaria

# Food and Agricultural Import Regulations and Standards - Narrative

# FAIRS Country Report

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**Report Highlights:**

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Bulgaria, a member of the European Union (EU) since 2007, follows all EU directives and regulations pertaining to food safety, quality, and standards. The following report updates Attache Report and outlines the applicable legislation regarding U.S. food-product exports s to Bulgaria, particularly those rules that 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' *Attaché Report Food and Agricultural Import Regulations and Standards for the EU*. Additional updates and other relevant information can also be

found on the FAS Europe's website www.usda-eu.org.

**DISCLAIMER:** This report was prepared by U.S. Embassy Sofia's Office of Agricultural Affairs 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.

**Section I. Food Laws:**
Bulgaria joined the EU in 2007 and follows all available EU directives, regulations, and obligations. EU regulations are binding and directly applicable to the Member States. EU directives require Member States to harmonize national laws accordingly.

This report outlines applicable legislation regarding the exports of U.S. food products to Bulgaria, particularly those rules that differ from EU legislations and/or regulations. Exporters should be aware that when EU-wide legislation is incomplete, absent or there is room for interpretation, Bulgarian laws apply and imported product must meet existing Bulgarian requirements. For detailed information on EU legislation, please see:
*Attaché Report Food and Agricultural Import Regulations and Standards for the EU*, produced by FAS USEU in Brussels. This and other reports can also be accessed from the website: http://www.usda-eu.org/.

Food and beverage products originating in the United States do not require special Bulgarian permits and are not subject to special rules or regulations regarding retail sale in Bulgaria. However, all products must comply with the generally-applied rules and regulations for any food and beverage product sold within the EU. Bulgaria's food regulations apply to domestically produced and imported food products.

- **Bulgarian Food Law**

EU Regulation (EC) 178/2002 establishes general principles and objectives vis-à-vis Bulgaria's Food Law. Bulgaria's 2011 Food Law outlines the basic Bulgarian food and feed regulations. The Food Law is based in EU regulations and includes the traditional food safety aspects of detection and removal of physical, chemical, and biological hazards as well as other less conventional issues such as obesity prevention and food advertising rules. It applies to domestic and imported products. The Food Law establishes basic definitions, goals, and principles for food safety. It also defines procedural rules, coordination mechanisms between the different public administrations with responsibilities in official food control. It provides general food safety and health protection rules, regulates inspection, detention, and seizure rules of suspect food, and classifies breaches.

The Food Law was initially passed in October 1999 and has undergone numerous changes and amendment as a result of EU accession in 2007 and following harmonization with the EU legislation. The last changes were adopted in November 17, 2017.

The Food Law implementing regulations can be found at the Bulgarian Food Safety Agency (BFSA) website here. An English version is available upon request. Other major legislation which applies to food imports can be found in the Veterinary Medical Act (English version available upon request) where the latest changes were adopted on July 18, 2017. Imports of raw materials and foods of animal origin are regulated by this legislation (Art.24b Food Law).

Legislation which may have direct or indirect effect on food imports are:
The Plant Protection Law (last revision July 17, 2017);

The Feed Law (last revision July 17, 2017).

The following sources have a complete list of applicable EU and national legislation (English version Available upon request): EU and National Legislation, Documents, and Tariffs here, and National Legislation here.

Major revisions to the Food Law and Veterinary Medical Act began in 2016 but were interrupted by early Parliamentary elections. An updated Veterinary Medical Act was approved and implemented in July 2017 (see the link above). Additional draft amendments to the Food Law were also considered by the current Cabinet in December 2017. To date, these amendments are being reviewed following a public comment period. In addition, the Government of Bulgaria (GOB) is also considering other new legislation, chiefly the Agricultural and Food Supply Chain Act. The draft 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 approved by the Parliament in early 2018.

At the EU level, a new regulation on harmonized food controls, regulation 2017/625, will become applicable on December 14, 2019, repealing current regulation 882/2004. A "rapid alert system" for food and feed (RASSF) is in place to share cross-border information when risks to public health are detected in the food chain.

The EC is currently finalizing a "fitness check" of General Food Law regulation 178/2002, evaluating whether all key components of the regulation are still "fit for purpose". For more information, see the European Parliament's analysis: General Food Law – Introduction to the founding principles and the fitness check.

In March 2017, the European Commission launched a single web portal for stakeholder feedback on all initiatives throughout the law-making process. The "REFIT" program, launched in 2013, evaluates whether existing legislation is still fit for purpose and makes changes where needed. Information on the Better Regulation Package and the REFIT program is available on https://ec.europa.eu/info/law/law-making-process/better-regulation-why-and-how_en.

- **Relevant Competent Authorities**

Bulgaria has a central system for testing and controlling the feed and food chain. The GOB has total oversight over the control carried out in customs, and on monitoring and sampling plans throughout the food and feed chain. Sampling plans are based on risk assessment and sampling is primarily done during production, wholesale, and processing.

The Ministry of Agriculture and Foods controls agricultural product imports intended for human consumption, through BFSA. It also controls imports of animal feed/ingredients and live animals not intended for direct human consumption. BFSA was established in 2011 through a major reform by uniting three executive agencies, including the former Plant Protection and Phytosanitary Agency, and the Veterinary Medical Service (both under the Ministry of Agriculture), with the Food Hygiene Agency (formerly under the Ministry of Health).

Food safety is the responsibility of BFSA, which coordinates the food and feed chain control. Prior to

2016, BFSA oversaw the Bulgarian Risk Assessment Center, although the July 2016 Risk Assessment Center Act established it as an independent agency under direct supervision of the Ministry of Agriculture. It is responsible for risk assessment and management, as well as making scientific recommendations for policy decisions. It works directly with the European Food Safety Agency.

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) (Art.28/ Food Law) Law on the Establishment of Bulgarian Food Safety Agency – published in Official Gazette #8/January 25, 2011, last revision on July 20, 2017. The BFSA has well developed website which makes an effort to list all regulations, documents, certificates, tariffs, registers, and any other relevant information, including links to the EU regulations. Most information is available in Bulgarian while the references to the EU regulations are in English. Contact information for BFSA can be found in Appendix I.

**Section II. Labeling Requirements:**

On December 13, 2014, general rules on the labeling, presentation and advertising of foodstuffs were established by Food Information to Consumers (FIC) Regulation (EC) 1169/2011. The regulation applies to all pre-packaged food and drink products marketed in the EU, including those imported from third countries. The mandatory nutrition declaration requirement introduced by the FIC regulation became applicable on December 13, 2016. U.S. standard labeling does not fully comply with EU labeling requirements.

For detailed information on the EU-harmonized labeling legislation, please see the GAIN report "New EU Food Labeling Rules Published", supplemented by GAIN report "How to Comply with the EU's New Food Labeling Rules". http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/eu-labeling-requirements/.

Bulgaria applies EU-harmonized legislation to:

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

The current draft Food Law amendments include new provisions for labeling which would more fully harmonize GOB regulations with the EU. However, national exceptions are likely to be included when allowed. FIC Regulation allows EU Member States to deviate from EU rules. Article 39 of the FIC regulation sets conditions for Member States to adopt additional mandatory national measures, including measures for country of origin labeling. The use of stickers in the Bulgarian language attached to the original label of imported products and/or use of Bulgarian language on the original label are currently being debated. Another point of discussion pertains to Bulgarian labeling for small-sized packaged foods products.

The FIC Regulation exempts alcoholic beverages from mandatory nutritional labeling and ingredient

listing, but Article 41 allows Member States to maintain national rules on the listing of ingredients until EU-harmonized provisions are adopted. At present Bulgaria applies nutritional labeling for alcoholic beverages on a voluntary basis.

**General Labeling Requirements**

In Bulgaria, Chapter III of the Food Law presents requirements about labeling of food products. http://babh.government.bg/uploads/File/Dokumenti_naredbi/Naredba_etiketirane_na_hrani.pdf

There is also Regulation of Food Labeling and Food Presentation (December 13, 2014) which introduced Regulation (EC) 1169/2011 labeling requirements in local legislation: http://www.babh.government.bg/userfiles/files/KH/Doc/Ordinance~Labeling-foods.pdf

Mandatory labeling information includes:

- Product name
- List of ingredients and quantity of certain ingredients or category of ingredients
- Allergens listed in Annex II
- Nutrition declaration
- Alcoholic content when it is over 1.2% in volume
- Net weight in packaged products
- Expiration date
- Storage and use conditions
- Use instructions when essential to make a proper use the product
- Company identification: name and address of the manufacturer or packer or seller established
- Within the European Union
- Batch information
- Country of Origin

Labels should not mislead or confuse the consumer about the nature of the product, its identity, qualities, composition, quantity shelf-life, origin, or type of processing. It cannot attribute properties not offered by the product, especially regarding health claims.

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 their 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 source of vegetable oils and fats.

Quantitative Ingredients Declaration (QUID)

Article 22 of the FIC regulation requires the indication of the quantity of an ingredient or category of ingredients in the following cases:

- Where the ingredient or category of ingredients appears in the name of the food or is usually
- associated with that name by the consumer;
- Where the ingredient or category of ingredients is emphasized on the labeling in words, pictures or graphics;
- Where the ingredient or category of ingredients is essential to characterize a foodstuff and to
- distinguish it from similar products;

The QUID declaration, expressed as a percentage, must appear either in or immediately next to the name of the food or in the list of ingredients. Annex VIII to the FIC regulation sets out the technical rules and exemptions from the QUID requirement. On November 21, 2017, the EC published updated guidelines on QUID requirements in the Official Journal C 393. The guidelines explain when QIUD is mandatory, and which products are exempt from QUID.

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. Part D of the same Annex sets out rules for the indication of flavorings, smoke flavorings and the use of the term "natural."

Allergen Labeling

Article 21 of the FIC regulation stipulates that each product or substance capable of inducing an allergic reaction must be indicated in the list of ingredients with reference to the name of the substance or product as listed in Annex II to the FIC regulation. Following a public consultation launched in November 2014, the Commission published an update of its guidance document on allergen labeling on July 13, 2017.

Country of Origin Labeling

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

Regulation 1169/2011 extended the mandatory country of origin labeling to meat listed in Annex XI (swine, sheep and goat, poultry) and when the country of origin of a food is not the same as its primary ingredient.

Language Requirements

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

In order to avoid non-compliance with the new labeling rules, translations of mandatory information must be accurate. Automated online translation tools may generate incorrect translations and should not be used unless edited. The new 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 also visible.

Specific rules on the use of stickers to provide mandatory labeling information are not included in FIC regulation 1169/2011. On this issue, the EC refers to point 2.1.1 of their Questions and Answers on the Application of Regulation 1169/2011 document which says that
"labels should not be easily removable so as to jeopardize the availability or the accessibility of the mandatory food information to the consumer."

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. All elements of the mandatory nutrition declaration should be in the same field of vision on the food label or package.

Mandatory content of the nutrition declaration:

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

Nutrition declarations per portion or per consumption unit, in addition to the declaration per 100 grams or milliliters are allowed provided that the number of portions/consumption units is clearly indicated on the package.

Detailed rules on the presentation of the nutrition declaration are set out in Annex XV to the FIC regulation. Annex V to the FIC regulation establishes a list of products that are exempted from the mandatory nutrition declaration requirement.

## Health /Nutritional Claims Labeling

*Nutrition Claims*

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

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.

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.

## Alcoholic Beverages

Alcoholic beverages containing more than 1.2 percent of alcohol by volume are exempted from the obligation to bear a nutrition declaration and a list of ingredients. The FIC regulation required the EC to prepare a report by end 2014 examining whether the exemption for alcoholic beverages should be maintained. On March 13, 2017, the Commission finally published its long awaited report. Following the conclusions of the report, the Commission gave the EU alcoholic beverage industry one year to present a self-regulatory proposal covering all beverages (beer, wines and spirits). If the Commission considers the proposed self-regulatory labeling scheme unsatisfactory, it will launch an impact assessment to review further policy options. At present, the brewing industry in Bulgaria makes nutritional declarations and list of ingredients on beer on a voluntary basis.

Allergen labeling is compulsory on all alcoholic beverages. On beverages containing more than 1.2 percent of alcohol by volume (excluding wines), the actual alcoholic strength by volume must be indicated in accordance with Annex XII to FIC regulation 1169/2011. The alcoholic strength must be indicated by a figure with maximum one decimal place followed by the symbol "% vol." The alcoholic strength must be given in the same field of vision as the product name and the net quantity. For wines, rules for the indication of the alcoholic strength are set out in specific legislation.

## 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. Labeling requirements established in product-specific legislation complement the horizontal rules set out in FIC Regulation 1169/2011. For example, EU wine regulations do not include provisions on allergen labeling. This means that wine labels not only have to comply with the requirements set out in wine regulation 607/2009 but also with the allergen labeling requirement set out in FIC regulation 1169/2011.

For labeling rules on gluten free foods, trans-fats, warnings on labels and for minimum front size on labels, please, see:
*Attaché Report GAIN E17080 Food and Agricultural Import Regulations and Standards for the EU*.

**Section III. Packaging and Container Regulations:**

- Size and Content

Bulgaria applies EU-harmonized legislation to packaging. There are two EU Directives related to the making-up by weight or by volume of certain prepackaged products (Council Directive 76/211/EEC) and laying down rules on nominal quantities for pre-packed products (Directive 2007/45/EC) that were transposed into Bulgarian's National Law Chapter 3 of the Food Law.

The maximum tolerable margin of error between the actual content and the quantity indicated on the label, and methods to check this are in Council Directive 76/211/EEC, as amended. Directive 2007/45/EC abolished mandatory pack sizes at both EU and national levels. The Directive frees sizes for all prepackaged products except wine and spirits, and coffee. Mandatory nominal quantities for wines and spirits are included in the Annex to Directive 2007/45/EC (http://ec.europa.eu/growth/single-market/goods/building-blocks/legal-metrology/).

- Packaging Waste Management

Bulgaria as a Member State is required to take measures to reduce packaging waste and must introduce systems for reuse, recovery and recycling of packaging materials. Council Directive 94/62/EC harmonizes national measures concerning the management of packaging and packaging waste and its impact on the environment. An overview of current EU legislation applicable to packaging and packaging waste is available on the ECs website

- Packaging and Materials Which Contact with Foods

Materials used in food packaging must comply with Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food requirement as well as with the established in Regulation (UE) 10/2011 on plastic materials and articles intended to come into contact with food, Regulation (EC) 282/2008 on recycled plastic materials in contact with food and Regulation (EC) 2023/2006 on good manufacturing practices for materials and articles intended to come into contact with food.

Commission Implementing Regulation 321/2011 bans the use of Bisphenol A in plastic infant feeding bottles.

On November 28, 2017, the European Commission published a "roadmap" to evaluate whether regulation 1935/2004 is still fit for purpose and delivers as expected. The evaluation is scheduled to be finalized mid-2019.

A summary of EU and Bulgarian legislation as well as guidance documents and contact information for Bulgaria with regard to the submission of applications for authorization can be found here:

http://ec.europa.eu/food/safety/chemical_safety/food_contact_materials_en.

**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. Regulation 1331/2008 establishes a common authorization procedure for food additives, food enzymes and food flavorings based on safety evaluations carried out by the European Food Safety Agency (EFSA). Commission Implementing Regulation 234/2011 explains in detail how applications to update the EU positive lists should be drafted (content, data requirements and presentation). EFSA then verifies the suitability of the data.

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 I to regulation 1333/2088 lists the definitions of 26 different categories of food additives. Only additives included in the EU's positive list are authorized under specific conditions. Flour beaching agents like chlorine, bromates, and peroxides are not allowed in the EU.

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.

In July 2016, EFSA completed a re-evaluation of approved food colors. As a result, Annex V to Regulation 1333/2008 was amended to introduce mandatory labeling information for six food colors: Quinoline Yellow (E104), Sunset Yellow (E110), Ponceau 4R (E124), Tartrazine E102), Azorubine/Carmoisine (E122) and Allura Red AC (E129).

Foods containing these colors have to be labeled "may have an adverse effect on activity and attention in children". Commission Regulation 232/2012 lowered the limits for food colors Quinoline Yellow (E104), Sunset Yellow (E110) and Ponceau 4R (E124). Food color Red 2G (E 128) was removed from the EU's positive list.

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. From the list of food additives under re-evaluation, EFSA has reevaluated 150 individual food additives (as of October, 2017) and still needs to reevaluate 166 food additives before December 31, 2020.

The Commission's food additives database together with its user guide provides detailed information on the different food additives allowed in the EU.
https://ec.europa.eu/food/safety/food_improvement_agents/additives_en.

Flavorings

Regulation 1334/2008 on flavorings and certain food ingredients with flavoring properties sets specific rules for the use of the term "natural". Annex I establishes a list of substances that are authorized for use in the EU. The authorized uses of flavoring substances are listed according to the category of food to which they may be added and are also available in an on-line database allowing consumers, food businesses, and regulatory authorities to verify which flavoring substances are authorized.

The procedure for the safety assessment and the authorization of smoke flavorings intended for use in or on foods is established in Regulation 2065/2003. 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. Specific labeling requirements are set in Articles 10-13 of Regulation 1332/2008.

Processing Aids

Processing aids are subject to national legislation. Requests should be addressed to the Bulgarian Food Safety Agency.

EU harmonized rules exist only for certain categories of processing aids: a list of extraction solvents allowed in the production of foodstuffs and food ingredients, along with their conditions of use has been established in Council Directive 2009/32/EC.

**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 rules for the authorization of plant protection products (PPPs). PPPs (also referred to as 'pesticides') contain at least one approved active substance. Only PPPs containing active substances included in the list of approved active substances as established in Commission implementing Regulation 540/2011 may be authorized for use in the EU.

Before any PPP can be placed on the market or used, it must be authorized 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:
http://ec.europa.eu/food/plant/pesticides/sustainable_use_pesticides/index_en.htm.
For application for pesticide registration in Bulgaria the contact is the BFSA.

- Endocrine Disruptors

Endocrine disruptors (EDs) refer to substances with the potential to alter and cause unintentional adverse health effects to the endocrine systems of humans and wildlife. Both the Plant Protection Products Regulation 1107/2009 (Pesticides) and the Biocidal Products Regulation 528/2012 (Biocides) introduced "endocrine disrupting properties" as one of the categories of hazard-based cut-off criteria. This would allow the EU to ban certain products from the market based on hazard identification rather than risk assessment without taking exposure into account.

On June 15, 2016, the EC presented two draft measures outlining scientific criteria to identify EDs under the Plant Protection Products Regulation (1107/2009) and Biocidal Products Regulation (528/2012), using the World Health Organization definition for EDs as a basis. On October 4, 2017, the European Parliament rejected the Commission's proposal for scientific criteria to identify EDs under the Plant Protection Regulation which means that interim criteria continue to apply.
Commission Delegated Regulation 2017/2100, adopted on September 4, 2017, sets scientific criteria for the determination of EDs in biocidal products.

- 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. MRLs apply to 315 fresh products and to the same products after processing. A general default MRL of 0.01 mg/kg applies where a pesticide is not specifically mentioned.

See http://ec.europa.eu/food/plant/pesticides/max_residue_levels_en and the list of authorized active substances or pesticide-MRL combinations online database.

On June 17, 2016, the EC notified a document to the WTO explaining the on-going review of MRLs (last updated June 12, 2017) in the EU to non-EU countries, highlighting the active substances and relevant MRLs that are scheduled to be reviewed in the near future.

Bulgarian National Pesticides Plan can be found here.

- Import tolerance

Tolerance for pesticide residues was harmonized in the EU in 2008. Bulgaria adheres to EU-

harmonized legislation on pesticides and contaminants.

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.

On November 13, 2017, the EC launched its public consultation (open until February 12, 2018) and stakeholder survey (open until December 31, 2017) on the "REFIT" evaluation of EU legislation on pesticides and pesticides residues. Please, see:
*Attaché Report GAIN E17080 Food and Agricultural Import Regulations and Standards for the EU* for more details.

Contaminants

Bulgaria applies EU-harmonized legislation regarding food contaminants. Please, consult the USEU website section on contaminants and http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/contaminants/

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 for: dried figs and dried apricots or all dried fruit, mixtures of spices, sunflower and pumpkin seeds, pistachios, hazelnuts or all tree nuts, liquorice placed on the market for the final consumer, herbs and herbal teas, and cocoa powder. Please, see GAIN report: "Additional EU Maximum Levels for Ochratoxin A on the Horizon".

In November 2017, the EU adopted a Regulation 2017/2158 establishing benchmark levels to reduce the presence of acrylamide in food. The new regulation requires that food business operators apply mandatory measures to reduce the presence of acrylamide, proportionate to the size and nature of their establishment.

- Official Controls of Maximum Levels in Foodstuffs

The following regulations concern the sampling methods and methods of analysis for the official controls of the levels of the different contaminants. Annex I describes the methods of sampling; Annex II concerns the sample preparation and the performance criteria for the methods of analysis:

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

Private Industry Standards

While the official standards are set by the public administration, the large majority of food retailers require certification of good agricultural practices. The private certification schemes include not only stricter limits for MRL but also with other additional requirement. The most widely used schemes in Bulgaria include Globalgap, BRC, and IFS.

Aflatoxin in Tree Nuts

In April 2015, the EU approved the pre-export checks (PEC) program for U.S. almonds. U.S. almonds were included in the Annex to Commission Implementing Regulation (EU) 2015/949 which lists all EU-approved Pre-export Check programs. The acceptance of the U.S. program reflects the EU's recognition of aflatoxin controls performed at U.S. origin in line with Article 23 of the EU Regulation on Official Food and Feed Controls (Regulation (EC) No 882/2004). The USDA Agricultural Marketing Service began issuing PEC almond certificates on August 1, 2015. Following the publication of Commission Implementing Regulation (EU) 2017/1269 on July 14, 2017, the U.S. pre-export program for peanuts 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 and Bulgaria as a Member State now tests 10 percent of all incoming shipments.

Residues in Animals and Animal Product

Please, see:
http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/residue-plans/

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.

Directive 96/23/EC states that any third country exporting to the EU must submit a plan setting out its guarantees on the monitoring of the groups of residues and substances referred to in Annex I to Council Directive 96/23/EC. Furthermore, a split system has to be in place guaranteeing that animals have not been treated with growth promotants if their products will be exported to the EU.

**Section VI. Other Regulations and Requirements:**

Certification and Documentation Requirements:
http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/

An overview of legally required certificates in the EU and references to the U.S. authorities issuing these certificates is available on http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/.

Composite Products

U.S. exports of "composite products" are continuing to be challenging due to burdensome certification requirements introduced in a 2012 EC Regulation. Composite products are defined as foodstuffs intended for human consumption that contain processed products of animal origin and ingredients of plant origin. Composite products include a wide variety of products, including cheesecakes, high protein food supplements, pizza, and lasagnas. While the U.S. is eligible to ship hormone-free meat, dairy products, egg products, and fishery products separately, it is often no longer possible to ship the composite products that combine these eligible ingredients.

All composite products containing a processed meat product are subject to a veterinary check. Generally speaking, composite products that contain more than 50 percent of animal origin products also require a certificate, and there are certification requirements concerning the heat treatment for all dairy products.

The EU has created a model health certificate for imports of composite products, which was implemented in 2012. A detailed "Product Decision Tree" to clarify the scope of the legislation was made available by the EC in 2013. This guidance greatly expanded the number and types of products affected by the legislation. The decision tree is included in the further guidance that was developed and published in 2015 to address a wide range of implementation questions related to the import and transit of composite products.

For more information see http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/.

Inspections

BFSA is responsible for carrying out inspections in the food and feed chain. Products can be checked at import or at all further stages of marketing. Sampling plans are based on risk assessment and it is primarily done at the wholesale and the processing level.

Infringements of EU food and feed legislation are reported through RASFF via the RASFF portal. Repeated non-compliance may lead to suspension of imports or special import conditions for products from the third country concerned, applicable on the entire EU territory.

Criteria for laboratories conducting food controls have been harmonized but it is the Member States' responsibility to designate laboratories that are allowed to perform analyses. In Bulgaria, BFSA labs in charge of official import control can be found here.

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.

Bulgaria has eight BIPs which are listed as approved BIPs for veterinary control. Seven BIPs are on roads and one is an airport. Three BIPs are approved for live animals checks (Kalotina, Kapitan

Andreevo and Sofia). Full list of Bulgarian BIPs can be found here.

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 that are not subject to veterinary checks.

European Parliament and Council Regulation 854/2004 establishes specific rules for the organization of official controls on products of animal origin.

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

Product samples destined for human consumption have to comply with the food regulations applicable in the EU. In order to send product samples to commercial trade shows, it is advised to take contact with the FAS Sofia for trade shows in Bulgaria.

Inspection fees for non-animal origin products are not harmonized in the EU. The list of all inspection fees charged by the BFSA can be found here.

An overview of sanitary and phytosanitary requirements can be found here:
DG Health and Consumers "International Affairs – Import Conditions" and DG Trade "Trade Helpdesk".

**Section VII. Other Specific Standards:**

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

Genetically Modified Foods and Feeds

Bulgaria has a centralized system for testing and controlling the unauthorized presence of genetically engineered (GE) products in the feed and food chains. The BFSA is responsible for testing at international borders and/or ports of entry, monitoring, and sampling plans throughout the food and feed chain. Sampling plans are based on risk assessment. Sampling is done at the production and the processing level.

A food containing an GE ingredient can be released on the market only after EU approval is granted based on Regulation 1829/2003 (articles 12-13) (Art.23/e Food Law). These rules apply to products that have undergone varying degrees of processing. The regulation does not require labeling of food products that are not food ingredients, such as processing aids.

Meat, milk or eggs obtained from animals fed with GE feed or treated with GE medicinal products do not require labeling. The traceability rules require all business operators to transmit and retain information on GE products in order to identify both the supplier and the buyer of the GE product.

Currently, there is a debate regarding the new Food Law and if it should introduce mandatory labeling for meat, dairy, or eggs derived from animals fed with GE feeds.

Each individual GE event must be approved before it can be used in food and feed. The EU register of authorized GE event can be consulted on the European Commission's website at http://ec.europa.eu/food/plant/gmo/eu_register/index_en.htm. All foods containing GE products or containing ingredients produced from GE must be labeled, even if they no longer contain detectable traces of GE. The labeling requirement does 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 using the following wording:

- Where the food consists of more than one ingredient, the words "genetically modified" or "produced from genetically modified [name of ingredient]" must follow in brackets immediately after the ingredient concerned. A compound ingredient with a GM component should be labeled "contains [name of ingredient] produced from genetically modified [name of organism]."

- Where the ingredient is designated by the name of a category (e.g. vegetable oil), the words "contains genetically modified [name of organism]" or "contains [name of ingredient] produced from genetically modified [name of organism]" must be used.

- Where there is no list of ingredients, the words "genetically modified" or "produced from genetically modified [name of ingredient]" must appear clearly in the labeling.
Please, consult https://ec.europa.eu/food/plant/gmo/traceability_labelling_en

The Bulgarian Food Law has been changed in 2010 to ban use of GE ingredients and GE products in manufacturing of baby foods regardless of their safety evaluation (Art. 4a/4 for the Food Law).

In terms of labeling, the exact amount of the GE content, and the GE event unique code (Art 10/1 Food Law) should be placed on the label. According to art.4/6 of Regulation 1830/2003 of the EU Parliament and Council of September 22, 2003 and Directive 2001/18, the font used should be twice bigger and in color and fond different than that of the other components of the label. If the product consists of or contains GE above the threshold set up in Directive 1830/2003, the GE type, quantity and the unique code and the words "Contains GMO" should be written on the label in size not less than 25 percent of the package in capital letters and in contrasting color to the rest of the package.

Advertising of GE food or foods containing GE ingredients or products is not allowed when children are used for the presentation of the product or when children consume such products (Art.9a/Food Law).

If an applicant would like to request an approval for a new food containing GE ingredients, this request should be accompanied by a risk assessment study with the effects on human health and the environment (Art.23/b Food Law).

Novel Foods

*New Rules as of January 1, 2018*

A new EU framework regulation 2015/2283 on Novel Foods was adopted in November 2015 and published in Official Journal L 327 on December 11, 2015. Most provisions of the new Novel Foods Regulation become applicable on January 1, 2018. Main elements of the new Novel Foods Regulation include:

*Definition*: A novel food is defined as food that has been not 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 new regulation. The definition also covers food produced with "non-traditional breeding techniques."

*Authorization procedure*: Under the new centralized authorization, procedure authorizations would take up to 18 months compared to 42 months under the current rules. Applications for authorizations must be submitted to the EC and EFSA will carry out the risk assessments. In November 2017, the EFSA application helpdesk published an overview highlighting the main steps of the authorization procedure.

*EFSA Risk Assessments*: The new regulation sets out the risk assessment process by EFSA and introduces deadlines. On November 10, 2016, EFSA published guidance documents on novel foods and traditional food from third countries explaining in detail what kind of information applicants need to provide and how it should be presented.

*EU Positive List:* The new regulation provides for the establishment of EU list of novel foods. On October 4, 2017, the Commission published a draft Implementing Regulation establishing the positive list which is expected to be adopted by January 1, 2018.

The positive list establishes:

- The name of the authorized novel food
- Conditions under which the novel food may be used
- Additional specific labelling requirements

Experts belonging to Bulgarian Food Safety Agency participate in the EU decision making process by attending the discussions in the Novel Food Working Group. New authorizations can be submitted to Bulgarian competent authorities (BFSA).

Article 23a of the Food Law introduces the procedure for approval and release on the market of new ingredients and substances as novel foods. A special Commission on Novel and GE Foods to the Minister of Health accepts requests for approval for such foods on the market. The Commission has an advisory role and consists of 15 scientists appointed for 4 years.

Food from Clones

At the moment, foods derived from animal clones falls under the scope of Novel Food Regulation 258/97. Under this regulation, food produced by "new breeding practices" needs a pre-market approval based on a risk assessment. 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.

Engineered Nanomaterials

Engineered nanomaterials require a novel food authorization before being used in food. The definition currently set out in the Food Information to Consumers Regulation 1169/2011 is transferred to the new Novel Foods Regulation. The Commission is expected to update the definition early 2018.

Nanotechnology

Currently, EU legislation that explicitly addresses nanomaterials in food includes the following regulations:

FIC Regulation 1169/2011 defines engineered nanomaterials as "any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale." The current definition uses size as the only defining criterion and does not include a threshold value. The presence of engineered nanomaterials in food products must be clearly indicated on the label. The name of such ingredients must be followed by the word "nano" in brackets (Art. 18 of Regulation 1169/2011).

The definition of engineered nanomaterials is set out in the new Novel Foods Regulation but will be updated in early 2018.

Food Additives**:** Regulation 1333/2008 states that when "there is a significant change in the production methods or in the starting materials used" for food additives already on the EU list of approved food additives, "or there is a change in particle size, for example through nanotechnology, the food additive prepared by those new methods or materials shall be considered as a different additive and a new entry in the Community lists or a change in the specifications shall be required before it can be placed on the market."

Food Contact materials – Regulation 450/2009 on active and intelligent packaging states that "new technologies to engineer substances with different chemical and physical properties than the same substances at a larger scale, for example nanoparticles, should be assessed at a case-by-case basis as regards their risk until more information is known about such new technology."

Fortified Foods

European Parliament and Council Regulation 1925/2006 established an EU-wide regulatory framework

for the addition of vitamins and minerals and of certain other substances such as herbal extracts to foods. It lists the vitamins and minerals that may be added to foods and sets criteria for setting maximum and minimum levels.

A EC proposal setting harmonized maximum and minimum permitted levels of vitamins and minerals in foods and food supplements is already nine years overdue (original deadline set by Regulation 1925/2006 was January 2009). Vitamins and minerals must be expressed as a percentage of the "Reference Intakes" listed in Annex III to the "Food Information to Consumers" regulation 1169/2011 (see also Section V "Nutrition Declaration." The use of vitamins and minerals not included in the annexes to Regulation 1925/2006 is not allowed.

A "Community Register" on the addition of vitamins and minerals and of certain other substances is available on the European Commission's website here.

## Dietetic or Special Use Foods

Regulation 609/2013 regulates 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. Regulation 609/2013 became applicable on July 20, 2016. Under the new rules, pictures of infants are no longer allowed on labels. Foods that no longer fall within the scope of Regulation 609/2013 will be regarded as regular foods.

Commission Delegated Regulation 2016/128 sets out specific requirements for food for special medical purposes. The EFSA has published scientific and technical guidance to help the EC apply new rules on foods for special medical purposes.

Commission Delegated Regulation 2017/1798 sets out new rules for "total diet replacements for weight control". The new rules will become applicable on October 27, 2022. Please see GAIN report "The Skinny on New EU Rules for Weight Loss Products."

New rules on the reduction of acrylamide levels in food, set out in Commission Regulation 2017/2158, will become applicable on April 11, 2018. The new rules will also apply to baby food and processed cereal-based food intended for infants and young children. Commission Delegated Regulation 2016/217 sets out specific compositional and information requirements for infant-formula and follow-on formula.

## Organic Foods

Since June 1, 2012, the EU and the United States have their respective countries' certified organic products mutually recognized. All products traded under the agreement must be accompanied by an organic export certificate. The Bulgarian Food Law contains special provisions regarding organic foods in Article 6.

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 EC proposal for a new framework regulation, launched in

2014, will be formally adopted early 2018. Please see GAIN "New EU Organic Regulations for Early 2018."

The term "organic" and all its derivatives or diminutives such as "bio" and "eco" may be used only to label products that comply with EU organic production rules and if at least 95 percent of the ingredients of agricultural origin are organic. The Annex to Regulation 834/2007 lists the term "organic" in all the official EU languages. For more information see http://ec.europa.eu/agriculture/organic/index_en.

On July 1, 2012, the use of the EU organic logo became mandatory on all pre-packaged organic products produced in the EU. Organic products imported from third countries may carry the EU organic logo if they comply with the EU production rules. When the EU organic logo appears on the label, the indication of the place of farming is required.

Commission Implementing Regulation 2016/1842 published on October 19, 2016, sets new rules for the certification of EU organic food imports. Since October 19, 2017, only certificates initiated through the EU's Trade Control and Expert System (TRACES) are valid.

*Organic Wine*: Commission Implementing Regulation 203/2012, applicable since August 1, 2012, sets out specific rules for the production and labeling of organic wine. Only wines produced in accordance with this regulation qualify as "organic wine" and can carry the EU organic logo. Labeling wine as "made from organic grapes" is no longer allowed in the EU which means that U.S. wines labeled as such cannot be imported into the EU. Sorbic acid and desulfurication are not allowed and the maximum sulfite content may not exceed 100 mg per liter for red wine (150 mg per liter for conventional) and 150 mg per liter for white/rosé wines (200 mg per liter for conventional). In the United States, the addition of sulfites is not allowed in organic wines. Commission Implementing Regulation 508/2012 only authorizes imports of U.S. wines that are certified to comply with the EU's organic wine rules.

Wine, Beer and Other Alcoholic Beverages

*Wine:* Commission Regulation 607/2009, as amended by Commission Implementing 1185/2012, lays down detailed rules on protected designations of origin and geographical indications, traditional terms and labeling.

Wine must also comply with the allergen labeling rules established by FIC Regulation 1169/2011. For detailed information on the EU's wine legislation see GAIN report "EU Wine Policy" and the EC's website http://ec.europa.eu/agriculture/wine/legislation/index_en.htm.

*US-EU Wine Agreement:* In March 2006, the U.S. and the EU and the U.S. signed the "Agreement between the United States and the European Community on Trade in Wine". The Agreement covers wine with an actual alcohol content of not less than 7 percent and not more than 22 percent. All U.S. wine imports must be accompanied by certification and analysis documentation using the format specified in Annex III (a) to the Agreement. More information on the simplified EU import certificate form can be obtained from the Alcohol and Tobacco Tax and Trade Bureau at http://www.ttb.gov/agreements/us_ec_wine_agreement.shtml. The Agreement's "Protocol on Wine Labeling" sets conditions for the use of optional particulars on wine labels. Commission Regulation 1416/2006 concerns the protection of U.S. names of origin in the EU.

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

*Spirits:* European Parliament and Council Regulation 110/2008 lays down general rules on the definition, description and presentation of spirit drinks. Commission Implementing Regulation 716/2013 lays down rules for the application of Regulation 110/2008 as regards the use of compound terms and geographical indications of the spirit drinks. This regulation prohibits the use of the term "spirit drink" as part of a compound term.

In December 2016, the EC presented a proposal to replace the current spirit drinks regulation 110/2008 with a new one. If adopted, the new regulation would introduce new procedures for the management (applications, registrations, objections) of geographical indications. Annex III of the existing regulation listing all the spirit drinks with a geographical indication would be deleted and replaced with a publicly accessible updated electronic register of spirit drinks with a protected geographical indication.

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

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

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

*Commission Report on Labeling of Alcoholic Beverages:* In March 2017, the EC presented a report assessing whether nutrition labeling and ingredient listing should be mandatory for alcoholic beverages. The FIC Regulation 1169/2011 currently exempts alcoholic beverages from such labeling. Following the conclusions of the report, the Commission invited the EU alcoholic beverages industry to come forward with a self-regulatory proposal covering all sectors (wine, beer, spirit drinks). For more information see:
GAIN report "European Commission Report on Labeling of Alcoholic Beverages."

Vertical Legislation and Product – Specific Legislation

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

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

*Honey***:** On May 15, 2014, the EU adopted Directive 2014/63/EU amending Directive 2001/110/EC relating to honey. It defines pollen as a natural constituent of honey and should not be considered to

be an ingredient of honey. This means that GM pollen present as a quantity of more than 0.9 percent of the honey (not the pollen) would need to be labeled as such. Since pollen only forms around 0.5 percent of any batch of honey, it will never exceed the GM labeling threshold.

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

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. Key aspects in the marketing of food supplements such as minimum and maximum levels of vitamins and minerals or the use of other substances such as botanical extracts remain the competence of the Member States. Directive 2002/46 defines food supplements as food which means that all exports of food supplements must not only comply with Directive 2002/46 but also with horizontal rules applicable to all foods including rules on additives, novel foods, hygiene, contaminants and GE. U.S. exporters of whey protein supplements should work with their importers to determine whether products should be accompanied by a certificate for processed dairy products or one for composite products. For more information see GAIN "Certification and Labeling of EU Whey Protein Supplements."

Marketing food supplements in the EU is a complex issue. GAIN "Exporting Food Supplements to the EU" provides detailed information on marketing food supplements in the EU.

In Bulgaria, the new Food law is likely to contain special provisions regarding marketing of food supplements. This also includes a new set of requirements for online marketing and sales of food supplements which has not been regulated to date and which is not harmonized on the EU level.

Frozen Foods

Council Directive 89/108/EEC sets rules for quick-frozen foodstuffs and for their packaging and labeling, and was transposed into national law through the Food Law. Quick-frozen foodstuffs sold to the final consumer should carry the following additional labeling indications: the product name with the indication "quick-frozen"; the date of minimum shelf life; the period during which the purchaser may store the product; the storage temperature and/or type of storage equipment required; batch identification; a clear indication of the type "do not re-freeze after defrosting". At the EU-level, the general rules on the labeling, presentation, and advertising of foods products were established under FIC Regulation (EC) 1169/2011.

Food Irradiation

Framework Directive 1999/2/EC outlines the marketing, labeling, import and control procedures and technical aspects of food irradiation. Irradiated foods or foods containing irradiated ingredients must be labeled "irradiated" or "treated with ionizing radiation." Please see:

http://ec.europa.eu/food/safety/biosafety/irradiation_en.

On September 5, 2017, the EC launched an evaluation of the current rules related to the irradiation of food. As part of this evaluation, a 12 week open public consultation is to be carried out by the end of 2017. The evaluation is expected to be finalized in the fourth quarter of 2018 and may result in a new legislative proposal.

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 the use of irradiation in foods.

Special Use Foods

On July 20, 2016, the EU's new "foods for specific groups" rules set out in European Parliament and Council Regulation 609/2013 became applicable. This regulation repeals all the directives on "foodstuffs intended for particular nutritional uses" (PARNUTS). The scope of the new regulation is limited to infant formula, follow-on formula, processed cereal-based food and baby food, food for special medical purposes and total diet replacement for weight control. Under the new rules, pictures of infants are no longer allowed on the packaging and no text or pictures may idealize the use of formula.

Foods that no longer fall within the scope of Regulation 609/2013, such as for example meal replacements and low calorie cereal bars will be regarded as "normal" foods and must comply with the FIC Regulation 1169/2011, Nutrition and Health Claims Regulation 1924/2006 and Fortified Foods Regulation 1925/2006. Rules on gluten-free foods were transferred from the PARNUTS directive to the FIC Regulation 1169/2011.

As a general rule, labeling requirements set out in the FIC regulation also apply to food categories covered under regulation 609/2013. However, given the specific nature of the products covered, regulation 609/2013 introduces additional labeling requirements and derogations from the FIC regulation.

For detailed information on the new dietetic food rules see GAIN report "New EU Rules on Dietetic Foods", complemented by GAIN report "New EU Rules on Dietetic Foods – Update" and http://ec.europa.eu/food/safety/labelling_nutrition/special_groups_food_en.

Food for sportspeople does not fall within the scope of regulation 609/2013. A EC report on food and beverages labeled specifically for sportspeople concluded that there is no need for specific EU-harmonized provisions as existing horizontal EU food rules already provide an adequate legal framework for these products. U.S. exporters should check with their importers whether re-notification may be necessary. Pease see GAIN report "New EU Rules for Sports Food".

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

"The Skinny on New EU Rules for Weight Loss Products."

Seafood

Detailed information on shipping seafood and fishery products to the EU is provided in the exporter guide "Exporting Seafood to the European Union – October 2016 Update" at http://www.seafood.nmfs.noaa.gov/pdfs/howtoexportseafood2016.pdf. Information on labeling can be found in the EC's "Pocket Guide to the EU's new fish and aquaculture consumer labels", published in December 2014. In May 2016, the Commission released a report on the feasibility of an EU eco-label scheme for fishery and aquaculture products.

Pet Food

Information on requirements to export pet food to the EU/Bulgaria can be found here Pet food.
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/Bulgaria must comply with EU requirements including rules on labeling, hygiene, animal health, certification and the use of additives. Please, see:
GAIN report "Exporting Pet Food to the European Union"

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 feed for pets. Please, see https://ec.europa.eu/food/safety/animal-feed/medicated-feed_en.

Commission Recommendation 2011/25/EU established guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products. Please, see http://ec.europa.eu/food/safety/animal-feed_en.

Meat and Fish Labeling

Please, see:
*Attaché Report GAIN E17080 Food and Agricultural Import Regulations and Standards for the EU* for labeling of beef, veal, pork, sheep, goats and poultry meat.

Vegetation and Vegan Foods

The FIC Regulation 1169/2011 requires the EC to set out rules for the voluntary labeling of foods as "suitable for vegetarians and vegans." 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 umbrella organization the European Vegetarian Union (EVU).

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 setting out definitions and designations that may only be used for the marketing of dairy products.

This decision was especially important for the Bulgarian market where a significant percentage of dairy products produced with plant-based oils (palm oil) were labeled as 'dairy" causing confusion and misinformation among consumers. It was also important for official control inspectors which had to introduce extra requirements for separate retails shelves for this type of products to be differentiated from conventional dairy products.

A list of exceptions for non-dairy products that may be labeled with reserved dairy names was established by Commission Decision 2010/791. For more information see GAIN report E17046 on the ECJ ruling.

**Section VIII. Copyright and/or Trademark Laws:**

- **Trademarks**

In the EU, trademarks can be registered at the national, regional or EU level.

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.

PATENT OFFICE OF THE REPUBLIC OF BULGARIA
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/

A trade mark can be registered also at 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.

The website of the Office for Harmonization in the Internal Market provides detailed information on the definition, registration process and ownership of trademarks: https://oami.europa.eu/ohimportal/en/trade-marks. Full details on the registration process are available on the EUIPO website. Rules on the protection of trademarks in the EU are set in EU Directive 2015/2436. Commission Implementing Regulation 2017/1413 sets out detailed rules on application procedures.

Information on EU trade mark protection criteria can be found on the European Commission's website at http://ec.europa.eu/growth/industry/intellectual-property/trade-mark-protection/index_en.htm.

In Bulgaria the legal basis for trademarks is laid down by Law on Patent and Utility Model Registration (last amendment in 2007). The trademark protection is granted for 10 years after which it

can be renewed.

The full list of applied national legislation, please see:
http://www1.bpo.bg/index.php?option=com_content&task=view&id=75&Itemid=122

The Patents Office of Bulgaria is the public body responsible for the registration and granting the different types of Industrial Property ranking from industrial property titles, including brands and commercial names (or distinctive signs), inventions, and industrial designs. The European legislation applied in Bulgaria can be found here:
http://www1.bpo.bg/index.php?option=com_content&task=view&id=128&Itemid=174

Bulgaria applies international agreements in this area and the international legislation applied in Bulgaria can be found at:
http://www1.bpo.bg/index.php?option=com_content&task=view&id=80&Itemid=127

Bulgaria is a member of the World Intellectual Property Organization (WIPO) and
a signatory to the following agreements:

-- Paris Convention for the Protection of Intellectual Property;
-- Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcast Organizations;
-- Geneva Phonograms Convention;
-- Madrid Agreement for the Repression of False or Deceptive Indications of Source of Goods;
-- Madrid Agreement and Protocol on the Registration of Trademarks;
-- Nice agreement on the International Trademark Classification
-- Madrid Agreement on the International Classification and Registration of Trademarks;
-- Patent Cooperation Treaty; Universal Copyright Convention;
-- Bern Convention for the Protection of Literary and Artistic Works;
-- Lisbon Agreement for the Protection of Appellations of Origin and their International Registration;
-- Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of
Patent Protection;
-- Nairobi Treaty on the Protection of the Olympic Symbol;
-- Vienna Agreement Establishing an International Classification of the Figurative Elements of Marks;
-- Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks;
-- Strasbourg Agreement Concerning the International Patent Classification;
-- Locarno Agreement Establishing an International Classification for Industrial Designs;
-- WIPO Copyright Treaty; and
-- WIPO Performances and Phonograms Treaty.

- **Designation of Origin and Geographical Indications**

Several food product names considered as generic in the U.S. such as for example feta, parmesan and Parma ham, are protected under EU law.

European Parliament and Council Regulation 1151/2012 sets out rules on optional quality terms such as "mountain product" and regulates three EU-wide quality labeling schemes. It covers the "Protected Designation of Origin" (PDO) scheme, the "Protected Geographical Indication" (PGI) scheme and the "Traditional Specialties Guaranteed" (TSG) scheme. Registration under the different schemes is also open to non-EU countries. Wines and spirits are covered by specific legislation and do not fall within the scope of the regulation.

The provisions on labeling and the use of EU logos for PDOs, PGIs and TSGs set out in Regulation 1151/2012 became applicable on January 4, 2016. The European Commission's website provides guidance on how to register a PDO/PGI or how to object to a PDO/PGI proposed for registration.

Lists of protected names of Bulgarian foods is available here. Bulgaria has five TSG products (meat products), one PDO Product (honey) and two PGI products (rose oil and a meat product).

Please, see more details in
*Attaché Report GAIN E17080 Food and Agricultural Import Regulations and Standards for the EU*.

**Section IX. Import Procedures:**

As an EU member, 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 imported from outside the EU based on tariff classification of goods and the customs value. Once import goods are cleared in one Member State, they can be moved freely throughout the EU territory.

Since June1, 2016 Council Regulation (EU) 952/2013 is the new framework regulation on rules and procedures for customs throughout the EU. Implementing provisions were published in Official Journal L 343 on December 29, 2015: Commission Delegated Regulation 2015/2446 and Commission Implementing Regulation 2015/2447 lay down detailed rules for the implementation of certain provision of the new UCC including Binding Tariff Information and origin of goods. The new 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 guidance document on "Customs formalities on entry and import into the European Union" is available on DG Taxud's website. It is possible to obtain Binding Tariff Information from a Member State Customs Authority. In the case of Bulgaria, Customs Agency ascribed to the Ministry of Finance, is the responsible entity. Contact data for Customs Agency can be found in Appendix I.

On October 2, 2017, the European Commission launched the "Customs Decisions System", a new pan-EU electronic system that will make it easier for traders to get permission to import goods into the EU. Importers in all the Member States (and in Bulgaria) will be 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 customs value of a good is the CIF price at the European border derived from the product price found on the invoice and the transportation costs reflected in the airway bill or the bill of lading.

Commission Regulation 900/2008 lays down analytical methods and other technical provisions to calculate the starch/glucose and sucrose/invert sugar/isoglucose content in processed products. These calculations are used to determine the additional duties on flour and sugar in processed products.

Goods are only released after payment of the import duty and other taxes that may be due.

Duties payable on goods imported into the EU/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

Other taxes applicable to agricultural products include the Value Added Tax (VAT) and inspection fees which are not harmonized throughout the EU. Bulgaria standard VAT rate is 20% percent. The reduced rate applicable to hotel and tourist services is set at 10 percent.

Animal products are subject to inspection fees. The information on the inspection fees payment process for plant and animal products can be consulted in the BFSA website.

A list of excise duties applicable on alcoholic beverages and tobacco can be found at http://ec.europa.eu/taxation_customs/taxation/excise_duties/index_en.htm.

Council Directive 92/83/EEC harmonizes the structures of excise duties on alcohol and alcoholic beverages and establishes common definitions of alcoholic products that are subject to excise duties as well as exemptions. The EC is currently revising the existing rules and may come forward with a new legislative proposal. For detailed information see European Parliament Briefing "Excise duty on alcohol."

Customs Clearance

The EC's "Trade Helpdesk" provides a complete overview of documents needed for customs clearance: http://trade.ec.europa.eu/tradehelp/.

Import Documentation and Process

The following documents are required for ocean or air cargo shipments of food products into Bulgaria:

- Bill of Lading and/or Airway Bill
- Commercial Invoice
- Phyto-sanitary Certificate and/or Health Certificate when applicable
- See "SECTION VI. Other Regulations and Requirements"

- Import Certificate

Most food products require an Import Certificate issued by the competent Bulgarian authorities. This certificate must be obtained by a registered importer as it is intended for tariff classification purposes.

The import process requires:

- Pre announcement by Common (veterinary) Entry Document (CVED or CED)
- Documentary Check
- Identity Check
- Physical check

Agricultural products are examined when they enter Bulgaria by the Bulgaria Border Inspection Posts (BIP). There are 8 border inspections points in Bulgaria. TRACES software has been applied since 2014. All BIPs can execute both veterinary and phyto-sanitary control and inspect all products for human consumption.

Regulation about Requirements to Border Inspection Points and Border Inspection Veterinary Control (last revision January 2007)
http://babh.government.bg/uploads/File/Dokumenti_naredbi/naredba_47_granichen_kontrol.pdf

Order for phyto-sanitary inspections at BIPs (May 2011)
http://babh.government.bg/uploads/File/Zapovedi_Granichen_k_l/Zapoved.pdf

In addition to 8 approved by the EC border inspections posts /BIP/ for veterinary control, designated entry points are added as follows: Vrashka Chuca, Strazimirovtsi, Logodaj, Lesovo, Malko Tarnovo, Oltomantsi.

Designated point of entry (DPE) in accordance with Commission Decision 2008/298/ EC can be found here.

First points of entry (FPE) in accordance with Regulation 1151/2009 EU:
http://babh.government.bg/uploads/File/Aktualno_Border_controls/FPE%20reg.1151(1).pdf

Designates point of entry (DPE) for import of food of non-animal origin in the EU according to Regulation (EC) № 1152/2009
http://babh.government.bg/uploads/File/Laboratorni_deynosti/13-0351-5-Reg-1152.pdf

Competent authority on certificates is the Bulgarian Food Safety Agency (BFSA). Agency responsibility covers products intended for human consumption and those for non-human consumption. Goods are only released for free circulation within the EU once the documentary and analytical requirements are checked and the import duty and other taxes that may be due are paid. Information on import duties can be consulted in the EU on-line customs data base.

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.

Temporary Entry

Temporary entry may be permitted for goods in transit (up to 24 months), manufacturing for re-export, and/or for temporary storage. Generally, the exporter must pay normally applied import duties and VAT, which are then reimbursed upon re-export of the merchandise to a destination outside of the EU.

Samples and Advertising Material

Product samples have to comply with the food regulations applicable in the EU. Exemptions exist for meat and meat products, for which a waiver may be obtained from the listing requirement described on the FAS USEU website section on certification.

**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/

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

**Ministry of Economy**
Str. Slavyanska 8, Sofia 1000

Tel.: (+359) 2-940-71 Fax: (+359) 2-987-2190
E-mail: e-docs@mi.government.bg Website: http://www.mi.government.bg

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

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

**Bulgarian Institute for Standardization**
1797 Sofia, Lachezar Stanchev" Str. Nr 13
"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/

**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

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

**Bulgarian Retail Association**
1000 Sofia, 150 Kliment Ochridski Blvd
Tel.: (+359) 2-962-4055; (+359) 8-9702-0733
Fax: (+359) 2-962-0162
E-mail: upr.savetbra@gmail.com Website: http://bra-bg.org/

**Bulgarian Association for Modern Trade**
Sofia 1756, Iztok area, 5"Lachezar Stanchev" Street
Sofarma Business Towers, Tower B, fl. 4, office 1
Tel.: (+359) 8-957-7746 and (+359) 2-4433-444.
E-mail: office@moderntrade.bg Website: http://www.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

**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