Bulgaria

Food and Agricultural Import Regulations and Standards - Narrative

FAIRS Country Report

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Report Highlights:
Bulgaria, a member of the European Union (EU) since 2007, follows all EU directives and regulations. This report is an update of BU1603 and outlines the applicable legislation regarding the export of U.S. food products to Bulgaria, particularly those rules that differ from EU legislation. This report should be read in conjunction with the GAIN report Food and Agricultural Import Regulations and Standards for the EU available at United States Mission to the EU (USEU) website at http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/fairs-reports/. Updates of the information provided are also available in the USEU/FAS website www.usda-eu.org.
**DISCLAIMER:** This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service in Sofia, Bulgaria, for U.S. exporters of domestic food and agricultural products. While every possible care was taken in the preparation of this report, information provided may not be completely accurate either because policies have changed 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 1. Food Laws:
Bulgaria has been a member of the EU since 2007. As a member of the European Union (EU), Bulgaria follows all EU directives, regulations, and obligations where available. While EU Regulations are binding and directly applicable to the Member States, EU Directives have to be transposed into National law. EU Decisions are binding and directly applicable to whom they are addressed.

This report outlines the applicable legislation regarding the exports of U.S. food products to Bulgaria, particularly those rules that differ from EU legislation or regulation. 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 Food and Agricultural Import Regulations and Standards GAIN report *Food and Agricultural Import Regulations and Standards for the EU*, see reports produced by the U.S. Mission to the EU in Brussels, Belgium which can be accessed from their website: [http://www.usda-eu.org/](http://www.usda-eu.org/). In addition, please see the report about Bulgarian Food and Agricultural Import Regulations and Standards BU1546 and Bulgarian Food and Agricultural Import Regulations and Standards BU1603.

Food and beverage products originating in the United States do not require any 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 required for any food and beverage product sold within the EU market. Bulgaria’s food regulations apply to both domestically produced and imported food products.

- **Bulgarian Food Law**

At the EU level, Regulation (EC) 178/2002 sets out general principles and objectives in food law. In Bulgaria, the Food Law published first in 1999, outlines the basic Bulgarian food and feed regulations.

The current law has been amended many times, especially after Bulgaria's accession to the EU in 2007. Since this was very comprehensive and important legislation on food trade, the MinAg took the decision to develop completely new legislation to be in full harmonization with the latest EU legislation, especially EU Regulation 1169/2011. Three amendments to the Food Law were passed in 2016 – (Official Gazette #28 of April 8, in Official Gazette #44 of June 10 and in Official Gazette #88 of November 8). The amendments introduced new rules for trade in tobacco products and foods donated for charity purposes to the first Bulgarian Food Bank and were parts of larger legislative packages entering in force from January 1, 2017. No changes related to food safety or food trade were introduced.

The following sources contain all relevant international, EU and national legislation and implementing regulations applicable in Bulgaria:
International, EU and National Legislation, Implementing Regulation and Tariffs can be found here.

International rules and agreements - link including international phyto-sanitary norms (FAO, International Standards for Phyto Sanitary Measures) - link and International Plant Protection Convention.

EU Legislation, Implementing Regulations and Documents can be found here. EU Directives (link).

National Legislation can be found here. National Laws; National Implementing Regulations (Ordinances), and the Food Law and respective implementing regulations can be found here. Most Frequently Used Examples of Documents here.

A draft for a major revision of the Food Law was submitted to the Parliament in 2016 following intensive consultations with the industry and aimed at full harmonization with the EU legislation. It is expected that the Food Law will be debated by the Parliament either in January 2017 or after April 2017 due to the current political crisis and expected early elections in April 2017. A major change may occur in the area of labeling of imported foods and drinks, see GAIN report BU1651.

In addition, the Bulgarian government is working on introduction of new legislation – the Agricultural and Food Supply Chain Act. The bill was developed following extensive consultations with industry in 2016 and is currently being submitted to the Parliament. It is oriented towards full harmonization with the EU food laws and REFIT program.

- Relevant Competent Authorities

Bulgaria has a centralized system for testing and controlling the feed and food chain. The central government has total oversight over the control carried out in customs, and on monitoring and sampling plans throughout the food and feed chain. The Ministry of Agriculture and Foods controls agricultural product imports intended for human consumption, through Bulgarian Food Safety Agency (BFSA). It also controls imports of animal feed/ingredients and live animals not intended for direct human consumption.

The BFSA is the competent authority on official control on all food imports, exports and manufacturing with the exception of bottled water (mineral, spring, and table water). Contact data for BFSA can be found in Appendix I.

In 2016 the Ministry of Agriculture and Foods (MinAg) initiated legislative changes which introduced an institutional shift of the Risk Assessment Center from the Bulgarian Food Safety Agency to the Minister of Agriculture. Two laws were amended in this respect (Law for Risk Assessment Center, Official Gazette #44, June 6, 2016 and Bulgarian Food Safety Agency Law, Official Gazette #44, June 6, 2016). The goal of this change was to provide a greater independence for scientific risk assessment and to
make the connection between the Risk Assessment Center and the Minister of Agriculture closer so that unbiased science-based consultations can be provided to the policy makers more efficiently.

Another institutional change was the shutting down of the National Grain and Feed Agency. The duties performed by this Agency are assumed by the Food Safety Agency and MinAg Regional Offices. This was reflected by the Feed Law (Official Gazette, #58, July 26, 2016).

Legislation which may have direct or indirect effect on food imports are: The Plant Protection Law (last revision – Official Gazette #28, April 8, 2016) and the Veterinary Medical Law (last revisions in 2016 – Official Gazette #14 of February 19, Official Gazette #34 of May 3 and Official Gazette #58 of July 26, 2016). These changes contain mainly requirements for domestic producers (farmers) and are not related to trade.

**Section II. Labeling Requirements:**

- **General Labeling Requirements**

The U.S. standard label does not comply with EU labeling requirements. As of December 13, 2014, general rules on the labeling, presentation and advertising of foodstuffs will be laid down by Regulation (EC) 1169/2011. This regulation consolidates general labeling requirements in a single text. For detailed information on the EU-harmonized labeling legislation, please see the USEU website section on labeling, USEU report on New EU food labeling rules, and GAIN report “How to Comply with the EU’s New Food Labeling Rules.”

Please, see GAIN report Food and Agricultural Import Regulations and Standards for the EU.

Bulgaria applies EU-harmonized legislation to:

- General Labeling Requirements
- Nutritional Labeling
- Product-Specific Labeling

Chapter 3 (Article 10/4) of the Bulgarian Food Law presents requirements about labeling of food products. There is an implementing Regulation of Food Labeling and Food Presentation (December 13, 2014) which introduced Food Information to Consumers (FIC) Regulation (EC) 1169/2011 labeling requirements in local legislation.

- **Compulsory information required includes:**
  - Product name
  - List of ingredients and quantity of certain ingredients or category of ingredients
  - Allergens listed in Annex II
- Alcoholic content when it is over 1.2% in volume
- Net weight in packaged products
- Expiration date (date of minimum durability)
- 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
- Country of origin or place of provenance in accordance with the provisions of Article 26
- Nutrition declaration

- **Warning on labels** - Annex III to FIC regulation 1169/2011 establishes a list of products that require a special warning on the label. Please, see GAIN report *Food and Agricultural Import Regulations and Standards for the EU.*

- **Minimum font size** - Article 13 of FIC regulation 1169/2011 introduces a minimum font size for printing the mandatory information on food and drink labels. Please, see GAIN report *Food and Agricultural Import Regulations and Standards for the EU.*

- **Language Requirements**

  The Government of Bulgaria permits multi-language labeling and stickers; however, one of the languages must be Bulgarian (Art.9/1 Food Law). 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 which in Bulgaria is Bulgarian. In order to avoid non-compliance with the new labeling rules, translations of mandatory information must be accurate.

- **Ingredients List**

  In the list of ingredients “Vegetable oils” and “Vegetable fats” must be followed by a list of specific vegetable sources.
- **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. Allergens must be highlighted in the list of ingredients.

- **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. Dates must be given in the following order: day/month/year.

- **Quantitative Ingredients Declaration (QUID)**


Please, see GAIN report *Food and Agricultural Import Regulations and Standards for the EU*. If an ingredient is emphasized on the label, the quantity in percent must be indicated on the list of ingredients.

- **Additives and Flavorings** - Please, see GAIN report *Food and Agricultural Import Regulations and Standards for the EU*.

- **Country of Origin**


In the EU country of origin labeling is mandatory for beef and veal, fruit and vegetables, eggs, poultry meat, wine, honey, olive oil, aquaculture products and for organic products carrying the EU logo. 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 (please, see country of origin labeling). Article 39 of the FIC regulation sets conditions for
Member States to adopt additional mandatory national measures, including measures for country of origin labeling. In Bulgaria, the country of origin per the Food Law is mandatory for all food products although it is not strictly observed.

- **Alcoholic Beverages**

Alcoholic beverages containing more than 1.2% of alcohol by volume are still exempted from the obligation to bear a nutrition declaration and a list of ingredients. In late 2016, Bulgarian brewing industry committed on a voluntary agreement to label all locally manufactured beers with energy and calories content by the end of 2017. Allergen labeling is compulsory on all alcoholic beverages (see “Allergen Labeling”). The alcoholic strength must be indicated by a figure with maximum one decimal place followed by the symbol “% vol.”

- **Nutritional Labeling**


Under FIC regulation 1169/2011, the nutrition declaration becomes mandatory on December 13, 2016. Nutrition information must be presented in tabular format and in a specific order expressed per 100 grams/ milliliter. Please, see GAIN report *Food and Agricultural Import Regulations and Standards for the EU.*

- **Gluten – Free and Trans Fats**

Harmonized compositional and labeling rules for foods for persons with gluten intolerance were previously set out in the EU’s directive on foods for particular nutritional uses (Directive 41/2009). This Directive was transposed in Bulgarian *Ordinance for Specific Use Foods* Official Gazette #86, November 2010.

With the adoption of the [new dietetic foods regulation 609/2013](#), it was decided that gluten-free foods would be regulated under the FIC regulation. Commission Implementing Regulation 828/2014, applicable since July 20, 2016, sets out conditions for using “gluten-free” and “very low gluten” statements on food labels. Please, see GAIN report *Food and Agricultural Import Regulations and Standards for the EU.*

- **Use of Stickers**

Specific rules on the use of stickers to provide mandatory labeling information are not included in FIC
regulation 1169/2011. On this issue, the European Commission 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.” Some Member States may allow the use of stickers while other may not. U.S. food manufacturers or exporters are encouraged to contact their potential importer to learn the labeling requirements applicable.

Currently debated Food Bill by the Parliament in Bulgaria includes a controversial proposal to eliminate the practice of using stickers in Bulgarian language for imported foods and beverages and to require all imported foods to have Bulgarian language on the original label - please, see BU1651. It still remains to be seen if this proposal will be approved by the authorities.

Please, see a checklist for Compliance with the FIC Rules in GAIN report Food and Agricultural Import Regulations and Standards for the EU.

- Other Specific Labeling Requirements

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.

Health Claims
Health claims are only allowed if the importance of a balanced diet and healthy lifestyle is also stated on the label. 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. Any producer can use the permitted health claims provided the conditions set out in Regulation 432/2012 are met. The EU’s online “Register of Nutrition and Health Claims” lists the authorized health claims as well as the rejected claims and the reasons for their non-authorization. Please, see GAIN report Food and Agricultural Import Regulations and Standards for the EU.

Genetically Modified Foods and Feeds –

Regulation about GMs and their release in environment and on the market (last revision October 2005) can be found here. A food containing an GE ingredient can be released on the market only after EU approval is granted based on Regulation 1829/2003 (Art.23/e Food Law). The 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). 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 consumer 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 accompanies by a risk assessment study with the effects on human health and the environment (Art.23/b Food Law). See
Non-GMO
EU-harmonized legislation defining “non-GM,” ‘GM-free” or similar labeling terms does not (yet) exist. National provisions and operator-specific “GM-free” and similar labeling schemes are planned to be implemented in Bulgaria in the Food Law in 2017.

Organic Food Labeling

For more information see the European Commission’s website at http://ec.europa.eu/agriculture/organic/index_en. Please, see GAIN report Food and Agricultural Import Regulations and Standards for the EU.

Since June 1 2012 the European Union 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. More information about this partnership can be found on the USDA Organics Home Page for International Agreements. The Bulgarian Food Law contains special provisions regarding organic foods in Art. 6.

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. For more information please see USDA Agricultural Marketing Service: National Organic Program (International Trade Policies: European Union)

Wine, Beer and Other Alcoholic beverages
The EU’s Single Common Market Organization Regulation 1308/2013 establishes framework rules for 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. Commission Implementing Regulation 579/2012 sets out the modalities for the labeling of allergens on wine. There is no specific EU-harmonized legislation for beer. In late 2016, the Bulgarian brewing industry committed on a voluntary agreement to label all locally manufactured beers with energy and calories content by the end of 2017.

Spirit Drinks
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.
Special Use Foods


Bulgarian Ordinance for Special Use Foods Official Gazette #86, November 2010 can be found here.

Meat Labeling

Please, see GAIN report Food and Agricultural Import Regulations and Standards for the EU.

Health and Identification Marks


Frozen Foodstuffs

Please, see GAIN report Food and Agricultural Import Regulations and Standards for the EU. The EU legislation is transposed into Bulgarian legislation Ordinance for fast frozen foodstuffs, Official Gazette #84 of September 27, 2013.

Vertical and Product Specific Legislation

Vertical legislation on the manufacture and marketing of specific products has been developed for sugars, cocoa and chocolate products, honey, fruit juices and similar products, preserved milk, coffee extracts and chicory extracts and fruit jams and similar products.

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 error between the actual content and the quantity indicated on the label, and methods to check this are fixed in Council Directive 76/211/EEC.


**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 European Commission’s website http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01994L0062-20150526&qid=1446639081652&from=EN.

**Materials in contact with foodstuffs**

European Parliament and Council Regulation 1935/2004 specifies the main requirements for all materials that come into contact with foodstuffs. It also sets out labeling and traceability requirements and the procedure for the authorization of substances through the European Food Safety Authority (EFSA).

Plastics: Adhesives 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.
In Bulgaria the above EU legislation was transposed in the national law by articles in the Food Law and by Ordinance 2, January 1, 2008, last amended in August 2013 and Ordinance 3, June 4, 2007, last amended in September 2008.

Section IV. Food Additives Regulations:

- **Additives**

Bulgaria applies EU-harmonized legislation regarding food additives. For detailed information on the EU-harmonized legislation on food additive regulations, please consult the GAIN report *Food and Agricultural Import Regulations and Standards for the EU* as well as 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. The use of flour bleaching agents chlorine, bromates and peroxides are not allowed in the EU, and respectively in Bulgaria.

The above EU legislation about food additives was transposed in Bulgarian Food Law and in Ordinance 47 of December 28 2004, last amended in Official Gazette #90 of November 16 2010.

- **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 of Regulation 1334/2008 establishes a list of substances that are authorized for use in the EU also available in an on-line database.

- **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.

Information for the risk assessment of food enzymes submitted by industry is in the process of being evaluated by EFSA. Based on EFSA’s risk assessment, the Commission will establish an EU positive list of authorize enzymes.

- **Processing Aids**
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 strictly adheres to EU-harmonized legislation on pesticides and contaminants.

- **Pesticides**


- **Endocrine Disruptors** - Please, see GAIN report Food and Agricultural Import Regulations and Standards for the EU.

- **Maximum Residue Levels (MRL)**

The complete list of MRLs, and commodity combinations allowed in the EU can be obtained from the Commission’s webpage. Since September 2008 all MRLs in the EU have been harmonized by European Parliament and Council Regulation 396/2005 on food or feed of plant and animal origin.

The Bulgarian National Pesticides Plan can be found here. The implementing national regulation for MRL in foods is Ordinance 2 of January 23, 2015, Official Gazette #9 of February 3, 2015.
• 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.

• Official Controls - Please, see GAIN report Food and Agricultural Import Regulations and Standards for the EU.

• Contaminants


Bulgaria applies EU-harmonized legislation regarding food contaminants. Please consult the USEU website section on contaminants.

Maximum Levels

EU- wide harmonized maximum levels for contaminants are set in the Annex of Commission Regulation 1881/2006. The Annex to Regulation 1881/2006 includes maximum levels for nitrates, mycotoxins, heavy metals and other. Please, see GAIN report Food and Agricultural Import Regulations and Standards for the EU for official control of maximum level in foodstuffs.

• Aflatoxin Levels in Tree Nuts

In 2015 the EU approved the pre-export checks (PEC) program for U.S. almonds and peanuts. 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 U.S. peanut program which was approved in 2009 is also covered by the general provisions of this regulation. The USDA Agricultural marketing Service started to issue PEC almond certificates on August 1, 2015. Under the regulation import authorities are directed to subject consignments of U.S. almonds and peanuts with a PEC certificate to a less than 1% control level at the border. The PEC program is voluntary; a PEC certificate is not a requirement for import into the EU. Shipments without a PEC certificate do not benefit from the reduced inspection levels upon import in the EU.

Bulgaria is a good market for tree and ground nuts and the United States is the primary supplier to Bulgaria. Initially, the border authorities faced challenges with clearance of U.S. shipments with PEC certificates. However, continuous professional assistance and collaboration provided by the U.S.
industry (Almond Board of California and U.S. Peanut Council) and FAS/Sofia resulted in liberalization of import procedures in December 2016 (see GAIN report BU1642).

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. Member states have to test 20 percent of all incoming shipments until the list in the Annex of the regulation is amended. This regulation does not impose any requirements on exporters.


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.

Section VI. Other Regulations and Requirements:

- Certification

The Bulgarian Government applies EU-harmonized legislation for other related regulations and requirements including product inspection, registration and certification. For detailed information on certification, please see the USEU certification site, and Certification and Documentation Requirements.

Composite Products: U.S. exports of “composite products” are continuing to be restricted due to burdensome certification requirements introduced in a 2012 European Commission 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. Please, see GAIN report Food and Agricultural Import Regulations and Standards for the EU and http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/.

- Product inspection:

BFSA is responsible for carrying out inspections in the food and feed chain. Products can be checked at imports 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 the Rapid Alert System on Food and Feeds (RASFF). The database with RASFF notifications is accessible via the RASFF portal. 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.

BFSA list of designated laboratories for testing of foods of animal origin can be found here. The list of all other laboratories for food safety control can be found here.

Inspection fees for non-animal origin products differ from one Member State to another. For Bulgaria, please, see the currently applicable import fees here. Measures in case of non-compliance also vary widely, ranging from non-admittance of a product to forced destruction. This may be a decisive factor in choosing a port of entry for products where problems are more likely.

**Facility and Product Registration Requirements**

- **Facility Registration**


- **Product Registration**

  Generally, there is no EU requirement to register imported foods except for the introduction of novel foods. When introducing foodstuffs with particular nutritional uses, Bulgarian Food Safety Agency needs to be notified. Exporters of vitamin-enriched foods or nutritional supplements are mandated to notify respective departments at BFSA.

**Section VII. Other Specific Standards:**


  The Novel Food Regulation (EC) 258/1997 lays down detailed rules for the authorization of novel foods and novel food ingredients, including foods derived from, containing, or consisting of GEs. It defines novel foods as foods and food ingredients that were not used to a significant degree in the EU before May 15, 1997. The Regulation was adopted in the local legislation (Art.23 Food Law). 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.

The EU catalogue on Novel Foods can be consulted in the EU Commission’s website. For more information see the European Commission’s website at http://ec.europa.eu/food/safety/novel_food/index_en.htm, GAIN report “Negative List for Novel Foods and Ingredients” and GAIN report Food and Agricultural Import Regulations and Standards for the EU.

- **Food from Clones**

Please, see GAIN report Food and Agricultural Import Regulations and Standards for the EU. http://www.usda-eu.org/topics/animal-cloning/

- **Nanotechnology**

Please, see GAIN report Food and Agricultural Import Regulations and Standards for the EU and FAS USEU website section on nanotechnology.

- **Fortified Foods**


European Parliament and Council Regulation 1925/2006 as amended by Regulation (EC) 1170/2009 establishes an EU-wide regulatory framework for the addition of vitamins and mineral 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. The use of vitamins and minerals not included in the annexes to Regulation 1925/2006 is not allowed. Maximum permitted levels of vitamins and minerals in foods and food supplements are not yet EU harmonized. For additional information, visit FAS USEU website section on fortified foods.

- **Dietetic Foods**


In June 2013 the EU adopted Regulation 609/2013. The scope of this regulation is limited to infant formula and follow-on formula, processed cereal-based food and baby food, food for special medical purposes and total diet replacement for weight control. Regulation 609/2013 became applicable on July 20, 2016. Under the new rules, pictures of infants are no longer be allowed on labels. Foods that no longer fall within the scope of Regulation 609/2013 will be regarded as regular foods. Commission Delegated Regulation 2016/217 sets out specific compositional and information requirements for infant-formula and follow-on formula. Commission Delegated Regulation 2016/128
sets out specific requirements for food for special medical purposes (FSMPs). For additional information, visit FAS USEU website section on dietetic foods and see GAIN report “New EU Rules on Dietetic Foods”.

- **Food Irradiation**

Harmonization of EU rules on food irradiation has been slow and only a few products have so far received EU-wide approval. 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.” For more information see the European Commission’s website at http://ec.europa.eu/food/safety/biosafety/irradiation_en.

Implementing Directive 1999/3/EC establishes a Community list of foods and food ingredients authorized for irradiation treatment. The list of Member States’ authorizations of food and food ingredients which may be treated with ionizing radiation can be consulted in the link. Art.22 of the Bulgarian Food Law regulates the use of irradiation in foods.

- **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” which can be downloaded from the Department of Commerce – NOAA Fisheries’ website at http://www.seafood.nmfs.noaa.gov/pdfs/howtoexportseafood2016.pdf.

Information on labeling can also be found in the European Commission’s “Pocket Guide to the EU’s new fish and aquaculture consumer labels”, published in December 2014.

- **Pet Food**

Please, see GAIN report Food and Agricultural Import Regulations and Standards for the EU. http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/pet-food/

- **Vegetarian and Vegan Foods**

Please, see GAIN report Food and Agricultural Import Regulations and Standards for the EU Section VIII. Copyright and/or Trademark Laws:
• **Trademarks**

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


Trademarks registered at the national level are protected in one EU Member State. Applications must be submitted directly to the relevant national IP-office. Applications for registering under the Community Trademark Register must be submitted to the Patent Office of Bulgaria.

**PATENT OFFICE OF THE REPUBLIC OF BULGARIA**

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In Bulgaria the legal basis for trademarks is laid down by [Law on Patent and Utility Model Registration](http://www.ipa.bg/) (last amendment in 2012). The trademark protection is granted for 10 years after which it can be renewed. The full list of applied national legislation, please see [here](http://www.ipa.bg/). The European legislation applied in Bulgaria can be found [here](http://ec.europa.eu/growth/industry/intellectual-property/trade-mark-protection/index_en.htm). Bulgaria applies international agreements in this area and the international legislation applied in Bulgaria can be found [here](http://ec.europa.eu/growth/industry/intellectual-property/trade-mark-protection/index_en.htm).

Please, consult GAIN report *Food and Agricultural Import Regulations and Standards for the EU* and [BU1603](http://www.usda.gov/bureaus/international) for more details.

• **Protected Geographical Indications**


[European Parliament and Council Regulation 1151/2012](http://eur-lex.europa.eu) sets out rules on optional quality terms 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 open to third 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](http://eur-lex.europa.eu) became applicable on January 4, 2016.
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.

There is a Bulgarian regulation about specific official control on use of PDO, PGI and TSG schemes for foods: Ordinance 6 of May 5, 2011, last amendment in Official Gazette 69 of August 19, 2014.

Please, consult GAIN report Food and Agricultural Import Regulations and Standards for the EU and BU1603 for more details.

Section IX. Import Procedures:

- Union Customs Code

As a member of the European Union (EU), Bulgaria follows all EU directives, regulations, and obligations where available. Since the EU is a customs union, all Member States apply the same import duties on goods imported from outside the EU (United or Union Customs Code/UCC) 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.

As of June 1, 2016 Council Regulation (EU) 952/2013 is the 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 2015/2466 and Commission Implementing Regulation 2015/2447. 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. The EU’s 2016 Tariff Schedule was published on October 30, 2015 in Official Journal L 285.

It is possible to obtain Binding Tariff Information (BTI) 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.

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

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. A guidance document on “Customs formalities on entry and import into the European Union” is available on DG Taxud’s website.

In late 2015 Bulgarian Excise Taxes Law was amended (Official Gazette #92, November 27, 2015, please, see the new changes here and here) and currently applicable excise duties can be found in Chapter V, Article 33 for alcohol and Article 37-39 for tobacco and tobacco products.
• Customs Clearance

The European Commission’s DG Trade “Export Helpdesk” provides a complete overview of documents needed for customs clearance: http://exporthelp.europa.eu/thdapp/display.htm?page=rt%2frt_Requirements.html&docType=main&languageId=en

Bulgarian Customs Agency is the institution in charge of collection of excise duties upon imports, all details about procedure and required documents can be found here.

• Import Duties

The EU’s on-line “Taric customs database” can be consulted to look up commodity codes and relevant import duties. Taric is a multilingual database covering all measures relating to tariff and trade legislation. The EU’s 2017 Tariff Schedule was published on October 28, 2016 in Official Journal L 294.

Duties payable on goods imported into Bulgaria 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
- inspection fees - not harmonized in the EU, see the fees for Bulgaria here
- Value Added Tax (VAT) - not harmonized in the EU, for Bulgaria VAT uniform and is at 20%.
- excise duties (alcohol and tobacco) - not harmonized in the EU (see above for the Bulgarian excise duties).

• 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
- 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 and food products are examined when they enter Bulgaria by the Bulgaria Border Inspection Posts (BIP). TRACES software system is applied in all BIPs. The lists of all 8 BIPs and performed import control at each of them as well as contact data, can be found here.

Complete list of all BIPs, implementing import regulations and import procedures can be found at BFSA, website, Border Control webpage.


Some BIPs can perform only documentary checks and some can also perform identity and physical checks per Regulation (EC) 2015/175, Regulation (EC) № 885/2014 - please, see the list of these BIPs here.

Designates point of entry (DPE) for import of food of non-animal origin in the EU according to Regulation (EU) № 884/2014, can be found here. Designates point of entry (DPE) for imports of food of non-animal origin in the EU according to Regulation (EU) № 669/2009 can be found here. Designated Point of Entry (DPE) for import of feed of non-animal origin in the EU according to Regulation (EU) № 669/2009 can be found here.

In addition to 8 approved by the EC border inspections posts /BIP/ for veterinary control, entry points are added as follows: Vrashka Chuca, Strazimirovtsi, Logodaj, Lesovo, Malko Tarnovo, Oltomantsi: http://www.nvms-gvc.com/granichnipunktove.htm

Competent authority on certificates is the Bulgarian Food Safety Agency. 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.

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. As local importers have primary responsibility to the Bulgarian Government for imported food products entering Bulgarian territory, they are in the best position to provide guidance to U.S. exporters through the market-entry process. For additional information on the Bulgarian Market, please consult the latest Bulgaria’s Exporter Guide.

Appendix I. Government Regulatory Agency Contacts:

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

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

**Bulgarian Food Safety Agency**
Bul. Pencho Slaveikov 15A, Sofia 1606, Bulgaria
Tel.: (+359) 2-915-98-20 Fax: (+359) 2-954-9593
E-mail: bfsa@bf sa.gov

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

**Ministry of Economy and Energy**
Str. Slavyanska 8, Sofia 1000, Bulgaria
Tel.: (+359) 2-940-71 Fax: (+359) 2-987-2190
E-mail: e-docs@mee.government.bg
Website: [http://www.mi.government.bg](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/](http://en.bda.bg/)

**National Center of Public Health and Analyses**
Acad. Ivan Evst. Geshov 15 blvd Sofia 1431 Bulgaria
Tel.: (+359) 2-8056-444 Fax: (+359) 2-9541-211
E-mail: ncpha@ncpha.government.bg
Website: [http://ncpha.government.bg](http://ncpha.government.bg)
Bulgarian Institute for Standardization
Lachezar Stanchev" Str. Nr 13
"Izgrev" Complex
1797 Sofia, Bulgaria
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/

Appendix II. Other Import Specialist Contacts:
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://www.amcham.bg

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

Bulgarian Industrial Association
Str. Alabin 16-20, Sofia 1000 Bulgaria
Tel.: (+359) 2-932-0911 Fax: (+359) 2-987-2604
E-mail: office@bia-bg.com Website: http://www.bia-bg.bg

Association of Producers, Importers and Traders of Spirits (SpiritsBulgaria)
40, Bratia Bukston Blvd., Sofia 1618 Bulgaria
Tel.: (+359) 2-956-60-90 Fax: (+359) 2-956-60-92
E-mail: office.apitsd@gmail.com Website: http://www.spirits.bg

Bulgarian Association of Food and Beverage Industries
Address: 1606, София; ул."Владайска”29
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

Bulgarian Retail Association
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“ St.,
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/

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
Website: http://ec.europa.eu/bulgaria/about_representation/contact/index_bg.htm

The USDA’s Foreign Agricultural Service Office for Bulgaria located in Sofia, can also assist U.S. exporters in obtaining specific national legislation on all food product directives. You may contact us at the following address:

Foreign Agricultural Service
Office of Agricultural Affairs
American Embassy Sofia
16, Kozhiak St. 1408 Sofia Bulgaria
Tel.: (+359) 2-939-5720/5704/5774
Fax: (+359) 2-939-5744
Email: AgSofia@fas.usda.gov