ECONOMIC COMMISSION FOR EUROPE

COMMITTEE FOR TRADE, INDUSTRY AND ENTERPRISE DEVELOPMENT
Working Party on Technical Harmonization and Standardization Policies
Eleventh session, 29-31 October 2001
Item 7 of the provisional agenda

HORIZONTAL LEGISLATIVE AND INSTITUTIONAL FRAMEWORK CONCERNING TECHNICAL HARMONIZATION POLICIES

It is recalled that at its tenth session (November 2000), the Working Party invited delegations to provide written information on their national horizontal legislation concerning technical regulations, standardization and conformity assessment procedures with a view to compiling such information.

The proposal for such a compilation was developed by the Rapporteurs on Harmonization who prepared this document which contains information on Czech Republic, Hungary, Slovakia, Slovenia and Sweden.

This document is presented for information to delegates. It is reproduced in the form in which it was received by the secretariat
Introduction

At the tenth session of the Working Party, delegations were invited to provide written information on their national horizontal legislation concerning technical regulations, standardisation and conformity assessment procedures.

The rapporteurs on harmonisation prepared a form covering the following items:

- Technical regulations
- Standardisation
- Conformity assessment
- Accreditation
- Metrology
- Implementation and Administration of International Obligation Related to Technical Barriers to Trade (Possible organigramme)

The Rapporteurs on Harmonization filled the forms to describe the state of play in Sweden and in the Czech Republic. Some countries from central Europe that are in advanced stage of harmonisation of their technical legislation with EC law were asked to do the same review on behalf of their countries. The result of this examination is presented to the delegations as an example to be taken as a model when they themselves provide such information.

The filled sheets are enclosed in alphabetical order.
CZECH REPUBLIC

Technical regulations


Standardisation

Act No 22/1997 Coll.

Conformity assessment

Act No 22/1997 Coll.

Accreditation

Act No 22/1997 Coll.

Metrology


Implementation and Administration of International Obligations Related to Technical Barriers to Trade

Communication of the Ministry of Foreign Affairs No 191/1995 Coll., on conclusion of Agreement on establishment of the World Trade Organisation (WTO)
Partly: Act No 22/1997 Coll.
Note: Government Order (procedures of providing information on drafts of technical regulations and standards - transposition of 98/34/EC Directive) to Act 22/1997 Coll. – under preparation;
Government Resolution (general principles of preparation, adoption and application of technical regulations and standards – principles related to WTO/TBT) – under consideration and preparation.
Note:
Texts of the relevant acts referred above, in English unofficial translations are available on http://www.unmz.cz
Organigramme - Czech Structures for Technical Harmonisation, General Chart

a) establishing by Law, appointing by ministerial designation,
b) cooperation
c) coordination of technical harmonization process
d) authorization, designation
e) supervising
d) accreditation, technical competence evaluation
e) imaginary boarder between governmental area and non-governmental bodies

1) Note: including interministerial working and coordination groups
HUNGARY

**Technical regulations**

Government Decree 2158/2001 (VI.27.) on the Law Harmonisation Program aiming to harmonise the Acquis Communautaire by December 31, 2001

**Standardisation**

Act XXVIII of 1995 on national standardisation

**Conformity assessment**

Government Decree 182/1997 (X.17.) on the detailed rules on the designation of testing, inspection and certification bodies for conformity assessment of technical products

Decree 4/1999 (II.24.) of the Ministry of Economic Affairs on the detailed rules on the designation of testing, inspection and certification bodies for conformity assessment of technical products

Decree 22/1999 (VIII. 04.) of the Ministry of Transport, Communications and Water Management on the detailed rules on the designation of testing, inspection and certification bodies for conformity assessment of certain communications and information technology products

Decree 48/1999 (X.6.) of the Ministry of Health on the detailed rules for the designation of testing, inspection and certification bodies for conformity assessment of medical devices

**Accreditation**

Act XXIX of 1995 on accreditation

**Metrology**

Act XLV of 1991 on metrology

**Implementation and Administration of International Obligations Related to Technical Barriers to Trade**

Act IX of 1998 on the announcement of the Marrakesh Agreement and its annexes (including the TBT Agreement)

Government Decree harmonising Directive 98/34/EC and its amendment, Directive 98/48/EC (this decree is under preparation and will be finalised by the end of 2001)
General Chart on the structure for Technical Harmonisation

Institutions cooperating in the field preparing regulations: authorities, industrial and trade chambers, consumer protection agencies

Hungarian Standards Institution
Accreditation, Metrology

Parliament, Government
Ministry of Economic Affairs (MEA)
Designation Committee of MEA concerning conformity assessment
Conformity Assessment Bodies
Market surveillance authorities
Market
SLOVAKIA

Technical regulations

The Act No. 264/1999 Coll. on technical requirements for products and on conformity assessment (Act No. 264/1999 Coll.)

Standardisation

Act No. 264/1999 Coll.

Conformity assessment

Act No. 264/1999 Coll.

Accreditation

Act No. 264/1999 Coll.

Metrology

Act No. 142/2000 Coll. on Metrology

Implementation and Administration of International Obligations Related to Technical Barriers to Trade


Note:
The Amendment to Act 264/1999 (now in its second reading in the Parliament) stipulates the obligation of all regulatory authorities to send a draft of technical regulation to the Slovak Office of Standards, Metrology and Testing to be proceed through the TBT WTO enquiry point.
Government Order (procedures of providing information on drafts of technical regulations and standards - transposition of 98/34/EC Directive) to Act 22/1997 Coll. – under preparation;

Note:
Texts of the relevant acts referred above, in English unofficial translations are available on http://www.normoff.sk
Organigramme - Slovak Structures for Technical Harmonisation, General Chart

a) established by Law, (appointed by ministerial designation in the case of SNAS, by designation of SOSMT in case of SUTN)
b) cooperation
c) coordination of technical harmonization process
d) authorization, designation
e) supervising
d) accreditation, technical competence evaluation
e) imaginary boarder between governmental area and non-governmental bodies

Interministerial Coordination Boards:
1. for state policy in standardisation
2. for state policy in assessment
3. for notification (TBT WTO, SPS WTO, 98/34 – in preparation, EFTA, CEFTA)
4. for state policy in quality
SLOVENIA

Technical regulations

Act on Technical Requirements for Products and Conformity Assessment (O.J. of RS, No. 59/1999)

Standardisation

Standardisation Act (O.J. of RS, No. 59/1999)

Conformity assessment

Act on Technical Requirements for Products and Conformity Assessment (O.J. of RS, No. 59/1999) and
Decree on the Method of Designating Conformity Assessment Bodies (O.J. of RS, No. 24/2000)

Accreditation

Accreditation Act (O.J. of RS, No. 59/1999)

Metrology

Metrology Act (O.J. of RS, No. 22/2000)

Implementation and Administration of International Obligations Related to Technical Barriers to
Trade

Decree on the Notification Procedure in the Area of Standards, Technical Regulations and Conformity Assessment
Procedures (O.J. of RS, No. 66/2000)
Organigramme - Structures for Technical Harmonisation, General Chart

a) established by Law, appointed by ministerial designation
b) co-operation
c) co-ordination of technical harmonisation process
d) authorisation, designation
e) supervising
d) accreditation, technical competence evaluation
e) imaginary boarder between governmental area and non-governmental bodies

Ministry of Education, Science and Sport
Ministry of the Economy
Other Ministries
Other Offices and Subjects
Designated/Notified Bodies (conformity assessment in regulated area)
Authorized Metrology Centres, Calibration Services Centres, Accredited Calibration Centres
Slovenian Institute for Standardisation
Slovenian Accreditation
Metrology Institute
SWEDEN

Technical regulations

Law (1994:1500) concerning accession of Sweden to the European Union
Ordinance (1994:2035) concerning certain obligations for authorities following from the membership in the European Union

Law (1976:633) concerning promulgation of Laws and other Statutes
Ordinance (1976:725) concerning promulgation of Laws and other Statutes
Ordinance (1999:654) concerning amendment in the Ordinance (1976:725)

Law (1992:1534) and (1994:1588) concerning CE marking

Standardisation

Statues of Swedish Standards Council, SSR (with government involvement)

Conformity assessment/Accreditation

Law (1992:119) concerning Conformity Assessment
Ordinance (1993:1065) concerning Conformity Assessment

Ordinance (1996:81) with Instructions for Swedish Board for Accreditation and Conformity Assessment (SWEDAC), with subsequent amendments

Metrology

Law (1992:1514) concerning Quantity Units, Measurements and Measuring Device
Ordinance (1993:1066) concerning Quantity Units, Measurements and Measuring Device
Ordinance (1989:527) concerning National Standards Laboratories for Measurement

Implementation and Administration of International Obligations Related to Technical Barriers to Trade

Implementation Regulation (KFS 1999:1) to the Ordinance on Technical Rules

Ordinance (1996:830) concerning information on national measures derogating from the principle of the free movement of goods within the Community
Ordinance (1999:762) concerning obligations for information on national measures restricting the free movements of goods

Ordinance (1998:279) with Instructions for the National Board of Trade, with subsequent amendments
Swedish Structures for Technical Harmonization, General Chart

Ministry for Foreign Affairs

+ 9 more Ministries

National Board of Trade

Regulatory Authorities

SWEDAC

More than 140 Authorities (of which approx. 1/3 issue technical regulations)

Conformity Assessment Bodies, No of accreditations:

<table>
<thead>
<tr>
<th>Category</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratories</td>
<td>556</td>
</tr>
<tr>
<td>Certification Bodies</td>
<td>67</td>
</tr>
<tr>
<td>Inspection Bodies</td>
<td></td>
</tr>
<tr>
<td>Type A, B and C</td>
<td>2086</td>
</tr>
</tbody>
</table>

Recognised National Standardisation Bodies:

- SIS, Swedish Standards Institute
- SEK, Swedish Electrotechnical Commission
- ITS, Information Technology Standardization