

**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 considering 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 regarding the measures taken by the Republic of Bulgaria to ensure the implementation and administration of the Agreement is submitted as a revision of the notified information in document G/TBT/2/Add.32/Rev.2.

2. The Republic of Bulgaria, as a future EU member as of 1 January 2007, finalizes the adoption of the European regulatory measures with a view to establish a fully compatible legal system with the EC.

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 for Products (published in State Gazette No.86 of 1 October 1999, amend. SG No.63/2002, SG No.93/2002, No.18/2003, No.107/2003, No.45/2005, No.77/2005, No.88/2005, No.95/2005, No.105/2005, No.30/2006) 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 the essential Requirements for 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 the placed on the market and/or put into service products; the technical inspection of high-risk equipment.

5. A new Ordinance on Conformity Marking was adopted (Council of Ministers' Decree No.191 of 16 August 2005, SG No. 69 of 23 August 2005). The new Ordinance repeals the Ordinance on Conformity Marking with the Essential Technical Requirements for Products, adopted by Council of Ministers' Decree No. 164 of 3 August 2000 (SG No.66 of 11 August 2000). The Ordinance on Conformity Marking defines the rules for using and drawing of the conformity marking which certifies that the conformance has been assessed against the essential Requirements for Products defined in the Ordinances, implementing the New Approach Directives, under the Law on Technical Requirements for Products. The rules for its affixing are equivalent to the rules for affixing the "CE" marking in the European Union. The new Ordinance introduces the "CE" marking which will be applicable by the date of accession to the EU and will replace the "CO" marking for all products covered by the New Approach Directives.

6. At this time twenty two of the twenty five New and Global Approach Directives falling within the scope of Chapter "Free Movement of Goods" have been adopted as ordinances under the Law on Technical Requirements for Products and entered into force.

7. Transposition of New Approach legislation creates the legal basis for the development of the relevant conformity assessment system offering services to manufactures.

A. CONFORMITY ASSESSMENT BODIES

8. According to the Law on Technical Requirements for Products the State Agency for Metrological and Technical Surveillance (SAMTS) is the body responsible for designation of conformity assessment bodies under 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 the designating authority. Directorate "Designation of Conformity Assessment Bodies" within SAMTS is responsible for ascertaining the technical competency and capability of bodies, applying for designation, to perform the procedures for conformity assessment of products with the essential requirements of New Approach Directives. The Directorate contributes to the establishment of a national conformity assessment system by assisting and coordinating designated bodies' participation in international projects and programmes.

9. By October 2006 fifty nine (59) designations have been granted in the scope of eighteen (18) ordinances implementing the New Approach Directives (one designation means one designated body under a particular ordinance).

10. With respect of preparation for signing PECA (Protocols to the Europe Agreements on Conformity Assessment and Acceptance of Industrial Products) in the six sectors under negotiations (gas appliances, EMC (electromagnetic compatibility), LVD (low voltage directive), machinery, toys and lifts) nine designated bodies proposed by SAMTS for notification were assessed by EU experts contracted by the European Commission.

B. MARKET SURVEILLANCE

11. The Law on Technical Requirements for Products as a horizontal framework law regulates the carrying out of market surveillance activities as required by the respective New Approach Directives. According to the provisions of this law SAMTS carries out market surveillance activities through its specialized administrative units.

12. An Ordinance on the conditions and procedure for carrying out market surveillance has been adopted and brought into force. The latter provides possibilities for effectively carrying out the market surveillance activities.

C. INTERACTION OF MARKET SURVEILLANCE WITH OTHER BODIES:

13. SAMTS, through Directorate General "Market Surveillance", respects the provisions of the following agreements and instruction:

- Agreement for cooperation and joint activities with the Commission on Trade and Consumer Protection;
- Agreement for cooperation and joint activities in the field of construction products with the National Construction Control Directorate;
- Agreement for cooperation and joint activities in the field of machinery and personal protective equipment with the Labor Inspection;
- Common Instruction covering the regulations and procedures of interaction between the Customs authorities and State Agency for Metrology and Technical Surveillance.

D. METROLOGY

14. The Law on Measurements (State Gazette No.46 of 7 May 2002, as last amended by State Gazette No.88/2005) has been in force since 7 November 2002 and established the basis for ensuring traceability, accuracy and reliability of measurements and created the legal basis for transposition of the legislation in the field of legal metrology and pre-packages.

15. In accordance with the last amendments of the Law on Measurements SAMTS has been reorganized into State Agency for Metrological and Technical Surveillance after the Directorate General for National Center of Metrology (DG NCM) and the Directorate General for Measures and Measuring Instruments (DG MMI) have been segregated from the SAMTS. On the basis of the directorates segregated the Bulgarian Institute for Metrology (BIM) has been established to serve as the governmental authority with responsibilities in the field of fundamental and legal metrology. By the establishment of these new institutions a potential conflict of interests between the different activities related to conformity assessment, designation of conformity assessment bodies and market surveillance is avoided.

16. The Bulgarian Institute for Metrology has been assigned with the following functions:

- to develop, keep and improve national measurement standards;
- to ensure the traceability of the national measurement standards to international measurement standards or to measurement standards of Member States of the Meter Convention;
- to ensure the traceability of measurements;
- to disseminate the units of the national measurement standards to the subsequent in accuracy measurement standards in the country by means of calibration.

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

17. Signing of PECA is one of the important international agreements contributing to removal of technical barriers to trade at regional level.

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

F. STANDARDIZATION

19. The new Law on National Standardisation was adopted by the Parliament on 20 October 2005 and published in State Gazette No. 88 of 4 November 2005. The law entered into force on 5 May 2006 and this has changed the statute of the Bulgarian Institute for Standardisation (BIS) into an independent non-governmental, non-profit organization. BIS is responsible for the notifications foreseen in Annex 3 of the Agreement on Technical Barriers to Trade and presents them in the Information Center of ISO/IEC in Geneva, Switzerland. BIS responds to enquiries of interested parties and submits information through its National Enquiry points for standards. Work proceeding on draft standards, as well as their references after approval, is announced in the Official Bulletin of BIS.

G. ACCREDITATION

20. The Law on the Accreditation performed by the Bulgarian Accreditation Service was adopted by the Parliament on 29 November 2005 (published in State Gazette No.100 of 13 December 2005) and entered into force on 14 January 2006. The law aims to ensure sustainable regulation of accreditation activities, which were regulated by secondary legislation before its adoption.

21. The Executive Agency Bulgarian Accreditation Service (BAS) is the national accreditation body in the Republic of Bulgaria. All accreditation procedures are developed in compliance with the requirements of BDS EN 45000 and ISO 17000 series of standards and EA Guides. In relation to the entry into force of the new standard ISO/IEC 17011:2004 the management system of BAS was modified in 2005.

22. At present BAS operates the following accreditation schemes:

- accreditation of testing and/or calibration laboratories;
- accreditation of product certification bodies;
- accreditation of quality management systems certification bodies;
- accreditation of personnel certification bodies;
- accreditation of environmental management systems certification bodies;
- accreditation of inspection bodies;
- accreditation of verifiers;
- attestation of conformity of laboratories with the principles of good laboratory practice.

23. 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 becoming a signatory to the EA Multilateral Agreements in the field of the quality systems for certification and personnel certification. BAS has successfully completed the evaluation procedures for signing EA MLA (European Accreditation Multilateral Agreement) for certification of quality systems and for certification of personnel. At its meeting in March 2005 EA MAC has voted

the accession of BAS to the EA MLA in these two areas, and on 8 June 2005 at the General Assembly meeting the Protocol on BAS accession to the EA MLA was signed. The evaluation procedure for the remaining areas has started in October and November 2006.

H. TRANSPARENCY

24. Council of Ministers' Decree No.165 of 14 July 2004 on the organization and coordination of the exchange of information in the field of technical regulations and rules on information society services transposes in the Bulgarian legislation the requirements of Directive 98/34/EC and its amendment 98/48/EC.

25. This Decree regulates the order for coordination and exchange of information related to technical regulations, which lay down technical specifications and other requirements for products, the rules on services. It assigns the president of the State Agency for Metrological and Technical Surveillance, through the International Cooperation and European Integration Directorate, to fulfill the obligations of a National Information Center for the exchange of information on draft technical regulations with the European Commission.

26. After the ratification by the National Assembly of the Convention on Information and legal co-operation concerning "Information Society Services" with an Act (published in State Gazette No.38/2005), the Council of Ministers' Decree No.165 of 14 July 2004 has been amended with the aim to ensure the implementation of the provisions of the Convention on Information and legal co-operation concerning Information Society Services.

IV. ADMINISTRATION OF THE TBT AGREEMENT

27. The obligations under the TBT Agreement of relevant national authorities to meet the requirements on notification procedures is set out in Decree of the Council of Ministers No.307/1996 on the coordination and implementation of the obligations arising from the membership of Republic of Bulgaria in the WTO as last amended by the Decree of the Council of Ministers No.67/2003. According to Decree No.165 of the Council of Ministers from 14 July 2004 on the organization and coordination of the exchange of information in the field of technical regulations and rules on information society services (State Gazette No.64 of 23 July 2004, amend. SG No.91 of 15 November 2005) the president of SAMTS, through the Directorate for International Cooperation and European Integration, is assigned to fulfill the obligations as National Information Center for the exchange of information on draft technical regulations with the European Commission and with the Secretary General of the Council of Europe.

28. In line with these two Decrees and with the Rules of the organizational structure of the State Agency for Metrological and Technical Surveillance (State Gazette No. 20/2003; amend. SG No.48/2005, SG No.78/2005; SG No.96/2005; SG No.15/2006; SG No.28/2006; SG No.40/2006) the State Agency for Metrological and Technical Surveillance performs the functions of a National Enquiry Point for the following draft documents: (1) technical regulations under Article 10 of the Agreement on the Technical Barriers to Trade under Annex 1A to the Marrakech Agreement establishing the World Trade Organization; (2) technical regulations and rules on information society services.

29. The Enquiry point on technical regulations and conformity assessment procedures is fully operational and performs information exchange as foreseen in Article 10 of the TBT Agreement. It has been established at the State Agency for Metrological and Technical Surveillance and as required by the relevant international agreements, replies to enquiries and information on notifications of draft technical regulations, Bulgarian standards implementing the European harmonized 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, translated in Bulgarian. Information about the received notifications is published in the Official Bulletin of the State Agency for Metrological and Technical Surveillance. The texts of the adopted new technical regulations are published in the State Gazette.

30. Address, telephone, fax numbers and E-mail address of the National Enquiry Point for technical regulations and conformity assessment procedures:

State Agency for Metrological and Technical Surveillance
21, 6th September St
1000 Sofia, Bulgaria
Tel.: +359 2 981 44 51
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Contact person: Ms. Violetta Veleva

31. Address, telephone, fax numbers and E-mail address of the National Enquiry Point for standards

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3A, 165 Street, Izgrev
1797 Sofia, Bulgaria
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