COMMISSION STAFF WORKING DOCUMENT

"The challenges for European standardisation"

INTRODUCTION

This paper has been developed in support of a Commission Communication on the "Role of European Standardisation in the Framework of European Legislation and Policies". As a follow-up of the European Parliament's Resolution in 1999[1] and of both the Council Resolution of 28 October 1999[2] and the Council Conclusions of 1 March 2002[3] on European standardisation, **the Commission** has analysed the areas in which standards play a role to support European legislation and policies beyond the legislation establishing the Single Market for goods and services (see annexes 1 and 2). At the same time, it **has identified,** in the light of the changing conditions under which European standardisation in the enlarged EU needs to operate and taking account of the challenges due to digitalisation and globalisation, **the challenges the European standardisation system is currently faced with and the instruments available to European standardisation policy**. The first conclusions were discussed with stakeholders in standardisation via public web consultations. This analysis will demonstrate that the actions proposed to meet needs in an ever-changing environment are not only addressed to the European Standards Organisations (ESOs), but related to all stakeholders in European standardisation, comprising the European Commission, national authorities, the European Standards Organisations, National Standards Bodies, industry and NGOs. **The particular objective of the following Commission staff working document is to explain the specific challenges European standardisation is facing and to provide recommendations for further activities, aimed at all stakeholders in standardisation.**

1. ENLARGEMENT

European legislation and policies supported by standards can only work properly when they are complemented by a sound and well functioning European standards system including all of the Member States' National Standards Bodies .

The National Standards Bodies of the new Member States undertook enormous efforts to become full members in the European standards system by 1st January 2004. The Commission recognises these efforts. However, besides full membership of National Standards Bodies from the new Member States, there still remains **the challenge of the full integration of these organisations into the "European standardisation culture".** Therefore, the standards bodies of the new Member States should actively contribute to European standardisation. Where infrastructures in the new Member States are not yet fully operational, national governments, the relevant National Standards Bodies and stakeholders will need to make

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1 Resolution on the report from the Commission to the Council and the European Parliament "Efficiency and Accountability in European standardisation under the New Approach", OJ C 150 of 28.5.1999

2 Council Resolution of 28 October 1999 on "the Role of Standardisation in Europe" (OJ C141 of 2000 05-19)

3 Council conclusions on standardisation of 2002-03-01, (OJ C66 of 2002-03-15)

further efforts. **National governments, the standards organisations and stakeholders from the new Member States are invited to contribute fully to the European system**.

Due to the structure and size of enterprises in the new Member States, the involvement of Small and Medium-sized enterprises (SMEs) in standardisation work and the use of European standards present a particular problem in the sense that access to standards must be improved. **The Commission notes that there is a particular need for actions to enhance the availability of standards in the languages of the new Member States and to improve involvement of SMEs in European standardisation.**

2. THE STRATEGIC IMPORTANCE OF STANDARDISATION FOR ENTERPRISES AND EFFICIENCY

For enterprises, **the use of standards is a strategic tool to raise competitiveness**. However, in many cases, high level management in industry is not aware of the strategic advantages the use of standards and their participation in standardisation work have for their enterprises. Moreover, standardisation is seen as a cost. Accordingly, there is a tendency, when needing to reduce costs, to save money by firstly reducing the participation of their employees in standardisation work. Such a decision will, in the medium-term, lead to strategic disadvantages for these enterprises and affect their position in the market. **The awareness of senior managers of enterprises with respect to the advantages of standardisation must therefore be improved.**

At the same time, efficiency in the standards development process must be improved. The speed of transposition of European standards into national standards must be increased. The latest Internal Market Scoreboard reports on the transposition deficit records of National Standards Bodies[4]. The reduction of delays in the development of standards is one of the main objectives in the European standardisation infrastructure. To some extent, however, a certain timeframe for the development of standards has to be accepted, since one of the indispensable core elements for the acceptance of voluntary standards is consensus. Consensus building needs, by its very nature, a certain time frame. A balance between efficiency and openness, in particular with respect to the enlarged ESOs (with up to 30 members), must be maintained.

There are, of course, other factors beyond the control of the ESOs which cause delays and these have to be accepted. Standardisation cannot move quicker than cultural changes often needed in some sectors. The pace of standardisation will always be dependent on the acceptance and pace of implementation of the European policy which the standards support.

Management of the standardisation process is, in the first place, the responsibility of European Standards Organisations and their national members, including the respective stakeholders. It is the task of the European Standards Organisations, their members and stakeholders to improve the standardisation process continuously and to ensure effective project management. Early consideration of all the potential problems, including those that arise for reasons beyond the control of the ESOs, should become standard practice when deciding to start standardisation work in a particular area. This will assist with planning and help manage expectations.

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[4] Internal Market Scoreboard n° 13 of July 2004, available at http://europa.eu.int/comm/internal_market/score/index_en.htm"

Since the Commission's report of September 2001 and the Council Conclusions of 1 March 2002, which have taken up this issue again, the European Standards Organisations have continued to review their processes, to increase efficiency and improve consensus. A recent enquiry amongst the three European Standards Organisations has confirmed this but has also shown that the results of these efforts vary significantly which is mainly due to the very different nature of each standards organisation.

ETSI, as a standards organisation serving quicker and ever changing market needs, has started to introduce electronic working tools and is continuously striving to improve the efficiency of its processes. The standards development process is measured by the ETSI Secretariat in several ways in order to monitor the lead times in the production of all deliverable types.

CENELEC installed an audit system to assess, on the basis of defined benchmarks, the functioning of the technical bodies. These technical bodies are required to report regularly to the Technical Board with respect to their work programme, the progress of work and target dates of work items. Together with an improved IT infrastructure, these measures have led to a significant reduction in the time needed to elaborate standards.

In 1992 only 60% of electrotechnical standards were produced in under four years. However, since 1999, this percentage has increased to almost 80%. Indeed, 50% of the electrotechnical standards are now produced in less than three years time.

For **CEN,** in 2002, the average period for developing standards was still slightly over six years. This long development period is, compared with the other two organisations, certainly due to the specific situation that CEN has to act in all industrial sectors and that the industrial actors themselves have a great influence on the speed of the standards development. Whereas, for example, in the machinery sector standards are developed very quickly, in the construction sector it took more than 10 years until the first standard was developed.

In order to speed up standards development, CEN has established a special advisory group to the Chairman of the Technical Board. This group has established a whole set of actions in order to increase efficiency. These actions comprise: a feasibility study prior to the adoption of new work, an accelerated timeframe for the development of European Norms and the promotion of the use of New Deliverables. Moreover, CEN improved its IT infrastructure for producing and disseminating European standards, allowing it to conduct the exchange of documents electronically. If these actions are carried out, the timeframe for the development of a standard is expected to be reduced to three years.

The European Standards Organisations are invited to continue their activities and to show further substantial progress in improving efficiency. They are also invited to consider making use of a benchmarking exercise with this objective in mind.

With regard to the transposition of European standards into national standards, the National Standards Bodies are invited to undertake efforts to accelerate this task.

3. NEW STANDARDISATION PRODUCTS ("NEW DELIVERABLES") AND THEIR ROLE IN EUROPEAN POLICIES

The rapid development of technologies and processes in some sectors, in particular in the information and communication technology (ICT) sector, has led to an industry need for the equally rapid creation of specifications which do not have the status of a formal standard. In order to respond to this need, **there has been a mushrooming of industrial fora and consortia developing such specifications**. It is considered doubtful whether, in the light of the speed of development and the limited participation of experts, the fundamental principles for accountability of standardisation such as openness, consensus and transparency are followed in a robust fashion. **The increasing development of new technical specifications by consortia, which operate outside of the standardisation framework and independently of standardisation principles, has to be considered as a major challenge to the current standardisation system.**

The European Standards Organisations are aware of these developments. Following a request of the Council in its Resolution of October 1999, as a response, they have extended their range of deliverables beyond the formal European standard (EN) by **a common portfolio of three New Deliverables (the Technical Specification (TS), the Technical Report (TR) and the Guide (G)).** These incorporate fora and consortia into the system, but do not strictly follow the formal procedure for the development of European standards and are not adopted by national vote.

In addition to the above three common New Deliverables, CEN and CENELEC have developed the **"CEN/CENELEC Workshop Agreement (CWA)"** in their product range. Proposals for workshops may come from any interested party. Workshops originated in the ICT area, but are now expanding outside of this, and may cover any area within the scope of CEN/CENELEC's activities. Participation is open to all interested parties, including those from third countries. **The usual development time for a CWA in the ICT sector is between 12 and 18 months.**

With the development of these new types of documents, the European Standards Organisations are providing alternatives to face the challenge of documents developed outside the standardisation system. These alternatives may provide an appropriate response to market needs. **The European Standards Organisations are encouraged to continue with this approach while reviewing with stakeholders, and in particular industry, the appropriateness of the response to their needs.**

New deliverables may be used to support European legislation and policies, as it is already the case in the ICT area (see again annex 3)**, on a case by case basis.** However, due to fact that the principles of standardisation are not always observed in a robust fashion, the decision on whether to use a new deliverable should be explored early in the process and then the final document would need to be assessed for its suitability against the policy.

4. PARTICIPATION OF INTERESTED PARTIES

The acceptability of standards depends, to a large extent, on the full involvement of all relevant, interested parties. **The participation of societal stakeholders[5] in the standardisation process has a strong and important dimension of accountability.** It reinforces the quality of the consensus and makes the standards more representative.

However, standards development is time-consuming and costly in terms of the human and financial resources that have to be provided to achieve a meaningful input into the process. The participation of SMEs and societal stakeholders can be hampered by a lack of resources and technical expertise. This can, in turn, affect the consensus-reaching process and therefore cause delays in standards development.

4.1 Participation at ESO level

The Commission is aware of this situation and of the necessity of a broad societal stakeholder participation in standards development. It is therefore providing financial support to European organisations and associations representing SME and societal stakeholder interests. This enables them as associate members in the European Standards Organisations to participate more effectively in the standardisation process at the European level and to co-ordinate the involvement of all national experts in the standardisation development process. These stakeholders are **NORMAPME**[6]**,** representing SME interests (SMEs account for more than 90% of European industry but are often not aware of how standards can be used as a strategic tool to increase competitiveness), **ANEC**[7] - consumer interests, **TUTB**[8] - worker interests, and **ECOS**[9] - environmental interests.

As these groups operate at the European level, they can help to promote and co-ordinate the participation of interest groups at the national level.

4.2 Participation at NSB level

Standardisation in Europe is based on the principle of national representation. Therefore, **it is primarily the task of the national members of the ESOs to ensure that all relevant, interested parties have the opportunity to contribute to the development of European standards**.

An enquiry amongst the Member States has shown that the efforts of their National Standards Bodies and public authorities to ensure the representation of interest groups are highly variable. These efforts range from allocating valuable resources to doing nothing. Furthermore, within individual Member States, the efforts made for each of the different interest groups vary greatly. For example, some NSBs have allocated staff to deal specifically with consumer interests but they have no similar initiatives with respect to SMEs or environmental interests. However, all of these interests are equally important in the context of sustainable development. Therefore, efforts must be increased to ensure that European standardisation is recognised by the industrial stakeholders, particularly SMEs, as a strategic

[5] Those representing consumer, health, safety and environmental interests in standardisation.

[6] http://ueapme.com/normapme

[7] http://www.anec.org/

[8] http://www.etuc.org/tutb/

[9] European Environmental Citizens Organisation for Standardisation http://www.ecostandard.org

tool to raise competitiveness. **Member States are invited to take further steps ensuring the proper participation of all societal stakeholders in their National Standards Bodies.**

4.3 Participation of authorities in the area of harmonised standards

Finding the appropriate level of participation for public authorities in standardisation at the national level is important. On the one hand, the standardisation system needs to be allowed to work independently but, on the other hand, public authorities have detailed knowledge of the national regulatory background to a particular subject. Finding the appropriate level of participation for public authorities ensures that standards correctly translate relevant legal requirements. Therefore, early involvement in European standardisation helps to avoid safeguard clauses[10].

5. THE SHORTCOMINGS OF THE EXISTING LEGAL FRAMEWORK REGARDING STANDARDISATION IN COVERING NEW DEVELOPMENTS

There has been an enormous increase in the use of standards to support European legislation and policies. Standards in the service sector have become more and more important. In addition, the range of products has been extended to a whole set of new standards documents ("New Deliverables") beyond the formal standard.

Against this background, it is doubtful whether the current legislative framework, which is mainly established by the "Directive 98/34 of the European Parliament and of the Council of 22nd June 1998 laying down a procedure for the provision of information in the fields of technical standards and regulations and of rules on information services"[11], is still sufficient to cover all of these developments and needs.

Mandates are currently issued in areas beyond the Single Market for goods, e.g. ICT, worker protection, consumers, environment, services. The scope of application of the Directive 98/34 in its present version, however, only relates to "products". **It should therefore be extended to services** to cover the needs of today.

At the same time, it **is unclear whether the new standardisation documents, which do not have the status of a formal standard, are covered by Directive 98/34**. The present definition of the term "standard" in this directive is very broad and would allow the inclusion of the new standards documents into the scope of application of this Directive. As a consequence, the Commission would be permitted, in accordance with the respective provisions of the Directive, to issue mandates for new standards documents. On the other hand, however, these documents would be subject to the information procedure and the standstill/withdrawal obligations stipulated by the Directive. In this case, similar specifications developed by private fora and consortia would have greater appeal to stakeholders on grounds of flexibility of development and time to market. Therefore, **a clarification of existing procedures with particular regard to new standards documents is needed**.

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[10] Official procedure established under Directive 98/34 and the different sectorial New Approach Directives to object to a standard formally.

[11] OJ L 204 of 21.7.1998, OJ L 217 of 5.8.1998

Finally, **the current legal framework does not specify which principles European Standards Organisations must observe** to be recognised as being “European”. In fact, a standards body is recognised as a European standards body if **the principles of "openness, transparency, consensus, full participation of all stakeholders and coherence"** are observed. These principles are identical with the recent Commission's proposals for "good governance" and "better regulation" and **their observance is indispensable for both the accountability of European standardisation and the acceptance and legitimacy of European legislation and policies**. It is evident that these principles are generally observed by the European Standards Organisations. In addition, they are explicitly set out in the new "Co-operation Guidelines", signed between the ESOs, the European Commission and EFTA[12]. However, these Guidelines are a political document and do not provide the legitimacy necessary for European standards supporting European legislation and policies. Thus, for the sake of completeness, **these principles should also be clearly laid down in a legally binding act.**

6. FINANCING

In its Resolution of October 1999 and its Conclusions of 2002, the Council invited public authorities to acknowledge the strategic importance of standardisation by giving concrete expression to their commitment to it, in particular by contributing to maintaining an adequate and efficient standardisation infrastructure. It considered that whilst traditional sources of income were likely to change, standards bodies and public authorities in the Member States had to consider how the financial viability of the European standardisation infrastructure could best be preserved. The Council also confirmed its intention to continue to provide Community financial support to European standardisation within appropriate budgetary limits.

6.1 The Commission's financial contribution to the system

The Commission's financial contribution to the system in support of internal and external policies has remained stable over recent years (see annex 4). Since 1985, in order to ensure continuity in financial support provided by the Commission, the ESOs have signed framework contracts with the Commission which lay down the legal, administrative and financial terms underpinning the provision of financial support for the conduct of standardisation work. **A new Framework Partnership Agreement (FPA), defining the respective roles and responsibilities of the Commission and the European Standards Organisations, for financing various standardisation activities based on five pillars (see below), has been in place since the beginning of 2004.**

The five pillars of financial support to European standardisation

1. Annual performance contracts in order to improve efficiency, quality and visibility of the three European Standards Organisations through the achievement of specific tasks. The objective is to reduce the delays in standards production, to optimise the use of European standards, to raise the level of awareness of the opportunities offered by standardisation, to improve electronic working and to promote the benefits of European standardisation.

[12] OJ C 91 of 16.4.2003

2. Quality of European standardisation: the objective is to enhance the quality of European standards used in support of EU legislation by :

   – supporting translations into Community languages other than French, English and German,

   – supporting consultants' activities to ensure the compliance of these ENs with the EU directives' essential requirements.

3. Support to European standardisation work (production of ENs, etc) mainly on the basis of EC mandates adopted through the 98/34 Committee procedure in support of various EU policies and legislation.

4. External visibility and promotion of the European standardisation system in the world.

5. Co-operation and technical assistance contracts managed by External Relations Directorate-Generals.

6.2 The viability of the system

Beyond the needs to support EU legislation and new policy areas, there is a **strong interest for the EC to support a European standardisation system capable of avoiding barriers to trade and increasing the competitiveness of European industry for products and services.**

At present, however, there is no legal act explicitly allowing for the financing of European standardisation. In order to overcome this gap, **a new single basic act** is needed which enables the Commission to provide financial support for all activities of European standardisation. **This act must be comprehensive** and take into account the increased use of standardisation in all policy areas, e.g. ICT, transport, environment and consumer protection. At the same time, the new act will need to take into account the particular needs of European standardisation.

The viability of the system also has to be considered from the point of view of the financing of Central Secretariats to ensure greater coherence and stability in the system after enlargement. **The existence of efficient and stable central infrastructures is a pre-requisite for the functioning of the European standardisation system.** At present, in the case of CEN and CENELEC, the financing of the central infrastructures depends exclusively on EU and EFTA funding as well as on membership fees. In comparison, the National Standards Bodies benefit from a broad direct income base for their financing including income from products and services.

The Commission considers that contributions from public authorities, (including the Commission) and National Standards Bodies are not enough to ensure the financial viability of the European system. The possibility of providing additional sources of financing for central infrastructures has to be explored with CEN and CENELEC. The presence of stakeholders' representatives in all ESOs' boards would also be a source of stability, efficiency and creativity. **The Commission proposes that ESOs, in cooperation with stakeholders, explore further options to ensure the viable financing of the European standardisation system, taking into account the ways in which National Standards Bodies are funded.**

Finally, in given policy areas (e.g. in the area of ICT) there may be a need for setting up pre-standard specifications to be elaborated by organisations and consortia outside the three European Standards Organisations. This may be, in particular, the case where the European Standards Organisations are not willing or able to develop European standards. The forthcoming legal basis for providing financial support to European standardisation should enable the Commission, on the basis of procedures ensuring fair competition, to provide financial support.

7. THE EUROPEAN PRINCIPLES OF GOOD GOVERNANCE IN INTERNATIONAL STANDARDISATION BODIES

Within the WTO, there are a number of international standardisation organisations which produce "international standards" within the meaning of the TBT agreement, e.g. the International Maritime Organisation, or the framework of agreements and conventions for international road, rail, inland waterway, and combined transport. These "standards" are developed exclusively amongst Government representatives without direct participation of individual stakeholders to whom they are targeted. **There is a potential to enhance the application of European principles of good governance and accountability. The Commission will seek to find opportunities to render the procedures and structures under which these standards are developed more open and transparent.**

8. THE GLOBAL DIMENSION OF STANDARDISATION

Global trade continues to increase. **The use of international standards can enhance market access and facilitate trade**. Like most other trade blocs, Europe follows a philosophy of **coherent standards identical to or based on international standards**. Europe promotes, at several levels (see below), the philosophy of a coherent standards environment with accountable institutions where market players and, if needs be, authorities can rely on a single, voluntary standard supported by all interested parties.

The Commission's undertakings to promote its philosophy in standardisation

– **Participation in Business Dialogues** such as the Transatlantic Business Dialogue (TABD), the Mercosur-European Business Forum (MEBF) and the EU-Russia Industrialists' Round Table (EU-Russia IRT) where standardisation is among the regular topics of talks between businesses.

– **Support to Co-operation and Partnership Agreements of the European Standards Organisations with the International Standards Organisations (ISO, IEC, ITU)** to avoid duplication of work at the regional and international level and ensure the operation of a coherent international system (***Dresden, Vienna agreements)***

– **Promotion of standards-receptive regulatory models** such as the United Nations Economic Commission for Europe (UN/ECE), in particular its Working Party on Technical Harmonisation and Standardisation Policies, which has developed a concept similar to the New Approach and encourages governmental co-operation on essential legal requirements

– **Technical assistance** plays a pre-eminent role in the pursuit of the Commission's objectives regarding the promotion of its standardisation philosophy. Technical assistance **is also accompanying the Community's objectives to create common economic areas with the European Union's neighbouring countries** such as Russia and the countries from the Mediterranean basin.

However, in order to be in a position to do this, and to demonstrate the effectiveness of the European system, **the Community needs a strong standards system at European level** which is able to ensure that international standards, elaborated and transposed into European standards to support Community policies, are coherent with these policies. A diversified system based on many competing National Standards Bodies could never play such a role. **Member States and their National Standards Bodies are therefore requested to continue to support a strong and coherent European standards system. At the same time, it is necessary that European industry and stakeholders are fully engaged in European standardisation so that they can be a driving force at the level of international standardisation.**

The Commission will continue to promote international standards elaborated by the International Standards Organisations (ISO, IEC and ITU) and their uniform transposition in the European Union.

ANNEX 1
New EU legislation and legislative proposals supported by standards (since September 2001, the last report from the Commission on actions taken on European standardisation)

A) AREAS IN WHICH NEW LEGISLATION SUPPORTED BY STANDARDS IS ALREADY IN PLACE

1) The new **Directive on General Product Safety**[13] pursues the objective of better defining the criteria for assessing product safety and clarifies the role of European and national standards in this regard.

2) **The Directive on Interoperability of the trans-European conventional rail system**[14] establishes the conditions to be met to achieve the interoperability of the trans-European conventional rail system. The development of a number of Technical Specifications for Interoperability (TSIs) that determine the interoperability of constituents and interfaces is required. According to this Directive, the Commission, assisted by a Committee, is entitled to decide if the harmonised standards, elaborated by the European Standards Organisations, comply with these TSIs.

3) In the **ICT sector**, there exists a whole set of new legislation in which Europe-wide codes of conduct under the aegis of the European Standards Organisations are being used to support that legislation. Examples are

– the Directive on Data Protection[15],

– the Directive on "Electronic Signatures"[16],

– the Directive on E- invoicing, and

– the new regulatory framework for electronic communications networks and services (which consists of five Directives[17] altogether),

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13 OJ L 11 of 15.1.2002

14 Directive 2001/16/EC of the European Parliament and of the Council of 19 March 2001 on the trans-European conventional rail system (OJ L110, 20/4/2001)

15 OJ L 281 of 23.11.1995

16 Finalised as Directive 1999/93/EC. In this context, the Commission, on 14.7.2003, adopted a Decision, by which it published a list of generally recognised standards (workshop agreements) for electronic signature products (OJ L 175 of 15.7.2003)

17 Directive 2002/21/EC of the European Parliament and the Council of 7 March 2002 on a common regulatory framework for electronic communications networks and services (Framework Directive); Directive 2002/20/EC of the European Parliament and the Council of 7 March 2002 on the authorisation of electronic communications networks and services (Authorisation Directive); Directive 2002/19/EC of the European Parliament and the Council of 7 March 2002 on access to, and interconnection of, electronic communications networks and associated facilities (Access Directive); Directive 2002/22/EC of the European Parliament and the Council of 7 March 2002 on universal service and user's rights relating to electronic communications networks and services (Universal Service Directive); Directive 2002/58/EC of the European Parliament and the Council of 31 July 2002 on the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications

4) The **Regulation relating to Fertilisers**[18] aims at consolidating 18 existing Directives in order to simplify Community legislation on the harmonisation of Member States' legislation in the field of fertilisers and to ensure the free movement of these products within the European Union whilst specifying the characteristics to which they must conform. In this proposal, European standards will now design and harmonise the test methods and analyses regarding the content of different fertilising elements which, in previous legislation, were regulated in the annexes of the Directives themselves.

5) **The regulation of the European Parliament and of the Council on the interoperability of the European Air Traffic management network** sets out a comprehensive approach towards standardisation as an instrument for the creation of seamless air traffic management systems in a more integrated air traffic network, and for the introduction of new technologies in the sector[19].

6) In the environment sector standards support the implementation of the **Directive on the energy performance of buildings[20], the Directive on the promotion of the use of biofuels or other renewable fuels for transport[21] and the Directive on waste electrical and electronic equipment[22].**

7) **The Regulation** (EC) No 882/2004 of the European Council and of the Council of 29 April 2004 **on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[23]** expressly refers to methods of sampling and analysis developed by CEN in case that there are no relevant Community rules.

8) The **Directive 2004/22/EC** of the European Parliament and of the Council of 31 March 2004 **on Measuring Instruments**[24] uses standards to give presumption of conformity to the essential requirements of the various measuring instruments covered.

B) COMMISSION PROPOSALS FOR NEW LEGISLATION SUPPORTED BY STANDARDS

In the transport area, with a view of increasing the interoperability and of making the use of new containers more efficient and safer, the proposal of the **Directive on Intermodal Loading Units (ILUs)**[25] stipulates essential requirements and confers presumption of conformity to these requirements if harmonised standards, mandated by the Commission and elaborated by one of the European Standards Organisations, are used.

The proposal for a Directive on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields and waves) refers to standards with regard to the assessment, measurement and calculation of workers' exposure to electromagnetic fields.

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18 OJ L/2003/304/ 1 (Volume 46: 21/11/2003)
19 OJL/2004/96/26
20 OJ L 1 of 4.1.2003
21 OJ L 123 of 17.5.2003
22 OJ L 37 of 13.2.2003
23 OJ L 191 of 25.5.2004
24 OJ L 135 of 30.4.2004
25 Proposal for a Directive of the European Parliament and of the Council on Intermodal Loading Units (COM(2003) 155 final)

A similar example which foresees the same procedures in using standards to support Community legislation is the proposal for a Community Framework Directive for Eco-design Requirements for Energy-using Products (EuP-Directive)[26] which will allow for the establishment of eco-design requirements.

The same applies for the proposal for a Directive on Electronic Road Toll Systems[27] which aims to ensure migration towards the future interoperability of the existing different electronic toll systems.

The proposal for a new approach Directive on the placing on the market of pyrotechnical articles[28] allows the use of standards to provide the methods for testing such articles.

[26] COM(2003)453 final ***(LS)***

[27] Communication from the Commission developing the trans-European transport network: Innovative funding solutions Interoperability of electronic toll collection systems. Proposal for a Directive of the European Parliament and of the Council on the widespread introduction and interoperability of Electronic road toll systems in the Community (COM(2003), 132 final)

[28] No official document available yet

ANNEX 2
Orientations in the area of ICT standardisation

Key issues

Europe needs a standardisation structure that fits the current liberalised market. In fact, over the last decade, **the marketplace has fundamentally changed** and changes seem to be lasting: the liberalisation of the market which has brought competition within and between sectors; the globalisation of markets with technology developments pursued in global strategic partnerships and coalitions and a reduced role from government. But perhaps most important is **the shift away from hardware to software**. The monolithic world of the past has been replaced by a heterogeneous technology development and standards environment and new complex relationships between networks and business models as well as contractual and strategic business relationships – often at **global level -** between all key players.

– **The specific challenges of ICT standardisation The current EU standardisation policy ,takes its origin from the Directive 98/34**, originally Directive 83/189 which implements the Internal Market objectives. In the area of ICT, Council Decision 87/95/EC has provided a complementary reference for ICT standardisation. The EU standardisation system is based on full openness, democracy, transparency and inclusiveness. Clear IPR rules are agreed as well as national implementation of EU agreed standards. The deliverables of the ESOs' formal consensus process are the traditional ENs.

The legal framework has been effective in supporting the New Approach areas. Its adequacy to today's market conditions, however, in the ICT sector is questionable[29].

The ICT market is in constant evolution, it is characterised by globalisation, telecommunication liberalisation, convergence between telecommunication and information technologies, and in the near future with media and broadcasting services. ICT technologies are pervasive; all industries are ICT users; subsequently the ICT standardisation community is in constant change. **There is no stable community in the way that exists in traditional domains such as construction, machinery or pharmaceuticals.**

– While **consortia/fora standardisation** is exceptional in the traditional sectors it becomes an **increasing practice in the ICT sector**; examples of such consortia standards are: Bluetooth, Internet, DVD, MHP, IEEE 802.11 and 802.16. All these standards have been developed outside the remit of the formal European and International Standards Organisations; often by the same industries that form the membership of the formal standards organisations. Some of these standards have been successful and reached broad market acceptance. Industry and business want standards and standardisation infrastructures to offer solution-driven standards

[29] The EU regulatory acts that affect ICT have internal market objectives; they are however not new Approach legislation. Moreover the policy objectives for the relevant EU legislative acts often services for which ICT solutions enact as enabler but ICT is not the prime objective of these acts: e.g. privacy, electronic signature, VAT. The EU ICT standardisation infrastructures should reflect these characteristics if the are to produce the timely and "solution driven" standards that industry/business wants. The current ESO structures, being characterized by its openness and stability, may be perceived to be ill responding.

available in time and in a flexible manner; the solution chosen by industry can range from the full formal standard, through the limited consensus for a standard, best practices, guidelines and ultimately the proprietary standard. **The choice will depend on the circumstances; it is for the market to decide.**

Industry should, however, not be driven outside the boundary of formal standardisation by weakness, real or perceived, of the formal standardisation structures.

– On the ICT market, the players in the new value chain have commercial incentives to achieve end-to end interoperability at the network/device interface while allowing for competitive differentiation of applications and services.

Standardisation is essential, but not sufficient to achieve network interconnection and interoperability of services at the international level. Moreover, standardisation in support of interoperability requires activities beyond traditional standardisation; such as interoperability testing, reference implementations and guidance. **Standardisation in support of interoperability has developed in two different patterns:**

Infrastructure standardisation: this sector is characterised by long term solutions and large investments conditioned by a priori consensus on the level of interoperability. The market is usually dominated by large players; until recently the incumbents. These requirements are resulting in open and formal standards produced by the ESOs; the infrastructure domain is conditioned by legal frameworks especially the communication framework directives.

Inversely, **the IT business is characterised by short term development, fragmented market with aggressive competitors**; interoperability can be met by various solutions such as gateways, API's etc. However the lack of interoperability between systems/applications and services will impede the collaboration between business, prevent emergence of new e-services and facilitate the dominance of proprietary solutions, thus undermining a long-term competitive market.

Efficiently and timely responding to these different patterns will require the ESO's to reflect the differences in their structures and processes.

– When bringing **innovative technology solutions or new services to the market** industry seeks prior standardisation amongst partners. The standardisation effort covers interoperability aspects, other technical issues but may also cover more commercial aspects. The standardisation effort should be flexible and be able to quickly evolve in response to market requirements. Therefore, industry often prefers to perform this type of standardisation in support of innovation within an industry consortium; it is less open but there exists a commitment to implement and a restricted IPR policy. **At a later stage, probably when the return on investment related to the innovation phase has been recovered, industry would agree to bring the fora standardisation into the public domain; the consensus reached within the fora can be broadened through formal standardisation bodies.**

– In the ICT domain, the link between R&D and standardisation is of particular importance; standardisation is in a position to leverage the consensus reached within an R&D project at the European and/or international level, thus the results of EU

research will subsequently be consolidated. Due to the complexity of the issue, the high technical expertise required in a particular domain, the fast technological evolution and the specialised user community, formal standardisation may however not be an option; more restricted groupings would certainly have an advantage. In addition, the formal standardisation process, especially ex-ante standardisation efforts, would benefit from targeted R&D initiatives to speed up the standardisation work. Projects such as COPRAS (standardisation liaison for the 6th framework programme) should be further promoted.

The increasing use of fora/consortia infrastructure by industry will be challenging for the ESOs in their actual structures and processes. This impacts **on the role of the public authority.** The Commission's interest in ICT standardisation can be described in following categories:

– Standardisation in support of regulation/legislation: internal market or not, and new approach legislation or different types of legislation. Whilst the Internal Market/New Approach situation is precisely defined (e.g. the current legal basis for standardisation provided by Directive 98/34) the situation is less evident for the case of ICT. As ultimately national public authorities will need to provide legal recognition for the standardisation deliverables in view of compliance with the legal frameworks, a reflection should be initiated on how standardisation can be used in support of these legal frameworks, taking into account the specificities of the ICT market. The possible role of consortia/fora standardisation: the possible co-operation or integration with the ESOs in this particular case should be evaluated against the need for openness, democracy, inclusiveness etc as required for standards aiming at this particular use.

– Standardisation in support of EU policies in the ICT area, not being embedded in legal frameworks: in this particular case, public authorities are interested in the provision of transparent, open and democratic platforms for consensus building which allow all relevant stakeholders to participate. The main aim is to achieve the objectives set by the policies with the support of standardisation while taking into account public interest aspects. Also for this particular use of standardisation deliverables, the co-operation with consortia and fora, the specific process and rules; an in depth reflection should be initiated.

– Standardisation in support the competitiveness of EU industry: should in principle be in accordance with the EU competition policy. Public authorities should not be involved in this domain. It is, however, important that open, neutral and accessible platforms are provided for reaching consensus.

Possible follow-up:

The changed environment for ICT standardisation should be reflected in a **reorientation of the EU standardisation policy and the role of the ESOs;** The formal ESOs can play a major part in a more integrated process provided following issues are taken care of:

– Provide international representation

– Have a flexible and more integrated approach that ensures timely development of standards, or additional standards-related documents, that are responsive to the

specific needs of industry and do not inhibit innovation. This could be achieved through increased fora hosting as proposed at the ETSI GA , or through a more elaborated co-operation with fora and consortia at the ICT-SB level

– A more efficient implementation of the convergence aspects, as the current rather historical work repartition between the ESOs is confusing for business and industry.

– Disseminate and promote the adoption of those standards that are needed by industry.

– Develop an integrated standardisation policy including better liaisons with R&D, collaborative initiatives, clarification of legal aspects, IPR policy, interoperability aspects and international dimensions as well as a better support towards implementation of standards notably via public procurement.

ANNEX 3
The eEurope Standardisation Action Plan (challenges and results)

The Commission has supported this standardisation initiative in the years 2000-2002 with an overall budget of 12,5 M€. For the years 2003-2005, further financial support will be provided.

As a result of the eEurope Standardisation Action Plan, some very good results have been achieved which have strengthened the role of European ICT standardisation as a platform for industrial consensus building. However, still more needs to be done to improving the visibility of standardisation in support of the eEurope initiative and to disseminate the results better. In this respect, the free availability of eEurope standardisation deliverables has proved to be a factor for success.

The results of the eEurope Standardisation Action Plan will be carefully analysed and evaluated by the Commission's services in order to prepare for a conceptual framework within which clear targets and performance indicators for funded standardisation work in support of the eEurope initiative will be set. This requires, however, a more intensive dialogue with Member States and the relevant stakeholders as well as enhanced efforts to promote the practical use standards in support of eEurope.

In the field of ICT standardisation, interoperability is the most important challenge to reach the target of the eEurope 2005 Action Plan of "interoperable e-business solutions for transactions, security, signatures, procurement and payment". As described in the Communication on "Adapting e-business policies in a changing environment", it is primarily the responsibility of the private sector to implement this ambitious task. However, European, national and regional authorities can play an important role in bringing together the different economic players and promoting e-business interoperability through large scale test-beds. In order to avoid further fragmentation and to facilitate cross-border electronic transactions, the many standardisation initiatives in this field need, however, to be much better co-ordinated at European level than is currently the case.

ANNEX 4

The financial support to European standardisation in figures

Summary of commitments made in 1998 - 2004

The overall allocation of commitments 1998 - 2004 (in million euros)

(The financial support was provided from the budget line B5-3130B between 1998 and 2003 and from B5-3140B between 1998 and 2000. Other support given from other budget lines has not been included. In 2004 the standardisation budget line is called 02 04 03.)

Year	Amount committed
1998	20,9
1999	19,9
2000	16,7
2001	16,1
2002	16,0
2003	14,8
2004 (estimated)	18,7

The repartition of financial support in different fields, commitments made in 2000 - 2004 (in million euros)

Year	Annual performance contracts	Consultants	Translations	Standardi-sation work: eSAP	Standardi-sation work: other	External visibility	Other	**Total**
2000	4,96	2,01	1,54	5,07	3,03	0,04	0,06	**16,71**
2001	5,80	1,47	1,81	4,25	2,55	0,00	0,26	**16,13**
2002	6,32	2,11	1,72	2,79	2,96	0,04	0,00	**15,95**
2003	7,83	1,73	1,05	2,26	1,53	0,31	0,10	**14,80**
2004 (budget)	6,37	2,00	2,68	3,00	2,99	1,12	0,55	**18,70**
Total	**31,29**	**9,32**	**8,80**	**17,37**	**13,05**	**1,51**	**0,96**	**82,29**
2000	29,7%	12,1%	9,2%	30,4%	18,1%	0,2%	0,4%	**100%**
2001	36,0%	9,1%	11,2%	26,3%	15,8%	0,0%	1,6%	**100%**
2002	39,6%	13,2%	10,8%	17,5%	18,6%	0,3%	0,0%	**100%**
2003	52,9%	11,7%	7,1%	15,2%	10,3%	2,1%	0,7%	**100%**
2004	34,1%	10,7%	14,3%	16,0%	16,0%	6,0%	2,9%	**100%**

(budget)								