

**IMPLEMENTATION AND ADMINISTRATION OF THE AGREEMENT
ON TECHNICAL BARRIERS TO TRADE**

Communication from the Republic of Bulgaria

Revision

The following statement under Article 15.2 of the Agreement on Technical Barriers to Trade has been received from the Republic of Bulgaria.

I. INTRODUCTION

1. In accordance with Article 15.2 of the WTO Agreement on Technical Barriers to Trade (TBT) and pursuant to the decision of the TBT Committee of 14 July 1995 concerning the Statement on Implementation and Administration as contained in document G/TBT/1/Rev.8 of 23 May 2002, the following information concerning the measures taken by the Republic of Bulgaria to ensure the implementation and administration of the Agreement is being transmitted.

2. The Republic of Bulgaria has adopted a number of regulatory measures with respect to the fact that as a candidate country for the EU membership it has been developing a legal system fully compatible with the EC legal system according to the provisions foreseen in Articles 69 and 70 of the Europe Agreement Establishing an Association between the European Communities and their Member States and the Republic of Bulgaria.

II. IMPLEMENTATION OF THE TBT AGREEMENT

3. The basic law in accordance with which the Republic of Bulgaria approved and formally undertook obligations under the Agreement on Technical Barriers to Trade, is the Law on ratification of the Protocol for the Accession of the Republic of Bulgaria to the Marrakech Agreement Establishing the World Trade Organization and of the Marrakech Agreement Establishing the World Trade Organization. The Law was adopted by the National Assembly on 24 October 1996 and published by Decree of the President No. 380 of 29 October 1996 in State Gazette No. 93 of 1 November 1996. The date of entry into force of the TBT Agreement for the Republic of Bulgaria is 1 December 1996.

III. REGULATORY MEASURES

4. The Law on Technical Requirements to Products (published in State Gazette No. 86/01.10.1999, amend. SG No. 63/2002, SG No. 93/2002 and SG No. 18/2003) is a horizontal framework law. Its priority objective is the implementation of the principles under the New Approach and the Global Approach. This law establishes the provisions governing the procedure for setting out

essential requirements to products intended for placing on the market and/or putting into service; the obligations of persons placing products on the market and/or putting them into service; the designation procedure for carrying out conformity assessment of products to the essential requirements; the surveillance of products placed on the market and/or put into service; the technical surveillance as regards the compliance with technical requirements, rules and norms on safe operation of high-risk equipment.

5. Ordinance on Conformity Marking with the Essential Technical Requirements to Products (published in SG No. 66/11.08.2000). The Ordinance on Conformity Marking with the Essential Technical Requirements to Products defines the rules for using and drawing of the conformity marking which certifies that the conformance has been assessed against the essential requirements to products defined in the Ordinances according to Article 7 of the Law on Technical Requirements to Products. The rules for its affixing are equivalent to the rules for affixing the CE marking in the European Union.

6. The major part of the New Approach directives has been transposed into the Bulgarian legislation as ordinances under this law. Transposition of New Approach legislation (16 directives transposed by May 2003) creates the legal basis for the development of the relevant conformity assessment system offering services to manufactures. The following ordinances transposing the New Approach Directives have been adopted:

- Ordinance on the essential requirements and conformity assessment of appliances burning gaseous fuels, transposing Directive 90/396/EEC (published in SG No. 75/12.09.2000, in force as of 13.06.2001);
- Ordinance on the essential requirements and conformity assessment of construction products, transposing Directive 89/106/EEC (SG No. 93/14.11.2000, in force as of 14.11.2001; as last amended SG No. 75/ 28.08.2001);
- Ordinance on the essential requirements and conformity assessment of electrical equipment designed for use within certain voltage limits, transposing Directive 73/23/EEC (SG No. 62/13.07.2001, in force as of 14.01.2003);
- Ordinance on the essential requirements and conformity assessment of electromagnetic compatibility, transposing Directive 89/336/EEC (SG No. 78/11.09.2001, in force as of 12.09.2002; as last amended SG No. 13/11.02.2003);
- Ordinance on the essential requirements and conformity assessment of equipment and protective systems intended for use in potentially explosive atmosphere, transposing Directive 94/9/EC (SG No. 81/21.09.2001, in force as of 01.07.2003; as last amended SG No. 13/11.02.2003);
- Ordinance on the essential requirements and conformity assessment of simple pressure vessels, transposing Directive 87/404/EEC (SG No. 85/02.10.2001, in force as of 03.10.2002; as last amended SG No. 87/13.09.2002).
- Ordinance on the essential requirements and conformity assessment of machinery, transposing Directive 98/37/EC (SG No. 91/23.10.2001, in force as of 27.10.2001, the transitional period expired on 27 April 2003; as last amended SG No. 13/11.02.2003);
- Ordinance on the essential requirements and conformity assessment of toys, transposing Directive 88/378/EEC (SG No. 62/13.07.2001, in force as of 14.07.2002; as last amended SG No. 13/11.02.2003);

- Ordinance on the essential requirements and conformity assessment of lifts and their safety components, transposing Directive 95/16/EC (SG No. 94/02.11.2001, in force as of 03.08.2002);
- Ordinance on the essential requirements and conformity assessment of recreational craft, transposing Directive 94/25/EC (SG No. 96/09.11.2001, as last amended SG No. 13/11.02.2003);
- Ordinance on the essential requirements and conformity assessment of explosives for civil uses, transposing Directive 93/15/EEC (SG No. 26/12.03.2002, in force as of 31.12.2002; as last amended SG No. 13/11.02.2003);
- Ordinance on the essential requirements and conformity assessment of personal protective equipment, transposing Directive 89/686/EEC (SG No. 48/14.05.2002, in force as of 16.11.2003; as last amended SG No. 13/11.02.2003);
- Ordinance on essential requirements and conformity assessment of pressure equipment, transposing Directive 97/23/EEC (SG No. 87/13.09.2002, in force as of 13.03.2004 and as regards the part for designated bodies as of 17.09.2002);
- Ordinance on the essential requirements and conformity assessment of household electric refrigerators, freezers and combinations thereof, transposing Directive 96/57/EC (SG No. 84/03.09.2002, in force as of 05.03.2004);
- Ordinance on the essential requirements and conformity assessment of radio and telecommunications terminal equipment, transposing Directive 99/5/EC (SG No. 79/16.08.2002, in force as of 12.09.2002; as last amended SG No. 13/11.02.2003);
- Ordinance on the essential requirements and conformity assessment of non-automatic weighing instruments, transposing Directive 90/384/EEC.

A. CONFORMITY ASSESSMENT BODIES

7. According to the Law on Technical Requirements to Products, the State Agency for Metrology and Technical Surveillance (SAMTS) is a notifying authority for all ordinances, transposing the relevant New Approach Directives, with the exception of the Ordinance on the essential requirements and conformity assessment of construction products for which the Ministry of Regional Development and Public Works (MRDPW) is a notifying authority.

8. Conformity assessment of products covered by the New Approach Directives, in cases where the legislation requires a mandatory participation of a third party, is carried out by designated bodies authorized by SAMTS, and in the case of construction products - by the Ministry of Regional Development and Public Works.

9. Till May 2003 the State Agency for Metrology and Technical Surveillance has already designated 5 of these bodies (7 authorizations issued). The Ministry of Regional Development and Public Works has designated 6 bodies (6 authorizations issued). Six applicant bodies are under a designation procedure in the field of toys, EMC, SPV, gas appliances, pressure equipment, machinery, ATEX, LVD and R&TTE.

10. According to the Law on Technical Requirements to Products accreditation of the applicant body gives a presumption for compliance with the technical competence requirements. Most of the designated bodies have laboratories accredited according to EN ISO/IEC 17025 and EN 45001. One of the bodies is accredited according to EN 45012.

B. CERTIFICATION

11. By Council of Ministers' Decree 221/25.09.2002 (SG No. 94/04.10.2002) the Testing and Certification Directorate was segregated from the former State Agency for Standardisation and Metrology as an Executive Agency Certification and Testing (EACT) under the Minister of Economy and its Rules of the organizational structure were adopted. The State Agency for Standardisation and Metrology does not perform certification and standardization functions.

12. A number of certification bodies are working in the regulated and non-regulated area.

C. STANDARDIZATION

13. The Law on the National Standardisation (published in SG No. 55/1999, in force as of 19.09.1999, as last amended SG No. 13/5.02.2002, amendment into force as of 06.04.2002) regulates the development, approval, distribution and application of Bulgarian standards. National standardization is based on the principles of voluntary status, openness and transparency, equality and consensus of all interested parties in the process of development of Bulgarian standards. The Law lays down new procedures and rules for the implementation of European and international standards.

14. By Council of Ministers' Decree No. 152/19.07.2002 (SG No. 73/26.07.2002) the Rules of the organizational structure of the Bulgarian Institute for Standardization (BIS) was adopted and BIS is established as a National standardization body with the status of independent legal entity under the Council of Ministers, taking on the functions of the Standardisation Directorate of State Agency for Standardisation and Metrology (at present State Agency for Metrology and Technical Surveillance).

15. The Bulgarian Institute for Standardisation is recognized as the Bulgarian official standardization body representing the country in all areas of CEN and CENELEC competency. Half of the National TCs are organized in accordance with the CEN, CENELEC, ETSI, ISO and IEC TCs organization principle. BIS intends to apply for CEN and CENELEC membership in the second half of 2004 when all membership criteria will be fulfilled.

D. MARKET SURVEILLANCE

16. The Law on Technical Requirements to Products regulates the surveillance of products placed on the market and/or put into service, covered by the New Approach directives

17. The Ordinance on conditions and procedure for the conduction of market surveillance has been adopted on 17 May 2003 by the Council of Ministers. According to the Law the President of the State Agency for Metrology and Technical Surveillance carries out the market surveillance through the Directorate General Market Surveillance (DG MS).

18. Surveillance in the field of construction products is performed by SAMTS/DG MS together with the Ministry of Regional Development and Public Works. According to the last amendments of the Law on Technical Requirements to Products, market surveillance of medical devices will be regulated by a separate law.

19. Directive 92/59/EEC on General Product Safety was transposed into the Bulgarian legislation by the Law on Consumers' Protection and Trade Rules (SG No. 30/1999). According to this law the Commission for Trade and Consumers' Protection (CTCP) at the Ministry of Economy is the inspection/surveillance body.

20. In 2002 in order to achieve better results in the field of surveillance of non-nutritive (industrial) products an agreement on common activities between CTCP and SAMTS was signed. This agreement has recently been updated and the provision of employees having respective qualification for joint inspection activities is an obligation of the Agency.

E. METROLOGY

21. The Law on Measurements (SG No. 46/2002, in force as of 07.11.2002) transposes the basic provisions of Directives 71/316/EEC, 75/106/EEC and 80/181/EEC. The law creates the legal basis for transposition of the legislation in the field of legal metrology and pre-packages. This law shall regulate the public affairs related to the ensuring of traceability, accuracy and reliability of measurements. In compliance with national interests, the purpose of the law shall be to protect people's life and health and the environment from harmful influences, as well as persons' and legal entities' properties from unfavorable effects, which might be caused by incorrect measurement results. Only units of measurement allowed by the law shall be used in the Republic of Bulgaria. National standards and a system of certified reference materials shall be created in the country for ensuring the traceability of measurements. The new Law on Measurements shall revoke the Law on Measurements (SG No. 45/1998, amendments SG No. 55/1999 and No. 108/2001).

22. Ordinances adopted under the Law on Measurements:

- Ordinance on pre-packages, transposing Directives 75/106/EEC, 76/211/EEC and 80/232/EEC (SG No. 19/28.02.2003, in force as of 08.05.2003);
- Ordinance on packages used as measuring container bottles, transposing Directive 75/107/EEC (SG No. 19/28.02.2003, in force as of 08.05.2003);
- Ordinance on units of measurement allowed for use in the Republic of Bulgaria, transposing Directive 80/181/EEC (SG No. 115/10.12.2002, in force as of 13.12.2002);
- Ordinance on the order for authorization of persons carrying out verification of measuring instruments subject to metrological control (SG No. 17/21.02.2003);
- Ordinance on the order for approval of national measurement standards of the Republic of Bulgaria and the way of utilization and conservation of measurement standards (SG No. 33/11.04.2003).

F. PROTOCOLS TO THE EUROPE AGREEMENTS ON CONFORMITY ASSESSMENT AND ACCEPTANCE OF INDUSTRIAL PRODUCTS (PECA)

23. The conclusion of Protocols to the Europe Agreements on Conformity Assessment and Acceptance of Industrial Products (PECA) contributes to the removal of technical barriers to trade at regional level.

24. The negotiations of the Republic of Bulgaria for conclusion of PECA were launched on 19 September 2002. During the preliminary mission of the European Commission the relevant legislation and the readiness for signing of PECA were presented. The quality of the transposition of the European legislation into the Bulgarian one was assessed as satisfactory. Submission of additional information, as well as preparation of the amendments of the relevant normative acts with respect to comments of the European experts was undertaken. Obligations for the implementation of the European legislation in the field of legal metrology and prepackages, for the establishment and strengthening of the necessary administrative structure as well as for strengthening of the market surveillance structures were presented.

25. Sectors under negotiations for signing of the PECA are machinery, lifts, gas appliances, toys, EMC, LVD.

G. ACCREDITATION

26. 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 (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.

27. The Executive Agency Bulgarian Accreditation Service is the National body for accreditation of:

- testing and/or calibration laboratories;
- bodies for certification of products, quality management systems, environmental management systems, personnel and environmental verifiers;
- inspection bodies.

28. The Agency maintains a database of external assessors and in order to maintain and develop their competence it organizes training courses and seminars.

29. In the context of its basic priority to join the European Cooperation for Accreditation (EA) as a full member, BAS activities in the last 3 years were 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.

30. 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. In December 2002 BAS submitted an application for a signatory to the EA Multilateral Agreements in the field of quality system certification and personnel certification.

31. BAS has developed a Strategy for its accession to EA MLA in different fields. The full transition to the new standard for laboratories BDS EN 17025:2001 is also of crucial importance for joining EA MLA in the fields of testing and calibration and thus, for the product certification. The two years transitional period for the new standard started in August 2001 (after the adoption of the standard as Bulgarian).

32. A preliminary peer evaluation was performed in May 2003.

IV. ADMINISTRATION OF THE TBT AGREEMENT

33. 14. The obligations of relevant national authorities to meet the requirements on notification procedures under the TBT Agreement are set out in the Decree of the Council of Ministers No. 307/1996, SG No. 1/1997, amend. by Decree of the Council of Ministers No.67/2003, SG No. 27/2003, on the coordination and implementation of obligations arising from the membership of the of Republic of Bulgaria in the WTO. According to the same Regulation and to Decree No. 47 of 24 February 2003 for adoption of the Rules of the Organizational Structure of the State Agency for Metrology and Technical Surveillance, the responsibility for the implementation and administration of the TBT Agreement lies with the State Agency for Metrology and Technical Surveillance (SAMTS). The obligations foreseen in Annex 3 of the TBT Agreement are performed by the Bulgarian Institute for Standardization. Coordinating functions lie with the Ministry of Economy.

34. The Enquiry Point foreseen in Articles 10 of the Agreement has been established at the State Agency for Metrology and Technical Surveillance (SAMTS) and as defined by international agreements, provides answers to reasonable enquiries and information on notifications of draft

technical regulations, standards and conformity assessment procedures. The Enquiry Point ensures the dissemination of notifications and information provided by the Secretariat of the Committee for Technical Barriers to Trade to the relevant government authorities and NGOs.

35. The address, telephone, fax numbers and E-mail address of the National Enquiry Point are as follows:

State Agency for Metrology and Technical Surveillance
21, 6th September Street
1000 Sofia
Bulgaria

Tel.:	(+ 359 2) 981 44 51
Fax:	(+ 359 2) 986 17 07
E-mail:	intldiv@sasm.orbitel.bg
Contact person:	Ms. Violetta Veleva

36. The Enquiry point is fully operational and performs information exchange as foreseen in Article 10 of the TBT Agreement.

37. Work on draft standards and their references after approval are announced in the Official Bulletin of the Bulgarian Institute for Standardization. Information on notifications received is published in the Official Bulletin of the State Agency for Metrology and Technical Surveillance. The texts of the adopted new technical regulations are published in the State Gazette.
