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**CONFORMITY ASSESSMENT**

**Review of Developments in Conformity Assessment at  
International, Regional and National Level**

This paper has been submitted by the Ministry of Economic Affairs of Hungary.

It contains information on recent developments in conformity assessment related areas in Hungary.

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### **Short summary of the harmonisation process in the Republic of Hungary in the fields of commodity assessment, standards and inspection**

Article 73 of the Europe Agreement establishing an association between the European Communities and their member states on the one part and the Republic of Hungary on the other part signed on 16<sup>th</sup> December, 1991, pronounced as a Law by the Hungarian Parliament in an Act I. of 1994, stipulates a co-operation to reduce divergences in the field of standards and commodity assessment. On the basis of this co-operation a long process has started with the transformation of the Hungarian Standards Authority into a non-governmental institute, with the establishment of the National Accreditation Body and with the establishment of the General Consumer Protection Inspectorate.

Consequently the practice of technical regulation based on mandatory standards has completely changed. The transposition of the EU standards into Hungarian voluntary standards have started and has reached a level of more than 70 percent of the issued EU standards by now. In the meantime a series of governmental and ministerial regulations have been issued to create new regulatory circumstances with the establishment of a new institutional system in these fields, such as the CE marking, the designation authority, the conformity assessment bodies, the establishment of market surveillance and the reconciliatory bodies, application for membership in the ETSI and CEN/CENELEC, etc. This development has created a consequent and transparent order in the transposition activity of the old and new approach directives of the European Union into Hungarian legislation as well as in the standardisation process, duly fitting to the accession negotiations. In this process more than 200 EU regulations has been built into Hungarian legislation, *inter alia*, those of the eight fields of the new approach directives:

- machinery
- electrical safety
- electromagnetic compatibility
- hot water boilers
- gas appliances
- medical devices
- Good Laboratory Practice for medicinal products for human use
- Good Manufacturing Practice for medicinal products for human use: inspection and batch certification

The consequent harmonisation process gave Hungary a possibility to start negotiations with the EU Commission on a protocol on conformity assessment and acceptance of industrial products to be attached to the Europe Agreement. These negotiations led to the initialling of the protocol in July, this year, with the annexes of the mentioned eight fields. In the meantime, harmonisation continues actually in the field of pressure vessels and the equipment in potentially explosive space on the one hand, and negotiations have started on the extension of the protocol to the EEA countries, on the other hand. Switzerland and the Czech Republic also proposed to Hungary to agree an extension of the protocol bilaterally having both a valid protocol with the EU. The Hungarian government has favourably considered the invitation of these countries.

The Hungarian Government approved a medium-term programme on legal harmonisation, institution building and enforcement of legislation, called National Programme on the Acceptance of the Acquis of the European Union, in 1999. In this programme a well-defined sequence of steps is worked out on harmonisation, institutional building and enforcement. This process is managed by the Ministry of Economic Affairs, as a horizontal co-ordinator of the harmonisation process.

In the process of Hungarian harmonisation and institutional building the next step will be the starting of operation of the Notification and Information Centre. This entity which starts its activity as a unit of the Ministry of Economic Affairs of the Republic of Hungary will soon satisfy the notification needs of the EU and WTO.

As another side of the coin, the Hungarian legislation, namely the law on consumer protection and the pursuant government and ministerial legislation stresses the details of general product safety, and the co-operation of different authorities in the field of consumer protection and market surveillance. At the same time the customs law and the customs procedure regulations give authorisations to the customs authority to control goods on the border as well as on markets, fairs and shops on the basis of presumed fakeness and falsification of trademarks as well as of items charged by excise law. This activity of the customs authority can take place on an ex-officio basis or upon request of the respective manufacturers of the trademark owner's products.

The market surveillance has a growing role in Hungary. Networks of 20 directorates, 19 county directorates and one for the capital, have been established and their activity is continuously strengthened. In this context the directorates cooperate with the customs authority in the field of market and fair control.

The latest development of market surveillance is the establishment of reconciliatory bodies to strengthen public awareness and to arbitrate in cases. This network has been also developed on district/county basis and by now they have solved more than 300 disputes out of the 400 cases.

Being aware of the importance of general product safety, the role of the consumer protection and the market surveillance, the Hungarian authorities work on further strengthening of the co-operation among the inspectorates, between the inspectorates and the customs authority to establish a more regular and more frequent control of imported goods. The Hungarian authorities draw special attention on the establishment of border control of presumably dangerous medicinal products and veterinary articles, foodstuffs and toys as defined in the EU directive 339/93. For this development Hungary has applied for Phare assistance in this year.

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