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**REPORT FROM THE COMMISSION
TO THE COUNCIL AND THE EUROPEAN PARLIAMENT**

**ON ACTIONS TAKEN FOLLOWING THE RESOLUTIONS
ON EUROPEAN STANDARDISATION
ADOPTED BY THE COUNCIL AND THE EUROPEAN PARLIAMENT IN 1999**

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**I.    INTRODUCTION**

1.    In 1999, both the Council[1] and the European Parliament[2] adopted Resolutions on standardisation. These Resolutions related to the Commission Communication on "Efficiency and Accountability in European Standardisation under the New Approach"[3]. Both Resolutions recognised the achievements of European standardisation under the New Approach. They identified the main challenges and set a clear agenda for future work. The Council Resolution turned out to be an action plan for stakeholders in European standardisation.

2.    This report from the Commission aims to set out the most relevant developments since 1999, as requested by the Council and Parliament. After setting the broader context surrounding standardisation in the Community and EFTA, it analyses developments in the more specific key areas mentioned by the Resolutions. As some of the actions identified in the Resolutions are still ongoing, this should be viewed as an interim report. This report basically takes a horizontal view on European standardisation matters.


**II.    THE BROADER CONTEXT: MILESTONES SINCE 1999 AND THEIR BEARINGS ON EUROPEAN STANDARDISATION**

3.    European standardisation is a voluntary activity by and for the parties interested in drawing up common standards and technical specifications in response to their needs. These common specifications are agreed on the basis of well-established principles in the legally recognised European Standards Organisations CEN, CENELEC and ETSI. European standards have become a crucial factor in the functioning of the Single Market and the European Economic Area. They also play an important role in supporting a number of other policy objectives of the Community, including the competitiveness of enterprises, innovation, the protection of health and safety, consumer interests, and environmental protection. The need for common standards is underlined by the increasing globalisation of trade and the convergence of technologies.

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[1]    Resolution of 28 October 1999 on the role of standardisation in Europe, OJ C 141, 19.5.2000.
[2]    Resolution of 12 February 1999 on the report from the Commission, OJ C 150, 28.5.1999.
[3]    COM(1998) 291 final of 13.5.1998.

4.      Since 1999, some political milestones have been reached which are important for European standardisation:

4.1.    Current **reflections on governance** in Europe[4] 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 use of standards in relation to Community legislation and policies requires the respect of certain principles regarding the standardisation process and the bodies responsible for it, in particular concerning the full involvement of all relevant interested parties.

4.2.    The Lisbon European Council[5] intended to boost Europe's competitiveness at world level and coined the expression *e*-Europe. Subsequently at Feira, 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**.

4.3.    At the meeting of the European Council in Göteborg a strategy for **sustainable development** was adopted[6]. This strategy requires that as from 2003 all proposals for decisions in EU policy areas must be assessed with regard to their economic, social and ecological effects. "Greening" the market is seen as a key issue for the Sixth Environment Action Programme 'Our Future – Our Choice' 2001-2010[7]. The program also signals the need to integrate environmental protection requirements into other Community policies, including standardisation. Environmental aspects are considered to be an engine for innovation and business opportunities and should be taken into account throughout all phases of a product's life cycle. The Commission's Green Paper on integrated product policy (IPP)[8] recognises the important role standards could play in the design, manufacturing, use, re-use and recycling of environmentally friendly products.

4.4.    Global trade continues to increase. The use of international standards can **enhance market access and facilitate trade**. International standardisation offers globally applicable solutions to the parties concerned. The absence of international standards with global recognition can be a source of trade frictions.

4.5.    The Community attaches great importance to ensuring a high and consistent level of **protection for consumer health and safety.** The Commission has proposed to make extensive use of European standards under the Community law on general product safety which reflects the contribution standards can make to the proper functioning of the internal market and the protection of consumer health and safety.

4.6.    In the light of its commitment to **sound financial management** the Commission puts an emphasis on a strong link between financial support and the implementation of its policies, for instance, through activity-based budgeting. Although European standardisation is largely financed on a private basis, the Commission reviews its

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[4]     *cf*. European Governance: a White Paper, COM(2001) 428 final of 25.7.2001.
[5]     Lisbon European Council 23 and 24 March 2000: presidency conclusions, SN100/00.
[6]     *cf*. http://ue.eu.int/en/Info/eurocouncil/index.htm.
[7]     COM(2001) 31 final of 24.1.2001.
[8]     COM(2001) 68 final of 7.2.2001.

policy on granting financial contributions to the European standardisation organisations. In many instances Community support includes a share from EFTA.

## III. KEY POLICY ISSUES

### III.1. Principles of Standardisation

5.     **Community law recognises CEN, CENELEC and ETSI** as European standards organisations[9]. There are also a number of Community legal acts that define the meaning of standards[10]. Although not identical, these definitions are consistent with those established by the relevant guides on general terms and the definitions concerning standardisation and related activities published by international standards organisations[11].

6.     **In its 1999 Resolution, the Council reiterated the principles** of European standardisation by confirming that it is a voluntary, consensus-driven activity, based on openness and transparency within independent and recognised standards organisations. It further specified that standards should have a high degree of acceptability as a result of the full involvement of all relevant interested parties in the standardisation process and that standards should be coherent with each other. The Council also emphasised that standards should be based on sound scientific research[12] and should allow for technological innovation and competition. These principles have been implemented by the European standards organisations and their national counterparts for a long time[13].

7.     Since the Resolution, the meaning of these principles has been further substantiated.

7.1.   At international level, the WTO agreement on technical barriers to trade (TBT) draws a clear distinction between standards with which compliance is voluntary and technical regulations with which compliance is mandatory. WTO members shall use international standards as a basis for technical regulations, provided they deem the standards appropriate for the fulfilment of legitimate objectives and for attaining the desired level of protection at domestic level. The use of international standards allows for a level playing field and creates a presumption of conformity with international trade rules. While the agreement places an emphasis on the use of international standards as a basis for technical regulations, it does not specify what international standards are or which organisations produce them. This situation prompted the **WTO to adopt principles for the development of international**

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[9]     Annex I of Directive 98/34/EC.
[10]    e.g. Art. 1 of Directive 98/34/EC; Art. 1(3) of Council Decision 87/95; Annex III of Directive 93/36/EEC.
[11]    ISO/IEC Guide 2:1996.
[12]    The European Community Framework programme for research, technological development and demonstration has adopted pre- and co-normative research as one of its priority objectives. Several dedicated calls for research projects in support of standardisation were published during the 5th Framework programme and have received Community funding of about € 30 million. Furthermore, as a means for the exploitation of its results, the Joint Research Centre provides input to the work of technical committees and working groups of the European standards organisations, in particular regarding the harmonisation, validation and benchmarking of analytical methods.
[13]    *cf.* Joint CEN/CENELEC/ETSI Statement "Basic principles and organisation of European standards work", Luxembourg, 3-4.12.1991.

**standards** in relation to the core provisions of the TBT agreement. The WTO considered transparency, openness, impartiality, consensus, effectiveness, relevance and coherence as key principles that should apply to international standardisation (see also III.6).

7.2. 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**[14]**.** 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.

7.3. Subject to an analysis of an individual case, standards will almost always restrict competition if they are used in the context of a broader agreement which aims at excluding actual or potential competitors. They may restrict competition if they grant the parties joint control over production and/or innovation. 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 may also be 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.

8. The **acceptability of standards** depends to a large extent on the full involvement of all relevant interested parties**.** Societal stakeholders' participation[15] in the standardisation process has a strong accountability dimension. It reinforces the quality of the consensus and makes the standards more representative. The Council therefore invited all interested parties to participate actively in the elaboration of standards and to contribute to the management of the standardisation process.

9. While standardisation will remain for most sectors a market-driven and self-funded activity there is public interest in the maintenance of a standardisation infrastructure that is open and impartial, and that operates in a transparent way. This is especially important in areas in which standards support legislation. Standards development is time consuming and costly in terms of the human and financial resources that have to be provided in order to achieve a meaningful input into the process. The participation of small and medium-sized enterprises (SMEs) and societal stakeholders can be hampered by a lack of resources and technical expertise. Significant differences in the levels of expertise represented can also hamper the consensus-finding process and therefore cause delays in standards development.

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[14]     OJ C 3 of 6.1.2001, p. 2-30.
[15]     Societal stakeholders represent consumer, health, safety and environmental interests in standardisation.

10.       Financial support from public authorities needs to take this into account. In a decentralised European standardisation system it is important that stakeholder participation is balanced, notably at a national level since most of the European and international draft standards undergo a national inquiry before final adoption. A balanced participation of stakeholders is equally important at the European level of the standardisation process. The Commission analysed the **situation of various stakeholders** concerning their participation in standardisation at European level and the following can be said:

10.1.      The European Association for the Co-ordination of Consumer Representation in Standardisation**, ANEC**, was founded in 1995 and **has continued to be financially supported by the Commission**. By co-ordinating a network of technical experts across Europe, ANEC participates in standardisation work. ANEC calls for a balanced representation of interested and concerned parties in standardisation[16]. They examined the national arrangements for consumer participation in standardisation in the EU and EFTA[17] and concluded that the situation had improved compared with 1995. However, **a gap persisted between the well-developed consumer representation in national standardisation** in the north of Europe and an unsatisfactory consumer representation in southern European countries.

10.2.      The European Trade Union Technical Bureau for Health and Safety, **TUTB**, represents the interests of employees in health and safety aspects of European standardisation and co-ordinates a network of technical experts. It **has continued to receive financial support from the Commission**. Together the Commission and TUTB monitor the work of CEN and CENELEC, in particular in relation to the safety of machinery, personal protective equipment and ergonomic design.

10.3.      **NORMAPME,** the European Office of Craft, Trades and Small and Medium-Sized Enterprises for Standardisation Technical Office, represents the interests of these businesses in European standardisation. Since 1995 the Commission has granted subsidies to NORMAPME. **The Commission recently launched a call for tender with the aim of offering a stable service to SMEs** in an effort to promote their position in European standardisation[18].

10.4.      The Commission intends to further collaborate with the European standards organisations and concerned parties to reach its environmental objectives. It also plans to support **a service that will be in charge of representing environmental interests** in the European standards bodies[19]. For the full integration of the environmental dimension, the mere participation of representatives from this service is not sufficient. It depends also on the willingness of all participants in the standardisation process. The Commission intends to develop a paper on standardisation and the protection of the environment in 2002.

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[16]      Position paper of March 2001 on the 1999 Council Resolution on the role of standardisation in Europe, (ANEC2001/GA/007).

[17]      Report of May 2001 on consumer participation in standardisation, (ANEC2001/GA/014).

[18]      *cf.* open invitation to tender 2001/S117-079423, OJ S 117 of 21.6.2001.

[19]      *cf.* open invitation to tender 2001/S71-048238, OJ S 71 of 11.4.2001.

**III.2.    Standardisation and Market Needs**

11.    The Council Resolution of 1999 invited the European standards organisations to adapt to new market needs by diversifying their range of products and services and developing a graduated system of products. It also requested the Commission to examine how a Community framework of principles for the use of new deliverables of standardisation should be developed and to explore whether differences between standardisation in the ICT field and other sectors could be addressed[20].

12.    **Acceptance of standardisation is related to the market relevance of standards**, and not only to the participation of the parties concerned. Market relevance largely depends on the quality and technological state of advancement of standards, their applicability, their perceived neutrality and on their development time. In this context it should be noted that while the catalogue of harmonised standards has increased in response to mandates under New Approach and other European directives[21], the majority of European standards are developed in response to pure market needs. However, as market needs constantly evolve **new standardisation products and services can bring about added value to their users** and complement the existing range of products and services offered by the standards organisations.

13.    The rapid development of technologies and processes in some sectors, in particular in the information and communications technology (ICT) sector, has led to **a need for the equally rapid creation of common specifications**. Reflections on the role of standardisation to facilitate competition and satisfy public interest as well as on the role of new global industry fora in the ICT sector need to be pursued. But also in other sectors, for instance, in the environmental field the time it takes to arrive at a European standard is of concern considering that environmental problems will persist and perhaps get worse within this time. In view of a sometimes over-lengthy process in standards organisations, private consortia and fora have mushroomed in order to produce the specifications required by the market. However, renewed interest in more stable business and technical solutions can be observed in the ICT field and the beginning of a rapprochement between consortia and standards organisations may be expected.

14.    The trend for the development of common specifications outside standards organisations has spread outside the ICT to other sectors and the need for rapid consensus-building and speedy development of common specifications has become a more general issue in standardisation. The specific **provisions in Community law relating to standardisation in the ICT field**[22], particularly public procurement, have therefore become less relevant. There is also a tendency for non-technical consensus documents like guidelines and codes of conduct to be used in a particular sector or field of activity. Other back-up activities for standardisation include counselling and support services for standards users and market watch functions.

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[20]    Council Resolution of 28.10.1999, points 13-15, OJ C 141 of 19.5.2000.
[21]    *cf.* Single Market Scoreboard: N°6 of 22 May 2000, N°7 of 24 November 2000, N°8 of 28 May 2001.
[22]    *cf.* Council decision 87/95/EEC on standardisation in the field of information technology and telecommunications.

15.      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.

16.      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.

17.      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.

18.      In June 2000, the European Council of Feira, Portugal, endorsed the comprehensive *e*-Europe 2002 Action Plan,[23] 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**[24]**.** 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 ESOs for Community support where necessary for these standardisation actions.

19.      Discussions took place between the Commission and the Advisory Group of Senior Officials on Standardisation and Conformity assessment 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

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[23]      COM(2001) 140 final of 13.3.2001.
[24]      http://www.cenorm.be/isss/Major_Activities/eEurope/eeur.htm
         http://www.etsi.org/eeurope/eeurope.htm

any possible negative impact on competition[25]. **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 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.

20.     For new deliverables to be used in public policy, the documents, processes, and organisations that create new deliverables need to conform to certain principles that guarantee their acceptability. In response to the 1999 Council Resolution, **the Commission services have drawn up a preliminary document**[26] setting out these criteria in detail and consulted these principles with an advisory body consisting of Member State representatives. After further decisions from the European standards organisations and their members concerning a graduated system of products and a further extended range of deliverables, this document will be reconsidered. If necessary, its status will be more formalised.

21.     New European standardisation deliverables and services do not always seem to be fully supported at national level. However, commitment on the part of national standards organisations and the Member States is necessary to provide support for new deliverables and prevent conflicting solutions developing. A regular **exchange of information on new deliverables** between the national and European standards organisations would allow synergies to be exploited and work started at European level, at the right time and where appropriate.

**III.3.    Role of Public Authorities**

22.     Public policies must compensate for market imperfections and seek to realise some of the potential socio-economic benefits of standardisation, including the promotion of SMEs and the fostering of worker, consumer and environmental interests. Likewise, innovation policy has to strike a balance between the means to protect the rights of innovators, such as patents, and the means to disseminate innovation through open, voluntary standards. It is therefore in **the interest of the public authorities to maintain a stable and transparent legal, political and financial framework for standardisation**[27].

23.     The 1999 Council Resolution[28] highlighted the legitimate interest of the public authorities in European standardisation, given the new dimension it has taken as a result of the wide use made of it by Community policies. The Commission explained the potential of standards in its Communication on the broader use of standardisation

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[25]     cf. Guidelines on the applicability of Art. 81 of the EC Treaty to horizontal co-operation agreements, OJ C 3 of 6.1.2001, p. 2-30.
[26]     SOGS N363R3.
[27]     Council Resolution of 28.10.1999, OJ C 141, 19.5.2000.
[28]     See above.

in Community policy[29]. Consequently, the **European standards organisations further extended their areas of activity in response to European policies**. This shows the spirit of partnership existing between the European regulator and the European standards organisations, as illustrated below.

23.1. European standards can play a major role in the **defence procurement** of national ministries and armament agencies. Studies have shown that replacing national military specifications with European or international civil standards could increase efficiency and lower procurement costs for governments. In November 2000, the Commission organised a conference on European defence procurement in the 21st century which explored, amongst others, the possibility of harmonising, at European level, the standardisation processes in the defence sector, and for creating interfaces with civil standardisation. European Standards Organisations were invited to contribute to the debate and the **CEN was identified as a platform for compiling a European Handbook** of Defence Standards and Procedures.

23.2. The White Paper on **Food Safety**[30], which was published at the beginning of 2000, showed that the Commission regarded ensuring the highest standards of food safety in the EU as one of its main priorities. In this regard, it should be noted that methods of analysis are necessary to check compliance with safety requirements for food or materials that come into contact with food. As progress in the development of new analytical methods is very rapid, in principle, the Commission tries to avoid laying down specific methods of analysis in legislation, even if in some cases, it was considered appropriate. The establishment of quality criteria for validated methods is a more flexible and preferable approach. Validated methods give enforcement authorities, industry and certification laboratories the means of ensuring conformity with legal limits. The use of European standards is one possibility for bringing about a degree of harmonisation in this field and CEN has already established about 50 standards in the area of "Food analysis – Horizontal Methods" and has been mandated for 28 methods of analysis in the field of food contact materials.

23.3. 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)[31] and the Commission proposal for a directive on a common regulatory framework for electronic communications networks and services[32] 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 to support the requirements of the Directive on electronic signatures[33]. 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.

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[29]    COM(1995) 412 final of 30.10.1995.
[30]    COM(1999) 719 final of 12.1.2000.
[31]    Directive 1999/93/EC, OJ L 13, 19.1.2000, p.12.
[32]    COM(2000) 393 final of 12.7.2000.
[33]    More information on the European Electronic Signature Standardisation Initiative (EESSI) can be found on http://www.ict.etsi.fr/eessi/EESSI-homepage.htm.

23.4.    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. T he Commission invited CEN to complete its work on the development, validation and testing of DSRC and other related standards[34]. 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.

24.    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[35]. Alternative, complementary approaches can sometimes provide more effective solutions. The challenge is to ensure high levels of protection while avoiding over-regulation[36]. 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[37].

24.1.    The Commission proposal for a **new directive on general product safety, replacing Council Directive 92/59/EEC,**[38] 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.

24.2.    On 7 February 2001 the Commission adopted a **Green Paper on Integrated Product Policy (IPP)**[39]. 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 potential instruments contributing to the goals of IPP. Accordingly the Green Paper asked for reactions on how the New Approach could best be applied to new initiatives in the field of product design and how environmental characteristics could be integrated systematically into product standards.

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[34]    COM(1998) 795 final of 21.12.1998.
[35]    COM(2001) 79 of 7.2.2001.
[36]    COM(2001) 130 of 7.3.2001.
[37]    Council Resolution on the role of standardisation in Europe, OJ C 141, 19.5.2000.
[38]    COM(2000) 139 final of 29.3.2000.
[39]    COM(2001) 68 final of 7.2.2001.

24.3. 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 standards[40]. 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 development[41].

25. The partnership between the Community and the European standards organisations requires distinct roles for the each of the parties. The Council emphasised this in 1999 when asking for new mechanisms for cooperation and transparency to be created[42]. In addition to the General Guidelines for Cooperation between the European Commission and the European standardisation organisations of 1984[43] and the Council Resolution of 1992[44] **the Commission services drew up a preliminary working document on the role of public authorities in standardisation**[45]. This document takes as a starting point the need for authorities to fulfil public interest obligations while respecting the voluntary nature of standardisation and the independence of standardisation organisations. It focuses on standardisation under the New Approach.

26. If the public authorities see that a harmonised standard does not entirely satisfy the essential requirement(s) of a New Approach Directive, the publication of the references of the standard concerned or its relevant parts can be withdrawn. This is done through a "standards safeguard clause" which is also called a "**formal objection**." **Detailed guidelines were established** for the administrative procedure concerning formal objections by Member States or the Commission against harmonised standards, in collaboration with the Advisory Committee under Directive 98/34/EC[46]. However, it should be noted that out of the totality of the harmonised standards under the New Approach, ten standards have been the subject of formal objections since 1999.

27. With a view to even **further improving** the system and preventing formal objections, the European standards organisations could adopt additional mechanisms as proposed by the Council and the European Parliament. One option would be to further increase the transparency of the European system and to provide information on any remaining reservations on the part of the stakeholders at national level. The Commission made this suggestion during discussions with the European standards organisations. Only CEN is known to have pursued the matter.

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[40]    http://europa.eu.int/comm/enterprise/electr_equipment/eee/index.htm.

[41]    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.

[42]    *cf.* Council Resolution of 28.10.1999, OJ C 141, 19.5.2000.

[43]    The guidelines were initially agreed between the Commission, CEN and CENELEC. They are currently under review tacking account of the activities of the European Telecommunications Standards Institute ETSI and other relevant developments since 1984.

[44]    *cf.* Council Resolution of 18.6.1992, OJ C 173, 9.7.1992.

[45]    SOGS N 302.

[46]    cf. 98/34 Committee document n° 49/99 Rev. 2 of 3 April 2000.

**III.4. Efficiency**

28.     Industry, the public authorities and other concerned parties are interested in having an efficient standardisation system through which they can draw up and agree on high-quality standards, available within a reasonable time, so that they can be used effectively in the market. **The management of the standardisation process is, in the first place, the responsibility of the European standards organisations and their members.** Since 1999, the European standards organisations have continued to review their processes to increase efficiency and improve consensus.

29.     **On-line working**, the **provision of deliverables free of charge and over the Internet** and greater use of web-based applications put ETSI at the forefront of efficiency. In CEN, the implementation of a similar project called *e*-CEN, which aims at working, accessing and ordering standards via the Internet is well advanced. CEN also launched **a benchmarking initiative to identify best practices** on a number of issues. CENELEC installed an **audit system** to assess the functioning of its technical bodies on the basis of defined benchmarks. Even if their make-up and organisational arrangements are different, the three European standards organisations could certainly learn from each other by exchanging best practices. As requested by the Council[47], ETSI made use of **indicative voting** in order to improve access for all the interested parties at the earliest possible stage in the process and to avoid bottlenecks with the risk of unnecessary delays. Electronic working in CEN will also open up the possibility for indicative voting.

30.     A number of measures have been initiated at the **national level**: a good example is the benchmarking exercise initiated by the Finnish standards organisation and to which the Commission contributed financially. The project resulted in the identification of 59 best practices in the standardisation processes of four national standards organisations. Best practices were identified in areas such as customer services, management, sales and marketing. The exercise concluded with a number of operational recommendations for the group of participating standards organisations and with specific recommendations for each of them. The impact of standards has also been examined from various angles through a number of studies[48].

31.     To complete the picture and to identify issues for the further improvement of standardisation and standardisation policies the Commission has initiated a **study on the overall impact of standardisation in the EU and EFTA**, as requested by the Council[49]. An external study team was commissioned to examine which aspects of economy and society have been affected by standards, and to what extent[50]. The study design proposes to look into aspects such as health and safety of workers, protection of consumers, environment, innovation and trade. Evidence for such an impact assessment will be collected for some of the sectors regulated under the New Approach. Other sectors to be looked at include future growth sectors where the potential of European standards could be considerable. Another study is being

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[47]     Point 23 of the Resolution of 28.10.1999, OJ C 141, 19.5.2000.

[48]     *cf.* DIN Deutsches Institut für Normung e.V. (Hrsg): Gesamtwirtschaftlicher Nutzen der Normung, Beuth Verlag, GmbH, Berlin/wien/Zürich 2000; and, Swann, G.M.P., The economics of standardisation: report for the Standards and Technical Regulations Directorate of the Department of Trade and Industry, Manchester Business School, 2000.

[49]     Point 25 of the Resolution of 28.10.1999, OJ C 141, 19.5.2000.

[50]     *cf.* Award Notice Nr. 043202, OJ S 63, 30.3.2001.

conducted under the Community research programme on Competitive and Sustainable Growth. It deals with the interaction between "Standardisation and Intellectual Property Rights" [51]. Its aim is to examine the technical, legal and economic relationship between the standardisation process and the registration of intellectual property rights (patents, trade marks, copyright, software protection).

32.     Work on European standards has progressed since 1999. **Annex 1 shows the evolution for the number of European standards adopted in the past 18 months**. It illustrates the fact that only a small fraction of the European standards are developed under a mandate from the Commission. The vast majority of them are purely market initiated. This aspect is substantiated by the fact that European standardisation costs are borne for more than 90% by the market players.

33.     As regards standardisation in relation with the 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 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.

34.     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. On a general basis and as a means to **improve efficiency under standardisation mandates** the Commission has now arranged for regular sectoral review meetings with the aim of tracing progress and stopping financial support in areas that do not progress.

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[51]     *cf.* OJ S 15, 22.1.2000.

35.     Mandates are reference documents for standardisation activities by which public authorities ask the European standardisation authorities to develop technical specifications. Directive 98/34/EC provides the general framework for the drawing-up of mandates which can be complemented by provisions in individual directives using this instrument. Standardisation mandates are important interfaces between public policy and the voluntary environment of standardisation. **Since 1999 the Commission has presented 26 mandates to the European standards organisations**. 13 of the mandates relate to the New Approach, 7 mandates deal with consumer protection requirements such as for lighters, ladders, the fire-resistance of nightwear, child safety, etc. The rest of the mandates relates to legislation in the field of energy, environmental protection and the internal market (postal services). Standardisation activities concerning high speed rail network interoperability have resulted in 52 European standards, with another 49 progressing. Another example of a public-interest related mandate is the work requested on humanitarian de-mining.

36.     The Council stressed that mandates[52] should be prepared accurately and efficiently and that standardisation covered by mandates should be subject to thorough monitoring[53]. To further improve the scope, drawing-up and management of mandates and to complement a future edition of the New Approach Guide, the **Commission services have compiled and discussed with Member States a preliminary document on the role and preparation of standardisation mandates**[54]. This exercise will be followed up with a similar document on the monitoring of standardisation mandates.

**III.5.    Financing**

37.     The issue of the future financing of European standardisation will increase in importance. For industry to continue to contribute**, the system will need to maintain its attractiveness and prove its added value to competitiveness**. Except for ETSI, which functions more on the basis of members' contributions, the CEN and CENELEC system relies heavily on the sales of standards by their national members. Sales are coming under increasing pressure. The national standards organisations in Europe are now seeing their collections of standards become not only increasingly similar, but also more easily available electronically. The competition for sales is becoming more acute and transnational. The question is therefore how the European standardisation system based on decentralised national organisations of different size will continue to remain financially viable. This issue is becoming even more urgent with the prospect in the next few years of European standards organisations incorporating additional standards organisations from candidate countries, all of them of a relatively small size.

38.     The Council raised this issue and the Commission suggested that the European standards organisations carry out a joint **study** on the matter. The three organisations studied how best to meet the challenges ahead - in different ways, however.

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52      *cf.* Council Resolution of 7.5.1985, OJ C 136, 4.6.1985.
53      *cf.* Council Resolution of 28.10.1999, OJ C 141, 19.5.2000.
54      SOGS N404.

38.1.    **CEN** commissioned a management consultancy to carry out a study on its financing system. The study revealed that **market players** essentially finance the CEN system. In 2000 they **contributed 93% of the total estimated cost of €700 million**. The relatively small contributions from the European Community and EFTA (2%) can be seen as good value for money compared to the relatively strong influence that EC and EFTA have in promoting their policies through this system. The study also makes it very clear that the commitment of the market players, notably industry, will be conditional on improving the efficiency and user-friendliness of the system. The study recommended that alternative ways of financing the standardisation activities or new types of standardisation such as Workshop Agreements (see also III.2) have to be further explored. It said that the diversification of standardisation products and other services was essential if the CEN system were to maintain its attractiveness. The Commission welcomes CEN's initiative to study their financing system and stresses that the findings of the study are by-and-large in line with the priorities for EC/EFTA support to CEN. The Commission, however, considers the role of the CEN Management Centre of increasing importance, notably to strengthen cohesion within the expanding system.

38.2.    The **ETSI** study also makes it clear that the major part of standardisation costs are paid by members through their direct participation in the work. ETSI intends to maintain and extend its membership base, to include for instance "internet players". To retain this growing membership, ETSI sees the need to ensure high efficiency at work, a broad range of deliverables, and openness to projects with partners committed to the principles of standardisation, as in the case of the third generation partnership project. The study also states that recognition of and support for EC/EFTA policy is essential for ETSI members**.**

38.3.    **CENELEC** seems to deal with the same challenges, but took a less proactive attitude in addressing them, having decided to base their reactions on the findings of the study undertaken by CEN.

39.      Since 1990, the European Community and EFTA have focused their support for the European standardisation system on the production of harmonised standards for implementing New Approach Directives**. From 1998 onwards EC/EFTA financial support was based on three pillars**. Support was dedicated, (a) to the central secretariats of the European standards organisations, (b) to the quality of the standardisation process, and (c) to the preparation of specific work items. Measures to enhance quality included the work of the "New Approach" consultants and translations into the less common Community languages. Specific work items included the production of harmonised standards related to New Approach directives, European standards related to Community policies such as consumer protection, or standards activities related to European policy initiatives such as *e*-Europe.

40.      **In 2001, EC/EFTA support for the European standards organisations was reviewed** in order to increase the coherence, efficiency and visibility of European standardisation, at both European and international levels. To better achieve these objectives and in line with sound financial management principles, the Commission agreed a list of tasks with the three European standards organisations and asked for regular reports on the individual tasks. The new arrangement sets priorities (a) to improve awareness building for and planning of new standardisation activities; (b) to ensure better management of standardisation work and the respective financial procedures; (c) to implement electronic working tools to speed up the standardisation

process and to enable broader participation; (d) to enhance performance and market relevance through the launch of a benchmarking programme between the three European standards organisations; and (e) to increase information and communication on the benefits of European standardisation in support of EU policies.

**III.6.    Enlargement of the EU and the international dimension**

41.    Standards, particularly international standards, are able to facilitate trade and market access, to improve the quality and safety of products and services, and to disseminate knowledge, technology and management practices across borders. This is why they have become a crucial element in economic integration and world trade. With regard to European integration, the Council explicitly welcomed in 1999 the efforts of the candidate countries and their standards bodies to become members of the European standards organisations[55].

42.    Nearly all candidate countries are full members of ETSI, mostly through their established membership in the European Conference on Postal and Telecommunications Administrations (CEPT) and via the direct participation of enterprises and administrations in ETSI. In addition, the standards bodies of the candidate countries are affiliate members of CEN and CENELEC with the aim of becoming full members. The national standards body of the Czech Republic had become full members of CEN and CENELEC by 1997. **Since 1999 the affiliate members of the European standards organisations have made significant efforts in preparing for full membership.** The most important criteria for qualifying as full members are the transposition of 80% of European standards (ENs) and the acceptance of the copyright policy of CEN and CENELEC. Furthermore, the candidate countries need to put in place a legal framework under which standardisation can be carried out as a voluntary, non-governmental activity. According to information from CEN and CENELEC, **some national standards bodies of applicant countries have submitted their formal application for full membership in 2001**. More are expected to follow by 2002.

43.    The efforts made by the candidate countries and their standard bodies to become full members of CEN and CENELEC were accompanied by financial support from the Community's regional technical assistance programme which aimed at improving the overall quality assurance systems in the candidate countries (PRAQ)[56]. The PRAQIII programme expired by the end of 2000. **Further financial support and technical assistance will continue to be provided via the PHARE programme on a country-by-country basis under the Accession Partnerships** taking into account the specific needs of the beneficiaries in the respective candidate country.

44.    It is important that the extension of the membership of CEN and CENELEC does not lag behind the enlargement of the Community. It would be detrimental to the functioning of an expanded internal market if new Member States had the legislation in place but failed to be part of the European standardisation system which supports Community legislation and policies. Extending the membership of CEN and CENELEC will also require changes to their internal procedures. **CEN and**

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[55]    Council Resolution of 28.10.1999, §17, OJ C 141 of 19.5.2000.
[56]    Programme régional relatif à l'Assurance Qualité (PRAQ).

**CENELEC are therefore currently preparing recommendations for structural and procedural changes**, including consideration of the new institutional arrangements and rules for the Community which are provided for in the Nice Treaty. The Commission welcomes these initiatives.

45.     **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 part of the Community's external trade policy[57], and the Community must comply with international agreements concerning standards such as the WTO Agreement on Technical Barriers to Trade (TBT Agreement). In addition, the Commission services drew up a document on the **European policy principles on international standardisation**.[58] The document 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. It can serve as a reference document and guidance material as requested by the Council.

46.     The Community policy in relation to standards and standardisation plays a role in international and multilateral negotiations as well as in bilateral and region-to-region agreements. In principles there are three types of **Community activity** in this regard. The Community (1) promotes a common understanding on principles for international standardisation, (2) encourages the creation of standards-receptive legal conditions, and (3) it provides technical assistance to third countries to help them align their regulations, standards and conformity assessment infrastructure with European and international requirements. One of the objectives of the Community's technical assistance is to better integrate developing countries into the world economy by enhancing their effective participation in international standardisation. Since 1999, a number of activities have been pursued in these fields.

46.1.   The **second triennial review of the TBT Agreement** offered the opportunity to share the Community's views[59] on the principles concerning international standardisation with some 140 countries. The Community explained that international standards used in legislation needed to be drawn up in a spirit of openness and impartiality towards any participating nation, as well as transparently. The Community stressed that international standards had to be coherent, that is, they should not specify requirements that differed or contradicted. Consequently, the Community considers the status of the bodies that draw up international standards important. Constitution as an international body is seen as a condition for guaranteeing impartial treatment of national positions and for ensuring consistency between international standards. During the discussions in the WTO the Community endorsed the principle of singularity, that is, in each area of standardisation no more than one international body should be active[60].

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[57]     COM(96) 564 final of 13.11.1996.
[58]     SEC(2001) 1296 of 26.7.2001.
[59]     G/TBT/W/87, 14.9.1998 and Rev. 1, 30.9.1999; G/TBT/W/133, 11.4.2000; G/TBT/W/149, 1.11.2000
[60]     *cf.* G/TBT/W/149, 1.11.2000.

46.2.    By November 2000 the second triennial review of the TBT Agreement concluded**,** amongst other things, with a **decision on the principles for the development of international standards**[61]. The Community considered the agreement a suitable way of improving the implementation of the TBT Agreement. Although not explicitly comprising criteria applicable to the bodies that draw up international standards, the decision ensures that participation in a particular international standardisation activity is open to the relevant bodies of at least all WTO members[62]. It stresses that participation should take place, where possible, through one delegation representing the relevant standardisation activity in the territory of a WTO member. Furthermore, the set of criteria ensures that international standards are consistent and do not conflict with each other. From the Commission's point of view, international bodies that operate on the basis of national representation are suitable for implementing these principles.

46.3.    The role international standards can play in trade facilitation and market access is hampered if ignored by regulation. The Council also called upon Europe's trading partners to introduce **standards-receptive regulatory** models[63]. First steps have been taken to achieve greater convergence with trading partners on this. For instance, the **ASEM**[64] Standards and Conformity Assessment Meeting agreed upon **guidelines for best regulatory practice**. While the application of these guidelines is voluntary, they serve as practical references for the ASEM partners in the fulfilment of their obligations under the TBT Agreement. Amongst other things, the guidelines specify that regulation, if regulation is needed, should be specified in terms of performance characteristics and may be met or presumed to be met by compliance with standards which should be aligned with international standards to the greatest possible extent.

46.4.    The **benefits of standards-receptive regulatory models have also been subject to discussions in the OECD**. In this field, the OECD has analysed and discussed some of their members' experiences with regulatory reform. It concluded that international harmonisation of technical rules, for instance, through international standards may be one means of avoiding unnecessary barriers to trade. To this end, a new project was started in order to explore the possibilities and preconditions for international harmonisation and the role standards can play in the field of telecommunications terminal equipment[65].

46.5.    The **United Nations Economic Commission for Europe (UN/ECE)**, in particular its Working Party on Technical Harmonisation and Standardisation Policies, provides an interface between the regulatory and the standardisation community. For two years, an ad-hoc group of experts on standardisation and regulatory techniques has been working on an **international model for technical harmonisation via the use of international standards**[66]. This concept allows governmental co-operation on essential legal requirements, if regulations are needed for certain products or groups

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[61]    Annex 4 of G/TBT/9, 10.11.2000.
[62]    cf. Council Resolution point 39, OJ C 141, 19.5.2000, stressing that interested parties such as workers', consumers' and environmental interest groups should be fully involved in the standardisation process at all relevant stages.
[63]    *cf*. Council Resolution point 34, OJ C 141, 19.5.2000.
[64]    The Asia-Europe Meeting consists of the 15 Member States of the EU and 10 Asian states: Brunei Darussalam, China, Indonesia, Japan, Korea, Malaysia, Philippines, Singapore, Thailand, Vietnam
[65]    TDTC/WP(2001)11 Rev. 1.
[66]    UN/ECE/TRADE/WP.6/2000/8 .

of products. Governments would also identify the relevant international standards and conformity assessment procedure applicable to meet the common regulatory objectives.

47.     With regard to the interface between regulation and standardisation and in respect of the independence of the respective parties, the Council stressed the need to ensure that European interests be coherently presented in international standards bodies and intergovernmental fora[67]. This requires appropriate mechanisms for exchange of information and consultation between the relevant parties. The Commission services have started to operate **a newsgroup for exchange of relevant information** with senior officials from Member States, EFTA and the candidate countries. There is also a regular exchange on international matters with the Advisory Group of Senior Officials on Standardisation and Conformity Assessment and with the Advisory[68] Committee under Directive 98/34/EC.

48.     **Closer working relationships have also been established with the European standards organisations**. Relevant international developments are very attentively followed by ETSI. CENELEC has created a platform for their members which is active in international standardisation. CEN has created a group which regularly meets to discuss international issues. Commission staff are invited to participate in this group with observer status. It should be noted that the three European standards organisations have also created closer links with regional standards entities in South and Latin America, such as with AMN, the Mercosur Association for Standardisation.

49.     While reaffirming Europe's strong commitment to international standardisation – the Council stressed the exemplary nature of the **cooperation agreements between the European standards organisations and their international partners** – the European parties **need to take account of Community legislation and national requirements, if applicable**. The Council explicitly referred to essential requirements of Community legislation and national requirements in the non-harmonised field, such as occupational health and safety provisions[69]. This results in case-by-case consideration of whether and to what extent, for instance, a harmonised standard can be based on relevant international work. For CEN and CENELEC this assessment is carried out under their framework arrangements with ISO and IEC, the Vienna and Dresden Agreement, respectively. In the telecommunications field, a cooperation agreement has been concluded between the ITU and ETSI. To facilitate the transposition of international standards and to allow for a maximum of coherence it is considered important that standards are written in a modular fashion, and that standards treat product-related aspects separately from related processes, production methods and environmental requirements, if applicable.

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[67]     Council Resolution of 28.10.1999, point 37, OJ C 141, 19.5.2000.
[68]     The Advisory Committee under Directive 98/34/EC meets twice a year with its participating observers, the national and European standards bodies.
[69]     Point 38 of the Council Resolution of 28.10.1999, OJ C 141, 19.5.2000.

**IV.**    CONCLUSION

50.    This document is a mid-term report in response to the 1999 Resolutions of the Council and the European Parliament. It describes a number of initiatives that have taken place or are ongoing with a view to further improving the European standardisation system, to make it fit for extended membership and to promote it at international level. The Commission proposes to discuss this report with the Council and the European Parliament with a view to receiving opinions and guidance concerning further work and reporting.

# Annex 1

# Number of European Standards as of 31.10.1999 and 30.6.2001

European Standards

| | ETSI (31/10/99) | ETSI (30/6/01) | | CEN (31/10/99) | CEN (30/6/01) | | CENELEC (31/10/99) | CENELEC (30/6/01) |
|---|---|---|---|---|---|---|---|---|
| ■ mandated | 114 | 203 | | 717 | 1029 | | 754 | 790 |
| ■ Not Mandated | 2269 | 3051 | | 5462 | 6862 | | 3309 | 3795 |