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COMMISSION STAFF WORKING PAPER

IMPACT ASSESSMENT

Accompanying document to the

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on European Standardisation and amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/105/EC and 2009/23/EC

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Disclaimer:

This report only commits the Commission's services involved in its preparation and does not prejudge the final form of any decision to be taken by the Commission.

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1. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

1.1. Identification

Lead DG: Enterprise and Industry – WP reference: 2010/ENTR/021.

1.2. Organisation and timing

The Impact Assessment Steering Group was set up on 17 December 2009 and met 5 times between 7 January and 13 December 2010. It was chaired by DG ENTR and staff from Directorates-General ENTR, INFSO, COMP, SANCO, MARKT, DIGIT, RTD and SG participated and contributed to the discussions of the Group.

1.3. Consultation of the IAB

The Impact Assessment Board delivered its opinion on 11 February 2011. It recommended a number of clarifications with respect to the scope of the options and recommended to demonstrate better the existence of the identified problems. The opinion requested greater clarity on option 3B addressing the problem of fora and consortia standards. The Board also asked to better assess the impacts of all the policy options, including by examining possible synergies and trade-offs between the three options. Finally, the different positions of the stakeholders should be better reflected in the main text of the IA report.

The clarifications with respect to the scope of the options were added to problems 1 and 2, and the existence of the identified problems was elaborated in greater detail, inter alia through the addition of a few examples and a new Annex 5 which outlines the discarded options. A more detailed governance structure was added to the assessment of option 3B (fora and consortia standards). The impacts of all the policy options was reorganised and possible synergies and trade-offs between the three options were added in the assessment and the comparison sections. The different positions of the stakeholders are now reflected in the assessment of the options and Annex 1, which sets out the results of the consultation process, was complemented by more precise information on the outcome of the consultation.

1.4. Consultation and expertise

This impact assessment builds on the external expertise[1] and a very broad consultation of stakeholders, a detailed overview of which can be found in Annex 1. The Commission's minimum standards have all been met.

[1] The most important reports used for the purposes of this impact assessment are outlined in Annex 1 and can be consulted on http://ec.europa.eu/enterprise/policies/european-standards/standardisation-policy/policy-review/index_en.htm. The other external expertise is mentioned in the footnotes of this document.

2. POLICY CONTEXT AND KEY CONCEPTS

2.1. Policy context

In its EUROPE 2020 strategy for smart, sustainable and inclusive growth[2], the Commission highlights the **necessity to improve the method of standard setting and the use of standards in Europe** to leverage European and international standards for the long-term competitiveness of European industry and for the achievement of important policy goals in areas such as e-government, e-health or e-accessibility. This initiative implements the Europe 2020 Flagship Initiatives on the Innovation Union[3], Industrial Policy[4], a Digital Agenda for Europe[5], a Resource Efficient Europe[6] and the Single Market Act[7], as well as the Disability Strategy 2010-2020[8]. It is part of a CWP 2011 Strategic initiative.

On 21 October 2010, the **European Parliament adopted a report on the future of European standardisation**[9] according to which the review of European standardisation should preserve its many successful elements, remedy its deficiencies and strike the right balance between the European, national and international dimensions. Furthermore, it recognises that interoperability is a key to innovation and competitiveness, especially in the ICT sector.

2.2. Standardisation: key concepts

Standardisation within the EU relies on **voluntary cooperation** amongst businesses, users, public authorities and other interested parties (consumers, NGOs and other stakeholders). In Europe, this voluntary cooperation is **managed by independent organisations which are subject to WTO-criteria**[10] and ideally leads to agreement between the participants on the adoption of a standard. Standardisation agreements have as their primary objective the definition of technical or quality requirements with which current or future products, production processes, services or methods may comply[11]. Certain parts of the economy have their own standards, e.g. accounting and transport services[12], which fall outside the scope of this impact

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2 COM(2010)2020.
3 COM(2010)546.
4 COM(2010)614.
5 COM(2010)245.
6 COM(2011)21.
7 COM(2011)206.
8 COM(2010)636.
9 A7-0276/2010.
10 See Annex 3.
11 See point 257 of the Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements [C(2010) 9274/2], OJ C ….
12 For example, the International Accounting Standards (IAS) and International Financial Reporting Standards (IFRS) and related interpretations (SIC/IFRIC) issued by the International Financial Reporting Interpretations Committee have a worldwide impact. Standards are issued by an international private organisation called the International Accounting Standards Board (IASB) and must go through due process of endorsement before becoming part of EU law in accordance with Regulation (EC) No 1606/2002 of the European Parliament and of the Council on the application of international accounting standards. In the transport sector, the Convention on International Civil Aviation, signed in Chicago on 7 December 1944 (the Chicago Convention), to which all Member States are parties, provides for minimum standards to ensure the safety of civil aviation and environmental protection relating thereto.

assessment. **Standards are not regulations**. Standards are voluntary[13] while regulations are obligatory and have the force of law.

This document only concerns the European standardisation system in which the three European standardisation organisations CEN, CENELEC and ETSI play a key role, and the standards for interoperability in the field of ICT. The definitions used for the purpose of this impact assessment are also set out in Annex 3.

2.3. The relevance of standards and European standardisation as policy tools

Standards and standardisation are very effective policy tools for the EU. Although standards and standardisation have much wider benefits for the European economy[14], they are used as policy instruments to ensure, inter alia, the functioning of the single market, the interoperability of networks and systems, in particular in the field of ICT, a high level of consumer and environmental protection, and more innovation and social inclusion.

Standards are indispensable in the digital society to ensure the interoperability of networks and systems, especially in the field of ICT. In a digitally driven society, ICT solutions are used in any economic sector as well as in our daily lives. ICT solutions, applications and services have to be able to communicate with each other; they should be interoperable. **Interoperability requires standards**.

European standards play a **very important part in the functioning of the internal market for industrial products.** European standards replace national and often conflicting standards which, as such, may create technical impediments to a national market. European standards can, for the purpose of this impact assessment, be divided into 2 categories:

- European standards developed at the request of the Commission, on the basis of a so-called "mandate" in which the ESOs are requested to draw up technical specifications of a normative nature that meet the requirements set out in the mandate. These standards can be subdivided into 2 subcategories:
  - Harmonised standards which ensure that products meet the essential requirements set out in EU legislation. Compliance with a European "harmonised" standard guarantees the required level of safety of products. However, use of harmonised standards is still voluntary and a manufacturer may use any other technical solution which demonstrates that his product meets the essential requirements. The percentage of European standards that are harmonised standards has increased in the last two decades from 3.55% to 20% in 2009. This shows the increasing

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Technical standards developed by specialised organisations constitute the backbone of the railway and maritime sector.

[13] The TBT Agreement defines a standard as a document "approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method." A more detailed overview can be found in Annex 5.

[14] See Annex 2.

importance of standards as an instrument to accompany EU legislation[15].

– Other European standards to support European policies;

- The remaining European standards are adopted outside EU legislation on the initiative of undertakings, NSBs or other stakeholders, or at the request of the Commission.

The percentage of the European standards portfolio mandated by the Commission has increased in the last two decades from 18% in 1999 to 34% in 2009. Despite this increase, **the large majority of European standards remains industry–initiated**, indicating that these instruments mainly respond to the needs of the industry and are mainly privately driven.

Even if EU legislation did not refer to European standards, **the mere existence of standards is trade-enhancing** because of their cost-decreasing effect and the reduction of information asymmetries between the supply and the demand sides, especially in the case of cross-border transactions. Several econometric studies have established a **clear connection at a macroeconomic level between standardisation in the economy, productivity growth, trade and overall economic growth**. The economic benefit of standardisation can vary significantly between different EU countries. Studies show that the impact of standards on annual GDP growth could rage from 0.3 to 1 percentage point[16]. For Germany this impact is estimated at 1% of the gross national product, for France at 0.8% and for United Kingdom only at 0.3%. There are no studies on aggregated impact on the EU level.

The effectiveness of standards and standardisation as policy tools for the EU implies that **European policymakers have a strong interest in an effective and efficient standardisation system** which provides a flexible and transparent platform for consensus building between all participants and which is financially viable. Therefore, a **specific legislative framework governing European standardisation** has been developed over the years and currently consists of the following pieces of legislation:

(1) Directive 98/34/EC[17] sets up the cooperation between the three ESOs (CEN, CENELEC and ETSI), the NSBs and the Commission. It contains, inter alia, a procedure in the field of standards designed to monitor the new standardisation activities introduced by the NSBs. Systems have been set up mainly to allow other bodies to comment, participate in the work or request that an initiative be taken at European level.

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15 Detailed figures can be found in Annex 3 while Annex 4 contains an overview of EU legislation using European standards as a means to presume conformity with the essential requirements.

16 Swann G.M.P., "The Economics of Standardization: An Update', Report for the UK Department of Business, Innovation and Skills (BIS), 2010.

17 Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998, laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204 of 21.07.1998), as amended by Directive 98/48/EC (OJ L 217 of 05.08.1998).

(2) Decision No 1673/2006/EC[18] establishes the rules concerning EU contribution to the financing of European standardisation to support the implementation of specific policies, measures, actions and EU legislation. It specifies the bodies and the standardisation activities eligible for EU financing, as well as the financing arrangements.

(3) In the case of IT equipment, and in support of interoperability, specific provisions are included in Council Decision 87/95/EEC[19] requiring Member States to ensure that in public procurement orders reference is made to European or international standards.

2.4. The cost of European standardisation[20]

The **cost of the creation of standards within the ESOs** was approximately 3,000 million euro in 2009. The approximate cost of creating one standard is estimated at approximately €1,000,000. This includes the costs of experts, the organisation of meetings, travel etc.

The ESOs point out that this cost is **financed primarily by industry** (93-95%) followed by national governments (around 3-5%) and the European Commission/EFTA contribution (around 2%).The fact that industry bears most of the cost of the system, together with the voluntary character of standards, reflects its high interest in standards and implies that the benefits outweigh the cost. Therefore, for society as a whole, the cost of creating standards is minimal compared to the benefit for the economy, even erring on the side of caution regarding the data.

3. PROBLEM DEFINITION AND SUBSIDIARITY

3.1. Problems with respect to standardisation at European level

The use of standards and European standardisation as policy tools is a success story. Their contribution to the achievement of the internal market and as instruments for interoperability is tremendous. However, public consultations and the report of the European Parliament indicated that certain problems need to be addressed.

3.1.1. Problem 1: the process for adopting European standards requested by the Commission is not fast enough

In a rapidly changing world and society, especially in sectors characterized by very short product lives and development cycles, standards must keep pace with rapid technological development. **Some stakeholders argue that the entire process of creating European standards is too slow[21]**, although complaints about slowness of

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18 Decision No 1673/2006/EC of the European Parliament and of the Council of 24 October 2006 on the financing of European standardisation, OJ L315, 15.11.2006.

19 Council Decision 87/95/EEC of 22 December 1986 on standardisation in the field of information technology and telecommunications, OJ L36, 7.2.1987

20 See Annex 3 for more details.

21 See the report of the European Parliament on the Future of European Standardisation [A7-0276/2010].

standardisation may be less relevant for technologies with long lead times for development and redeployment[22].

At the moment, the **development time** of CEN and CENELEC deliverables is between 36 and 21.5 months, depending on the type of procedure[23], with a complementary tolerance of 9 months for all these deliverables. Production of a CEN Workshop Agreement or a Technical Specification typically takes only 12 – 24 months and can take as little as 5-6 months. As regards ETSI, the typical time frame is 24 to 36 months. Although the duration of the process could still shorten slightly within CEN/CENELEC so that they would be similar to those of ETSI, at a certain point it becomes difficult to make further progress without jeopardising some fundamental principles of the standard-setting process, especially the principle of consensus. However, these periods do not take into account the time between the identification of the need for a non-mandated standard by interested parties and the date when the ESOs actually start working on the standard. It should be underlined that the Commission has little or no influence on the time needed for developing a European standard which was not mandated by it.

Therefore, this impact assessment will only focus on the speed of the development of the **European standards mandated by the Commission**, of which the entire development process can be much longer than the periods set out above. It took more than 10 years, for example, to adopt a common test procedure for cement, and about 15 years for the harmonised product standard and the standard on conformity evaluation of cement.

For the European standards mandated by the Commission, there are four main stages in the development process:

(1) The first stage, the preparation of the mandate and the positive opinion of the committee set up under Directive 98/34/EC, usually takes between 6 to 12 months. In addition, planning requests for European standards and EU policy objectives are not always communicated sufficiently clearly to the ESOs. Until now, this has been done in a variety of ways and at a variety of different levels, for example through the mandates and different work programmes addressed to the ESOs[24].

(2) The second stage, the acceptance of the mandate by the ESO and the start of work on the standard, is fairly variable. Under open mandates[25], work on a

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22 Sherif M.H., « When is Standardization slow ? », in The International Journal of IT Standards and Standardisation Research, 2003, vol. 1., issue 1, pp. 19-32.

23 36 months for EN's developed in accordance with the normal enquiry procedure and Formal Vote track, 23.5 months for EN's developed in accordance with the shorter "Unique Acceptance Procedure" and 21.5 months for Technical Specifications and Technical Reports.

24 The Commission developed a rolling "Action Plan for European standardisation" in conjunction with European Free Trade Association (EFTA), the ESOs, the NSBs and the Member States: http://ec.europa.eu/enterprise/policies/european-standards/standardisation-policy/implementation-action-plan/index_en.htm. This action plan is complemented by an "ICT Standardisation Work Programme: http://ec.europa.eu/enterprise/sectors/ict/standards/work-programme/index_en.htm.

25 Open mandates mean that the ESOs may, during standardisation work, add or modify to a certain extent the subjects referred to in the programme submitted, after having informed the Commission services and, in the event of a major amendment, the Standing Committee.

new standard can start immediately or, in some cases, a few years after acceptance of the mandate. The number of mandates issued and average response times vary between ETSI and CEN/CLC and so have been shown separately in the two tables below. ETSI reported a total of 17 mandates issued over the past three years (with between 0 and 9 per year). In the two years where mandates were issued, the average time for ETSI Board acceptance was 3 months (average times are for ETSI board acceptance). CEN/CLC reported a total of 64 mandates issued over the past three years, with average response times each year varying between 10.4 and 13.6 months.

ETSI	**Mandates issued**	**Average response time (months)**
2007	8	3
2008	0	n/a
2009	9	3
CEN/CLC	Mandates issued	Average response time (months)
2007	22	10.4
2008	21	13.6
2009	21	12.3

The current procedures employed for consulting on and responding to EC mandates and the average timeframes taken to implement each step are shown in the tables below.

Procedures - ETSI	**Average time (wks)**	**Notes**
1. Comments on draft mandate via membership	5	Varies between 4 and 6 weeks
2. 98/34 adopted mandate for ETSI Board approval	6	Maximum
3. Response to EC	3	Varies between 2 and 4 weeks depending on the need for further consultation
4. Phase 1: work programme	30	Varies between 24 and 36 weeks (minimum) depending on size and complexity of tasks or need for financial support and coordination with other ESOs/SDOs
5. Phase 2: Development of standards	Variable	Very variable, depending on complexity and contractual issues (EC grant agreement when required). EN development requires at least 1.5 years where the mandate task is relatively clear and there are no interdependencies with

		work from elsewhere

Procedures – CEN/CLC	**Average time (wks)**	**Notes**
1. Analysis of the mandate in CCMC, consultation of the competent technical body (if any) and/or important stakeholders, elaboration of a proposal for Technical Board (BT) decision	5.9	Average timeframe for 2009, excluding two exceptional cases (which would take the average timeframe to 9.7 weeks)
2. Formal decision process by correspondence in BT	6	

(3) The third stage is the development of the standard itself as described above. For this stage, the average period in years between the date of acceptance of the work and the date of publication of the standard was as follows:

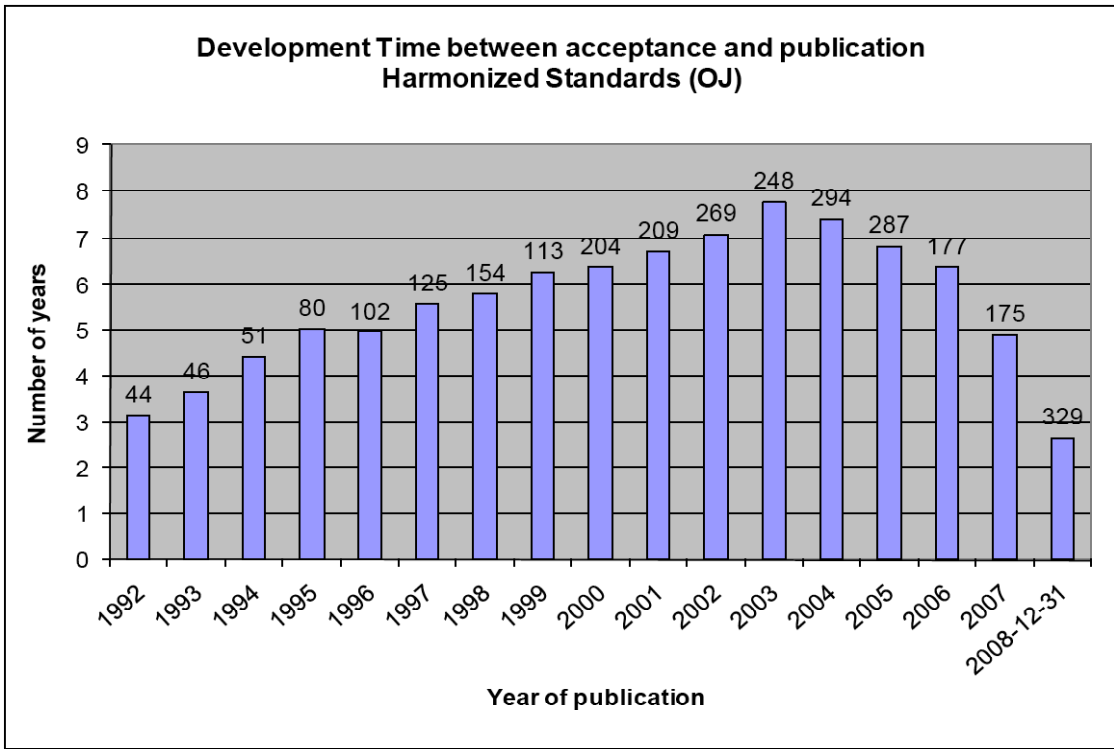
Average duration (in years) for drafting mandated standards			
Publication year	CEN	CENELEC	ETSI
2005	6.20	3.45	1.08
2006	5.46	3.23	1.55
2007	4.37	2.85	1.83
2008	2.92	3.84	1.87
2009	2.42	2.34	1.79

Two factors determine the length of this stage. On one hand, the above-mentioned principle of consensus constitutes a crucial factor. Broad involvement of the large number of interested parties increases the risk of deadlock and stalemate: while one participant rejects all or part of a proposed standard, it cannot be ratified. Participants may not manage to agree, given the range of vested interests, or some may wish to delay (or even prevent) the appearance of a standard long enough to prepare for it. The standard-setting approach aims at bringing together the different participants gradually. On the other hand, the availability of technical experts could in some cases be used as a deliberate strategy to block or delay technical work in a committee.

Relatively long timescales are therefore inherent in this stage of the standardisation process[26].

(4) The duration of the fourth stage, namely the publication of the reference of the harmonised standard in the OJ and the objection procedure, varies very widely. It depends primarily on the diversity of procedures. None of the directives specifies when publication should take place and there are important differences between objection procedures[27]. Thus, the entire process for mandated standards can easily take 3 years and often much longer.

The internal processes within CEN were revised, especially as regards the time taken to develop European standards. Historically much of the standardisation work carried out under New Approach Directives took many years to complete, with some individual standards taking as long as a decade to reach the market. Through various communications and ongoing dialogue with the ESOs, the Commission sought to encourage revisions to processes that might shorten these development times. CEN implemented a range of changes to its processes to enable such improvement, with a very clear and marked effect, as demonstrated in the box below. This illustrates, for example, that the 248 harmonised standards published by CEN in 2003 took an average of almost eight years to produce (from acceptance of the work item to publication of the standard in the Official Journal) while the 329 harmonised standards published to 31 December 2008 took an average of less than three years.



[26] Borraz O., « Governing Standards : The Rise of Standardization Processes in France and in the EU », in Governance : An International Journal of Policy, Administration, and Institutions, Vol. 20, No. 1, January 2007, pp. 57-84.

[27] A detailed overview can be found in Annex 4.

ETSI and CENELEC also improved the efficiency of their core activities and operations in order to shorten procedures. Within ETSI, for example, new IT applications were developed and staffing levels around key Technical Body support roles were increased. Many of the functions of the Central Secretariat of CENELEC are directed specifically towards areas of work requested by the Commission or otherwise required by the Commission as a result of its administrative requirements (e.g. handling mandates for standardisation work, establishing contracts and preparing financial quotations, managing the New Approach consultants, etc).

A comparative analysis of the more informal processes adopted in the ICT-sector by global fora and consortia such as OASIS, OMG, W3C, ETSI, and ISO/IEC/JTC1 reveals that, if these bodies seek consensus, the speed of their processes (from the start of work on a new item until completion) does not differ much (typically between 12 and 24 months, but in extreme cases as little as 6 months) and formal and informal procedures tend to converge over time, as the latter increasingly get market recognition and legitimacy[28]. The success of the informal standardisation processes in the field of ICT owes much not only to its speed, but also to the search for extreme simplicity, with a strong preference for solutions taken from concrete industry practice, in order to ensure high levels of interoperability. The main difference between ESOs and informal standardisation bodies in the ICT-sector is that the latter do not require a formal national ratification procedure and that draft specifications or standards are usually made available for comment over the internet at an early draft stage. However, formal voting remains restricted to Members.

The **main negative consequence** of a slow standard-setting process for all European standards is that conflicting national standards continue to exist, which may create technical barriers in the supply chain or barriers to trade if the national standard is used as a protectionist instrument. Another consequence is that, in the specific case of harmonised standards, businesses cannot use the relevant standard to confer a presumption of conformity and must demonstrate compliance with the essential requirements in accordance with the conformity assessment module set out in the applicable EU legislation. In both cases, businesses are prevented from saving costs incurred due to fragmentation of the internal market or conformity assessment procedures. Conflicting national standards or the absence of harmonised standards lead to higher transaction costs and higher per-unit costs caused by the need to produce divergent batches. Industry reacts to this situation by establishing informal standardisation channels for the rapid development of technical specifications to ensure interoperability which gain an international reach. In addition, the absence of a European standard could lead to safety risks. The development of a safety standard for portable ladders, for example, took an extremely long period of some 10 years. According to estimates (IDB database, 2009) within the EU the yearly accidents related to ladders amount to 413,000 and 25% of the recorded accidents involved elderly people.

[28] Simcoe T., "Delay and de jure standardization: exploring the slowdown in Internet standards development" in Greenstein S. and Stango V., Standards and Public Policy, Cambridge, 2007. See also Annex 7 for a comparative table.

3.1.2. Problem 2: Underrepresentation of SMEs and societal stakeholders in the European standardisation process

Several studies showed that SMEs encounter a series of problems with respect to standards and standardisation[29]. During the public consultation, 69% of respondents declared that the participation of SMEs in European standardisation should be reinforced. One of the most important problems, according to many stakeholders, is that **SMEs are in general under-represented in standardisation activities**, in particular at European level.

Indeed, standard-setting is a labour-intensive and time-consuming activity and, for the most part, only large businesses and government agencies specialising in standards issues can afford to allow one individual to spend a significant amount of his/her time attending standard-setting meetings. For smaller businesses, where job descriptions are broader, the fixed cost of participation may simply be too high. According to a study prepared at the request of the Commission[30], the four **most important barriers to access by SMEs to the standardisation process** are: (a) the amount of time required; (b) the travel and subsistence costs; (c) the cost of participating in technical committees (fee) and (d) the cost of becoming a member of a standardisation body (fee). The amount of time is considered to be the greatest barrier.

While SMEs are generally quite well represented in the technical committees of the NSBs, it is rare for SMEs and their representatives to form part of the delegations that participate directly in the Technical Committees and Working Groups of the ESOs. In theory, participation in the standardisation activities of CEN and CENELEC is open to all interested stakeholders via the NSBs but meetings at European level involve a considerable burden in terms of time and travel costs for SMEs[31].

Standards have a **broad impact on society**. Often they relate to the safety and well-being of citizens, the efficiency of networks, the environment and other public policy fields. Many standards increase safety for consumers while others have a direct environmental impact. Minimum safety standards are used to solve imperfect information problems. By conveying information about the negative effects of products, they allow customers to avoid products that might harm them, the public, or the environment, and they allow regulators to exclude unsafe products from the market. These standards allow buyers to confirm that products and processes have the characteristics they want without the additional transaction costs of independent testing. Standards are gradually playing a new role in society. Standardisation is evolving from a technical discussion on facilitating exchanges and adding value to the organizations, to the provision of a normative framework for economic operators in environmental, social or economic issues.

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29 For further details, see Annex 6.

30 http://ec.europa.eu/enterprise/policies/european-standards/files/standards_policy/access_to_standardisation/doc/access_to_standardisation_study_eim_en.pdf.

31 http://ec.europa.eu/enterprise/policies/sme/market-access/standardisation/index_en.htm#h2-5.

Although standards play a major role in society, the **opinion of relevant societal stakeholders is not sufficiently integrated in the standardisation process**[32] in the EU. Many perceive standards as a technical matter of relevance to the internal workings of a product or service, but which do not concern them directly. Because of this asymmetric information, these societal stakeholders often underestimate the importance of standards to their interests and that leads some to avoid involvement in the process.

In order to address the problem of insufficient representation of SMEs and societal stakeholders in standardisation activities, **financial contributions** are paid, inter alia, under the following programmes:

– The Entrepreneurship and Innovation programme[33] supports SME involvement in the field of European standardisation. EU financial support for the representation of SMEs in standardisation at European level increased from an annual amount of €700,000 to €1 million in 2008 and €2.1 million from 2009. This money is used to promote SMEs' participation and defence of their interests in standardisation and to improve their information about, and use of, European standards. According to an external evaluation, the Commission's intervention scheme for the period 2002 to 2008 directly addressed this need by providing the resources and mechanisms for direct participation of SME representatives in the technical bodies of the ESOs[34].

– The programme of Community action in the field of consumer policy[35] includes financial contributions to European consumer organisations representing consumer interests in the development of standards for products and services at EU level. In 2009, the grant amounted to about €1,460,000 and to €1,386,000 in 2010. The programme covers the period from 31 December 2006 to 31 December 2013.

– Grants are paid under the LIFE+-Programme[36] to strengthen the participation of NGOs in the European standardisation process in order to ensure balanced stakeholder representation and the systematic integration of environmental aspects. In 2009, the grant amounted to approximately €185,000.

– The participation of trade unions in the development of technical standards is also partly financed by the EU budget since many standards have an impact on the health and safety of workers, for example through the design of work equipment.

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32 See also the report of the European Parliament on the Future of European Standardisation [A7-0276/2010].

33 Decision No 1639/2006/EC of the European Parliament and of the Council of 24 October 2006 establishing a Competitiveness and Innovation Framework Programme (2007 to 2013), OJ L310, 9.11.2006.

34 http://ec.europa.eu/enterprise/policies/sme/files/craft/craft-priorities/doc_stand/evaluation_mainreport_en.pdf.

35 Decision No 1926/2006/EC of the European Parliament and of the Council of 18 December 2006 establishing a programme of Community action in the field of consumer policy (2007-2013), OJ L404, 30.12.2006.

36 Regulation (EC) No 614/2007 of the European Parliament and of the Council of 23 May 2007 concerning the Financial Instrument for the Environment (LIFE+), OJ L149, 9.6.2007.

The **criteria for eligibility for these grants, the conditions for their use and the type of financial contributions available vary widely**. Some organisations receive grants for actions while others also receive operating grants. The principle of gradual decrease for operating grants which are not flat-rate grants pursuant to Article 113 of the Financial Regulation, applies to some but not all beneficiaries.

Organisations representing SMEs and societal stakeholders at European level can, under certain conditions, become associate members of CEN which allows them to participate, without voting rights, in the General Assembly, open sessions of the Administrative Board, Technical Board, Sector Activities and the CEN Certification Board. As a member of the Technical Board, an Associate Member can also apply for and hold the secretariat of Technical Committees and participate in Technical Committees (TCs) and Subcommittees, upon request, as an observer. Associate Members can also receive documentation for all meetings for which requests for participation have been granted. A similar system exists in CENELEC. However, the absence of voting rights in CEN and CENELEC prevents organisations representing SMEs and societal stakeholders having a more decisive influence on technical work. The role of observer diminishes the influence of the participant in the technical discussion on a standard and in the final decisions that will be taken about the standard. The lack of voting rights means that these organisations are not as influential as they should be and can only carry arguments if they have strong evidence to back up their claims.

Although the national delegation principle within the ESOs contains a number of checks and balances designed to produce standards without anti-competitive effects, the **most negative consequence** of the problem of insufficient participation of SMEs and societal stakeholders is that participants in standardisation may influence the results of the process, get the know-how and technical understanding relating to these results and implement the standard before it is publicly available.[37] As a result, the participating undertakings will most likely have a head start and therefore a significant competitive advantage in the relevant downstream markets[38]. In an industry where lead time is a crucial factor, active participation in standardisation thus confers an appreciable competitive advantage vis-à-vis non-participating competitors. If participation in the standard-setting process is not open in the sense that it does not allow all competitors (and/or stakeholders) in the market affected by the standard to take part in choosing and elaborating the standard, the risks of a likely restrictive effect on competition will exist by excluding certain companies from the ability to influence the choice and elaboration of the standard. The greater the likely market impact of the standard and the wider its potential fields of application, the

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37 In the Commission decision No 87/69/EEC in Case IV/31.458, *X/Open Group*, OJ L35, 6.2.1987, p. 36-43, the Commission considered that even if the standards adopted were made public, the restricted membership policy had the effect of preventing non-members from influencing the results of the work of the group and from getting the know-how and technical understanding relating to the standards which the members were likely to acquire. In addition, non-members could not, in contrast to the members, implement the standard before it was adopted (see paragraph 32). The agreement was therefore in these circumstances seen to constitute a restriction under Article 101(1).

38 Koenig C. and Trias A., "Some standards for standardisation: a basis for harmonisation and efficiency maximisation of EU and US antitrust control of the standard-setting process", European Intellectual Property Review, 2010, v. 32, n. 7, pp. 320-331.

more important it is to allow equal access to the standard-setting process[39]. These negative consequences hit SMEs especially when a harmonised standard would not take into account the needs of manufacturing SMEs[40]. In that case, the competitiveness of the SME would be affected since it would either have to alter its production processes, or use the conformity assessment module laid down in the relevant directive which often entails the intervention of a conformity assessment body.

3.1.3. Problem 3: "Fora and Consortia Standards" cannot currently be referenced in public procurement of ICT.

In the field of ICT, many standards ensuring interoperability were not developed by the ESOs but by global fora and consortia. This applies particularly in the case of **Internet and World Wide Web related standards**. A few, such as MPEG, issued by DVB, are subsequently published by formal standardisation organisations such as ISO standards[41]. Since the 1980s, **global fora and consortia**, such as IETF, W3C and OASIS have emerged as world-leading ICT standards development organisations primarily covering the Internet and Web domains[42]. Mostly due to a lack of highly specialized expertise, the traditional standard-setting organisations do not cover the ICT domain and so a major part of global ICT standardisation work is currently done outside the formal European or international standardisation system.

The number of "Fora and Consortia Standards" used today on a global scale is impressive. They are used for browsing the World Wide Web for business or social purposes, sending e-mails or engaging in any form of electronic collaboration. For wireless communication, the IEEE 802.11 standard on WiFi is used; the identification of internet resources is based on URI (Unified Resource Identifier) set by IETF; the transport layer of internet communication, TCP/IP is defined by IETF; HTML and XML are set by W3C; audio and video signals are compressed following the MPEG standards published by DVB and ISO; the Web Accessibility guidelines for disabilities are set by W3C and OASIS has the expertise in technical standards for web services[43].

Referencing of standards in public procurement can be an important means of fostering innovation while providing public authorities with the tools needed to fulfil their tasks, especially in lead markets[44] such as e-health. Public procurement of a

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39 See the Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements, OJ C11 of 14.1.2011, p. 1.

40 See, for example, the judgment of 12 May 2010 in Case T-432/05, *EMC Development AB* v. *Commission*, not yet reported, where the applicant basically argued that this had been the case. The applicant submitted that European standard EN197-1 "was designed, thanks to the close cooperation between Cembureau and CEN/TC 51, to favour existing major cement producers in the market" (point 68 of the judgement).

41 Van Eecke P., Truyens M., "Standardization in the European Information and Technology Sector: Official Procedures on the Verge of Being Overhauled", 5 Shidler J. L. Com. & Tech. 11 (2009), available at http://www.lctjournal.washington.edu/vol5/a11VanEecke.html.

42 For a detailed description, see Annex 7.

43 Jakobs K., « ICT Standardisation – Co-ordinating the Diversity » in: Innovations in NGN: Future Network and Services, 2008. K-INGN 2008. First ITU-T Kaleidoscope Academic Conference, Geneva, 2008.

44 Communication: A lead market initiative for Europe - COM(2007) 860.

certain value has to comply with Directive 2004/18/EC[45] which differentiates between formal standards and other technical specifications for which a description of functional requirements is additionally requested. At the moment, **referring to "Fora and Consortia Standards" in public procurement which is subject to Directive 2004/18/CE is only possible in exceptional circumstances**[46]. Since "Fora and Consortia Standards" do not, as such, fit into any of the categories of standards to which public authorities may refer in their calls for tenders, cautious public authorities will refrain from referring to these standards. The consequence is that the ITC that they are procuring may not be interoperable with ITC purchased by other authorities. This difficulty often prevents public authorities from defining their ICT strategies and architectures, including cross-border interoperability between organisations[47].

Although the public sector is by far the largest procurer of ICT services and applications, especially software[48] **Fora and Consortia Standards have not found their way into the available European ICT standardisation "catalogue**" produced by the ESOs. For instance Internet or Web technologies cannot be referenced since those technologies and the related applications and services are not covered by European standards. In fact, the "business models" of CEN and CENELEC either envisage revenues from sales of standards or the full reimbursement of standard development costs. Both models are hardly compatible with the practices of some major fora and consortia which typically envisage free distribution of standards

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45 Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts, OJ L134, 30/04/2004, p. 114 – 240.

46 Article 23(3)(a) of Directive 2004/18/EC specifies that technical specifications in public procurement to which the Directive applies, must be formulated either by reference to technical specifications defined in Annex VI and, in order of preference, to national standards transposing European standards, European technical approvals, common technical specifications, international standards, other technical reference systems established by the European standardisation bodies or - when these do not exist - to national standards, national technical approvals or national technical specifications relating to the design, calculation and execution of the works and use of the products. Each reference shall be accompanied by the words "or equivalent"". According to Annex VI a "standard" means a technical specification approved by a recognised standardising body for repeated or continuous application, compliance with which is not compulsory and which is an international, a European or a national standard. A "European technical approval" means a favourable technical assessment of the fitness for use of a product for a particular purpose, based on the fulfilment of the essential requirements for building works, by means of the inherent characteristics of the product and the defined conditions of application and use. European technical approvals are issued by an approval body designated for this purpose by the Member State. A "Common technical specification" means a technical specification laid down in accordance with a procedure recognised by the Member States which has been published in the Official Journal of the European Union while a "technical reference" means any product produced by European standardisation bodies, other than official standards, according to procedures adopted for the development of market needs.

47 Commission White Paper "Modernising ICT Standardisation in the EU - The Way Forward", COM(2009)324.

48 With market revenues of over €200 billion in Europe and growth rates of between 6% and 8%, software is the largest and the fastest-growing segment of the information and communication technologies (ICT) market The European software industry is a significant contributor to the European economy and a key driver of innovation and change. Spending on software and related services is worth around €258 billion to the European economy, or around 2.6% of GDP4. The software industry creates tax revenues, is a major source of high-value jobs, and has downstream multiplier effects throughout the economy (Source: report of an Industry Expert Group to DG INFSO "Towards a European Software Strategy" March 2009)

online and cover costs through relatively high membership fees. In addition, ESOs may be unwilling to endorse or rubberstamp standards developed by third parties and be responsible for their maintenance while global fora and consortia may not see any added value in transposing their deliverables, already broadly implemented at global level, into a formal regional standard.

This situation has a range of negative impacts. During the public consultation, 77% of respondents recognised this as a problem[49]. Indeed, European public authorities are not in a position to refer to and thus exploit the potential of innovative ICT technologies which slows down the implementation of public goals in areas such as e-health, e-accessibility, e-government. Moreover, the European Digital single market cannot be realised as Member States will select their own solutions (which may not be interoperable with other Member States) and thus block the digital market for instance for content related matters. In the field of eHealth services, for example, a study carried out for the Commission by Empirica GmbH in 2008 on "ICT standards in the health sector: current situation and prospects" painted a bleak picture, finding a lack of well-developed e-health standards for particular applications and concrete use cases, and conflicting standards, versions and implementations, i.e. a lack of standards that are widely used, implying that standards often conflict and interoperability problems often occur. Many of the conflicting standards are proprietary. There may also be different or flawed implementations of the same standard that are not interoperable. In some cases even different versions of the same standard may conflict. For health service providers, this situation may imply that computerised systems remain stand-alone and unable to exchange data with each other in-house or externally. The lack of ICT systems interoperability and of widely accepted standards directly implies compromised quality of healthcare and unnecessarily high costs for the health systems. To the extent that EU Member States seek cross-border health services and, in the long run, an internal market for health services, such interoperability problems need to be solved at the EU or international level. The work to harmonise eHealth standards is further complicated by the number of standards developing organisations active in the area, not only the ESOs and ISO, but also Fora and Consortia such as IHTSDO for terminology, HL7 for electronic messaging, DICOM for digital healthcare imaging, openEHR for eHealth records and IHE for interoperable systems.

3.2. How would the problem evolve, all things being equal?

As regards the speed of the European standard-setting process, the figures set out above show that the duration of the process could still shorten slightly within CEN/CENELEC to equate to those of ETSI. However, it is likely to become increasingly difficult to make further progress without jeopardising some fundamental principles of the standard-setting process, especially the principle of consensus.

Little or no evolution can be expected in relation to the other problems.

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[49] See Annex 1 and the report of the European Parliament on the Future of European Standardisation [A7-0276/2010].

3.3. Simplification and update potential

At the moment, the co-existence of three different legal instruments on European standardisation (Decisions 87/95/EEC and 1673/2006/EC and Directive 98/34/EC) creates a number of ambiguities. These issues are listed below and could be easily rectified if the legal framework is revised.

3.3.1. Procurement of existing standards

At the moment, Decision No 1673/2006/EC specifies that EU financing will be provided:

– in the form of grants without a call for proposals, to European standardisation bodies to carry out the production and revision of European standards or any other standardisation product which is necessary and suitable for the implementation of Community policies and legislation and complementary activities set out in Article 3 of the Decision; or

– in the form of grants after a call for proposals, or by public procurement procedures, to other bodies to carry out, in collaboration with the European standardisation bodies, the performance of preliminary or ancillary work in connection with European standardisation, such as studies, programmes, evaluations, comparative analyses, research work, laboratory work, inter-laboratory tests and conformity evaluation work.

The procurement of existing standards by the Commission is not expressly mentioned in the Decision. Yet, procuring standards is possible under Chapter V of the Financial Regulation[50]. Resolving this legal ambiguity would not have any budgetary impact.

3.3.2. Simplification of the financing of European standardisation

The evaluation of the Community financing of standardisation[51] suggests that a shift to a radically simpler, faster and more stable arrangement is necessary to increase the efficiency of financial support and ensure that it is fully utilised - and indeed extended - in future. It recommends that the Commission seek to identify a significantly simpler and less bureaucratic set of arrangements in the medium term, and that in the interim the administrative requirements and financial controls be defined as clearly as possible and then applied fairly, proportionately and consistently across the various contracts.

In its proposal for the recast of the Financial Regulation applicable to the general budget of the European Union[52], the Commission pointed out that the currently applicable rules on grants have proved insufficient to alleviate the administrative

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50 Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities, OJ L248, 16.9.2002.

51 Evaluation of the Contribution of Community Financing of Standardisation to the Fulfilment of Policy Objectives of the Commission, submitted by GHK/Technopolis on 30 June 2009. http://ec.europa.eu/enterprise/dg/files/evaluation/2009-06-30__final_report_and_appendices_en.pdf. Its main conclusions can be found in Annex 9.

52 COM(2010)260 of 28.5.2010.

burden imposed on operational services and beneficiaries. According to the proposal, this administrative burden prevents services from using their resources on policy objectives and on timely delivery, while it creates excessive red tape for beneficiaries. It has two direct causes: excessive similarity between procurement and grant rules/procedures, although the objectives are different (acquisition vs. support); and the fact that controls for grants focus on real costs (real-cost based grant) rather than on expected results (deliverables) of projects.

This proposal for the recast of the Financial Regulation intends to shift the Union scheme towards a performance-based system, based on the definition of agreed indicators and objectives (outputs and outcomes), and to proceed to a robust simplification of lump sums (lump sums, standard scales of unit costs and flat rates), clearly disconnected from any verification of actual costs of implementation. Under this new system, the Commission would be able to establish lump sums, scales of unit costs and flat rates on the basis of a provisional budget submitted by the applicant taking into account its internal accounting practices, including only acceptable cost categories, which are consistently applied to similar operations by the applicant. In parallel, the proposal indicates that the real-cost regime, maintained as the default regime**,** should be reviewed (clarification of various types of costs, costs actually incurred, in kind contributions, profit).

The rules on the financing of European standardisation could be aligned with these simplifications in the recast of the Financial Regulation.

3.3.3. National standards for services

Articles 2 to 4 of Directive 98/34/EC establish cooperation between the standardisation bodies and the Commission for standards on products[53]. This cooperation includes the exchange of information on national standardisation initiatives so that NSBs are encouraged to bring their initiatives to European level, thus promoting the internal market and European harmonisation. Formally speaking, this cooperation does not apply to standards on services which are not included in the scope of the Directive.

Importance of services for the economy has steadily increased over time in most OECD countries. This process known as "tertiarization" does not only mean that services occupy increasing shares of GDP but also that they play an increasingly important role in intermediate inputs for manufacturing, and high-tech manufacturing in particular. The tendency of knowledge intensive business services firms to develop new services as part of a product package that includes physical, tangible

[53] According to Article 1(6) of the Directive, a standard is a technical specification approved by approved by a recognised standardisation body for repeated or continuous application, with which compliance is not compulsory and which is an international, European or national standard. A technical specification is defined as a *"specification contained in a document which lays down the characteristics required of a product such as levels of quality, performance, safety or dimensions, including the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures"* as well as *"production methods and processes used in respect of agricultural products as referred to Article 38(1) of the Treaty, products intended for human and animal consumption, and medicinal products as defined in Article 1 of Directive 65/65/EEC, as well as production methods and processes relating to other products, where these have an effect on their characteristics."*

goods is a prominent feature of what has been coined a "convergence process". This process encompasses manufacturing firms which have also begun to offer services as part of package including both the physical product as well as services. High-tech products are, for example, often sold in combination with maintenance services.

The output of manufacturing still consists to the largest extent of manufactured products. Service output of manufacturing, however, grows quite fast and displayed annual growth rates of 5 to 10 % for the period 1995-2005. Service output of manufacturing was growing in all Member States but the Czech Republic between 2000 and 2005 which is the latest available year of data. Taking into account that the latest recession hit manufacturing industries relatively harder than services, the shares of service output of manufacturing is likely to have increased further.

In general, the delineation between services and goods is becoming less relevant in the reality of the internal market. In practice, it is not always possible to clearly distinguish standards on products from standards on services. Many product standards have a service component while standards on services often also partly relate to products. Therefore, most NSBs notify their intentions about all new or amended standards in accordance with the internal rules of the ESOs, irrespective of their scope and despite the current absence of an obligation to notify envisaged service and process standards[54]. However, this de-facto situation is not foolproof: if, for example, a NSB deliberately chooses not to notify its plans for a new national service or process standard to protect their national market, the other NSBs and the ESOs will remain unaware of these plans so that the matter cannot be discussed in view of a possible initiative for a European standard.

The public consultation shows that most respondents were in favour of including service standards in the scope of Directive 98/34/EC[55] or its possible successors. Just over half (58%) of the NSBs stated that there would be no additional administrative workload or cost associated with the notification of service standards, and a further quarter (25%) stated that the costs would be negligible or insignificant. The lack of additional administrative costs are explained by the fact that notification is current practice for most NSBs and many are not developing significant numbers of national service standards anyway.

3.3.4. European standards for services

European standards on services are already covered by Decision No 1673/2006/EC on the financing of European standardisation. The older Directive 98/34/EC, however, only applies to standards on products and the consultative committee of representatives of Member States set up by Article 6 of the Directive cannot formally propose that the Commission ask the ESOs to draw up a European standard on

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54 See reports on the implementation of Directive 98/34/EC : COM(2009)690 and SEC(2009)1704, COM(2007)125 and SEC(2007)350, and COM(2003)200. See also http://www.cen.eu/boss/Support/Support%20processes%20-%20Index/notifproc/Pages/default.aspx. and http://portal.etsi.org/nso/handbook.asp.

55 It should be noted, however, that articles 8 to 10 of Directive 98/34/EC, i.e. the provisions concerning the notification of draft technical regulations, have no bearing to standardisation. Therefore, these articles as well as other articles of the Directive concerning the notification of draft technical regulations fall outside the scope of this impact assessment.

services (Article 6(3)). In theory, the Committee should not even be consulted for such requests (Article 6(4)).

Correspondingly, the Commission addressed Programming Mandate M/340 in the field of services to CEN, CENELEC and ETSI in 2003, in which it requested the delivery of a programme of standardisation work in support to the Internal Market for services, giving priority to areas where intra-community trade already existed or was desirable. In July 2005, the Commission addressed the Second Programming Mandate M/371, in the field of services to CEN which resulted in 11 feasibility projects. Other mandates, for example, relate to postal services (mandates M/312 and M/428), cinematographic works (mandate M/365), business-support services to SMEs (mandate M/370), customer-contact services (mandate M/378) and supply chain security (mandate M/419).

However, Article 26(5) of the "Services Directive"[56] obliges the Member States, in cooperation with the Commission, to encourage the development of voluntary European standards with the aim of facilitating compatibility between services supplied by providers in different Member States, information to the recipient and the quality of service provision.

Consequently, there is a case for aligning and simplifying the procedures for all mandates to ESOs, regardless of their subject-matter, by including the possibility to ask ESOs to draft European standards on services into the legal text. There was general support for this possibility in the general consultation.

3.4. Subsidiarity

European standardisation supports European legislation establishing the Single Market (see Annex 4) and contributes to increasing the competitiveness of European industry. The harmonisation of standards at European level overcomes technical barriers to trade which could be caused by conflicting national standards. Therefore, this impact assessment only examines problems and policy options that relate to standardisation at European level. Correspondingly, measures to improve standardisation at national level are not considered.

All problems outlined above concern primarily the functioning of the internal market. Consequently, any legislative proposal with respect to European standardisation would have to be based on Article 114 TFEU, which is the legal basis of all directives referred to in Annex 4. The proportionality of the options will be assessed later in this report.

[56] Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market, OJ L376, 27.12.2006.

4. OBJECTIVES

4.1. General policy objectives

This initiative aims at increasing the contribution of standards and European standardisation to a better functioning internal market, stimulating growth and innovation and fostering the competitiveness of EU enterprises, especially SMEs.

4.2. Specific objectives

(1) Reduce the time taken by the standardisation process for standards developed at the request of the Commission;

(2) Ensure that SMEs and societal stakeholders are adequately represented in the standardisation process, especially for standards developed at the request of the Commission;

(3) Broaden the use of ICT standards and thus enhance interoperability through a more integrated European public procurement market for ICT products and services, especially in connection with the establishment of an "e-Internal Market";

(4) Remove ambiguities in the existing legal framework.

5. POLICY OPTIONS

Each policy option listed below (with the exception of the baseline options) would be accompanied by the simplification measures analysed above.

5.1. Policy options for problem 1: the process for adopting European standards requested by the Commission is not fast enough

- Option 1.0 is the **baseline option** against which the remaining options are assessed, namely the current situation as described above.

- Policy Option 1.A: specify **deadlines for the delivery of European standards**, for example in the grant agreements and in the mandates.

- Policy Option 1.B: **create a European Agency for Standards** that would manage the standard-setting process. The agency would merge and replace the existing ESOs. The agency would act as a secretariat for European standardisation while the national delegation principle would be upheld. It would be responsible for developing European standards, in close cooperation with NSBs.

- Policy Option 1.C: **transparent and simplified procedures for harmonised standards and other European standards requested by the Commission**. The first element would consist of a more organised regular annual programming cycle which might help ESOs to better respond to new and ongoing priorities. Secondly, mandates would not require the individual favourable opinion of the committee but comments of the representatives of the Member States on the subject of the individual mandates would be sought when the work programme

was discussed. Thirdly, ESOs would be obliged to answer any standardisation request from the Commission (i.e. a mandate) within two calendar months. Finally, the procedure for objecting to harmonised standards would also be shortened.

5.2. Policy options for problem 2: Under-representation of SMEs and societal stakeholders in the European standardisation process

- Option 2.0 is the **baseline option** against which the remaining options are assessed. It does not propose any new measures compared to the current situation. It is described above.

- Policy Option 2.A: **Facilitate direct representation of SMEs and societal stakeholders within the ESOs**. This would include the amendment of the voting arrangements and an extension of the number and the formal rights of "Associated Members" in CEN[57] and "Cooperating Partners" in CENELEC[58]. Since administrations, administrative bodies, NSBs, network operators, manufacturers and users can already be members of ETSI[59], in the case of ETSI only amendment of the voting arrangements would be necessary.

- Option 2.B: **Grant voting rights to organisations representing SMEs** and societal stakeholders within the European standardisation organisations. This would include the amendment of the voting arrangements and an extension of the number and the formal rights of "Associated Members" in CEN[60] and the "Cooperating Partners" in CENELEC[61]. Since administrations, administrative bodies, National Standards Organizations, network operators, manufacturers and users can already be members of ETSI[62], in the case of ETSI only an amendment of the voting arrangements would be necessary whereby these organisations would play a more prominent role in the technical work.

- Option 2.C: **Strengthen the position of organisations representing SMEs and societal stakeholders within the ESOs by providing for the possibility of an operating grant.** A more active role for organisations representing SMEs and societal stakeholders in the technical work of the standardisation process could be ensured if separate organisations representing SMEs, the interests of consumers

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57 Associate Members of CEN are organizations representative, at European level, of social and economic interests, the statutes of which are governed by European legislation, or by the national legislation of one of the CEN national Members' countries, and which comply with other conditions mentioned in the Statutes of CEN (Article 6.3).

58 Cooperating Partners of CENELEC are independent European or international organizations representing, with a sufficient degree of representativity within their defined area of competence, a sector or subsector of the electrotechnical field.

59 Article 6.1 of the Statutes of ETSI.

60 Associate Members of CEN are organizations representative, at European level, of social and economic interests, the statutes of which are governed by European legislation, or by the national legislation of one of the CEN national Members' countries, and which comply with other conditions mentioned in the Statutes of CEN (Article 6.3).

61 Cooperating Partners of CENELEC are independent European or international organizations representing, with a sufficient degree of representativity within their defined area of competence, a sector or subsector of the electrotechnical field.

62 Article 6.1 of the Statutes of ETSI.

and environmental considerations and another defending social interests could benefit from an operating grant. This possibility would have to be introduced in the legislation concerning the financing of European standardisation which would provide for a more transparent and financially sound system of supporting these organisations, by clearly setting out the criteria for the financial support by the EU.

5.3. Policy options for problem 3: "Fora and Consortia Standards" cannot currently be referenced in public procurement of ICT.

- Option 3.0 is the **baseline option** against which the remaining options are assessed. It does not propose any new measures compared to the current situation. It is described above.

- Policy Option 3.A: **Revive the implementation of the mechanisms of Council Decision 87/95/EEC** concerning public procurement and the policy dialogue. Public authorities could be reminded about the existing legislation and its implications for the use of standards in public tenders, including the need to notify exceptions when referring to non-European technical specifications. This could be done through a communication from the Commission to the Member States.

- Policy Option 3.B: **Allow for the referencing of "Fora and Consortia Standards" in public procurement of ICT**. The objective is to expressly allow referencing of "Fora and Consortia Standards" in public procurement for interoperability purposes in those areas where no appropriate European standards are available, e.g. in the Internet domain, or in domains where a fora and consortia specification has much broader market acceptance than an ESO standard e.g IEEE WiFi specifications compared to the ETSI Hyperlan standard. To help public authorities use the best available standards, it would be necessary to identify certain requirements or attributes to which the standardisation process and the standard comply. These attributes e.g. openness, transparency, balance, stakeholder involvement, IPR policies, would ensure that the standards respect public policy objectives and societal needs. Compliance with these attributes would be assessed with the help of a "consultative platform" that would be composed of, inter alia, representatives from Member States, ESOs, ISOs, the most relevant private fora and consortia, SMEs, industry, and consumer organizations.

- Policy Option 3.C: **Grant selected private fora and consortia the Status of Recognized Entities under Directive 98/34/EC**. Directive 98/34/EC puts in place an information and co-ordination mechanism between national standardisation bodies and 'recognised' European standardisation entities to harmonise the production of standards at the European level. 'Recognised' bodies have a right of information and consultation on national standardisation activities to prevent the development of national standards already available in the European catalogue, unless they are specifically mandated by national governments.

5.4. Discarded options

During the public consultation, stakeholders raised several other issues, which were not retained for further analysis in this impact assessment report. These issues are listed in Annex 5. As a consequence of the consultation, some options were refined.

6. ANALYSIS OF IMPACTS

None of the options has impacts on fundamental rights, the number and the quality of jobs, technological developments, developing countries, public health or public authorities.

6.1. Problem 1: the process for adopting European standards requested by the Commission is not fast enough

6.1.1. Policy Option 1.0: Base-line scenario

As described above. It serves as a reference against which the other options are assessed.

6.1.2. Policy Option 1.A: specify deadlines on the delivery of European standards.

The **advantage** of this option is that European standards would be available after a fairly short period. The assumption is that ESOs would accept shorter deadlines and that they could persuade technical experts willing to spend more time on developing a standard. The positive economic benefits of the earlier availability of a standard can be deducted from the relation between standards portfolio and growth. According to the AFNOR study[63] "the positive variation in the stock of standards of 1% induces an increase of 0.12% in the growth of the TFP (Total Factor Productivity). Thus the conclusion that earlier availability of standards would lead to more standards on the market and result in more growth. Faster standard development may have a positive impact on competitiveness as businesses could in addition save costs thanks to the "defragmentation" of the internal market and to the simplification of conformity assessment procedures. Shorter standard development may also encourage innovation and new technologies.

Financial incentives to encourage ESOs to speed up the process are a necessary part of this option, as well as financial sanctions in case of late delivery. The financial incentive is a valuable element of this option, especially in the light of the financial simplification referred to above. Indeed, if one would shift the financing scheme towards a more performance-based system, based on the definition of agreed indicators and objectives (outputs and outcomes) and a simplification of lump sums, the speed of the standard-setting process for standards elaborated at the request of the Commission should be taken into consideration.

However, there are some disadvantages linked to this option. Firstly, the obligatory deadlines and corresponding financial consequences for failure to deliver can only be

[63] The economic impact of standardisation. Technological change, standards growth in France, AFNOR, June 2009.

applied to standards mandated by the Commission, which are a small percentage of the total (34%). A drawback of this option is **that ESOs may decline requests** for new items for standardisation, in particular for technically complex or contentious issues. Facing deadlines may encourage some NSOs to avoid standardisation at European level so that there would be fewer European standards and more, probably conflicting, national standards on the same subject.

Secondly, deadlines for European standards could have a **negative impact on the quality of the standard**. Time can only be gained by reducing consensus and correspondingly curtailing (or avoiding) one of the intermediate consultation stages. The objective of the need for a consensus and a broad consultation is mainly to protect the standardisation process from being influenced by the private commercial interests of vendors or users, thus ensuring that it leads to standards that serve the public interest. A standard founded on a broad consensus following a sufficient consultation had a number of positive effects on the market for which the standards are destined, for example it means that asymmetries in the cost of access to information are reduced, entry barriers are lowered, price-performance calculation is simpler, and the ability of suppliers to impose switching costs is also reduced[64].

Thirdly, deadlines for all European standards and the production of at least the same number of standards in less time could lead to **increased costs** (more frequent meetings for example).

Estimated annual costs of working groups of creation of new standards (euros)	
	3 year process
Experts costs (1 meeting /6 days/month*10 experts*600 euro)	432,000
Laboratory costs	400,000
Travel costs	86,400
Total	***918,400***
Number of working groups (CEN/CENELEC)	1,704
Estimated active working groups (35%of total existing wg)	596
Cost 35% working groups CEN/CENELEC	547,733,760
Cost ETSI (estimated of the basis of number of deliverables)	2,306,247,411

64 David, P.A., and Shurmer, M. "Formal standards-setting for global telecommunications and information services. Towards an institutional regime transformation?" Telecommunications Policy (20:10) 1996, pp 789-815.

Number of annual deliverables (CEN/CENELEC/ETSI)	3,069
Total costs	**2,853,981,171**
Cost per deliverable	**929,938**

On the one hand, this option would result in an estimated **additional annual cost** per standard of around €150,000 to €200,000 if standards were to be finalised in 2 years. According to the current share of standard creation costs, this would translate into an additional cost per standard for the Commission of €3,000 to € 4,000, for national governments of €4,500 to €6,000 and for industry of €142,000 to 190,000. On the other hand, if one assumes that the relevant working group meets on a more or less permanent basis and starts new work when a consensus is reached on the previous topic, this option would necessarily result in the **development of more standards which has positive economic effects.** The increase in speed would only be possible if industry and other stakeholders agree to share the additional cost or if the Commission finances it.

Unless specific measures are taken, deadlines for European standards would necessarily have a **negative impact on the involvement of SMEs and societal stakeholders**. In other words, this option would worsen the problem of the lack of involvement of SMEs and societal stakeholders. The willingness of businesses, and especially SMEs, to take part in standardisation activities would be reduced since they would have to use their scarce standardisation resources in a shorter and therefore more labour-intensive period.

During the **consultation process**, ETSI highlighted that standardisation is a voluntary activity and it is not realistic for the EC to expect that financial support will immediately bring all the necessary stakeholders to the table. 86% of respondents in the public consultation do not wish to have the EU's financing of standardisation subject to conditions of speed of delivery. This is true for each one of our six categories of stakeholders (80% of citizens; 92% of companies; 84% of industry associations; 65% of public authorities; 90% of European and national standards bodies and 92% of public interest organisations) and for the 19 SMEs as well (in this case, the percentage of replies indicating an opposition is even equal to 100%). Respondents perceived the time needed for the standard-setting and definition process as reasonable in most cases. Increasing speed is often perceived as having a negative impact on the quality of the outcome of the process. If, however, a need emerges to further speed up the process, respondents say that possible speed-related conditions in EU financing would not improve the situation. As an alternative, they suggest increasing the use of IT solutions in working methods, tools and processes of National and European Standards Bodies. Some replies also suggest concentrating resources and efforts only on the development of those standards which are relevant for market players.

6.1.3. Policy Option 1.B: create a European Agency for Standards that would manage the standard-setting process.

Work in European standardisation is already done at European level by the ESOs, CEN, CENELEC and ETSI. This option would merge the three ESOs into one agency that would develop European standards.

The **advantage** of this option is that the agency would be supervised by the European legislator and that it would become more difficult to decline mandates for European standards. The creation of a new European standardisation agency would probably mean that requests for harmonised standards would be handled as a priority. Furthermore, it would seem a priori logical to suppose that the smaller the number of European organisations dealing with standardisation, the lower the level of duplication of administrative resources and expenses would be, and the greater the cost-efficiency. If one prefers more integrated standards covering different sectors, it would also seem logical to replace the current sectoral approach with an integrated approach whereby all European standards would be drafted under the auspices of one single body which would pool all the available expertise. In addition, the participation of SMEs in the standardisation process could be improved. A single European standardisation agency could also lead to faster standard development. In this case, the positive effects would be similar as described above for option 1. A.

However, this option has a number of considerable drawbacks. It requires, above all, **close cooperation with the NSBs** to make it viable. An agency on European standardisation could not operate without their support. An agency could not provide the **level of expertise** necessary to perform effectively the tasks of a technical committee. It is commonly held that experts from industry and other stakeholders are better placed to provide the right level of technical knowledge. An agency that would replace and merge the existing ESOs would be likely to face the same challenges as nowadays, namely that the actual work in the technical committees is done by experts delegated by the NSOs which would have corresponding voting rights. Therefore, **consensus between the experts would still be necessary**, regardless whether the work was done under the auspices of an ESO or an agency. Moreover, a speedily elaborated specification could still face a negative vote by members who considered that the proposed standard did not fulfil the necessary requirements.

This option would certainly lead to **substantial additional costs for the EU-budget**. The Commission currently contributes around 47% of the total income of the three ESOs (€44,000,000), which covers part of the ESOs's secretariat staff costs, some consultancy costs as well as activities such as translation of standards, visibility actions to promote EU standards and preliminary or feasibility studies for standards. This contribution amounted to 21.2 million euro in 2009. The rest of the ESOs income is mainly financed by members´ fees and contributions. ESOs currently employ 208 permanent staff. The costs of the current system are shown in the following table:

Costs 2009 (euros)	Commission	Other parties (industry, MS)	Total
Contribution to ESOS budget	**21.200.000**	**23.472.000**	**44.672.000**
Operating grant (staff+administrative costs)	10.400.000		
Action grants (translation, visibility, standardisation projects)…)	10.800.000		
Standards creation costs (NSB and industry experts)		2.724.243.150	2.724.243.150
Total	**21.200.000**	**2.724.243.150**	***2.768.915.150***
Annual Mandates /ESOSDeliverables	24	3000	
Staff ESOS	**208**		
ETSI	120		
CEN	65		
CENELEC	23		

It has to be kept in mind that **the number of standards mandated by the Commission is a fairly small proportion of the total deliverables issued by ESOs**. The Commission issues around 20 mandates per year. For each mandate we can count from 1 up to more than 100 standards produced. However, the great majority of European standards remain industry–initiated and financed. The total number of deliverables issued by ESOs in 2009 was around 3,000.

The assumption is that standardisation work would continue to be carried out as it is under the current system, where most of the costs of the experts developing the standards would be financed by the private sector. If the ESOs were merged and transformed into an EU executive agency, it is likely that **the EU budget would have to generate the total income of the agency**, including the part currently financed by other parties mainly through fees. The assumption is that there would not be payment of fees by stakeholders in order to facilitate participation by SMEs and societal stakeholders. If the agency was of a size comparable to the EACI or the ERCEA[65], this would lead to an additional annual cost for the EU budget of at least €20,000,000.

There would be a negative impact in terms of costs, while positive impacts in terms of improvement of the quality of the standardisation process are not clear. It is also questionable whether standardisation activities, in which the main players are private, should be performed by a public EU agency, particularly while the current structure seems to be responding to industry needs.

During the **consultation**, all three ESOs said that they expect that the creation of a new agency will make the ESS more complex. They reported that a new organisation would result in more meetings, additional costs, a lack of clarity over the boundaries

65 Executive Agency for Competitiveness and Innovation (EACI): EU contribution: €15,000,000 - staff: 152; Education, Audiovisual and Culture Executive Agency (EACEA): EU contribution: €46,000,000 - staff: 412; European Research Council Executive Agency (ERCEA): EU contribution: €32,000,000- staff: 330; Trans-European Transport Network Executive Agency (TEN-T EA): EU contribution: €9,000,000 - staff: 99.

between the EC and the new agency and more difficult coordination amongst stakeholders at different levels. ETSI reported that it could see no benefits to the proposed approach.

6.1.4. Policy Option 1.C: transparent and simplified procedures for harmonised standards and other European standards requested by the Commission.

A more organised regular annual programming process would increase the workload of the services of the Commission but would have a **general positive impact**. It would enable ESOs to anticipate upcoming requests and shorten the acceptance process. The second part of this option, i.e. the replacement of the favourable opinion on individual mandates by a general discussion on the overall EU standardisation work programme would offer an equivalent level of transparency vis-à-vis representatives of Member States. The main difference is that the consultation would be part of a more general consultation on overall standardisation planning and the choice of priorities. The third part of this option would oblige the ESOs to answer any standardisation request from the Commission (i.e. a mandate) within two calendar months. The last part of this option consists of shortening and streamlining the various procedures for objections[66] which would offer the advantage that harmonised standards would be more rapidly available on the market for use by businesses.

This option would have a **positive impact** on the internal market and the competitiveness of businesses (including SMEs) by reducing the overall period of standardisation by up to 1 year, while having no negative impacts or supplementary costs. This acceleration in the standardisation process would come from shortening the period for issuing mandates by approximately 6 months (by removing the separate consultation of the committee) while another 6 months could be cut at the end of the process through efficiency gains when objections are raised. Competitiveness advantage for businesses would come from benefiting earlier from the presumption of conformity granted to those using such harmonised standards. It is however impossible to quantify this positive impact as it can only be estimated once the subject of the standard, the turnover of the businesses concerned and the cost of conformity assessment of their products in the absence of a standard are known.

Although this option has an overall positive impact without any negative impacts, the main **disadvantage** is that it would only apply to harmonised standards and standards developed at the request of the Commission, so it would have no impact on the speed of other European standardisation work. In addition, it would lead to an additional workload of the Commission and corresponding administrative costs of about €250,000 per year.

During the **consultation** of January-February 2010, CEN/CLC reported that a two-month timeframe for responding is achievable and at no additional cost. ETSI reported that a two-month time frame for responding was not achievable. Instead, 3 months is the minimum possible timeframe due to the need to coordinate with the other ESOs and other involved SDOs and to consult with the ETSI Board before

[66] A detailed overview can be found in Annex 4.

acceptance (although this would be dependent on the reaction of the technical organisation and board of ETSI to a specific request). Achieving this timeframe would probably not incur any additional financial costs. ETSI reported that the following changes would be necessary for the ESOs to be able to respond to mandates within in a shorter timeframe: firstly, a stronger and earlier consultation on the mandate drafting process to ensure that the community has a better understanding of what is needed, which can accelerate the ESO acceptance process; secondly, improvements to the presentation of content and clarity of purpose of draft mandates, and thirdly, a simplification of the contractual process for grant agreements that presently require at least 9 months. ETSI reported that there would be no cost implications associated with these changes, nor any other implications. CEN/CLC reported that the BT formal approval could be further shortened in order to be able to respond to mandates within a shorter timeframe. CEN/CLC did not report any associated cost implications to this change. CEN/CLC also highlighted that some of the delays are due to factors outside the control of the ESOs, but that instead reside with the Commission.

6.2. Problem 2: Involvement of SMEs and societal stakeholders in the European standardisation process

6.2.1. Policy Option 2.0: base-line scenario (i.e. the financial contribution to SME and societal stakeholder representation)

As described above. It serves as a reference against which the other options are assessed.

6.2.2. Policy Option 2.A: Facilitate direct representation of SMEs and societal stakeholders within the European standardisation organisations

Long term direct participation of technically aware staff of individual SMEs and societal stakeholders in the meetings and discussions of a technical committee allows this staff to build a reputation within the standardisation organisations. In addition, staff can work directly to influence the process.

Participation in the standardisation process requires a **strong technical understanding of proposed standards and their context**. In addition, participants need to be prepared to commit up front to substantial investments of the time and energy necessary to follow ongoing internal discussions about the subject of the future standard. Many questions are moving targets – discussions can progress quickly and the challenges presented when a standard is proposed may evolve just as quickly. Also, the relative value of a contribution is frequently judged by the contributor's willingness to follow-up and finds workable answers to questions raised. Furthermore, long-term commitment to the standards development process is necessary.

On-going and active participation in a technical committee or working group requires a very significant commitment of time. The generally accepted guideline is that meaningful participation in any technical committee or working group requires a baseline of approximately 20% of a person's working hours (1 day of work and meetings per week plus tri- or semi-annual conferences). The average costs of participation can hardly be calculated given the wide range of size, scope and level

of technical complexity of standards. Even generalizations should be taken with a pinch of salt. The cost depends, of course, on a number of factors including the size and complexity of the work to be done, the availability of existing work upon which the standard can be based, the number and quality of resources available to contribute to developing the solution, etc. The individual components of cost that go into developing and setting or approving a standard include membership dues or participation fees paid by participants to the standards organization, costs associated with salaries and support for technical resources (people) involved, travel costs for committee meetings and overhead costs. Membership dues are a relatively minor cost of participating in standards work, compared to the cost of participation. A hypothetical technical committee consisting of 10 engineers working for three years to develop a specification, and devoting each an average of 20% of their working time to the project could easily come to a total € 1,000,000 given the cost of an engineer, including salary, benefits, office space and equipment, travel costs etc. (see details under option 1.A). Furthermore, this covers just the work involved in developing the standard.

The second phase would **include costs associated with the approval of the work, including public and member reviews and voting**. This could add hundreds or possibly thousands of hours of additional work by technical people, increasing the costs even further. There are no precise estimates of these additional costs but, depending on the complexity of the reviewing process, they could amount to a significant share of the original development costs. Finally and most importantly there are the 'lost opportunity' costs of not doing something else that can be particularly relevant for SMEs. At company level, this could be as simple as having an engineer working on standardisation rather than on the company's own R&D project or other activities.

Although such direct participation is clearly the most effective way for an individual SME to have an impact on a particular standard proposal, the **sheer number of technical committees and working groups** impedes direct public representation to a large extent. For example, CEN had 1939 Technical Bodies in 2009, namely 292 active Technical Committees, 33 active CEN Workshops, 62 Sub-committees and 1395 Working Groups. At the end of 2008, there were 338 active CENELEC Committees, Sub-Committees, Task Forces and Working Groups. ETSI had 27 technical committees/ETSI Projects, 6 Industry Specification Groups and a few Partnership Projects and Special Committees.

At a more general level, one could expect that the individual participation of SMEs would lead to an ineffective distribution of information to the SMEs that are not participating in the standardisation process. Finally, this option would inflate the number of participants in the standardisation process so that it would be likely to have a negative impact on the speed of the standard-setting process. This would cause additional difficulties for problem 1 above.

Although this option is not expected to have any consequences for the EU budget, it would be very costly for the participants, inefficient and ineffective for all parties concerned.

During the **consultation** process, many respondents emphasized the importance of the principle of national delegation. In this respect, CEN and CENELEC said that

moving away from this principle would require modification of all internal regulations and dramatically change the way the ESO works. There would be fundamental issues to be solved around new processes and procedures and such a radical change would incur heavy costs. Concerns were also expressed about the implications for balanced representation and a fragmentation of the European standardisation system.

6.2.3. Policy Option 2.B: Grant voting rights to organisations representing SMEs and societal stakeholders within the European standardisation organisations

Organisations representing SMEs and societal stakeholders can, under certain conditions, become **associate members** of CEN which allows them to participate, without voting rights, in the General Assembly, open sessions of the Administrative Board, Technical Board, Sector Activities and the CEN Certification Board. As a member of the Technical Board, an Associate Member can also apply for and hold the secretariats of Technical Committees and participate in Technical Committees (TCs) and Subcommittees, upon request, as an observer. A similar system exists in CENELEC. In ETSI, representative organisations are ordinary members and they do have a vote, but given that there are 20,000 weighted votes in ETSI and each of the comparable activities gets one of these, the voting rights are somewhat symbolic.

Granting voting rights to a very limited number of representative organisations on technical work within CEN would have a **very positive impact** on the involvement of SME and societal stakeholders. Other delegations with voting rights would have to take into account the views expressed by delegates of SMEs and societal stakeholders. **No negative impacts** could be identified. This option seems entirely compatible with the principle of national delegation, especially if voting rights were granted to a very limited number of European organisations representing SMEs and societal stakeholders on the technical aspects of the standard. This option is not expected to have any consequences for the EU budget.

However, granting voting rights to organisations other than NSBs needs to be negotiated and agreed with the members of the ESOs, so the **feasibility of this option is uncertain**. Furthermore, it may entail the payment of a higher membership fee which would increase the cost of this option for organisations representing SMEs and societal stakeholders. This may mean a slight increase in the financial contribution paid by the EU to the costs incurred by organisations representing SMEs and societal stakeholders at European level.

During the public **consultation**, 69% of respondents declare that, even if the national delegation principle already guarantees a good level of involvement, the participation of consumer organisations, environmental NGOs, trade unions and social partners, and SMEs within standardisation bodies and committees should be further promoted. This is true for 78% of citizens; 58% of companies and 65% of industry associations. The majority of public authorities (97 %) European and national standards bodies (90%) and in the case of NGOs/environment/consumer/public interest organisations (93%). are in favour of further participation. Favourable replies are in the majority (71%) also in the case of the 19 SMEs. Stakeholders also suggested modifying the voting procedures within standardisation bodies in order to further stimulate the setting-up of mixed groups.

6.2.4. Policy Option 2.C: Strengthen the position of organisations representing SMEs and societal stakeholders within the ESOs by providing for the possibility of an operating grant

An important advantage of this option is that these organisations have access to a larger pool of expertise and knowledge than individual SMEs or societal stakeholders. Moreover, these organisations are much more effective at exchanging information to their members: individual SMEs and societal stakeholders would be less effective in exchange information with other interested SMEs and societal stakeholders, in the absence of a specialised network and dedicated resources.

The assumption is that the current level of EU financing would be maintained. EU financial support for the representation of SMEs in standardisation at European level amounts to approximately €2,000,000 per year. The financial support to organisations representing consumers and environmental concerns in standardisation varies respectively around €1,320,000 and €185,000 per year.

Unlike a grant for an action, which helps to co-finance a one-off action over a given period (which has a budget specific to that action irrespective of the body's other activities) an **operating grant** is broader based: its purpose is to provide financial support for the existence and functioning of a body over a period that is equivalent to its accounting period to enable it to carry out a set of activities. Operating grants are intended to cover the normal operating expenses which enable a body to have an independent existence and to implement a range of activities that correspond to the pursuit of its statutory objectives, which must contribute to the development and implementation of an EU policy. In practice, the costs which are likely to be eligible are those relating to staff costs, general administrative expenditure necessary for the running of the body (or overheads), and expenses linked to its normal activities as approved in the work programme drawn up for the purposes of the grant. In view of the nature of the grant, the body's entire budget is involved, unless the body has developed several areas of activity one or more of which are not connected with the activities for which the Commission wishes to provide financial support.

The **positive aspect** of this option is that it provides for the possibility of continuous support to organisations representing SMEs and societal stakeholders so that they could consolidate their role in the standardisation process. The other positive aspect is that the possibility of an operating grant contains a strong impetus for ESOs to continue considering these organisations as solid partners in the standardisation process so that the opinions of these organisations are adequately taken into account during the technical work on European standards. By strengthening the financial instrument to ensure that the objective of correct SME and societal stakeholder representation is met, the financial support and the objectives of the EU would be clearly linked so that financing would be deployed purposefully in pursuit of specific objectives (such as SME and societal stakeholders' representation).

In principle, if operating grants are renewed they should be gradually reduced according to the **principle of degressivity**. The basic philosophy of operating grants is that they should provide temporary support for an organisation to allow it to achieve financial independence in the longer term. However, this degressivity would contradict the EU policy under which the position of SMEs and societal stakeholders must be strengthened in order to ensure the inclusiveness of the European

standardisation system. In addition, it seems likely that more and more European standards will be developed in the future so that the workload of organisations representing SMEs and societal stakeholders in the European standardisation system will increase. These organisations have a permanent role which is essential for EU activities and policies because of the context in which they operate and their statutory objectives. Therefore, this option would require an exception to the degressivity principle in the basic act underlying the award of the grants. Furthermore, this option requires that the budgetary amounts which are currently scattered over several budgetary lines would be at least maintained by the budgetary authority.

No negative aspects could be identified. This option is not expected to have any other consequences for the EU budget than those outlined above.

As already set out above, 69% of respondents of the public **consultation** declare that the participation of consumer organisations, environmental NGOs, trade unions and social partners, and SMEs within standardisation bodies and committees should be further promoted. A minority of respondents (large companies, mainly) is against the option of financially supporting the less represented stakeholders, since they consider that this could be viewed as a discriminatory measure in relation to other actors.

6.3. Problem 3: "Fora and Consortia Standards" cannot currently be referenced in public procurement of ICT.

6.3.1. Policy option 3.0: base-line scenario

As described above. It serves as a reference against which the other options are assessed.

6.3.2. Policy Option 3.A: Revive the implementation of the mechanisms of Council Decision 87/95/EEC concerning public procurement and the policy dialogue.

Under this option, Fora and Consortia Standards could be considered as "common technical specifications" under Article 1(2) of Council Decision 87/95/EEC, i.e. a technical specification drawn up with a view to uniform application in all the Member States. There could be two situations:

(1) The Fora and Consortia Standard is not similar to an existing standard or functional specification. Strictly speaking, Fora and Consortia Standards do not fall within the scope of Decision 87/95/EEC, as set out in Article 3. Therefore, these Fora and Consortia standards would have to be transformed into a European standard, following the procedures of the Decision, so that they can be used in public procurement.

(2) The Fora and Consortia Standard is similar to an existing standard or functional specification. In that case, Article 5(3) of the Decision allows Member States to take account of special circumstances which may justify the use of standards and specifications other than those provided for in the Decision where an existing standard or functional specification would be technically inadequate for its purpose. In that case, contracting authorities would have to apply the formalities set out in Article 5(5). Moreover, the Commission could recognise Fora in accordance with point 3 of the Annex to

the Decision, which provides for the "*determination of the most efficient methods of ensuring the rapid application of* […] *technical specifications within the context of the present Decision"* in the public procurement sector.

Neither situation is satisfactory. The former leads to supplementary charges, responsibilities and costs for ESOs that would have to transform the Fora and Consortia Standard into a European standard. A substantial part of the costs would have to be borne by the Commission. In addition, the ESOs would be responsible for the regular review and update of the standard. This would lead to an **extra administrative burden for ESOs and an additional cost for the EU-budget**.

The most important problem with the latter situation is the **lack of legal certainty**. Firstly, it is difficult to determine if Article 5 of the Decision would apply since the circumstances referred to in Article 5(3) no longer correspond to the technological reality on the market. Therefore, this possibility may require a very broad interpretation of the provisions of Decision 87/95/EEC. Secondly, the question would remain whether the provisions of the Decision were still compatible with the general provisions of Directive 2004/18/EC which obliges contracting authorities to formulate technical specifications either by reference to standards or equivalent documents or in terms of performance or functional requirements, provided that such parameters are sufficiently precise to allow tenderers to determine the subject-matter of the contract and to allow contracting authorities to award the contract. Thirdly, this possibility would mean that contracting authorities would have to apply the formalities set out in Article 5(5) which were not conceived for cases like this. **Due to this legal uncertainty, the impacts on the internal market, SMEs, public authorities, consumers and innovation would be minimal**. However, there would be no budgetary impacts.

The **advantage** of this option is that no legislative change is required and the corresponding administrative costs for the EU legislator and the Member States could be avoided.

During the public **consultation**, only 3% of respondents considered that the provisions of Decision 87/95/EEC are a sufficient legal basis for allowing contracting authorities to use Fora and Consortia Standards for the purpose of public procurement.

6.3.3. Policy Option 3.B: Allow for the referencing of "Fora and Consortia Standards"

The **main advantage of this option** is that the possibility of referencing selected Fora and Consortia Standards for procurement purposes on a firm legal basis is expected to counter the tendency towards market fragmentation and to have a positive impact on the internal market, especially for businesses delivering goods or services complying with these Fora and Consortia Standards. Correspondingly, the referencing of Fora and Consortia Standards can be expected to enhance the competitiveness of enterprises, with the creation of a competitive advantage for businesses concerned, in particular the European ICT industry. Also, the fact that these specifications are officially endorsed would reassure enterprises about their stability and provide an incentive to invest.

SMEs are expected to benefit in two main ways. First, the referencing of Fora and Consortia Standards would reduce information costs, as it would be easier for operators to ascertain what specifications were available for their products. Second, the availability of a broad range of recognized Fora and Consortia Specifications would create new business opportunities for SME, as they could build on existing protocols and procedures and innovate with lower costs and diminished technological and market assessment risks. In standardised and modular markets, SMEs would have greater opportunities to provide add-ons and applications. The impact of this option on innovation would probably be marginal.

This option would also have **positive indirect impacts on consumers**, considering the proliferation of high-tech consumer electronic products that exhibit network effects. In markets with network effects, the benefit to consumers of joining a network depends on the number of other consumers who join. This has several implications for competition in network markets. Firstly, expectations of consumers regarding the expected future size of a network are critical in determining the adoption of network products. Thus consumer expectations that one technology will become predominant may indeed lead to that effect. Secondly, competition in markets with network effects is likely to lead to standardisation on a single technology. In other words, the long-term co-existence of competing incompatible specifications is unlikely. This is because a small initial advantage will likely influence consumer expectations about the adoption of a particular Fora and Consortia Specification. This in turn will lead to more consumers adopting the technology. Because the value of the product increases with the number of adopters, the value of the network increases to future adopters[67] Widely accepted markets specifications help consolidate a larger customer base (as opposed to offering products/support based on disparate proprietary technologies). The same effect occurs for end-users since vendors are pooled together, which increases competition and drives prices down, producing better quantity and quality of end-user options[68].

These positive impacts, however, could have **corresponding risks**, in particular as regards competition and intellectual property rights. An important risk, for example, is that Fora and Consortia Standards could contain proprietary technologies, whereby a factual monopoly in a technology would result in a factual monopoly in the market for services and products based on the technology. This would then favour the single supplier of that technology[69]. However, the same situation applies with regard to ESO standards which can also contain proprietary technologies and an analogous approach is therefore needed.

Therefore, this option requires **additional safeguards** to address these risks:

(1) Firstly, the **"Fora and Consortia standards" would need to fulfill a number of predefined criteria**. These criteria would be inspired by the Commission's White Paper on "Modernising ICT Standardisation in the EU –

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67 Gandal N., "Compatibility, Standardization, & Network Effects: Some Policy Implications", 2002, http://www.tau.ac.il/~gandal/netpolicy.pdf.

68 Vomin V.F. and Pedersen M.K., "Open Standards and their early adoption: Implications for the Government Policy", 2006, http://www.itst.dk/it-arkitektur-og-standarder/standardisering/abne-standarder/baggrundsrapporter/OStEA_Delphi_report3_Final1.pdf.

69 See Annex 7.

The Way Forward"[70], and would be selected and assessed by the Commission. For example, it would be necessary that the Fora and Consortia Standards at least observe FRAND IPR policies, as is the case with the ESOs, or operate on a royalty free basis.

(2) Secondly, the selection process would have to be done with the **assistance from stakeholders through a consultative "Platform"** consisting of a very wide range of stakeholders and interested parties and without recourse to remunerated external expertise. The objective of the "platform" would be to help evaluate, inter alia, the openness of the standards development process, the quality of the Fora and Consortia Standards, the implemented IPR policies and the vendor and platform neutrality of their work product. The "platform" should guarantee that all stakeholders are fairly represented, that appropriate criteria are enacted, and that trustworthy results are made available.

Therefore, **this policy option would not entail any outlays from the EU budget** except the budget for running the platform which could be estimated at about €120,000 per year during the first 2 years (start-up phase) and €60,000 per year during the following years.

This impact of this option on public authorities would be very positive. Referencing to Fora and Consortia Standards in public procurement is expected to lead to greater competition among suppliers, products and services, and this should translate into lower costs.

At the moment, it is impossible to quantify the consequences of this option for several reasons:

(1) There is no comprehensive repository in the public domain of all existing private and public Fora and Consortia Standards currently in use. Looking at the ICT-sector, approximately 70,000 standards were developed in the ICT industry between the eighties and 2004[71] (more than four times the total number of ISO standards at the same date and roughly 10% of the entire PERINORM database grouping official national and international standards worldwide). If the same growth patterns had been maintained over the last five years – considering that each year some 3,000 new ICT specifications appear - this figure would likely have increased to anywhere between a total 80,000 and 90,000 specifications. Furthermore, considering that the 3GPP project alone resulted in over 14,000 specifications, some practitioners believe that the total figure is now closer to 100,000 units.

(2) It is impossible to calculate the financial savings enabled by this option. In theory, one could attempt to calculate them on the basis of econometric

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70 A list of possible attributes is set out in point 2.1 of the Commission's White Paper on "Modernising ICT Standardisation in the EU – The Way Forward", COM(2009)324 of 3.7.2009. It should be noted that, for those standard-setting agreements which risk creating market power, the Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements [C(2010)9274 of 14.12.2010] set out the conditions under which such agreements would normally fall outside the scope of Article 101(1) TFEU.

71 See WTO, World Trade Report, 2005

estimates of the premium price commanded by control of proprietary standards enabling network effects in the software market in the past which were found as high as 18% - 46% of costs. Public procurement is deemed to account for a total 14% of total ICT expenditure in Europe that is currently estimated at around € 670 billion. The software market is an estimated € 60-70 bn (of which an estimated 16-20% procured in public markets) which extends to exceed €200 bn if related consulting services are included, as these are usually bundled to the provision of software. In practice, however, there are too many uncertainties in this model to come to solid estimates.

Other **intangible benefits** include the fact that enhanced standardisation for interoperability purposes has the potential to speed up the adoption of IT solutions in the public sector and allow the provision of better services through diversified channels. Referencing to Fora and Consortia Standards can hasten the conception and integration of information systems. The reduction of delays due to the adoption of common norms and standards allows a quicker implementation of online services. Better interoperability decreases on a case by case basis the costs of misunderstanding, the cost of operating semantic transformations, the costs of establishing platforms to transport and translate date, the cost of developing interfaces between applications, the cost of maintaining developments and settings and configurations which are parameters known to influence investment decisions.

The public **consultations** gave very mixed results on this option. In one consultation, the large majority of respondents are against the possibility to refer to the documents developed by fora and consortia in legislation and public policies. However, the positive replies to this question came mainly from companies and associations working in the ICT domain. In the other consultation, most respondents were in favour of this option.

6.3.4. Policy Option 3.C: Grant Selected Private fora and consortia the Status of Recognized Entities under Directive 98/34/EC.

The impacts of this option depend on a number of external factors, such as the willingness of the selected fora and consortia to be recognised and to submit to controls with respect to the WTO-criteria on standardisation. Fora and consortia might be reluctant to apply for recognition due to the additional cost of accreditation, its periodical renewal (e.g. cost for internal audit[72]) and the costs related to compliance with the process requirements and considerations regarding their "independence". In case of recognition, fora and consortia would have to comply with certain procedural aspects of formal standardisation which may slow down future standard development.

Obviously, these fora and consortia are subject to **competition law** to the extent that they can be considered to be an undertaking or an association of undertakings within the meaning of Articles 101 and 102 TFEU[73]. In that case, one should assess, under

[72] The magnitude of audit costs is difficult to determine, as no real equivalent of the accreditation system envisaged by this option appears to exist. However, based on parameters referred to the American National Standards Institute (ANSI), one could envisage a figure in the order of US$ 10,000 to US$ 15,000 (between around 7.000 to 11.000 €)

[73] See judgment of 12 May 2010 in Case T-432/05, EMC Development AB v. Commission.

Article 101(1) TFEU, whether an agreement between undertakings, which is capable of affecting trade between Member States, has an anti-competitive object or actual or potential restrictive effects on competition. In addition, one should then determine , under Article 101(3) TFEU, which only becomes relevant when an agreement is found to be restrictive of competition within the meaning of Article 101(1), the pro-competitive benefits produced by that agreement and to assess whether those pro-competitive effects outweigh the restrictive effects on competition[74].

The recognition of private fora and consortia would pose some **notable governance and co-ordination problems**. In general terms, the areas of overlap between the various recognised standardisation organisations would increase coordination costs. Based on some conservative estimates, the largest fora and consortia would have to withdraw, as a result of the recognition, from 3% to 5% of their standard portfolios, with cumulative effects leading to a total possible 10%-30% as long as their number increases. It is unclear whether recognition would produce negative effects on fora and consortia in terms of reduced room for manoeuvre and thus possible lost opportunities.

Private fora and consortia usually have sizeable membership fees, which could **discourage SME participation in the standardisation process and represent discrimination**. The costs for a European SME of participating as a member in a given private standardisation project can easily increase by 50% to 100% annually as compared to the prevailing practice within an ESO. The size of this additional burden tends to decrease the higher the number of projects an SME is interested in, but certainly represents a barrier for niche producers with very specific interests. This explains previous research findings that it is generally ICT SME with a broad IPR portfolio that tend to follow standardisation, including the works of the private fora and consortia. Membership dues are in any case a relatively minor cost of participating in standards work, compared to the cost of participation in standardisation activities. All in all the number of SME that have enough resources to take part into ICT standardisation activities is very unlikely to exceed a few hundred across Europe. The main competitive advantage these SME without IPR could draw from the participation in a standard developing organization relates to the information value of such participation with regard to the latest technological developments and the transient competitive edge this can provide. To this end, a crucial distinction should be made in the degree of “openness” between those private consortia that make draft specifications available for comment very early in the standardization phase and therefore do not discriminate as far as access to strategic knowledge is concerned and those who give this possibility to members only. Finally, the consolidation and concentration process of consortia activities in ICT standardisation decreases the variety of options, especially for small- and medium-sized enterprises, to join consortia. Their relative influence in the reduced number of (probably larger) consortia will probably also be lower. On the other hand, monitoring consortia activities will be easier through concentration on a smaller number of consortia, which have not shifted the focus of their activities. In total, small and medium-sized enterprises would face increased challenges in actively participating in consortia, but fewer problems in passively observing their activities.

[74] See Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements [C(2010)9274 of 14.12.2010].

Consequently, larger companies are more likely to gain by their active standardisation engagements.

In any event, **this option would require careful scrutiny of the procedural guarantees offered by the fora and consortia**, as part of the selection process. A key characteristic of some consortia is that the commercial considerations of their members play an overt role in influencing standard development, whereas in the case of traditional standardisation bodies such motivations, even if not necessarily less significant, are more covert. Therefore, although such consortia often follow the same rules as the official standardisation bodies, the rules are adapted to the interests of the community that the consortia serve. For example, although the consensus principle is often part of the private standard consortia voting system, the range of actors involved is much smaller, hence limiting the array of technical and commercial interests involved in developing the standard. Participation can be also strictly controlled and limited to a particular category of actors, whereas transparency can be restricted to the members of a particular community. In addition, the lack of official status means that there is no need to follow strictly all the stages in the bureaucratic process, in the same way that standardisation bodies must. At the same time, it also means that such organisations have to account only to their members. Consequently, consensus is easier to achieve and standard development is quicker. At the same time, the access to standards use as well as standardisation process can be severely restricted, and the benefits are more than often unequally distributed among the members. Furthermore, there is a risk that a broad recognition of fora and consortia would lead to the opposite result to that which European standardisation aims to achieve. European standardisation aims inter alia at eliminating conflicting standards, through cooperation and coordination. However, fora and consortia develop standards in similar or even identical fields so that the likelihood of conflicting standards would increase.

This option would entail **additional costs for the fora and consortia**, especially in demonstrating compliance with WTO-criteria and in particular for the process requirements and considerations regarding their “independence”. In case of recognition, the fora and consortia would have to comply with the procedural aspects of formal standardisation and would have to fulfil the duties of a recognized body. Neither of these aspects adds value to the content and quality of the standard. It would also require **additional resources from the EU budget** since it would be reasonable for organisations complying with all criteria to be entitled to benefit from a financial contribution from the EU.

This option was not supported in the **consultation** process. Respondents highlighted that further fragmentation of the European standards landscape would place a greater time, cost and effort burden on stakeholders (especially weaker ones) to be able to monitor, follow and / or participate in relevant standards development activities, which would lead to more scattered, less effective stakeholder participation and ultimately more situations where standards are developed without relevant stakeholder involvement. There were also concerns, especially from stakeholder organisations, about the operational implications of an expanded system. In particular, their concerns relate to (i) barriers to accessing other F&C (higher fees, less appropriate tools/processes), (ii) the strength of certain interest groups in other F&C and opportunities for private parties to manipulate standardisation outcomes for their own interests, (iii) the increasing difficulty in delivering a single coherent

standardisation response to a market need, risk of conflicting standards / requirements and greater difficulties in complying with them, and (iv) decreased legitimacy, respect for and trust in the formal standardisation process.

7. COMPARING THE OPTIONS

The policy options for the three problem areas are compared below according to the criteria of effectiveness (i.e. to what extent they fulfil the specific objectives), efficiency (i.e. at which costs they do so) and coherence with other EU policies. Given the qualitative nature of the impact assessment, the following scores were chosen for illustrative purposes: low, medium and high.

7.1. Problem 1: the process for adopting European standards requested by the Commission is not fast enough

COMPARISON OF THE OPTIONS FOR PROBLEM 1		
OPTIONS	**EFFECTIVENESS**	**EFFICIENCY**
Policy Option 1.0: Base-line scenario	N.A	N.A
Policy Option 1.A: specify deadlines on the delivery of European standards	**HIGH**: very positive economic benefits. In some cases, ESOs could decline requests for new items for standardisation, in particular for technically complex or contentious items. Possible negative impacts on the consensus about the content of the standard, unless specific measures are taken to ensure involvement of SMEs and societal stakeholders.	**HIGH**: the increase of the costs of carrying out the work at a faster speed is moderate compared with the very positive economic benefits.
Policy Option 1.B: create a European Agency for Standards that would manage the standard-setting process	**LOW**: the possible benefits of a closer supervision by the European legislator and a more efficient overall structure in 1 organisation would be outweighed by the need for expertise, consensus and respect for the common principles about standardisation. Faster development of EU standards would reduce costs linked to the fragmentation of the internal market and to conformity assessment procedures.	**LOW**: This would lead to an additional annual cost for the EU budget of at least €20,000,000. The extra cost for the EU budget related to a standardisation agency could be higher than the current cost.

	Gains could be smaller than for option 1.C as the speed gained through this option is less clear. No support in the public consultation.	
Policy Option 1.C: transparent and simplified procedures for harmonised standards and other European standards requested by the Commission	**HIGH**: the overall period for the standardisation work could be reduced with 1 year so that the harmonised or any other standard requested by the Commission could be available to businesses much earlier. Businesses would benefit earlier from the presumption of conformity granted to those using such harmonised standards No negative impacts on ESOs which supported the idea.	**HIGH**: no extra costs could be identified.

Consequently, options 1.A (provided that specific measures are taken to ensure involvement of SMEs and societal stakeholders) and 1.C are clearly dominant from the perspective of effectiveness and efficiency.

7.2. Problem 2: Underrepresentation of SMEs and societal stakeholders in the European standardisation process

COMPARISON OF THE OPTIONS FOR PROBLEM 2		
OPTIONS	**EFFECTIVENESS**	**EFFICIENCY**
Policy Option 2.0: base-line scenario (i.e. the financial contribution to SME and societal stakeholders representation	N.A.	N.A.
Policy Option 2.A: Facilitate direct public representation of SMEs and societal stakeholders within the European standardisation organisations	**MEDIUM**: the most effective, but also most time and resource intensive, approach. It requires a strong technical understanding of proposed standards and their context and a very significant commitment of time. Negative impact on information exchange with other interested SMEs and societal stakeholders. Strong concerns of interested parties with respect to principle of national delegation. Negative impact on problem	**LOW**: Membership dues are in any case a relatively minor cost of participating in standards work, compared to the cost of participation. Risk of fragmentation.

	1 (trade-off and coherence problem).	
Policy Option 2.B: Grant voting rights to organisations representing SMEs and societal stakeholders within the European standardisation organisations	**MEDIUM**: the effectiveness is high but moderated by the uncertainty about the feasibility of this option. Support during the public consultation.	**HIGH**: Some organisations representing SMEs and societal stakeholders already participate, as an associate member or equivalent in CEN and CENELEC, or as members in ETSI. Voting rights could strengthen the position of these organisations.
Policy Option 2.C: Strengthen the position of organisations representing SMEs and societal stakeholders within the ESOs by providing for the possibility of an operating grant	**HIGH**: strong impetus to encourage ESOs to ensure that the opinions of organisations representing SME and societal stakeholders s are adequately taken into account during the technical work on European standards. Positive impact on information exchange with other interested SMEs and societal stakeholders. Large support during the consultation.	**HIGH**: The possibility of continuous financial support would consolidate the position of representing organisations in the ESOs, provided that an exception to the principle of degressivity was granted and the current level of funding maintained.

Thus, option 2.C is clearly dominant from the perspective of effectiveness and efficiency.

7.3. Problem 3: "Fora and Consortia Standards" cannot currently be referenced in public procurement of ICT.

COMPARISON OF THE OPTIONS FOR PROBLEM 3		
OPTIONS	**EFFECTIVENESS**	**EFFICIENCY**
Policy option 3.0: base-line scenario	N.A	N.A.
Policy Option 3.A: Revive the implementation of the mechanisms of Council Decision 87/95/EEC concerning public procurement and the policy dialogue	**LOW**: absolute lack of legal certainty. No support during the consultation process.	**LOW**: extra administrative burden for ESOs and an additional cost for the EU-budget
Policy Option 3.B: Allow for the referencing of "Fora and Consortia Standards"	**HIGH**: this option would have a general positive impact. Although some concerns were expressed	**HIGH**: the cost-effectiveness of this measure is optimal if these standards are selected and assessed on

	during the consultation, the ICT businesses expressed their full support.	the basis of predefined criteria or attributes and following consultation of interested parties
Policy Option 3.C: Grant Selected Private fora and consortia the Status of Recognized Entities under Directive 98/34/EC	**MEDIUM**: depends on a number of external factors which are difficult to assess. Important negative side-effects on SME and stakeholder participation in the standardization process (trade-off and coherence difficulties for problem 2). Little support during the consultation.	**LOW**: costly procedures, notable governance and coordination problems.

Therefore, option 3.B is clearly dominant from the perspectives of effectiveness and efficiency.

7.4. Preferred options

Consequently, it is suggested that the following options be retained:

- The combination of policy Options 1.A (deadlines on the delivery of European standards) and 1.C (Transparent and simplified procedures for harmonised standards and other European standards requested by the Commission);

- Policy Option 2.C: Strengthen the position of organisations representing SMEs and societal stakeholders within the ESOs by providing for the possibility of an operating grant;

- Policy Option 3.B: Allow for the referencing of "Fora and Consortia Specifications".

None of these options has negative side-effects.

The three preferred options have all a positive impact on competitiveness, while options 1.A and 1.C having the strongest impact.

– Options 1.A and 1.C: In the case of shorter and more transparent process for development of harmonised standards, businesses can use the presumption of conformity due to the compliance with the standard early on and do not have to demonstrate compliance with essential requirements. Therefore businesses save costs and conflicting national standards could be avoided.

– Option 2.C: SMEs are an important source of innovation. Maintaining and enhancing their participation con tribute to the development of innovative standards and to mitigate risks of proprietary rights

– Option 3.B: In as much as risks regarding proprietary technologies are mitigated, the referencing of Fora and Consortia Standards can be expected to enhance the

competitiveness of enterprises, in particular the European ICT industry thanks to their specific standardisation coverage and speed.

7.5. Choice of legal instrument

The suggested options as well as the simplification items do not require amendment of the legislation of Member States. These items only concern the ESOs, the NSBs, organisations representing SMEs and societal stakeholders, and the EU Institutions. Therefore, a Directive would not be an appropriate instrument in this case.

The legal instrument would have to be of general application, in particular for the part on the use of Fora and Consortia standards in procurement which would have to directly applicable in all Member States. In addition, the legislative instrument would contain a number of obligations that would be directly applicable to the ESOs, the NSBs, organisations representing SMEs and societal stakeholders, and the Commission. Therefore, the most appropriate legal instrument would be a regulation.

8. MONITORING AND EVALUATION

The Commission will publish an annual report on the implementation of the entire regulation. This report will be partly based on the information gathered by the Commission and the regular reporting by the ESOs, especially regarding the evolution of problems 1 and 2.

The length of the European standard-setting process would be measured on the basis of the information about the length of the actual standardisation process which the ESOs already annually provide to the Commission, the provisional date of issuing a mandate as indicated in the Commission work programme and the date of publication of the reference of the harmonised standard in the OJ or the (partial) withdrawal following an objection, whichever the latest. However, it would be necessary to launch a further evaluation, at fairly short notice, to assess if additional measures could be taken to make European standard setting (including for the European standards that are not requested by the Commission) faster and more efficient.

Organisations representing SMEs and societal stakeholders would have to provide, as part of the annual reporting about the activities partly funded by the EU grant, detailed information about their activities in the standardisation bodies as well as an evaluation of the extent to which their points of view are actually taken into account in standardisation work. The reporting by the ESOs on the evolution of the problem of under-representation of SMEs and societal stakeholders in the European standardisation process might require a specific contribution from the NSBs, especially as regards the representation of SMES and societal stakeholders in mirror national standardisation committees and the actions in place at national level to support participation of SMEs and societal stakeholders.

The references of the selected Fora and Consortia standards in calls for tenders issued by public authorities will be gathered as an indicator for the evaluation of the solution to problem 3.

In addition, it would be appropriate to provide for a fuller evaluation of the functioning of the Regulation after a few years. This would be particularly relevant in measuring the evolution of problem 3 where the need to increase EU competitiveness by promoting the rapid adoption of pan-EU interoperable products and services in public procurement would require a further evaluation of the ICT standards used in public procurement and the uptake of e-Government services.

By 2013 at the latest, an independent review will be launched to measure and assess if the strategic objectives of the Strategy on European standardisation are being achieved, as set out in the communication COM(2011)311.

9. ANNEXES

9.1. ANNEX 1 – CONSULTATION AND EXPERTISE

9.1.1. Standardisation system – external studies

In 2008, the Commission services commissioned a study to assess the "**Access to standardisation"**[75] The objective of the study was to evaluate to what extent the current European Standardisation System was open to participation by all necessary stakeholders. The study did not only evaluate the system as it is, but also how stakeholders themselves perceived it. The time required for participation, travel and subsistence costs as well as the fees were identified as the main barriers.

Detailed barriers to participation by specific groups of stakeholders as mentioned by standardisation organisations are presented in Annex III.

In January 2009 the Commission established an independent expert group, the **Expert Panel for the Review of the European Standardisation System (EXPRESS)**, with the aim of making strategic recommendations regarding standardisation in Europe for the decade to come.

The Panel was composed of 30 experts from European, national and international standards organisations, industry, SMEs, NGOs, trade unions, academia, fora and consortia and public authorities from EU Member States.

EXPRESS delivered its report "Standardisation for a competitive and innovative Europe: a vision for 2020"[76]to the European Commission in February 2010

9.1.2. ICT – external studies

In 2006, the Commission launched a study[77] to analyse the current European ICT landscape and standardisation policy and to make recommendations for future development. The final report of the study was published in July 2007. Following a web-based public consultation on the results, the comments received were published on the Europa website and discussed at an Open Meeting in February 2008 where broad support for policy changes was expressed.

In order to support the assessment of likely impacts of policy options, DG ENTR contracted a study on "Future Standardisation Policy: Impact Assessment of Policy Options" in January 2009. The final report was presented in January 2010[78].

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75 http://ec.europa.eu/enterprise/policies/european-standards/files/standards_policy/access_to_standardisation/doc/access_to_standardisation_study_eim_en.pdf

76 http://ec.europa.eu/enterprise/policies/european-standards/files/express/exp_384_express_report_final_distrib_en.pdf

77 Study on "Specific Policy Needs for ICT Standardisation" by DLR Piper, Belgium

78 Report presented by the Italian consultant Economisti Associati and published on the DG ENTR website

9.1.3. Main stakeholders

The main stakeholder groups are as follows:

– International Standards Bodies – ISO, IEC, ITU

– European Standards Organisations (ESOs) – CEN, CENELEC, ETSI. A more detailed description of ESOs is presented in Annex V

– National Standards Bodies (NSBs) – which are members of CEN and CENELEC

– Member State Authorities (MSA) – National authorities from Member States of the European Standardisation System, including EU Member States, plus EFTA countries and EU candidate countries. They are represented on the Senior Officials Group for Standardisation (SOGS),

– Third Countries National Standardisation Organisations – American National Standards Institute (ANSI)

– Fora and Consortia (FORA AND CONSORTIA) – private organisation developing standards outside the official ESOs system

– Commission Services (EC) – responsible for European standardisation policy

– Industry Associations(including ICT, software and ICT solution using industries)

– Societal stakeholders (consumer and environmental organisations, unions, SME's and employers representatives) – ANEC, ECOS, ETUI, NORMAPME,

– Companies (including SMEs) – standards' users

– EFTA secretariat

9.1.4. Results of the publication consultation on the Standardisation package

9.1.4.1. Executive summary

Within the scope of the Impact Assessment exercise concerning the reform of the European Standardisation System, this public consultation was carried out between March 23rd and May 21st 2010.

The aim of this consultation was to give all standardisation stakeholders the possibility to express their views on the current functioning of the European Standardisation System and on the possible improvements that could be implemented.

Due to the high interest in standardisation and a large publicity, this initiative has been very successful in terms of number of replies. A total number of 483 answers from various categories and nationalities of stakeholders were received. A detailed analysis of the respondents is presented in point 3 of this report.

The 14 questions were grouped into 4 main topics:

- Adaptation of the European Standardisation System to the rapid evolution of technologies

- Avoidance of the creation of new technical barriers to trade for products and services in the internal market

- Adaptation of the European standardisation system to new markets and societal challenges

- Cost of standards

As a summary of the replies, we can conclude that, independently from the category of stakeholders (citizens, companies, industry associations, public authorities, organisations of public interest, European and National Standards Bodies), there is a general satisfaction with the current structure and functioning of the European standardisation system.

Respondents clearly highlight that it is vital to preserve the national delegation principle. In addition to this, they are not in favour of opening up the process to new standardisation actors (e.g., fora and consortia) because of potential concerns in terms of the transparency and limited stakeholder involvement.

Respondents also underline the beneficial inputs and outcomes which derive from the public-private partnership nature of the system currently in place and they are concerned with any potential interference of Brussels-based authorities.

Last but not least, from the replies that have been collected, a strong need emerges to further promote the importance of standards in general and to make standards more user-friendly and accessible, also in terms of purchasing price.

In general, respondents showed their appreciation for this public consultation initiative and the possibility they had to express their views on the review of the European standardisation system.

9.1.4.2. Respondents

In the period from March 23rd 2010 to May 21st 2010, a total number of 483 replies were sent to the three functional mailboxes for this public consultation (citizens, public authorities and organisations). The distribution of replies amongst the different categories of stakeholders is as follows:

	Number of responses	% of total respondents
Citizens	68	14,1%
Companies (it includes 19 SMEs)	158	32,7%
ESOs & NSBs	29	6,0%
Industry associations	162	33,5%
Organisations of public interest (it includes NGOs, environmental and consumer associations and trade unions)	17	3,5%
Public authorities	39	8,1%
other categories	10	2,1%
TOTAL	483	

In geographical terms, Germany is the biggest contributor with 213 replies.

Other bigger contributors are as follows: France (58/483 - 15%), UK (25/483 - 5,2%) and Spain (17/483 - 3,5%)

Out of the 10 categories of stakeholders reported above, the following six ones were selected for the purpose of this analysis:

	Number of responses	% of total respondents
Citizens	68	14,1%
Companies	158	32,7%
ESOs & NSBs	29	6,0%
Industry associations	162	33,5%
Organisations of public interest (it includes NGOs, environmental and consumer associations and trade unions)	17	3,5%
Public authorities	39	8,1%

A breakdown of the results by these six categories will be provided for each question.

It must be mentioned that some of the replies present are similar and/or often identical. For instance, this is the case of the 26 replies that were sent by companies belonging to the Saint Gobain Group, or the 21 replies that were sent by companies which are part of the German Industry Association VDMA.

In those cases, each single reply is considered as an individual one, thus following the same policy that was adopted for the publication of the replies on the Europa website. Actually, it would be unfair not to take into account the contribution of a single reply just because it comes from a group or just because a reference is made to the opinion of an association.

It is true that this choice will give a considerable weight, in statistical terms, to the opinions of these associations or groups. However, it would be discriminatory to ignore the contribution of one of these replies – that, once again, come from individual entities - to this public consultation.

9.1.4.3. Methodological approach

The consultation document and the fourteen questions it contains aimed at gathering stakeholders' opinions and views on a potential review of the European Standardisation System. The final goal was to make stakeholders react to some propositions of change and suggest possible alternative solutions.

Open-ended questions were identified in the majority of cases as the most adequate means to accomplish this goal, since they allow respondents to make comments and observations supporting their position with regard to one particular topic.

An illustration of the results of this consultation with a breakdown by category of respondents will be presented in the following section of this document. No breakdown by country was undertaken since it does not seem relevant for the purpose of this public consultation.

Due to the large amount of replies, far beyond initial expectations, the need to facilitate analysis of the responses imposed some methodological constraints. The qualitative nature of this consultation was preserved and the opinions and suggestions expressed by stakeholders were duly noted down and taken into account. At the same time, when feasible an attempt is made to provide a sort of quantitative/statistical analysis of the responses so as to make the main results of each question easier to access and comment on.

Therefore, for some of the questions (1-2-3-5-10) a "yes"/"no" or "not possible to define" analysis was carried out. For some other questions (4-6-7-8-9), where this analysis could not be conducted, a "trend analysis" was carried out. To be more precise, in addition to the qualitative analysis, each individual reply was classified according to the following three categories:

- Category "No": the reply denotes a general indication not to change or modify the system in place with regard to the specific issue explored through the question;

- Category "Yes": the reply denotes a general indication to modify or change the system in pace with regard to the specific issue explored through the question;

- Category “Unclear/No possible to define”: the respondent does not take a clear position on the possibility to change the system in place.

The results of this quantitative analysis will not reflect the richness of the replies. Nevertheless, such statistical analysis may provide a useful indication of stakeholders’ general attitude with regards to a specific topic.

9.1.4.4. Results

For each question, a summary table indicating the percentage of respondents - with a breakdown by the chosen six categories of stakeholders – is presented. Respondents’ views – in terms of Yes/No/NotDefined – are synthetically reported in the same table for those questions where this classification was possible (this is the case of question 1-2-3-5-10). The percentages for this classification refer only to those respondents who actually provided a reply to the question.

In order to provide the reader with the same background information that respondents could find in the consultation document, the introductory paragraphs for each section of questions are provided in italics.

Avoidance of the creation of new technical barriers to trade for products and services in the internal market

The emergence of national service standards and alternative standardisation documents (like Publically Available Specifications) developed by National Standards Organisations (NSO) constitutes a risk of technical barriers to trade within the internal market. Since the 80’s, the Commission and the standardisation bodies (ESOs and NSOs) shall be informed – in the field of products - of the new subjects for which NSOs have decided, by including them in their standards programme to prepare or amend a standard. The same procedure could be envisaged for national programmes of service standards (including process standards) and alternative standardisation documents.

1) Do you think that service standards (including process standards) and alternative standardisation documents should be included in the scope of Directive 98/34/EC or its successor?

Services standards (including process standards) in the scope of Directive 98/34/EC or its successor:

	Number of responses	% on total	% Yes	% No	% ND *
All	411	85%	74%	20%	6%
Citizens	51	75%	86%	10%	4%
Companies	140	89%	75%	20%	5%
ESOs & NSBs	29	100%	97%	0%	3%

Industry associations	137	85%	63%	33%	4%
Organisations of public interest	15	88%	47%	20%	33%
Public authorities	32	82%	97%	0%	3%

*not possible to define

Alternative standardisation documents in the scope of Directive 98/34/EC or its successor:

	Number of responses	% on total	% Yes	% No	% ND *
All	411	85%	31%	61%	8%
Citizens	51	75%	37%	59%	4%
Companies	140	89%	41%	54%	5%
ESOs & NSBs	29	100%	28%	48%	24%
Industry associations	137	85%	26%	69%	5%
Organisations of public interest	15	88%	13%	80%	7%
Public authorities	32	82%	19%	75%	6%

*not possible to define

As the two tables above clearly show, respondents generally split this question into two separate ones.

On the one hand, most respondents are in favour of including service standards in the scope of Directive 98/34/EC or its possible successors. This is true for all the six categories of stakeholders and also for those 19 companies that registered as SMEs (75% is the percentage of "Yes" in their case, with just 19% of "No" replies).

On the other hand, 61% of respondents are against the inclusion of alternative standardisation documents. Actually, among all the categories, there is a general concern that these documents are the result of a process which does not reflect the views and opinions of all the relevant stakeholders. A more positive attitude towards the inclusion of alternative standardisation documents can be seen in the case of companies and industry associations working in the ICT field.

2) Are you aware of specific cases where national service standards and alternative standardisation documents have caused technical barriers to trade?

	Number of responses	% on total	% Yes	% No	% ND *
All	401	83%	12%	75%	13%
Citizens	51	75%	8%	82%	10%
Companies	139	88%	9%	82%	9%
ESOs & NSBs	28	97%	25%	71%	4%
Industry associations	132	81%	11%	73%	16%
Organisations of public interest	14	82%	14%	86%	0%
Public authorities	31	79%	35%	35%	30%

*not possible to define

Three quarters of respondents are not aware of any specific cases where national service standards and alternative standardisation documents have caused technical barriers to trade. A difference must be pointed out in the case of public authorities, where replies are equally split among those respondents who are aware of specific cases and those who are not.

The cases of technical barriers mentioned in the replies have to do, *inter alia*, with integration requirements for migrant workers, interoperability in the railway domain, medical equipments and technologies, education of sport trainers and planning and building-related activities in the construction sector. The fields of tourism, e-government, e-health and labelling are also mentioned.

It must be said that, in some of the "No" replies, while replying that they are not aware of specific barriers due to existing national standards and/or standardisation documents, some stakeholders point out that the lack of harmonised standards does represent an impediment to the effective provision of a specific service. For instance, some concerns are raised about ticketing and booking procedures for cross-border transportation of passengers in the railway sector.

Adaptation of the European standardisation system to the rapid evolution of technologies

The traditional standardisation process lasts an average of 1 to 3 years. This pace very often does not correspond to the speed with which new technologies are developed, and some sectors have been reluctant to ask the standards organisations to develop standards, even if such standards would have contributed to extend their market or rationalise their processes. Others, especially the ICT sector, have developed interoperability specifications in fora and consortia, outside the ESOs as described in the Commission White Paper – Modernising ICT standardisation in the EU – the Way Forward. However, neither the current legal framework of European standardisation (Decision 87/95/EEC), nor the rules on public procurement allow referencing of such fora and consortia specifications in regulations of public policies.

3) For areas other than Information and Communication Technology (ICT), should it be possible to refer to documents developed by fora and consortia in legislation and public policies? If it should, how should it be implemented?

	Number of responses	% on total	% Yes	% No	% ND *
All	421	87%	13%	83%	4%
Citizens	52	76%	6%	87%	7%
Companies	146	92%	13%	84%	3%
ESOs & NSBs	29	100%	10%	90%	0%
Industry associations	143	88%	15%	81%	4%
Organisations of public interest	13	76%	38%	62%	0%
Public authorities	32	82%	9%	81%	10%

*not possible to define

As clearly emerges from the table, the large majority of respondents are against the possibility to refer to the documents developed by fora and consortia in legislation and public policies. This is true also for the sub-category of the 19 SMEs, where the percentage of "No" replies is equal to 94%.

Respondents recognise that these documents are already part of ICT standardisation and they generally say that they understand this inclusion because of the peculiarities of the sector. However, they oppose having this option in the case of standardisation in general. Respondents explain their opposition by referring to the nature of the actors which produce these documents and to the procedures these actors follow in the standard development process. In particular, responses tend to highlight the

following potentially problematic issues: the small number of stakeholders involved in these fora and consortia, and the limited transparency of the internal processes and procedures. According to stakeholders, one of the risks is the official recognition of the decisions made by a small number of highly influential actors.

The issues of transparency and limited stakeholder involvement are also mentioned in many of the replies which are in favour of this inclusion. Actually, conformity to conditions of transparency and openness is often indicated as the key implementation requirement.

In general, we observe that respondents appear quite open to the possibility of using these documents as a starting point for discussions in the standardisation processes within officially recognised standards development bodies.

Finally, it must be said that many positive replies to this question tend to come from companies and associations working in the ICT domain. This can be easily understood since the inclusion of documents developed by fora and consortia is already accepted as required for ICT standardisation.

4) How could ESOs and NSOs be encouraged to accelerate their standards development process? Should for example the EU financing for standardisation be subject to conditions in terms of speed of delivery whilst maintaining the openness of the process?

	Number of responses	% on total
All	416	86%
Citizens	50	74%
Companies	144	91%
ESOs & NSBs	29	100%
Industry associations	143	88%
Organisations of public interest	13	76%
Public authorities	31	79%

The analysis of the main trends shows that 86% of respondents do not wish to have the EU's financing of standardisation subject to conditions of speed of delivery. This is true for each one of our six categories of stakeholders (80% of citizens; 92% of companies; 84% of industry associations; 65% of public authorities; 90% of European and national standards bodies and 92% of public interest organisations) and for the 19 SMEs as well (in this case, the percentage of replies indicating an opposition is even equal to 100%).

There is a general tendency to perceive the time needed for the standard-setting and definition process as reasonable in most cases. Increasing speed is often perceived as having a negative impact on the quality of the outcome of the process.

If, however, a need emerges to further speed up the process, respondents say that possible speed-related conditions in EU financing would not improve the situation. As an alternative, they suggest increasing the use of IT solutions in working methods, tools and processes of National and European Standards Bodies. Some replies also suggest concentrating resources and efforts only on the development of those standards which are relevant for market players.

Adaptation of the European standardisation system to new markets and societal challenges

European standardisation has been developed on the model of the international standards organisations, to contribute to rationalisation of production, growth of labour productivity, opening of markets and safety of products. Globalisation, new global challenges, "Better regulation" public policies, new societal demands as well as a growing share of services in the global economy and the boosting of innovation to resolve the current economic crisis request standardisation to adapt its traditional structures.

Standards remain voluntary instruments. Their effect depends on their credibility and of the level of consensus that they represent. The current diversification of the use of standards requires a broadening of the range of partners involved in the standardisation process, therefore more openness, transparency and balanced representation.

Standards facilitate global trade and access to markets. Standards need to be accessible to all users, and the availability of translations of standards can help disseminate new technologies.

5) Should the WTO principles of transparency, openness, impartiality, consensus, efficiency, relevance and consistency[79] be integrated in the legal framework of European standardisation (especially in EU Directive 98/34/EC or in its successor)? How should this be implemented?

	Number of responses	% on total	% Yes	% No	% ND *
All	415	86%	32%	54%	14%
Citizens	50	74%	16%	74%	10%
Companies	143	91%	17%	61%	22%

[79] As approved in the Decision of the Committee on principles for the development of international standards, guides and recommendations with relation to article 2, 5 and annex 3 of the WTO/TBT Agreement (G/TBT1/rev.8 23 may 2002).

ESOs & NSBs	29	100%	31%	48%	21%
Industry associations	140	86%	39%	51%	10%
Organisations of public interest	14	82%	79%	14%	7%
Public authorities	33	85%	61%	27%	12%

*not possible to define

It can be observed that more than half of the respondents are against the integration of WTO principles of transparency; openness, impartiality, consensus, efficiency, relevance and consistency into the legal framework of European standardisation (the same trend can be observed in the case of the 19 SMEs, where the percentage of "Nos" amounts to 82%). Respondents tend to say that these principles are already followed and adopted by standards bodies at both national and European level. The explicit inclusion of these principles within European legislative documents – respondents indicate - would just lead to a multiplication of the numbers of actors involved in the European standardisation system and to the consequent official recognition of documents elaborated by organisms like fora and consortia. As already observed, the activity of these actors and the documents they produce is generally criticised for a lack of transparency, openness and balanced representation.

It can be observed that percentages are different in the case of public authorities and NGOs/environment/consumer/public interest organisations. However, this difference can be explained by the fact that these categories of respondents appear to be more focused on the relevance of these principle in itself and are therefore mainly in favour of their explicit inclusion in legislation documents.

6) How could the participation of Consumers' organisations, NGOs, Trade Unions and social partners, and SMEs be best promoted? What should be the role of public authorities (European Commission and Member States) in supporting such a participation in a transparent, open, impartial, consensual, efficient, relevant and consistent European standardisation system?

	Number of responses	% on total
All	418	87%
Citizens	49	72%
Companies	143	91%
ESOs & NSBs	29	100%

Industry associations	144	89%
Organisations of public interest	15	88%
Public authorities	32	82%

The analysis of the main trends shows that 69% of respondents declare that, even if the national delegation principle already guarantees a good level of involvement, the participation of consumer organisations, environmental NGOs, trade unions and social partners, and SMEs within standardisation bodies and committees should be further promoted. This is true for 78% of citizens; 58% of companies and 65% of industry associations. The majority of public authorities (97 %) European and national standards bodies (90%) and in the case of NGOs/environment/consumer/public interest organisations (93%). are in favour of further participation. Favourable replies are in the majority (71%) also in the case of the 19 SMEs. In the case of SMEs, this percentage may look lower than expected but is probably due to the fact that some SMEs have reported the opinion of the industry associations they are part of, and, as figures show, industry associations tend to be already quite satisfied with the current level of stakeholder participation.

Financial support to participation by public authorities, reduced membership and participation fees and awareness raising initiatives are the most frequently suggested solutions in order to better promote the participation of consumer organisations, NGOs, trade unions and social partners, and SMEs. Stakeholders also suggest modifying the voting procedures within standardisation bodies in order to further stimulate the setting-up of mixed groups. A revision of the list of participants aiming at a further inclusion of under-represented areas of civil society, an increased use of IT tools and technologies and a comparison of best practice experiences in Europe are also suggested.

It must also be said that a minority of respondents (large companies, mainly) are against the option of financially supporting the less represented stakeholders, since this could be viewed as a discriminatory measure in relation to other actors.

7) How could the national standardisation organisations deepen their cooperation, and mutualise their activities? Could the following tasks be shared amongst several national standards organisations? a) Management of the Secretariats of Technical Committees; b) Notification of new national standardisation projects, c) Promotion/Sales of standards or d) Other?

	Number of responses	% on total
All	383	79%
Citizens	49	72%
Companies	137	87%

ESOs & NSBs	29	100%
Industry associations	126	78%
Organisations of public interest	5	29%
Public authorities	32	82%

The analysis of the main trends shows that three quarters of respondents (75%) are opposed to changes with regards to the current level of cooperation among the NSOs. Favourable replies are only 12% in the case of citizens; 8% for companies; 10% for industry associations; 13% for public authorities; 3% for European and national standards bodies and 20% for public interest organisations). This is true for the 19 SMEs as well, where 76% declare to be satisfied with the situation as it is.

In order to understand this "negative" attitude from respondents, two things must be highlighted.

First, respondents in general declare that the level of cooperation among NSOs has already improved a lot. They also tend to affirm that the options suggested within the questions are already in place.

Second, many stakeholders fear that the way the question is formulated indirectly supports - or encourages support for - the establishment of a Brussels-based form of control (even in the form of a single European standardisation body) of the standardisation process. In the eyes of these respondents, this would generate more bureaucracy, costs, and might undermine the independence of standardisation actors. These concerns explain why many replies stress the importance of the national delegation principle and call for the preservation of the private-public partnership nature of the current standardisation system.

Without prejudice to the national delegation principle, how could the European Standards Organisations manage directly, on a case by case basis, some standardisation activities, especially some Technical Committees?

	Number of responses	% on total
All	394	82%
Citizens	50	74%
Companies	138	87%
ESOs & NSBs	29	100%
Industry associations	132	81%
Organisations of	11	65%

public interest		
Public authorities	28	72%

The analysis of the main trends shows that about three quarters of respondents (76%) are opposed to the idea of having European Standards Organisations manage directly, on a case by case basis, some standardisation activities, especially some Technical Committees. The percentage of replies in favour is just 6% in the case of citizens; 22% for companies; 10% for industry associations; 4% for public authorities; 7% for European and national standards bodies and 36% - slightly higher than the average - for public interest organisations. This is true also in the case of the 19 SMEs as well, where no one was in favour of this change.

As was the case for question No. 7, the fear of a potentially strong interference of Brussels-based authorities in the European standardisation process, and a consequent potential prejudice to the national delegation principle, justifies this opposition by respondents.

8) What support should the European Commission provide to facilitate the use of European standards as a means to open global markets? What would be the operational means that the Commission should use? (Support experts' participation in international standardisation activities, translation of European standards into extra-EU languages?)

	Number of responses	% on total
All	397	82%
Citizens	51	75%
Companies	142	90%
ESOs & NSBs	29	100%
Industry associations	124	77%
Organisations of public interest	14	82%
Public authorities	32	82%

Respondents tend to suggest the following measures to facilitate the use of European standards as a means to open global markets: supporting, also in financial terms, the participation of European experts in international standardisation activities; promoting the use of European standards in international trade agreements and in the working groups of international trade organisations, and providing translations of European standards in non-EU languages. With regards to this last measure, it must be said that a minority of stakeholders are opposed to it, since they believe that the English version is sufficient for use in international activities and that the European Commission should focus on guaranteeing the translation of standards in all EU languages.

9) Under which conditions do you think that the European Commission could launch, on a case by case basis, calls for tenders, open to the ESOs and to other organisations, to develop standards supporting EU policies and legislation?

	Number of responses	% on total	% Yes	% No	% ND *
All	408	84%	10%	83%	7%
Citizens	49	72%	4%	86%	10%
Companies	143	91%	8%	86%	6%
ESOs & NSBs	29	100%	0%	79%	21%
Industry associations	138	85%	13%	83%	4%
Organisations of public interest	13	76%	46%	46%	8%
Public authorities	30	77%	10%	83%	7%

*not possible to define

The analysis of the main trends shows that 83% of respondents are against the launch, on a case by case basis, of calls for tenders open to European Standards Bodies and other organisations aiming at developing standards in support of EU policies and legislation. This is true for all categories of stakeholders (86% in the case of citizens and companies; 82% in the case of SMEs; 83% of industry associations and public authorities; 79% in the case of European and national standards bodies), with the exception of public interest organisations, where both negative and positive replies score the same (46%).

As was the case for questions 1, 3 and 5, concerns regarding a potential increase in the number of actors involved in the European standardisation process and that these new actors (fora and consortia.) may not guarantee transparency and openness are the main reasons behind this strong opposition.

These concerns are reflected also in the case of the favourable replies, where it is strongly highlighted that every potential contractor resulting from these calls must strictly ensure a balanced and transparent consultation process.

10) What is, in your views, the most efficient level of participation in the process of Standards Development: National, European or International?

	Number of responses	% on total
All	416	86%

Citizens	49	72%
Companies	143	91%
ESOs & NSBs	29	100%
Industry associations	142	88%
Organisations of public interest	15	88%
Public authorities	32	82%

The analysis of the replies shows that there is a general tendency not to indicate a preference among the national, the European and the international standardisation level in terms of efficiency. All levels are seen as equally important and their efficiency is perceived as depending on the circumstances and factors taken into account.

At a general level, it is worth underlining that many respondents, even if they decided not to select it as the most efficient level of participation, took advantage of this question to strongly defend the important role of the national standardisation level. This level is seen as the one where the standardisation process really starts and where all the actors, even the small ones, are involved and can exert their influence.

Finally, in the case of those replies where a clear preference is expressed, we can observe some interesting relations between the preferred level of standardisation and the business sector in which the stakeholder is involved: for instance, operators of the construction sector tend to select the European level as the most efficient one, whereas the preference goes to the global level for respondents operating in the ICT sector.

11) In your opinion, is where is the major added value in European standardisation with respect to national standardisation?"

	Number of responses	% on total
All	406	84%
Citizens	47	69%
Companies	140	89%
ESOs & NSBs	29	100%
Industry associations	138	85%

Organisations of public interest	14	82%
Public authorities	32	82%

From the replies that were collected, it emerges that the development of harmonised standards, the removal of trade barriers and the creation of a single market represent by far the major added value of European standardisation. Companies and industry associations in particular benefit from a reduction of transaction costs, an increased level of interoperability and the development of a common technical language within the European market.

Cost of standards

The costs of purchasing standards have been identified as an important barrier to their use, especially by SMEs. Purchasing a full collection of standards is sometimes necessary to answer a call for tender, access specific markets or take full advantage of the benefits of the "New Approach" regulation. Some stakeholders consider that the price of standards – different in every National Standards Organisations - is too high with respect to their public interest function.

12) What are, in your views, the most serious barriers to the use of standards by enterprises: costs of standards (purchasing price)? Costs of operational implementation? Access to information? Knowledge of existing standards?[80]

	Number of responses	% on total
All	411	85%
Citizens	51	75%
Companies	145	92%
ESOs & NSBs	26	90%
Industry associations	143	88%
Organisations of public interest	8	47%
Public authorities	32	82%

[80] These barriers have been identified in the Study « Access to Standardisation » - EIM March 2009, commissioned by the European Commission

The replies indicate that the *lack of knowledge and awareness* about both the importance of the standardisation process and the content and field of application of standards themselves represent the most serious barrier to the use of standards. Stakeholders generally complain about the difficulty to access information about which standards to apply, the complexity of the technical language used, and the large amount of standards (and updates) that may concern one specific product.

Both problems accessing information and the complexity of technical language contribute to making *implementation costs* another key barrier to the application of standards. Stakeholders declare that some training would be needed in order to help market players, above all the smaller ones, access information concerning standards and understand which specific regulations directly concern the products they produce and sell.

Although the *price of standards* – in a draft classification of the most recurrent issues raised by respondents – ranks third after *lack of knowledge and awareness* and *implementation costs*, it does emerge as another major barrier to the use of standards. The price is perceived as too high, above all by smaller operators. However, it must be pointed out that it is not the price itself that appears to be the key issue. Actually, the problem is that for a specific product more than one standard is needed and previews of standards do not often provide buyers with a clear idea of the relevance of specific standards to their needs (in other words, they may end up buying standards they do not really need). Furthermore, compliance with standards is sometimes not a voluntary choice but *de facto* a mandatory one. Therefore, actors have no option but to buy standards.

Many respondents have the feeling they are paying for standards twice: firstly, they actually need to pay to be involved in the standardisation process; secondly, they need to pay to buy the outcome of the process they have been directly involved in.

Finally, respondents complain about the sometimes huge differences in the prices of the same standards among the different National Standards Bodies and the fact that they cannot choose where to make their purchase.

13) What could the standards organisations do, in addition to their current practice, to facilitate the access to standards, especially by SMEs?

	Number of responses	% on total
All	394	82%
Citizens	43	63%
Companies	140	89%
ESOs & NSBs	27	93%
Industry associations	139	86%

Organisations of public interest	7	41%
Public authorities	32	82%

It can be observed that respondents generally took advantage of this question to put forward their solutions to the issues raised in question No. 13.

Concerning *lack of knowledge and awareness*, respondents suggest increasing the communication effort to promote the importance of standards and to illustrate the benefits these voluntary standards generate for a company. Standards bodies are also invited to adopt a more common technical language, to provide more user-friendly summaries and to make use of IT technologies and solutions (eg., simple email alerts) in order to keep market players up-to-date with newly developed standards. Respondents also suggest emphasising the importance of standards and standardisation in general in education programmes and seminars.

In order to reduce *implementation costs*, different measures are recommended: further investment in training and workshops (with the support of industry and trade associations), the provision of guidelines in the different national languages and the adoption of more user-friendly language in the editing of standards.

As far as the price of standards is concerned, many respondents observe that standards should ideally be free. At the same time, they are aware that the sale of standards is a vital part of standards bodies' business model. Therefore, some "softer" measures are suggested in order to deal with this issue:

– availability of mandatory standards at a reduced price when bundles/packages of standards are bought;

– free availability of the main content of each standard for web consultation only;

– free summaries in local languages so as to limit the risk for companies to purchase standards they do not need;

– specific cooperation agreements with associations of SMEs aiming at making standards available at a cheaper price for this category of market players.

The European Commission and public authorities in general are asked to give financial contributions to every measure helping to make standards less expensive for companies and users in general.

Still on the price of standards, two standards bodies – DIN and DKE – are often mentioned as examples to be followed. Respondents were particularly satisfied with some initiatives undertaken by these two organisms, like the provision of free summaries in the local language and the sale of bundles of standards at a reduced price.

9.1.5. Detailed results of the public consultation on ICT Standardisation

9.1.5.1. Introduction

In 2006, the Commission launched a review with a study to analyse the current EU ICT standardisation policy and bring forward recommendations for its future development. The study report was published in July 2007 and a web-based consultation followed. The comments received were published on the Europa website and an open conference was held in February 2008 to examine the study recommendations and those comments.

As a result, it was decided to present a White Paper to ascertain the degree of consensus on the possible proposals for policy choices and specific measures that would help the European ICT standardisation policy to better respond to industry and societal needs.

An open consultation on the White Paper was launched on 3 July and closed on 15 September 2009. Responses could be provided through the Commission's web-based interactive policy making tool (IPM), through a dedicated email address or by post.

Following the wide publicity given to the consultation, especially through standardisation related committees and organisations, a total of 130 responses were received; 53 from industry or business organisations, 27 from standardisation bodies, 18 from individuals, 17 from public authorities and the rest from research or other societal organisations. All of the responses have been published in full on the 'Europa' website[81].

The objective of the consultation was to ascertain the degree of consensus on the possible proposals for policy choices and specific measures that would help the European ICT standardisation policy to better respond to industry and societal needs.

The White Paper discussed possible proposals in 6 main policy domains of European ICT standardisation policy:

- Attributes of ICT standards associated with EU legislation and policies
- The use of ICT standards in public procurement
- Fostering synergy between ICT research, innovation and standardisation
- Intellectual property rights in ICT standards
- Integration of fora and consortia in the ICT standardisation process
- Enhancing the dialogue and partnership with stakeholders

[81] http://ec.europa.eu/enterprise/sectors/ict/standards/extended/consultation_2009_en.htm.

While the overall response to all the proposals contained in the White Paper was broadly positive, most respondents provided extensive comments and additional input that will facilitate further refinement of thinking on many of the issues.

The proposed attributes for ICT standards to be associated with EU legislation and policies and the link between those attributes and WTO criteria were very much welcomed. Some respondents suggested that certain attribute definitions needed further clarification while others called for clear and transparent processes and procedures for evaluating the compliance of specifications with the attributes. In addition, some felt that any future ICT standardisation policy needed to cover the coherence of standards.

A need for more flexibility for public procurement was widely supported as was the need for public procurement to be based on open and transparent processes allowing for fair competition. There was also broad support for the compliance with the attributes as a means of identifying standards which could be referred to in public procurement activities.

Although most respondents felt that greater synergy between ICT R&D and standardisation would benefit researchers and standardisers alike, there was strong opposition to any mandatory requirements governing the relationship between those activities. Many respondents also pointed out that the strong business driver of standardisation was not always present in R&D activities.

With regard to the treatment of intellectual property rights (IPR) there was a large consensus that standards developing organisations should set open, transparent, fair and predictable IPR policies which also take account of emerging business models. While many respondents felt that the use of *ex-ante* declarations of maximum licensing rights was an option which should be considered by each SDO in order to increase predictability, it should not become a mandatory approach.

While better cooperation between fora and consortia and ESOs was supported, the majority of respondents (but not the national standardisation organisations) were also of the opinion that the possibility of directly referencing specific fora and consortia deliverables in support of EU legislation or policy was needed as well.

Finally, the creation of a multi-stakeholder platform, as an extension of SOGITS, was very widely welcomed. However, it was also felt that its composition, rules and procedures would need to be carefully and clearly defined.

9.1.5.2. Questionnaire

The White Paper discussed possible proposals in 6 main policy domains of European ICT standardisation policy:

- Attributes of ICT standards associated with EU legislation and policies
- The use of ICT standards in public procurement
- Fostering synergy between ICT research, innovation and standardisation

- Intellectual property rights in ICT standards
- Integration of fora and consortia in the ICT standardisation process
- Enhancing the dialogue and partnership with stakeholders

Within each area, the White Paper raised a number of specific questions to identify the potential legislative or other changes which could be envisaged to help a new ICT standardisation policy to reach the objectives set, including interoperability goals.

9.1.5.3. Respondents

Of the 133 responses received, 1 arrived by post and the rest were evenly shared between the IPM tool and email.

18 individuals responded and 112 answers were made on behalf of organisations.

The 112 answers on behalf of organisations were subdivided as follows:

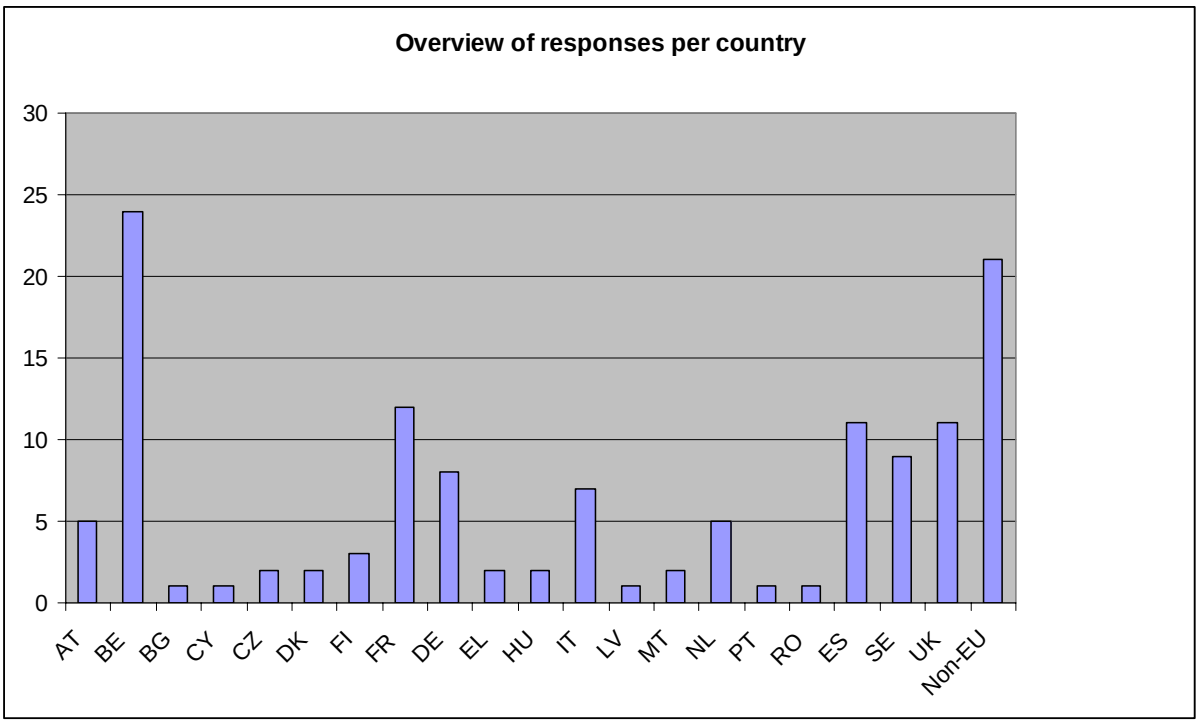
- 35 ICT service and product suppliers,
- 27 standardisation organisations (10 international organisations, 9 national standardisation bodies, 4 European organisations and 4 US organisations),
- 17 industry associations (covering users and producers),
- 17 Member State public authorities,
- 6 organisations representing societal interests,
- 5 organisations with a specific R&D focus, and
- 3 SME associations.
- 2 other organisations

69 respondents supported all of the possible proposals although most provided additional comments to explain their views.

51 respondents did not agree with one or more of the possible proposals, again providing supporting justification.

6 respondents focused on one particular issue and did not reply to the rest of the questionnaire.

4 responses were unclear.



Responses were received from a total of 20 Member States however some of these responses were made on behalf of European or global companies and organisations.

9.1.5.4. Attributes of ICT standards associated with EU legislation and policies

One specific question was raised in the White Paper in this area:

Do you agree that the attributes for standards to be associated with EU legislation and policies should be integrated in the future ICT standardisation policy as set out in section 2.1 of the White Paper?

	Number of Responses	% of total respondents	% of Positive/Negative responses
Positive	115	77%	96%
Negative	5	3%	4%
No answer/unclear	10	1%	-
Total	130	80%	100%

To facilitate the use of the best available standards in support of EU legislation and policies, the White Paper proposed that requirements be laid down, in the form of the list of attributes, for such standards and their associated processes. Compliance with the attributes would help ensure that wider policy objectives as well as public interest expectations were met.

The vast majority of respondents welcomed the suggestion to integrate the proposed set of attributes into the revised European ICT standardisation policy and to use this set of requirements as a basis for evaluating the eligibility of ICT standards for association with European legal frameworks and policies.

The link between the proposed set of attributes and the criteria set by WTO for International standardisation organisations was very much welcomed. Many respondents noted that the principles of openness, consensus, balance and transparency were already applied by the European standardisation bodies and by certain fora and consortia.

Various respondents underlined the need to analyse the criteria thoroughly, especially those attributes that relate to the standards themselves with a view to allowing them to be used for evaluating a specific standardisation deliverable in a given context. In particular, they felt that the attributes covering IPR policy requirements, relevance, technology neutrality and quality needed careful consideration to make sure they unambiguously related to any standardisation deliverables.

Some respondents called for further clarification of the attributes defining the standardisation processes that led to a specific deliverable such as openness, consensus, and balance.

Attention was also drawn to the fact that organisations such as IETF, OASIS and W3C are widely perceived as being as open and transparent in their processes as the formal standardisation bodies while however, reaching compliance with the attributes by other means than those applied within formal standardisation. For example, participation in their activities is usually open to any organisation or individual on the basis of direct membership.

Several respondents furthermore stressed the need for adequate processes to ensure that consumer and SME expectations were met using the attributes list, while others suggested adding “coherence” either to the list of attributes or as a general consideration in any revised legislation to avoid any risk of duplicating, conflicting and competing standards.

Nearly all respondents furthermore pointed to a need to define and implement clear assessment processes, including responsibilities and decision-making procedures, to evaluate compliance of standards with the attributes list. In that regard several relevant evaluation processes were cited such as the ARO process applied within ISO/IEC JTC1 and the CAMSS process developed in the context of the EIF.

9.1.5.5. The use of ICT standards in public procurement

Two specific questions were raised in the White Paper in this area:

Do you agree that the public procurement provisions of Council Decision 87/95/EEC should be updated so that public authorities can more easily acquire ICT services, applications and products that fulfil their specific requirements and in particular an adequate level of interoperability?

	Number of Responses	% of total respondents	% of Positive/Negative responses
Positive	115	77%	96%
Negative	4	3%	4%
No answer/don't know	11	2%	-
Total	130	81%	100%

Do you agree with the need to clarify that when they are defined within the context of ICT strategies, architectures and interoperability frameworks, the implementation of standardised interfaces can be made a requirement in public procurement procedures, provided the principles of openness, fairness, objectivity and non-discrimination and the public procurement directives are applied?

	Number of Responses	% of total respondents	% of Positive/Negative responses
Positive	112	74%	93%
Negative	7	5%	7%
No answer/don't know	11	2%	-
Total	130	81%	100%

Many respondents underlined the potential impact of public procurement with respect to fast market take up of innovative solutions. They also recognised the potential support to the further deployment of standards via public procurement.

Respondents largely highlighted the dramatic evolution that has taken place in the ICT environment over the last decade, the subsequent growth in the need for electronic data exchange between public administrations and between those administrations and business and citizens. In domains such as eGovernement, eLearning, eAccessibility and eHealth, interoperability was seen as a key issue in reaching policy objectives.

Respondents therefore largely agreed with the suggestion that the public procurement provisions of Council Decision 87/95/EEC should be updated so that public authorities can more easily acquire ICT services, applications and products that fulfil their specific requirements and in particular an adequate level of interoperability.

Most respondents furthermore agreed that the requirements within given ICT architectures and strategies are such that public authorities may in specific cases need to impose specific interfaces in order to meet their interoperability objectives.

Many comments however stressed the need to respect the principles of openness, fairness, transparency and non-discriminations when referencing standards and specifications in public procurement. They therefore felt that the standards referred to in public procurement should also comply with the attributes set out in the White paper.

Several respondents also highlighted the impact of IPR issues in public procurement, some of them arguing that IPR should at least be made available at fair, reasonable and non-discriminating conditions, while others argued that royalty-free conditions were needed in order to guarantee fair competition and support innovation.

A few respondents were however of the opinion that no additional flexibility was required in order to allow procurement of effective ICT services. They felt that the necessary levels of fair competition, openness and transparency can already be realised by adherence to the public procurement legislation laid down by Directive 2004/14 and by referring only to standards issued by the recognised standardisation organisations CEN, CENELEC and ETSI.

9.1.5.6. Fostering synergy between ICT research, innovation and standardisation

Three specific questions were raised in the White Paper in this area:

Do you agree that standardisation and research stakeholders should be regularly consulted to ensure that relevant European research initiatives contribute most effectively to ICT standardisation activities?

	Number of Responses	% of total respondents	% of Positive/Negative responses
Positive	114	76%	94%
Negative	6	5%	6%
No answer/don’t know	10	1%	-
Total	130	81%	100%

Do you agree that standardisers should adapt their procedures where necessary to ensure that contributions from research organisations, consortia and projects facilitate the timely production of ICT standards?

	Number of Responses	% of total respondents	% of Positive/Negative responses
Positive	108	74%	92%
Negative	12	7%	8%
No answer/don’t know	10	1%	-

Total	130	81%	100%

Do you agree that Member States should similarly consider regular consultation of standardisation and research stakeholders to ensure that relevant national research initiatives contribute most effectively to ICT standardisation activities?

	Number of Responses	% of total respondents	% of Positive/Negative responses
Positive	114	77%	96%
Negative	6	3%	4%
No answer/don't know	10	1%	-
Total	107	80%	100%

The general thrust of the suggestions put forward in the White Paper was accepted by respondents. They largely felt that the facilitation of knowledge transfer between R&D and standardisation would certainly raise awareness of the potential benefits standardisation can provide.

However, although respondents clearly support the idea of establishing regular dialogues between the R&D and standardisation communities, the majority expressed concern about the dangers of bureaucratising such relationships and were firmly opposed to the introduction of any mandatory links between R&D projects and standardisation.

Many respondents, mostly representing industry, drew attention to the fact that the transfer of technology into standardisation is always a business decision. Moreover many R&D results do not automatically call for further standardisation efforts. Respondents feared that an institutional link between standardisation and R&D would lead to the publication of many standards with no direct business relevance and little prospect of implementation.

The majority of respondents therefore support dialogue between ETPs and standardisation at the planning phase of R&D initiatives and an increased exchange of information between both communities.

On that basis most respondents saw no need for additional measures to improve standardisation processes or the procedures of standards developing organisations. For formal organisations and fora and consortia alike, the R&D community already has sufficient opportunities to liaise with and participate in standardisation activities.

With a few exceptions, most of the Member States do not appear to have major R&D initiatives that would be of interest with regard to ICT standardisation. Respondents in general were also of the opinion that the dialogue between the Research community and standardisation at national level should be established in an informal and non-bureaucratic manner.

9.1.5.7. Intellectual property rights in standardisation

One specific question was raised in the White Paper in this area: do you agree that ICT standards developing organisations should, subject to competition law and respecting the owner's IPR: 1) implement clear, transparent and balanced IPR policies which do not discriminate among different business models, 2) ensure the effectiveness of procedures for IPR disclosures, and 3) consider a declaration of the most restrictive licensing terms, possibly including the (maximum) royalty rates before adoption of a standard as a potential route to providing more predictability and transparency?

	Number of Responses	% of responses	% of Positive/Negative responses
Positive	104	69%	88%
Negative	16	10%	12%
No answer/Unclear	10	2%	-
Total	130	81%	100%

The IPR related suggestions triggered a large number of comments and contributions to the ongoing policy discussion on how to deal with IPR in ICT standardisation. All respondents except one provided contributions on this topic. In fact a number of respondents only reacted to the IPR related proposals and to no other aspect of the White Paper.

The majority of respondents agreed with the problem analysis in the White Paper. IPR is perceived as one of the most critical issues in ICT standardisation, especially when looked at in relation to the suggestions made concerning public procurement and further cooperation with fora and consortia.

Respondents for the most part agreed that ICT standard-developing organisations should take account of all stakeholders' interests (IPR owners, standard implementers and end users) and implement clear and balanced IPR policies which do not discriminate and allow competition among different business models.

Most respondents seem happy with the FRAND approach to IPR licensing, although several felt that it could be improved to provide more clarity, transparency and predictability. Some respondents were of the opinion that FRAND with no royalty-free option was the only way to deal with IPR in standardisation, arguing that this would ensure the return on investment required to finance further research activities. The majority of respondents supporting FRAND policies, however, supported the inclusion of royalty-free approaches, noting the development of other business models providing income to support further R&D. Several respondents felt that IPR should always be made available on a royalty-free basis for standards associated with legal frameworks and/or public policies.

Many respondents drew attention to the fact that the fast evolution of ICT technologies and the subsequent increase in the number of patents in the ICT domain have dramatically increased the complexity of monitoring the implementation of IPR policies. Moreover, the time spent negotiation on licensing arrangements was said by many to be out of step with the speed of evolution or innovation.

Although many felt that there might be scope for improving FRAND, the possibility of requiring a declaration of the most restrictive licensing terms, including (maximum) royalty rates before adoption of a standard, was not generally accepted as a route to providing more predictability and transparency.

While the users of technologies broadly supported the proposal, technology providers generally have no wish to see such an approach become mandatory, arguing that it would prolong standardisation discussions and probably increase the royalties. Some technology providers and industry associations however, could consider the inclusion of *ex-ante* declarations of royalty rates on a voluntary basis.

Most standard-developing organisations also opposed the proposal. They were of the opinion that "commercial" discussions should not take place in standardisation organisations. A few though, could accept a voluntary approach within their IPR policies and very few already envisaged such a possibility.

Some respondents also drew attention to the copyright issue, noting that that the free availability of standards would increase accessibility and consequently the likelihood of implementation, especially in SMEs.

9.1.5.8. Integration of fora and consortia in the ICT standardisation process

Two specific questions were raised in the White Paper in this area:

1. Do you agree with enabling the referencing of specific fora and consortia standards in relevant EU legislation and policies subject to a positive evaluation of the standard and the forum or consortium processes with regard to the attributes list as described in chapter 2.1 of the White Paper?

	Number of Responses	% of responses	% of Positive/Negative responses
Positive	104	69%	87%
Negative	16	11%	13%
No answer/don't know	10	2%	-
Total	130	81%	100%

2. Do you agree that better cooperation should be promoted between fora and consortia and ESOs on the basis of a process which would lead to standards issued by the ESOs?

	Number of Responses	% of responses	% of Positive/Negative responses
Positive	110	73%	91%
Negative	10	8%	9%
No answer/don't know	10	1%	-
Total	130	81%	100%

The majority of respondents felt that the dynamics of the ICT sector and the growing need for interoperability solutions required fast and effective implementation of standards. They felt this was illustrated by the fact that in new and innovative domains, like the internet, several non-ESO standard-developing organisations such as IETF, OASIS and W3C have gained wide market acceptance and are recognised as leaders in their specific domains.

The majority of respondents therefore agreed with the proposal to enable direct referencing of specific fora and consortia standards in relevant EU legislation and policies to help achieve interoperability objectives, subject to a positive evaluation of the standard and the related forum or consortium processes with regard to the attributes list. Respondents were of the opinion that this would permit a balance to be achieved between public interest expectations and market requirements.

Many respondents provided additional comments to highlight that the referencing of fora and consortia standards in European policies and legislation to ensure interoperability should focus primarily on existing specifications in technical domains that are not covered by the ESOs and for which the technical responsibility clearly belongs to the specific forum or consortium. In that context, the stakeholder platform and the Member States would have a key role in monitoring the coherence of ICT standards and in ensuring that they responded to identified public interest expectations, being compliant with the attributes as well as providing business relevance.

16 respondents, including 9 national standardisation bodies and CEN/CLC, opposed the possibility of directly referencing any fora or consortia specifications in legislation or policies. These organisations believe that the ESOs should keep a monopoly on standards for referencing in EU legislation and policy referring to the success of the "New Approach" internal market/product safety legislation. A majority of respondents, however, supported the proposals made by the White Paper in relation to the revision of the Council Decision 87/95 fostering the implementation of standards to achieve interoperability.

Moreover several national standards bodies highlighted the range of existing processes which allow the transposition of fora and consortia specifications into European standards which, they say, makes the proposal for direct referencing superfluous. However, the implicit assumption that fora and consortia would be willing to transfer their specifications to ESOs was rejected by several respondents.

In opposition to the national standards organisations, most of the national authorities responding to the White Paper consultation generally welcome these proposals subject to clear and transparent procedures for evaluating fora and consortia specifications. Several would also like to see SMEs and consumer organisations being helped to participate in the activities of international standards developing organisations.

Some respondents were of the opinion that fora and consortia fully complying with the attributes should be recognised as ESOs and included as such in the annex of Directive 98/34/EC. Other respondents feared that the strong industry focus in some fora and consortia may not afford sufficient access to societal representation and ran the risk of producing specifications which were not technology neutral.

A great many comments stressed the need for differentiation between fora and consortia highlighting the gulf between on the one hand, well-established organisations which have implemented advanced open, transparent and effective processes and which have a broad membership and on the other hand, the "closed groups" which are not open to the participation of all stakeholders and often have a limited scope and set of objectives.

A large majority of respondents agreed with the proposal to promote better cooperation between fora and consortia and ESOs on the basis of a process which would lead to standards being issued by the ESOs. Some added however, that such a cooperation process should be subject to case by case arrangements clearly defining all aspects of the cooperation and the related responsibilities e.g. for maintenance, participation, visibility, publication and copyright. Moreover, since the cooperating organisations do not necessarily have identical IPR policies, an agreement on IPR issues prior to the start of the cooperation was critical.

Several respondents, mainly industry and non-formal standards developing organisations, were opposed to such a 2 steps process. Not only is the process lengthy, but many fora and consortia see no added value since it focuses on procedural aspects and does not lead to a wider implementation of their specifications, which in most cases are already implemented at global level.

In that regard several respondents noted the risk that successive processes could change the content of a specification which would be confusing; if change was excluded, it would at best be a duplication or rubber stamping which should be avoided. They also felt there was a danger of European isolation from global standardisation as other regions implemented the specifications immediately and do not transpose them into national standards.

9.1.5.9. Enhancing dialogue and partnership with stakeholders

Two specific questions were raised in the White Paper in this area:

Do you agree with the establishment of a permanent, multi-stakeholder, ICT standardisation policy platform (with a wider membership than the Member State SOGITS Committee previously established by Council Decision 87/95) to advise the Commission on all matters related to the European ICT standardisation policy and its effective implementation?

	Number of Responses	% of responses	% of Positive/Negative responses
Positive	113	75%	93%
Negative	7	5%	7%
No answer/don't know	10	1%	-
Total	130	81%	100%

Do you agree that the ESOs and other ICT standard developing organisations should be invited to review the function and composition of the current ICTSB to make it more efficient?

	Number of Responses	% of responses	% of Positive/Negative responses
Positive	113	76%	97%
Negative	4	2%	3%
No answer/don't know	13	3%	-
Total	130	81%	100%

The overwhelming majority of respondents agreed with the proposal to extend the current Member States committee SOGITS, set up by Council Decision 87/95, to allow the participation of all ICT standardisation stakeholders and transform it into a permanent multi-stakeholder ICT standardisation platform. A few respondents were of the opinion that such a platform should be set up and monitored by the ESOs.

In their comments and contributions, respondents underlined that the platform should enhance the dialogue on ICT standardisation policy between all stakeholders involved but the composition of the platform was critical, and should be balanced, including SME and consumer representatives.

Respondents agreed with the scope and tasks set out in the White Paper and noted that the Member States must be able to execute their responsibilities in accordance with the rules and procedures of the Institutions. Comments underlined the need for the platform to focus on the implementation of ICT standards for Europe ensuring an adequate level of interoperability and coherence, while balancing industry expectations with public interest needs.

With respect to the "ICTSB" successor, the majority of respondents supported the proposal made by the White Paper. They felt that the ICTSB should be composed of relevant standards developing organisations and could be hosted by the ESOs. They

also noted that the ICTSB should complement the platform by coordinating standard setting to support policy orientations set by the platform.

9.1.6. Consultation of Member State Authorities, European Standards Organisations, National Standards Bodies and Fora and Consortia

During January-February 2010, Member State Authorities (MSA), European Standards Organisations (ESOs), National Standards Bodies (NSBs) and Fora and Consortia (F&C) were consulted with the assistance of the Technopolis Group.

Each of the main groups of stakeholder consulted is listed in the table below, with the number of organisations, representatives or countries (depending on the stakeholder group) targeted in each and details of the coverage of responses received. The total response coverage was 96%, meaning that only 5 of the 129 target organisations, representatives and countries failed to provide a response within the time available. Full coverage was also achieved in 6 of the 9 stakeholder groups.

Stakeholder Group		**Targets**	**Coverage**	**Coverage (%)**
European Standardisation Organisations (ESO)	Organisations	3	3	100%
National Standards Bodies (NSB)	Representatives	67	66	99%
Member State Authorities (MSA)	Countries	33	30	91%
Fora and consortia (F&C)	Organisations	6	6	100%
Stakeholder Organisations (SH)	Organisations	13	12	92%
International Standards Organisations (ISO/IEC)	Organisations	2	2	100%
Total		124	119	96%

Only the questions and replies that directly or indirectly concern the problems outlined in this impact assessment are set out below.

9.1.6.1. Objective 1 - Service standards and alternative standardisation deliverables

Question 1.1: Make an obligation to each National Standards Organisation to notify all national service standards.

The Commission wanted to understand the numbers of national service standards developed in the last five years, the proportion of these that had been notified to the Commission on a voluntary basis, and the costs and implications of a new requirement for all national service standards to be notified in future.

Replies by the NSBs:

- The average number of service standards developed by each NSB over the last five years is around 15, an average of three per NSB per year.

- 89% of the NSBs that responded currently notify all of their new work items on service standards to the Commission, via CEN/CLC.

- One responding NSB produces a large number of service standards each year but does not currently notify these. Among the *other* NSBs that responded the proportion of service standards notified on a voluntary basis over the past five years was 96%.

- The majority of NSBs expect there to be either no (58%) or negligible (25%) additional costs were they to be required to notify all service standards in future.

- The costs associated with a move to oblige all NSBs to notify all national service standards do not appear to be significant for 'Member State' NSBs but may be for those who do not currently notify (mainly accession and EFTA countries). However, based on the available data it is not possible to provide a firm estimate of those costs. The expected procedure and basis for calculation of costs would have to be more clearly defined before an accurate cost estimate could be provided.

- There do not appear to be any significant practical barriers or negative implications to adoption of this provision for the vast majority of NSBs. None argued against this provision.

- The situation with regard to service standard development within ETSI NSOs is unclear and would need to be investigated further if the provision is expected to extend into the telecommunications sector.

Replies by the ESOs:

- CEN/CLC do not expect there to be any significant costs or negative implications of the provision, although some adjustment to IT systems and reporting procedures would be necessary.

- ETSI indicated that there would be a significant additional cost and workload but that these were difficult to identify accurately as ETSI is currently unaware of the level of national service standardisation in the ICT (telecommunications) sector and the nature and level of reporting expected by the EC.

Replies by the MSAs:

- The majority of MSAs do not expect there to be any significant costs or practical implications associated with the adoption of this provision.

- A small number do envisage (relatively minor) additional costs that may need to be provided by them to their NSBs in order to support the new notification requirements.

- Additional detailed comments were provided by a small number of MSAs in relation to the possible legal arrangements at European and national levels.

Question 1.2: Open the possibility for the Commission to impose standstill on national service standards development process and to request European Standards Bodies to develop European service standards.

The Commission wanted to understand the additional workload for the Commission to review the notifications, impose standstill procedures where necessary and issue an additional 10 mandates per annum. It also wished to understand the additional workload for the ESOs and NSBs in evaluating and responding to those mandates, along with any practical implications of the provision.

Replies by the ESOs:

- ETSI foresees additional workload of ~140 person days per annum (costs of ~€85,000) and CEN/CLC foresee additional workload of ~200 person days per annum (costs of ~€100,000).

- These costs could increase if there is a need for coordination among the ESOs or more widely (with other bodies) or if the mandates relate to particularly large or complex standardisation projects.

- The stated costs do not include work following acceptance of the mandate (e.g. contracting, detailed planning, execution of the work).

- The costs in dealing with the mandates would be higher if EC financing is provided for the standardisation work, due to the considerable administrative burden associated with the financial and administrative arrangements. If there is a need to establish new technical bodies to respond to the mandates this may also impose additional costs at ESO-level.

Replies by the NSBs:

- Most NSBs could not provide an estimate of costs as the work involved in responding to each mandate is very different in nature and complexity.

- Where NSBs could provide cost estimates, the average workload foreseen is an additional 95 person days (i.e. 9.5 per mandate) at an additional cost of €30k. There was, however, a broad range of estimates from a low of 40 days (4 per mandate) to a high of 160 days (16 per mandate).

- Several NSBs suggested that adoption of this provision would not present any problems, and no significant practical implications were noted.

Replies by the MSAs:

- The majority of MSAs stated that there would be no significant practical implications or costs to the MSAs associated with this provision.

- Some additional costs could be incurred by MSAs and NSBs if a greater body of European standardisation work is foreseen (costs associated with discussion / coordination between Member States).

- Some MSAs pointed out that national standards development work might sometimes be useful as a precursor to European standardisation. Stopping it too early (through standstill) could have a negative impact in some cases.

- Other comments urged caution in slowing down or interrupting standardisation activities at national level, so EU level activity should be initiated quickly following any standstill procedure.

- The ESS already has good processes for identifying the appropriate level for standardisation activity (national, EU, International) and so further intervention by the Commission should be managed carefully and efficiently.

Question 1.3: Make an obligation to each National Standards Organisation to notify all national standards and other normative documents.

The Commission wanted to understand the costs and implications of extending notification procedures to all standardisation deliverables produced at national level.

Replies by the NSBs:

- The average number of new work items on national standardisation products (all types) developed by each NSB over the last five years is around 280, an average of 56 per NSB per year. There was a very significant range in the level of activity, with some NSBs developing no new work items and others producing in excess of 330 per year.

- The likely number of notifications that would have to be reviewed by the Commission is >2,000 per annum across all of the NSBs. However, roughly 80% of the new work items developed by the NSBs are already being notified on a voluntary basis, so the additional number of work items notified may be in the order of 4-500 per annum.

- Roughly half of the NSBs notify all new work items as part of current practice so there are no significant practical implications or costs for these NSBs, although not all agree that this would be a positive development.

- For those NSBs not currently notifying all new work items, the average additional administrative workload per annum was estimated to be ~70 person days at a cost

of just over €33k. However the very broad range of estimates provided suggest that the basis for calculating these costs may have been different in different NSBs and a more detailed or specific exercise to arrive at a cost estimate may be warranted.

- NSBs that provided data indicated that the average additional workload per annum associated with making all draft standardisation documents available to the Commission would be in the order of 60 person days per NSB per annum, at a cost of ~€36k. Again, it appears that these cost estimates may be unreliable due to uncertainties as to the expected procedures involved (e.g. physical documents vs. electronic, translated vs. not translated, made available at enquiry stage vs. other points in the process, etc.).

- A small number of NSBs noted that there may be confidentiality / IPR issues associated with transfer of 'private' documents developed by industry consortia.

- Some NSBs believe that extension of notification procedures and introduction of the possibility of standstill for industry specifications (PAS) would have a negative impact on the willingness of industry groups to develop these 'informal' documents within the NSB 'system', affecting adversely the NSBs' competitive position and causing industry to carry out a greater level of standardisation activity out of sight of the NSBs.

Replies by the ESOs: Both CEN/CLC and ETSI indicated that it was difficult to calculate a reliable estimate of the additional costs of this provision (workload and €) at this stage. However, ETSI estimated that the provision would require at least an additional 65-70 person days in year one and additional costs of ~€42,000, but that these costs may be lower in subsequent years once processes and IT tools have been set-up. CEN/CLC noted that IT developments and additional reporting workload are foreseen

Replies by the Stakeholder Organisations:

- The provision provoked a mixed response from stakeholders, with some suggesting that notification of all work items may help to improve transparency, reduce duplication of effort and enable a greater proportion of standardisation work to be harmonised at European or international levels. This could serve both to minimise new barriers to trade, support the internal market, reduce duplication of effort and improve the coherence between national, European and International standardisation.

- Others, however, argued that the requirement for notification and the attendant threat of standstill might drive participants to develop their informal standards outside of the NSB system, reducing transparency and reducing the extent to which these documents can be developed through a broader and stronger consensual process. This may reduce the number of actors involved in formal standardisation activities and may limit the extent to which informal standards developed first at national level could eventually be transferred to European level.

- Any implementation of this provision should, in the view of stakeholders, be introduced carefully and gradually, and standstill only imposed in cases where there are clear and obvious benefits to acting at a European level.

- Existing processes are already in place to decide the level at which it is most appropriate for a given document to be developed. Not all national work has European level significance or sufficient demand from other countries, and there is a danger that if European work is initiated too soon it may fail while at the same time the Commission will have prevented national level activity from proceeding. This would obviously serve to curtail rather than enhance standardisation activity.

- Other possible negative implications identified by stakeholders include a slowing down of standards development work, reduced flexibility of formal standardisation to respond to local needs, fostering negative sentiments concerning the (increased) level of EU-level political control over national standardisation activity, and hampering innovation by requiring greater justification for new, industry-led initiatives.

Replies by the MSAs:

- Most MSAs stated that there would be no costs or practical implications to their own activities as a result of this provision.

- Some MSAs expressed support for the provision, on the grounds that full notification would enable all documents to be covered by the same legal framework.

- Other MSAs argued against the provision, suggesting that it may reduce the number of cases where stakeholders use NSBs to support the development of their own 'informal' standards, reducing the level of oversight that NSBs can provide into new developments at national level.

- It was also noted that notification may not be necessary in all cases (e.g. not necessary for best practice guides that do not impose any requirements but are merely a support tool).

Question 1.4: Open the possibility for the Commission to impose standstill on all national standards and normative document development process and to request European Standards Bodies to develop European standards or normative documents.

The Commission wanted to understand the additional workload for the Commission to review the notifications, impose standstill procedures where necessary and issue an additional 10 mandates per annum. It also wished to understand the additional workload for the ESOs and NSBs in evaluating and responding to those mandates, along with any practical implications of the provision.

Because the questions surrounding this provision mainly related to the additional administrative costs and workload involved in developing (EC) and responding to

(ESOs, NSBs) an additional 10 mandates per annum, the relevant answers have already been provided in relation to Provision 2 above. These were as follows:

- ETSI foresees additional workload of ~140 person days per annum (costs of ~€85,000) and CEN/CLC foresee additional workload of ~200 person days per annum (costs of ~€100,000) although these costs could increase if there is a need for coordination among the ESOs or more widely (with other bodies), if the mandates relate to particularly large or complex standardisation projects, if the mandate requires the setting up of new TCs/TBs or if Commission financing accompanies the mandates. The stated costs do not include work following acceptance of the mandate (e.g. contracting, detailed planning, execution of the work).

- Most NSBs could not provide an estimate of costs as the work involved in responding to each mandate is very different in nature and complexity, but where estimates could be provided an additional workload of around 95 person days (i.e. 9.5 per mandate) at an additional cost of €30k per NSB was envisaged.

- Most MSAs do not foresee any significant additional costs but some noted that the workload within their NSB would increase (and would have to be paid for somehow) and that increased notification would require greater levels of dialogue, information exchange and opinion sharing between Member States.

NSBs and MSAs provided additional comments as follows:

- NSBs reiterated concerns that the threat of possible standstill proceedings being imposed on 'informal' standardisation work might drive industry / stakeholders to develop these outside the formal standardisation system, leading to further fragmentation of the market and disconnecting NSBs from informal national standardisation activity.

- NSBs have extended their portfolios to embrace informal, low-consensus normative documents in order to remain connected to this activity and improve the basis on which such documents are produced. It is not always appropriate for these documents to be turned into national or European standards, although this may be a natural consequence to their successful development and use on an informal basis (first).

- The provision would be inequitable as it would impose requirements on NSBs in relation to informal documents that are not imposed on other fora and consortia (SDOs), thereby placing NSBs at a competitive disadvantage.

- The provision may slow the development of informal standards and technical specifications, acting a s brake on innovation, and may cause the EC to interfere in the production of tools that serve a purely national need.rr

9.1.6.2. Objective 2 – Improving access to harmonised standards

Question 2.1: National Standards Bodies to provide free access to Harmonised Standards supporting New Approach directives.

The Commission wished to understand the financial implications of this provision for the operating budgets of the NSBs by understanding the scale of 'lost' income if European harmonised standards could no longer be sold. It also wished to understand the implications from the perspective of ISO/IEC were European standards based on ISO/IEC documents to be made available for free.

Replies by the NSBs:

- In the vast majority of cases the NSBs were not able to provide figures for the sale of European harmonised standards, and only just over half provided figures on the revenues generated from the sale of all products containing standards. Figures for sale of standards could not be provided in most cases because NSBs' information systems do not provide disaggregated data at this level.

- For those that could provide data on the sale of all standards documents, annual revenues average €3.8 million per NSB, broadly in line with the figures provided by the Commission.

- Grossed up annual sales figures for all products containing standards for all 40 NSBs totalled just over €150 million per annum.

- The annual 'losses' that would be incurred by NSBs if harmonised standards would no longer be sold (i.e. would be made available for free) cannot be calculated accurately, and only a minority of NSBs could provide any kind of estimate. However, based on the limited data available we can estimate that NSBs would lose revenues of between 10% and 20% of their total operating budgets, equivalent to €50 - €100 million per annum in total across all 40 NSBs. However, even this very broad estimate is subject to a high degree of uncertainty and the proportion of overall revenues lost may be below 10% in some cases and significantly more than 20% in others.

- NSBs pointed out that the 'costs' of this provision would go far beyond a loss of income from the sale of European HS:

  – It would disrupt the existing business model, requiring significant changes to business processes and operating procedures, based on the need to apply different funding models for different parts of the operations;

  – The change may create confusion on the part of industry as to why some standards are free while others are not and may impact on the ability of NSBs to continue to charge the same amounts for non-harmonised standards;

  – Neither the Commission nor the MSAs would be in a position in most cases to compensate the NSBs for these losses.

- NSBs also stated that the provision would stand in contravention to the copyright rules of ISO and IEC and would not be permissible under the terms of the Vienna and Dresden agreements. Attempts on the part of NSBs to provide free access to

European harmonised standards based on ISO/IEC standards would result in copyright infringements, may result in legal action, and may lead ISO/IEC to no longer make their standards available for adoption as European standards. This could lead to significant disconnection between European and International standardisation, with negative consequences at both levels.

- NSBs also stated that there is insufficient evidence to show that the purchase price of standards is a significant barrier to take up and use of standards by SMEs, and it is appropriate that tools that cost money to produce and add value to business operations should be charged for. Moreover, other barriers to take-up (such as lack of information on standards, low awareness of the benefits that they provide, the costs of meeting the requirements imposed by the standards, and so on) are shown to be more significant barriers for SMEs. Initiatives are underway to further address these problems.

- Finally, NSBs confirmed that many steps have been taken to improve SMEs' access to standards and to reduce the prices they have to pay. Standards represent good value for money and making them freely available through the use of public subsidies would devalue them.

Replies by ISO/IEC: ISO/IEC stated that the provision would compromise the entire ISO/IEC system, have a significant negative impact on operations and jeopardise the agreed established process by which the costs of international standardisation are spread across stakeholders and users. In short, without this commercial sales activity the system could not continue in its current form or at its current levels. Specific additional points raised included:

– ISO/IEC central offices get significant revenues from the sale of standards and their operations would be jeopardised by the proposal

– Most members of ISO/IEC, on which the system depends, rely on the sale of standards to finance their operations. Without that income they could not support international standardisation at the same level

– The provision would be in direct contravention of the rules of ISO/IEC which place the commercial exploitation of publications as fundamental to the financial integrity of their respective systems. ISO/IEC also stated that numerous studies have confirmed that the (purchase) price of standards is negligible in relation to the value they add. They attract and reassure customers, demonstrate market leadership, create competitive advantage, develop and maintain best practice. It is therefore appropriate that users pay a nominal fee to purchase these business tools

Replies by the MSAs: A small number of the MSAs provided comments, reaffirming the points expressed above, specifically that they would not be in a position to compensate NSBs for the losses, that the financial model of the national, European and International standardisation systems would be jeopardised, and that there is a lack of evidence that the provision would be effective.

Question 2.2: Member States or the Commission to compensate losses generated for the budget of NSBs due to free access to Harmonised Standards.

The Commission wished to understand whether MSAs and or the Commission itself would be in a position to compensate NSBs for the shortfalls in their operating budgets were European Harmonised Standards to be made available for free. The Commission also wished to understand what might be an appropriate basis for allocating any future compensation package.

Replies by the MSAs:

- The majority of the MSAs that responded indicated that they would not be willing and / or able to compensate NSBs for the losses. The main reasons related to:
  - The potential scale of the compensation package necessary, depending on the NSB in question, was estimated at anywhere between €180k per annum and €6 million per annum. MSAs already provide significant financial support for standardisation and many envisaged that the current level of support may need to be doubled, something that is not feasible in the current economic climate which is placing considerable pressure on public finances;
  - Lack of adequate justification for the provision that would give rise to this need, namely that there is not a sufficient case for making harmonised standards available for free. It was also mentioned that if the Commission is correct in its assumptions and that making HS available without charge would increase demand, then the scale of the compensation package required would also increase. However, many MSAs clearly do not feel that this change is necessary or appropriate.
- Only one MSA indicated that they would be in a position to compensate their NSB for the losses.
- Several MSAs were not able to provide a definitive response, mainly on the grounds that a more in depth analysis of the likely costs and the political and practical consequences that this change would bring would be needed. Any final decision would have to be a political one and the MSAs were not in a position to pre-judge the outcome of that political process.
- Some MSAs suggested that, in principle, free access to harmonised standards would be beneficial in promoting the use of HS among SMEs and may provide a better implementation of New Approach Directives, thereby improving the operation of the internal market. Free access may also promote the wider adoption of European HS internationally, bringing trade benefits between Europe and the rest of the world.
- However, a similar number of MSAs stated that free access would not lead to improvements in implementation, given that the purchase costs are often very small in relation to the costs of implementation and given that the standards are still often not available in national languages. Some MSAs suggested that sorting

out the (lack of) translation of standards into national languages was a more significant barrier than their purchase price, and that improved financing for this activity would be a more effective use of limited resources.

- A small number of MSAs argued that free access to HS would diminish their value and that users should recognise and value the benefits that the use of standards can bring.

- Most MSAs were unable or unwilling to specify an appropriate basis for a compensation package, either because they did not agree with the provision, would be unable to provide financial support, or believed that the compensation package should be drawn up by and funded by the Commission. Where suggestions were given these were either based around past sales, future distribution volumes, the costs of the HS development process, or the costs of distribution / dissemination. No clear consensus emerged as to how any compensation package should be organised.

Replies by the ESOs:

- ETSI indicated that the provision was not relevant to it as all ETSI deliverables are already made freely available.

- CEN/CLC indicated that because it does not sell standards any compensation package would have to be directed to the national members (NSBs/NCs).

- CEN/CLC also stated that the private or semi-private (independent) status of the NSBs was important and that a greater reliance on public financing could distort the system and have (negative) repercussions on the attitudes and behaviour of private stakeholders.

- CEN/CLC indicated that any action that impacted on the sustainability and financial robustness of its members could have a negative impact on the central secretariat.

- Finally, CEN/CLC pointed out that, given the problems with the current EC financing system and the unwillingness of many NSBs to participate in co-financed mandated work, it is perhaps unrealistic to imagine that NSBs could be fully compensated for the losses through an increase in this type of funding.

Replies by the NSBs:

- Most NSBs stated that if HS were to be made freely available then the NSBs' work to support their development could only be continued if the Commission or MSAs were in a position to provide full compensation for all the losses incurred.

- A compensation package based on past sales would not be feasible so should instead be based on 100% of the real costs of all work to support the development, implementation, revision and dissemination of HS going forward. This should include any administrative costs associated with accessing the funding.

- Several NSBs do not believe that the Commission or the MSAs would be in a position to provide such compensation.

- Several NSBs also stated that such a change would diminish the important principle that standardisation should be an industrial activity, and so indicated that reducing private contributions and increasing public ones would be a retrograde step. The current financing model is more robust, appropriate and less open to political will and influence than the one that might have to be adopted if HS were to be made freely available.

- Regardless of whether an appropriate and workable compensation package could be achieved, this does not address the fundamental issue of ISO/IEC agreements and copyright rules which would have to be overcome before HS could be made freely available.

9.1.6.3. Objective 3 – Improving stakeholder access to the standards development process

Question 3.1: Request Member States to monitor and report on the balance of representation of stakeholders in NSB mirror committees.

The Commission wished to understand the costs to itself, to the NSBs and to the MSAs of the development and implementation of a monitoring and reporting system designed to detail the balance of representation of up to 10 (defined) groups of stakeholder within national mirror committees. It also wished to understand any practical implications of the establishment of such a monitoring and reporting system.

Replies by the NSBs:

- Half of the NSBs provided a cost estimate for the set-up and ongoing implementation of a new monitoring and reporting system. Based on these estimates the average cost per NSB to set up the system would be ~€112k, with the range of estimates running from €0 to €500k. The ongoing annual implementation costs are estimated at €75k per NSB per year, with the range of estimates running from €2k to €650k. It should be noted that because the system to be developed and implemented has not yet been defined in any detail the cost estimates are subject to a high degree of uncertainty. However, the total costs to the NSBs (i.e. across all 40) can be estimated at ~€4.5 million for initial set-up and €3 million for annual implementation.

- It will be imperative for a detailed specification for the monitoring and reporting system to be defined and agreed at a European level prior to implementation at national level. Some iteration may be required so that differences in interpretation and in national structures can be resolved.

- A significant minority of NSBs already monitor and report on the balance of stakeholder representation in their standardisation committees, and the costs of complying with the Commission's system could be relatively low if it mirrors that already in place. However, many NSBs expect that this would not be the case.

- A significant number of NSBs stated that the 'concept' of balanced representation would have to be defined. This may be difficult or impossible to do intelligently, other than at the level of individual committees in individual countries, as an 'appropriate' balance will depend on the work programme of the committee in question, factored by the relevance of the issues to the national stakeholder groups and also their willingness and ability to get involved.

- National mirror committees are already open and making all relevant actors aware of the work and allowing all to participate leads to the achieved 'balance'. It is not appropriate or feasible to enforce a remotely defined 'idealised' balance within national committees. For this reason many NSBs fail to see the merits in a centralised (and potentially bureaucratic) reporting system as it could (or should) not form the basis for corrective action.

- Other actions to improve stakeholder access to standardisation (e.g. supporting financially stakeholder groups that are known not to have as much representation as might be desirable) may be a more effective use of resources than a monitoring and reporting system.

Replies by the MSAs:

- Most MSAs felt unable to provide an estimate of their costs to install and maintain an annual monitoring and reporting system.

- Ten MSAs provided an estimate of the costs, which were calculated at an average of €150k for initial set-up and an average of €40k per annum for ongoing implementation. However, one MSA provided very different estimates to the others and if this 'outlier' is removed the average set-up costs would be estimated at €55k per MSA and ongoing implementation costs would be €22k per MSA per year.

- MSAs confirmed that the balance of representation within national standardisation committees was an important issue and they should be (and are) vigilant in ensuring that this is achieved as much as possible. Many MSAs place formal requirements on their NSBs in this regard.

- While the principle and ambition underlying the provision is important, several MSAs stated that this issue requires further consideration. The very significant costs to the MSAs, NSBs and participants in implementing and maintaining the reporting system could be excessive, and disproportionate to the utility of the information provided. It is not clear how different levels of participation would be judged and what an ideal 'balance' might look like.

- More suitable ways forward may be to limit the requirement to committees dealing with mandated European standards only, to provide more effective support to under-represented stakeholder groups, and / or to ensure careful monitoring of complaints about the balance of participation or barriers to access to committees.

- MSAs also noted that the situation is sometimes different in smaller countries where there are insufficient numbers of national experts available to represent all groups in all committees

The ESOs did not identify any implications / costs to them as a result of this provision

Question 3.2: NSBs to provide free access to national committees for SMEs, NGOs, consumer organisations and trade unions.

The Commission wished to understand the current scales of fees (tariffs) requested by NSBs for participation in standardisation committees for each type of committee and each type of participant. It also requested information on the number of stakeholder groups / organisations paying those fees in each of the last five years and the total volume of revenues generated through these charges. The Commission also wished to understand any other practical implications or costs of this provision.

Replies by the NSBs:

- Just over half of the NSBs do not charge any fees for participation in national committees, although many are only able to do this because they generate sufficient revenues form other sources (e.g. the sale of standards) to cover their costs.

- Among those that do charge fees there are many and various charging models in place, including different scales for different types of organisation, fixed uniform fees for all types of participant, exclusions (i.e. free access) for some groups and not others, free access based on the payment of a membership fee, 'entry' fees payable only once, and so on. There are too many different charging models in place to summarise here.

- None of the NSBs appear to differentiate their charges based on the type of committee accessed or on the types of standards being developed within them.

- Only ten (25%) of the NSBs provided data on the number of stakeholders paying fees, as most of the remainder do not levy any charges. Just over 1,000 organisations pay fees each year to each of these NSB on average. The numbers ranged from a low of 34 per year for one NSB to a high of almost 6,000 per year for another.

- Only six NSBs could provide data on the volume of revenues generated. The total volume of fees generated annually across these six was €3.5 million, equivalent to just over €580k each per annum. The volume of revenues generated annually ranged from a low of €44k to a high of just over €1.4 million.

- NSBs stated that the decisions as to whether to charge for access to committees, and how much to charge and on what basis have been agreed at national level between the stakeholders involved.

- There are clear interdependencies between the revenue streams employed within each NSB. Various mixes of public and private financing are employed depending on the national context, and within the private revenues, a combination of membership fees, income from sale of standards, certification and other commercial activities are used in various configurations to ensure the financial stability of the NSB. Any moves by the Commission to remove one source of revenues would have to be addressed by a corresponding increase from another source.

- Many NSBs charge reduced fees for minority stakeholder groups and SMEs although not all differentiate at these levels.

- NSBs appear to be more supportive of the idea that minority stakeholder groups should be provided with free access than the idea that SMEs should participate for free. In some cases providing free access to SMEs would have a profound effect on income levels, and NSBs believe that it is appropriate for SMEs to contribute as they are one of the main users / beneficiaries of the standardisation work (while consumers, NGOs, trade unions, etc. are not).

- Several NSBs do not believe that charges for access to committees are a hindrance to involvement, as evidenced by the fact that recent moves to provide free access to certain committees has not resulted in greater levels of participation by minority stakeholder groups or SMEs.

- NSBs also pointed out that various initiatives are underway to improve stakeholder participation in national committees without interfering with the NSBs' business models.

The ESOs did not identify any implications / costs to them as a result of this provision

The MSAs did not identify any implications / costs to them as a result of this provision but several pointed out that stakeholder involvement and balanced representation is important. Others pointed out that the costs of providing free access would be high for their NSB and / or that they do not support the provision

Question 3.3: Member States to ensure that minority stakeholders are represented in all national standardisation committees, including by providing financial support for representative groups at national level.

The Commission wished to understand (i) the extent to which minority stakeholder groups (MSGs) at national level receive financial support to enable them to participate in standardisation; (ii) the mechanisms and charges in place at NSB-level for providing these groups with access to national committees; (iii) the funding provided by MSAs to enable MSG participation; (iv) the nature of the reporting relationship between NSBs and the MSG funding bodies concerning their involvement in standardisation; and (v) the estimated costs to install and maintain a system of support for MSGs. The Commission also wished to understand any significant practical implications associated with this provision.

Replies by the NSBs:

- Most of the NSBs stated that no direct public financing is provided to enable MSGs to participate in national standardisation committees. In many cases this is because access is free..

- In around a third of the cases NSBs indicated that some support is provided, either through the 'general' funding of these groups, through the provision of travel and subsistence grants or through payments to reduce the level of membership fees that have to be paid.

- NSBs did not identify any 'special' mechanisms for providing MSGs with access to standardisation, and most indicated that a principle of open and equitable access is applied to all groups. However, funding provided to MSGs is known in some cases to enable free or reduced access to committees which otherwise would have to be paid for in full or at a higher rate.

- Regardless of the financing / charging situation most NSBs relay information on new work items and new committees to MSGs to facilitate their access, with some proactive targeting in place. In some cases dedicated committees and IT tools have been installed in order to enhance MSG access to standardisation work.

- The majority of NSBs stated that no special reporting procedures are in place between them and their MSAs with regard to participation by MSGs, because no funding is provided to MSGs or no special distinction is made between them and other types of participant. In a minority of cases special reporting is in place, with NSBs providing information on participation levels through annual reports, dedicated regular reports or 'on request'.

- Most NSBs were unable to provide an estimate of the costs of installing a system of support for MSGs at national level, and the small number that felt able came up with very different estimates, ranging from a low of €2.4k to a high of €600k.

- Several NSBs indicated that free access would not in and of itself be sufficient to guarantee MSG involvement and that payment of expert fees and travel and subsistence costs may be necessary also to ensure higher levels of involvement.

- Some NSBs appear to believe that such support is appropriate while others disagree and argue instead that the principle of open and equitable access would be compromised by this kind of positive discrimination.

- NSBs also pointed out that funding for participation would only address part of the problem, as MSGs often do not have sufficient resources and systems to consult their members effectively. Therefore, while funding may enable representatives to attend it is not necessarily the case that a 'position' can be adopted and carried forward to standardisation meetings.

Replies by the MSAs:

- Roughly a quarter of the MSAs indicated that funding is provided to MSGs to support their participation in standardisation, covering a range of different types of support targeted to specific groups. The nature and level of funding provided to MSGs varied, in some cases being allocated to the NSB to enable MSG access and in other cases being allocated directly to MSGs. The amounts allocated varied from €100k to €1.4 million per annum.

- Most MSAs could not provide an estimate of the costs of installing and maintaining a system of support to MSGs at national level, as this 'system' of support has not yet been defined in any way. Around a third did attempt to provide an estimate, with these averaging around €200k per MSG per year. However, the MSAs clearly envisaged very different types and levels of support, ranging from a low of €2.4k to a high of €1.1 million per MSG per annum. We therefore do not believe that it is possible to provide any kind of reliable estimate in the absence of some kind of standard specification as to the nature of support to be provided.

- There is no clear consensus as to whether MSAs are supportive of this provision. In some cases it is felt to be unnecessary because MSGs can already access standardisation committees for free and / or direct support for participation is already provided. In other cases there appears to be some support for the idea but there is not enough information to enable NSBs and MSAs to identify costs and implications.

- A small number of MSAs indicated that awareness and interest in participation remains a significant barrier to MSG participation and this should be tackled before any direct support for participation, while others do not support the idea of 'positive discrimination' as it runs counter to standardisation principles and may lead to distortion in the behaviour of MSGs within the process.

The ESOs did not identify any implications / costs to them as a result of this provision

Question 3.4: Member States to report to the Commission on actions in place to support participation of SMEs, NGOs, consumers and trade unions.

The Commission wished to understand the costs to the MSAs of installing a system of annual reporting on the actions in place at national level to ensure representation by MSGs, as well as the costs to the Commission in reviewing and assessing those reports. The Commission also wished to understand any other costs or practical implications of the provision.

Replies by the MSAs:

- Most MSAs were not able to provide an account of the necessary procedures or the costs associated with a system of reporting on actions in place at national level to ensure the participation of MSGs in standardisation.

- 13 MSAs provided cost estimates but the procedures envisaged varied considerably resulting in very different estimates, ranging from a low of just €129 to a high of just over €190k.

- Some MSAs suggested that the provision would place an additional and unnecessary burden on already scarce resources while a similar number stated that the provision could be accommodated relatively easily and at little cost.

- A small number of MSAs stated that they did not see the value in such a reporting system and that the administrative costs would outweigh the benefits realised. It is clear that MSAs support their respective NSBs and MSGs in different ways and that making comparisons may lead to wrong conclusions.

- It was suggested that discussions / presentations through SOGS may be a more cost-effective way to share good practice and drive improvements in MSG participation at national level.

The ESOs did not identify any implications / costs to them as a result of this provision

Replies by the NSBs:

- Most NSBs did not comment, as the provision would affect the MSAs rather than themselves. However, some felt that the reporting system would place an additional burden on them as it is envisaged that NSBs may need to provide information and data on MSG involvement in standardisation committees, along with other actions in place at NSB level to support MSG participation. In some cases NSBs felt that the additional costs would outweigh the benefits realised.

- A small number of NSBs reiterated that many actions have been put in place at EU and national levels to support MSG involvement in standardisation and that these efforts have not been recognised within the current exercise. The implication behind this set of provisions is that not enough is being done and that there is a need for corrective action, which many NSBs feel is not the case.

9.1.6.4. Objective 4 – Improving Member State involvement in the EU standardisation process

Question 4.1: Member States to be obliged to send official experts to take part in all national mirror committees mirroring European TCs dealing with mandated standards under Directive 98/34/EC.

The Commission wished to understand the number of mandated standards developed under 98/34 in the last five years, the number of formal objections raised in relation to these standards, and the number of cases where formal objections are likely to have been avoided had MSA officials been present in all relevant national mirror committees. It also wished to understand the number of ESO TCs currently preparing mandated standards under 98/34, and the level of MSA official representation on these committees. Finally, the Commission wished to understand the number of days that would need to be devoted by an MSA expert in each relevant national mirror

committee in order to contribute to the development of a mandated European standard and what the average costs of MSA experts per day is.

Replies by the ESOs:

- ETSI reported that there are currently 18 technical bodies (TBs) dealing with 34 'active' mandates and that 10 of these technical bodies (as a minimum) would require MSA expert involvement. Because ETSI operates under direct participation principles and because all MS public administrations are members they are able to attend and participate in all ETSI meetings.

- While it could be argued that all TBs should have MSA expert involvement, standardisation is a voluntary activity and participation is a decision taken by each public administration on a case-by-case basis.

- CEN/CLC reported that there are 347 active TCs that are developing or have developed harmonised standards. In principal MSA experts should be present in all of these TCs, given that they are stakeholders within the context of Harmonised Standards.

Replies by the NSBs:

- NSBs could not report on the current level of MSA representation on national committees mirroring the development of mandated European standards because their information systems cannot link MSA participation to specific (mandated) work items.r

- However, 14 NSBs were able to provide data on the number of active national mirror committees and the level of MSA representation on these. The results showed that these NSBs collectively operate just over 2,000 mirror committees and there is MSA representation on 66% of these. In some cases where there is no MSA involvement the committee will not be involved in mirroring mandated European standards, but the number of such cases cannot be determined. It is expected that the true level of MSA representation on such committees would be higher than 66%.

- NSBs pointed out that all of their committees are open to MSA involvement and participation or not is a decision for the relevant MSA based on their level of interest in the work of each committee. All new work items are notified to MSAs so there are no apparent barriers to participation by MSAs where they feel that it is appropriate and where they have the necessary resources.

- NSBs estimated that ~10 person days input would be required on average each year by an MSA expert participating on a national committee mirroring the development of a mandated harmonised standard. However, depending on the nature of their involvement the actual level of input could be slightly less or considerably more.

- NSBs pointed out that MSA involvement in national mirror committees is encouraged, but warned against any kind of 'compulsory' participation as MSAs

do not always have an interest or may not always be able to add value through their involvement. Participation is and should be voluntary and based on the needs and interests of stakeholders, and should not be enforced top-down.

Replies by the MSAs:

- Data provided by 19 MSAs indicated that the costs in EUR per day for an MSA official participating in standardisation work averages just less than €500 per day. The range of costs varied substantially, from a low of €35 to a high of €1,200. However, in some cases only the 'expenses' were included while in other cases salary costs plus travel and other incidentals were included. As such it is not possible to rely on these figures.

- A small number of MSAs stated that they would not support any proposal to impose an obligation on their participation in national mirror committees working on the development of mandated European standards.

- Several MSAs stated that there is no evidence that the current voluntary system of participation presents any problems or that formal objections would be avoided through increased levels of involvement.

- Several MSAs pointed to the additional costs and practical implications of the provision, in particular a lack of necessary human and financial resources.

- A small number of MSAs felt that greater levels of involvement may be desirable as a means to enhance MSA competencies and interest in relation to standardisation and to assist other participants in understanding the legislative requirements.

Question 4.2: European Commission to be able to finance mirror committees in all EU Member States.

The Commission wished to understand (i) how many of the current ESO Technical Committees developing European standards have mirror committees at national level and how many do not; (ii) what are the current costs of NSB secretariat activities for mirror committees; and (iii) what are the current costs of NSB secretariat activities for running national enquiries and national implementations. It also wishes to understand any other costs or practical implications of this provision.

Replies by the NSBs:

- Based on the information provided by NSBs we can estimate that just less than half of the NSBs are mirroring all ESO TCs, just over a third are mirroring most and roughly one in five are mirroring less than half of the ESO TCs. A definitive number of cases where ESO TCs are not being mirrored cannot be determined based on the data provided, but we can estimate that there is a shortfall of at least 1,500 committees across the 15 NSBs where it is clear that not all ESO TCs are being mirrored.

- Most NSBs could not provide a clear estimate of the costs of the secretariat functions they perform in relation to the running of national mirror committees, but an average cost of €22,000 was identified based on data supplied by 12 NSBs. The majority of the estimates provided were in the range €10k - €20k per committee per annum.

- Most NSBs could not provide a clear estimate of the costs of the secretariat functions they perform in relation to the running of national enquiries and national implementations, but an average cost per standard of €1,600 was identified based on data supplied by nine NSBs. The basis of calculation of the estimates was highly variable and so a more precise definition of what costs should and should not be included would be needed before a more reliable estimate could be established.

- Most NSBs would welcome additional financial support for standardisation at national level but questioned whether the focus of this provision was appropriate. NSBs suggested that the money could be better spent on:

  – Measures to support the involvement of MSGs in national standardisation, particularly for smaller countries where other sources of income are more limited and curtail the range of support that can be provided by NSBs to these groups

  – Translation of European standards into national languages. While the Commission does provide some support for this the NSBs still carry the majority of the costs and the financial arrangements are excessively bureaucratic, diminishing the true level of support provided

- Several NSBs pointed out that it is not appropriate or necessary to run national mirror committees in all cases where European standards are being developed, as in some cases the standards have no relevance to the national context. In these cases supporting the secretariat function would be meaningless in the absence of any stakeholder demand for participation.

CEN/CLC reported a small number of concerns in relation to this provision, specifically (i) the long-term sustainability of such an action and the significant level of financing required; (ii) the risks of discriminating between EU NSBs and those from EFTA countries or accession states, and (iii) the lack of clarity surrounding whether only the secretariat functions would be supported and not the participation of industry and other stakeholders.

Replies by the MSAs:

- MSAs also reported a number of concerns, although the majority of those that responded stated that they would welcome the provision. Potential positive benefits identified as a result of the support were (i) greater levels of participation by stakeholders (ii) increased activity in areas where secretariat functions cannot be supported through the sale of standards, (iii) increased sustainability of NSBs in certain (small) Member States, and (iv) improvement of standard production quality.

- Concerns reported by MSAs revolved around the scale of the funding required and the potential for considerable added bureaucracy and administrative costs. It would also not be possible to focus the funding only on European activities, as mirror committees would be involved in national and international work as well. It may also prove difficult to find participants in some areas even though the secretariat functions are supported.

9.1.6.5. Objective 5 – Accelerate the standards development process

Question 5.1: ESOs to systematically use IT harmonised tools to support the participation of stakeholders in the European standardisation process.

The Commission wanted to understand (i) the extent to which existing IT tools are available to and used by existing ESO TCs and NSB MCs in the development of EU standards, (ii) what IT systems are 'missing' at ESO and NSB level that would need to be put in place in order to ensure that all NSB MCs can make use of the available IT tools, and (iii) what the costs of implementing these additional IT solutions would be.

Replies by the ESOs:

- The ESOs have undertaken considerable investment into modern technology in recent years, and all three ESOs provided extensive details about the various existing IT tools available.

- IT systems are now available to and used by ESO and NSB committees throughout the standards development process, helping to reduce delivery times and increase transparency.

- CEN/CLC noted that different tools are available according to sector and / or which national member holds the secretariat, but that all European TCs can benefit from similar facilities.

- The three ESOs reported that there were no significant requirements for additional IT tools or developments (and therefore no additional costs implied), beyond fine-tuning and maintenance.

- CEN/CLC did however identify a small number of areas where enhancements could be made to (i) the current NMC services (a common CEN/CLC NMC interface and centralised NMC platforms for purely national work) and (ii) the tools available to support CEN/CLC technical bodies (web-tools to support the drafting process and central meeting management facilities), and there are planned and ongoing projects within the ESOs in these areas aimed at further increasing the level of automation available (e.g. virtual meeting facilities for TCs in 2010).

Replies by the NSBs:

- The NSBs confirmed the comprehensive and detailed ESO account of the existing IT systems that are available to support national MC participation in European standardisation

- The vast majority of NSBs stated that all of these tools are available, in use and functioning well at the national level and that all of the national MCs are able to make use of these IT tools.

- They also complemented the ESOs on the considerable advances that had been introduced and believe that these IT solutions have contributed to a more effective and efficient process.

- The majority of NSBs reported that there are no 'missing' IT tools at ESO or NSB levels that would need to be put in place.

- Nevertheless, many other NSBs stated that the proposed common CEN/CLC NMC interface and platforms, improved 'virtual meeting' facilities and new meeting management applications / tools are all welcome developments that will provide efficiency gains at national level.

- A small number of NSBs suggested that take-up of the available tools is lower than desirable and that additional actions might be useful. However, the main barriers identified to greater use are a lack of awareness, willingness and training, rather than availability or functionality.

- A small number of cost estimates were provided for specific desirable improvements.

Question 5.2: Make it an obligation for European Standards Organisations to answer any standardisation requests from the Commission within 2 months.

The Commission wanted to understand the number of mandates issued by the EC to the ESOs, the time taken to respond to each of these, and the current ESO/NSB procedures and timeframes for consulting on and responding to these mandates. The Commission also wished to understand whether a two-month timeframe for responding to mandates would be achievable (or what would be achievable), whether additional changes would be necessary and the other costs and implications incurred by ESOs/NSBs in meeting a requirement to respond within this timeframe.

Replies by the ESOs:

- ETSI reported 17 mandates being issued over 3-years, with a 3-month average acceptance time.

- CEN/CLC reported a total of 64 mandates issued over the past 3 years, with average response times each year varying between 10.4 and 13.6 months per year.

- All three ESOs provided details of their procedures and average timeframes for consulting on and responding to mandates.

- CEN/CLC reported a 2-month timeframe was achievable, while ETSI reported that 3-months would be the minimum timeframe possible due to the need to coordinate and consult before acceptance. These targets would be achievable without any significant additional financial costs.

- The ESOs reported that current delays are often due to factors outside of the control of the ESOs, and instead reside with the EC. Achieving shorter response times would require stronger and earlier consultation on mandate definition and drafting, improvements to the presentation and clarity of drafts, simplified contractual processes and for the EC to stick to a defined timeframe.

Replies by the NSBs: A small number of NSBs added that the time taken to respond to mandates is dictated by the time taken to consult national committees and other stakeholders, reach a position and prepare a response, all of which cannot always be undertaken as quickly as the Commission might wish.

Question 5.3: ESOs to be obliged to develop European standards requested by the EC in TCs managed directly by the Central Secretariats and not by the NSBs.

The Commission wanted to understand (i) the number of ESO TCs currently developing European standards under mandates, (ii) the changes to processes and procedures that would be required if TCs developing mandated European standards were to be managed by the ESOs under European-level representation principles, and (iii) what the costs and implications of this for ESOs, NSBs and stakeholders would be.

The Commission also wished to understand (i) whether there might be any implications at the international level (on the Vienna and Dresden Agreements and on national participation and voting rights) were the European Standardisation System to move away from the national delegation principle, and (ii) the number of cases in the last 2 years where European interests would have been outvoted in ISO/IEC if the EU NSBs had only one collective vote, rather than 27.

Replies by the ESOs:

- The ESOs reported that there are 352 TCs currently developing European standards under mandates issued by the EC (334 CEN/CLC and 18 ETSI).

- ETSI and its stakeholders are already operating under European-level representation principles and so no change would be necessary for this provision. However, if more TBs were required in response to specific mandates, there may be a need to increase the size of the secretariat support.

- CEN/CLC, by comparison, are currently coherent with the national delegation principle and believe a move to European-representation would require modification of all internal regulations and dramatically change the way the ESO works. There would be fundamental issues to be solved around new processes and procedures and such a radical change would incur heavy costs.

- CEN/CLC also noted that the provision may have implications for balanced TC representation and may encourage members to look more to International Standards processes where possible.

- ETSI does not participate in ISO/IEC, but CEN/CLC reported that a move away from the national-delegation principle might undermine the weight of the European NSBs in the approval processes and result in a loss of influence.

- None of the ESOs were able to give a figure for the number of cases where European interests would have been outvoted at ISO/IEC in the last two years if EU NSBs had only one vote.

- However, CEN/CLC noted that while the possibility of being outvoted is a serious issue, the biggest impact would be the loss of influence (e.g. seats at the Council, Board, TMB/SMB, etc.).

Replies by the NSBs:

- The information provided by the NSBs in relation to the required changes to processes and procedures required for ESO-managed TCs largely mirrored that provided by CEN/CLC (above).

- The NSBs are confused as to why the Commission would consider such a proposal since it clearly jeopardises European interests (especially voting) and do not see any benefits to the provision.

- Their main concerns in relation to the Vienna and Dresden agreements are covered by the implications identified by ISO/IEC below.

- None of the NSBs were able to provide data on the number of cases where European interests would have been outvoted in the last two years with only one collective vote at ISO/IEC, although several ventured that there would have been 'many' cases.

Replies by ISO/IEC:

- ISO/IEC reported that moving away from the national delegation principle would have substantial impacts and would place the future of the Vienna and Dresden Agreements in doubt.

- The four main concerns set out by ISO/IEC were (i) that the quality of the secretariat work of committees (expertise, resources and support) would need to be assured, (ii) that the representativeness of national votes would be brought into question, (iii) that the national connection to stakeholders would be jeopardised, and (iv) that it is uncertain whether individual European participation in ISO/IEC would need to be revised to reflect the new single consolidated European representation and standards development process.

- Based on the changes proposed, ISO/IEC would thus insist that their respective agreements with the ESOs be critically reviewed (with input from other parts of the world) to ensure that the commitment and appropriate mechanisms remain in place to continue to recognise the primacy of international standards, whilst recognising the particular needs of Europe.

9.1.6.6. Objective 6 – Improve the effectiveness of European standardisation

Question 6.1: Introduce the WTO/TBT principles of standardisation as a requirement for European Standards Organisations to be included in directive 98/34/EC and receive standardisation mandates to develop harmonised standards in the EU.

The Commission wanted to know whether individual NSBs had already signed the WTO/TBT code of practice, and to understand: (i) [*For those that have signed*] what the implications have been in terms of new or amended procedures actually implemented and the additional costs associated with these procedures, and (ii) [*For those that have not yet signed*] what the reasons are for this, whether the NSB has plans to do so in the near future, and if so, what stage the discussions are at and what the likely outcome of those deliberations will be. The Commission also wanted to understand whether there would be any other practical implications or costs to the ESOs and NSBs of the provision.

Replies by the NSBs:

- Based on the replies, 37 of the 40 NSBs have signed the WTO/TBT code.
- The vast majority of these NSBs stated that there were no implications (or costs) in terms of new or amended procedures to be implemented, as they were already compliant before signing.
- Four NSBs provided brief details about additional actions that were taken (including changes to notification procedures, IT tools and access to information) and in one case the cost (€30,000).
- Two of the NSBs that have not signed reported that they do intend to sign up to the code of practice. One of these NSBs explained further that they had not previously been requested to sign, but were now in early stage discussions and expected a positive outcome in the near future.
- No other substantive comments were received in relation to this provision from the NSBs.

Replies by the ESOs: All three ESOs reported that there would not be any practical implications or costs to them of this provision as ETSI is already signed up to the code and CEN/CLC and their members are already formally committed to WTO/TBT principles.

Question 6.2: ESOs to open the possibility to approve documents developed by forums and consortiums as European Standards following a simplified procedure, provided those F&C have developed the documents according to the WTO/TBT standardisation principles.

The Commission wanted to understand (i) the likely number (and names) of SDOs that may have to be approved by the ESOs and the likely number of documents to be transposed each year, (ii) whether other SDOs would cooperate with such a system

and be prepared to sign up to and abide by the WTO/TBT code of conduct, and what charges / other requirements (if any) these SDOs would impose, were their standardisation documents to be transposed into European standards, (iii) what procedures the ESOs would have to put in place in order to develop a 'fast track' approval procedure for documents created by other SDOs and the estimated 'unit' cost (i.e. per SDO, per document), plus (iv) any other practical implications or costs of the provision.

Replies by the SDOs (F&C):

- All of the responding F&C reported that they already adhered to and operated according to the WTO/TBT principles and / or would be prepared to sign up to and abide by the code of conduct.

- They also all reported that they *would* in principle cooperate with the proposed system, although most indicated some concerns, potential challenges and issues that would need addressing, namely:

  – The possible confusion caused (and costs incurred) by two different documents (ESO and F&C version) being available and implemented separately and referenced in different ways;

  – The additional burden of keeping track of modifications, extensions and updates made by either party and any confusion caused by one version lagging behind the other;

  – Issues of maintenance and change control, and whether either party could create derivative works and diverging subsequent versions of the specification;

  – Issues related to transposition into another IPR regime, with a need to assess the terms and conditions under which a standard can be used, implemented and accessed;

  – Questions regarding who would receive recognition/payment for transposed specifications;

  – Other issues relating to patent policy, disclosure obligations and royalty charges.

- Two F&C in particular had major reservations and would prefer to explore alternatives first, such as the possibility of directly referencing F&C standardisation documents.

- Further investigation, thought and discussion around these issues would be needed before F&C would be able to agree on any charges and other requirements that might be imposed.

Replies by the ESOs:

- All three ESOs reported that they already have procedures in place to adopt specifications from other SDOs, however these are not currently used for this purpose at all (ETSI) or to any great extent (CEN/CLC) and there are likely to be cost implications to increased approval activity.

- ETSI estimated the process would cost €18,000 per SDO document (although this would vary).

- All three ESOs also highlighted that there may be issues with ownership and IPR to be overcome.

Replies by the NSBs: The main point raised by NSBs was that it is already possible to use the CEN/UAP and PQ procedures for the specifications drafted by SDOs and to adopt them as ENs, and it is unclear why another procedure would be necessary.

Question 6.3: Extend the list of recognised ESOs beyond CEN, CENELEC and ETSI and make it possible to allocate standardisation requests (mandates) to these other organisations

The Commission wanted to understand (i) the likely number (and names) of SDOs that would be expected to be 'approved' as formally recognised ESOs and the likely number of mandates and volume of co-financing that might be transferred to these SDOs each year, (ii) whether other SDOs would be prepared to accept these standardisation mandates from the EC, (iii) the likely impact on ESOs and NSBs if some proportion of the mandates were transferred, (iv) the likely impact on stakeholder participation in EU standards development if the number of 'recognised' ESOs developing EU standards were to increase, and (v) other practical implications or costs.

Replies by the SDOs (F&C): All of the responding F&C reported that they would, at least in principle, be prepared to accept EC standardisation mandates, although further discussion and a closer review of the possible contractual relationships and practical details would be needed before this could be taken further.

Replies by the ESOs:

- All three ESOs reported that the impact of transferring mandates to other SDOs would be significant for these organisations, though for slightly different reasons.

- ETSI expect the provision to lead to a reduction in membership and membership fee income, as industry invests in alternative forums, damaging the infrastructure and financial stability of ETSI. It would be faced with either increasing fees to maintain budget, or reducing support to certain issues and losing staff. A reduced budget may also reduce the EC/EFTA Operating Grant.

- One-third of standards currently elaborated by CEN/CLC are mandated harmonised standards, so a reduction in mandates would result in less work for CCMC and reduced staff.

- The ESOs also raised wider concerns about potential damage to the ESS through increased competition, fragmentation, loss of coherence and clarity and reduced visibility internationally.

- They would expect to see all SDOs applying the same rules and guarantees as currently provided and clearly defined responsibilities and obligations (e.g. for maintaining/updating standards).

Replies by the NSBs:

- The NSBs indicated that the provision would not necessarily have a significant impact on them in terms of loss of work or revenues, but would have significant negative implications for the coherence of the ESS more generally.

- The extent of impact would depend on the number of SDOs involved, the number of mandates given to other bodies, and also the extent to which other SDOs follow WTO/ESS principles.

- The provision may go against the principle of national delegation, cause exclusion of certain national stakeholders, and make it more costly and difficult to track developments or participate.

- The provision would require increased coordination and communication activity in order to guard against fragmentation and conflicting standards, adding complexity and cost to the system.

- Responsibilities and obligations (e.g. for maintaining/updating/withdrawing standards and ensuring quality) will be difficult to define and maintain with increased numbers of SDOs.

Replies by Stakeholders:

- A few Stakeholder Organisations suggested the provision would bring positive benefits in terms of increasing pressure on ESOs to improve services and become more efficient, effective and responsive, as well as creating greater flexibility and choice as to where to pursue standardisation.

- However, the majority foresaw various negative consequences that would have negative implications (directly or indirectly) for stakeholders and their participation.

- In particular they highlighted that further fragmentation of the European standards landscape would place a greater time, cost and effort burden on stakeholders (especially weaker ones) to be able to monitor, follow and / or participate in relevant standards development activities, which would lead to more scattered, less effective stakeholder participation and ultimately more situations where standards are developed without relevant stakeholder involvement.

- There were also concerns about the operational implications of an expanded system and the ability of other F&C to support the continuing success of the ESS.

In particular, Stakeholder Organisations raised their concerns about (i) barriers to accessing other F&C (higher fees, less appropriate tools/processes), (ii) the strength of certain interest groups in other F&C and opportunities for private parties to manipulate standardisation outcomes for their own interests, (iii) the increasing difficulty in delivering a single coherent standardisation response to a market need, risk of conflicting standards / requirements and greater difficulties in complying with them, and (iv) decreased legitimacy, respect for and trust in the formal standardisation process.

Question 6.4: Commission to be able to request development of standards to any organisation via call for tenders to all Standards Developing Organisations meeting the WTO/TBT requirements

The Commission wanted to understand (i) whether F&C would be likely to respond to calls for tender issued by the EC for the development of European standards, (ii) what the impact of the provision would be on the Commission's own procedures and workload, and (iii) what the implications or costs would be for the ESOs and NSBs and in particular their business robustness

Replies by the F&C: Most F&C reported that they would, at least in principle, respond to calls for tender from the EC where these were felt to be relevant, although greater clarity over the practicalities of such a provision would need to be investigated further before such a system could be agreed

Replies by the ESOs:

- All three ESOs expected the provision to lead to a fragmentation of the ESS and a reduction in the ESO operating grants, which in turn would either lead to increased fees or reductions in staff and secretariat support services provided to the EC and stakeholders.

- CEN/CLC also expect the reduced income to cause a certain 'refocusing' of standards development work, reducing standards development in areas with high added value in social, public or regulatory terms, but with low expected commercial return.

- CEN/CLC also felt that the increased commercial pressure on income may result in NSBs reconsidering the amount of yearly financing of ESO activities and to limit activities to core business and more lucrative standardisation documents.

Replies by the NSBs:

- Most of the comments provided by NSBs did not relate directly to the impact of the provision on their business robustness, but focused on possible wider consequences of the proposed change.

- In particular, most NSBs suggested that the negative impacts would include undermining the current basis of European standardisation and many of its most important principles, leading to a loss of coherence and transparency, and weakening consensus as fewer actors and countries would be able to participate in

the development process. Some NSBs went so far as to state that they would be unable to guarantee the implementation of European standards at national level if they were developed outside of the scope of the established ESS.

- In addition, expected income from selling standards may become a more significant driver for ESO and NSB business decisions, as the balance between best sellers and "niche" standards cannot be ensured any longer.

- NSBs also highlighted that although F&C may work faster and cheaper than NSBs due to their simpler structures and less restrictive (and lower quality) procedures, the outputs achieved may be of far lower utility because the same level of input and consensus has not been achieved.

- A number of questions were also raised by NSBs relating to the practical implementation of the provision (e.g. concerning eligibility criteria, assessment criteria, tender evaluation processes and procedures and methods for ensuring compliance with WTO/TBT principles).

Question 6.5: Commission and ESO to establish an accreditation system of Standards developing organisations in the EU

The Commission wanted to understand the likely roles and procedures and the necessary infrastructure/operating costs of an EU-level accreditation system for SDOs. To this end, it also wished to understand various aspects of an existing comparable system, namely the accreditation elements of ANSI's operations (including the procedures and process in place to carry out accreditation, the criteria used to accredit SDOs, processes for ensuring procedures and practices are followed, and the costs and fees involved). The Commission also wanted to understand any costs and implications of the provision on ESOs and NSBs.

Replies by the ESOs: The ESOs also felt unable to provide information on the 'look' of a new accreditation system.

Replies by the NSBs:

- The NSBs also felt unable to provide information on the roles, procedures and costs of a new agency, based on the information provided at this stage.

- Indeed, most responding NSBs questioned why such a proposal was being considered when the existing system is effective, well-functioning and the preferred model for the majority of stakeholders. The need for, purpose and benefits of a new accreditation agency were unclear.

- Based on the information available, there were concerns that the provision would lead to two parallel systems (unworkable, duplicative, costly and complex, with little added value), that it would increase bureaucracy, reduce transparency/coherence and ultimately be a regressive step.

9.1.6.7. Objective 7 – Simplify the interface between the EC and the SDOs

Question 7: The Commission to create an agency or a similar organisation to manage the operational relations with standards development bodies

The Commission wanted to understand (i) the consequences for the Commission of the creation of a new agency to manage calls for standardisation work in, and (ii) whether there would be any practical implications or costs to the ESOs of this provision.

Replies by the ESOs:

- All three ESOs expect that the creation of a new agency will make the ESS more complex. They reported that a new organisation would result in more meetings, additional costs, a lack of clarity over the boundaries between the EC and the new agency and more difficult coordination amongst stakeholders at different levels.

- ETSI reported that it could see no benefits to the proposed approach.

- CEN/CLC added that a lack of clarity about the objectives of the proposed organisation mean that a thorough assessment of the practical implications and costs cannot be made.

9.2. ANNEX 2 – ECONOMIC ASPECTS OF STANDARDS IN THE EU

9.2.1. Benefits of standards

Academic research and studies carried out in different EU countries (and also outside the EU) agree on the beneficial overall effects of standards both for companies and sectors as well as the economy as a whole.

9.2.2. Microeconomic benefits

Various economic studies spell out the benefits that companies and industries in the European Union derive from the standardisation process.

These benefits can be seen in several areas:

(a) Cost reduction or cost savings derived mainly from economies of scale, the possibility to anticipate technical requirements, the reduction of transaction costs and the possibility to access standardised components. According to the World Bank[82], one of the most important economic benefits of standards is that they **increase productive and innovative efficiency**. They allow suppliers to achieve lower per-unit costs by producing large homogeneous batches. In addition, producers gain skills and experience by focusing on fewer product variations. By allowing producers to concentrate on a manageable number of product options instead of fragmenting their R&D efforts, variety-reducing standards also increase innovative efficiency. Surveyed companies agreed that they would incur additional costs without standardisation bodies because their in-house standardisers would have to work alone.

(b) Improved market access as a result of increased competitiveness due to increased efficiency, reduced trading costs, simplified contractual agreements (because the characteristics and functionalities of the product are clear as a result of the standards) and increased quality.

(c) Better relations with suppliers and clients derived from increased safety for consumers, increased trust, reduced liability risk and wider choice of suppliers for the same reasons mentioned above. Minimum safety standards are the most straightforward example of standards used to **solve imperfect information problems**. By conveying information about the harmful effects of products, they allow customers to avoid products that might negatively affect them, the general public, or the environment, and they allow regulators to exclude unsafe products from the market. These standards allow buyers to confirm that products and processes have the characteristics they want without the additional transaction costs of independent

[82] Quality Systems and Standards for a Competitive Edge (drafted by J. Luis Guasch, Jean-Louis Racine, Isabel Sánchez and Makhtar Diop), The International Bank for Reconstruction and Development/The World Bank, 2007.

testing. By codifying market preferences, standards also save sellers the additional costs of defining consumer preferences. By reducing information asymmetries, standards can help mitigate adverse selection problems[83].

(d) **Standards spur innovation** and technological transfers. They increase the efficiency of R&D investment and reduce the costs of research due to shared development efforts and knowledge sharing between different actors. Otherwise one company or group of companies would have to meet all the cost of providing information on the state of the art of a particular technology. When information on innovations is codified in standards and this information is non-proprietary, it is accessible to everybody, at least in principle. Firms, universities, and research organizations can use the knowledge embodied in standards to adopt innovations or generate new ideas. Standards play a particularly useful role in disseminating knowledge in industries where products and processes supplied by various providers must interact with one another. They ensure that information on innovations in one part of the sector will be diffused to other parts of the sector.

Optimized returns on investment resulting from the possibility to confront competing possible options for the development of a certain product or technology early in the process and to avoid investments in those that will not be widespread.

Compatibility and interface standards add economic value to goods with network externalities and facilitate the development of networks. Compatibility standards can increase direct **network externalities** by allowing products to work as part of a system or network. They allow each individual participant in the network to derive benefits from interacting with other participants in the network.

There are no quantitative data available on the impact of standards on companies' results. Some studies (Collaz 1979) estimated it at around 1% of turnover, although later studies (Blind 2004) concluded that this figure should be revised downwards.

Specific effects of standardisation for specific sectors of the economy vary according to their characteristics. Studies and surveys carried out in companies indicate that the sectors that benefit the most from standards are those more innovative, with bigger R&D and patents, bigger market concentration and more exports oriented. The size of the companies and the concentration of the market might also play a role. Benefits are also higher in the case of long lifespan products because the cycle of creation of a standard is long. The greater role in recent years of ¨de facto standards¨, more flexible, might therefore be explained because the life of products is getting shorter.

Studies point out to sectors such as aeronautics and aerospace and telecommunication as benefitting the most from the impact of standards.

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83 Quality Systems and Standards for a Competitive Edge (drafted by J. Luis Guasch, Jean-Louis Racine, Isabel Sánchez and Makhtar Diop), The International Bank for Reconstruction and Development/The World Bank, 2007.

Surveys also point out that sectors such as transport, communications services, business related services and highly regulated sectors benefit more from standards**.** The biggest needs for standards can be found in more fragmented markets, business services (that benefit more than consumer services), companies operating at international level, labour intensive services, and innovative companies**.**

9.2.3. Macroeconomic benefits

Econometric studies (DIN 2000, Blind 2004, DTI 2005, AFNOR 2009) in several EU countries (France, Germany, United Kingdom) have established a **positive influence of standards on innovation (specially on dissemination of innovation), on technological change, on productivity and on trade**. This reflects a connection between standards and economic growth. Standards are a fundamental element of a country's technical and economic infrastructure and influence technological development, which undoubtedly influences economic performance.

The existence of standards is trade-enhancing because of their positive cost-decreasing effect and the reduction of information asymmetries between the supply and the demand side, especially in the case of cross-border transactions[84].

Studies also point out to the **relation between the increase in the stock/portfolio of standards and the increase in productivity and GDP growth**. An increase of the national stock of standards of 1 % would contribute to around 0.12% of productivity growth and between 0,02%-0.1% of output growth. This would result in an overall impact on the economic growth of existing standards that has been estimated (DIN 2000) in 1% of German GDP per year. Similar figures have been estimated for France (0,8%) and other technological leading economies and slightly lower figures appear for the United Kingdom. With all precautions (the impact could be different for EU countries with a lower technological base) and lacking similar data at EU aggregated level, we can estimate that the impact of standards on annual GDP growth could rage from 0,3 to 1%. This, in terms of EU GPD value would give the figure between 35,000.37 and 120,000, million euro in 2009 (EU GDP 2009: 11,785,474.9 million euro according to Eurostat).

9.2.4. Possible negative effects of standards

Standards can have anticompetitive effects if only one or a few companies are able to internalize their benefits or control their content. In this case, **standards can be used as strategic instruments to expand market power**. This occurs when the content of the standards covers technological areas in which a limited number of firms have property rights, exclusive knowledge, or the exclusive resources needed to use a technology. Distortion of standardisation, e.g. in the form of vendor specific extension or technologies, will subsequently distort the market built upon that standard, translating standard-bias into market-bias, resulting in failure of competition, and increasing the risk of monopolization. This effect is amplified by an

[84] Blind K , « The role of standards for trade in services : hypotheses and first insights" in "The handbook of innovation and services : a multi-disciplinary perspective", edited Gallouj F. and Djellal F, Edward Elgar Ltd., 2010; Den Butter F., Groot S., Lazrak F. "The Transaction Costs Perspective on Standards as a Source of Trade and Productivity Growth", Tinbergen Institute Discussion Paper, 2007.

inherent bias for very large corporations in standardisation, whereas innovation is often driven by small and medium enterprises (SMEs). As a result, standardisation has the potential to be abused by large players to create market bias and capture markets from the innovators[85].

The realisation of the innovative and competitive benefits of standards depends upon the availability of standards to all potential innovators and competitors. **Exclusive rights on a standard, for example through intellectual property rights**, undermine the utility of standards. Participants in the standardisation process attempt to mitigate the risk of patent hold-ups on standards[86]. Nevertheless, there is still a substantial risk of third party claims which cannot be addressed. Furthermore, the assurances provided are usually non-binding and do not constitute ex-ante permission to implement, leaving the possibility for future market capture by patent holders or exclusion of specific groups of competitors, e.g. user-driven and collaborative innovation models[87].

9.2.5. Types of standards by their economic effects

Generally speaking, economic literature distinguishes different **types of standards by their economic effects**. For the purpose of this impact assessment, the following classification[88] will be used:

- Standards for interoperability (or compatibility) define physical or virtual relationships between independent entities for the purpose of interoperability or communication. Most of a country's infrastructure uses compatibility standards to connect a number of disparate private and public entities, for example railway standards and network industries.

- Minimum quality and safety standards allow consumers to assess the quality or safety of a product before purchasing it. These standards are developed to specify acceptable product or service performance along one or more dimensions such as functional levels, performance variation, service lifetime, efficiency, safety, and environmental impact. A standard that specifies a minimum level of performance often provides the point of departure for competition in an industry[89].

- Variety-reducing (or inter-changeability) standards define the common characteristics of two or more entities. In this way they provide inter-

85 Quality Systems and Standards for a Competitive Edge (drafted by J. Luis Guasch, Jean-Louis Racine, Isabel Sánchez and Makhtar Diop), The International Bank for Reconstruction and Development/The World Bank, 2007.

86 See, for example, Geradin D. and Rato M., "Frand Commitments and EC Competition Law: a Reply to Philippe Chappatte", in European Competition Journal, 2010, p. 129; Chappatte P, "Frand Commitments – The Case for Antitrust Intervention", European Competition Journal, 2009, p. 319.

87 Greve, G.C.F., "Inside Views: Innovation Policy: The Balance Between Standards and Patent Regulation", Intellectual Property Watch, 26 February 2009.

88 See Blind K., "The Economics of Standards: Theory, Evidence, Policy", Edward Elgar Publishing Ltd, 2004; Quality Systems and Standards for a Competitive Edge (drafted by J. Luis Guasch, Jean-Louis Racine, Isabel Sánchez and Makhtar Diop), The International Bank for Reconstruction and Development/The World Bank, 2007.

89 Tassey G., "Standardization in technology-based markets", Research Policy, 2000, vol. 29, issue 4-5, pages 587-602.

changeability and generate economies of scale and economies of learning in production. The majority of standards fall into this category. A well-known standard of this type is the international paper standard, ISO 216, which defines the A4 format used in most of the world except for North America. The widespread use of A4 paper has many advantages other than economies of scale in paper production itself. It avoids the need to rework documents to fit different formats and allows consumers to choose between competing paper brands, calculate shipping weights from the number of pages (most A4 sheets have the same weight), and fit papers from different sources into the same envelopes and binders, among many other advantages.

- Information and measurement standards establish a common technical language in which to compare physical attributes and convey descriptive technical information. They include unit standards, such as the number system and weights and measures.

9.3. ANNEX 3 – EUROPEAN STANDARDISATION ORGANISATIONS

9.3.1. Definitions – International context

There is a **wide variety of definitions** with respect to standards[90]. For the purpose of this impact assessment, the following definitions are used:

(1) A "Standard" means a technical specification approved by a recognised standardisation body or agreed upon between economic operators, for repeated or continuous application and with which compliance is **not compulsory**. It can be an international, European, national or Fora and Consortia standard

(2) An "International Standard" means a standard adopted by an international standardisation organisation[91] and made available to the public;

(3) A "European Standard" means a standard adopted by a European standardisation body and made available to the public;

(4) A "National Standard" means a standard adopted by a national standardisation body and made available to the public;

(5) A "European Standardisation Organisation" or "ESO" means a body referred to in Annex II to Directive 98/34/EC, i.e. CEN, CENELEC and ETSI. Annex 3 of this impact assessment contains a detailed description of these bodies;

(6) A "National Standardisation Body" or "NSB" means a body referred to in Annex II to Directive 98/34/EC;

(7) A "Fora and Consortia Standard" or "FCS" means a technical specification, convention or system developed by fora and consortia[92] compliant with WTO criteria in the development of new standards but which has not been defined

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90 The ISO/IEC Guide 2: 2004, defines a standard as a document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context. The terms as defined in ISO/IEC Guide 2 cover products, processes and services. The TBT Agreement, however, deals only with technical regulations, standards and conformity assessment procedures related to products or processes and production methods. Consequently, the corresponding definition of a standard is also limited to products or processes and production methods. Furthermore, standards as defined by ISO/IEC Guide 2 may be mandatory or voluntary. For the purpose of the TBT Agreement, standards are defined as voluntary and technical regulations as mandatory documents. Standards prepared by the international standardization EU are based on consensus. The TBT Agreement covers also documents that are not based on consensus.

91 For example, ISO (International Organisation for Standardisation), IEC (International Electrotechnical Commission), ITU (International Telecommunications Union), UNECE (United Nations Economic Commission for Europe), OECD (Organisation for Economic Co-operation and Development), OIML (Organisation Internationale de la Métrologie Légale), Codex Alimentarius (a unit of the FAO), OIE (Office International des Epizoöties), IPPC (International Plant Protection Convention - also a unit of the FAO), International Pharmacopoeia (World Health Organisation), ICH (International Conference on Harmonisation), IMO (International Maritime Organisation), ICAO, Central Office for International Carriage by Rail.

92 See Annex 7.

or endorsed as a formal standard by an international standardisation organisation, a European Standardisation Organisation (ESO) or a National Standardisation Body (NSB).

Basic reference for the **principles of standardisation** is the "Code of good practice for the preparation, adoption and application of standards" (hereinafter "Code of good practice"), which constitutes, as its Annex 3, an integral part of Agreement on technical barriers to trade (hereinafter "TBT Agreement")[93].

The Code of good practice is open to acceptance by any standardising body within the territory of a Member of WTO[94]. The three ESO have accepted the Code of good practice. Nevertheless, under Article 4.1 of the TBT Agreement, the obligations of WTO Members (including the European Union and its Member States) with respect to compliance of standardising bodies with the provisions of the Code of good practice continue to apply irrespective of whether or not a standardising body has accepted the Code of good practice.

9.3.2. General overview of the European Standardisation Organisations

The European Standardisation Organisations for the purposes of this impact assessment are the European Standardisation Bodies as referred to in Annex I of Directive 98/34/EC[95], namely:

– CEN (European Committee for Standardisation),

– CENELEC (European Committee for Electrotechnical Standards) and

– ETSI (European Telecommunication Standards Institute).

CEN and CENELEC are not-for-profit international associations under Belgian law, gathering exclusively the National Standards Bodies (NSBs) of the EU and EFTA countries and of Croatia. CEN and CENELEC decision making processes are based on consensus.

Preparatory documents and draft European standards are developed in Technical Committees to which every NSB can send a delegation, whilst the Secretariat of the Committee is managed by one of them (the decision of allocation of the secretariat is also made by consensus). National Delegations generally include 1 to 5 delegates, appointed by the national mirror committees where all national stakeholders can be represented. Each national delegation presents a consensual national position within the European Technical Committee. Once a stable draft European standard has been developed by the Technical Committee, it is approved by weighted votes of the NSBs.

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93 http://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm#annexIII.

94 For a detailed list, please consult http://www.standardsinfo.net/info/livelink/fetch/2000/148478/6301438/docs_wto/TbtList_13.09.2010.pdf.

95 Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204 of 21 July 1998) as amended.

All approved European Standards must be implemented as national standards by all CEN and CENELEC Members, and conflicting national standards must be withdrawn, thus allowing the creation of a coherent system of standards throughout the EU.

ETSI's governance is based on direct membership of companies and organisations, including NSBs. ETSI develops European standards (EN) according to the same procedure as CEN and CENELEC. However, its main task is the publication of technical specifications, developed directly by expert committees and made available on ETSI's web site.

9.3.3. Main Deliverables of the ESOs

9.3.3.1. CEN/CENELEC

CEN/CENELEC deliverables differ in the levels of transparency, consensus and approval required before issue. These deliverables are:

(1) the European Standard (EN), leading to full implementation as a national standard Europe-wide, which also serves the European regulatory purposes of the New Approach;

(2) the Technical Specification (TS), that serves as normative document in areas where the actual state of the art is not yet sufficiently stable for a European Standard;

(3) the Technical Report (TR) for information and the transfer of knowledge;

(4) the Workshop Agreement (CWA), which aims at bringing about consensual agreements based on deliberations of open Workshops with unrestricted direct representation of interested parties;

(5) the Guide (CEN or CENELEC Guide), which gives information about standardisation principles and policies and guidance to standards writers.

Apart from the CWA, which has direct industry representation in Workshops, these products are worked out among CEN/CENELEC members, who in turn consult their interested parties, usually by means of national mirror committees.

9.3.3.2. European Standard (EN)

The European Standard is a normative document made available by CEN/CENELEC in three official languages. The development of a European Standard includes a public enquiry, followed by an approval by weighted vote of national members and final ratification. The European Standard is announced at national level, published or endorsed as an identical national standard and every conflicting national standard is withdrawn.

The content of a European Standard does not conflict with any other CEN/CENELEC Standard.

A European Standard is periodically reviewed. During the elaboration and whole lifetime of the European Standard, standstill applies.

The EN is the appropriate deliverable where there is a need for national implementation and withdrawal of conflicting national standards. The values that the EN derives from the characteristics of its development process are:

– Consensus: General agreement, characterized by the absence of sustained opposition to substantial issues by any important interest parties concerned and by a process that involves seeking to take into account the view of all parties concerned and to reconcile any conflicting argument. Consensus does not imply unanimity. It makes sure that the standard is wanted by the parties concerned and prepared with voluntary commitment to their use.

– Openness (open to all stakeholders): all interested parties have the right to participate in (via national delegations) and contribute to the development of an EN.

– Transparency: At the initiation phase, the project is made public (via announcement in standards bulletins, etc.). If it may have an impact on international trade it is also notified to a defined body (Code of Good Practice for Standardization of the WTO TBT agreement). The CEN programme of work is available as public information and everybody may react during the obligatory public comment phase (the CEN enquiry).

– National Commitment: the formal adoption of EN is decided by a weighted majority vote of all CEN National Members and is binding on all of them (Formal vote). The standstill principle applies, i.e. National Members agree that no national individual action, during the preparation or after the approval of an EN, that would prejudice the European work, is taken and that no publication or revision of national standard, not in line with an existing EN, shall take place. Moreover, National Members must implement the European Standard which includes the withdrawal of any conflicting national standards.

– Technical Coherence: the European standards form a collection which should ensure continuity and consistency of technical content for the benefit of users, both at European and national levels.

An EN is reviewed at least within five years from its publication or earlier when requested.

9.3.3.3. Technical Specification (TS)

A Technical Specification is a normative document made available by CEN/CENELEC in at least one of the three official languages.

A Technical Specification is established and approved by a technical body (Technical Committee or BTTF) by a weighted vote of National Members. The Technical Specification is announced and made available at national level, but conflicting national standards may continue to exist.

A Technical Specification may compete against another Technical Specification with the same scope, but a Technical Specification may not conflict with a European Standard. This means that an existing Technical Specification should be withdrawn if the publication of a subsequent EN brings the Technical Specification into conflict with that EN.

During the preparation of a Technical Specification, or after its approval, no standstill obligation exists except if the Technical Board has specifically so decided.

The maximum lifetime of a Technical Specification is 6 years (i.e. one three-year period and one confirmation).

CEN/CENELEC introduced the Technical Specification to provide an appropriate consensus/transparency solution to a market need where there is no immediate need for national implementation and withdrawal of conflicting national standards.

A Technical Specification can be transformed into a European Standard (EN) and so it also serves as a 'pre-standard'. This pre-standardisation role is further acknowledged through the possibility of allowing 'competing' Technical Specifications which permits CEN to test two (or more) solutions to a specific market need: with experience, the preferred solution could then be transformed into a European Standard. The Technical Specification can act as a pre-standard but it can also be accepted that the 'appropriate consensus' represented by the Technical Specification could continue to meet a market need without eventual conversion into an EN.

A Technical Specification may be established with a view to serving for instance the purpose of:

– publishing aspects of a subject which may support the development and progress of the European market but where a European standard is not feasible or not yet feasible;

– giving guidance to the market on or by specifications and related test methods;

– providing specifications in experimental circumstances and/or evolving technologies.

Furthermore, a CEN Technical Committee may decide to publish an EN work item as a Technical Specification where:

– there had been insufficient support at the CEN Enquiry for the work item to progress to an EN;

– no consensus can be reached on the submission of the work item to Formal Vote within the given target date.

It may also be preferable to publish two or more Technical Specifications if, for instance, the draft EN had dealt with more than one class of product, or included alternative methods of test. Technical Specifications may, therefore, compete with each other.

9.3.3.4. Technical Report (TR)

A Technical Report is an informative document made available by CEN in at least one of the official languages.

A Technical Report is established and approved by a technical body (Technical Committee, Technical Board or BTTF) by a simple majority vote of national members.

During the preparation of the Technical Report or after its adoption, there is no standstill obligation. The obligation at national level is limited to announcement of the existence of the TR and conflicting national standards may continue. Adoption as a national deliverable is optional.

A Technical Report gives information on the technical content of standardisation work.

A Technical Report may be established as an informative document in cases where it is considered urgent or advisable to provide information to the national members, the European Commission, the EFTA Secretariat or other governmental agencies or outside bodies, on the basis of collected data of a different kind from that which is normally published as an EN.

A Technical Report may include, for example, data obtained from a survey carried out among the national members, data on work in other organizations, or data on the "state-of-the-art" in relation to national standards on a particular subject.

No time limit is specified for the lifetime of Technical Reports, but it is recommended that Technical Reports be regularly reviewed by the responsible technical body to ensure that they remain valid.

9.3.3.5. Workshop Agreement (CWA)

A Workshop Agreement is a document made available by CEN/CENELEC in at least one of the official languages.

A Workshop Agreement is a technical agreement developed in an open structure, the CEN or CENELEC Workshop (WS), and not in a Technical Committee.

A Workshop Agreement is adopted through consensus, which is reached by the Workshop participants who are responsible for its contents. The main activity of a Workshop is the development and publication of a Workshop Agreement. In addition to this main activity, a Workshop may be used as a forum to organise other project activities within CEN/CENELEC, such as the exchange of experiences with regard to implementing a specification, exchange of views with regard to new technologies and their business opportunities (conferences and seminars), creation of common web-sites, etc. For all Workshops, an approved business plan indicating the voluntary contributions of the participants to support these activities is essential.

During the preparation of a Workshop Agreement or after its adoption, there is no standstill obligation.

The Workshop Agreement is announced and possibly made available at national level, and conflicting national normative documents may continue to exist.

A Workshop Agreement may not conflict with any European normative document, but may compete with any European normative document. This means that an existing CWA must be withdrawn if the publication of a subsequent EN brings the CWA into conflict with that EN.

A Workshop Agreement should be valid for a limited duration of 3 years or until its transformation into another deliverable. When 3 years have passed, the CMC should consult the former Workshop participants to see whether a renewal of the publication for a further 3 years is appropriate; if not, the CWA should be withdrawn.

9.3.4. ETSI

9.3.4.1. European Standards

ETSI adopts and publishes European Standards (ENs) in the telecommunications series.

Before a draft EN (telecommunications series) is submitted for ETSI approval, a Public Enquiry should have been carried out for the draft by the NSOs. Any comments received during the time set shall be given due consideration by ETSI.

A draft EN (telecommunications series) is approved by the weighted national voting procedure.

The NSOs shall ensure the visibility of EN (telecommunications series) at national level, either by publication of an identical text, or by endorsement (that is, by publication of an endorsement sheet or by announcement in an official journal) within a short time of their adoption. ENs (telecommunications series) thus published or endorsed have the status of national standards. When an EN (telecommunications series) has been approved and adopted on a specific matter, the NSOs must ensure that all conflicting national standards on that specific matter are withdrawn.

9.3.4.2. ETSI Standards and ETSI Guides

ETSI also publishes ETSI Standards (ESs) and ETSI Guides (EGs). These documents are drawn up by Technical Committees, ETSI Projects or ETSI Partnership Projects, or be received from other sources, and are, following approval at that level, submitted to the membership approval process.

All full members and all associate members have the right to vote for adoption of ETSI Guides (EGs) and ETSI Standards (ESs). If the deliverable is not adopted as a result of the vote, an analysis of the distribution of the votes among associate members and full members shall be conducted. The deliverable shall be adopted for use within Europe if at least 71 % of the weighted votes cast by full members are positive.

9.3.5. The Mandates to the ESOs

Through a mandate, the public authorities ask the ESOs to draw up technical specifications of a normative nature that meet "their" requirements[96]. The concept of a mandate is based on the principle of partnership, cooperation and the clear division of tasks between the public authorities and the ESOs.

9.3.5.1. The process

The mandate is normally drawn up on the initiative of a Commission department. However, Article 6(3) of Directive 98/34 stipulates that the 98/34/EC Committee may ask the Commission to invite the ESOs to draw up a European standard. The initiative for a mandate stems from the public authorities. This does not prevent the various players on the market, such as consumers, from contacting these authorities to demonstrate the value of having a mandate, and so of having European standards, in a particular area.

The draft mandate, after informal consultation of various interested parties, is submitted to Committee 98/34/EC for formal consultation, as stipulated in Article 6(4)(d) of Directive 98/34/EC. This consultation is required for mandates under the New Approach directives, but also for any other request for standardisation to the ESOs.

When the mandate has received a favourable opinion by Committee 98/34/EC, the Commission forward the final version of the mandate in English, French and German to the ESOs by official letter. The mandates can be addressed to any one of the ESOs, or any combination of them, as the work envisaged requires.

Mandates are accepted or refused by the ESOs according to their own internal rules, through the CEN and CENELEC Technical Boards and the ETSI Board.

The acceptance of the standardisation mandate begins the standstill period, as specified in Article 7.1 of Directive 98/34/EC. From this moment the national standardisation bodies do not take "any action which could prejudice the harmonisation intended".

In the event of refusal, it will, in the first instance, be for the Commission's services, together with the European standardisation body concerned, to analyse the situation and find a solution. In a second step, the 98/34/EC-Committee should be consulted.

The withdrawal of a mandate by the Commission must be subject to a consultation with the 98/34/EC-Committee.

A mandate also specifies the dates of adoption of the standards and if possible the dates on which these documents must be ready for public survey.

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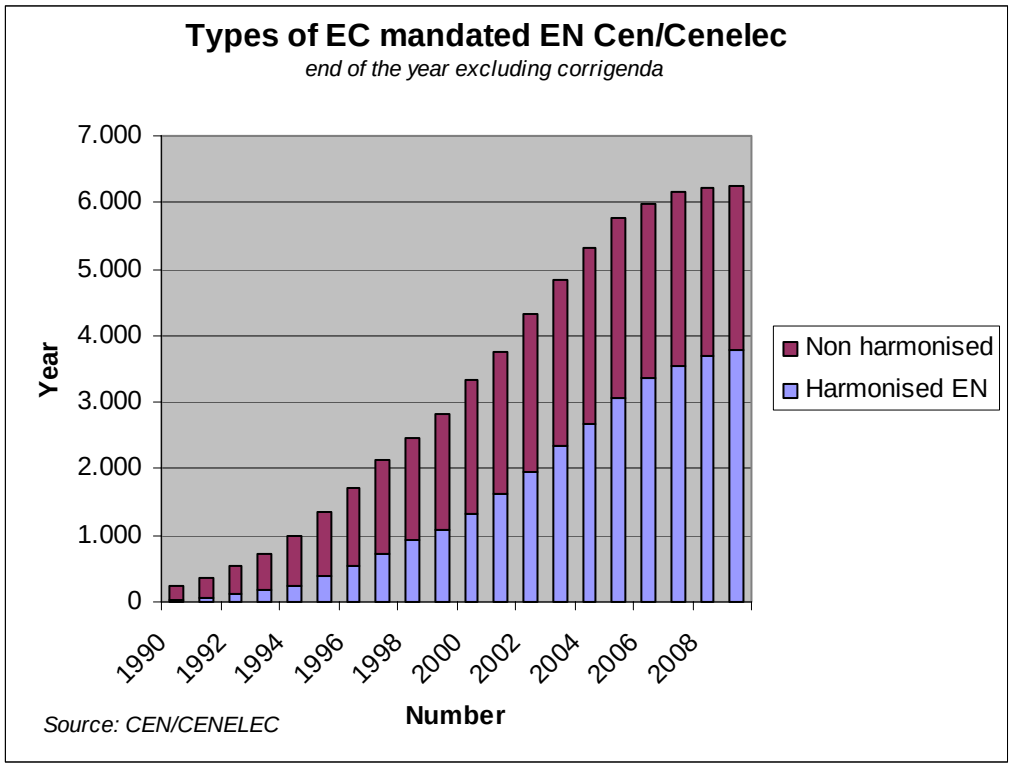
[96] Vademecum on European Standardisation of 21 November 2008 see: http://ec.europa.eu/enterprise/policies/european-standards/documents/vademecum/index_en.htm.

It is common for the ESOs to request co-funding for the mandated work following acceptance – by means of action grants – although the issuance of the mandate itself does not mean funding will necessarily be available and the request for funding must undergo a thorough evaluation process by the Commission services.

A mandate can be issued on the basis of:

- Either legislation (e.g. a New Approach directive),
- Or policy (e.g. to support the creation of lead markets or to promote policy objectives such as accessibility).

It can also be a combination of these two elements.



During the period 2006-2009, for example, a total of 86 mandates were issued to the ESOs. The number of mandates concerning New Approach Directives has fallen compared to previous years.

Mandates 2006-2009 – total						
Type	**2006**	**2007**	**2008**	**2009**	**2010**	**Total**
After formal objection (New Approach)	4	2	0	0	0	6
Amendments (New Approach)	4	0	1	4	0	9
New Approach mandates	5	7	2	7	4	25
Mandates under other legislation	7	5	9	8	10	39
Mandates under EU policy	4	6	6	2	6	24
Total	**24**	**20**	**18**	**21**	**20**	**103**

9.3.5.2. Areas in which mandates can be used

Mandates specify the public authorities' expectations towards the European Standardisation Organisations. They indicate the general context of the standardisation work, as regards a given European policy and/or the legislation concerned. It is a unilateral act inviting the ESOs to draw up standards, responding to certain conditions - such as the risks to be covered - and assuming certain tasks. Mandates must be regarded as the framework which refers to the public interest requirements and which enables the standards bodies to develop quality standards that meet these requirements.

In principle, there are three types of mandates: study mandates, programming mandates and standardisation mandates.

(1) ***The study mandate*** aims to determine if European standardisation is relevant and feasible in a specific field or for a certain subject. This type of mandate is most common in non-regulatory fields or for new sectors.

(2) ***The programming mandate*** asks the European Standardisation Organisations to draw up a standardisation programme in a given time. This programme has to contain inter alia the subjects to be standardised, the relevant technical organisations as well as the completion dates laid down. It can also include an inventory of the existing standards to be revised in order to meet the set requirements.

(3) ***A standardisation mandate*** calls on those drawing up standards or other alternative standardisation deliverables to prepare and adopt within a given time European standards in a specific field, possibly on specific subjects. It can also include the verification, and, if necessary, the revision of existing standards.

Apart from these three types of mandates, there are also so-called **"combined" mandates**. This involves mandates asking the ESOs to prepare in a first phase a

work programme and in a second phase the implementation of this programme. This normally happens in the case of major standardisation work where several families of products and/or several issues (safety, for instance) need to be dealt with.

In principle, any type of publication by the ESOs may be the subject of a standardisation mandate. However, in practice, and *a fortiori* for the directives under the New Approach, it is mostly limited to EN standards in order to ensure that the various principles of European standardisation (such as identical transposition at national level) are applied.

Mandates 2006-2010 by subject area						
Subject	**2006**	**2007**	**2008**	**2009**	**2010**	**Total**
Services	1	0	0	0	0	1
ICT	0	1	1	3	0	5
Energy	2	1	1	3	7	14
Transport	3	1	1	1	1	7
Environment	2	2	3	2	2	11
Consumer protection	4	0	4	1	4	13
Other	0	6	5	0	2	13
New Approach	12	9	3	11	4	39
Total	**24**	**20**	**18**	**21**	**20**	**103**

9.3.6. EC financial support to ESOs

The financing decision 1673/2006/EC establishes rules concerning the Commission's contribution to the financing of European standardisation in order to support the implementation of specific policies, measures, actions and legislation.

The Commission provides financial support to the Central Secretariats of European standardisation bodies with the aim of improving the quality of harmonised standards and promoting European standardisation at international level. The European Commission and EFTA establish Framework Partnership Agreements (FPAs) with each ESO, under which proposals for financing can be addressed to the Commission. The FPAs fix the administrative and financial rules concerning the financing of standardisation activities and set out the general context and terms under which financial support can be allocated. The current FPA entered into force on the 1st of January 2009 and was concluded for a period of 3 years with the possibilty of renewal for the maximum of 2 years.

The table below shows the number of specific grant agreements signed between the ESOs and the Commission between 2004 and 2009:

Numbers of standardisation grant agreements – (2004-2010)				
Year	CEN	CENELEC	ETSI	Total
2004	27	6	12	45
2005	9	5	13	27
2006	20	2	7	29
2007	10	2	6	18
2008	15	2	11	28
2009	11	2	10	23
2010	18	1	11	30
Total	**110**	**20**	**70**	**200**

There are six main areas or forms of activity that can receive financial support from EC/EFTA under the FPAs, as follows:

- **Operating Grants** (OGs), previously Annual Performance Contracts (APCs) – to support the existence and functioning of the Central Secretariats (or Management Centres) of the three ESOs

- **Standardisation Work** – financing provided to support the production and revision of standards and other standardisation products in support of European legislation and policies

- **Visibility Actions** - programmes of technical assistance, cooperation with third countries and the promotion and enhancement of the European standardisation system

- **Preliminary studies** – the performance of work in connection with European standardisation (studies, programmes, evaluations, comparative analysis, and other supporting actions)

- **Translation** - of European standards or other standardisation products into community languages other than the official languages of the ESOs

- **Quality Assessment** - the verification of the quality and conformity of European standards, or any other standardisation products, to the corresponding Community legislation, carried out by New Approach Consultants.

The table below shows the EC contribution to the European standadisation by the categories of activity supported.

Commission Financial Support to Standardisation															
	Support to Central Secretariats of ESO / Operating Grants		New Approach Consultants		Translation		IT Standardisation		Non-IT Standardisation		Visibility of European Standard System		Other		Total
Year	M€	%	M€	%	M€	%	M€	%	M€	%	M€	%	M€	%	M€
2000	4,96	*29,7*	2,01	*12,0*	1,54	*9,2*	5,07	*30,3*	3,03	*18,1*	0,04	*0,2*	0,06	*0,4*	16,71
2001	5,80	*35,9*	1,47	*9,1*	1,81	*11,2*	4,25	*26,3*	2,55	*15,8*	0,00	*0,0*	0,26	*1,6*	16,14
2002	6,32	*39,6*	2,11	*13,2*	1,72	*10,8*	2,79	*17,5*	2,96	*18,6*	0,04	*0,3*	0,00	*0,0*	15,94
2003	7,83	*52,9*	1,73	*11,7*	1,05	*7,1*	2,26	*15,3*	1,53	*10,3*	0,31	*2,1*	0,10	*0,7*	14,81
2004	6,37	*42,2*	1,72	*11,4*	1,49	*9,9*	3,05	*20,2*	2,24	*14,8*	0,22	*1,5*	0,01	*0,1*	15,10
2005	6,30	*63,3*	1,80	*18,1*	0,00	*0,0*	1,04	*10,4*	0,07	*0,7*	0,59	*6,0*	0,16	*1,6*	9,96
2006	6,73			*38,5*	1,19	*6,8*	2,88	*16,5*	6,51	*37,3*	0,08	*0,5*	0,08	*0,5*	17,47
2007	9,85			*56,7*	0,00	*0,0*	4,91	*28,3*	1,58	*9,1*	0,20	*1,2*	0,82	*4,7*	17,36
2008	10,40			*57,8*	0,00	*0,0*	4,00	*22,2*	3,30	*18,4*	0,08	*0,4*	0,20	*1,1*	17,98
2009	10,40			*49,1*	1,20	*5,7*	2,50	*11,8*	5,20	*24,5*	1,55	*7,4*	0,35	*1,7*	21,20
2010	10,17			*42,5*	1,20	*5,0*	4,47	*18,7*	7,86	*32,8*	0,20	*0,8*	0,05	*0,2*	23,94

% of total budget

9.3.7. Costs and financing of the European Standardisation system

Data provided by the European Standardisation Organisations, and a study carried out by Roland Berger (2000[97]) and own estimations (*methodology below*) indicate an estimated cost of the creation of standards of the European Standardisation System of around €3 000 million in 2009 . According to the study, this cost results mainly from the expense of industry experts' participation in the system (around 82%), followed by the costs of National Standardisation Bodies and other national institutions (16%) and the costs of the management centres of European Standardisation bodies (around 2%).On the basis of the related costs of experts, organisation of meetings, travel etc, we estimate an approximate cost for creation of a standard of around €1m.

The study argues that the system is financed primarily by industry [93-95%], followed by national governments [around 3-5%] and European Commission/EFTA contributions [around 2%]. The fact that industry bears the bulk of the cost of the system, together with the voluntary character of standards, seem to indicate that, for industry, the benefit outweighs the cost. Therefore, any initiative taken to reform the system should not discourage industry participation.

Sources and methodology

a) Costs

The report "Future financing of the CEN system" prepared by Roland Berger for CEN in December 2000 estimated the cost of the CEN system at that point in time. It was concluded that the total cost of the system amounted to 704 million euro with three main expenditure components: National Standardisation Bodies and other national organisations, Common Management Centre and industry experts' participation. On the basis of this figures, estimation was made for the three European Standardisation Organisations, CEN, CENELEC and ETSI updated to 2009.

From the CEN data we extrapolated the costs for CENELEC and ETSI for 2000 and projected them for 2009. The cost for the management centres of the CEN, CENELEC and ETSI was based on the figures contained in the annual reports of these institutions. The costs for experts participation was estimated in relation to the evolution of the annual deliverables of each organisation. The costs for National Standardisation Bodies were estimated on the basis of figures related to income provided by NSB to the Commission in a survey carried out in 2008.

Figures were also compared with results obtained from EC financial data in relation to number of meetings carried out within the standardisation process and the related costs of experts.

Data from 2000 were adjusted to inflation (data Eurostat).

b) Financing

[97] The future financing of the CEN system (Roland Berger, December 2000)

2009 data on financing from industry and Member States were extrapolated on the basis of the Roland Berger report (2000) and data from ESOs.

Estimated cost of European Standardisation system (euros)										
2000	**CEN**	**CENELEC**	**ETSI**	**Total**		**2009**	**CEN**	**CENELEC**	**ETSI**	**Total**
National Standardisation Bodies and other national organisations (*Roland Berger 2000 and Commission survey on revenues of NSB 2008*)	183.000.000			*367.816.868*						*446.875.123*
European Standardisation Organisations Management Centers (*annual reports*)	11.000.000	3.253.000	20.213.000	34.466.000			15.574.000	4.981.000	24.107.000	44.662.000
Experts participation (*estimated in relation to annual standards and adjusted to inflation*)	510.000.000	172.850.299	1.053.592.814	*1.736.443.114*			307.212.285	129.860.265	1.840.305.476	*2.277.378.026*
Total				***2.138.725.982***						***2.768.915.150***
Deliverables										
All deliverables portfolio (*Cen/Cenelec/ETSI*)	6.389	4.145	6.132	**16.666**			13.744	6.170	23.822	**43.736**
Annual production all deliverables (*Cen/Cenelec/ETSI*)	835	283	1.725	**2.843**			414	175	2.480	**3.069**
EU inflation (Eurostat)	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2.009**	**Accumulated inflation 2001-2009**
	0,02	0,02	0,02	0,02	0,022	0,022	0,023	0,037	0,01	
	1,02	1,02	1,02	1,02	1,02	1,02	1,02	1,04	1,01	1,21
Revenue NSBs 2000 (*data 2008 adjusted to inflation*)	367.816.868									
Revenues NSBs 2008 (*Commission survey*)	442.450.617									

9.3.8. Other Statistics

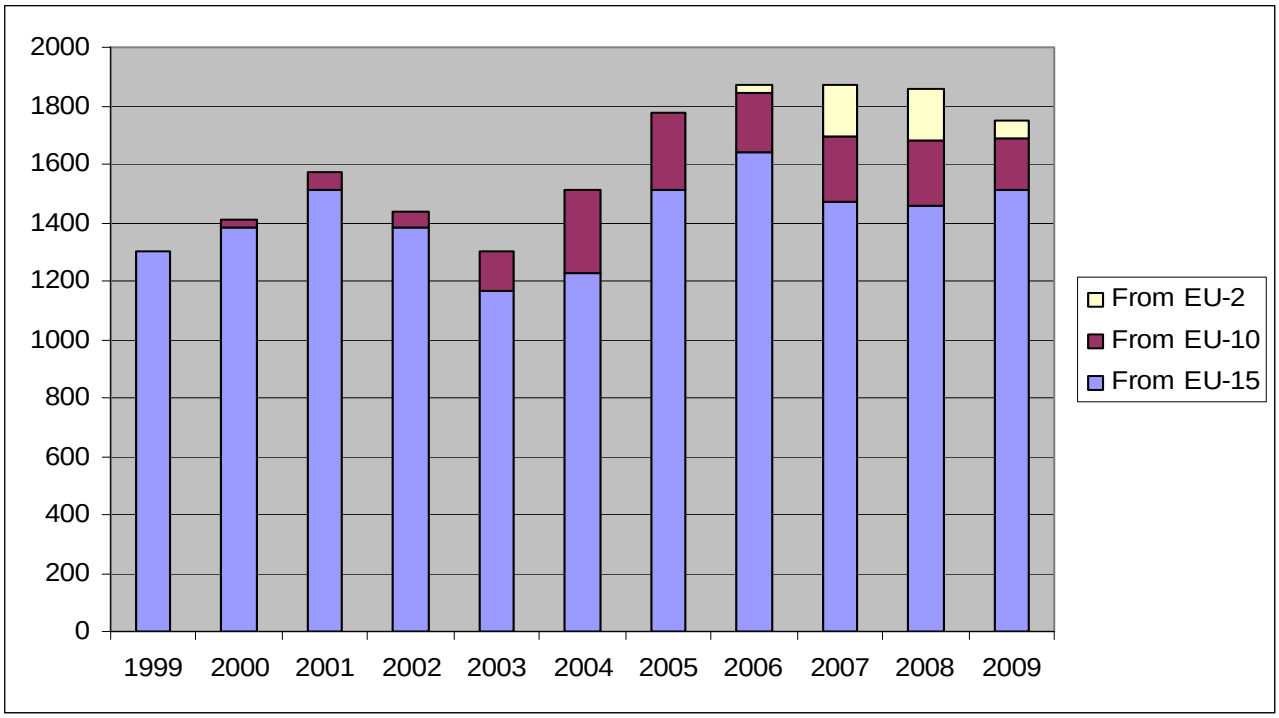
9.3.8.1. Breakdown of new national standardisation activities from notifications (CEN and CENELEC) 2006-2009 by state

Country	2006	2007	2008	2009	Total
AT	357	219	219	196	991
BE	6	50	50	30	136
BG	na	25	25	12	50
CH	27	34	14	38	113
CY	na	0	0	2	0
CZ	23	55	56	70	204
DE	503	450	448	424	1825
DK	8	9	9	8	34
EE	16	10	10	9	45
ES	190	131	129	208	658
FI	10	11	11	3	35
FR	238	243	242	277	1000
GR	3	2	0	0	5
HU	11	11	11	7	40
IE	3	1	1	4	9
IS	0	0	0	0	0
IT	107	132	133	123	495
LU	0	0	0	0	0
LT	19	18	18	3	58
LV	14	18	18	33	83
MT	1	0	0	0	1
NL	64	56	56	59	235
NO	20	19	19	17	75
PL	69	65	65	14	213
PT	13	1	1	0	15
RO	32	150	150	45	377
SE	9	14	14	21	58
SI	6	28	28	11	73
SK	45	19	19	29	112
UK	127	153	145	159	584

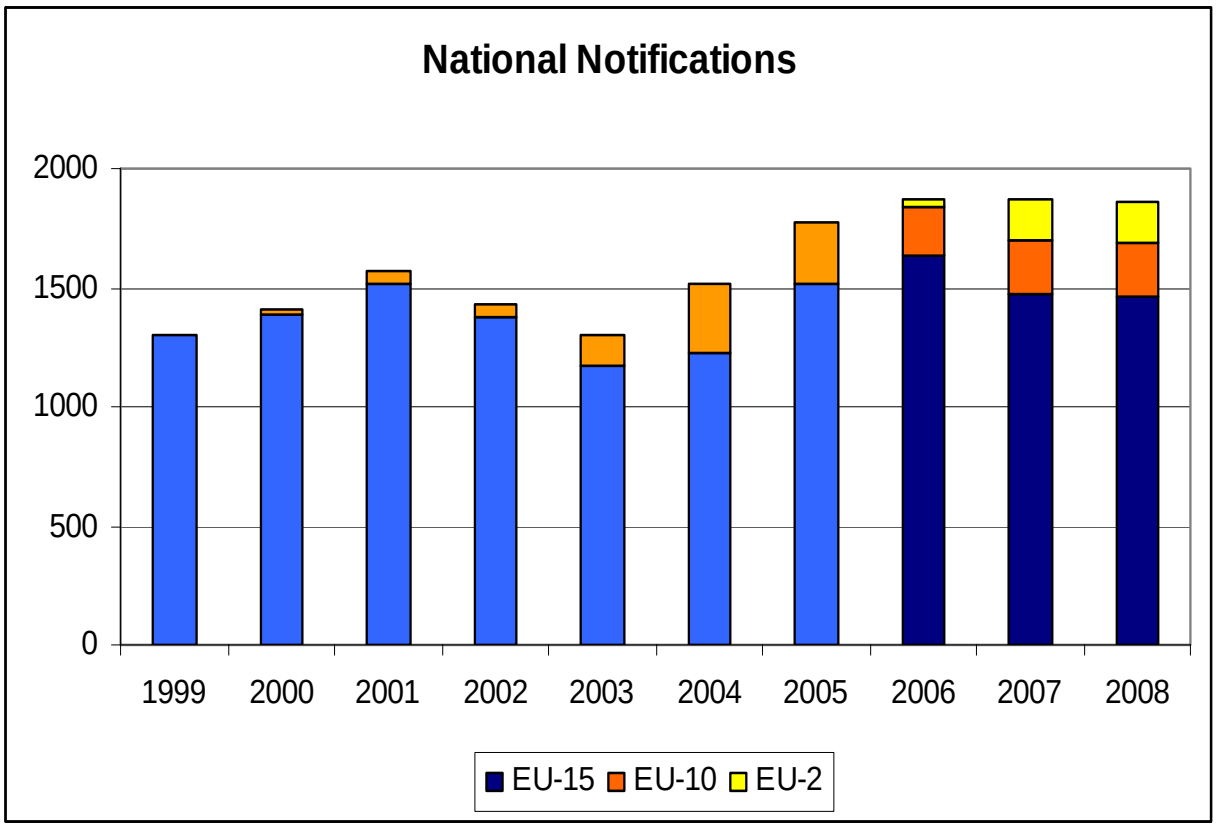
CEN	1905	1904	1835	1769	5644
CENELEC	16	20	56	99	191
From EU-15	1638	1472	1458	1512	4568
From EU-12	236	399	400	235	1035
From EFTA	47	53	33	55	133
TOTAL	1921	1924	1891	1802	5736

9.3.8.2. New national standardisation activities from notifications (CEN and CENELEC) 2006-2009

	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
EU-15	1305	1383	1511	1380	1168	1227	1512	1638	1472	1458	1512
EU-10		28	62	55	135	287	261	204	224	225	178
EU-2								32	175	175	57



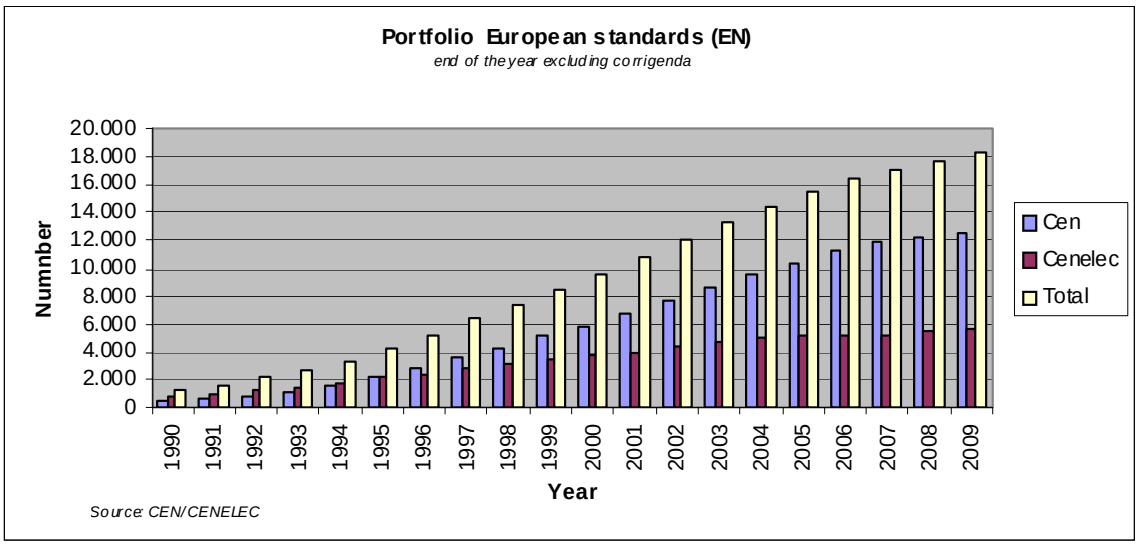
9.3.8.3. Breakdown of new national standardisation activities from notifications (CEN and CENELEC) 1999-2008 by group of countries



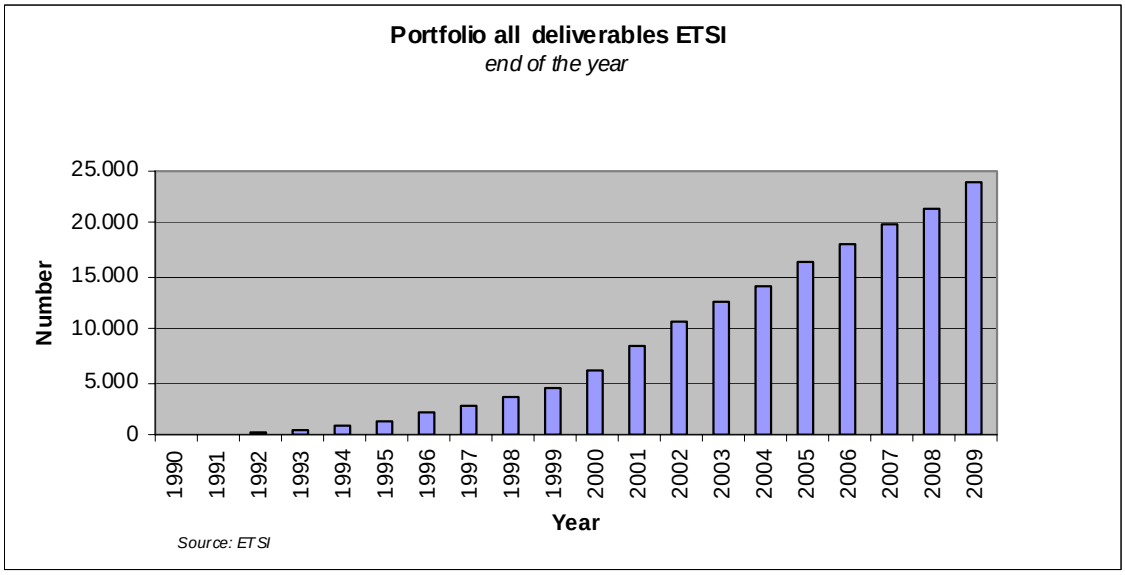
9.3.8.4. Evolution of number and type of standards over time

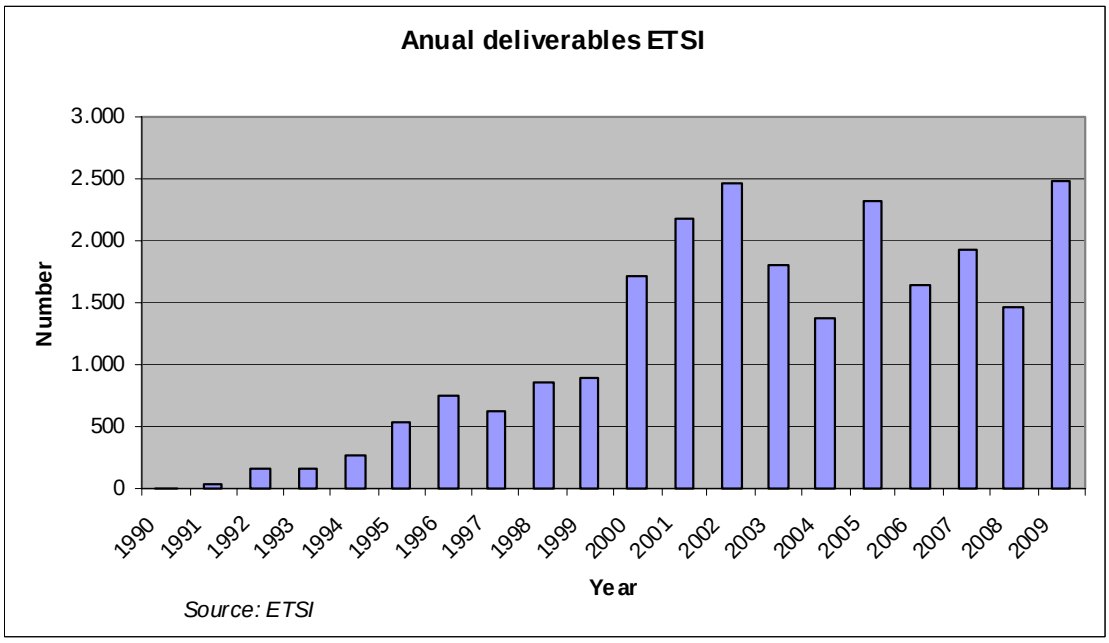
Data provided by the ESOs, indicate that the portfolio of total deliverables (European standards and other deliverables) from CEN and CENELEC together have increased significantly since the beginning of the 1990s from 1,735 in 1990 to 19,914 in 2009. Annual production of all deliverables shows an increasing trend until 2001 and a decreasing one since then.

Most of the deliverables produced by CEN and CENELEC are European standards (EN) (92% in 2009). Therefore, their trend is similar to that described for the portfolio of all deliverables. The portfolio of European standards (EN) developed by CEN/CENELEC has increased significantly from 1,280 in 1990 to 18,286 in 2009. This shows the increasing role of standards in the European economy. Annual production of EN shows an increasing trend until 2001 with a decrease since then.



The ETSI portfolio of total deliverables shows a sharp increase from 18 in 1990 to 23,822 in 2009. In 2009, European Standards represented around 18% of the total ETSI portfolio; the biggest percentage, around 70%, corresponds to technical specifications. Annual deliverables from ETSI have shown a significant constant increase until 2002, with an uneven evolution since then and an all-time high in 2009.

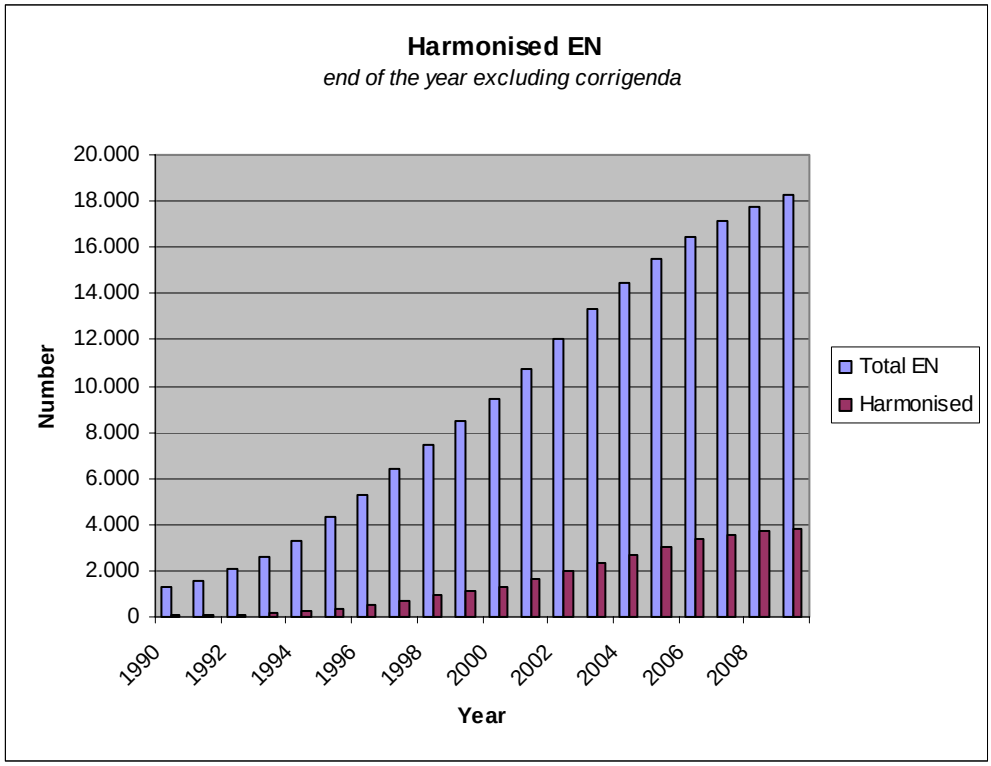




The percentage of the European standards portfolio mandated by the European Commission has increased in the last two decades from 18% in 1999 to 34% in 2009. Despite this increase, the large majority of EN remains industry–initiated, indicating that these instruments mainly respond to the needs of the industry and are mainly privately driven.

Some European standards directly support EU directives and confer a presumption of conformity with EU law. The percentage of European standards that are harmonised standards has increased in the last two decade from 3.55% to 20% in 2009. This shows the increasing importance of standards as an instrument to accompany EU

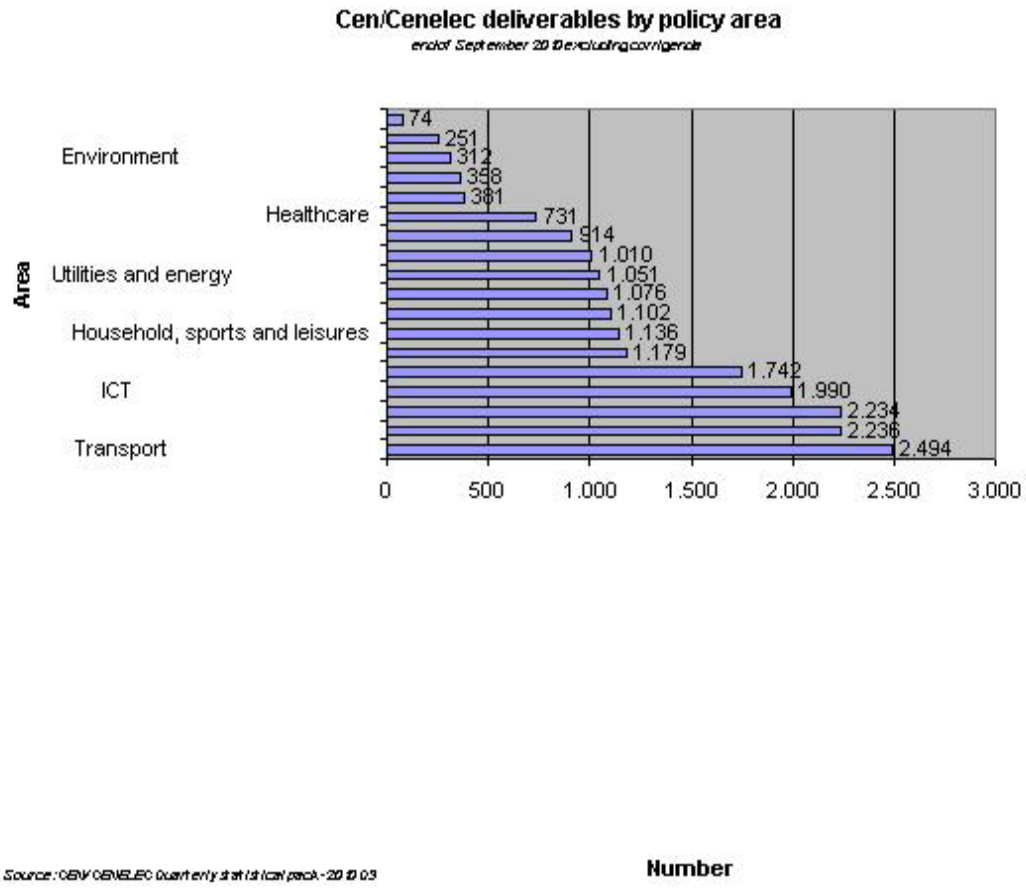
legislation.



9.3.8.5. Evolution and number of existing standards by sector

If we analyse European standards from the sectoral perspective, we find a significant concentration in a few areas. Around 70% of European standards and other deliverables produced by CEN/CENELEC focus on the areas of transport, mechanical engineering, building and civil engineering, ICT, materials, electrical engineering, household goods, and electronics. This shows that even where standards do not derive from EC mandates and/or harmonised legislation the primary focus of industry seems to be in those sectors.

The areas in which we find the biggest percentage of harmonised standards are: health and safety (52%), household, leisure and sports (51%), healthcare (46%), heating, ventilation and air conditioning (43%) and electrical engineering (35%).


Cen/Cenelec deliverables by policy area
Area
Environment
Healthcare
Utilities and energy
Household, sports and leisures
ICT
Transport
74
251
312
358
381
731
914
1.010
1.051
1.076
1.102
1.136
1.179
1.742
1.990
2.234
2.236
2.494
0
500
1.000
1.500
2.000
2.500
3.000
Number

9.4. ANNEX 4 – SECONDARY EU LAW USING EUROPEAN STANDARDS

9.4.1. New Approach directives

The New Approach is a legislative technique used in the area of free movement of goods, particularly for industrial products. It moved away from the "Old Approach" of prescriptive detailed technical requirements written into the legislation, to specify only the essential public interest requirements with which products must comply. The result is a technology-neutral legal framework. A manufacturer therefore has flexibility as to how to comply with the requirements and demonstrate such compliance. The final step is the application of the CE marking by the manufacturer to signify that the product complies with the law.

The New Approach was designed to be fully complementary to the old way of legislating and as such many common elements are covered but in a different way. Common elements include:

– Clear identification of scope;

– Use of common expressions, such as "placing on the market" or "manufacturer";

– Requirements which products must comply with in order to achieve the objectives of the legislation, expressed in terms of essential requirements or in detailed technical specifications included in the legislation;

– Determination of the technical means and procedures for demonstrating conformity with these requirements;

– Specific requirements for the labelling or marking of products;

– A "free movement clause", prohibiting any national measure from restricting the free movement of products which comply with the legislation, to ensure the free circulation of products throughout the EU;

– Very general market surveillance/enforcement requirements. Member States must take appropriate measures to ensure that only compliant products circulate on the market;

– A safeguard mechanism setting out the EU procedure where a national measure restricts circulation.

Instead of setting out detailed technical requirements in the legislation, New Approach directives limit themselves to defining essential requirements in relation to issues such as health, safety, consumer protection and the protection of the environment. The legislation fixes the level of safety which products must meet but does not pre-determine the technical solutions used to achieve this level of safety. The choice of various solutions leading to the same result is therefore left to manufacturers.

Technical specifications, in the form of European "harmonised" standards, coming under the framework of the New Approach directives, allow products to meet the

essential requirements and may be considered as an 'easy' way to achieve compliance with the legislation (presumption of conformity). The use of harmonised standards guarantees the required level of safety of products, but this is voluntary and a manufacturer may use any other technical solution which demonstrates that his product meets the essential requirements.

The directives also set out requirements for conformity assessment which, depending on the product, must be done either by third party testing, an inspection or certification body or the manufacturer himself. Certain directives require the intervention of third party conformity assessment bodies, known as notified bodies. These bodies are chosen ("designated") by Member States on the basis of certain minimum criteria (competence, impartiality, integrity, etc) which are set out in the directives. They are then "notified" to the Commission, after which they are authorised to carry out conformity assessment activities according to the procedures set out in the directives.

The New Approach also introduced a common marking of conformity, which has become its most visible and well known element. The CE marking is in effect a declaration by the manufacturer that the product conforms to all the essential requirements of the relevant legislation and that it has been subject to the applicable conformity assessment procedures. Since products bearing the CE marking are presumed to be in compliance with all applicable directives and hence benefit from free circulation, the CE marking operates as a "passport" to the whole EU market.

9.4.2. New Approach Directives

- **Simple Pressure Vessels Directive:** Directive 2009/105/EC of the European Parliament and of the Council of 16 September 2009 relating to simple pressure vessels ;

- **Toys Safety Directive:** Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys ;

- **Construction Products Directive:** Council Directive 89/106/EEC on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products;

- **Electromagnetic Compatibility Directive**: Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC ;

- **Personal Protective Equipment Directive:** Council Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment;

- **Non-automatic Weighing Instruments Directive:** Directive 2009/23/EC of the European Parliament and of the Council of 23 April 2009 on non-automatic weighing instruments;

- **Active Implantable Medical Devices Directive**: Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices;

- **Gas Appliances Directive:** Council Directive 90/396/EEC on the approximation of the laws of the Member States relating to appliances burning gaseous fuels;

- **Hot Water Boilers Directive**: Council Directive 92/42/EEC on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels;

- **Civil Explosives Directive**: Council Directive 93/15/EEC on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil uses;

- **Medical Devices Directive:** Council Directive 93/42/EEC concerning medical devices;

- **ATEX Directive:** Directive 94/9/EC of the European Parliament and the Council on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres;

- **Recreational Craft Directive:** Directive 94/25/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft;

- **Lifts Directive**: European Parliament and Council Directive 95/16/EC on the approximation of the laws of the Member States relating to lifts;

- **Pressure Equipment Directive:** Directive 97/23/EC of the European Parliament and of the Council on the approximation of the laws of the Member States concerning pressure equipment;

- **Machinery Directive**: Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast) ;

- **In-vitro Diagnostic Medical Devices Directive**: Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices;

- **R&TTE Directive:** Directive 1999/5/EC of the European Parliament and of the Council on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity;

- **Cableway Directive**: Directive 2000/9/EC of the European Parliament and of the Council relating to cableway installations designed to carry persons;

- **Measuring Instruments Directive**: Directive 2004/22/EC of the European Parliament and of the Council on measuring instruments;

- **EUP Directive**: Directive 2005/32/EC of the European Parliament and of and of the Council establishing a framework for the setting of eco-design requirements for energy using products.

9.4.3. List of directives which are based on certain elements of the New Approach

- **Low Voltage Directive**: Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits;

- **Packaging and Packaging Waste Directive**: European Parliament and Council Directive 94/62/EC on packaging and packaging waste;

- **Interoperability of Trans-European High-speed Rail System Directive**: Council Directive 96/48/EC on the interoperability of the trans-European high-speed rail system;

- **Marine Equipment Directive**: Council Directive 96/98/EC on marine equipment;

- **Interoperability of the Trans-European Conventional Rail System Directive**: Directive 2001/16/EC of the European Parliament and of the Council on the interoperability of the trans-European conventional rail system;

- **Energy Efficiency Requirements for Household Electric Refrigerators Directive**: Directive 1996/57/EC of the European Parliament and of the Council on energy efficiency requirements for household electric refrigerators, freezers and combinations thereof;

- **Transportable Pressure Equipment Directive**: Council Directive 1999/36/EC on transportable pressure equipment;

- **Noise Emission Directive**: Directive 2000/14/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors

- **Energy Efficiency Requirements for Ballasts for Fluorescent Lighting Directive:** Directive 2000/55/EC of the European Parliament and of the Council of 18 September 2000 on energy efficiency requirements for ballasts for fluorescent lighting**.**

9.4.4. Other standards-receptive directives

- **Airborne noise emitted by household appliances**: Council Directive 86/594/EEC of 1 December 1986 on airborne noise emitted by household appliances;

- **General product safety**: Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety;

- **Postal services**: Directive 97/67/EC of the European Parliament and of the Council of 15 December 1997 on common rules for the development of the internal market of Community postal services and the improvement of quality of service;

- **Restrictions on the marketing and use of certain dangerous substances and preparations**: Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations;

- **Energy labelling of household appliances**: Council Directive 92/75/EEC of 22 September 1992 on the indication by labelling and standard product information of the consumption of energy and other resources by household appliances;

- **Waste electrical and electronic equipment**: Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE).

- **Electronic communications networks and services**: Directive 2002/21/EC of the European Parliament and of the Council of 7 March 2002 on a common regulatory framework for electronic communications networks and services (Framework Directive).

9.4.5. Other standards-receptive EU legislation

- Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out **requirements for accreditation and market surveillance** relating to the marketing of products and repealing Regulation (EEC) No 339/93.

9.4.6. Formal objections

The "New Approach directives" contain safeguards in cases where a harmonised standard cannot enable products to meet the essential requirements of the directives concerned. When such cases occur, the Member States or the Commission may introduce a formal objection to the standard in question on which the Committee is consulted.

The procedure begins with a formal objection, either received by the Commission through the Permanent Representation or launched by the Commission itself. The documents are then circulated to the Committee, and normally a Member State expert group is also consulted. Once a draft Commission Decision is ready, the Committee is consulted on it. On receipt of a positive opinion, the Decision proceeds to the next stage.

The number of objections is fairly low but nevertheless on the rise (sees point 7 of this annex) with most occurring in relation to the directives on machinery, toys and pressure equipment.

DIRECTIVE	**PROCEDURE FOR OBJECTIONS TO A HARMONISED STANDARD**
Council Directive 86/594/EEC of 1 December 1986 on **airborne noise emitted by household appliances**	Article 9 1 Where a Member State or the Commission considers that the harmonised standards referred to in Article 8 (1) (a) do not fully satisfy the requirements of Article 6, that Member State or the Commission shall bring the matter before the Standing Committee set up by Directive 83/189/EEC, hereinafter referred to as the 'Committee', setting out its reasons for doing so. The Committee shall deliver an opinion as a matter of urgency. In the light of the Committee's opinion, the Commission shall notify the Member States as to whether or not the standards concerned should be withdrawn from the publications referred to in Article 8 (1)(a).
Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to **construction products**	Article 5 1 Where a Member State or the Commission is of the opinion that the harmonised standards or European technical approvals referred to in Article 4 (2), points (a) and (b), or the mandates referred to in Chapter II, do not satisfy the provisions of Articles 2 and 3, that Member State or the Commission shall notify the committee referred to in Article 19, setting out its reasons. The committee shall deliver an urgent opinion. In the light of the opinion of the committee, and after consultation with the committee set up under Directive 83/189/EEC where it concerns harmonised standards, the Commission shall inform Member States if the standards or approvals concerned should be withdrawn in the publications referred to in Article 7 (3). 2 On reception of the communication referred to in Article 4 (3), the Commission shall consult the committee referred to in Article 19. In the light of the opinion of the committee, the Commission shall notify Member States whether the technical specification in question should benefit from the presumption of conformity and, if so, publish a reference to it in the Official Journal of the European Communities. If the Commission or a Member State believes that a technical specification no longer fulfils the conditions necessary for presumption of conformity with the provisions of Articles 2 and 3, the Commission shall consult the committee referred to in Article

	19. In the light of the opinion of the said committee, the Commission shall notify the Member States whether the national technical specification in question should continue to benefit from presumption of conformity, and, if not, whether the reference to it referred to in Article 4 (3) should be withdrawn.
Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to **personal protective equipment** (89/686/EEC)	Article 6 1 Should a Member State or the Commission consider that the harmonised standards referred to in Article 5 do not completely satisfy the relevant basic requirements referred to in Article 3, the Commission or the Member State concerned shall refer the matter to the committee created pursuant to Directive 83/189/EEC (1), setting out its reasons. The committee shall deliver an opinion without delay. In the light of the committee's opinion, the Commission shall notify Member States of whether or not it is necessary to withdraw the standards concerned from publications made pursuant to Article 5.
Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to **active implantable medical Devices**	Article 6 1 Where a Member State or the Commission considers that the harmonised standards referred to in Article 5 do not entirely meet the essential requirements referred to in Article 3, the Commission or the Member State concerned shall bring the matter before the Standing Committee set up under Directive 83/189/EEC, giving the reasons therefor. The Committee shall deliver an opinion without delay. In the light of the opinion of the Committee, the Commission shall inform Member States of the measures to be taken with regard to the standards and the publication referred to in Article 5.
Council Directive 92/42/EEC of 21 May 1992 on **efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels**	[No procedure for objections]
Council Directive 93/15/EEC of 5 April 1993 on the harmonization of the provisions relating to the placing on the market and supervision of **explosives for civil uses**	Article 5 Where a Member State or the Commission considers that the harmonised standards referred to in Article 4 do not fully satisfy the essential requirements referred to in Article 3, the Commission or the Member State concerned shall bring the matter before the Standing Committee set up by Directive 83/189/EEC, giving its reasons. The Committee shall deliver its opinion without delay. In the light of the Committee's opinion the Commission shall inform the

	Member States of the measures to be taken regarding the standards and the publication referred to in Article 4.
Council Directive 93/42/EEC of 14 June 1993 concerning **medical devices**	Article 5 1 If a Member State or the Commission considers that the harmonised standards do not entirely meet the essential requirements referred to in Article 3, the measures to be taken by the Member States with regard to these standards and the publication referred to in paragraph 1 of this Article shall be adopted by the procedure defined in Article 6 (2). Article 6 1 The Commission shall be assisted by the Committee set up by Article 5 of Directive 83/189/EEC, hereinafter referred to as 'the Committee'. 2 Where reference is made to this Article, Articles 3 and 7 of Decision 1999/468/EC (1) shall apply, having regard to the provisions of Article 8 thereof. 3 The Committee shall adopt its rules of procedure.
Directive 94/9/EC of the European Parliament and the Council of 23 March 1994 on the approximation of the laws of the Member States concerning **equipment and protective systems intended for use in potentially explosive atmospheres**	Article 6 1 Where a Member State or the Commission considers that the harmonised standards referred to in Article 5 (2) do not entirely satisfy the relevant essential health and safety requirements referred to in Article 3, the Commission or the Member State concerned shall bring the matter before the Committee set up under Directive 83/189/EEC, hereinafter referred to as 'the Committee', giving reasons therefor. The Committee shall deliver an opinion without delay. Upon receipt of the Committee's opinion, the Commission shall inform the Member States whether or not it is necessary to withdraw those standards from the published information referred to in Article 5 (2).
Directive 94/25 of the European Parliament and the Council of 16 June 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to **recreational craft**	Article 6 1 Where a Member State or the Commission is of the opinion that the harmonised standards referred to in Article 5 do not fully meet the essential requirements referred to in Article 3, the Commission or the Member State shall notify the committee set up under Directive 83/189/EEC In the light of the opinion of the committee, the Commission shall inform Member States if the standards concerned should be withdrawn from the publications referred to in Article 5.
European Parliament	Article 6

and Council Directive 95/16/EC of 29 June 1995 on the approximation of the laws of the Member States relating to **lifts**	1 Where a Member State or the Commission considers that the harmonised standards referred to in Article 5 (2) do not entirely satisfy the essential requirements referred to in Article 3, the Commission or the Member State concerned shall bring the matter before the Committee set up under Directive 83/189/EEC, giving the reasons therefor. The Committee shall deliver an opinion without delay. Upon receipt of the Committee's opinion, the Commission shall inform the Member States whether or not it is necessary to withdraw those standards from the published information referred to in Article 5 (2).
Council Directive 96/48/EC of 23 July 1996 on the **interoperability of the trans-European high-speed rail system**	Article 11 Where it appears to a Member State or the Commission that European specifications used directly or indirectly for the purposes of this Directive do not meet the essential requirements, partial or total withdrawal of the specifications concerned from the publications containing them, or their amendment, may be decided upon in accordance with the procedure set out in Article 21(2) after consultation of the Committee set up under Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services.
Council Directive 96/98/EC of 20 December 1996 on **marine equipment**	[No procedure for objections]
Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning **pressure equipment**	Article 6 Where a Member State or the Commission considers that the standards referred to in Article 5 (2) do not entirely meet the essential requirements referred to in Article 3, the Member State concerned or the Commission shall inform the Standing Committee set up by Article 5 of Directive 83/189/EEC giving the reasons therefor. The Committee shall issue an opinion as a matter of urgency. Taking into account the Committee's opinion, the Commission shall notify the Member States as to whether or not those standards should be withdrawn from the publications referred to in Article 5 (2).
Directive 97/67/EC of the European Parliament and of the Council of 15 December 1997 on common rules for the development of the internal market of Community **postal services** and	Article 20 The harmonisation of technical standards shall be continued, taking into account in particular the interests of users. The European Committee for Standardisation shall be entrusted with drawing up technical standards applicable in the postal sector on the basis of remits to it pursuant to the principles set out in Council Directive 83/189/EEC of 28 March1983 laying down a procedure for the provision of information in the

the improvement of quality of service	field of technical standards and regulations. This work shall take account of the harmonisation measures adopted at international level and in particular those decided upon within the Universal Postal Union. The standards applicable shall be published in the Official Journal of the European Communities once a year.
Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on **in vitro diagnostic medical devices**	<u>Article 5</u> 2 If a Member State or the Commission considers that the harmonised standards do not entirely meet the essential requirements referred to in Article 3, the measures to be taken by the Member States with regard to these standards and the publication referred to in paragraph 1 of this Article shall be adopted by the procedure defined in Article 6(2). <u>Article 6</u> 1 The Commission shall be assisted by the committee set up by Article 5 of Directive 98/34/EC. 2 The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter, if necessary by taking a vote. The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes. The Commission shall take the utmost account of the opinion delivered by the committee. It shall inform the committee of the manner in which its opinion has been taken into account.
Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on **radio equipment and telecommunications terminal equipment** and the mutual recognition of their conformity	<u>Article 5</u> 2. Where a Member State or the Commission considers that conformity with a harmonised standard does not ensure compliance with the essential requirements referred to in Article 3 which the said standard is intended to cover, the Commission or the Member State concerned shall bring the matter before the committee. 3 In the case of shortcomings of harmonised standards with respect to the essential requirements, the Commission may, after consulting the committee and in accordance with the procedure laid down in Article 14, publish in the Official Journal of the European Communities guidelines on the interpretation of harmonised standards or the conditions under which compliance with that standard raises a presumption of conformity. After consultation of the committee and in accordance with the procedure laid down in Article 14, the Commission may withdraw harmonised standards by publication of a notice in the Official Journal of the European

	Communities.
Directive 2000/9/EC of the European Parliament and of the Council of 20 March 2000 relating to **cableway installations designed to carry persons**	Article 2 2. "European specification" shall mean a common technical specification, a European technical approval or a national standard transposing a European standard. 3 The references of European specifications, which may be common technical specifications, European technical approvals within the meaning of Directive 93/38/EEC or national standards used to transpose harmonised European standards, shall be published in the Official Journal of the European Communities. 4 Member States shall publish the references of national standards used to transpose harmonised European standards. 7 Where a Member State or the Commission considers that a European specification as referred to in paragraph 2 does not entirely satisfy the essential requirements referred to in Article 3(1), the Commission or the Member State concerned shall bring the matter before the committee referred to in Article 17 giving the reasons therefor. The committee shall deliver an opinion without delay. In the light of the committee's opinion and following consultations with the committee set up pursuant to Directive 98/34/EC in the case of harmonised European standards, the Commission shall inform the Member States whether or not it is necessary to withdraw the European specifications in question from the published information referred to in paragraph 3.
Directive 2001/16/EC of the European Parliament and of the Council of 19 March 2001 on the **interoperability of the conventional rail system**	Article 11 Where it appears to a Member State or the Commission that European specifications used directly or indirectly to achieve the objectives of this Directive do not meet the essential requirements, partial or total withdrawal of the specifications concerned from the publications containing them, or their amendment, may be decided upon in accordance with the procedure set out in Article 21(2) after consultation of the committee set up under Directive 98/34/EC.
Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on **general product safety**	Article 4 2. The Commission shall publish in the Official Journal of the European Communities the references of the European standards adopted in this way and drawn up in accordance with the requirements referred to in paragraph 1. If a standard adopted by the European standardisation bodies before the entry into force of this Directive ensures compliance with the general safety requirement, the Commission shall decide to publish its references in the Official Journal of the European Communities.

	If a standard does not ensure compliance with the general safety requirement, the Commission shall withdraw reference to the standard from publication in whole or in part. In the cases referred to in the second and third subparagraphs, the Commission shall, on its own initiative or at the request of a Member State, decide in accordance with the procedure laid down in Article 15(2) whether the standard in question meets the general safety requirement. The Commission shall decide to publish or withdraw after consulting the Committee established by Article 5 of Directive 98/34/EC. The Commission shall notify the Member States of its decision.
Directive 2004/22/EC of the European Parliament and of the Council of 31 March 2004 on **measuring instruments**	Article 14 Where a Member State or the Commission considers that a European harmonised standard as referred to in Article 13(1) does not fully meet the essential requirements referred to in Annex I and in the relevant instrument-specific Annexes, the Member State or the Commission shall bring the matter before the Standing Committee set up under Article 5 of Directive 98/34/EC, giving its reasons for doing so. The Committee shall deliver an opinion without delay. In the light of the Committee's opinion, the Commission shall inform the Member States whether or not it is necessary to withdraw the references to the national standards from the publication referred to in the third subparagraph of Article 13(1).
Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to **electromagnetic compatibility** and repealing Directive 89/336/EEC	Article 6 1 "Harmonised standard" means a technical specification adopted by a recognised European standardisation body under a mandate from the Commission in conformity with the procedures laid down in Directive 98/34/EC for the purpose of establishing a European requirement. Compliance with a "harmonised standard" is not compulsory. 2 The compliance of equipment with the relevant harmonised standards whose references have been published in the Official Journal of the European Union shall raise a presumption, on the part of the Member States, of conformity with the essential requirements referred to in Annex I to which such standards relate. This presumption of conformity is limited to the scope of the harmonised standard(s) applied and the relevant essential requirements covered by such harmonised standard(s). 3 Where a Member State or the Commission considers that a harmonised standard does not entirely satisfy the essential requirements referred to in Annex I, it shall bring the matter before the Standing Committee set up by Directive 98/34/EC (hereinafter "the Committee"), stating its reasons. The Committee shall deliver an opinion without delay. 4 Upon receipt of the Committee's opinion, the Commission shall take

	one of the following decisions with regard to the references to the harmonised standard concerned: (a) not to publish; (b) to publish with restrictions; (c) to maintain the reference in the Official Journal of the European Union; (d) to withdraw the reference from the Official Journal of the European Union. The Commission shall inform the Member States of its decision without delay
Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on **machinery**, and amending Directive 95/16/EC	Article 10 Where a Member State or the Commission considers that a harmonised standard does not entirely satisfy the essential health and safety requirements which it covers and which are set out in Annex I, the Commission or the Member State shall bring the matter before the committee set up by Directive 98/34/EC, setting out the reasons therefor. The committee shall deliver an opinion without delay. In the light of the committee's opinion, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in the Official Journal of the European Union.
Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to **electrical equipment designed for use within certain voltage limits** (codified version)	[No procedure for objections]
Directive 2007/23/EC of the European Parliament and of the Council of 23 May 2007 on the placing on the market of **pyrotechnic articles**	Article 8 4. Where a Member State or the Commission considers that the harmonised standards referred to in paragraph 2 of this Article do not fully satisfy the essential safety requirements set out in Annex I, the Commission or the Member State concerned shall refer the matter to the Standing Committee set up by Directive 98/34/EC, giving its reasons. The Standing Committee shall deliver its opinion within six months of such referral. In the light of the Standing Committee's opinion the Commission shall inform the Member States of the measures to be taken regarding the harmonised standards and the publication referred to in paragraph 2.

Directive 2009/23/EC of the European Parliament and of the Council of 23 April 2009 on **non-automatic weighing instruments**	Article 7 Where a Member State or the Commission considers that the harmonised standards referred to in Article 6(1) do not fully meet the essential requirements set out in Annex I, the Commission or the Member State concerned shall bring the matter before the Standing Committee set up under Article 5 of Directive 98/34/EC, hereinafter referred to as "the Committee", giving its reasons for doing so. The Committee shall deliver an opinion without delay. In the light of the Committee's opinion, the Commission shall inform the Member States whether or not it is necessary to withdraw those standards from the publications referred to in Article 6(2).
Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of **toys**	Article 14 1 When a Member State or the Commission considers that a harmonised standard does not entirely satisfy the requirements which it covers and which are set out in Article 10 and Annex II, the Commission or the Member State concerned shall bring the matter before the Committee set up by Article 5 of Directive 98/34/EC, giving its arguments. The Committee shall, having consulted the relevant European standardisation bodies, deliver its opinion without delay. 2 In the light of the Committee's opinion, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in or from the Official Journal of the European Union. 3 The Commission shall inform the European standardisation body concerned and, if necessary, request the revision of the harmonised standards concerned.
Directive 2009/105/EC of the European Parliament and of the Council of 16 September 2009 relating to **simple pressure vessels**	Article 6 Where a Member State or the Commission considers that the harmonised standards referred to in Article 5(1) do not entirely meet the essential safety requirements set out in Annex I, the Commission or the Member State concerned shall bring the matter before the standing committee set up under Article 5 of Directive 98/34/EC, hereinafter referred to as "the committee", giving the reasons therefor. The committee shall deliver an opinion without delay. In the light of the committee's opinion, the Commission shall inform the Member States whether it is necessary to withdraw those standards from the publications referred to in Article 5(1).
Directive 2009/142/EC of the European Parliament	Article 6 1. Where a Member State or the Commission considers that the standards referred to in Article 5(1) do not entirely meet

and of the Council of 30 November 2009 relating to **appliances burning gaseous fuels**		the essential requirements set out in Annex I, the Commission or the Member State concerned shall bring the matter before the standing committee established under Article 5 of Directive 98/34/EC, hereinafter referred to as "the committee", giving the reasons therefor. The committee shall deliver an opinion without delay. In the light of the committee's opinion, the Commission shall inform the Member States whether or not it is necessary to withdraw those standards from the publications referred to in the first subparagraph of Article 5(2).
	2.	After receipt of the communication referred to in the second subparagraph of Article 5(2), the Commission shall consult the committee. Upon receipt of the committee's opinion, the Commission shall, within one month, inform the Member States whether the national standard(s) in question are to enjoy the presumption of conformity. If they are, the Member States shall publish the reference numbers of those standards. The Commission shall also publish them in the Official Journal of the European Union.

FORMAL OBJECTIONS (2002-2010)						
	Standard	**Directive**	**Decision**	**Date**	**Decision number**	**O.J. Reference**
1	EN 848-3 "Safety of woodworking machines — One-side moulding machines with rotating tool — Part 3: Numerical control boring machines and routing machines	98/37/EC machinery	Presumption of conformity not withdrawn	17/12/2002	2002/1002/EC	L 349/103 24/12/2002
2	EN 613:2000 'Independent gas-fired convection heaters'	90/396/EEC appliances burning gaseous fuels	Presumption of conformity not withdrawn	18/03/2003	2003/189/EC	L 74/26 20/03/2003
3	EN 521:1998 'Specifications for dedicated liquefied petroleum gas appliances — Portable vapour pressure liquefied petroleum gas appliances',	90/396/EEC appliances burning gaseous fuels	Presumption of conformity not withdrawn	18/03/2003	2003/190/EC	L 74/28 20/03/2003
4	EN 1495:1997 'Lifting platforms — mast climbing work platforms'	98/37/EC machinery	Partial withdrawal of presumption of conformity	21/03/2003	2003/224/EC	L 83/70 01/04/2003
5	30 standards relating to thermal insulation products, geotextiles, fixed fire-fighting equipment and gypsum blocks	89/106/EEC construction products	Presumption of conformity not withdrawn	9/04/2003	2003/312/EC	L 114/50 08/05/2003
6	EN 1970:2000 'Adjustable beds for disabled persons — Requirements and test methods'	93/42/EEC medical devices	Presumption of conformity not withdrawn	20/04/2004	2004/376/EC	L 118/76 23/04/2004
7	EN 12180:2000 'Non-active surgical implants — Body contouring implants — Specific requirements for mammary implants'	93/42/EEC medical devices	Presumption of conformity withdrawn	20/04/2004	2004/389/EC	L 120/48 24/4/2004
8	EN 71-1:1998 "Safety of Toys – Part 1: mechanical and physical properties	88/378/EEC toys	Partial withdrawal of presumption of conformity	9/03/2005	2005/195/EC	L 63/27 10/03/2005

9	EN 143:2000 -"Respiratory protective device – Particle filters - Requirements, testing, marking"	89/686/EEC Personal Protective Equipment	Presumption of conformity partially withdrawn	16.03.2006	2006/216/EC	L 080/76 17.03.2006
10	EN 13000 - Cranes	98/37/CE Machinery	Presumption of conformity partialy withdrawn	24.11.2005	2006/731/EC	L 299/26 28.10.2006
11	EN 13683 :2003 - Garden equipment - Integrally powered shredders/chippers	98/37/CE Machinery	Non publication of the reference on the OJ	24.11.2005	2006/732/EC	L 299/29 28.10.2006
12	EN ISO 14122-4 - Safety of machinery - Permanent means of access to machinery - Part 4: Fixed ladders (ISO 14122-4:2004)	98/37/CE Machinery	Non publication of the reference on the OJ	24.11.2005	2006/733/EC	L 299/30 28.10.2006
13	EN 848-3 - Safety of woodworking machines - One side moulding machines with rotating tool - Part 3 : numerical control boring machines and routing machines	98/37/CE Machinery	Presumption of conformity partially withdrawn	02.03.2006	2006/704/EC	L 343/102 08.12.2006
14	EN 10080:2005 – Steel for the reinforcement of concrete	89/106 Construction Products	Presumption of conformity withdrawn	15.09.2006	2006/893/EC	L 291/35 21.10.2007
15	EN 71-1:2005 - Hemispheric toys - 5.12 first indent (former A 10)	88/378/EEC Toys	Presumption of conformity partially withdrawn	25.09.2006	2007/184/EC	L 85/7 27.03.2007
16	EN 71-1:2005 - Suction cups - 8.4.2.3 (former A 11)	88/378/EEC Toys	Presumption of conformity partially withdrawn	25.09.2006	2007/224/EC	L 96/18 11.04.2007

17	EN 12929-2:2004 - Safety requirements for cableway installations designed to carry persons — General requirements — Part 2: Additional requirements for reversible bicable aerial ropeways without carrier truck brakes	2000/9/EC cableway installations designed to carry persons	Presumption of conformity non withdrawn	26.11.2008	Decision in the communication C(2008)7289	Not published
18	EN 3-8:2006 - Portable fire extinguishers - Part 8: Additional requirements to EN 3-7 for the construction; resistance to pressure and mechanical tests for extinguishers with a maximum allowable pressure equal to or lower than 30 bar	97/23/EC Pressure Equipment	Publication of the reference on the OJ	13.11.2008	2009/111/EC	L 48/13 19.02.2009
19	EN 3-9:2006 - Portable fire extinguishers — Part 9: Additional requirements to EN 3-7 for pressure resistance of CO2 extinguishers	97/23/EC Pressure Equipment	Non publication of the reference on the OJ	13.11.2009	2009/140/EC	L 40/33 11.02.2010

9.5. ANNEX 5 – DISCARDED OPTIONS

During the public consultation, stakeholders commented on several possible options which, mainly on the basis of the comments made by stakeholders, were not retained for further analysis in this impact assessment report for the reasons set out below.

9.5.1. Fundamental changes to the EU financing of European standardisation

An external evaluation of the financial support allocated to the ESOs by EC/EFTA through operating and action grants signed between 1 January 2004 and 31 December 2007[98] shows, inter alia, that the financing of European standardisation by EC/EFTA is both appropriate and necessary, and widely supported by all stakeholders. The evaluation indicates that this financing is very useful to the European standardisation system, providing additional management capacity and expertise and helping to offset the costs to industry of standard development. The evaluation suggests that, under improved conditions, there would be a strong case for an increased budgetary allocation due to the significant benefit the support delivers.

While the Commission has a strong policy interest in ensuring that standardisation work goes ahead, EU/EFTA financing is not so high as to motivate stakeholders, in particular businesses, to carry out unnecessary standard development work that ultimately will not be taken up. As a result, business input into the process is not financed by the EU. Instead, the financing is concentrated on the infrastructure that coordinates and administrates the work, and then only to share the cost of this activity. The financing does not support the national mirror committees or national delegations through which most industry and other stakeholder input is provided. As such, the financing of standardisation does not follow a traditional 'market failure' logic wherein public money is used to support economically or socially useful activity that industry will not finance itself (except as regards the participation of SMEs and societal stakeholders). In fact, if businesses are not willing to put their own resources into standardisation work, then nor should the Commission or EFTA, as this would foster the development of redundant standards. Instead, the financing follows more of a cost-sharing model, where it is recognised that common interests are being pursued and that it is therefore appropriate that some level of support is provided through public financing.

9.5.2. Making European standards available free of charge

CEN and CENELEC adopt European standards which are transposed into national standards which are then sold by NSBs. Some stakeholders argue that if the Commission pays a financial contribution to the development of European standards, those standards should be made freely available, rather than being sold by the NSBs. This is considered particularly important for SMEs who may struggle to afford the purchase price of the standards they need to use.

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98 Evaluation of the Contribution of Community Financing of Standardisation to the Fulfilment of Policy Objectives of the Commission, submitted by GHK/Technopolis on 30 June 2009. http://ec.europa.eu/enterprise/dg/files/evaluation/2009-06-30__final_report_and_appendices_en.pdf.

At first glance, the idea of making all European standards freely available seems an attractive concept. However, there are also strong arguments against making all European standards freely available:

(1) The Commission does not pay the entire cost of development of European standards. The vast majority of the costs are borne by industry. The financial contribution of the EU relates only to a share of certain specific elements of the overall input.

(2) There would be very significant financial implications to the adoption of this option, with losses at NSB level running into many tens and possibly more than a hundred million euros annually (across all European NSBs). The total operating budget in 2008 for the 32 NSBs was €437m, an average of just over €13.6m each. The budgets ranged between less than €200k and over €70m, but were skewed towards the lower end of this range. Nearly half (47%) of the NSBs had an operating budget in 2008 of less than €2.5m, while less than a third (29%) had a budget of more than €10m. The total revenue from the sale of standards for the 32 NSBs was €113m, an average of just over €3.5m each. As with overall budgets, the revenue from the sale of standards varied considerably between NSBs, ranging from €25k to €25m. Over one third (34%) of NSBs received less than €500k in sales, while another third (34%) received more than €3m. Based on the figures provided for the 32 NSBs, just over one quarter (26%) of the operating budgets of these NSBs in 2008 (in total) was made up from the sale of standards. For the individual NSBs, this proportion varied between 2% and 62%, with a reasonably even spread between the two extremes. There is no obvious correlation between the overall size of an NSB's operating budget and the proportion of sales that are accounted for by the sale of standards.

(3) Purchasing a standard is a legitimate business cost or investment. There are many things that businesses need to buy in order to operate effectively, and within the overall scheme of things the purchase price of standards is a relatively modest element.

(4) Making standards freely available implies that large sections of industry that have made no contribution to their development would gain the same rights of free access as those that have contributed significantly to their development.

(5) The public sector would have to take over a substantial element of the financing of the NSBs and may also have to increase the extent to which it supports the wider costs of development of standards, reducing the extent to which standard development is industry-driven as opposed to publicly-driven. The principles of the New Approach strongly suggest that standard development should be left to the market, and this principle arguably extends to questions about how development costs are financed/recouped. The danger is that a push for free standards would involve a shift towards a model where the public sector pays a much higher share of development costs, potentially leading to a situation where the public sector exercises greater control over how and where standards are developed, who participates, etc. This would

inevitably mark a shift away from the principles of the New Approach, with unclear and possibly unwelcome consequences for the functioning of the system as a whole.

Consequently, this option was not further analysed.

9.5.3. Making harmonised standards available free of charge

The vast majority of NSBs were unable to provide an estimate of the income from the sale of European Harmonised Standards separately from the sales of all standards. Many NSBs also provided supporting arguments (see below) as to why such an estimate is in any case not a sound basis for estimating the losses to the NSBs and the system more widely.

Four of the NSBs did provide an estimate of the income from sales of Harmonised standards, but in one case only one year's data could be provided and in another the figures did not include sales of harmonised standards that are based on ISO or IEC standards. The income data for the sale of European harmonised standards provided by the four NSBs totalled €1.46 million across the five year period, an average of €365.4k for each NSB across the five year period. This equates to an average annual loss per NSB of €73k each. It should be noted, however, that where an NSB could not provide estimates for each of the last five years an 'average amount per year' has been calculated from the data provided in order to give a full five year total. It should also be noted that in one case the sales of European HS based on ISO/IEC data has not been included in the figures. Because data only covers four out of 40 NSBs it is not possible to gross these figures up to identify total income from sale of European HS in any reliable way.

Most NSBs stated that it was not possible to provide income data for European HS separately from other European standards and / or sales of other publications such as national standards because their information systems do not record separate figures for these different revenue streams. Some of these NSBs pointed out that due to the various access models and charging arrangements, often linked to membership and other products developed for customers, it would be a very complex and time-consuming (in some cases impossible) task to provide a realistic estimate. Several NSBs rejected the idea that the purchase price of European HS is a significant barrier to their use by SMEs. Some pointed to information contained in 'SME access' studies carried out either by the Commission or by CEN /CLC that shows that lack of awareness of the benefits of standards, lack of understanding of which standards to use, lack of information on standards and the costs of implementing standards are more significant barriers. Several NSBs also pointed out that they are constantly striving to improve access to standards in general and harmonised standards in particular, and that they are providing more information about standards and more competitive (i.e. lower priced) products, often tailored to SMEs, in order to improve access and take-up.

During the consultation of January-February 2010, only 10 provided a quantitative estimate of the losses average annual losses, in EUR, to the NSB if harmonised standards would be made freely available. The other 30 NSBs reaffirmed their earlier comments, stating that it is not possible to provide an estimate of the annual loss of

revenue as the sale of European harmonised standards cannot be identified separately. Of the ten NSBs providing quantitative information, eight provided an estimate of the annual losses arising were European HS to be made freely available. Among these eight NSBs the estimated total annual losses would be €11.37 million, equivalent to just over €1.42 million per NSB. This is close to (~95% of) the total income from sales of all products containing standards for these eight NSBs, although the ratios varied significantly, from a low of ~20% of all income from sales of standards to ~120% of the income from sales of standards. The reasons for the variations and the high overall estimate of losses as a proportion of sales of (all) standards can be explained by the fact that different NSBs have used different methods for calculating potential losses. Three NSBs that did not provide a € estimate of the losses nonetheless stated that they would lose between 20% and 30% of their total revenues if the ability to sell European HS would be withdrawn. If these estimates of the share of total income lost are correct then the total losses to all European NSBs would be in the order of between €100-150 million per annum.

Due to the lack of accurate data on NSB income from sales from European HS and due to uncertainties surrounding the 'knock-on' effects to other revenue streams it is not possible to provide a robust estimate of the financial impact of this provision on NSBs. However, a 'lower' estimate might be that NSBs would lose 40% of their total income from sales of standards, equivalent to ~10% of their total operating budgets. This would equate to roughly €50 million per annum across all European NSBs. An 'upper' estimate might be that NSBs would lose 20% of their total operating costs, equivalent to around €100 million per annum in total across all European NSBs.

In any event, there would be very significant practical implications to the adoption of this option, including disruption to the established business models of standardisation at national, European and International levels, and contravention of legal agreements and frameworks outside the scope of Directive 98/34/EC. Moreover, the specific consultation of January-February 2010 shows significant opposition to the adoption of this option at ESO, NSB and MSA levels, although it has some backing 'in principle' by some MSAs.

9.5.4. Member States to compensate losses generated for the budget of NSBs due to free access to Harmonised Standards

83% of MSAs responding to the specific consultation of January-February 2010 stated that they would not be willing and / or able to compensate for losses. They pointed to issues of funding (the scale of losses to NSBs and the inability of public funds to compensate) and the potential lack of benefits as reasons for this response. Four MSAs highlighted the potential scale of the compensation package necessary, quoting figures of between €180,000 and €6 million as estimates of the potential losses to NSBs. They reported that a large proportion of national standardisation activities are already being funded by the state, and that the real scale of any potential financing need may be equivalent to a significant proportion of these existing levels of financing. Two MSAs also raised their concerns as to how the compensation system would work and whether the financing package would increase with the number of standards distributed. They suggested that free access to HS may increase demand and therefore the necessary compensation costs further.

The most commonly reported reason given by MSAs was that the necessary budget would not be available to compensate the NSBs for loss of income (mentioned by eleven MSAs). It was reported that the provision would require a substantial increase in the demands on state budgets, and that this was unlikely to be acceptable, particularly in the current financial climate when public spending is being tightened. Other individual MSAs highlighted related concerns, namely (i) the risk of inconsistency in the annual approval of state funding in the future, (ii) the need to consider not only the loss of income, but also the cost to the whole HS development process and the costs arising from changing the financing model, and (iii) the lack of a suitable mechanism to allow such a compensation package to be provided. Other MSAs (six in total) reported that they are not convinced that there is sufficient justification for the provision and for the additional state financial support. Specifically, they reported that (i) it is not clear that the price of standards is a significant barrier to access, or that free access would substantially increase uptake, and that (ii) an important aspect of the ESS is that it ensures orientation to market needs and avoids misuse of funds, which may be damaged by the provision.

CEN/CLC reported that as it does not sell standards itself, any compensation package should be directed to the NSBs and NC members of CEN/CLC. However, the majority of these NSBs/NCs are (semi) private independent organisations, whose legal status is recognised as important by industry and the majority of stakeholders in order to preserve independence in the standardisation process. CEN/CLC believe that if these organisations were to accept receipt of EC/MSA financial support to compensate their financial loss, it would result in an increased dependency on these bodies, which may in turn have repercussions on the attitude of other actors. Such an approach also raises concerns for CEN/CLC as to the long-term sustainability commitment of all Member States and the need for a wide coordination to ensure that the same activities are supported similarly and fairly in all countries. CEN/CLC also highlighted that, given that no more than 2% of standardisation work is co-financed and the fact that NSBs are not keen to participate in co-financed mandated work (due to the heavy administrative workload), it may be unrealistic to believe that any loss of income could be compensated through use of additional co-financed mandates.

There does not at present appear to be any clear basis for compensating NSBs for the losses that would be incurred from making harmonised European standards freely available, with the majority of MSAs currently unable or unwilling to be able to confirm that they would be in a position to provide a compensation package. There is little consensus as to how any compensation package should be organised, largely due to widespread rejection of the related option that gives rise to the need for compensation measures. However, it appears most likely that the package would have to be based on the full costs incurred by NSBs in supporting the development, implementation, dissemination and distribution of European HS.

Even if an appropriate compensation package could be implemented, fundamental issues relating in particular to the use of ISO/IEC standards as the basis for European standards would still have to be overcome.

9.5.5. NSBs to provide free access to national committees for SMEs, NGOs, consumer organisations and trade unions

During the consultation of January-February 2010, 21 NSBs (57%) stated that they do not levy any charges for participation in standardisation committees, although several pointed out that this position is only possible due to the income generated from the sale of standards. There were a small number of caveats to this general position. In two cases participation is only granted to members, for which an annual fee is charged (€1,500 in one case, €500 in the other). One other NSB noted that it is considering moving to a compulsory membership model in future (but doesn't operate one presently). One other NSB stated that it expects to begin charging a fixed rate for committee membership (€500 per committee per year). It should be noted that in some cases it is not clear whether the 'free access' to committees is only available for members. One NSB operates a system with different charging mechanisms in different sectors. Detailed information could therefore not be provided. One NSB operates a system where the members of each committee decide who will contribute and in what proportion. Two NSBs operate a form of 'fixed rate' charging. In one of these cases the rate is fixed at €50 for all types of participant apart from public authorities where no charge is made. In the other case the rate is fixed at between €200 and €700 depending on the project workload in the relevant EU or International committees. Two NSBs charge a one-off 'entry' fee (€420 in one case, €360 in the other) for each expert, irrespective of how many committees they participate in or for how long. The entry fee includes a one day training course in standardisation. Ten NSBs operate some kind of tiered system of charges (different levels of fees to different types of participant).

Across the ten NSBs that provided data, the average number of organisations paying fees for participation in standardisation committees each year from 2005-9 was 10,045. This equates to an average of just over 1,000 organisations paying fees per NSB per year. Due to differences in the extent to which certain groups are or are not charged, and the numbers of committees operating at national level, there was a very broad range in the numbers of organisations paying fees, from a low of 34 to a high of almost 6,000.

For the six NSBs providing financial data on revenues generated, the total volume of fees generated between them per year was calculated to be just over €3.5 million. This equates to an average revenue of just over €580k per NSB per year. Once again there was a broad range in the data, with one NSB generating only €44k in fees each year on average, while at the other end of the spectrum one NSB generated just over €1.4 million in fees. In some cases these revenues relate to membership fees rather than revenues specifically relating to participation in committees. In all cases the data provided did not allow us to assess the revenues generated by different types of organisation.

The three NSBs that provided data on the share of revenues derived from each category of organisation paying contributions for participation in committees employed different categories so it was not possible to combine these two data sets into an overall result. However, broadly speaking public authorities and state bodies accounted for between 12% and 36%; enterprises and professional bodies between 50% and 80%; research organisations between 7% and 9%, and 'others' around 10%.

Because the charging models are very different it is not possible to provide a breakdown by type of committee or types of organisation. In most cases the charging models are not based around the type of committee and in only around half of the cases are different levels of fees charged to different types of organisation. The categories used to organise different types of participant are different in each case, making any kind of aggregation of the data by organisation type impossible.

Most NSBs would not be affected by the option as they do not currently charge for access to national committees. A small number of NSBs and MSAs clearly do not support this option, others appear to support the idea of free access in principle but most have not provided an indication either way.

Nevertheless, it is uncertain that there would be a legal basis for pursuing this option and that it would meet the subsidiarity test. A more detailed investigation would be necessary, including of the costs associated with providing free access to certain groups in those countries where such charges are applied appears warranted as a basis for further understanding the costs and implications of this option.

9.5.6. Member States to ensure that minority stakeholders are represented in all national standardisation committees, including by providing financial support for representative groups at national level

Support to enable MSG participation in standardisation at national level appears to be in place in around a third of the countries covered by the consultation. The nature of support provided varies, as does its scale, the groups it is directed to, how it is administered and so on. Most of the NSBs stated that the principle of open and equitable access applies, meaning that all groups have equal rights as regards access to standardisation committees and there is no 'positive' or 'negative' discrimination. In most of these cases participation in standardisation is free to all groups, and in the remaining cases the same fee is charged regardless of the type of participating organisation. Therefore, in these countries the principle followed is that all groups are treated equally and all have equal access. In a small number of cases funding for MSGs enables free or reduced cost access to standardisation committees. Regardless of the financing situation, many NSBs indicated that they relay information on new work items and new committees to MSGs to ensure that they are kept informed about new opportunities to participate. Some also proactively target information on specific opportunities to specific groups. In several cases the NSBs operate dedicated committees to facilitate coordination of MSG involvement in standardisation at national level. One NSB stated that IT tools have been developed that enable MSGs to participate remotely via tele- or video-conferencing.

NSBs and MSAs were asked to estimate the cost to install and maintain a system of support for MSGs at national level (cost per stakeholder group per country per annum). 29 of the 40 NSBs (73%) provided a response to this question, but only 6 felt able to provide an estimate of costs. The six NSBs providing an estimate of costs each came up with very different estimates, varying from €2,400 per annum (based on two person days support per month), €10,320 per annum (based on 10 participants in an average of 8 committees for 1 day per year), €44,345 per annum (costs not explained), €55,000 per annum (based on current support to three MSGs, totalling €165,000 per annum), €83,600 per annum (cost basis not clear) to €600,000 (costs

not explained). Only one NSB provided an estimate of the 'installation costs' (€217, 360, basis unclear).

Several NSBs indicated that 'free access' to standardisation committees is not sufficient to ensure stakeholder participation, as many of the MSGs lack the human resources and expertise to become involved. Several mentioned that MSGs would need (or indeed would 'expect') to be paid to participate, and installing such a system of financial support may prove to be rather costly, and not something the MSAs would necessarily be able to afford. Even if such a funding system could be established, some of the MSGs would still have difficulty in finding people with the necessary expertise to participate, although the assurance of a fee would certainly help boost participation rates.

However, some other NSBs do not agree that a system of financial support along the lines envisaged would be appropriate. One of the core principles is that standardisation should be open and transparent and that it should provide equal access to all interested stakeholders. There is a danger that the introduction of strong financial incentives for participation by certain groups would run counter to these principles. In addition, stakeholder participation should be based around awareness of the benefits that participation will bring, rather than as a means to obtain funding. There is accordingly a risk that participation by MSGs will not be effective as it could be because the wrong drivers are in place.

One final issue that was mentioned is that some of the groups lack the necessary human resources and networks to consult their members effectively, and so providing funding for participation on standardisation committees would only address part of the problem. If the MSGs are not equipped with sufficient levels of human resources and expertise to understand developments in standardisation, consult on those developments, and reach agreed positions it is unclear what role the MSG 'experts' would be able to play in the standardisation meetings.

The 12 MSAs (44% of those responding) providing quantitative figures estimated a cost of €200,000 per stakeholder per annum on average. However, individual estimates varied greatly (between €2,400 and €1.1 million), as did the systems envisaged and the tasks required. Each of the estimates provided and any supplementary information on the methodology used to calculate these costs are summarised in the table below.

Estimated cost	Comments
€ 2,400	Based on 2 person-days per month
€ 2,500	(No further explanation)
€ 5,000	(No further explanation)
€ 10,320	Based on 10 stakeholders in 8 TCs each, requiring one person-day of support per year
€ 25,000	Development of a new structural unit, with 5 employees
€ 75,000	Average - costs will vary per group
€ 100,000	Includes the costs of personnel dedicated to the administration and operation of MSGs as well as the participation of up to ten representatives from those MSGs
€ 100,000	Based on current Government support for consumer travel/expenses
€ 190,000	Based on the costs of translation/interpretation of English documents, covering mandated standards (1 employee), all other European standards of interest to MSG (2 employees), and all other relevant normative documents (2 employees) at ~€40,000 per employee
€ 210,000	Based on current experience of funding trade unions, covering participation in ~50 national TCs (particularly those relating to Ergonomic and Social responsibility)
€ 577,000	(No further explanation)
€ 1,100,000	Based on experience of co-financing SME participation. Covers (i) the co-financed costs of SME-commissioned experts representing them in European/international standardisation work (€1 million), and (ii) the management of the MSG group, involving identifying the professions concerned, highlighting the standardisation issues they face, selecting the most interesting projects and monitoring work in progress (1 FTE at €100k per year)

One MSA reported that the possibility of developing a national system for supporting the representation of MSG interests in national TCs using public funds could be considered in cases where there was real interest from the MSG in an activity and where the support materialised in participation in relevant committees. However, they reported that actions aimed at improving MSG awareness of the importance of participation in standardisation activities and the implementation of standards should be increased and diversified first. Another MSA stated that they would not support this provision as financial support to MSGs might lead to a distortion of the behaviour of those parties in the standardisation process.

In order to obtain a more reliable understanding of the costs and implications of this option one would need to make clear whether the objectives are to ensure that MSGs have free access to standardisation committees only or whether the costs of participation are also to be covered (fees, travel, subsistence). It would also be necessary to specify what level of involvement is envisaged (i.e. participation in all committees or only some) and whether other activities of the MSG/NSB to support MSG participation are envisaged. Nevertheless, the legal basis for pursuing this option is uncertain and more information is needed to perform the subsidiarity test.

9.5.7. Member States to be obliged to send official experts to take part in all national mirror committees mirroring European TCs dealing with mandated standards under Directive 98/34/EC

No information has been provided to support a link between MSA official involvement in mandated European standards development and the raising of formal objections. MSA officials are involved in at least 66% of the national mirror committees and their involvement in committees dealing with mandated standards under 98/34/EC may be much higher. The average costs of MSA involvement cannot be reliably established based on the data provided as it is not clear what costs should be included or what role they would be expected to play.

The specific consultation of January-February 2010 indicates that there appears to be little support for the placing of an obligation on all MSAs to place an expert in all national committees mirroring mandated standards under 98/34/EC.

The principle of voluntary participation as and where appropriate and where resources allow would appear to hold in the absence of any firm evidence that the current level of participation weakens the resulting standards or leads to formal objections.

Therefore, this option was not examined in detail.

9.5.8. European Commission to be able to finance mirror committees in all EU Member States

Most NSBs currently have a full or nearly full complement of national mirror committees in place. Even so, the number of 'missing' national mirror committees is estimated to be >1,500 across the countries involved in the specific consultation of January-February 2010. Costs of secretariat functions to support national mirror committees, national enquiries and national implementations cannot be reliably determined but based on the estimates provided it would cost in excess of €20 million per annum to fill all of the identified gaps, implying the need for any support to be targeted in specific areas or countries.

It does not appear appropriate or necessary for national mirror committees to be in place in all areas in all countries, as some ESO TCs are developing standards that have little or no relevance at national level and there would not be sufficient participation by stakeholders to justify the costs. While NSBs and MSAs would welcome additional financial support from the Commission at national level, stakeholders argue that it may be more appropriate to allocate any additional financing to (i) measures to improve the involvement of MSGs in national standardisation, and /or (ii) measures to improve the level of translation of European standards into national languages.

Consequently, this option was not examined in further detail.

9.5.9. ESOs to systematically use IT harmonised tools to support the participation of stakeholders in the European standardisation process

During the specific consultation of January-February 2010, ETSI reported that it is recognised as a worldwide leader in the use of IT tools to support its members activities in standardisation. Although the issue of mirror committees is not relevant to ETSI, its NSOs work electronically with ETSI and use the ETSI platform in their daily collaboration with the ESO.

Similarly, CEN/CLC report that they have developed tools and applications to support the whole standards development process electronically, from inception through to national implementation, monitoring and decision-making. They report that many sub-processes are already fully electronic and that planned/ongoing projects aim to further increase the level of automation available. In addition, CEN/CLC note that the high investments made by CEN and CENELEC in modern technologies have contributed considerably to reducing the delivery time of standards over the last years and increasing transparency.

CEN/CLC provided further details about the various IT tools available to and used by existing ESO TCs and NSB MCs involved in developing EU standards. These points are summarised below:

- The work of CEN/CLC TCs is supported by electronic collaborative platforms. Different tools are available according to sector and/or which national member holds the secretariat, but all European TCs can benefit from similar facilities and their participants can access their working documents at any time, from anywhere in the world.

- CEN/CLC provides electronic templates to TC secretaries to guide the drafting of standards, and all standards documents are exchanged electronically between the parties involved.

- CEN has set up an exchange platform to support the standards preparation process between TC secretaries, translators and CCMC.

- The CEN and CENELEC Work Programmes are available on-line (CEN PROJEX-ONLINE and password-protected access on the CENELEC web site) to the players directly involved in the standardisation process, providing high transparency on all the CEN and CENELEC projects and standards' details, planning, interactions and legislative aspects as well as monitoring tools.

- For a wider audience, the CEN and CENELEC Work Programmes are available on the CEN and CENELEC Web Sites respectively with powerful search facilities.

- CEN/CLC Technical Body documents can also be made available automatically to national MCs, with or without human intervention:

  – CEN provides an NMC environment and web services that can be used by national members to provide access to CEN documents to their

NMCs, in a similar way to ISO. It does not, however, currently provide a centralised environment to support purely national work;

– CLC provides access to CENELEC/TC documents via a joint IEC/CLC platform. The IEC/CLC Collaboration Tool also provides platforms to support purely national work to interested national members.

- CEN and CENELEC electronic platforms and distribution channels are also available to make draft standards and standards available to Members and Affiliates (specific CEN and CENELEC systems). The documents are available in a few seconds and only to authorised users

- A significant data flow between CCMC and National Members is also supported electronically:

  – From CCMC to National Members, Affiliates and other authorised partners: A similar file delivery service (with identical data structure) is ensured by CEN and CENELEC, allowing the National Committees to feed their local Information systems with project data and start national workflows (CEN PROJEXDATA & CENELEC PROJEXDATA)

  – From National Members and Affiliates to CCMC: On the CEN side bulk data update of the CCMC database by CEN Members' and Affiliates' data, such as National Implementations and titles, data delivered in the framework of Directive 98/34 is fully electronic (i-Projex). CENELEC supports automatic or semi-automatic electronic delivery according to the type of information

- The standards acceptance process is managed electronically via the CEN and CENELEC electronic voting systems. National votes are registered on-line and balloting results are available immediately at closure. In CEN, eBalloting facilities are also available to support the Governance Bodies' decisions.

- The access to the collaborative platforms and electronic voting systems is managed via the centralised repository of users and roles, allowing a decentralised management by responsible National Members (CEN/Global Directory and CENELEC Expert Management System).

- The electronic working platforms (including NMC), electronic voting applications and users directories are collaborative projects with ISO and IEC respectively.

Further details on planned/ongoing projects within CEN/CLC to further increase the level of automation available were provided, as follows:

- Virtual meeting facilities (tele- and web-conferencing) will be available as of 2010 to CEN and CENELEC technical committees (ensured by CCMC) and will allow the organisation of more and faster working meetings, participation of team members who cannot attend physically, reducing travelling time and costs

- A common CEN/CLC bulk data delivery interface is under consideration

- On the CEN side, mutual visibility on results of parallel ballots to CEN and ISO technical committees involved via the eBalloting application is currently under development

During this consultation, stakeholders said that there has been considerable investment into modern technology and IT systems are now available to and used by ESO and NSB committees throughout the standards development process that are considered to be functioning well in the vast majority of cases. Most organisations report that there are no 'missing' IT tools at ESO or NSB levels that would need to be put in place and there are no significant requirements for any additional developments.

While IT tools have undoubtedly helped to improve the speed and efficiency of European standardisation over recent years, these tools (or a lack of them) are not the main driver of the time that it takes to develop standards.

Therefore, this option was discarded for further analysis.

9.5.10. ESOs to be obliged to develop European standards requested by the EC in TCs managed directly by the Central Secretariats and not by the NSBs

The ESOs reported in the consultation of January-February 2010 that there are 352 TCs currently developing European standards under mandates issued by the EC (334 CEN/CLC and 18 ETSI). ETSI and its stakeholders are already operating under European-level representation principles and so no change would be necessary for this option. However, if more TBs were required in response to specific mandates, there may be a need to increase the size of the secretariat support. CEN/CLC, by comparison, are currently coherent with the national delegation principle and believe a move to European-representation would require modification of all internal regulations and dramatically change the way the ESO works. There would be fundamental issues to be solved around new processes and procedures and such a radical change would incur heavy costs.

CEN/CLC also noted that the option may have implications for balanced TC representation and may encourage members to look more to International Standards processes where possible. ETSI does not participate in ISO/IEC, but CEN/CLC reported that a move away from the national-delegation principle might undermine the weight of the European NSBs in the approval processes and result in a loss of influence. None of the ESOs were able to give a figure for the number of cases where European interests would have been outvoted at ISO/IEC in the last two years if EU NSBs had only one vote. However, CEN/CLC noted that while the option of being outvoted is a serious issue, the biggest impact would be the loss of influence (e.g. seats at the Council, Board, TMB/SMB, etc.). During the specific consultation of January-February 2010, ISO/IEC reported that moving away from the national delegation principle would have substantial impacts and would place the future of the Vienna and Dresden Agreements in doubt. The four main concerns set out by ISO/IEC were (i) that the quality of the secretariat work of committees (expertise, resources and support) would need to be assured, (ii) that the representativeness of national votes would be brought into question, (iii) that the national connection to stakeholders would be jeopardised, and (iv) that it is uncertain whether individual

European participation in ISO/IEC would need to be revised to reflect the new single consolidated European representation and standards development process.

Therefore, it is not clear to any of those consulted what the benefits, if any, of this option would be. There is no evidence that the option would accelerate the standards development process or improve the balance of representation of stakeholders (indeed the opposite may be true). Stakeholders argue that there would be a very significant cost and disruption associated with the change in procedures necessary in Europe, with many negative implications and few if any benefits. They also claim that this option would negatively impact on the influence of European countries in international standardisation, with negative consequences for European industry in the global markets. According to the results of the specific consultation of January-February 2010, this option would place the future of the Vienna/Dresden Agreements in doubt, might seriously undermine European involvement in ISO/IEC, jeopardise its interests, increase the number of cases where European interests are outvoted and cause a significant loss of influence.

Consequently, this option was not analysed any further.

9.5.11. ESOs to open the option to approve documents developed by forums and consortiums as European Standards following a simplified procedure, provided those F&C have developed the documents according to the WTO/TBT standardisation principles

During the specific consultation of January-February 2010, all of the responding F&C reported that they already adhered to and operated according to the WTO/TBT principles and / or would be prepared to sign up to and abide by the code of conduct. They also all reported that they *would* in principle cooperate with the proposed system, although most indicated some concerns, potential challenges and issues that would need addressing, namely the possible confusion caused (and costs incurred) by two different documents (ESO and F&C version) being available and implemented separately and referenced in different ways, the additional burden of keeping track of modifications, extensions and updates made by either party and any confusion caused by one version lagging behind the other, issues of maintenance and change control, and whether either party could create derivative works and diverging subsequent versions of the specification, issues related to transposition into another IPR regime, with a need to assess the terms and conditions under which a standard can be used, implemented and accessed, questions regarding who would receive recognition/payment for transposed specifications and other issues relating to patent policy, disclosure obligations and royalty charges.

All three ESOs reported that they already have procedures in place to adopt specifications from other SDOs, however these are not currently used for this purpose at all (ETSI) or to any great extent (CEN/CLC) and there are likely to be cost implications to increased approval activity. ETSI estimated the process would cost €18,000 per SDO document (although this would vary). All three ESOs also highlighted that there may be issues with ownership and IPR to be overcome. The main point raised by NSBs in the specific consultation of January-February 2010 was that it is already possible to use the CEN/UAP and PQ procedures for the specifications drafted by SDOs and to adopt them as ENs, and it is unclear why another procedure would be necessary.

There is evidently some interest and willingness from both the ESOs and F&C to build on existing cooperative activity and to have a formalised process for referencing other SDO specifications. However, there are a number of important concerns and questions about the practicalities of the option and there is likely to be considerable resistance to any requirement to transfer ownership or control of specifications to the ESOs. Consequently, this option was discarded at an early stage.

9.5.12. Extend the list of recognised ESOs beyond CEN, CENELEC and ETSI and make it possible to allocate standardisation requests (mandates) to these other organisations

The F&C consulted in January-February 2010 appear to be interested in the option and generally willing to explore further the possibilities of recognition for their organisations and receiving EC mandates.

Other respondents appear to be considerably less supportive of the idea. There is some evident interest in being able to recognise and reference certain activities already undertaken by other SDOs, but expansion of the ESS to include these other organisations as more integral players in that system raises numerous concerns and fundamental objections from most respondents, who suggest that the negative implications may far outweigh, or even counteract, any benefits sought. The option is widely expected to damage the infrastructure and financial stability of the current ESOs, lead to greater fragmentation of the ESS and a consequent loss of coherence and clarity in the development of standards in response to market needs. The option is expected to lead to more scattered, less effective stakeholder participation and result in standards being developed without sufficient involvement or input from relevant stakeholders and therefore less legitimacy within the market. The scale of the negative implications would depend on the likely number of SDOs involved, the number of mandates envisaged and the specific cases that might require such an approach.

Nevertheless, the option would appear, on a fundamental level (and regardless of scale) to go against New Approach and national delegation principles and run counter to ongoing efforts to improve the current ESS, with a move away from further integration of standardisation processes and activities, reduced coherence and increased risks of duplication of effort, barriers to trade and confusion within the market, and consequently risks reducing the credibility of the ESS. It is clear that most would expect any newly recognised SDOs to have the same rules, responsibilities and obligations placed on them as with the current ESOs and that they would match the principles, processes and procedures that are currently in use. Greater alignment between new and old ESOs would allay some of the concerns raised, but achieving this may be complex, time consuming and costly, and may ultimately reduce any benefits (e.g. speed of standards development) that might have led to option being suggested in the first place. Therefore, this option was not examined in greater detail.

9.5.13. Commission to be able to request development of standards to any organisation via call for tenders to all Standards Developing Organisations meeting the WTO/TBT requirements

The specific consultation of January-February 2010 shows that there is little or no support for this option. Similar arguments are made as in previous options regarding the expected fragmentation of the ESS, loss of coherence and transparency and issues of weaker consensus being achieved as a result of the option. Some NSBs also suggest that there may be potential issues with national implementation of standards developed by other bodies.

ESOs and NSBs expect the option to lead to a reduction in the operating budgets of the ESOs and a consequent reduction and refocusing of activities undertaken by the ESOs and their members. There would also be less interest and ability to work in areas of high social, public or regulatory benefit (but low commercial return) than is currently the case.

It is not clear that the benefits of F&C (speed, price and simplicity) outweigh the drawbacks (lower quality and utility). It would be necessary for other SDOs to comply and adhere to various principles and processes associated with the current ESS if the option is to gain additional support amongst the various stakeholders, but achieving these standards will remove much of the benefit offered by the use of F&C.

Consequently, this option was not examined any further.

9.5.14. Commission and ESO to establish an accreditation system of Standards developing organisations in the EU

This option was developed in the light of the system established by ANSI, the body facilitating the development of American National Standards (ANS) by accrediting the procedures of SDOs, who work cooperatively to develop voluntary national consensus standards. Accredited SDOs must have procedures compliant with ANSI essential requirements for due process, which are ten principles related to developing ANS (openness, lack of dominance, balance, coordination/harmonisation, notification, consideration of views / objections, consensus voting, appeals processes, written procedures and compliance with other policies). Those SDOs seeking accreditation must apply with satisfactory evidence of compliance with these essential requirements and criteria. They must continue to adhere to updated requirements and are audited by ANSI at selected intervals to confirm adherence. Total annual expenditure by ANSI on its accreditation services was €3 million in 2009. However, this figure covers various activities and organisation types (not just standards development) and includes the ongoing accreditation of over 220 SDOs. An EU-level accreditation system would be unlikely to operate at the same scale. ANSI operates on a cost-recovery basis, with accredited SDOs paying fees and charges approximately equivalent to the costs of the system. They each contribute between €2,400 and €46,000 per annum depending on circumstances (including accreditation maintenance fees and fees based on scale of standards development and national/international participation activity).

Indeed, most NSBs responding during the specific consultation of January-February 2010 questioned why such a proposal was being considered when the existing system is effective, well-functioning and the preferred model for the majority of stakeholders. The need for, purpose and benefits of a new accreditation agency were unclear to them. Based on the information available, there were concerns that the option would lead to two parallel systems (unworkable, duplicative, costly and complex, with little added value), that it would increase bureaucracy, reduce transparency/coherence and ultimately be a regressive step.

The basic idea of an accreditation system as set out in the option has already raised concerns about duplication and complexity and led to several respondents of the specific consultation of January-February 2010 questioning the justification and potential benefits of such a system. It is clear from this information that the requirements on SDOs within the ANSI system are similar to those already required of actors within the existing ESS and that similar processes for maintaining adherence to principles exist. The annual costs of an ANSI-style accreditation system in Europe are likely to be below €3 million in the longer term, although the set-up costs may be considerable. Therefore, there were not sufficient arguments to examine this option in greater detail.

9.5.15. Request Member States to monitor and report on the balance of representation of stakeholders in NSB mirror committees

For the 20 NSBs providing estimated cost data during the consultation of January-February 2010, the total costs for the set up of the monitoring and reporting system is estimated to be €2.24 million, or an average cost of €112k per NSB. The range of estimated set up costs run from €0 to €500k per NSB. The ongoing implementation costs for the 20 NSBs are estimated to total €1.49 million per year, or €75k per NSB per year. The lowest estimate provided by a single NSB was €2,000 per annum and the highest was €650,000. Roughly a third of the NSBs provided an explanation / justification for their cost calculations in order to show how the estimates have been arrived at. For example, set up costs of 200 NMCs x 3 days per committee + IT tool and database development x 50 days = 650 days @ €770 per day = €500k. (Note this is not a real example). However, a similar number explained that their cost estimates were very rough or subject to a high degree of uncertainty because the monitoring and reporting system has not yet been defined.

Comments received from NSBs in relation to the cost estimates mainly revolved around the difficulties in working out the costs accurately (or even estimating them) in the absence of any detailed 'specification'. These comments were made both by NSBs that did provide cost estimates and also by those that could not. NSBs seem to be in agreement that the specification for the monitoring would have to be defined and agreed at European level before being implemented at national level. A small number of NSBs pointed out that the costs could be relatively low if the agreed system is close to the one already implemented at national level. However, most NSBs expect the costs to be significant, either because no monitoring system currently exists or because it is envisaged that the new system would require a complete overhaul of the existing monitoring activity.

93% of the 30 MSAs that contributed to the consultation of January-February 2010 provided some kind of response to this question. However, the vast majority of these MSAs stated that they were unable to provide an actual estimate of the costs to the MSA of a system to monitor and report on the balance of representation in national mirror committees. Instead, many MSAs provided other comments (see 'comments' below) concerning the provision more broadly. The estimates provided by ten MSAs for the cost of the set-up of a monitoring and reporting system total €1.5 million, an average of €149.9k each. However, it should be noted that the individual estimates varied considerably, between €0 and €1 million, with the highest estimate being considerably above the next highest estimate of €250k. Removing this 'outlier' would reduce the average estimated set-up cost considerably, to €55.5k per MSA.

The estimates provided by ten MSAs for the cost of the annual implementation of a monitoring and reporting system total €396.3k, an average of €39.6k each. However, again it should be noted that the individual estimates varied considerably, from €0 to €200k, with the highest estimate being considerably above the next highest of €100k. Removing this 'outlier' would reduce the average estimated annual implementation cost considerably, to €21.8k per MSA. Only four MSAs provided further details to explain the methodology behind the estimates they provided. These are summarised in the table below and show the variety of systems and necessary costs envisaged by the different MSAs when responding to this question.

Set-up	Implementation	Notes on estimates
€2k	€1.5k	Set-up covers launch of web-application and registration of chairmen. Implementation covers annual extraction of information from the database and finalisation of a report.
€18.1k	€2.6k	Set-up costs cover 140 person days (at €129) for 10 mirror committees. Implementation costs cover 20 person-days.
€25k	€17k	Costs cover extra staff members
€250k	€100k	Set-up covers: (i) European definition and mapping of stakeholder types, (ii) classification of existing MC members, (iii) set up of ICT systems to monitor/report, and (iv) completion of initial databases. Implementation covers updating the classification system and list of participants to include changes to MC formation and changes in member classifications (e.g. company growth), plus reporting.

There was general agreement between the 15 MSAs that provided additional qualitative information that: (i) Member States should be vigilant with regards to the balance of participation within standardisation committees, (ii) that it is in each Member State's interest to organise itself to best promote balanced representation at a national level, and that (iii) NSBs should be transparent and provide information publicly to demonstrate their openness to all participants. Indeed, three MSAs specifically reported that balanced representation within their national TCs is a key issue stipulated in existing MoUs, standards, agreements and other documents, and a

further two MSAs reported that their national standardisation systems were already open to participation by all stakeholders.

The general conclusion of this part of the consultation is that there would be very substantial costs associated with the set-up and ongoing implementation of a national monitoring and reporting system concerning the balance of representation of a defined set of stakeholder groups in national mirror committees. Such a system would have to be defined centrally and in significant detail in order to ensure a consistency of approach across the NSBs / MSAs in different countries. The difference between, on the one hand, open access systems that allow all stakeholders to participate and on the other, 'controlled' systems that enforce a pre-defined idealised balance are particularly salient here. The former is currently in place and the latter cannot be put into place, because what is an appropriate (and hence ideal) balance will vary from committee to committee and from country to country and cannot always be ensured.

The specific consultation of January-February 2010 did not reveal any significant objections to the option, although some respondents believe that the resulting information would be of limited practical utility and that therefore the resources could be better spent on more direct support to under-represented stakeholder groups. Balanced representation (however defined) may be less achievable in smaller countries where expertise and resources are limited.

9.6. ANNEX 6 – EXISTING STUDIES ON PROBLEMS OF SMEs IN EUROPEAN STANDARDISATION

The quotations, data and other information shown below have been extracted from the following documentation that reports on the problems faced by SMEs. The findings are presented under each of the main identified issues, and the numbers in parenthesis refer to the list of source documents.

Documents / sources

– I 'SMEs and Standardisation in Europe – 23 good practices to promote the participation of craft and SME enterprises in standardisation and the use of standards' (2006, EIM Business and Policy Research, for DG Enterprise and Industry).

– II 'Efficiency and accountability in European standardisation under the new approach' (1998, Report by the Commission to the Council and European Parliament COM (1998) 291 Final).

– III. 'Action plan: the European agenda for entrepreneurship policy' (2004, Commission Communication COM (2004) 70 Final).

– IV 'Information on occupational health and safety and standardisation for small and medium-sized enterprises – requirements and availability' (2001, Commission for Occupational Health and Safety and Standardisation – KAN).

– V 'Observatory of European SMEs' (2002, EIM in cooperation with ENSR partners). A survey of circa 8,000 SMEs, which paid attention to standardisation among some of the questions put to organisations.

– VI 'Observatory of European SMEs – analytical report' (2007, Gallup Organisation Hungary, for DG Enterprise and Industry).

– VII 'Study to evaluate the internal market and competitiveness effects of council directive 89/106/EEC construction products directive' (2007, PRC).

– VIII 'Towards an increased contribution from standardisation to innovation in Europe – discussion paper' (2007, DG Enterprise and Industry, Unit I.3).

– IX 'Towards and increased contribution from standardisation to innovation in Europe – Commission communication' (2008, Commission communication COM (2008) 133 Final).

Lack of understanding of the benefits of standardisation

- Only 60% of SMEs consider standards important issues to their business and the figure was lower for micro enterprises than for medium-sized enterprises (v);

- When managers were asked about the relative importance of the major features of the internal market, 38% regarded 'single market legislation, including harmonised technical standards', as important or very important. (vi);

- 52% of SMEs reported that they do not see any benefits in EU standards replacing national regulations'. By comparison 29% claimed that the process was beneficial for them (vi);

- The results of the EUROMANAGEMENT pilot action (1994) showed that there was a lack of information among SMEs on the basic mechanisms of the Single Market and the benefits to be gained from harmonised standards (x);

Lack of understanding of which standards can or should be applied

- SMEs and craft enterprises feel, to a large extent, that standards are something for the large corporate sector and think they are not involved. Consequently the participation of such enterprises in standardisation is rather low in terms of accessing relevant information and actually using standards in their own enterprises (ix);

- To improve awareness: It is necessary to bring standardisation and standards to the attention of market participants, in particular SMEs (ii);

- SMEs frequently lack an inexpensive and easily accessible source for information on standards (iv);

- Practically all SMEs expect a service centre that helps them procure information on standards to provide up-to-date and precise information on applicable standards; more than 90 % would like to be able to make an almost unlimited number of follow-up inquiries and low costs; and almost the same number would like the information to be converted more to their needs. They would also like better search possibilities regarding the actual contents of standards, information about standards that have been withdrawn, and information on the interpretation of product-related standards for specific industries (iv);

- 55% of SMEs said they did not receive relevant information on standards and standardisation (v);

- In response to the question 'which problems do you face regarding standards and standardisation?' 23% said 'lack of information on which standards have to be met' and 26% said 'lack of information on new standards' (v);

- Potential users of standards, in particular SMEs, may have difficulty identifying the standards relevant to them. The reasons for this include the existence of several standards, possibly with different status, addressing similar needs (viii);

- Regarding access to standards, other issues relate to the difficulty in identifying the group of standards relevant for a product or process (ix).

The cost of purchasing standards

- The cost of obtaining relevant standards may be relatively high for SMEs and other users, especially if the standards contain many cross-references to other standards (viii);

- Regarding access to standards, the cost of purchasing standards is increasingly cited as a problem by SMEs and other stakeholders (ix);

Complexity of standards / cost of implementation

- The technical aspects of standards are very similar for SMEs, craft enterprises and large enterprises, but more attention should be paid to simplicity of form and wording. Presently parties feel the need to 'downsize' existing standards in order to make them more easy to digest for smaller enterprises (ix);

- SMEs would advise that standards should: be comprehensible and clearly arranged; contain instructions for their implementation and concrete technical solutions (instead of general concepts); repeat excerpts from other standards instead of merely referring to them (iv);

- The contents of the standards used frequently meet the requirements of companies. 88% rated the comprehensibility and arrangement of the standards as good or very good (iv);

- To the question 'which problems do you face regarding standards and standardisation?' 21% said 'difficulties in applying standards correctly' (v);

- Potential users of standards, in particular SMEs, may have difficulty identifying the standards relevant to them. The reasons for this include the complexity of the technical specifications. Even if the right standards have been identified and are available, implementing and using them may still be very complex without adapted support (viii);

- Standardisation is a powerful tool for the dissemination of the state of the art to SMEs and facilitates the uptake of innovation by the market. However, this potential is often not realised because of barriers such as the complexity of the language of standards and the cost of deliverables. Other issues relate to the excessive number of cross-references between standards (ix).

Lack of understanding / cost of conformity testing and certification

- The majority of companies indicate that they find it expensive or difficult to evaluate the applicability of standards and to conduct external tests determining conformity. 75% of companies would like to verify whether they actually fulfil all the standards relevant to their manufacturing process (iv);

- To the question 'which problems do you face regarding standards and standardisation?' 16% said 'difficulties in obtaining certification of compliance with standards' (v);

- The report considers the cost and burden of CE-Marking for SMEs. It notes that the perceived problem is that, whereas CE-marking should bring savings in the overall testing and certification process for larger firms or firms close to state borders which sell in more than one Member State, many small firms will suffer either (ix) because they are in Member States where no 3rd party certification

requirement existed previously, so they have to do something for the first time, or (ii) because the product evaluation or conformity procedures are now more difficult, because of harmonisation. However, the report finds that whilst SME concerns need to be taken very seriously, there is reason to believe that the problem is not as serious as previously thought. Also, the dominant industry view of CE-marking seems to have shifted from concern that it is a burden and would drive some SMEs out of business, to acceptance that it is a good protective measure against low-quality non-EEA imports (with the caveat that it is not strict enough and not adequately enforced). A large number of companies and nearly all SMEs do not carry more than one national mark. The yearly cost of CE-marking will be less than the cost of previous national conformity marks for these companies (vii).

Lack of participation / representation in the standards development process

- SME and craft enterprises feel, to a large extent, that standards are something for the large corporate sector and think they are not involved. Consequently the participation of such enterprises in standardisation is rather low in terms of participation in Technical Committees where standards are actually developed (ix);

- The majority of measures found [by the study] at national level are aimed at raising awareness and providing information. Relatively little is done to support the participation of SME and craft enterprises in standardisation, or to defend their interests (ix);

- Specific constraints of SMEs in terms of human resources and finance, lead to relatively low active participation of SMEs in the standardisation process (ix);

- The Internal Market has made the lives of businesses, particularly SMEs, much easier. But the Internal Market is not complete. There are still obstacles. The Commission will also continue to promote the involvement of SMEs in standardisation (iii);

- 40% of the companies surveyed would be interested in participating in standardisation work; however, at present, only 12 % are actively involved. Considerable obstacles prevent SMEs from exerting a greater influence on standardization, especially the lack of free resources (iv);

- To the question 'which problems do you face regarding standards and standardisation?' 16% said 'lack of possibility of participation in development of new standards' (v);

- SMEs and other economic operators have great difficulty participating in the standard-making process as it is currently established: SMEs have problems allocating their limited human and financial assets to the resource-heavy and time-consuming process of standardisation, which includes many face-to-face meetings and often demands a membership fee. This is especially critical for micro-enterprises; it is necessary to address the concerns of SME representatives that standardisation processes are often dominated by large industry and do not take

SMEs' interests sufficiently into account. The need to attend standardisation meetings physically is probably the most significant barrier to SME participation. (viii);

- Standardisation is a powerful tool for the dissemination of the state of the art to SMEs and to facilitate the uptake of innovation by the market. However, this potential is often not realised because of barriers such as the time required to participate in standard-making (ix).

Lack of availability of standards in native language

- The technical aspects of standards are very similar for SMEs, craft enterprises and large enterprises, but more attention should be paid to simplicity of form and wording. Presently parties feel the need to 'translate' existing standards in order to make them easier to digest for smaller enterprises (ix);

- Potential users of standards, in particular SMEs, may have difficulty identifying the standards relevant to them. The reasons for this include the lack of standards in their own language (viii);

- Regarding access to standards, other issues relate to the lack of standards in national languages (ix).

9.7. ANNEX 7 – GLOBAL FORA AND CONSORTIA IN THE FIELD OF ICT

9.7.1. Introduction

The technological foundations of the Third Industrial Revolution are innovations in computing and electronics, including the invention of transistors, integrated circuits, digital computers and networks, and wireless technologies. These innovations can be described as modular innovations whereby system coordination became embedded in **standardised interfaces, so that a variety of products could work within the same system architecture**. Once multiple firms contributed components to the system, new strategies beyond horizontal and vertical integration became necessary to coordinate the system architecture and to make sure it functioned properly. This shift towards greater modularity was due in part to the increasing complexity of technology: in many cases, a single firm did not have the technological or organizational capabilities to produce all of the components necessary for an entire system. The most striking example of a network industry that needs standardised interfaces is the ICT sector in which **standards play an essential role in ensuring compatibility**. Such standards can serve to increase network effects and that in turn supports innovation[99]. In a digitally driven society, ICT solutions are used in any economic sector as well as in our daily lives. To fully exploit the potential provided by the digital society, ICT solutions, applications and services have to be able to communicate with each other; they should be interoperable. Interoperability requires standards and specifications.

The regulatory framework and the underlying ESO governance mechanisms that have proven very successful in tackling the harmonisation of national standards for internal market purposes have not proved as adequate to cope with the interoperability requirements of ICT policy. The issue is related to the proliferation of relevant ICT standards more or less informally created by global fora and consortia. Nowadays it can be roughly estimated that some 80% of the global ICT standardisation work of interest to the European ICT market is carried out outside the formal European standardisation system.

The phenomenon affects the IT and telecom industries differently, because formal standardisation in the latter is more protected by the need to have interoperability ensured over a relatively longer period of time (infrastructural investments have a pay-off period of decades) and by a stronger regulatory framework for standard referencing. But evolution in the IT industry and software and internet-related applications has been very fast and the disintermediation of the formal process much more advanced.

9.7.2. Global fora and consortia

The ICT standardisation landscape has dramatically changed over the last decade. Alongside the traditional standard stetting organisations, specialised and mostly global fora and consortia have become more active and several have emerged as

[99] Swann G.M.P., "The Economics of Standardization: An Update', Report for the UK Department of Business, Innovation and Skills (BIS), 2010.

world-leading ICT standards development bodies, such as those responsible for the standards covering the internet and the world wide web.

These fora and consortia include, for example, the following bodies:

(1) The Internet Engineering Task Force (IETF) is a large open international community of network designers, operators, vendors, and researchers concerned with the evolution of internet architecture and the smooth operation of the internet. It is open to any interested individual. The actual technical work of the IETF is done in its working groups, which are organized by topic into several areas (e.g., routing, transport, security, etc.). Much of the work is handled via mailing lists. The IETF holds meetings three times per year. The IETF's official products are documents, published free of charge as Requests for Comments (RFCs) which are frequently updated. As well as producing RFCs, the IETF is a forum where network operators, hardware and software implementers and researchers discuss future protocols, standards and products. It is also the forum where the basic technical standards for internet protocols are set and maintained. The IETF does not standardise transmission hardware nor specialized application layer protocols. However, the IETF standardises all the protocol layers in between.

(2) The World Wide Web Consortium (W3C) is an international community where Member organisations, a full-time staff, and the public work together to develop Web standards. Its membership is open to all types of organisations (including commercial, educational and governmental entities) and individuals. Any entity that can sign the Membership Agreement can become a Member. Members may be either for-profit or not-for-profit organizations. Most Members are specialised in web technologies and/or are developing web-based products, using web technologies as an enabling medium, conducting research on the Web, or developing specifications based on W3C work. W3C develops technical specifications and guidelines through a process designed to obtain consensus about the content of a technical report, to ensure appropriate technical and editorial quality, and to earn endorsement by W3C and the broader community. These specifications and guidelines cover, inter alia, web design and applications (i.e. the specifications for building and rendering Web pages, including HTML5, CSS, SVG, Ajax, and other technologies for Web Applications, the so-called “WebApps”), Web architecture (i.e. focusing on the foundation technologies and principles which sustain the Web, including URIs and HTTP), XML Technologies including XML, XQuery, XML Schema, XSLT, XSL-FO, Efficient XML Interchange (EXI), technologies to enable Web access anywhere, anytime, and using any device, browsers and authoring tools.

(3) OASIS (Organization for the Advancement of Structured Information Standards) is a not-for-profit consortium that drives the development, convergence and adoption of open standards for the global information society. It was founded in 1993 under the name SGML Open as a consortium of vendors and users devoted to developing guidelines for interoperability among products that support the Standard Generalized Markup Language (SGML). The name changed in 1998 to reflect an expanded scope of

technical work, including the Extensible Markup Language (XML) and other related standards. Companies, government agencies, non-profit associations, and academic and research institutions may become members. The Consortium hosts two of the widely known information portals on XML and Web services standards, namely Cover Pages and XML.org.

(4) IEEE (Institute of Electrical and Electronics Engineers) is a large technical professional society. It is designed to help professionals involved in all aspects of the electrical, electronic and computing fields and related areas of science and technology. There are more than 395,000 IEEE members in over 160 countries around the world. IEEE members are engineers, scientists and allied professionals whose technical interests are rooted in electrical and computer sciences, engineering and related disciplines. The IEEE-SA standards program produces standards for a broad range of technologies and industries. It has an active portfolio of nearly 1,300 standards with many more projects currently under development.

Overall, there are uncertainties as to the total number of standardisation consortia, especially in the field of ICT. CEN makes a periodical survey of these entities in the area of ICT and currently counts some 238, but makes a subjective screening not to include what they consider the most patently commercially-motivated ones. Other private sources that do not do any such screening list a total of 534[100]. The Japanese Government routinely monitors for its own ICT strategic development purposes the activities of some 120-130. Many fora and consortia work at different levels in numerous overlapping technology areas relevant to ICT and networks. Over 500 are listed in web-based catalogues of fora and consortia and, at one time (before the collapse of the dot com bubble), new fora and consortia were being created at the rate of at least one a week. It is impossible for service providers to keep track of all of these, and it is not clear to a service provider (or even to an equipment vendor) which group to work with for the standards they need. Vendors often create new fora to obtain a significant influence in the marketplace and to ensure that any resulting technical standards are based on their own product specifications. During the internet boom, consortia emerged at a very high rate and, contrary to expectations, in the last few years they have proved quite resilient to the end of that boom and have survived the consequent decline in their membership base and any possible reduction in total private investment in standardisation. It is not uncommon for European ICT multinationals anecdotally to report attendance at works of over 150 different standardisation entities.

100 www.consortiuminfo.org/links

9.7.3. Comparison of C&F Management Features with those of ESO and JTC1

	OASIS	OMG	W3C	ETSI	JTC1
IPR policy	RF FRAND RF Open Source	RF	RF	FRAND	FRAND
Liaisons	Numerous (including e.g. ISO, JTC1, ISSS, W3C)	Crossmembership (OASIS, W3C, NIST	Numerous (including e.g. ETSI, IETF, ITU, JTC1	Numerous (including e.g. ISO, JTC1, ITU, national/regional SDO many consortia)	Over 16 liasons
Overall # of members	Ca. 400 organizations Ca. 200 individuals	Ca. 800	Over 400	700+	67 (member states at JTC1 level)
Membership levels	4: Foundational sponsors Sponsors, Contributors, Individual (may not vote	5 (three main): Contributing Domain Platform Influencing Residual: Test and Analyst	2: Full, Affiliate (both have same rights)	4: Full, Associate, (may vote) Observer, Counsellor	2: (P)articipating (may vote) (O)bserving
Membership Fees	Foundational sponsors: from 50,000 to 44,000 USD according to the type of organization and the number of employees; Sponsors: from 16,000 to 9,500 USD according to the type of organization and the number of people employed; Contributors: from 8,000 to 1,100 USD according to the type of organization and the number of people employed; Individuals: US$300	Membership fees according to the annual gross revenue; only contributing members have full voting capacity. Fees range from 75,000 USD for contributing members to 550 USD for university members.	Depends on the country and on the annual revenue; the fee can be calculated via the website and may vary from 68,500 to 953 USD.	Based on turnover; from 2000 EUR (Universities, Non-profit organizations etc.) to 154,720 EUR.	Based on GNP
Individuals' capacity	member representative (but individual vote at TC level)	member representative	WG: member representative; AB: individual	(member) representative	individual
To establish new activity	3 'eligible persons; business plan; decision after 15 days, BoD may veto	RFP: initiated in TC (also SIG), TF elaborate RFP, approved by AB.	Initiated by W3C staff, general review at least 4 weeks; decided upon by	4 supporting Members prepared to contribute; decision after one month	No time frame specified

		Accepted by TC (vote). RFC: bypasses RFP	Director		
Average time until finalisation	16 – 24 months	12-15 months from RFP: shorter for RFC	Typically around 24 months	Around 4 years for a European Standard	Up to 48 months; ca. 12 months for PAS process
Openness technical activities	Every 'eligible person' may participate	Eligible members may submit proposed solutions Information (RFI) may be invited from outside	Open to all members	Open to Full and Assoc. ETSI members; external experts for STF62	Individual WG members must be authorised by national SDO
Transparency	description of process and voting procedure publicly available	Ability to track the adoption process. Finalized documents are publicly available	info on process and outcome publicly available; public may comment; TRs undergo public review	Limited (largely to members) transparency	Limited (largely to members) transparency
Required level of consensus	Balloting mechanism at TC and OASIS level; BoD may keep proposal from balloting	2/3 majority of eligible voters on finalized submission. Submitted to BoD for final decision	Consensus based, at both technical and W3C level, but W3C director's approval is always required	At TB level: consensus/voting At ETSI level: consensus/weighted individual voting by members	Balloting should only take place once consensus has been achieved; Pmembers cast votes
Implementations required?	Yes (three interoperable implementations	A precondition. Non-implemented can be 'retired'	Yes (one implementation)	No	No
Types of 'products'	Committee Drafts Standards	OMG specification ('adopted technology')	Working Notes Recommendations	ETSI Standard, ES European Standard, EN ETSI Technical Specification ETSI Technical Report, TR ETSI Guide, EG Special Report, SR	ISO Standard ISO/PAS ISO/TS Technical Specification ISO/TR Technical Report International Workshop Agreement (IWA)
Output	17 Committee Drafts (excluding ebXML specifications prior to 2002) 71 standards from 2003 to 2009	130+ in total http://www.omg.org/technology/documents/spec_catalog.htm since 2002: 114	55 Recommendations (2005-2009)	ES ETSI: 381 standards from January 2004 to August 2009, Total standards from January 2009: 567; EN –ES Telecommunicati	CA 420 technical standards modified between 2007-2009 11 Technical Standards published from 2003 - 2006

				ons: 414 from January 2004 to August 2009; 1744 from 1999 to 2009; EG Guide: 66 from January 2004 to August 2009 167 from 1999 to 2009	
Specs for free	Yes	Yes	Yes	Yes	No
Standards maintenance	No official mechanism, but new versions are produced relatively frequently	Codified revision process, including bug page.	Error tracking is part of the process; dedicated 'errata page'; approval of new version follows same procedures as for new TR	No official procedure for most deliverables; reaction to comments; approval of new version follows same procedures as new deliverables	Regular reviews every 5 years (3 years for PAS submissions); Amendments are also used

9.8. ANNEX 8 – SME TEST

(1) Consultation with SMEs representatives	One of the objectives of the Small Business Act (SBA) is to help SMEs to benefit more from the opportunities offered by the Single Market and third-country markets. For that purpose, the SBA stated that it would increasing "EU financial support (to €1 million in 2008 and € 2.1 million from 2009) to promote SMEs' participation and defence of their interests in standardisation and to improve SMEs' information on, and use of, European standards". In its report adopted on 21 October 2010 (see section 2.1), the European Parliament stresses that the SMEs are not adequately involved in the standardisation system. It believes that it is essential to increase their representation and participation in the system. Consequently, SMEs representatives have been widely consulted during the preparatory process (see point 9.1.3 of Annex 1). Questions 6 and 13 of the general consultation related specifically to problems encountered by SMEs. In parallel, specific studies were made to examine the problems of SMEs in standardisation. These studies are set out in more detail in Annex 6.
(2) Preliminary assessment of businesses likely to be affected	The studies showed that SMEs encounter a series of problems with respect to standards and standardisation. The main problems and barriers are the lack of understanding of the benefits of standardisation, the lack of understanding of which standards can or should be applied, the cost of purchasing standards, the complexity of standards/cost of implementation, the lack of understanding/cost of conformity testing and certification, the lack of participation/representation in the standards development process and the lacking availability of standards in the language used by the SME. The overall conclusion of these studies is that SMEs are enterprises which need to apply standards in the production of goods and services, like larger enterprises. However, due to their size and limited resources, SMEs have more difficulties in choosing the right standard, in understanding it and it implementing it. Standards may be drafted in an unnecessary complex way, with too many cross references to other standards, making it more difficult to understand and to implement them. The more SMEs participate in the technical committees, the more standards will be SME-friendly and the more SMEs will use and implement them.

	Although SMEs face similar problems as societal stakeholders, the concerns of SMEs differ since standards have to be suitable for SMEs in terms of their use and application while the broader societal interest lies in the results of the use of standards.
(3) Measurement of the impact on SMEs	One of the specific objectives of the initiative is to ensure that SMEs are adequately represented in the standardisation process (point 4.2). The impacts on SMEs are measured specifically in all options. The involvement of SMEs in the standardisation process is one the three main problems examined in this impact assessment.
(4) Assess alternative options and mitigating measures	At the end of the impact assessment, there was no indication that the selected options might result in a disproportionate burden for SMEs. Consequently, there is no element showing the need for SME specific measures in order to ensure compliance with the proportionality principle.

9.9. ANNEX 9 – CONCLUSIONS AND RECOMMENDATIONS OF THE EXTERNAL EVALUATION OF THE CONTRIBUTION OF EU FINANCING OF STANDARDISATION TO THE FULFILMENT OF POLICY OBJECTIVES OF THE COMMISSION

A study produced by the Enterprise Evaluation Consortium GHK / Technopolis[101] draws the following conclusions and makes the following recommendations. The views expressed are those of the authors and do not necessarily reflect those of the Commission.

The focus of the evaluation was the financial support allocated to the ESOs by EC/EFTA through operating and action grants signed in the period 1st Jan 04 – 31st Dec 07. The overall aim of the study was to evaluate the extent to which EC/EFTA financing of European standardisation contributes to the implementation and achievement of the policy objectives of the Commission as laid out in relevant documentation. In addition, the evaluation has assessed the relevance, effectiveness, efficiency and utility of the system of financing, including the associated management and administrative procedures. Finally, the evaluation has considered whether the system of financing is optimised and makes recommendations for improvements where appropriate. The assessments are based on a review of all relevant documentation and data relating to the financing, plus extensive consultation with the European Commission, EFTA, the European and National Standards Bodies, industry and other stakeholders. Over 160 people were consulted during the course of the study.

1. OVERALL CONCLUSIONS

The overarching objective of the evaluation was to "assess to what extent the financing of European standardisation by the European Commission contributes to the achievement of the objectives of its policy". It also aimed to determine "whether the current financing scheme and the cost/benefit ratio are optimised to reach the objectives of the actions".

Our overall conclusions are as follows:

- The financing of European standardisation by EC/EFTA is both appropriate and necessary, and attracts strong support inside the Commission, from the standardisation bodies at EU and national levels, and from industry and other stakeholders

- The financing granted from 2004-7 has supported activities that are of clear and high relevance to the policy objectives of the Commission, as set out in the financing agreements and in various communications issued by the Commission

[101] Evaluation of the Contribution of Community Financing of Standardisation to the Fulfilment of Policy Objectives of the Commission, submitted by GHK/Technopolis on 30 June 2009. http://ec.europa.eu/enterprise/dg/files/evaluation/2009-06-30__final_report_and_appendices_en.pdf.

- The six main areas of activity that have attracted EC/EFTA financing each contribute significantly to the achievement of multiple Commission policy objectives, but to different extents and in different but mutually supporting ways

- The main role of the financing is to support and strengthen the ESO platform and to facilitate and support standards development work in areas closely linked to Commission policy and legislation

- The system of financing is effective and has delivered a high level of positive benefits in its intended areas of influence, but its efficiency has been severely hampered by administrative burdens which detract from the overall added value of the support

- The financing is of significant utility to the European standardisation system, providing additional management capacity and expertise and helping to offset the costs to industry of standards development in areas closely linked to Commission policy

- The overall financial allocation by EC/EFTA is modest in the context of the total costs of EU standardisation and in relation to the benefits that the financing delivers, but only appears to be under a moderate amount of pressure under the current arrangements. The pressure has been alleviated significantly by the withdrawal of some ESOs and NSBs from certain lines of support due to problems with the detailed, complex and unstable financial rules and the high administrative burden

- Under improved conditions there would be a strong case for an increased budgetary allocation due to the significant benefits that the support can deliver

The following sections present more detailed conclusions and recommendations, organised around the issues that the evaluation was asked to address and the questions that it was designed to answer. The main body of this report sets out the information and data that have been used to arrive at these conclusions and recommendations, and contains further, more detailed information that may be useful for strengthening the system of financing in future.

2. RELEVANCE

2.1. Commission policy objectives regarding standardisation

The terms of reference for the study asked the evaluators to identify and describe the policy objectives of the Commission regarding standardisation. A review of the supplied documentation has identified the following objectives of the Commission that are all intended, in some way, to be supported through the financing of standardisation:

Objectives relating primarily to <u>industrial policy</u>	**Objectives relating primarily to <u>public policy / societal needs</u>**
• To enhance the **competitiveness** of	• To provide a high level of protection

European Industry • To assist in the completion (and improve the functioning) of the **single market** • To assist European industry to access **world markets** • To facilitate **innovation** • To facilitate and ensure **interoperability** • To increase the **market relevance** of standards development • To facilitate the **take-up** of European standards • To ensure effective use of standards by **SMEs**	of **health and safety** • To contribute to **environmental protection** and sustainable development • To use standardisation as a tool for ensuring **accessibility for all** • To support the public interest dimension of standards
Objectives relating primarily to the existence of a strong EU standardisation system	**Objectives relating primarily to the extension of the EU standardisation system and the inclusion of relevant actors**
• To provide a flexible and transparent platform for **consensus building** • To strengthen the **institutional framework and structures** of European standardisation • To ensure the **financial viability** of European standardisation • To increase the **efficiency** of European standardisation • To improve the **synergies** between the European Standardisation Organisations • To improve the **timeliness** of standards development • To improve the **coherence** of European standardisation and of its institutional framework • To improve the **effectiveness** of European standardisation • To improve and extend the European **key mark** system	• To promote and increase the **visibility** of the European standardisation system • To assist with the integration of candidate countries • To ensure effective **participation** by all relevant actors • To increase the role of standards in support of European **policies and legislation** • To increase the role of standards in the area of **security** • To increase the role of standards in the area of **services** • To strengthen the link between **research** and standards • To promote the development and use of **international standards**

These objectives relate to both the positive benefits that standardisation brings to society and the economy, which help to explain *why* the Commission provides financial support to European standardisation, and to more purposeful objectives relating to desired improvements in the overall structure and performance of the EU standardisation system.

2.2. The relevance of the financial support to the achievement of these objectives

The study was asked to assess whether the allocation of financial support is relevant to the achievement of these objectives. We have found that the financing of standardisation by EC/EFTA is considered by all stakeholder groups to be highly appropriate and necessary and that the specific activities attracting financing in the period 2004-7 are very strongly linked to and are of clear relevance to the achievement of Commission policy objectives.

The different elements of the financing and the different activities supported are relevant to different groups of objectives as follows:

- The financial support provided to the central secretariats of the ESOs through **Operating Grants** can be seen to be of clear relevance to the achievement of all of the identified policy objectives. The financing enables the central secretariats to strengthen the EU standardisation system and platform, and provides additional capacity to enable a timely and effective response to Commission requests for standards development work and related activities in support of its policy and legislation. This includes standardisation activities designed to support industrial policy objectives (e.g. innovation, competitiveness, interoperability, single market), public policy objectives (e.g. health and safety, environmental protection, accessibility for all) and objectives relating to the extension of the EU standardisation system (e.g. into new areas of policy and legislation such as services) and the inclusion of relevant actors (e.g. SMEs, NGOs, etc.)

- The financing provided to support specific **standards development** projects (actions) is relevant to the achievement of industrial policy objectives, as the majority of the actions are intended in some way to improve interoperability, assist with the completion of the internal market, promote innovation and the take-up of innovative solutions, and thereby enhance the competitiveness of industry. The majority of the financed standards development projects are also of clear relevance to public policy objectives, given that they are often aimed at providing a high level of protection of health and safety, contribute to environmental protection or otherwise support the public interest dimension of standards. The standards development work is also of relevance to the extension of the European standardisation system, in particular by increasing the role of standards in support of EU policy and legislation

- The financing provided to support **visibility** projects is of most clear relevance to the policy relating to the extension of the system and the inclusion of relevant actors. The activities that have attracted EC/EFTA financing have been aimed at increasing the visibility of the European standardisation system both inside the EU but particularly internationally, and are of relevance to the objectives of helping to integrate candidate countries and ensuring the effective participation by all relevant actors. The financing of visibility projects is also of clear relevance to the industrial policy objectives of assisting European industry to access world markets, assisting in the completion of the internal market, and facilitating the take-up of standards (through, for example, an

increased awareness of European standardisation and increased participation within it)

- The financing for **preliminary work / supporting activities** has also been found to be of clear relevance to several of the identified policy objectives, including in particular by helping to increase the market relevance of standards development, facilitating the take-up of standards, and increasing the role of standards in support of EU policy and legislation

- The financing for **translation** of European standards is also judged to be of high relevance to Commission policy objectives, particularly those relating to industrial policy, by for example, helping facilitate the take-up of standards and ensuring their effective use by SMEs, and thereby helping to facilitate interoperability and assist with the completion of the internal market. The financing of translation is also of clear relevance to the objectives of extending the EU standardisation system and inclusion of relevant actors, by for example, helping to increase the visibility and use of European standards in specific countries and by assisting with the integration of candidate countries to the Community market

- The financing of quality assessment work carried out by New Approach consultants is of relevance to a range of policy objectives, in particular by increasing the role of standards in support of European legislation and helping to ensure a high level of protection of health and safety and in some cases environmental protection, thereby assisting in the completion of the internal market. This line of financing is also of relevance to the objectives of improving the efficiency and effectiveness of European standardisation and improving the timeliness of standards development

As indicated above, most of the financed activities have the potential to contribute to multiple different policy objectives of the Commission, though there are clear differences between the lines of support, with some contributing in general terms to large numbers of objectives while others are of more specific and direct relevance to a more limited set of objectives.

It is therefore concluded that there are clear links between the Commission policy objectives (industrial, environmental, market, regulatory) and European standardisation, *particularly* in those areas that have attracted EC/EFTA financing.

2.3. Mechanisms to ensure the relevance of the financial support

The study terms of reference asked us to assess how the Commission evaluates the relevance of the financial support requested by the ESOs with respect to their achievement of its policy objectives.

In the case of the Operating Grant, the link between the policy objectives and the financed activity is in large measure given or assured through the type of financing provided (this holds to some extent for the other areas of support also). The activities of the Central Secretariats are known to support many of the objectives of the Commission, and the provision of the Operating Grant is provided specifically

because of this contribution, and in order to provide additional capacity to deliver on those objectives. However, in addition, the ESO grant applications, submitted each year and based around the central secretariats' annual business plans make clear the ways in which the activities will contribute to Commission policy objectives, particularly by strengthening the ESO platforms and activities, and also by ensuring an effective and efficient management of requests issued by the Commission for standardisation work throughout the course of the year.

The OG proposals submitted by the ESOs are evaluated by the Commission with regard to their relevance to Commission policy objectives. However, it should be noted that the Operating Grants are intended as a subsidy or subvention to the day-to-day activities of the central secretariats *because* of the important role they play in supporting the achievement of Commission policy. The intention of the evaluation is therefore to *confirm* that relevance rather than as a mechanism to identify ways in which the ESOs could *better* support Commission policy.

However, a range of other mechanisms are used to convey the Commission's policy objectives to the ESOs, and the ESOs can clearly be seen to respond to those signals through revisions to their processes and improvements to their functioning. One obvious example is efforts undertaken by CEN to speed up the standards development process in response to signals from the Commission that this was a priority objective. Another example is efforts undertaken by all of the ESOs in recent years to better integrate environmental aspects into standardisation, which were carried out in response to a 2004 Commission communication on this specific topic. In the years following publication of this communication the ESOs, with the assistance of the Operating Grant, implemented a number of process improvements and developed specific tools to enhance the ways in which their technical bodies integrate environmental considerations into their work.

In the case of the more specific action grants issued to the ESOs to support standards development work, preliminary studies, visibility actions, etc. a formal proposal evaluation process is implemented in order to assess and ensure the relevance of the proposed work to the achievement of Commission policy. While the policy objectives themselves are not made explicit in the assessment process, Commission officials with responsibility for standardisation policy and those responsible for policy in specific sectors (e.g. railways, eHealth, chemicals, etc.) participate in the evaluation of the proposals and assess their relevance to Commission policy. Based on the information available there have been few if any problems relating to this aspect of the process, largely because the mandates or work programmes issued to the ESOs and against which the proposals are submitted, reveal the objectives of the Commission and serve to ensure that both the proposed actions and the financing are closely targeted in policy-relevant areas.

We have not encountered any cases where work supported from 2004-7 was of limited or unclear relevance to Commission policy, and most actions are relevant to the achievement of multiple objectives. Within the current system most of the ESO grant applications are evaluated largely on a case by case basis, on their own merits, rather than in competition with each other. It is not clear how the Commission might use the relevance criterion to choose between *competing* proposals for financing, although the work supported under the annual ICT standardisation action plans offers

perhaps the closest approximation to a competitive environment, with the number and value of proposals submitted exceeding the notional budget available for ICT standards development. Within that system, work intended to support directly the implementation of EU legislation is afforded the highest priority, so could be considered most relevant to the achievement of policy objectives. Work that is closely aligned and supports the implementation of 'flagship' or newly announced initiatives of the Commission is judged to be the next most relevant category of work to support. As such, there is something of a gradation in the adjudged relevance of the proposals, based not on the *number* of objectives addressed but rather on the adjudged 'importance' or 'priority' of the policy areas to which they contribute.

In addition to the evaluation process that is implemented by the Commission to ensure the relevance of the proposed work *prior* to the financing being granted, the work is also monitored during its execution and assessed at the end, and there is the potential at these points to identify problems with the relevance of the work to the achievement of Commission policy. However, the major effort at these stages is devoted to monitoring and assessment from a contractual and financial perspective, ensuring that workplans and timetables are being followed and that financial rules have been observed when submitting claims for payments. There is little or no desire on the part of the Commission to actively 'steer' the work to ensure or maximise its relevance to or fit with Commission policy objectives, other than in isolated cases for specific reasons. This seems largely appropriate, as the objective of the Commission is not to get involved or 'interfere' in the work at a technical level, but to use its financing to support and to some extent to encourage and accelerate the flow of work that is relevant to its policy objectives. The relevance test is therefore applied, correctly, prior to the initiation of the work.

Care is also taken not to 'distort' the market by pushing too strongly for standards development work in policy areas, or by specifying too precisely what is needed and how that work should be carried out. It is considered important by the Commission (and other actors) that its role should not extend too far into the technical level, and that it should instead act as an amplifier of European policy objectives and as an enabler and supporter of actions that fit with those priorities but which, crucially, have a sufficient level of industry support. The additional resources, in the form of financing, are offered in order to strengthen the activities rather than to cause them to go ahead, and the level of support offered is not sufficient to drive the work forward if there is no industry demand to carry it out. Again, this is an appropriate level of intervention under the principles of the New Approach, which sees standardisation as an industry-driven activity and not something that the public sector should be controlling or driving directly.

2.4. Alternative ways to support standardisation and the achievement of its objectives

The study was asked to assess whether there are alternative ways for the Commission to support standardisation to contribute to its objectives. Based on our consultation with all of the main groups of actors involved in the financing and the work, there are no obvious alternative ways for the Commission to support standardisation, although as we will go on to explain progression to a more stable and less complex financial support system appears warranted.

It should be noted that the support to standardisation comes not just through financial means, but by the development of European legislation and policies that have provided much of the basis for European standardisation over the past 20-30 years. Previously standardisation was carried out mainly at a national level, and the Commission has played a central role in encouraging the creation of a single market within Europe and the removal of national barriers to trade. This effort has been underpinned by a strong industry policy logic, with advancement of the competitiveness of EU industry at its heart. A significant number of commentators have highlighted the important role played by the Commission in promoting this 'single vision' and in arguing strongly and supporting actively a centralised European system of standardisation, albeit one that relies heavily on national-level activities and inputs. Reference is often made to the 'inferior' US approach to standardisation, which is described as highly fragmented and less efficient and effective as a result. Therefore the Commission supports standardisation not just through its financing but through its strong lead In promoting the concepts of a single Europe, a single market for products and services, and an EU-level standardisation system based on the principles of the New Approach. These are also seen to be key mechanisms through which the Commission has helped to support the achievement of its own policy objectives.

The study was also asked to assess whether there are areas or actions where means other than financing could better contribute to the achievement of the objectives. We did not identify any such area or actions, or indeed any other means by which the Commission could support the achievement of its objectives. Therefore we have concluded that there are no alternative systems or mechanisms that could better serve the defined needs than the current one. However, suggestions for improving the basis of the financial support *were* readily identified, and therefore form the bulk of the concrete recommendations that we make in this report.

2.5. Ways to increase the relevance of the financing to the achievement of Commission policy

As indicated above, all of the activities that have attracted financing from EC/EFTA from 2004-7 were found to be of clear and high relevance to the achievement of Commission policy objectives, and we therefore have no specific recommendations for improving the relevance of the support.

3. EFFECTIVENESS

3.1. Communication of policy objectives to the ESOs

In order to ensure the relevance of the financed activities to the achievement of Commission policy objectives it is important that those objectives are communicated clearly to the standardisation bodies. This is done in a variety of ways and at a variety of different levels.

The objectives that we have used to guide the study were identified from within communications, policy papers and other documents relating to European standardisation and in some cases relating specifically to the financing of standardisation by EC/EFTA. These documents all, in various ways, set out in

general terms the objectives of the Commission's standardisation policy, explaining both why the Commission wishes to support standardisation and the kinds of improvements it feels are necessary in order to improve the performance of the system as a whole.

Some of the most important documents among these include:

- General guidelines for the cooperation between CEN, CENELEC and ETSI and the European Commission and the European Free Trade Association (2003/C 91/04)

- Decision No 1673/2006/EC of the European Parliament and of the Council - On the financing of European standardisation

- Communication from the Commission to the Council and the European Parliament - on the role of European Standardisation in the framework of European Policies and legislation (COM (2004) 674)

The documents are communicated to the ESOs, and there is good evidence that they provide an effective means for conveying the Commission's standardisation policy to the ESOs in general terms. The ESOs are aware of the texts and have considered them all carefully and make use of them on an ongoing basis. This, therefore, is the first level at which the objectives are communicated to the ESOs.

The second level of communication of policy objectives is through the mandates and work programmes addressed to the ESOs and which provide specific requests for standardisation work. The documents often set out the 'policy context' behind the request for the work and convey in more detailed terms what the objectives of the Commission are in one or more specific policy areas and how the ESOs are being asked to contribute. These documents vary considerably in terms of how they set out to explain or convey the policy objectives that lay behind the requests, and naturally tend to focus more on what is required or where it is required rather than why its is required.

Again there is good evidence that the mandates and work programmes offer an effective means by which to convey further information about the Commission's policy objectives, intentions, needs and so on. There is evidence to suggest that some of these communications can also prove confusing to the ESOs but this tends to relate to uncertainties about what specifically is required rather than the general policy objectives that underpin the requests.

The third and perhaps most important way in which the Commission's policy objectives are communicated to the ESOs is through the many forms of dialogue, meetings, day to day communications and interactions that guide the relationship on an ongoing basis. This helps to 'fine tune' the communication of objectives at the level of specific actions and also helps to reinforce the importance of certain higher level objectives contained in the general policy documents used to guide this study.

Again, while this third level of communication is an effective means by which to convey policy objectives to the ESOs, it is clear that too much of the dialogue

between the two parties is taken up with discussions about financial rules and detailed administrative issues, detracting from the amount of time that can be devoted to explaining the 'bigger picture'. However, this third layer also supports to some extent an improved understanding of the Commission's policy objectives.

Overall, then, a largely effective set of mechanisms is in place that allows the ESOs to fully understand Commission policy at a sufficient level of detail to ensure that their activities fit with and support those objectives. Having said this, there is no single source or reference for the ESOs to refer to, and the flow of documents that in some way convey the Commission's policy objectives are many and various. In addition, while there are many documents that can be said to contain Commission policy objectives, there is no way to clearly discern their relative importance or priority vis-à-vis each other and how this might be changing over time. It is clear to us that the 29 policy objectives that we identified and have used in the course of our work are not all equally important, and indeed many are inter-related and mutually supportive while others 'stand alone'. As such, while all of the objectives are clear, their relative importance or priority at any given point in the policy cycle is far from clear. As such, they provide only a general indication of the kinds of benefits that standardisation is expected to deliver and the kinds of improvements that the ESOs are being asked to make.

As such there is a case for a more organised regular annual process by which the Commission could convey its policy objectives to the ESOs, and which may help them to better respond to new and ongoing priorities. There is also a case for describing the objectives in more purposeful terms, making them a little more specific and a little more actionable on the part of the ESOs.

We recommend that the Commission seeks to develop a clearer statement of its main policy objectives in the area of standardisation, and refreshes this list on an annual or multi-annual basis. The objectives should be cast in the form of specific, purposeful statements as to the kinds of benefits, impacts or changes that it wishes to make

3.2. Establishing the link between the objectives and the financial support

The policy objectives of the Commission and the financing are linked in a number of ways, both in official documents that provide the formal basis for the financing and through the processes and procedures of the Commission and the ESOs when deciding on specific actions.

At the first of these two levels the various documents that relate to the financing, including the Council Decision, the guidelines for cooperation, and the Framework Partnership Agreements all establish a general link between the financing and the objectives. This does not, however, go beyond general statements to the effect that the financing is provided because of the role played by the ESOs in helping the Commission to meet those objectives.

The more meaningful link is provided through the work programmes and mandates that constitute requests for standardisation work and through the proposals submitted by the ESOs in response. At this level the Commission's needs in very specific or

more general policy areas are set out and the ESOs are invited to propose work to address those needs. The grant applications that are then prepared by the ESOs, with inputs from their members and technical bodies, further establish the links between the actions to be financed and the policy objectives of the Commission. However, this is done within a reasonably open format, and there is no specific requirement (although a general convention) to provide an explanation of how the two fit together.

Based on our analyses the link between the financial support and the objectives are in some respects not as clear as they could be. In particular, the extent to which the financing is (or should be) being deployed purposefully in pursuit of specific objectives is unclear. It can be seen that there are 'spikes' in financial support directed to specific areas of policy (e.g. the environment) following the publication of a new communication, strategy or initiative in a particular policy area, but the duration of those spikes and how and when it is decided that enough attention and financing has been given is rather more difficult to determine.

At the same time we can identify certain trends, such as the fall off in the number of visibility actions from 2004-7, but have no way to account for these trends, other than to guess that this objective was more of a policy priority in 2004 than it was in 2007. There is little to indicate that any kind of assessment is being made to establish how much of the financing is being devoted towards each objective or policy area, or that any judgements are being made as to whether this is sufficient or not. As such we believe that the connections between the financial support and the objectives being addressed could be more effectively monitored and assessed.

We recommend that the Commission establishes a mechanism to assess, on a regular basis, the extent to which its financing is being deployed in pursuit of each of its main policy objectives, in order to more clearly establish the extent to which each 'area' is receiving sufficient support

3.3. The extent to which the financing has contributed to the Commission's policy objectives

The study was asked to evaluate the extent to which the financing of standardisation activities has contributed to the Commission's objectives of its standardisation policy, especially towards SMEs. We were also asked to assess the effect of the actions financed by the Commission, in view of the implementation of the EU standardisation policy.

At an overall level we can state that the financing of standardisation by EC/EFTA has made a significant positive contribution to the achievement of Commission policy objectives:

- Most of the financed actions are considered to have contributed to the achievement of (multiple) Commission policy objectives, or are expected to do so in the fullness of time

- The financial support has encouraged standardisation activities to become more aligned with Commission policy objectives and has provided impetus to activities in specific 'priority' areas

- The existence of expressed Commission policy need and the availability of financing in combination provide confidence and encourage commitment on the part of other actors, accelerating the work in those areas

- The financing allocated by EC/EFTA strengthens the activities by expanding the level of management and coordination support available, the level of expertise involved in the work, and its overall size and scale

- The financial support has been effective in enabling significant improvements in the operations of the Central Secretariats of the ESOs

- There is little overt focus on supporting SMEs through the financing, though there are some specific examples where actions have been financed that are directly targeted on SME needs

- The principle that standardisation activity should be an industry-driven venture is broadly observed, and the financing is not used to proactively 'direct' the standardisation work (which seems appropriate). However significant influence is exerted over time through a range of relatively subtle mechanisms

While the financing clearly supports the achievement of the policy objectives of the Commission there are unfortunately no reliable means available to determine the scale of the impacts or the economic return on investment. The policy objectives are stated in terms that are too open (non-specific) to gauge the extent to which they are being achieved, and insufficient data and evidence exists to quantify the scale of the benefits achieved through the financed activities, either separately or in aggregate.

Having said this, our evaluation has enabled us to build up something of a profile of the extent to which the different actors involved believe that the different policy objectives have been supported by the financing in the period 2004-7, and the results of these analyses are presented in the main body of the report, organised against each element of the financing. This is a fairly crude analysis, based on discussions and ratings assigned by interviewees as to the contribution or expected contribution of the supported actions to the achievement of Commission policy. This has confirmed that most of the policy objectives have been supported by multiple actions and that most are addressed by more than one of the forms of activity attracting support. This analysis has also demonstrated that some policy objectives have received little attention and there is little to indicate that the financing will have contributed significantly to their achievement, at least in comparison to other objectives.

To summarise this analysis we can say that the financing has had the strongest and most positive impact on the following objectives:

Industrial policy	– Facilitating interoperability – Assisting completion of the internal market

	– Supporting technological innovation within EU industry – Advancing the competitiveness of European industry
Public policy	– Providing a high level of protection of health and safety – Supporting the public interest dimension of standards
Strengthening European standardisation	– Providing a mechanism for consensus building on identified issues – Improving the effectiveness of European standardisation – Improving the timeliness of standards development
Extending the system and increasing inclusion	– Increasing the role of standards in support of EU policy / legislation – Increasing the visibility of the European standardisation system – Assisting the integration of candidate countries – Ensuring effective participation by all relevant actors

The study was specifically asked to assess how the Commission's financing policy and practices have contributed to the integration of new Member States. Our conclusion is that the financing of standardisation by EC/EFTA has effectively contributed to this objective both through support for a small number of specific actions targeted in this direction (visibility actions, training programmes, etc.) and through more general improvements (simplification, information) effected through the provision of Operating Grants to the ESOs.

This question and answer provides an opportunity to consider how the Commission actually uses its financing to address specific objectives of its standardisation policy, and whether there is a case for a more organised and concerted effort in specific areas. What this means is that when the Commission decides that one of the objectives of its standardisation policy is to assist with the integration of new member states, should there be an explanation as to how it intends to do this and an indication of the level of resource it feels is appropriate to devote towards that objective? This would certainly help to ensure that specific objectives are given a certain status through clear statements about what the Commission is hoping to achieve, which in turn would help to encourage proposals from the ESOs as to how EU standardisation could help to meet those objectives. In this way there could be a clearer communication of specific objectives, better targeting of resources on those objectives, and the basis for a clearer assessment (subsequently) as to the impacts that the financing and the supported actions have had on the achievement of those objectives.

Some of the more specific (or targeted) policy objectives where the intentions of the Commission remain somewhat unclear include, for example, improving and extending the European Keymark system, increasing the role of standards in security, and ensuring the effective take-up of standards by SMEs.

We recommend that the Commission seeks to explain more clearly how it intends to use its financing to pursue the achievement of specific policy objectives, and that it considers earmarking funding for those purposes

3.4. How does the Commission measure the achievement of its objectives?

The study was asked to assess how the Commission measures the contribution of standardisation to the achievement of its policy. Based on our work we have to say that it is not clear that the Commission seeks to measure (or even assess qualitatively) the contribution of standardisation to the achievement of its objectives on any kind of regular basis. Having said this, it is clear that due to the very general or 'high-level' nature of the objectives being pursued, the absence of performance indicators and data with which to gauge their achievement, and the inevitable problems associated with attributing the specific role that the financing plays in relation to all other inputs to those objectives, means that it is unlikely that any kind of robust quantitative assessment could be made.

However, the recommendations already made above concerning (i) the need for more purposeful statements of objectives and (ii) clearer explanations as to how the financing is expected to contribute to these should, if implemented, provide a better basis for assessing retrospectively the contribution that the financing has made to their achievement.

3.5. Effective deployment of the financing

The study terms of reference asked the evaluators to identify whether there are actions of the ESOs, which, although not financed by the EC, contribute to the achievement of its policy objectives, and whether the objectives would be better achieved with EC/EFTA financing support.

Based on our findings we can say that there are many and various actions performed by the ESOs that contribute to the achievement of Commission policy but where no financial support is currently given. One of the most obvious examples is work carried out by CENELEC under New Approach Directives (RTT, LV and EMC), which supports directly the implementation of Community legislation, but for which CENELEC no longer seeks financial support due to past negative experiences associated with many elements of the administration of the financial support. CENELEC and its members have elected to no longer seek support delivered through action grants due to the delays, high administrative burden, and the complex and unstable financial rules that do not fit well with how the ESO systems operate, involving as they do significant elements of subcontracting of tasks to experts appointed by TCs. However, given the open nature of the Commission's policy objectives it is clear that most of the activities the ESOs undertake can be seen to be of relevance to and support in some way Commission policy. However, a significant portion of that work does not currently attract financing.

It is clear that, based on the findings of this report, the financing brings significant benefits from the perspective of all actors, and in this sense a financial allocation by EC/EFTA for this work would be beneficial. However, the current punitive financial rules and the high administrative burden associated with accessing the support are

limiting seriously the propensity of the ESOs and their members to take-up the available financial support. Unless a more stable and reasonable basis for providing the support can be found there is a danger that the real underlying extent of demand / need for the support will not be revealed, and that a lot of work that could be enhanced by EC/EFTA financing will have to make do without it.

The study was also asked to identify whether there are actions carried out by the ESOs that could contribute to the achievements of the policy objectives of the Commission but which are *not* being performed, because of a lack of financing, and if so, would a Commission financial support help develop such actions. Based on our assessment it does not seem that there are any significant activities that are considered desirable / necessary that are not being performed at all because of a lack of financing, but it is clear that certain activities are carried out less frequently or with less resource due to limitations in the financial support available.

The first area identified where a majority of commentators felt that important work was going on at a lower level than is desirable and where the level of support might reasonably be increased is in the area of **translation**. Most commentators consider that making standards available in the national languages of their intended users is absolutely vital if the standards are to be widely used and the potential benefits of standardisation are to be fully realised. The 2006 evaluation of EC/EFTA support for translation identified a range of problems limiting the uptake of the available support, and we are pleased to report that a number of measures have now been put in place to overcome some of those problems. However, these changes have only recently been implemented and it is therefore important that the Commission monitors closely the extent to which these changes are having a material impact on the uptake of the support over the next few years.

We recommend that the Commission closely monitors the level of uptake of financing for translation over the coming 2-3 years to assess the effects of recent improvements to the financial arrangements, and that it takes corrective action as necessary if the changes are not having the intended (positive) effect

We have also identified strong support for increasing the level of financing for **visibility** actions, as this is widely seen as an area where EC/EFTA financing is both legitimate and most value adding in the sense that other actors are unable or unwilling to finance the work. More specifically, there is no strong case for industry to support the wider promotion of the European standardisation system, but it is considered to be vital for helping EU industry to access world markets, to assist with the integration of New Member States, and to support the take-up and use of European standards.

Problems with the administrative complexities of the financing as detailed elsewhere in this report have limited the willingness of some ESOs and their members to participate in these actions, but we have also identified a diminishing desire on the part of the Commission to encourage such actions in recent years, leading to a sharp fall in the extent of support for these activities. While much of the standardisation work is likely to proceed at some point in the absence of EC/EFTA financing, visibility actions are unlikely to, and we therefore recommend that the Commission

restate its commitment to promoting the European standardisation system internationally, and ensure that resources are made available for this purpose.

We recommend that the Commission restates its support for visibility actions and ensure that sufficient resources are available to support these projects in future

Over the period covered by the study EC/EFTA financing has successfully contributed to a number of preliminary scoping or feasibility studies that have investigated the potential for standards development in new areas such as services and fuel cells. It has also financed other 'supporting' activities such as 'helpdesks' to assist with the implementation of large suites of standards (e.g. pressure equipment) and encourage their wider take-up.

These actions are widely considered to be important areas for EC/EFTA financing for a number of reasons. The feasibility / scoping studies hold the potential to either confirm the need to proceed with standards development in new areas of Commission policy, and help to avoid the possibility that the Commission would encourage such work before the market is ready. The helpdesks have been shown to assist in the uptake of standards, thereby supporting directly the implementation of New Approach legislation. There is also the potential for other types of supporting or preparatory actions to be used in order to generate similar / additional benefits.

There was relatively few of these types of actions supported from 2004-7 and we believe that there is the potential for them to be supported more actively by the Commission, particularly as a means to investigate the role of standards in new policy areas and to support the dissemination and uptake of standards, thereby supporting both ends of the standards development cycle, while leaving industry to drive the main body of standards development work itself. We therefore suggest that the Commission also restate its support for these types of actions and ensure that financing is available to support them.

We recommend that the Commission restates its support for (i) preliminary studies that assess the potential for standards in new areas and (ii) other forms of support action that contribute to the wider take-up and use of European standards

As regards support for standards development work itself, there is clearly a strong case for EC/EFTA financing to continue to be used, as it clearly helps to provide impetus for and strengthen work going on in areas closely linked to EC policy and legislation. However, of all the forms of support provided it was the area where many stakeholder groups were more ambivalent about whether there was a real need and whether the financing might have negative effects as well as positive ones. We are reluctant to suggest that EC/EFTA should withdraw from this line of support, or even curtail its expenditure due to the clear and positive impacts that the financing has in encouraging and strengthening work in areas related to public policy and where the public interest dimension of the standards is clear.

We did, however, identify strong demand for increased support for a specific element of the standardisation work, namely **round robin testing** to validate the test methods

that form an integral part of many standards. The ESOs, NSBs and some industry stakeholders have indicated that certain areas of standards development work were effectively 'stuck' due to an inability to find financial resources to carry out round robin tests. The bodies of standards affected all support directly the implementation of Commission Directives or legislation and the accuracy and validity of the test methods is of vital importance in ensuring that compliance with the standards ensure the necessary level of protection of health and safety or environmental protection, and as such there is a strong case for public support.

We understand that the Commission's reluctance to finance round robin tests relates partly to the high costs and partly to the fact that this element of the work involves little input from the ESOs and NSBs, and as such the work may need to be tendered competitively. It is not clear whether this is actually the case as the programme of testing would have to be coordinated and directed in some way by the TCs responsible for developing the standards. Even if it turns out that the work has to be competitively tendered then this route should be followed in order to allow the standards development work to be completed in a timely fashion. As regards the costs, the overall EC/EFTA budget for standardisation is relatively modest given the scale of the benefits realised and there is certainly a case for seeking to increase the budget in the face of increased need. We therefore recommend that the Commission seek to find ways to provide a greater level of support to round robin testing.

We recommend that the Commission seeks ways to provide a greater level of support to round robin testing in order to ensure that important bodies of standards can be completed and used to support Community legislation

One final area where there is a case for increased funding from EC/EFTA is for the revision of standards, particularly where the need to revise standards has been prompted by changes to EC Directives or other forms of legislation. Under these circumstances, changes required to bodies of standards to ensure that they can continue to be used to support the implementation of the legislation is as much in the interest of the Commission as it is industry, and it therefore seems appropriate that EC/EFTA should help to support that revision process where possible.

We recommend that the Commission provides support for the revision of European standards in cases where the need to revise has been prompted by changes to Directives or other legislation

3.6. Strengthening the role of Units I3 and D4 *[currently Units C5 and D3]*

DG ENTR Units I3 and D4 *[currently Units C5 and D3 of the Enterprise and Industry DG of the Commission]* provide a valuable service in facilitating other Commission services' access to standardisation. This role is effective but based on the feedback received it could be further strengthened.

One of the key roles played by these two units is to promote the wider use of standardisation across the Commission, helping other policy units to understand the benefits that standards can bring and providing a route by which they can make use of standardisation in support of their own areas of policy and legislation. We spoke to a number of units that spoke very highly of the 'service' provided by these units,

some of which indicated that they would have struggled to address requests to the ESOs and provide an impetus to standardisation work without their help. Some of these units have indicated that more could be done to promote the benefits of standardisation within the Commission, and that standardisation could be given a higher profile. We are aware that resource constraints within units I3 and D4 limits the extent to which they can undertake such promotional work, although both have been effective in these roles in the past. We hope that in future more time can be given to continue this good work.

We recommend the Commission seeks to more actively promote the benefits of standardisation within the Commission, helping to extend the range of Directorates and policy units that use it in support of their policy

Many of the policy units manage their own links to the standardisation work being carried out in their policy areas. Most of these units are responsible for New Approach Directives and have long-standing links to the ESOs, and in some cases the Technical Committees that are undertaking the work. These units usually communicate directly with the ESOs and some also access the ESO's information systems directly in order to stay appraised of progress. In addition, some of the units meet regularly with the ESOs, through standing committees and other bodies connected to the standardisation work, with a minority also attending relevant Technical Committee meetings.

Some units, however, rely on unit I3 or D4 to keep them informed about the standardisation work that they have (or should have) a policy interest in, but lines of communication in many cases are weak, and in some cases non-existent, meaning that these units are not being kept properly informed about the work. Indeed, we struggled ourselves to identify which units have an interest in some of the actions, and there seems to be no centralised system for documenting the links and ensuring that regular communication is maintained. The situation was most acute with respect to ICT standards work, which has suffered from changes in how the work has been organised and managed from a contractual perspective, and from the fact that the work is no longer (or only rarely) requested through mandates developed by specific policy units. There are also clearly resource constraints inside many Commission units, and a lack of specific technical expertise that might help the units to engage in the standardisation work directly, without relying on Units I3 and D4. These factors certainly go some way to explaining the problems.

However, we believe that both unit I3 and D4 could and should develop clearer and stronger processes for connecting the actions for which they have contractual responsibility to the units whose policy areas the work is intended to contribute to, and for ensuring that the relevant units are kept regularly informed about the standardisation work. As such there is a need for the relevant policy contact or contacts to be named in the grant agreements and for some system to keep that information updated in the event of staff changes. In this way, units I3, D4 and the ESOs would always be aware of which individuals and units within the Commission have a policy interest in the work.

A related concern raised by some of the policy units concerned the nature of the information they receive in relation to the work, which is often considered to be too

technical in nature and not sufficiently tailored to their needs. The best way to facilitate their interest and engagement in the work would be to provide regular information on the work, in laypersons terms, identifying any specific issues that the Commission might need to be aware of. The ESOs, via their TCs/TBs would be in the best position to provide such information, though there would be a cost to this that could reasonably be met by EC/EFTA as part of the eligible costs of the actions.

We recommend the Commission establish (i) a clear process for linking specific actions that have attracted EC/EFTA financing to named officials within the relevant policy units, and (ii) an improved process for ensuring that those officials are provided with regular updates concerning the progress of the work and any issues arising.

The policy units are also interested in the impacts of the work and in particular would like to be kept informed about the extent of take-up of the standards and whether the standards are proving useful in resolving, for example interoperability problems or improving compliance with Directives. Such information is not easy to obtain, and there are no processes currently in place to collect it.

We believe that stronger engagement by the Commission in the work, facilitated by improved lines of communication with the ESOs, would help to strengthen the relationship between the Commission and the ESOs, and would allow the relationship to be based more around common objectives, the progress of the work, and the benefits realised than about the administrative rules, payment delays, and time delays, which unfortunately often seem to be the most salient feature of the support system.

4. EFFICIENCY

4.1. Proportionality of the financing allocated to the ESOs

The study was asked to assess whether the financial support allocated by the Commission to the ESOs is proportionate to their contribution to the achievement of the policy objectives. Based on our evaluation we conclude that the total volume of financial support provided by EC/EFTA for standardisation appears to be relatively modest, given the important role that standardisation plays in the implementation of EU legislation and policy. The Commission is able to make significant use of, and enjoys significant influence over, the standardisation system in relation to the scale of its financial contribution. In this sense the financing delivers very good value for money, and there is a case for an increased level of financing in specific areas in order to address identified needs.

We believe that there is something of a contradiction between the statements made by the Commission about the importance of standards to the economy and society and its very modest, some might say ungenerous, approach to financial support in this area. Despite the key role played by the ESOs in implementing the New Approach and supporting Commission policy and legislation, only €15 million per annum is currently spent and a significant portion of that is consumed in meeting the administrative burden that has to be complied with in order to receive that support.

Regrettably one of the ESOs, several NSBs and a number of Technical Committees and Bodies have elected to no longer apply for support delivered through action grants (other than the OGs) as a result of the financial and administrative difficulties and the delays that are associated with the financial support, and this is testament to the fact that the political ambition is not being met by corresponding levels of (useful) financial support. We might have expected that the standardisation unit (I3) would be keen to expand its budget and to do more to help and assist with the effort in areas that contribute to Commission policy, but the approach is invariably to question or doubt the need, or to seek to minimise the amount of support that is offered, despite the fact that the Commission's input into the overall costs of standardisation is very modest.

Under the current arrangements the budget only appears to be under a moderate amount of pressure. The pressure has been alleviated significantly by the withdrawal of some ESOs and NSBs from certain lines of support due to problems with the detailed, complex and unstable financial rules and the high administrative burden. Under improved conditions there would be a strong case for an increased budgetary allocation due to the significant benefits that the support can deliver. Many policy units plan to make more use of standards in future, and we have identified a range of areas where an increased level of financing would be useful, but it is not clear that the ESOs and their members and technical bodies will make full use of that support unless the administrative and financial problems can be significantly reduced. If this can be done, and we make a number of recommendations for doing so below, then there is significant potential for increasing the budget and using it to extend the range of ways and the number of areas in which the financing can support the implementation of Commission policy and legislation.

We recommend that the Commission seek to increase its budget for standardisation in the medium term, in order to better reflect the considerable benefits that the support can bring and in order to provide support to an increased range of activities across a broader range of policy areas. In order to ensure that the support is taken up and used effectively, an improved set of administrative arrangements should be put in place to ensure that the financing can be accessed easily and used for its intended purposes / benefits rather than being consumed in administrative costs.

We have also looked at the question of whether the volume of financing allocated to each ESO is proportionate to their relative contribution to Commission policy. This is not easy to answer as there are no agreed indicators for making such an assessment. It is clear that the three ESO systems and their central secretariats are very different, and it is clear that the range of sectors covered by each ESO impacts on the level of financing that each is allocated. However, a host of other factors also affect the volume of financing they receive, including conscious decisions on the part of some to limit their level of financial reliance on the EC/EFTA support. It is therefore not possible to say whether the current balance is correct, but we received no indications from any of those consulted that the balance was obviously wrong or required adjustment. Having said this, if the Commission clarifies its policy objectives and provides more detail on how it expects standardisation to contribute to those objectives, this may provide a better basis in future for arriving at a clearer perspective on how each of the ESOs is contributing to these. This could help to

determine the appropriate scale of the Operating Grants and may provide the basis for deciding a suitable 'allocation' for standards development work within a more straightforward future system of financing, if one could be found. However, under the current arrangements we do not see any strong need to undertake such an exercise.

4.2. The de-facto monopoly position of the ESOs

The study was asked to assess whether the de-facto monopoly of the ESOs generates a loss of efficiency regarding the financial support allocated by the Commission. It is our contention that the de-facto monopoly position of the ESOs *does* generate a loss of efficiency, but this is not because the ESOs abuse in any way the position that they hold, or seek to maximise their gains because they can access financing in a largely non-competitive environment. The loss of efficiency is created by the financial and administrative rules that are applied by the Commission *because* of the monopoly position.

Under normal circumstances the Commission issues open, competitive calls for tenders when wishing to support specific forms of activity undertaken by external organisations. However, the ESOs are formally recognised as the three European standardisation bodies, and as a result they are uniquely qualified to undertake certain types of work, specifically those relating to the 'core process' of developing recognised European standards (ENs). As such, the Commission financing rules indicate that a full competitive tender is not necessary, and specific provision is made in the financing decision to allow the Commission to direct requests to the ESOs and provide financial support without running an open tendering process. This facility is intended to make the financing of the actions more efficient, as it saves time and money associated with the full tendering process.

However, it seems that the de-facto monopoly status of the ESOs brings into play a number of other financial rules and creates a certain nervousness on the part of the Commission, which together have led to a situation where the financial controls and administrative requirements have now become excessively demanding and bureaucratic and seem to go far beyond the level applied to competitively tendered work. Many of those rules also appear to be a poor fit with the ESOs' natural ways of working, which inevitably involve a certain level of subcontracting, and there have been significant problems associated with frequent changes to the rules and an inconsistent application of the rules by different officials. This situation has created a significant loss of efficiency and has led to a situation where a significant element of the financing allocated to the ESOs is expended in administering the grants rather than carrying out the work. The administrative burden is no longer commensurate with the level of EC/EFTA contribution to the real costs of the work.

This situation has led to a breakdown in relationships between the Commission and the ESOs and their members, to the point where the support is no longer viewed in as positive terms as it should be, and where little time or energy is left for positive, creative discussions about how to enhance the system as a whole and how to maximise the value added by the support. The underlying trend now appears to be for the ESOs to avoid applying for action grants wherever possible. This is clearly a regrettable situation and one that needs to be addressed as a matter of urgency. It

should be noted, however, that significant efforts have been made in recent years to reduce the administrative complexity and develop improved process in order to increase efficiency, with some positive effects. However, further more substantial improvements would be beneficial, and a more straightforward, stable system of financial support would bring significant benefits. Our recommendations in this area are set out in Section 4.3 below.

The terms of reference also asked the evaluators to determine whether the achievement of the policy objectives of the Commission would be better supported if the Commission were to allocate grants or contracts to other organisations, especially as far as promotion actions are concerned. It is our conclusion that it is unlikely that the allocation of grants or contracts to other organisations for similar activities would better support the Commission's policy objectives. The ESOs are all highly organised, professional organisations that have, by a long way, the best command of European standardisation and are in the best position to carry out the full range of tasks that currently attract EC/EFTA financing.

4.3. How can the current method of financing be further simplified and streamlined?

The study terms of reference asked us to assess how could the current method of financing be further simplified and streamlined, and how could project management be further simplified, bearing in mind the role of the Central Secretariats of the European Standards Organisations and the role of National Standards Bodies.

As indicated in the preceding section and as discussed extensively in the main body of this report, the current method of financing has become bogged down by a high level of administrative burden, with unstable and complex financial rules, an atmosphere of mistrust, and significant delays in certain parts of the process that together significantly diminish the level of value added by the financing. Unfortunately, this has come to be the most salient feature of the system of financing implemented by the Commission and has come to dominate the basis of the relationship between the Commission and the ESOs. The problems have become so serious that take-up of the support is in decline, despite the considerable positive benefits that it can and often does bring to both parties.

We are aware that the situation has been improved in the past couple of years and that the new Framework Partnership Agreements signed this year (2009) offer the potential for smoother and less burdensome processes in relation to certain elements of the overall administration of the grants. However, while significant efforts have been made to improve the situation and address the significant backlog of actions where there has been a failure to agree on the final cost claims, significant problems remain and in many respects the damage has already been done.

It is our contention that a shift to a radically simpler, faster and more stable arrangement is necessary in order to increase the efficiency of the financial support and in order to ensure that it is fully utilised and indeed extended in future. The ESOs have signalled that there have been enough minor revisions to the rules and processes in recent years and that what is now needed is a period of stability and consistency in the application of the current rules and processes, and a serious attempt to find a

more suitable financial arrangement in the medium-term. In the short term we also believe that the Commission should apply a more constructive and proportionate approach to the resolution of any points of confusion or disagreement over the interpretation of the financial rules and administrative requirements, in order to facilitate improved uptake of the support as opposed to a further diminution of it.

We recommend that the Commission seeks to identify a significantly simpler and less bureaucratic set of arrangements in the medium term, and that in the interim the administrative requirements and financial controls are defined as clearly as possible and are then applied fairly, proportionately and consistently across the various contracts.

While the administrative problems surrounding the interpretation and application of the financial rules have been the most serious problem area, there are also notable problems concerning the (slow) speed of certain processes. We have identified that one of the major benefits of the Commission's financing support and policy lead can be to accelerate the onset of new standardisation work in areas closely linked to public policy, bringing confidence to stakeholders and providing impetus for the work to move forward. However, having signalled its need or wish to support standardisation in a particular area, the process of agreeing the financing and drawing up the contracts can in many cases delay the start of the work, in some cases by more than a year. This causes frustration among the standardisation bodies and industry, and in some cases has caused those involved to not apply for the support, electing to proceed instead with less resources in order to avoid the delays and administrative burden associated with EC/EFTA financing.

The main cause of the delays appears to relate to the time taken to evaluate and assess ESO grant applications, and to agree and sign the contracts. These problems affect both the annual Operating Grants and the individual grants for actions that support the standards development work, feasibility studies, visibility actions, and so on. The reasons for the delays appear to relate mainly to the time that the Commission takes to organise and undertake the evaluation process, and the number of iterations that proposals have to go through before the contracts can be agreed. There also appear to be problems with the Commission's own budgeting cycle, with signature of contracts sometimes being delayed pending a decision on the size of the budget for the coming year. There were also some suggestions that there have been specific shifts in policy priorities within the Commission, which has meant that standardisation work in new areas originally prompted by the Commission has subsequently (following a grant application) been de-prioritised, leading to uncertainties as to whether the work is still required. Such situations may also have delayed decisions on some occasions, but are perhaps not easy to always avoid within a policy environment.

Given the simplicity of the evaluation process used to assess the proposals it appears in many cases to take too long, and the process should be accelerated wherever possible in order to expedite the start of the work. It would be helpful if the Commission could agree and observe a maximum period of 1-2 months to undertake the evaluation of proposals and to render a decision or request for further information, with requests for minor revisions to otherwise acceptable proposals being agreed and made without the need for formal resubmission and reassessment

of grant applications. In cases where more substantial revisions to proposals are needed the ESOs should be given a further month to respond, and the Commission a further month to review the changes and take its decision. The drawing up and signing of contracts should take no more than a further month to achieve.

The Commission has indicated that one of the reasons why it takes so long to assess proposals and agree the contracts is the variable quality of the proposals submitted by the ESOs, which in many cases are adjudged to be insufficiently developed or containing mistakes that then need to be rectified. They suggest that if the ESOs implemented an improved 'quality control' process before releasing proposals there would be a reduced need for the Commission to ask for revisions or further information before the contract can be agreed. In response, the ESOs have indicated that the comments received are often very minor, and that under-developed proposals tend to occur when the Commission's requests are too open or unclear or when the time that their Committees have to respond to the requests is too short to allow a full and considered response. It is contended that the time given to prepare proposals is often less than the time that the Commission takes to read and assess them, and given the relative workloads involved, the evaluation process should be able to be carried out much more quickly than the development of the proposals.

We recommend that the Commission defines a clear process with agreed time limits for carrying out the evaluation of ESO proposals and issuing decisions, and strictly observes those time limits. In addition, requests for minor revisions to proposals should be negotiated directly and if complied with should obviate the need for a full re-evaluation of the proposals

The ESOs have also indicated that a standard template and guidelines for the development of proposals would be helpful, which go beyond those already developed and which provide a more functional specification concerning the types of information the Commission needs and the preferred length and format of the information. If such a template and associated guidelines can be agreed it should improve the extent to which the ESOs are able to get their proposals 'right first time'.

We recommend that the Commission define more clearly its requirements concerning the format and content of proposals, and that the ESOs observe these requirements in order to minimise the extent to which proposals have to go through multiple iterations before contract signature.

5. UTILITY

5.1. Is the financing vital to the ESOs?

The study terms of reference asked us to determine whether the financial support delivered by EC/EFTA is vital to the ESOs, and whether the ESOs would contribute the same way to the achievements of the Commission policy objectives if the financial support were not available.

Our conclusion is that the financial support is of significant utility to the ESOs, NSBs and industry and in many cases is the critical driver for the decision (by industry and

other stakeholders) to proceed with standardisation work in a given area. In other cases the financing affords additional priority to the work, and causes it to happen sooner rather than later. The ESOs would certainly not be able to contribute to the achievement of Commission policy objectives *to the same extent* in the absence of the financing, though it is clear that they would continue to contribute to the achievement of Commission policy objectives, due to the high degree of alignment between the Commission, the ESOs and industry stakeholders involved in the standardisation work. There are many points of common or shared interest and part of the rationale for EC/EFTA support is to contribute to the wider body of activity that contributes to community objectives as part of a 'fair deal' between the various stakeholders.

The question of whether the work is *vital* to the ESOs is more difficult to answer. Certainly the Operating Grants are vital in enabling the central secretariats to continue their operations at the current levels, respond to Commission requests and requirements, and to continue to drive the same level of improvement within the standardisation system than they are currently able. It is not however vital to their ultimate survival, nor should it be. The other forms of financing are vital to certain actions being undertaken, in particular the volume of visibility work, preliminary studies, supporting actions and a certain amount of translation work. The support is less vital to the continuation of the standards development work, but certainly has a significant role to play in encouraging and strengthening that work in defined areas related to Commission policy and legislation.

5.2. Industry perceptions of the financial support

The study terms of reference asked us to assess whether industry (including SMEs) perceives the financial support allocated to the ESOs as a useful contribution to the European policy. Feedback from industry representatives and industry participants consulted as part of this study strongly confirms that industry sees the financial support provided by EC/EFTA as of significant utility, not only to European policy but to industry itself by helping to co-finance at least some aspects of the system that industry might otherwise have to carry itself. It is clear that industry players see their own inputs into the overall standardisation effort as the largest share (which it is) and many believe that EC/EFTA could and should do more to help to offset the costs of the activities, which are significant and which in some sectors have been very considerable, extending over many years. There is a strong view from industry that the Commission should do more rather than less to support European standardisation from a financial perspective. Industry representatives and NSBs have also noted the important and valuable *non-financial* role played by the Commission in developing and promoting the New Approach principles and in observing those principles by limiting the extent to which it seeks to direct or control the standardisation process.

5.3. The counterfactual

The study terms of reference asked what would be the impacts if the Commission stopped its financing.

Our conclusion, based on the study findings, is that if EC/EFTA withdrew its financing entirely there would be a very significant negative impact on the activities

of the ESOs and the work undertaken in support of Commission policy would be significantly reduced or weakened. The various benefits that the financial support brings would be lost or significantly diminished and the ability of the Commission to influence the system would be weakened. This is not, therefore, a course of action we would recommend.

A related question contained in the terms of reference asked whether there are alternative sources of financing for the ESOs for the same actions. One way to answer this question is to say yes, there are alternative sources of financing and these are already being used to finance the actions. All of the financing provided by EC/EFTA is co-financing the activities, covering only a share of the real full costs. As such, other contributors to the system, primarily industry, are already 'alternative' sources of financing.

If we are asked whether there are alternative sources of financing for *those elements of the costs currently being carried by EC/EFTA*, the answer in most cases is no. As indicated above, industry already finances the vast majority of the costs of European standardisation and public sector inputs are fairly low in real terms. It is unlikely that alternative sources of financing could be found to support the additional capacity within the ESOs provided through the Operating Grants, and it is also unlikely that alternative sources of financing could be found for the visibility actions and preliminary / supporting actions, or for the translation of standards. In some cases alternative sources of financing for standardisation work could be found, but in most cases the activities would simply be carried out later, over a longer period of time, and with less management resource and expertise.

5.4. Negative effects of the financing

The study terms of reference asked whether there are any negative effects to the financing allocated to the ESOs.

We received a small number of indications that on occasion the financing may have prompted standards development work to start at EU level, undertaken by the ESOs, when there are already parallel developments underway either at international level (ISO) or within other fora that develop standards. However, in most cases such duplication of effort has been avoided and we believe that it is unlikely that 'parallel' efforts would be going on without each party having some awareness of the activities of the other. It is therefore unlikely that the financing has created any significant level of duplication.

The main negative effects that we have identified relate to the loss of goodwill and wasted effort associated with complex and unstable financial rules, which has created something of a rift between the Commission and the ESOs, at least with regard to the financial and administrative elements.

The financing is given in light of the fact that EC/EFTA and the standardisation bodies have common objectives and shared interests, and the financing is intended to *support* and *enable* the activities of the ESOs where their activities and objectives align with those of the Commission. It is therefore vital that the financing is provided within an atmosphere of mutual trust and respect, and that all parties work together to

ensure that the financing is delivering the maximum value and is used in the most effective ways possible, and with a minimum of administrative burden. It is therefore necessary for the Commission officers involved to see their primary role as to help and support the ESOs and to enable Commission policy units to make greater use of the system. Financial administration and control are or should be secondary roles, and ones that should not interrupt the core business of expanding and strengthening the system. It would seem that these 'principles' are regrettably not always being observed, and we hope that this report can signal the start of a new phase of stronger cooperation between the Commission and the ESOs.