

## ROADMAP

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Lead DG/contact person: DG ENTR/I.3  
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### Initial IA screening & planning of further work

#### A. Context and problem definition

What is the political context of the initiative? How does this initiative relate to past and possible future initiatives, and to other EU policies?

According to the international definition of ISO and IEC<sup>1</sup>, "*standards are documents established by consensus and approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for activities of their results, aimed at the achievement of the optimum degree of order in a given context*". Standards can enhance quality, secure inter-operability and thus facilitate innovation, set security levels, help protect environment, facilitate communication, protect health, etc.

Standardisation within Europe is a voluntary cooperation amongst industry, users, public authorities and other interested parties, managed by independent organisations. European standardisation has successfully contributed to the implementation of European policies and legislation over the past two decades. This refers in particular to the Internal Market legislation based on the "New Approach"<sup>2</sup> a concept that covers major industrial sectors, as well as to an increasingly large collection of other EU policy initiatives. The role of European standardisation in support of EU legislation has been confirmed in the legislative package providing a common framework for marketing products<sup>3</sup>. Furthermore, the Commission has reiterated in its Communication on standardisation and innovation of 2008<sup>4</sup>, as well

<sup>1</sup> ISO/IEC Guide 2 :2004 – Standardisation and related activities – General Vocabulary

<sup>2</sup> The « New Approach » is a legislative technique applied to the harmonisation of technical regulation within the internal market. Essential requirements necessary to safeguard public interest are harmonised in EU directives, whilst technical specifications of products are harmonised in voluntary European standards. Products complying with such harmonised standards are deemed to comply with the directive.

<sup>3</sup> This package includes :

- Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and
- Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

<sup>4</sup> Communication from the Commission to the Council, the European Parliament and the European Economic and Social Committee « Towards an increased contribution from standardisation to innovation in Europe » Com(2008)133 final (2008-03-11)

as in a number of other policy initiatives, the substantial contribution that standardisation is expected to make to European competitiveness, innovation and other policies. The Competitiveness Council endorsed and enlarged the Commission's proposals in its conclusions of 25 September 2008.

As part of the EU strategy for Growth and Jobs, the Commission and the Council of the European Union have identified standardisation as one of the key instruments to be improved in order to support and enable innovation. The Commission proposal for a new "Europe 2020" strategy confirmed this. "Speeding up setting of interoperable standards" is mentioned as an important factor to improve framework conditions for business innovation as part of the Flagship Initiative "Innovation Union".

The legal foundation for European standardisation has been laid down in Directive 98/34/EC<sup>5</sup> which recognises the three European Standardisation Organisations (ESOs) CEN<sup>6</sup>, CENELEC<sup>7</sup> and ETSI<sup>8</sup> and enables the Commission to request them to undertake standardisation work in specific areas. Although they are private, the ESOs are considered to be bodies pursuing an objective of general European interest. Directive 98/34/EC provides the key features for the current European standardisation system (ESS). Standardisation in the ICT sector has been framed by Council Decision 87/95/EEC<sup>9</sup>.

In its Communication Com(2008)133 final, of 11<sup>th</sup> march 2008, the Commission requested for a reform of the European Standardisation System (ESS), in order to make it more reactive to innovation and more supportive to competitiveness of EU enterprises. In its Conclusions of 25<sup>th</sup> September 2008, the Council encouraged the reform of the ESS, and invited the Commission to review its action plan for standardisation. In addition, the Small Business Act (Com(2008)394 final) encouraged the European Standards Organisations to review their Business Model and called for an adaptation of the ESS to the needs of SMEs.

The consultation on the "White Paper" for a new ICT Standardisation Policy (Com 2009(324) - Modernising ICT Standardisation in the EU - The Way Forward) has demonstrated the urgency of a reform of the standardization system in Europe. An Impact Assessment Study is being performed regarding scenarios for ICT standardization that emerged from the consultation. This Impact Assessment will be managed in close cooperation with the specific Impact Assessment on ICT standardization.

What are the main problems identified?

The Community competence in the area of standardisation has contributed to the success of European standardisation, enabling the development of European rather

<sup>5</sup> 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

<sup>6</sup> CEN : European Committee for Standardisation

<sup>7</sup> CENELEC : European Committee for eletro-technical Standardisation

<sup>8</sup> ETSI : European Telecommunication Standardisation Institute

<sup>9</sup> Council Decision of 22 December 1986 on standardization in the field of information technology and telecommunications

than national standards needed by all economic actors for the creation of the European internal market, supporting the ever increasing needs of European legislation and policies. However, besides the recognition of ETSI as an ESO in 1992, the EU standardisation framework has not been generally reviewed since its adoption. The general framework conditions influencing the impact of standards and their development and use have in the meantime changed significantly. Whilst the European Standardisation System is generally recognised as successful, it is faced with a number of challenges, such as:

- Having the flexibility and pro-activity to address the broadening scope of voluntary standardisation, as well as cross cutting issues (e.g. energy, health, accessibility for all), including through adequate partnering with fora and consortia ;
- Reaching out to the corresponding broadening of interested and affected stakeholders (e.g. public authorities, societal interests, SMEs), in particular to eventually support broader areas of European policies (e.g. environment, safety at work, health, services);
- Facilitating innovation by speeding up the standardisation processes and anticipating future business and societal needs in standardisation, thus bringing new knowledge to market solutions and facilitating inter-operability;
- Using information technologies to support the collective standards development work and the broader dissemination of standards;
- Reconciling the separation into three ESOs and the convergence of technologies;
- Promoting the benefits of standardisation through better measurement of impacts, improved management of developments and better communication towards the corporate, political and academic players;
- Clarifying the positioning of European standardisation vs. national and international standardisation

In this context of new challenges, it has become necessary to review the current European standardisation system in order for it to remain successful and to adapt it to the needs of the forthcoming decade by identifying measures to be taken or proposed by the European Commission and developing strategic recommendations for action by Member States, European and national standards bodies and all other standardisation stakeholders.

The Commission has launched several studies and evaluations of its policies, especially regarding the openness of the standards making process and the Community financing. An informal expert group, called “EXPRESS”, debated during the whole of 2009 towards strategic view of standardisation in 2020. The overall conclusions demonstrate that the European standardisation system needs to evolve.

The Commission has spotted, in the annual reports on notifications of national standards provided according to Directive 98/34, a tendency of national standards bodies to develop national service standards, whilst the Services directive encourages the development of service standards at European level, in view of ensuring a well functioning Internal Market. National standards bodies have enlarged their range of normative documents towards alternative “Publically Available Specifications” which, although very similar to standards in the development process

and content, are not covered by directive 98/34/EC and therefore not notified. A proliferation of such national documents may lead to a renewed fragmentation in the Internal Market.

The European Standards Organisations themselves have already begun reform initiatives building on FLES – the Future Landscape of European Standardisation initiative – in which CEN and CENELEC are cooperating to achieve greater integration. In parallel, ICT standardisation policy is also currently under review since 2007.

Two kinds of problems call for a revision of the legal framework of European Standardisation. Potential barriers to trade created by national standardisation, and lack of efficiency of the system, leading to de-facto standards being developed outside the traditional European Standards Organisations, leading to a risk of new barriers to trade and insufficient involvement of stakeholders.

NB : Specific problems to ICT standardisation are handled through a specific Impact Assessment conducted on the revision of Council Decision of 22<sup>nd</sup> December 1986 on standardization in the field of information technology and telecommunications.

### **Problem 1 : Barriers to intra EU trade**

Directive 98/34/EC aims at avoiding national standards to create new technical barriers to trade within the Internal Market. Every new or revised draft national standard must be notified to the European Commission and to all member States. The Commission may impose a standstill on the subject covered by the standard and requests the subject to be harmonised at European level. However, directive 98/34/EC covers product standards, whilst service standards remain outside its scope. In addition, beyond national standards, National Standards Organisations have been developing for the last few years alternative standardisation documents (e.g : called Publically Available Specifications), which are not covered by directive 98/34. Although these documents do not bear the specific status of a standard, their existence may endanger the integrity of the internal market, as they may well be quoted as references, e.g in contracts or public procurements. As documents with a national scope, they would oblige operators to adapt to each national market, bearing additional costs.

In order to avoid new barriers to trade in the internal market, it is necessary to envisage opening the scope of directive 98/34/EC to service standards and to alternative standardisation deliverables, and to accelerate the reaction time of the European Standards organisations.

### **Problem 2 : Deficiencies in access, transparency and efficiency of European standardisation**

Where standards are developed to support European legislation, the access of all relevant stakeholders to the standards development process becomes all the more crucial. The acceptance of voluntary standards by the market players is a direct function of the level of stakeholders consensus that standards materialise. Although standards are voluntary, their effect on market is important, as they provide a level

playing field for security, quality, interoperability, environmental and consumer protection. They can also support the dissemination of innovation, and contribute to open markets on global scale.

Despite the consensual mode of establishment of standards, there are risks that standards development may be biased in some cases by an over-representation of specific vested interests. In some cases, stakeholders (especially SMEs) complained that National Standards Bodies with certification activities initiate the development of standards suitable for certification, whilst those standards are not a priority for enterprises. The issue of an appropriate consideration of public interests is even more important when de-facto standards are developed by private organisations, called “Forums” or “Consortiums”, outside the formal European and national recognised standards organisations.

Specifically, as proved in a recent study launched by DG ENTR, European standardisation was criticized for a lack of openness and for a difficult access for SMEs and other stakeholders, leading to standards not appropriate for SMEs. Different business models of the national standards organisations, costs of standards, sectoral fragmentation of standardisation organisations and a lack of a harmonised tracking system of the participation of stakeholders have been pinpointed as main barriers for a more efficient and inclusive standardisation system.

More and more European standards are based on (or identical to) international standards. Participation of European stakeholders in global standards organisations is always more necessary. However, international standardisation is more costly (travel costs, longer process) and requires more dedicated expertise.

Low participation of Member States and Commission services in standards development can jeopardise the value of standards, especially for mandated standards supporting EU legislation. As an important stakeholder, being in charge of market surveillance, the presence of national authorities during the debates on standards is crucial for the well-functioning of New Approach directives, and to avoid ex-post formal objections.

The proliferation of forums and consortiums, that generate de-facto standards, co-exist and compete with standards developed by formally recognised European Standards Organisations. This creates the risk of additional barriers to trade and confusion on the market. These de-facto standards being widely recognised by some sector of the market and implemented, the current EU legal framework needs to take them into account. A revision of directive 98/34 as well as a possible revision of Decision 1673/2006 of the Council and the European Parliament should be considered.

As the value of a standard is a direct function of the consensus, and because standards can be considered as a market tool of public interest, it belongs to public authorities to ensure the full transparency, openness, consistency and efficiency of the standardisation process.

Is EU action justified on grounds of subsidiarity?

Around 90 % of standards applicable in the EU are either European or international standards. The Internal Market can only function smoothly if standards do not represent barriers to trade, and therefore they need to be harmonised in all EU Member States.

Proliferation of national standards and other national reference normative documents in Member States would create barriers to trade in the Internal Market. Manufacturers would need to adapt their products to each national market, which would increase production costs. It is likely that enterprises would not benefit from the full potential of the internal market. Directive 98/34/EC provides a mechanism by which the Commission can require Member States to impose standstill on their National Standards Organisation on a specific subject and request the European Standards Organisations to harmonise the subject, developing a European Standard.

Access issues that SME and other stakeholders may face with respect to standardisation are similar in all EU Member States. Tackling these questions at European level will generate synergies and benchmarking of best practices. The recognition of de-facto standards need to be implemented in a similar way in all Member States.

## **B. Objectives of EU initiative**

What are the main policy objectives?

- Strategic objectives

The EU initiative aims at increase the contribution of European Standards to the competitiveness of EU enterprises, especially SMEs, and performance of the European Standardisation Organisations.

- Specific objectives

The EU initiative aims at avoiding the appearance of new technical barriers to trade due to the proliferation of normative documents. It also aims at facilitating the access to standardisation to all stakeholders, especially SMEs, in order to make sure that the content of standards really reflects the consensus of all parties concerned. Improving the efficiency of the European Standardisation Bodies will make it cheaper and easier for stakeholders to take part in the standards development process.

Does the objective imply developing EU policy in new areas or in areas of strategic importance?

No

## **C. Options**

What are the policy options? What legislative or 'soft law' instruments could be considered? Would any legislative initiatives go beyond routine up-date of existing legislation?

There are 2 kind of problems the initiative plans to solve, and several options for each of them :

### **Problem 1 : Barriers to Trade in the Internal market**

#### **Option 1 : No action**

#### **Option 2 : Open scope of directive 98/34 to services**

- Make an obligation to each National Standards Organisation to notify all national service standards
- Open the possibility for the Commission to be able to impose standstill on national service standards development process and to request European Standards Bodies to develop European service standards
- Make an obligation for European Standards Organisations to answer any standardisation request from the Commission within 2 months

#### **Option 3 : Open scope of directive 98/34 to all documents published by national standards organisations**

- Make an obligation to each National Standards Bodies (NSB) to notify all national standards and other normative documents
- Open the possibility for the Commission to be able to impose standstill on all national standards and normative documents development process and to request European Standards Bodies to develop European standards or normative documents
- Make an obligation for European Standards Organisations (ESO) to answer any standardisation request from the Commission within 2 months

### **Problem 2 : Deficiencies in Access, transparency and efficiency of European standardisation**

#### **Option 1 : No action**

#### **Option 2 : Support the European Standards Organisations in their improvement programme**

- Introduce the WTO/TBT principles of standardisation (transparency, openness, impartiality, consensus, efficiency, relevance and consistency) 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.

- Request MS to monitor the balanced representation of stakeholders in NSB mirror committees
- ESO to open the possibility to approve documents developed by forums and consortiums as European Standards following a simplified procedure, provided forum and consortium have developed the document according to the WTO/TBT standardisation principles
- ESO to improve their IT tools supporting the participation of stakeholders in European standardisation process

### Option 3 : Impose criteria and obligations to member States and national Standards organisations

Beyond option 2, the following provisions would install mandatory management and enforcement mechanisms on Member States and National Standards Organisations :

- National Standards Bodies to provide free access for SMEs, NGOs, consumers organisations and Trade Unions to national committees dealing with :
  - Mandated European standards, or
  - European Standards, or
  - All standards (including national standards)
- National Standard bodies to provide free access to “*Harmonised Standards*” supporting “*New Approach*” directives ;
- Member States or the Commission to compensate losses generated for the budget of NSB due to free access to Harmonised Standards
- Member States to ensure that minority stakeholders are represented in mirror national standardisation committees, including by providing financial support
  - Mandated European standards, or
  - European Standards, or
  - All standards (including national standards)
- Member States to report to Commission on actions in place to support participation of SMEs, NGOs, Consumers and Trade Unions
- Member States to be obliged to send official experts to take part in all national committees mirroring European Technical Committees dealing with

mandated standards under directive 98/34/EC;

- MS to oblige their respective national standards institutes to decouple (operationally and financially) standardisation activities (of general interest) from certification and other commercial activities

#### Option 4 : Enforce a centralised monitoring system at European level

Provision of options 2 and 3 would strengthen the contribution of European standardisation within the current set up based on a largely decentralised system according to the national delegation principle. Provisions of option 4 would consolidate European standardisation by strengthening the management at European level and position the ESO as major operators on the global landscape of standardisation. In this context, the following provisions could be envisaged :

- European Standards Organisations to be obliged to develop European standards requested by the European Commission in Technical Committees managed directly by the Central Secretariats and not by National Standards Bodies (alternatively : applicable on a case by case basis, on specific requests specified in mandates). This would not change the national delegation principle, as the ESO would remain free to organise the work of their technical committees along this principle.
- European Commission to only co-finance European standards development when it is managed by Central Secretariats of European Standards Organisations (alternatively : applicable on a case by case basis, on specific requests specified in mandates)
- Extend list of recognised ESO beyond CEN, CENELEC and ETSI and make it possible to allocate standardisation requests (mandate) to other organisations, beyond CEN, CENELEC and ETSI, provided they meet the WTO/TBT criteria (alternatively : allow references to documents developed by other organisations in legislation and policies, without mandate nor extension of list of recognised ESO)
- European Commission to be able to finance participation of experts in international standardisation (Technical Committees and Working Groups)
- European Commission to be able to co-finance mirror committees in all EU Member States.
- European Commission to be able to finance directly translations of European Standards in non-EU official languages

#### Option 5 : Possibility for the European Commission to request the development of European standards via call for tenders.

In this option, the Commission would be able to request the development of European Standards (or similar documents) to the three currently recognised European Standards Organisations (CEN, CENELEC and ETSI) as well as to any other organisation able to demonstrate that it meets the WTO/TBT Principles of

transparency, openness, impartiality, consensus, efficiency, relevance and consistency. The interface between all existing Standards Developing Organisations and the European Commission would be managed specifically. The following provision would implement this option :

- Commission to be able to request development of standards to any organisation via call for tenders to all Standards Developing Organisation meeting the WTO/TBT requirements

Whatever option is retained (except option 1), there will be a need to proceed with :

- a revision of 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

- a revision of Decision 1673/2006/EC of the European Parliament and of the Council of 24 October 2006 on the financing of European standardisation

- a revision of Council Decision 87/95/EEC of 22 December 1986 on standardization in the field of information technology and telecommunications

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

This initiative can have an influence on all sectors regulated under the “New Approach” principle. Furthermore, it may also be related to the Service area, as the proposal will open the scope of directive 98/34/EC to services.

In addition, the Commission has just released a “White Paper” (Com(2009)324 final) called “Modernising ICT Standardisation in the EU : the Way Forward. Both exercises need to be closely linked and monitored, as they will both have an impact on the European Standardisation System.

Explain how the options respect the proportionality principle

The proposal will not go beyond what is required to reach the objectives.

#### **D. Initial assessment of impacts**

What are the significant impacts likely to result from each policy option (cf. list of impacts in the impact assessment guidelines), even if these impacts would materialise only after subsequent Commission initiatives?

Economic impacts :

- Improve support of standardisation to innovation deployment
- Improve value of European standards through an increased participation of stakeholders in their development
- Increased speed of standardisation

- Reduce risk of new barriers to trade in the internal market, especially for services
  - Increase of administrative burden for European and national Standards Organisations
  - Increase of administrative burden for Member States
  - Increase of budget allocated by Member States and the European Commission to Standardisation
  - Loss of financial resources for national standards organisations
- Social impacts
- Loss of jobs in some national standards organisations
- Environmental impact
- None

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

An increase of or re-orientation within the EU-Budget for standardisation (currently around 20 to 24 Million €/year) might be necessary.

Could the options have significant impacts on simplification/administrative burden or on relations with third countries?

Each option will have an impact on member States, national and European Standards Organisations. The notification of all standards and alternative deliverables (as opposed to only product standards, as it is the case until now) will represent a simplification, as MS and NSB will not have anymore to separate different types of standards. They will have to notify their entire work programme on one block.

The impact of the options proposed for problem 1 ("Barriers to Trade") will be minimum as most of the tools, procedures and structures are already in place and running in the context of the present scope of directive 98/34/EC. Options will open the scope, without creating new obligations.

Options proposed to solve problem 2 will facilitate access to standardisation for SMEs and make sure that all stakeholders can openly participate in standardisation. Standards developed with the involvement of all concerned stakeholders will be easier (and cheaper) to implement.

Who is affected?

The most directly affected by the initiative are the European (CEN, CENELEC and ETSI) and national standards organizations.

Industry and other stakeholders may also be affected, as it would have to adapt to, a new system. SMEs and other stakeholders will have more opportunities to participate in standardization. All stakeholders should be better involved in standardization, at lower costs. Ultimately, all stakeholders and in particular companies should be able to make better use of standards to develop innovative goods, services and processes.

### **E. Planning of further impact assessment work**

What information and data is already available? What further information needs to be gathered? How will this be done (e.g. internally or by an external contractor) and by when? What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

The initiative is the result of preparatory work, which is available as reports and documents :

- Report of the expert panel for the review of the European standardisation system (draft version available in september 2009, final version available in January 2010)

An independent group, the Expert Panel for the Review of the European Standardisation System (EXPRESS) was established by the European Commission in January 2009 to review the entire ESS, its functioning, coherence, financing and legal framework. The Panel is composed of 30 individual experts from European, national and international standards organisations, industry, SMEs, NGOs, academia, and public authorities from EU Member States and EFTA countries. The European Commission is using the Panel's advice via the report that EXPRESS delivered in February 2010. This report and other studies and reports will help the Commission to shape policy making and legislative proposals, which shall be submitted to an Impact Assessment.

- Evaluation of the contribution of community financing of standardisation to the fulfilment of policy objectives of the Commission (30 June 2009)
- Access to standardisation – Study for the European Commission, Enterprise and Industry Directorate General (Final report, 10 March 2009)
- SME Access to European Standardisation (Report commissioned by CEN and CENELEC – Final version available in September 2009)
- Reforming the European standardisation system (Internal DG ENTR Note dated 29 October 2008)
- CEN/CENELEC/ETSI common objectives (June 2006)
- Economic benefit of standardisation – DIN (2000)
- The empirical economics of standards (DTI – 2005)
- Impact économique de la Normalisation (AFNOR – June 2009)
- Standards and economic growth in Denmark (DS – 2003)

In addition, a study commissioned to a Consultant will provide the missing data and information to refine the impact assessment of each option and measure envisaged.

Which stakeholders & experts have been/will be consulted, how and at what stage?

The following stakeholders have been closely involved in all the preparatory works and will be consulted on the key elements of the legislative proposals :

- the European Standards Organisations, CEN, CENELEC and ETSI as well as some of their national members
- Industry federations (e.g : BusinessEurope, Orgalime, UEAPME)
- Organisation representing stakeholders in standardisation (ANEC, ECSO, ETUI and NORMAPME)

The open consultation will take place in the first months of 2010.