CONFORMITY ASSESSMENT

Bulgaria: latest legal and other developments in areas of conformity assessment, standardization and metrology

This paper has been submitted by the Bulgarian State Agency for Standardization and Metrology.

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TECHNICAL REGULATION AND CONFORMITY ASSESSMENT

1. The accession of Republic of Bulgaria into the European Union imposes full approximation of the regulatory matter regarding technical requirements to products, processes and services with these to the European legislation.

2. In order to achieve this goal Bulgarian authorities should:
   - Implement the European legislation (Acquis communautaire);
   - Establish adequate structures for the implementation of the harmonized legislation;
   - Establish an effective market surveillance system in order to guarantee the observation of the legislation.

LEGISLATION CONCERNING PRODUCT SAFETY:

3. The Law on Technical Requirements to Products (State Gazette 86/01.10.1999) is a horizontal framework for transposition of the New Approach Directives. The Law introduces the principles of the New Approach to technical regulation and the Global Approach to conformity assessment. A presumption of conformity with the essential requirements in case of conformity with the harmonized standards to the New Approach Directives is included. The Law provides for conformity marking, as an indication that a product is in conformity with the essential requirements and has been subject to the relevant conformity assessment procedure.

4. Draft Law amending the Law on Technical Requirements to Products was approved by the Council of Ministers with Decree No 238/23.04.2002 and submitted to the Parliament. With the adoption of the proposed amendments:

   - Chapter I, II and III, reflecting the European Commission comments and creating conditions for signing of Protocols to the Europe Agreement on Conformity Assessment and Acceptance of Industrial Products (PECA); provisions for consumer protection and authorized representative have been included;
   - Chapter IV “Market surveillance” that will enable the establishment of a secondary legislation necessary for the procedural development of the market surveillance system and detailed description of market surveillance activities are included;
   - Abolishment of the contradictions, concerning high-risk equipment, between the provisions of Chapter V of the Law on Technical Requirements to Products and the New and Global Approach principles.
5. With the adoption of the above-mentioned Decree, the State Agency for Standardization and Metrology will be transformed into State Agency for Metrology and Technical Surveillance.

6. The implementation of the Law on Technical Requirements to Products results in:

- Providing conditions of stimulating establishment of a system of conformity assessment bodies;
- Introduction of the Global Approach principles into the conformity assessment through implementation of the conformity assessment procedures, adopted in EU by Decision No. 93/465 EEC, which shall be described in the Ordinances transposing the directives concerned.
- Use of Accreditation in the mechanism of technical regulation for the purposes of licensing and notification of persons carrying out testing and certification in the area of application of the Law.
- Introduction of the conformity marking as a proof that the product complies to the requirements and has been subject to an appropriate conformity assessment procedure.

7. By the Decree No 164/03.08.2000 the Council of Ministers adopted the Ordinance on conformity marking (State Gazette 66/11.08.2000), which determines the graphic symbol and rules for affixing the conformity marking “CO”. The rules for affixing the “CO” marking are equivalent to the rules for affixing the CE marking.

8. The following Ordinances under the Law on Technical Requirements to Products have been adopted:


8.5. **Ordinance on the essential requirements and conformity assessment of machinery** (adopted with Council of Ministers’ Decree No 232/11.10.2001, published in the State Gazette No 91/23.10.2001), transposing Directive 98/37/EC. The Ordinance entered into force on 27.10.2001. 18 months after the entry into force of the Ordinance only machinery that meets the requirements of the Ordinance can be placed on the market.


8.9. **Ordinance on the essential requirements and conformity assessment of recreational craft** (adopted with Council of Ministers’ Decree No 247/01.11.2001, published in the State Gazette No 96/09.11.2001), transposing Directive 94/25/EC. The Ordinance entered into force on 05.11.2001. 18 months after the entry into force of the Ordinance only crafts and components thereof that meet the requirements of the Ordinance can be placed on the market.


8.11. **Ordinance on the essential requirements and conformity assessment of personal protective equipment** (adopted with Council of Ministers’ Decree No 94/07.05.2002, published in the State Gazette No 48/14.05.2002), transposing Directive 89/686/EEC. The Ordinance enters into force on 15.11.2003 except for Chapter 4 concerning the authorization of conformity assessment bodies, which enters into force on 15.08.2002.

**CERTIFICATION:**

9. The approximation of the Bulgarian legislation with the EU one in the field of “Free movement of goods” requires the separation of the **certification activity** from the State Agency for Standardization and Metrology.

10. The separation of the certification functions from the State Agency for Standardization and Metrology will be arranged by a Decree of the Council of Ministers establishing an Executive Agency “Testing and Certification” under the Minister of Economy.

11. According to the draft Law amending the Law on Technical Requirements to Products the State Agency for Standardization and Metrology (future State Agency for Metrology and Technical Surveillance) will designate conformity assessment bodies for all sectors, except construction products. Experts in the field of standardization and metrology and representatives of the relevant ministries will assist the Agency when assessing the applicants. The President of SASM has already approved the Designation Procedure.
12. The Ministry of Regional Development and Public Works will designate conformity assessment bodies in the field of construction products. Certification bodies, inspection bodies, testing laboratories and bodies, which can issue technical approvals, are subject to designation by the Minister of Regional Development and Public Works. Directorate “Technical Rules and Harmonization with the European Standards” within the ministry is responsible for the assessment of applicants and for the control of the designated bodies. When assessing the applicants the Directorate shall be assisted by expert teams comprising experts in the field of metrology, standardization and quality management systems and representatives of relevant competent institutions. On the basis of these assessments the minister issues the authorizations.

13. The State Agency for Standardization and Metrology has already designated one conformity assessment body responsible for all products and conformity assessment procedures within the scope of the Ordinance on the essential requirements and conformity assessment of appliances burning gaseous fuels. Two other certification bodies have applied for designation.

14. One application for designation of conformity assessment body under the Ordinance on machinery and the Ordinance on equipment intended for use in potentially explosive atmosphere and one application under the Ordinance on recreational craft are currently under assessment. The procedure for their designation is in progress.

ACCREDITATION:

15. The Government of Republic of Bulgaria has adopted the principle of integration of the tasks and functions related to accreditation in one National Accreditation Body. Consequently, the Executive Agency “Bulgarian Accreditation Service” (hereinafter referred to as BAS) was established as an independent national accreditation body to the Ministry of Economy by Decree of the Council of Ministers No.270/30.12.1999.

16. An Accreditation Council consisting of 21 members is constituted to BAS as a consultative body. With regard to the fact that the Council should be a good mirror of the stakeholders, recent changes (Council of Ministers Decree No130 of May 17, 2001 amending the Decree of the Council of Ministers No.270/30.12.1999) in the Council composition towards a better balance between representatives of the Government (Ministries), industry, employers, consumers, insurance sector and accredited laboratories and inspection and certification bodies were made. Standardization and Metrology are represented via the State Agency for Standardization and Metrology (SASM). Thus, a better member's ratio in favour of non-profit, non-governmental institutions was achieved.
17. By 31.03.2002 BAS has accredited 218 laboratories (including 196 testing laboratories and 22 testing/calibration laboratories or calibration laboratories), 2 product certification bodies, 2 quality management systems certification bodies, 1 personnel certification body and 30 inspection bodies.

18. In the context of its basic priority to join the European Cooperation for Accreditation (EA) as a full member, BAS activity in the last 2 years was aimed at improving its organization and system of accreditation in order to achieve compliance with the EA requirements - offering accreditation services in a competent, transparent, independent and non-discriminatory manner.

19. In March 2001, as a result of its application submitted in October 2000, BAS was accepted as a full EA member. In June 2001 BAS signed the EA Memorandum of Understanding and received the right to apply for a signatory to the EA Multilateral Agreements.

**STANDARDIZATION:**

20. The **Law on National Standardization** (SG 55/18.06.1999), which entered into force on 18 September 1999, has established the legal basis for the transition from mandatory to voluntary standards. This Law establishes the State Agency for Standardization and Metrology (SASM) as the national standardization body.

21. On 23 January 2002 the Parliament adopted amendments to the Law on National Standardization (State Gazette 13/05.02.2002), which has entered into force on 6 April 2002. With these amendments the Bulgarian Institute for Standardization (BIS) is appointed as the national standardization body. The Council of Ministers will adopt the Statute of BIS and the relevant amendments to the Statute of the State Agency for Standardization and Metrology (SASM) by June 2002. The Bulgarian Institute for Standardization will be established as a national standardization body with the status of independent legal entity under the Council of Ministers, taking on the functions of the Standardization Directorate of the State Agency for Standardization and Metrology.

22. One of the main tasks of the standardization body is the implementation of the European and international standards as Bulgarian standards. In connection with the application of the State Agency for Standardization and Metrology for a full membership in CEN/CENELEC the institution has a priority for implementing European standards in order to fulfill the requirements these European organizations have asked for to the national standard organizations.

23. Till the end of April 2002 the number of European standards transposed is 4397.
METROLOGY:

24. The Law on Measurements, adopted in 1998, is to a great extent in conformity with the Acquis in the field of Legal Metrology. It does not provide for the introduction of the Acquis in the field of pre-packaging.

25. The new Law on Measurements was adopted on 24.04.2002 (State Gazette 46/07.05.2002). The Law enters into force on 08.11.2002. The Law provides the legal basis for full compliance with the Acquis and transposes the basic requirements of the Council Directives on Common provisions for both measuring instruments and methods of metrological control (71/316/???), Units of measurements (80/181/???), Making-up by volume of certain pre-packaged liquids (75/106/???), Bottles used as measuring containers (75/107/???), Making-up by weight or by volume of certain pre-packaged products (76/211/???) and Ranges of nominal quantities and nominal capacities permitted for certain pre-packaged products (80/232/???).

26. The new Law removes the contradictions with the Law on Technical Requirements to Products concerning non-automatic weighing instruments and future New Approach Directive(s) on measuring instruments, which will be transposed under the Law on Technical Requirements to Products.

27. There are 2 competent bodies in the field of measuring instruments that are subject to mandatory control according to the Law on Measurements, adopted in 1998:
   - General Directorate "National Centre of Metrology" - for type approval,
   - General Directorate "Measures and Measuring Instruments" - for verification.

28. The State Agency for Standardization and Metrology has developed a plan for restructuring of the present administrative structures in order to cover all functions under the new Law on measurements - conservation of the national measurement standards, metrological control and metrological surveillance of pre-packaged products. The plan envisages restructuring to be completed by the date of entry into force of the new Law (08.11.2002).
Market Surveillance:

29. The State Agency for Standardization and Metrology (Market Surveillance General Directorate) is responsible for market surveillance within the scope of the Law on Technical Requirements to Products and is assisted through a Twinning Project in the build up of a functioning system and of a institutional basis for an effective market surveillance in the field of the New Approach Directives. The assistance consists in:

- Establishment of personnel capacity with qualification to assume MS responsibilities in the field of 20 NA Directives;
- Operational procedures for sampling, monitoring, dealing with complaints, enforcement, information, and statistics are in place, documented and applied;
- Developed, documented and operational on a network computerized management system for data, activities, cases, information exchange;
- Training of 3 trainers to work on professional and continuous education;
- Public relation matters.

30. The national authorities responsible for monitoring the market are already designated under different sector-specific laws:

- Under the Law on Technical Requirements to Products this authority is the State Agency for Standardization and Metrology.
- Under the Law on Foodstuffs the Hygiene-Epidemiological Inspectorates, National Veterinary Service and National Service on Plant Protection carry out the control on foodstuffs.
- Under the Law on Medicines and Pharmacies in Human Medicine the Executive Agency on Medicines and the Hygiene-Epidemiological Inspectorates carry out the control functions.

31. Cooperation between customs authorities and market surveillance bodies although not formally regulated is practically operational. Till the end of the year 2002 the national legislation will be supplemented in order to include legal obligations for the customs authorities compatible with the provisions of Regulation 339/93 - Council Regulation (EEC) No 339/93 of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries.

NOTE: Current situation by June 2002.

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