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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 [BU1364](#) 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 E15051](#) *Food and Agricultural Import Regulations and Standards for the EU*. 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 I. 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 ([FAIRS](#)), 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/>. In addition, please, see the report about Bulgarian Food and Agricultural Import Regulations and Standards [BU1546](#).

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 (Bulgarian only, English version available upon request) http://babh.government.bg/uploads/File/Dokumenti_zakoni/ZAKON_za_hranite.pdf) published in January 2011, outlines the basic Bulgarian food and feed regulations. This law is based in EU Regulations and Directives 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 domestically produced and imported products. The Bulgarian 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 sets out 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 July 2015. The Food Law implementing regulations can be found at:

<http://www.babh.government.bg/bg/legislation-bg-regulations.html>

Other major legislation which applies to food imports can be found in the Veterinary Medical Act (Bulgarian only, English version available upon request)

http://babh.government.bg/uploads/File/Dokumenti_zakoni/ZAKON_za_veterinarnomedicinskata_dejn_ost.pdf. and <http://lex.bg/laws/ldoc/2134685185>. 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 2014):

http://babh.government.bg/uploads/File/Dokumenti_zakoni/orz_ZZR.pdf

The Feed Law (last revision February 2015):

http://babh.government.bg/uploads/File/Dokumenti_zakoni/Zakon%20za%20furajite_Obn.,%20DV,%20Obr.%2055_2006,%20dop.,%20br.pdf

The following sources have a complete list of applicable EU and national legislation (Bulgarian only, English version available upon request):

EU and National Legislation, Documents, and Tariffs:

<http://www.babh.government.bg/bg/documents.html>

National Legislation:

<http://www.babh.government.bg/bg/legislation-bg.html>

Major revision of the Food Law and Veterinary Medical Act are planned for 2016. In addition, Bulgarian government is working on introduction of new legislation – Agricultural and Food Supply Chain Act and Risk Assessment Act. Both new pieces of legislation are planned for mid-2016 and are oriented towards full harmonization with the EU food laws and REFIT program.

In May 2015, the European Commission presented its “Better Regulation Package”, a so-called update of its own law-making practices in order to meet EU legislators’ and citizens’ expectations in terms of impact assessment, transparency, stakeholder consultation and implementation. 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 the European Commission’s website http://ec.europa.eu/smart-regulation/index_en.htm.

- **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. Sampling plans are based on risk assessment and sampling is primarily done at production, wholesale and the processing level.

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 was established in 2011 through a major reform by uniting 3 executive agencies – Plant Protection and Phyto-Sanitary Agency and Veterinary Medical Service, both under the control of the Ministry of Agriculture, and Food Hygiene Agency, part of the Ministry of Health.

Food Safety is the responsibility of the BFSA which coordinates the food and feed chain control. BFSA has a Risk Assessment Center which is responsible for risk assessment and management and work directly with European Food Safety Agency.

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) (Art.28/ Food Law) Law on the establishment of Bulgarian Food Safety Agency – published in Official Gazette #8/January 25, 2011.

http://babh.government.bg/uploads/File/Dokumenti_zakoni/ZAKON_za_Bylgarskata_agenciq_po_bezo_pasnost_na_hranite.pdf

Contact data for BFSA can be found in Appendix I.

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.

Section II. 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 [EU-28 FAIRS Report](#) well as the [USEU website section on labeling](#). Detailed information on labeling requirements that will apply from December 13, 2014 can be found in the [USEU report on New EU food labeling rules](#), supplemented by [GAIN report “How to Comply with the EU’s New Food Labeling Rules.”](#)

Bulgaria applies EU-harmonized legislation to:

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

- **General Labeling Requirements**

In Bulgaria, Chapter 3 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>

Information required includes:

- Product name
- List of ingredients and quantity of certain ingredients or category of ingredients
- 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

Misleading labeling attributing properties that the foodstuff does not have is not accepted. The label should not mislead or confuse the consumer about the nature of the foodstuff, 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 Government of Bulgaria 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.

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](#)).

In Bulgaria, however, the country of origin per the Food Law is mandatory for all food products.

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.

Product-Specific Labeling

For a number of products, specific labeling requirements have been established in addition to the general requirements described above. See Section VI for more details on above 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](#), as amended. Please, see [GAIN report E15051](#).

[Directive 2007/45/EC](#) abolished regulations on mandatory pack sizes at both EU and national levels. The Directive frees sizes for all prepackaged products except wine and spirits, and coffee. Detailed information on "Legal Metrology" is available on the European Commission's website <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. Please see [GAIN report E15051](#)

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

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.

For more detailed information on the EU's harmonized legislation on packaging and container regulations, please consult the [USEU website section on packaging](#), and [GAIN report E15051](#).

Section IV. Food Additives Regulations:

Bulgaria applies EU-harmonized legislation regarding food additives. For detailed information on the EU-harmonized legislation on food additive regulations, please consult the [EU-27 FAIRS Report](#) 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](#). Please, see [GAIN report E15051](#)

Additives that are authorized in food and their conditions of use are listed in Annex II to the [Food Additives Regulation 1333/2008](#). For additional information, please visit the FAS USEU website section on [Food Additives](#) and [GAIN report E15051](#).

[Regulation 1334/2008](#) on flavorings and certain food ingredients with flavoring properties sets specific rules for the use of the term "natural". Please, see [GAIN report E15051](#).

[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. Please, see [GAIN report E15051](#).

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](#). Please, see [GAIN report E15051](#).

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.

- Pesticide Registration

[Regulation \(EC\) 1107/2009](#) for placing plant protection products on the market replaced Directive 91/414/EEC. This legislation, which applies from June 14th, 2011, defines zonal authorizations. Bulgaria is included in the Zone C (South) along with Spain, Cyprus, France, Greece, Italy, Malta and Portugal). [Commission implementing Regulation 540/2011](#) establishes a list of approved active

substances.

The “Pesticide Package” also contains [Directive 2009/128/EC](#) for the sustainable use of pesticides. For application for pesticide registration in Bulgaria the contact is the Bulgarian Food Safety Agency.

- Maximum Residue Levels (MRL)

The complete list of MRLs, and commodity combinations allowed in the EU can be obtained from the [Commission’s webpage](#). Member States are responsible for risk assessment, surveillance and control. 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. Please, see [GAIN report E15051](#). Bulgarian National Pesticides Plan can be found here:

http://babh.government.bg/plan_pesticidi.html

http://babh.government.bg/uploads/File/Plan%20za%20pesticidi/Nacionalen_Plan_za_Deistvie_za_Ust_oichiva_Uпотреба_na_Pesticidi.pdf

For detailed information on EU-harmonized legislation on pesticide and contaminant regulations, please consult the [EU-28 FAIRS Report](#) as well as the [USEU website section on pesticides](#).

- Import tolerance

Tolerance for pesticide residues was harmonized in the EU in 2008. Bulgaria adheres to EU-harmonized legislation on pesticides and contaminants. If there is no EU legislation in place in the importing Member State, then the exporter can seek to obtain an "import tolerance" for active substances that have not been evaluated or used in Europe before.

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](#).

- Contaminants

Bulgaria applies EU-harmonized legislation regarding food contaminants. For detailed information on the EU-harmonized legislation on food additive regulations, please consult the [EU-28 FAIRS Report](#) as well as the USEU website section on [contaminants](#) and <http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/contaminants/>

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 Levels in Tree Nuts

Bulgaria is a good market for tree nuts and the United States is the primary supplier to Bulgaria.

[Commission Regulation \(EU\) 165/2010](#) increased the maximum aflatoxin levels for almonds and pistachios, as well as apricot kernels, hazelnuts and Brazil nuts, bringing them in line with the Codex Alimentarius levels for tree nuts adopted in July 2008.

The new levels, effective on March 9, 2010, changes to maximum tolerance for aflatoxin to the following:

	Ready-to-Eat (RTE)	For Further Processing (FFP)
Almonds	10 ppb total /8 ppb B1	15 ppb total/12 ppb B1
Hazelnuts, Brazil Nuts	10 ppb total/5 ppb B1	15 ppb total/8 ppb B1
Pistachios	10 ppb total/8 ppb B1	15 ppb total/12 ppb B1

For more information, see the [EU-28 Tree Nuts Report](#).

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 started to issue PEC almond certificates on August 1, 2015. The almond PEC program builds on and replaces the Voluntary Aflatoxin Sampling Plan (VASP) program, which stopped being required in September 2014 when the EU voted to remove California Almonds from Special Measures. For additional information check the [Almond Board of California](#) website.

With the publication of Commission Implementing Regulation (EU) 2015/949, all EU accepted programs have been combined in the one regulation. The U.S. peanut program which was approved in 2009 is now also covered by the general provisions of [Commission Implementing Regulation \(EU\) 2015/949](#). 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.

For additional information on aflatoxin PEC certification, see:

- <http://www.almonds.com/newsletters/handle/almond-industry-flexes-its-pecs>

<http://www.peanutsusa.org.uk/eu-food-aflatoxin-legislation>

- <http://www.ams.usda.gov/services/lab-testing/aflatoxin>

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.

Residues in Animals and Animal Product – please see E 15051

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/residue-plans/>

Section VI. Other Regulations and Requirements:

- **Product inspection**

Bulgarian Food Safety Agency 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.

- **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](#). [Council Directive 2000/29/EC](#), harmonizes the importation requirements of plants and plant products into the EU. Phytosanitary certificates, issued by an APHIS inspector, are required to accompany all plant and plant products entering the EU.

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. authority issuing these certificates is available on our website at <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 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.

All composite products containing a processed meat product are subject to a veterinary check.

Generally speaking, composite products that contain more than 50 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 published in 2013.](#) This guidance greatly expanded the number and types of products affected by the legislation. [Further guidance](#) 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/>.

Section VII. Other Specific Standards:

For detailed information on the EU-harmonized legislation on other specific standards, please consult the [EU-28 FAIRS Report](#) or the [USEU import rules](#) website.

Genetically Modified Foods and Feeds

Regulation about GEs and their release in environment and on the market (last revision October 2005) can be found here:

http://babh.government.bg/uploads/File/Dokumenti_naredbi/Naredba_za_osvobodjavane_na_GMO.pdf

Bulgaria has a centralized system for testing and controlling unauthorized presence of GE in the feed and food chain. The central government - Ministry of Agriculture and Foods/BFSA - has total control over the controls carried out in customs as well as 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 (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).

Labeling: The exact amount of the GE content, and the GE event unique code (Art 10/1 Food Law). 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 font 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 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 accompanied by a risk assessment study with the effects on human health and the environment (Art.23/b Food Law).

Novel Foods

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).

The EU catalogue on Novel Foods can be consulted in the [EU Commission's website](#). This catalogue provides information on whether or not a product would require authorization under the Novel Food Regulation. The list of novel food applications, authorizations, rejections, and withdrawals can be also found in the [Commission's website](#).

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 Member State's competent authorities (Bulgarian Food Safety Agency).

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.

An overview of the current novel foods regulatory environment and a negative list of substances and ingredients not authorized under the current novel foods framework can be found in the report [E14034](#).

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 will become applicable on January 1, 2018. Please, see [GAIN report E15051](#).

For more information see the European Commission's website at http://ec.europa.eu/food/safety/novel_food/index_en.htm and [GAIN report "Negative List for Novel Foods and Ingredients"](#).

Food from Clones

At the moment, food derived from animal clones falls under the scope of Novel Food [Regulation \(EC\) 258/1997](#). The two European Commission's proposals ([proposal on the placing on the market of food from animal clones](#) and [proposal on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes](#)) are currently being assessed by the European Parliament.

For additional information, visit the FAS USEU website section on [animal cloning](#).

Nanotechnology

Currently, EU food legislation on nanotechnology includes [Regulation 1169/2011](#) on the provision of food information to consumers, [Regulation 1333/2008](#) on food additives and [Regulation 450/2009](#) on active and intelligent materials and articles intended to come into contact with food. For additional information, visit 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. For additional information, visit FAS USEU website section on [fortified foods](#).

Dietetic or Special Use Foods

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/eu-labeling-requirements/dietetic-foods/>

In June 2013 the EU adopted [Regulation 609/2013](#) which completely overhauls the current dietetic food rules (see Section V “Special Use Foods”). 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 will apply as of July 20, 2016. Under the new rules, pictures of infants will no longer be allowed on labels. Foods that no longer fall within the scope of Regulation 609/2013 will be regarded as regular foods.

The European Food Safety Authority (EFSA) has published scientific and technical guidance to help the European Commission apply new rules on foods for special medical purposes (FSMPs). For more information see [EFSA’S FAQ document on FSMPs](#).

Regulation 609/2013 also requires the Commission to prepare a report on introducing harmonized rules on food intended for sportspeople. In order to comply with this requirement, the Commission has requested EFSA to provide scientific assistance. For more information see [EFSA’s technical report](#).

For additional information, visit FAS USEU website section on [dietetic foods](#) and [see GAIN report “New EU Rules on Dietetic Foods”](#).

Foodstuffs for Particular Nutritional Uses

Specific directives on foods and beverages for athletes or on foods intended for diabetics are still subject to Member State legislation. The introduction of foodstuffs intended for particular nutritional uses for which no specific rules are set must be notified to the Member State where the food is sold. Bulgaria’s competent authority is Bulgarian Food Safety Agency.

Organic Foods

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.

[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.

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% of the ingredients of agricultural origin are organic. See E 15051. For more information see the European Commission's website at http://ec.europa.eu/agriculture/organic/eu-policy/legislation_en#regulation.

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 \(International Trade Policies: European Union\)](#)

Vertical Legislation (Breakfast Directives)

[Directive 2001/112/EC](#) amended by [Directive 2012/12/EU](#) regulates to fruit juices and certain similar products intended for human consumption. Key amendments which affect to the fruit juice labeling rules include orange juice, nutrition claims, mixed juices and sugars and sweeteners. More information about EU fruit juice labeling requirements can be found in the [GAIN report "New EU Fruit Juice Labeling Rules."](#)

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, as of December 13, 2014 general rules on the labeling, presentation and advertising of foodstuffs will be laid down by [Regulation \(EC\) 1169/2011](#).

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 must be labeled "irradiated" or "treated with ionizing radiation". [Implementing Directive 1999/3/EC](#) establishes a Community list of foods and food ingredients authorized for irradiation treatment. The list contains only one food category: "dried aromatic herbs, spices and vegetable seasonings".

Until the EU positive list is expanded, national authorizations continue to apply. 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

[Council Regulation 2406/96](#) lays down common marketing standards for certain fishery products. NOAA (National Marine Fisheries Service) of the U.S. Department of Commerce is the unique competent authority for the certification of fishery and aquaculture products intended for the EU. More detailed information can be found in the Guide: "[How to export Seafood to the European Union](#)".

As of December 13, 2014, all seafood sold at retail must have nutritional information on the package. [Regulation 1169/2011](#) describes the minimum information to mention of labels intended for retail or mass caterers. Exporters should pay specific attention to Article 9 and following articles as well as all annexes of the Regulation.

A new requirement regarding labeling of frozen food is in place since July 1, 2012. The intention of [Regulation 16/2012](#) is to ensure that the information on the date of production and freezing is provided to the food business operator to whom the food is supplied and not to the consumers. 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

Information on requirements to export pet food to the EU can be found in the FAS USEU website section on [Pet food](#) as well as in the [GAIN Report Exporting Pet Food to the EU](#).

[European Parliament and Council Regulation 767/2009](#) sets out new rules for the labeling and marketing of feed and pet food. More information about EU pet food labeling requirements can be found in the [GAIN Report E50060](#).

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.

Health Claims

<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/nutrition-health-claims/>

Rules on the use of health claims are set out in [Nutrition & Health Claims Regulation 1924/2006](#). [Regulation 432/2012](#) establishes the EU positive list of functional health claims and their conditions of use. See E15051. Food products carrying claims must also comply with the provisions of the EU's "[Food Information to Consumers \(FIC\)](#)" [regulation 1169/2011](#). [Commission Implementing Decision 2013/63](#) sets out guidelines for national control authorities as regards the implementation of specific conditions for permitted health claims.

[Regulation 353/2008](#) sets out implementing rules for applications for the authorization of health claims as provided for in Article 15 of Regulation 1924/2006. A guidance document on how companies can apply for health claim authorizations can be downloaded from EFSA's website at <http://www.efsa.europa.eu/en/nda/ndaclaims.htm>.

[Commission Regulation 907/2013](#) establishes rules for the use of "generic descriptors" which could be interpreted by consumers as health claims. For more information see [GAIN report "Health Claims – New EU Regulation on Generic Descriptors"](#).

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.

Section VIII. Copyright and/or Trademark Laws:

- **Trademarks**

There are two ways to register a trade mark in the EU. A trade mark can either be registered at national level at the industrial property office of EU Member States or 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 trade marks: <https://oami.europa.eu/ohimportal/en/trade-marks>. 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. Also please refer to [Council Regulation 207/2009](#), which created a single, unitary trademark registration system for the entire European Community.

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/>

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**

In November 2012, [Regulation 1151/2012](#) on quality schemes for agricultural products and foodstuffs repealing [Council Regulation 510/2006](#), was published, and came into force on January 3, 2013.

Regulation 1151/2012 sets out the mechanisms to protect PDOs and PGIs in third countries. In any case, some regulations additional regulations need to be adopted for it to be fully functional.

Note: Wines and spirit drinks are covered by separate legislation.

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.

Additional information is available in the FAS USEU website section on [geographical indications](#) and in the [GAIN report E80061 "The EU's Traditional Specialties Guaranteed Scheme Explained."](#) and [GAIN report E15051](#).

Section IX. Import Procedures:

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 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.

[Council Regulation \(EEC\) 2913/92](#) establishes the Community Customs Code. As of June 1, 2016 this will be repealed by [Council Regulation \(EU\) 952/2013](#). Commission Regulation 2454/93 as amended by [Regulation \(EU\) 1099/2013](#) lays down provisions for the implementation of the Code. 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. 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 BFSAs 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.

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.

Documents required for border control on imports (certificates) for food products for human and non-human consumption

<http://www.nvms-gvc.com/>

<http://www.nvms-gvc.com/Sert.Products.htm>

Documents required for border control for imports (certificates) for feed and feed products

<http://www.nvms-gvc.com/Furaj.htm>

Documents required for border phyto-sanitary control for imports (certificates)

<http://www.nvms-gvc.com/Fito-control.htm>

The import process requires:

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

EU legislation related to veterinary border inspection procedures

http://www.nvms-gvc.com/Border_veter.-Legislation.htm

Agricultural products are examined when they enter Bulgaria by the Bulgaria Border Inspection Posts. There are 8 border inspection points in Bulgaria. TRACES software system is not applied yet but the BFSA plans are to introduce the system in the first quarter of 2014. Bulgaria has derogation for updating all BIPs to execute both veterinary and phyto-sanitary control until August 2014. Currently, four BIPs has this ability and the other 4 should be upgraded in the first half of 2014.

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, entry points are added as follows: Vrashka Chuca, Strazimirovtsi, Logodaj, Lesovo, Malko Tarnovo, Oltomantsi:
<http://www.nvms-gvc.com/granichnipunktove.htm>

Designated point of entry (DPE) in accordance with Regulation 284/2012 EC;
Designated point of entry (DPE) in accordance with Commission Decision 2008/298/ EC
http://babh.government.bg/uploads/File/Aktualno_Border_controls/DPE%20284_2012%20and%20DPE%202008_289.pdf

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](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. 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. 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.

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 Bulgaria

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, Bulgaria

Tel.: (+359) 2-981-0111

E-mail: press@mh.government.bg

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

Direction Public Health

Tel.: (+359) 2-9301-252

<http://www.mh.government.bg/bg/kontakti/>

Bulgarian Food Safety Agency

Bul. Pencho Slaveikov 15A, Sofia 1606, Bulgaria

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, Bulgaria

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

Fax: (+359) 2-9859-4528

E-mail: pr@customs.bg

Website: <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>

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 Bulgaria

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

Lachezar Stanchev" Str. Nr 13

"Izgreve" 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/>

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://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

NDK Prono fl. 15 offices 8&9, Sofia 1414 Bulgaria

Tel.: (+359) 2-963-1254

Fax: (+359) 2-963-1254

E-mail: apitsd@mail.bg

Website: <http://www.apitsd.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/>

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

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, Koziak St. 1408 Sofia Bulgaria

Tel.: (+359) 2-939-5720/5704/5774

Fax: (+359) 2-939-5744

Email: AgSofia@fas.usda.gov

End of Report