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CONFORMITY ASSESSMENT\*

Review of recent developments

Submitted by Bulgaria

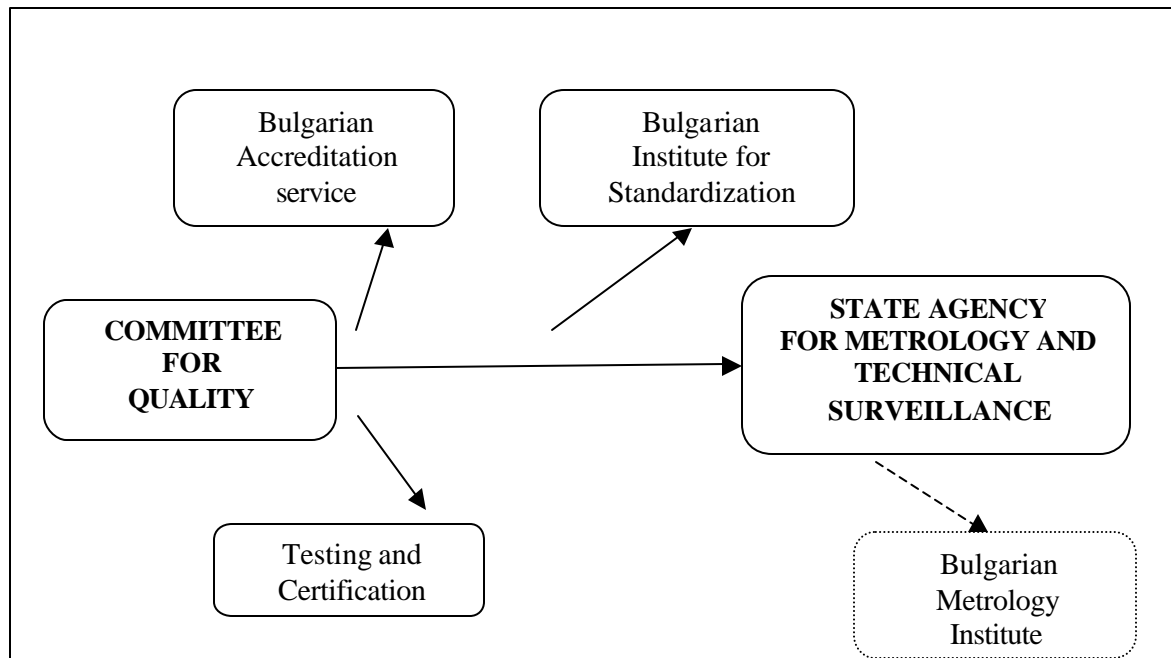
This document provides information on the latest developments in Bulgaria's conformity assessment system and is submitted by the State Agency for Metrology and Technical Surveillance of Bulgaria.

This document is presented to delegates for information. Apart from some minor editorial changes, the paper is reproduced in the form in which it was received.

\* The present document has been submitted after the official documentation deadline by the Trade and Timber Division due to resource constraints.

## I. INTRODUCTION

1. Regulations establishing the Bulgarian accreditation service, the Bulgarian Institute for Standardization and others, are developed in line with relevant EU principles and policies. The main reason for segregation of these institutions was to avoid sources of conflict of interest. Their new status allowed them to develop their activities in the service of the national industry.



2. The remaining part of the former Committee for Quality (at present, State Agency for Metrology and Technical Surveillance (SAMTS) sustains functions related to enforcement of technical legislation prescribed by two laws:

- (a) Law on Technical Requirements for Products;
- (b) Law on Measurements.

3. Other control functions (e.g. quality control of liquid fuels, control of fiscal devices) are also assigned to the Agency in accordance with its existing expertise.

4. In 2006, the main tasks of the State Agency are designation (and notification) of conformity assessment bodies, market surveillance of products under the New Approach directives, supervision of the use of measuring instruments, control of pre-packed goods and inspection of high-risk equipment.

## II. CHANGES IN LEGISLATION IN 2005-2006

5. The Law amending the **Law on Technical Requirements for Products (LTRP)** was adopted in May 2005. The Law, which deals with the preconditions for joining the European Single Market was coordinated with the European Commission in the framework of the negotiations for signing a PECA (Protocol to the Europe Agreement for conformity assessment and acceptance of industrial goods). The main amendments concern the precise definition of the obligations of operators responsible for placing products on the market after the signing of the Protocol and after accession of the country to the EU.

6. In connection with the amendments of LTRP, a Decree of the Council of Ministers on the amendment of ordinances adopted under the LTRP was adopted in February 2006. The amendments concern the procedure for granting designations to bodies for carrying out conformity assessment laid down in all ordinances as well as some provisions of ordinances under PECA annexes on the basis of European Commission comments.

7. The draft **Law on Medical Devices** is under agreement procedure before its approval by the Council of Ministers. The draft law aims at transposing the main principles and provisions of Directives 90/385/EEC, 93/42/EEC and 98/79/EC and ensuring their full transposition by secondary legislation.

8. The Law amending the **Law on Measurements** was adopted by the Parliament on 16.11.2005 and published in State Gazette No 95/29.11.2005. The law enters into force in 2006. It provides for the establishment of the Bulgarian Institute for Metrology on the basis of two directorates of the State Agency for Metrology and Technical Surveillance. The State Agency for Metrology and Technical Surveillance will be transformed into the State Agency for Metrological and Technical Surveillance and will retain the present functions of the remaining directorates.

9. A Bulgarian Institute for Metrology (BIM), established on the basis of the segregated directorates from SAMTS, shall be the state authority bearing the responsibilities in the field of fundamental and legal metrology.

10. The new **Law on National Standardisation** was adopted by the Parliament on 20.10.2005 and published in State Gazette No 88/04.11.2005. The law enters into force on 05.05.2006 and changes the statute of the Bulgarian Institute for Standardisation into an independent non-governmental, non-profit organisation. The law also transposes the relevant provisions of Directive 98/34/EC related to standards.

11. The **Law on Accreditation** performed by the Bulgarian Accreditation Service was adopted by the Parliament on 29.11.2005 (published in State Gazette No 100/13.12.2005) and entered into force on 14.01.2006. The law aims to ensure sustainable regulation of accreditation activities, which were regulated by secondary legislation before its adoption.

12. The Executive Agency Bulgarian Accreditation Service (BAS) to the Minister of Economy 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.

13. As a member of the European Cooperation for Accreditation (EA), BAS operates actively in order to meet the requirements for signing the Multilateral Agreements of EA (EA-MLA) for all fields of accreditation. On 08.06.2005 the Agency signed the EA MLA in the fields of Quality Management Systems Certification Bodies and Personnel Certification Bodies. The strategic objective of BAS is to sign the ?? MLA for the rest of the fields of accreditation.

14. At present, BAS has accredited 327 conformity assessment bodies (laboratories, certification bodies and inspection bodies). The number of BAS accreditations till 1.01.2005 is as follows:

- (a) testing laboratories – 123
- (b) calibration laboratories – 18
- (c) testing and calibration laboratories – 6
- (d) inspection bodies – 159
- (e) product certification bodies – 9
- (f) quality management systems certification bodies – 2
- (g) personnel certification bodies – 2
- (h) environmental management systems certification bodies – 1.

15. In 2006 Bulgaria is preparing to join the EU Single Market on Conformity Assessment and Acceptance of Industrial Products (PECA). The negotiations of Bulgaria for signing the Protocols to the Europe Agreements on Conformity Assessment and Acceptance of Industrial Products were launched at the end 2002 and finalized in 2006. The sectors under negotiations were Machinery, Lifts, Gas Appliances, Toys, Low-voltage equipment and Electromagnetic compatibility.

16. In five years, the number of conformity assessment bodies (CABs) providing services in support of the implementation of New Approach directives increased significantly, and nowadays there are more than 30 designated bodies.

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

<b>Directives</b>	<b>Number of bodies</b>	<b>Applicant bodies</b>
LVD	3	1
EMC	4	-
R&TTE	2	1
ATEX	1	-
Machinery	4	1 (extension)
Lifts	3	1
Personal prot. equip.	-	-
Gas Appliances	3	1
Simple pressure vess.	4	1
Pressure equipment	5	1
Toys	3	-
CIVEX	1	1 (renewal)
Constructions prod.	18	2
Non-aut. Weighing		1
Hot-water boilers		1

18. We can consider the number and scope of our CABs as adequate for the size of the national industry so efforts are concentrated on continuous improvement of the quality of their services. Within one year, a number of CABs and testing laboratories working under New Approach directives underwent two cycles of thorough assessments. Some CABs had to apply corrective actions in order to achieve full compliance with requirements for notified bodies but for their future prosperity the whole infrastructure needs to be strengthened.

19. The progress in enforcement of Community legislation and experience gained during the last 5-6 years is changing the understanding of our industry and CABs which can be proved by a number of indicators. Identification of common interest led to creation of representation and coordination structures. For example last year Bulgarian toy producers and importers established an association assisting them in meeting new requirements.

20. Designated CABs strengthen their cooperation at sectoral and horizontal level aiming at the alignment of operation and interpretation of legislation.

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