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COMMITTEE FOR TRADE, INDUSTRY AND  
ENTERPRISE DEVELOPMENT

Working Party on Technical Harmonization and  
Standardization Policies

Tenth session, 6-8 November 2000

Item 12 of the provisional agenda

**Market surveillance in the Czech Republic**

Response to the request from the CIS for Information on Western Experience  
in Control over Implementation of Standards and Regulations

This paper has been submitted by the Czech Trade Inspection and contains information on its activities.

It is recalled that in October 1999, the Working Party received a request from the CIS Interstate Council for Standardization, Metrology and Certification asking for information on western experience in control over implementation of standards and regulations (the request is reproduced in the Annex to this document).

This is a working document, circulated to the delegates for information. It is reproduced in the form and language in which it was received by the secretariat.

### **Response to the request from the CIS for Information on Western Experience in Control over Implementation of Standards and Regulations**

Market surveillance in the Czech Republic is the responsibility of the state administration. The Czech Republic has built-up a basic network of market surveillance authorities, most of them with a long time tradition of activities.

The main market surveillance authorities are: The Czech Agricultural and Food Inspection, the State Institute for Drug Control and The Czech Trade Inspection.

The Czech Agricultural and Food Inspection (CAFI) is an authority supervised by the Ministry of Agriculture. It carries out supervision over food safety and quality. Its principal activities comply with EC Directive 89/397/EEC on the official control of foodstuffs. Its activities cover inspection of food safety and quality, obligatory and voluntary certification of fresh fruit and vegetables and wine, monitoring of contaminants in food chains, inspection of observance of binding provisions for food production, distribution and trading, active participation in international organisations: OECD, FAO/WHO, UN/ECE, EC, CEFTA.

The testing laboratories of regional inspectorates are accredited in accordance with the European standards, 45000 Standard series and are engaged in interlaboratory proficiency testing and international laboratory proficiency testing - FAPAS (Food Analysis Performance Assessment Scheme) organized by MAFF (Ministry of Agriculture, Fisheries and Food) in the U.K. The CAFI has a total of 432 employees, in particular experts in the fields of chemistry, veterinary medicine, microbiology, food hygiene, food technology and agricultural production.

The State Institute for Drug Control (SIDC) is an authority supervised by the Ministry of Health. It is responsible for market surveillance in the field of human medicinal products, including registration, licensing, market supervision, enforcement, pharmacovigilance and some certification activities in the field of human medicinal products. The SIDC is empowered to suspend the use or marketing of a pharmaceutical product and/or to withdraw it from the market; in the case of non-compliance with good practices it has the right to suspend the licences of manufacturers and wholesalers. The SIDC also acts as the drug information centre for all the whole country both for health care professionals and lay public. Also complaints are collected and dealt with. Drug control has a long tradition in the Czech Republic, it dates back to 1918, the SIDC was established in 1952. Overall staff of the SIDC is 300 persons.

The SIDC is actively involved in a number of international bodies, which help to share training, expertise and confidence, including the European Pharmacopoeia Commission / the European Department for the Quality of Medicines of the Council of Europe / the Official Medicines Control Laboratories; OECD Panel for Good Laboratory Practice; the Pharmaceutical Inspection Convention/Scheme; Pharmaceutical Evaluation Report Scheme. Experts of the Institute participate as representatives of the Collaboration Agreement between Drug Regulatory Authorities in EU Associated Countries in three working parties of the European Commission and/or the EMEA.

This paper, however, gives an account of market surveillance activities of the Czech Trade Inspection relating to industrial products.

## **Czech Trade Inspection – Market Surveillance Authority**

The Czech Trade Inspection (CTI) is an executive supervisory authority (subordinated to the Ministry of Industry and Trade) in the field of consumer protection. Its activities are defined by Act No. 64/1986 Coll., on the Czech Trade Inspection, as amended, and some other Acts. The Act on the Czech Trade Inspection specifies the CTI's powers to carry out inspections, order specific measures and impose penalties. In addition it also directs the CTI to provide advisory services and co-operate with other state authorities, non-governmental organisations and professional associations. The CTI carries out inspections of individuals, firms and their employees which sell goods, provide services, or operate in a similar manner on the Czech market.

### **Structure of the Czech Trade Inspection**

The Czech Trade Inspection has 513 employees. It consists of a central inspectorate and 14 regional inspectorates. Each region covers up 5 – 7 state districts.

The central inspectorate:

- is the managing body which supervises the regional inspectorates;
- is the methodical centre for the inspection activities;
- deals with appeals from economic operators penalized for breaching the law;
- ensures service activities for the whole organisation regarding financial, staffing and technical matters.

The textile laboratory is a special section of the central inspectorate where textile products are tested. The laboratory has accreditation for testing methods.

The regional inspectorates carry out the inspection activities. They are divided into three sections:

- section for checking technical and health safety;
- section for common consumer protection on the market and service industries;
- legal section.

### **Relevant Legislation**

The CTI's main activities are connected to its supervision of the observance of the following legislation:

- Act No. 64/1986 Coll., on the Czech Trade Inspection;
- Act No. 634/1992 Coll., on Consumer Protection; and
- Act No. 22/1997 Coll., on Technical Requirements for Products Act.

Other laws where the CTI is mentioned as a supervisory authority are:

- Act No. 303/1993 Coll., on the Abolition of the State Tobacco Monopoly; and
- Act No. 136/1994 Coll., on Colouring and Marking of certain Hydrocarbon Fuels and Oils.

Act No. 110/1997 Coll., on Foodstuffs and Tobacco Products, which limited the CTI's powers in food inspection, came into force on 1 September 1997. The reason for adopting it was to remove overlapping competences of market surveillance authorities.

### **Competence of the Czech Trade Inspection**

The CTI generally specialises in the following areas:

- protection of the health, safety and the economic interests of consumers;
- securing the right to full information on goods and services;
- protection of state fiscal interests;
- surveillance of the technical safety of specified products.

When performing their supervisory activities the authorised employees of the CTI (“inspectors”) may enter the business premises.

If an inspector finds an irregularity or defect, the CTI may ban the purchase, supply, sale or use of products or goods that fail to satisfy legal requirements.

The director of a regional inspectorate is entitled to impose financial penalties up to CZK 20 million (US\$ 700,000). A disciplinary fine of up to CZK 5,000 may be imposed on a supervised natural person that interferes with an inspection.

### **Act on Consumer Protection**

The CTI formerly only had powers over retail and services. Under the Act on Consumer Protection the CTI also inspects:

- honesty of sale;
- compliance with criteria related to the quality and safety of goods;
- discrimination against consumers;
- provision of product maintenance and safety instructions;
- correct labelling of goods;
- whether dangerous products are sold or offered; and
- whether consumers are deceived.

### **Activities of the Czech Trade Inspection for the Protection of Intellectual Property Rights including Trademarks**

- Act No. 145/2000 Coll. came into force on 1 September 2000. It amended:
- Act No. 64/1986 Coll., on the Czech Trade Inspection;
- Act No. 634/1992 Coll., on Consumer Protection;
- Act No. 63/1986 Coll., on Czech Food and Agricultural Inspection .

The main objective of the amendment was to define the selling of fakes and illicit imitations as deceiving consumers and to give more powers to market surveillance authorities. The previous legislation gave only limited powers to the CTI. The amendment provides for an unambiguous definition that the offering, sale or storage of products or goods contravening the provisions on protection of intellectual property rights including trademarks is to be considered as deceiving consumers.

According to these amendments the Czech Trade Inspection is entitled:

- to carry out analyses to check the quality and safety of products or goods and to determine whether consumers are deceived;
- to attach or seize products or goods that fail to satisfy legal requirements.

In this field the CTI co-operates closely with Custom's office, Industrial Property Office, Ministry of Culture, Police of the Czech Republic and holders of trademarks.

The CTI's inspections were mostly focused on textile fakes. Special seminars and workshops to enhance inspectors' skills are arranged periodically. The CTI has its own accredited laboratory for laboratory tests on textile products. Textiles and footwear account for 20% of inspections carried out by the CTI.

### **Act on Technical Requirements for Products**

The Act on Technical Requirements for Products, which came into force on 1 September 1997, brought a considerable increase in the CTI's powers. The Act was amended by Act No. 71/2000 Coll.

The Act on Technical Requirements for Products designated the CTI as the market surveillance authority for the area of industrial products with the exception of foodstuffs and medicinal products.

The Act is horizontal law and it, itself, does not introduce any technical requirements.

Under the Act the Czech Government is entitled to adopt Orders setting technical requirements for individual sectors or groups of products, including conformity assessment procedures to be applied.

Market surveillance is applied when a product is placed on the market. This means that a market surveillance authority must actively check whether all the products on the market comply with the relevant regulations and whether the specified conformity assessment procedures have been observed.

The CTI supervises whether specified products placed on the market are accompanied by a declaration of conformity and whether the properties of these products are in accordance with those listed in the issued declaration of conformity.

EC directives based on the New Approach are gradually being transposed into Czech legislation in the form of Government Orders.

The Government Orders specify products representing an increased level of health or safety risk for persons, property or the environment. Compliance with essential requirements in the relevant technical regulations must be assessed for such products.

The following New Approach Directives have been implemented: low voltage equipment, simple pressure vessels, toys, construction products, electromagnetic compatibility, machinery, personal protective equipment, gas appliances, hot water boilers, medical devices, equipment for potentially explosive atmospheres, lifts, pressure equipment, active implantable medical devices, non-automatic weighing instruments.

Under the Act on Technical Requirements for Products importers and producers have greater responsibilities than they used to have before. This Act imposes a duty on them to ensure that all the requirements relating to product safety are fulfilled and to issue a declaration of conformity. All the procedures are compatible with those in EU. This approach is quite different from the previous preventive role of the state, when former state authorities decided whether products were safe.

This approach also places new demands on the market surveillance authority. When Act No. 22/1997 Coll. came into force the CTI had to reorient quickly to a new market surveillance system covering a wide and varied spectrum of commodities. This situation placed higher professional demands on the CTI's apparatus, including a demand for the creation of a team of specialists – who guarantee compliance with particular demands on commodities. The new specialisation also places higher demands on inspector training.

The market surveillance of various types of specified products often requires highly specialised testing equipment, which is not available to the CTI. That is the reason why the CTI closely co-operates with authorised bodies and other testing laboratories. This approach also demands the setting up of and elaboration of information systems for the evaluation and sharing of data with particular domestic or foreign state authorities.

Infringements of the Act have been discovered in about 25 percent of cases. However, it is necessary to point out that in all cases only minor infringements related to administrative procedures are involved.

In the same way the CTI helps, by means of media, management of special-interests or professional associations, to acquaint the business and consumer public with new legal amendments, and may carry out consultations in the course of inspections or within the framework of actions organised for that purpose. Every regional inspectorate has its own advisory service.

### **Co-operation – Technical Safety of Goods**

Market surveillance by the CTI is directly connected with the activities of other inspection authorities which deal with operational safety of specified products. This is why co-operation for example with:

- the State Health Institute;
- the Czech Safety Bureau;
- the Czech Telecommunications Bureau;
- the Czech Metrology Institute;
- the Czech Mining Bureau and Railway Bureau; and
- the Czech Environment Inspection;

was established.

Co-operation is in the form of consultations, the arranging of training and by means of common inspections. Consultations with authorised bodies on specified products take place regularly.

## **Information System**

The CTI has set up a basic information system. It is, however, entirely necessary to set up the network not only as a means of internal communication, but also for external communication and to create access to the needed databases, i.e.:

- Commercial and Trade Register;
- Trademarks Register;
- Statistical Economic Subject Register.

Here we face the problem of a lack of funds.

## **Conclusion**

The CTI has succeeded in coping with the new methods of market surveillance. The experience of market surveillance activities under the Act on Technical Requirements for Products and the Act on Consumer Protection shows that the trend towards professional specialisation in the field of inspection methodology, as well as in direct inspection activities of regional inspectors within the CTI, must continue.

New access to information and the establishment of a network, not only in regard of the checking of technical requirements, but also the other above mentioned activities of the Czech Trade Inspection (product piracy, etc.), will require some changes in the structure of the CTI.

In spite of the above, many problems remain. There are limited funds for taking samples and testing them, as well for more extensive information, better methodical support, training of inspectors and long-term training programs. That is the reason why checks on documents are still the prevailing method of inspection.

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Annex

Letter from the Republic of Armenia on behalf of the CIS Interstate Council for Standardization, Metrology and Certification



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УПРАВЛЕНИЕ СТАНДАРТИЗАЦИИ, МЕТРОЛОГИИ И СЕРТИФИКАЦИИ ПРИ ПРАВИТЕЛЬСТВЕ  
РЕСПУБЛИКИ АРМЕНИЯ

DEPARTMENT FOR STANDARDIZATION, METROLOGY AND CERTIFICATION UNDER THE  
GOVERNMENT OF THE REPUBLIC OF ARMENIA

S A R M

08.10.99 № 2

Mr. Christer Arvius,  
National Board of Trade,  
(Chairman of the UN/ECE Working Party  
on Technical Harmonization and Standardization Policies (WP.6))  
Stockholm, Sweden  
Fax: (0046 8 ) 690 48 40  
copy: Mr. Sergey Kouzmin, Secretary to Wp 6 (Fax: 004122 917 04 79)  
Subject: 16th Session of Eurasian Standardization Council (6-8 October, 1999.  
Armenia)

Dear Mr. Christer Arvius,

Thank you for your representative Mr. Kouzmin's participation in the work of EASC session and useful information about the work of the WG on Technical Harmonization and Standardization Policies (WP.6)).

We are grateful that the group raises questions which are of interest to CIS states and on behalf of EASC I would like to express an interest of the CIS states in the preparation of the international agreement on technical harmonization, in the work of the group of specialists on standards and technical regulations, on conformity assessment problems, on ISO 9000 and 14000 standards, in information of the experience of the western countries in state control (safety in industry, quality of goods in trade, etc.).

Participants expressed their special interest in UN/ECE proposal of using certification to fight against fake trade marks in CIS and expressed their readiness to cooperate with interested western companies.

To my regret, I would like also to attract your attention to financial problems which do not allow our experts to participate in meetings in Geneva and I would be grateful for financial support in solving this problem.

Yours sincerely  
A.Azizyan

Chairman of EASC,  
Head of SARM