



**Economic and Social
Council**

Distr.
GENERAL

TRADE/WP.6/2001/3/Add.2
11 October 2001

ENGLISH ONLY

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 5 of the provisional agenda

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

European Union: Recent development in the area of standardization

This paper has been submitted by the European Commission on the legal and organizational framework for preparation, adoption and application of standards and technical regulations in the European Union.

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

Introduction

Since the last meeting of the Working Party a number of developments can be reported for activities relating to standardisation and regulatory co-operation. An overview is presented in this submission. Details can be found in a comprehensive report from the Commission. This report is from 26 September 2001, has the reference number COM(2001)527 and can be found on the following web-site: http://europa.eu.int/comm/enterprise/standards_policy/index.htm.

Standardisation and Regulation

Current reflections on governance in Europe focus on alternative forms of regulation and on democratic legitimacy and expertise. Today, the Community's "New Approach", which is applied in many areas of Single Market legislation and which uses common European standards in support of legislation, is considered a well-implemented co-regulatory model.

The broader use of standards by public authorities is related to the considerable efforts that have been made to improve and simplify the regulatory environment in the EU. The Lisbon European Council stressed that business and citizens need a regulatory environment which is clear, effective and workable in a rapidly changing global market place, and that formal regulation is not always the answer. Alternative, complementary approaches can sometimes provide more effective solutions. The challenge is to ensure high levels of protection while avoiding over-regulation. The New Approach to technical harmonisation and standardisation is a model that combines these two requirements and the Council invited the Commission to examine whether the New Approach can be applied to sectors not yet covered as a means of improving and simplifying legislation wherever possible.

The Commission proposal for a new directive on general product safety, replacing Council Directive 92/59/EEC,¹ pursues, among other things, the objective of better defining the criteria for assessing product safety and clarifying the role of European and national standards in this regard. The proposal ensures - in line with the New Approach philosophy - that products which comply with European standards established by the European standards organisations, under a mandate from and published by the Commission, can be presumed to comply with the general safety requirement of the Directive.

Work is underway for a Commission proposal to harmonise the requirements concerning the environmentally friendly design of electrical and electronic equipment (EEE) and enable use of harmonised standards². This Directive is intended to ensure the free movement of these products within the internal market aiming to improve their overall impact on the environment, and thus providing an efficient use of resources and a high level of environmental protection compatible with sustainable development³.

As regards standardisation in relation with the existing New Approach Directives the programme of harmonised standards is near completion in the area of toys, non-automatic weighing instruments, gas appliances and simple pressure vessels. Good progress can be reported for personal protective equipment and medical devices, both fields covered by New Approach Directives. European Standardisation work in

1 COM(2000) 139 final of 29.3.2000.

2 http://europa.eu.int/comm/enterprise/electr_equipment/eee/index.htm.

3 See also the strategy for the integration of environmental protection and sustainable development into internal market policy, Council document 8970/01 submitted to the European Council in Göteborg, 15-16 June 2001.

the machinery safety area has advanced and there are now more than 360 harmonised standards of which 250 give presumption of conformity with the requirements of Community law. A programme of more than 700 harmonised standards is envisaged in relation to the Directive on pressure equipment. By mid-2001 some 450 standards were in place, 50 of which were harmonised. A great deal of work is still expected for packaging and packaging waste, explosives for civil use, potentially explosive atmospheres and recreational craft. Standardisation work for the latter is carried out with the International Standardisation Organisation (ISO). Electro-technical standardisation is also progressing and by the end of 2000 84% of the harmonised standards had been ratified. This work is essentially based on the corresponding work of the International Electrotechnical Commission (IEC) in the area of electromagnetic compatibility, electrical equipment in human and veterinarian medical practice, electrical equipment for railways and electrical safety of machinery.

Finally, an important development can be reported for standardisation in the field of construction products. Until recently, no harmonised standards existed for construction products. This has changed and an important step has come with the agreement on the first harmonised standards on construction products. Harmonised standards for cement, fixed fire-fighting systems, geotextiles, structural bearings and lifting plants are among this first group of harmonised construction products standards. Another 60 standards are in their final stages of development and a similar number are programmed for completion by the end of 2001. This development is expected to boost the internal market of construction products by removing technical barriers to trade, creating new markets and cutting compliance costs.

Standardisation and e-Europe

The Lisbon Council intended to boost Europe's competitiveness at world level and coined the expression *e-Europe*. Among other things, the European Council endorsed the Commission's proposal for an *e-Europe* action plan that will pave the way for the information society in Europe. Standards and common technical specifications are a necessary condition to make *e-Europe* happen.

In June 2000, the European Council of Feira, Portugal, endorsed the comprehensive *e-Europe* 2002 Action Plan, building on the Commission's *e-Europe* initiative of December 1999. The initiative aims at accelerating the uptake of digital technologies across Europe and ensuring that all Europeans have the necessary skills to use them. It plays a central role in the agenda of economic and social renewal for Europe set out by the Commission for the European Council in Lisbon. Ambitious targets and tight deadlines have been set for the achievement of the initiative. In June 2000, the three European standards organisations produced a common rolling action plan: The contribution of European standardisation to the *e-Europe* Initiative. This joint programme sets out and monitors the standardisation activity needed in order for the political targets and the deadlines to be met. Subsequently, an agreement was reached between the Commission and the European standards organisations for Community support where necessary for these standardisation actions.

The new field of electronic services and other developments concerning the information society is yet another area where European standardisation can provide support for European legislation and political initiatives such as *e-Europe*. The Directive on a Community framework for electronic signatures (1999/93/EC)⁴ and the Commission proposal for a directive on a common regulatory framework for electronic communications networks and services⁵ are examples of this. The former involves the joint work of a specialised group on electronic signatures and CEN and ETSI, to provide the standards needed

⁴ Directive 1999/93/EC, OJ L 13, 19.1.2000, p.12.

⁵ COM(2000) 393 final of 12.7.2000.

to support the requirements of the Directive on electronic signatures⁶. The latter provides for the selection of appropriate technical solutions for electronic communication services, which, in order to preserve coherence and interoperability in the internal market, would be formalised by the European standards bodies.

In the area of Road Telematics and Intelligent Transport European standardisation is progressing in fields such as the collection, exchange and broadcasting of traffic data, Dedicated Short Range Communication (DSRC) for applications like tolling, Automatic Vehicle Identification, Human Machine Interface Standards and Smart Cards. It is important for electronic fee collection systems to be interoperable across national borders to facilitate traffic flows in Europe. The Commission invited CEN to complete its work on the development, validation and testing of DSRC and other related standards⁷. In addition to the work from CEN, progress was achieved in this field by fora and consortia, and under memoranda of understanding by the interested parties.

Standardisation and Market Needs

The need to provide deliverables on a faster time-scale (the “time to market” factor) has resulted in a new portfolio of deliverables from the European Standards organisations. CEN has started producing Workshop Agreements (CWA). Proposals for Workshops at European level may come from any interested party. Participation is open to all interested parties (and not only members). Agreement is in principle based on a business plan, which is placed for comment on the Web. The CWA represents the consensus of Workshop participants. The ETSI Standard is a normative document. It is adopted following ETSI membership voting. The ETSI Standard can be made into an EN following the appropriate procedures. CEN, CENELEC and ETSI have also reached agreement on three new common deliverables that are to be added to their respective collection of European Standards (ENs) and included in their product range. The Technical Specification could serve as an entry point for specifications developed outside the formal system. The Guide is an informative document addressing users as well as standards makers. The Technical Report is an informative document, which may discuss technical solutions as well as providing information on the use of standards

European standards organisations have shown great flexibility in developing new deliverables and they have been prepared to respond to political initiatives. Further efforts for promoting new deliverables in response to (new) market needs should attract new participants. In this regard the willingness of standards organisations to integrate, in an open and receptive manner, the work started by new participants will be of crucial importance. The initial results concerning the expanded product range of European standards organisations can be illustrated by the success story of CWAs. Since 1998 more than 30 Workshops have been set up in various ICT and other fields. The Workshops attracted more than 1300 participants and led to 36 CWAs.

Discussions took place within the EU framework concerning the relevance of new deliverables to public policy. Discussions concluded that public authorities may want to monitor the development of new deliverables or examine them in the light of any negative impact on competition. In certain cases it may be of interest to use new deliverables in Community policies. They could be used across the board in Community activities and in those areas where consensus or a consensus process is required in a relatively short space of time. As market instruments, they are particularly relevant to activities to improve the competitiveness of European enterprises, bolster the internal market and strengthen the link with research, development and innovation. However, new deliverables should not be confused with formal standards. The discussions also showed that at this stage of development, new deliverables seem

⁶ More information on the European Electronic Signature Standardisation Initiative (EESSI) can be found on <http://www.ict.etsi.fr/eessi/EESSI-homepage.htm>.

⁷ COM(1998) 795 final of 21.12.1998.

inadequate as a replacement for harmonised standards as a support for the New Approach directives or in dealing with subjects such as health and occupational safety, nor is this their function.

Standardisation and Competition

With regard to the possible restrictions to competition caused by horizontal co-operation agreements between companies operating on the same market level(s), the Commission published a notice on the applicability of Article 81 of the EC Treaty. In this notice, standardisation is considered to be a type of horizontal co-operation agreement, either concluded between private undertakings or determined under the aegis of public bodies or bodies entrusted with the operation of services of general economic interest, such as the standards organisations recognised under Directive 98/34/EC.

Subject to an analysis of the individual case, standards may restrict competition if used as a means of excluding actual or potential competitors. The restriction of competition depends upon the extent to which the parties remain free to develop alternative standards or products that do not comply with the agreed standard. Competition is also restricted if standards grant exclusive rights for compliance testing to certain bodies or if they impose restrictions on conformity marking, unless this is imposed by regulatory provisions. The Commission considered that, in principle, standardisation agreements do not restrict competition if the standards were adopted by the recognised standards organisations, which are based on non-discriminatory, open and transparent procedures.

Standardisation and Sustainable Development

At the meeting of the European Council in Göteborg a strategy for sustainable development was adopted. Its starting point is that EU citizens shall be able to rely on economic stability, social security and a clean and health environment. "Greening" the market is seen as a key issue for the Sixth Environment Action Programme 2001-2010. It also signals the need to integrate environmental protection requirements into other Community policies, including standardisation. The Commission's Green Paper on integrated product policy (IPP) recognises the important role standards can play in the design, manufacturing, use, re-use and recycling of environmentally friendly products.

On 7 February 2001 the Commission adopted a Green Paper on Integrated Product Policy (IPP). Its objective is to launch a debate on the role and possible measures that could be taken on a European level to improve the environmental performance of a broad range of products throughout their entire life cycle. In the Green Paper standardisation is recognised as one of the main instruments for achieving the goals of IPP. Accordingly, it is recommended that standards should be used for the development of environmental design and that ways should be found, in co-operation with all the stakeholders, to ensure that "environmental soundness" is systematically associated with all European standards.

Standardisation and Trade

Global trade continues to increase. The use of international standards can enhance market access and facilitate trade. Hence, standards may give rise to trade frictions, in particular if there are no international standards with global recognition. International standardisation offers globally applicable solutions to the parties concerned.

Internationally traded goods need international standards wherever possible. As standardisation is a mainly market-driven activity, it is of key interest to European stakeholders to promote the European system and foster close links with international standardisation outside Europe. The Commission encourages European stakeholders to continue their efforts in this respect. Standardisation and the use of standards are also an important part of the Community's external trade policy, and the Community must comply with international agreements concerning standards such as the WTO Agreement on Technical Barriers to Trade (TBT Agreement). The Commission services issued a document on the European policy

principles on international standardisation. The document (reference number SEC (2001) 1296 of 26 July 2001) was drawn up in consultation with European stakeholders in international standardisation. It recapitulates and further clarifies existing policy in order to achieve better co-ordination and coherence. The European policy principles on international standardisation are:

- Internationally traded goods need international standards to facilitate trade and market access;
- The international standardisation process needs to be open, transparent and impartial; the resulting international standards must be effective, relevant and coherent;
- International standards organisations must strike a balance between efficiency and accountability;
- In certain areas it may be beneficial to channel standards, specifications and other work that has reached a certain consensus into the international standardisation process;
- International standards should be taken over regionally and nationally, and conflicting national standards should be withdrawn whenever possible; deviations from an international standard or justifications for not using the international standards at all should be indicated;
- Co-operative agreements between national, regional and international standards organisations help to avoid double work, to speed up the standardisation process and to enhance transparency concerning the taking over of international standards;
- International standards offer a potential for deregulation, but cannot do away with governmental responsibility for safeguarding legitimate objectives such as the protection of health and safety and the environment;
- The Community is in favour of the creation of standards-receptive legal environments and can share its extensive experience in this regard with its trading partners;
- Trading partners wishing to create a standardisation infrastructure can be supported by European partners, especially if they have an interest in using European standards for regional integration or close liaison with Europe.

* * * * *