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**REVIEW OF DEVELOPMENTS IN STANDARDIZATION ACTIVITIES
AND IN THE FIELD OF REGULATORY COOPERATION AT THE
INTERNATIONAL, REGIONAL AND NATIONAL LEVELS**

Czech Republic: Recent development in the area of standardization

This paper has been submitted by the Czech Republic on the legal and organizational framework for preparation, adoption and application of technical regulations in the country.

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TECHNICAL HARMONIZATION PROCESS IN THE CZECH REPUBLIC

I. INTRODUCTION

1. The following information describes the developments in the area of technical regulations, standardisation and conformity assessment procedures in the Czech Republic. It is based on the communication of the Czech Republic to the WTO Committee on Technical Barriers to Trade (WTO/TBT Committee) in June 2001 (G/TBT/2/Suppl.1).

2. Recently, the area of technical regulations and standards has also been evaluated under two international regimes. Under the Organisation for Economic Co-operation and Development (OECD) the Review on Regulatory Reform in the Czech Republic has already been finished and considerable progress in enhancing market openness through regulatory reform in this area has been made. The OECD Report on Regulatory Reform in the Czech Republic is accessible in electronic form (OECD on-line bookshop, www.oecd.org, for a fee). The WTO has been performing the Trade Policy Review 2001 of the Czech Republic including an evaluation of standards and technical regulations with respect to technical barriers to trade. The final report is under preparation.

II. REGULATORY MEASURES

3. The Czech Republic has been adopting regulatory measures to protect justified concerns (endangering the public health and/or safety of persons, property and the environment). With respect to the fact that it is a candidate country for European Union (EU) membership it has been developing a legal system fully compatible with EU systems. This process is based on the provisions of Article 75 of the Europe Agreement establishing an Association between the Czech Republic and European Union and its Member States. Therefore, the Czech Republic as a Member of the WTO has fulfilled its obligations by removing technical barriers to trade and facilitating trade conditions, with respect to the Agreement on Technical Barriers to Trade (TBT Agreement) and the Agreement on Application of Sanitary and Phytosanitary Measures (SPM) Agreement, and as a member of the OECD with respect to OECD provisions.

4. The adoption of Act No 22/1997 Coll., on technical requirements for products and on amendments to some Acts (hereinafter Act No 22/1997 Coll.), which came into force on 1 September 1997, has been one of the major steps concerning the placing on the market of industrial products. Its subsequent amendment by Act No 71/2000 Coll., has been a further step towards the full compatibility with relevant EC law. The last modification was linked with adoption of a new Act No 102/2001 Coll., on general product safety, as some aspects of general product safety covered so far by Act 22/1997 Coll. were now repealed being covered by that new Act.

5. Act No 22/1997 Coll., lays down the method of establishing technical requirements related to industrial products which are likely to pose danger to justified concern, the rights and obligations of the persons who place on the market or distribute products, and the rights and obligations of persons designated to carry out activities relating to the preparation and application of Czech standards and testing (conformity assessment) in the regulated sphere.

6. Act No 22/1997 Coll., lays down unequivocally that Czech standards are not mandatory. Standards, however, can be used as a tool for presumption of conformity with requirements laid down in relevant technical regulations. This Act also lays down procedures for conformity assessment by third party participation and for the designation (notification) of a legal entity (authorised body) for activities concerning the conformity assessment of products. Thus, the Act creates a legal framework for adopting

the EC New Approach Directives in the form of a set of Government Orders to implement this Act. So far, the following Government Orders have been adopted, which lay down technical requirements for low voltage electrical devices, for products with respect to their electromagnetic compatibility, for machinery, toys, personal protective equipment, simple pressure vessels, for equipment and protective systems intended for use in potentially explosive atmosphere, gas appliances, construction products, medical devices, incl. active implantable medical devices and in vitro medical devices, lifts, effectiveness of hot water boilers, pressure equipment, radio and telecommunication terminal equipment, for non-automatic weighing instruments and recreational crafts. As result, a fundamental reduction in the number of products subjected to mandatory conformity assessment by a third party has taken place, and the principle of conformity assessment by the manufacturer or importer under determined conditions („self-assessment“) has been widely introduced.

7. Act No 258/2000 Coll., on public health protection for specific areas of health protection concerns has been adopted to regulate placing on the market of products within the competency of the Ministry of Health including articles used by children under 3 years of age, cosmetics or materials and articles intended to come into contact with foodstuffs. The aforementioned commodities are consequently regulated by relevant implementing decrees to this Act.

8. Act No 102/2001 Coll., on general product safety, which came into force on 1 July 2001 is another important horizontal legal instrument fully compatible with the European Union. Its purpose is to ensure the safety of products placed on the market or into the circulation. The Act is closely linked with another horizontal law - Act No. 634/1992 Coll., on consumer protection.

9. Some product sectors are regulated by specific legislation. For foodstuffs, Act No 110/1997 Coll., on foodstuffs and tobacco products was adopted and later amended by Act No 306/2000 Coll. To implement the above Act, the Ministry of Agriculture and Ministry of Health adopted a number of decrees, covering both the horizontal aspects of the Act (e.g. labelling) as well as the requirements for individual products, which require regulation (i.e. tea, coffee, milk, dairy products, etc.). After the said amendment to the Act the whole sector is, at the moment, under the regime of voluntary testing except for infant formula and novel foods where the Ministry of Health shall approve any product prior to its placing on the market (pre-market approval).

10. In the area of motor vehicles, the Czech Republic follows the rules as agreed on an intergovernmental level for technical conditions relating to vehicles. Construction of motor vehicles is generally covered by the application of the Agreement of 1958 adopted in the frame of the UN Economic Commission for Europe and amended by Revision 2 coming into force on 16 October 1995. The Czech Republic has actively participated in the UN/ECE Working Group for Vehicle Construction (WP 29), recently re-named as the World Forum for Harmonisation of Vehicle Regulations. New Act No 56/2001 Coll., on the conditions of vehicle operation on roads came into force on 1 July 2001. In order to implement this Act, the Ministry of Industry and Trade has prepared a decree, which is also based on the aforementioned rules and relevant EC legislation. The decree entered into force in August 2001. Thus, the remaining national specifics for the vehicle approvals will be suppressed.

11. The sector of telecommunications is regulated by Act No 151/2000 Coll., on telecommunications and by two implementing decrees. Technical requirements for radio and telecommunication terminal equipment lays down Government Order No 426/2000 Coll. to Act No 22/1997 Coll. The Government Order has transposed EC Directive 99/5/EC. The placing of products in this area on the market has been also made fully compatible with EC legislation.

12. For other sectors specific regulations have been adopted e.g. Act No 157/1998 Coll., on chemical substances and chemical preparations as amended by Acts Nos 352/1999 Coll., 132/2000 Coll., and 258/2000 Coll., Act No 156/1998 Coll., on fertilisers as amended by Act No 308/2000 Coll., Act No 79/1997 Coll., on pharmaceuticals as amended by Act No 149/2000 Coll., Act No 153/2000 Coll., on genetically modified organisms and products, which are fully compatible with EC law.

III. STANDARDISATION

13. According to Act No 22/1997 Coll., the Government guarantees the development and publication of standards. The expenses incurred in the course of the development of standards at the request of a ministry or a central administration authority as well as the costs connected with the membership in international and European standardisation organisations are met by the state. The Ministry of Industry and Trade has designated the Czech Standards Institute (CSNI) to carry out the development and publication of Czech standards. CSNI is the only Czech national standardisation body.

14. Thus, a Czech standard, marked with a protected symbol "CSN", is not mandatory. However, the relevant ministries are responsible for the use of any international standard as a basis for a draft technical regulation according to Article 2.4 of the WTO TBT Agreement. The Czech Republic accepted the Code of good practice for the preparation, adoption and application of standards already in 1995. A draft standard is discussed with every person who reports at the beginning of elaboration of the draft, or who submits his opinion on the published draft standard within the given time limit.

15. Act No 22/1997 Coll. defines a new concept of a 'harmonised Czech standard'. This standard becomes a harmonised standard when it has fully transposed a harmonised European standard adopted by European standardisation organisations, i.e. CEN, CENELEC and ETSI. Where it appears necessary in order to meet technical requirements for products specified in a Government Order issued under this Act, the national authority - the Czech Office for Standards, Metrology and Testing (COSMT) - may specify, for the purposes of conformity assessment, other standards or technical documents from international organisations whose issuing has been published in the Official Journal of the COSMT (e.g. ISO, IEC, ISO/IEC, UN/ECE, Codex Alimentarius) or national standards. Such standards are referred to as specified standards. Compliance with a harmonised or specified standard and in cases resulting from an international agreement also compliance with a foreign standard is recognised as compliance with the requirements laid down by the Government order to which such a standard is related. European and international standards are implemented continuously. Timely publication of information on drafts of all standards under preparation, and on issued standards, their amendments or withdrawals are announced in the Official Journal of the COSMT. Uniformity and mutual coherency of standards and their accordance with legal regulations have been ensured, and a justified concern has been protected. In the Czech Republic, a major share - more than 90 % items of the annual standard increase - is represented by the implementation of European and international standards into the CSN system. Overall 90% of European Standards have been implemented, about 65% of them by translation into the Czech language.

16. The Czech national standardisation body has represented the Czech Republic in ISO, IEC and ETSI since 1993, receiving a full membership in CEN in April 1997, and a full membership in CENELEC in October 1997.

IV. CONFORMITY ASSESSMENT OF PRODUCTS

17. In cases, when legislation requires the mandatory participation of a third party, conformity assessment of products is carried out by authorised persons designated by the COSMT according to Act No 22/1997 Coll. Authorisation of subjects is performed on the same basis as for the notified bodies in the EU. At the moment, there are 32 authorised bodies for conformity assessment in the Czech Republic,

at least one for each sector. Conformity assessment procedures in these areas are fully in accordance with procedures used by the notified bodies of the EU Member States.

18. The participation of the Czech conformity assessment bodies in European structures is a major precondition for integration of the Czech Republic's testing into the European system and compliance with the practices used in the EU. It means, in particular, the participation of authorised bodies in the meetings of the co-ordinating groups of notified bodies and of representatives of the Czech Association of Measurement, Testing and Analytical Laboratories (CZECHOLAB) in the European organisation EUROLAB. Full membership of the Czech Committee for Conformity Assessment in the European Organisation for Conformity Assessment (EOTC) is also important for the integration of the Czech Republic into European structures.

19. Participation in European and international certification systems has contributed to the systematic verification of the competency of individual institutions with respect to their equipment and staff qualifications.

20. Many of authorised bodies participate in the activities of international certification systems. For instance, the Electrotechnical Testing Institute is a regular member of many certification systems of electrotechnical products such as IECEE-CB, CCA, CCA-EMC, ENEC, EMEDCA, KEYMARK, EEPKA and ECE/UN for the homologation of motor vehicle accessories according to the UN/ECE rules. The Technical and Test Institute for Constructions, Prague, is a member of the European Union for Technical Approvals in Construction (UEAtc), and an observer of the European Organisation for Technical Approvals (EOTA). Then, there is the Testing Laboratory of Agricultural, Food Industry and Forestry Machines, which is responsible for standardisation codes for official testing of agricultural and forest tractors in terms of the OECD. The area of testing packages intended for packaging and transportation of dangerous goods according to international transportation rules by rail, road, air and sea transport (ADR, RID, IATA-DGR and IMDG Code) is covered by the Packaging Information and Mechanical Testing Centre, and Engineering Test Institute.

V. ACCREDITATION

21. Based on the decision of the Ministry of Industry and Trade, the Czech Accreditation Institute, Public Service Company (CAI) has been designated to perform accreditation pursuant to Act No 22/1997 Coll. Within the framework of the accreditation system of the Czech Republic it is the only governmentally recognized national body which ensures the accreditation of testing laboratories, calibration laboratories, certification bodies for certification of products, quality systems, Environment Management Systems (EMS) and personnel, inspection bodies, environmental auditors for the Environment Management Auditing Systems (EMAS) programme and providers of proficiency testing schemes.

22. The CAI is a member of the following international organisations: European Cooperation for Accreditation (EA), International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF). It is a signatory of the EA Multilateral agreement (MLA EA) on mutual recognition of accreditation results in the field of testing, calibration and certification (1998), including EMS (2000), signatory of the IAF MLA on mutual recognition of accreditation results in the field of certification of quality systems according to ISO 9000 series (1999), and a signatory of the MRA ILAC Agreement on mutual recognition of results in the field of testing and calibration (2000).

23. A representative of the Czech national authority (COSMT) is for the time being a member of the European Accreditation Advisory Board.

VI. METROLOGY

24. Many changes in legislation and infrastructure have taken place in the area of metrology at the national level. Act No 505/1990 Coll., on metrology was amended by Act No 119/2000 Coll., in order to make possible the transposition of the relevant EU law into the national legislation. In order to implement the Act, the decrees of the Ministry of Industry and Trade to this Act have been issued, e.g. decrees on uniformity and accuracy of measuring instruments and measurements, on specified measuring instruments for the mandatory type verification and approval, on basic measuring units and their marking, and on the method of manufacturing of some types of the pre-packaged goods marked by the „e“ symbol. Many decrees are related to particular types of measuring instruments. The last part of the large package of decrees is prepared for adoption to be ensured the transposition of all EC directives on metrology into Czech law by the end of 2001.

25. The COSMT is responsible for the area of metrology on the Governmental level. The Czech Metrology Institute (CMI) is the only recognized national executive body in the area of legal metrology.

26. The Czech Republic is a member of the Metric Convention and International Organisation of Legal Metrology. In 1999, the Czech Republic has signed, as a member of the Metric Convention, the Mutual recognition of national measurement standards and of calibration and measurement certificates issued by national metrology institutes which is one of the tools for removing barriers to trade between the Member States of this Convention. CMI experts have participated in technical committees and/or working groups of international metrological organisations (OIML, EUROMET, WELMEC). CMI laboratories have taken part in inter-laboratory comparative tests organised in various measuring disciplines by the International Bureau of Weights and Measures (BIPM), and also in regional comparative tests organised by the international organisations EUROMET and EA. COSMT is a member of the international non-governmental organisation WELMEC, dealing with the harmonisation of legislation in the area of metrology. A Memorandum of Understanding (MoU) with the United States National Institute of Standards and Technology (US NIST) is operational.

VII. MARKET SURVEILLANCE

27. The responsibility for inspection to determine whether products placed on the market are in compliance with requirements laid down by regulations or standards referred in technical regulations or whether the products are safe with respect to general product safety principles is carried out by market surveillance bodies. According to Act No 22/1997 Coll., the Czech Trade Inspection performs surveillance. Pursuant to other acts there exist the following market surveillance bodies: the Czech Agricultural and Food Inspection, Hygiene Service, State Veterinary Administration, State Institute for Drug Control, Institute for State Control of Veterinary Immunologicals and Medicaments, and the Czech Environmental Inspection. Some more information on this topic was communicated to Members in the special paper to WP.6 of the Czech Republic (TRADE/WP.6/2000/19 of 25 October 2000).

VIII. MUTUAL RECOGNITION AGREEMENTS

28. The purpose of concluded mutual recognition agreements is to remove technical barriers to trade by simplifying administrative procedures for products placed on the market that are subject to conformity assessment or certification in the territory of contracting parties. It applies to industrial products which originate in the contracting parties, which are the subject of trade between the manufacturing and trading subjects of the Czech Republic and the other contracting party, and are subject to conformity assessment in at least one of the contracting parties (“justified concern”). The authorised body can recognise results of tests and findings carried out abroad also in the case when the relationship between the parties has no contractual basis, if the same level of protection of the justified concern, corresponding with the requirements of the relevant technical regulations, is ensured.

29. The Protocol to the Europe Agreement establishing an Association between the European Communities and their Member States, on the one part, and the Czech Republic, on the other part, on Conformity Assessment and the Acceptance of Industrial Products (PECA) is one of the important international agreements contributing to the removing of technical barriers to trade at the regional level. Compared to "classical" mutual recognition agreements the PECA is a special tool because of the fact that this Agreement is thoroughly based on the principle of harmonisation of the national legislation of the Czech Republic with EC law in accordance with the Europe Agreement. This principle shall lead to the removing of duplicate procedures before placing a product of one contracting party on the market in the territory of the other contracting party. PECA entered into force on 1 July 2001.

30. At the moment, parallel agreements to the PECA with the EEA-EFTA countries, Switzerland and Hungary are under preparation. They should come into force at the beginning of 2002.

31. Indicative List of the Current Mutual Recognition Agreement (MRA) Initiatives

| Parties | | Sectors | Concluded | Valid from | Type of recognition |
|---|--|--|-----------|---|---------------------|
| Czech Republic (COSMT) | Slovak Republic (Slovak Office for standards, Metrology and Testing) | except for foodstuffs and tobacco products, cosmetics, and construction products | yes | 1997-09-01 (1993-03-31) | CERT ACC |
| Czech Republic (Ministry of Industry and Trade) | Slovak Republic (Ministry of Construction and Regional Development) | construction products | yes | 1999-05-25 | CERT ACC |
| Czech Republic (COSMT) | Republic of Slovenia (SMIS) | electric equipment, machinery, medical devices, toys, personal protective equipment, construction products | yes | 1996-02-23 | ACC |
| Czech Republic (COSMT) | Republic of Poland (PCBC) | electromagnetic compatibility, machinery, toys, personal protective equipment, selected products, simple pressure vessels, equipment and protective systems intended for use in potentially explosive atmosphere, gas appliances, construction products, | yes | 1997-01-27, a new agreement under preparation | ACC |
| Czech Republic (COSMT) | Russian Federation (GOS-STANDART) | machinery, gas appliances, simple pressure vessels, personal protective equipment, construction products, toys, foodstuffs | yes | 1999-04-15 (1994-12-04) | ACC |
| Czech Republic (COSMT) | Ukraine (DIRŽ - STANDART) | without specification | yes | 1996-12-04 | ACC |

| Parties | | Sectors | Concluded | Valid from | Type of recognition |
|----------------|---------------------|--|-----------|--|--|
| Czech Republic | EU | machinery, low voltage equipment, electromagnetic compatibility, equipment and protective systems intended for use in potentially explosive atmosphere, gas appliances, personal protective equipment, lifts, simple pressure vessels, pressure equipment, hot water boilers, good manufacturing practice for medicinal products | no | 2001-07-01 | PECA: mutual recognition of conformity assessment results |
| Czech Republic | EEA-EFTA | machinery, low voltage equipment, electromagnetic compatibility, equipment and protective systems intended for use in potentially explosive atmosphere, gas appliances, personal protective equipment, lifts, simple pressure vessels, pressure equipment, hot water boilers, good manufacturing practice for medicinal products | no | Envisaged entering into force at the beginning of 2002 | parallel agreement to the PECA mutual recognition of conformity assessment results |
| Czech Republic | Swiss Confederation | machinery, personal protective equipment, low voltage equipment, electromagnetic compatibility, equipment and protective systems intended for use in potentially explosive atmosphere, gas appliances | no | Envisaged entering into force at the beginning of 2002 | parallel agreement to the PECA mutual recognition of conformity assessment results |
| Czech Republic | Republic of Hungary | machinery, low voltage equipment, electromagnetic compatibility, hot water boilers, gas appliances | no | Envisaged entering into force at the beginning of 2002 | parallel agreement to the PECA mutual recognition of conformity assessment results |

Note: ACC – test result acceptance
CERT – certificate recognition

IX. RELEVANT CONTACTS

32. Detailed information is available on the web pages of: the COSMT - www.unmz.cz, CMI - www.CMI.cz, CSNI - www.csni.cz, CAI - www.cai.cz, Czech Trade Inspection - www.coi.cz, Ministry of Industry and Trade - www.mpo.cz, Ministry of Agriculture - www.mze.cz.

Individual contacts: Czech Office for Standards, Metrology and Testing
International Relations Dept.
Mr. Libor Dupal
Director
Gorazdova 24, P.O. Box 49
128 01 Praha 2
Czech Republic
e-mail: dupal@unmz.cz
tel. +420224907132
fax. +420224914990

33. The drafts of technical regulations are notified under the procedures of WTO (Technical Barriers to Trade (TBR) and Application of Sanitary and Phytosanitary Measures (SPM) Agreements). Relevant source of information is available in the WTO/TBT Enquiry Point and WTO/SPM Enquiry Point:

WTO/TBT Enquiry Point
Czech Office for Standards, Metrology and Testing
Gorazdova 24
P.O. Box 49
128 01 Praha 2
Czech Republic
e-mail: wto.tbt@unmz.cz
Tel.: + 420 2 24907 135
Fax: + 420 2 24907 131
Contact Person: Libuše Romanovská, PhD

WTO/SPM Enquiry Point
The Ministry of Agriculture
Tišnov 17
117 05 Praha 1
Czech Republic
e-mail: kantorova@mze.cz
Tel.: +420 2 21812754
Fax: +420 2 24810478
Contact person: Vladimíra Kantorová

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