

Bulgaria

Overview

Products tested and certified in the United States to American standards are likely to have to be retested and re-certified to EU requirements as a result of the EU's different approach to the protection of the health and safety of consumers and the environment.

Bulgaria has its standardization, conformity assessment, accreditation and product certification bodies. In certain areas, such as processed foods, beverages and pharmaceutical products, individual ministries or agencies issue sector-specific standards and certificates. Bulgaria is making an effort to harmonize its national standards with international standards. Bulgaria is a participant in the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC) and International Technical Union (ITU).

The Bulgarian Institute for Standardization will answer questions regarding standards <http://www.bds-bg.org/> or the Bulgarian Institute of Metrology <http://www.bim.government.bg>.

The major requirements for product safety are regulated in ordinances issued by the appropriate ministries and comply with the respective EU directives.
(see http://www.bds-bg.org/pages/?button_id=38)

Standards Organizations

(1. Ministry of Economy, Energy and Tourism through its European Integration Department <http://www.mi.government.bg/integration/eu/harmonize.html> is responsible for harmonizing the Bulgarian legislation with the EU legislation including everything related to ensuring the whole metrology, standardization, certification and testing, verification and accreditation process is in compliance with the EU requirements. The law on metrology can be reviewed on this web site as well.

2. Bulgarian Drug Agency of the Ministry of Health <http://www.bda.bg> is responsible for registration, product testing & certification, and establishing standards for pharmaceutical products and implants. The Ministry of Healthcare <http://www.mh.government.bg> is responsible for certification, registration, import licensing and establishing standards for some medical equipment, medical and natural products. In some cases, the Ministry of Healthcare performs these activities jointly with the Drug Agency.

3. Ministry of Agriculture and Food <http://www.mzh.government.bg> is the authority responsible for agriculture and food products testing and certification, registration of technical documentation, product certification, assessment of conformity, and establishing the national policy as to the Mutual Recognition Arrangement (MRA's) with international standardization institutions. It is responsible for the in-country and border control health and sanitary policy. The Ministry is performing its functions related to standards, certification, verification and conformity assessment through its National Services that are listed on its web site; the most important one being the National Veterinary Medical Service <http://www.nvms.government.bg/index.php> through its Directorate for Public Health Control. In January 2011, Bulgaria passed new legislation according to which the National Veterinary Medical Service, Phyto Sanitary Office and Public Health Offices of the Ministry of Health would be united in a single Food Safety Agency which will be responsible for the whole food and feed chain.

The Executive Agency Bulgarian Accreditation Service <http://www.nab-bas.bg> has accredited several laboratories for veterinary, food, and phyto sanitary expertise to perform laboratory testing, inspection, certification, auditing and verification of food, phyto and veterinary products.

4. The Bulgarian Institute for Standardization (www.bds-bg.org) performs all activities related to standardization, verification, editing and registration of standards for industrial commodities, machinery and transport equipment, construction and materials, chemistry, textiles, foodstuffs, electrical engineering commodities.

The Bulgarian Institute for Standardization has signed Mutual Recognition Agreements (MRA's) with the following organizations:

DIN - Deutsches Institut für Normung
BSI - British Standards Institution
UNI - Ente Nazionale Italiano di Unificazione
ASTM International - American Society for Testing and Materials

The Bulgarian Institute for Standardization is a full member of the International Standard Organization (ISO), which is the core international standardization body, and of International Electrotechnical Commission (IEC). The Institute is also an affiliate member of the European Committee for Electrotechnical Standardization (CENELEC) and of the European Committee for Standardization (CEN).

Bulgaria as a Member country of the World Trade Organization (WTO) is required under the Agreement on Technical Barriers to Trade (TBT Agreement) to report to the WTO all proposed technical regulations that could affect trade with other Member countries.

NIST Notify U.S. Service

Member countries of the World Trade Organization (WTO) are required under the Agreement on Technical Barriers to Trade (TBT Agreement) to report to the WTO all proposed technical regulations that could affect trade with other Member countries. Notify U.S. is a free, web-based e-mail subscription service that offers an opportunity to review and comment on proposed foreign technical regulations that can affect your access to international markets. Register online at Internet URL: <http://www.nist.gov/notifyus/>

Conformity Assessment

(Conformity Assessment is a mandatory step for the manufacturer in the process of complying with specific EU legislation. The purpose of conformity assessment is to ensure consistency of compliance during all stages, from design to production, to facilitate acceptance of the final product. EU product legislation gives manufacturers some choice with regard to conformity assessment, depending on the level of risk involved in the use of their product. These range from self-certification, type examination and production quality control system, to full quality assurance system. conformity assessment bodies in individual member states are listed in NANDO, the European Commission's website.

Key Link: <http://ec.europa.eu/enterprise/newapproach/nando/>

To promote market acceptance of the final product, there are a number of voluntary conformity assessment programs. CEN's certification systems are the Keymark, the CENCER mark, and CEN workshop agreements (CWA) Certification Rules. CENELEC has its own initiative. ETSI does not offer conformity assessment services.

The conformity assessment body in Bulgaria is the Bulgarian Institute of Metrology <http://www.bim.government.bg>. The Agency is performing fundamental metrology, metrological control, monitoring and supervision; conformity assessment; technical inspection of high-risk equipment; market surveillance and quality control of liquid fuels.

Product Certification

Product certification is performed by the State Owned Certification JSC <http://exact.e-gov.bg>. The entity performs testing and certification of products and management systems.

To sell products on the EU market, U.S. exporters are required to apply CE marking whenever their product is covered by specific product legislation. CE marking product legislation offers manufacturers a number of choices and requires decisions to determine which safety/health concerns need to be addressed, which conformity assessment module is best suited to the manufacturing process, and whether or not to use EU-wide harmonized standards. Products manufactured to standards adopted by CEN, CENELEC and ETSI, and published in the Official Journal as harmonized standards, are presumed to conform to the requirements of EU Directives. The manufacturer then applies the CE marking and issues a declaration of conformity. With the CE marking, the product will be allowed to circulate freely within the EU. A manufacturer can choose not to use the harmonized EU standards, but then must demonstrate that the product meets the essential safety and performance requirements. Trade barriers occur when design, rather than performance, standards are developed by the relevant European standardization organization, and when U.S. companies do not have access to the standardization process through a European presence.

The CE marking addresses itself primarily to the national control authorities of the member states, and its use simplifies the task of essential market surveillance of regulated products. The CE marking is not intended to include detailed technical information on the product, but there must be enough information to enable the inspector to trace the product back to the manufacturer or the authorized representative established in the EU. This detailed information should not appear next to the CE marking, but rather on the declaration of conformity (which the manufacturer or authorized agent must be able to provide at any time, together with the product's technical file), or the documents accompanying the product.

Accreditation

There is only one national accreditation body in Bulgaria – the Executive Agency Bulgarian Accreditation Service http://www.nab-bas.bg/index_en.php. The Agency reports directly to the Minister of Economy, Energy and Tourism and is the only national institute for accreditation of laboratories, certification bodies and inspection bodies. The Agency web site lists all accredited organizations and laboratories nationwide.

Publication of Technical Regulations

Each law, regulation, ordinance, Council of Ministers decree, decision, nationwide technical regulation, agreement etc. enters into force after official publication in the national gazette (State Gazette). Final regulations, ordinances and laws are published in State Gazette and in the official journals of every issuing authority. The State Gazette is issued only in Bulgarian. There are several information system database providers, which translate legislation published in State Gazette. See <http://www.apis.bg/en/>, <http://www.ciela.bg> or www.daxy.com.

Labeling and Marking

Manufacturers should be mindful that, in addition to the EU's mandatory and voluntary schemes, national voluntary labeling schemes might still apply. These schemes may be highly appreciated by consumers, and thus, become unavoidable for marketing purposes.

Manufacturers are advised to take note that all labels require metric units although dual labeling is also acceptable. The use of language on labels has been the subject of a Commission Communication, which encourages multilingual information, while preserving the right of member states to require the use of the language of the country of consumption.

The EU has mandated that certain products be sold in standardized quantities. Council Directive 2007/45/EC harmonizes packaging of wine and spirits throughout the EU. Existing national sizes will be abolished with a few exceptions for domestic producers.

Key Link: http://ec.europa.eu/enterprise/prepack/packsiz/packsiz_en.htm

The Eco-label

The EU eco-label is a voluntary label which U.S. exporters can display on products that meet high standards of environmental awareness. The eco-label is intended to be a marketing tool to encourage consumers to purchase environmentally-friendly products. The criteria for displaying the eco-label are strict, covering the entire lifespan of the product from its manufacture, use, and disposal. These criteria are reviewed every three to five years to take into account advances in manufacturing procedures. There are currently twenty-three different product groups, and approximately 250 licenses have been awarded for several hundred products.

Applications to display the eco-label should be directed to the competency body of the member state in which the product is sold. The application fee will vary between €300 and €1300 depending on the tests required to verify if the product is eligible. The eco-label also carries an annual fee equal to 0.15% of the annual volume of sales of the product range within the European community. However, the minimum annual fee is currently set at €500 and maximum €25,000.

There are plans to significantly reform the eco-label in the near future, reducing the application and annual fees and expanding the product ranges significantly. It is also possible that future eligibility criteria may take into account carbon emissions.

Contacts

For more information on each group and its Bulgarian Standard Code (BDS) with EU cross-reference codes, please contact Stanislava Dimitrova at the U.S. Commercial Service - email: stanislava.dimitrova@trade.gov

Trade Agreements

Bulgaria joined the EU in January 2007; became a member of the World Trade Organization in December 1996 and joined the Central European Free Trade Agreement (CEFTA) in January 1999. Bulgaria has free trade agreements with the following countries: China (1995), Croatia

(1998), Turkey (1999); Macedonia (signed in 1999); Israel (2002); Albania (2003), Serbia and Montenegro (2004), Bosnia and Herzegovina (2004).

Web Resources

<http://www.mi.government.bg> (Ministry of Economy, Energy and Tourism)

<http://www.customs.bg> (State Customs Agency)

<http://www.bda.bg> (Bulgarian Drug Agency)

<http://www.mzh.government.bg> (Ministry of Agriculture and Food Supply)

<http://www.bds-bg.org> (Bulgarian Institute for Standardization)

<http://www.bim.government.bg> (Bulgarian Institute of Metrology - BIM)

<http://exact.e-gov.bg> (State Certification JSC)

http://www.nab-bas.bg/index_en.php (Executive Agency Bulgarian Accreditation Service)

<http://www.apis.bg/en/> (Law publications, law and business-information database management)

<http://www.ciela.bg> (Law publications, law and business-information database management)