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*Committee on Industry, Research and Energy*

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**2011/0150(COD)**

1.3.2012

## **OPINION**

of the Committee on Industry, Research and Energy

for the Committee on the Internal Market and Consumer Protection

on the proposal for a regulation of the European Parliament and of the Council on European standardisation and on 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 of the European Parliament and of the Council  
(COM(2011)0315 – C7-0150/2011 – 2011/0150(COD))

Rapporteur: Adam Gierek

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## SHORT JUSTIFICATION

The Regulation of the European Parliament and of the Council aims to increase the positive effect of European standards on the functioning of the market, economic growth, innovation and the competitiveness of firms. Among other things, it seeks to shorten the standardisation process in cases where standards are drafted at the request of the Commission, to ensure that SMEs and societal stakeholders are properly represented in the standardisation process (particularly in cases where standards are drafted at the request of the Commission) and to make the application of Information and Communication Technology standards more widespread, thereby improving interoperability and increasing the number of standards on innovative and rapidly developing production technologies, such as nanotechnology, biotechnology and nuclear technology, and also stepping up the consolidation of existing legislative frameworks.

The Committee on Industry, Research and Energy decided to take advantage of the amending of 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 of the European Parliament and of the Council, which became necessary in view of the development of technology and the globalised economy. It is vital that new legislation be drafted to consolidate previously introduced directives on standardisation policy and to update the aforementioned directives.

The most important changes concern the definition of the Commission's powers and those of the Committee on Technical Standards and Regulations. Recent changes include bringing standardisation in the area of services into the legislative framework and dealing separately with Information and Communication Technology. The basis for the financing of standardisation by the EU has also been revised.

### **Rapporteur's position**

The rapporteur welcomes the proposal for a new Regulation of the European Parliament and of the Council to consolidate existing EU standardisation policy and to introduce new elements to take account of new challenges, and is of the opinion that it provides a solid basis for the modernisation of links between the EU and the European standardisation system. Such elements include taking account of standardisation in the area of services and including it in the notification system. The section on financing European standardisation through the Commission – which creates an improved legal basis and simplifies procedures – is very welcome.

Nonetheless, certain elements of the proposal raise concerns regarding the operational effectiveness of public-private partnerships.

Changes to the provisions of the regulation are vital in order to transform the regulation into an implementation tool to support the single market, apply European standards with a view to enhancing competitiveness and innovation, facilitate the participation of stakeholders and ensure sustainable development. The European standardisation system should be improved by introducing new elements that give added value.

### Specific remarks

- 1) The European standardisation rules in force are not defined or mentioned.
- 2) There is no reference to the principle of national representation, which is the basis of European (and international) standardisation.
- 3) There are no provisions relating to the standstill principle, which is vital for the harmonisation of standards at EU level.
- 4) Many provisions are of a general character, which, in view of the extensive delegation of powers to the Commission, are too open to interpretation. Clarification is required. This also concerns certain definitions and actions, especially in those areas in which the Commission has introduced proposals that affect the functioning of the existing system and its coherence.
- 5) The Commission's draft proposal suggests that the specifications of various fora and consortia be applied instead of European standards, with the terms of such specifications being easier to fulfil. One of the foundations of the democratic process of standardisation is social consensus. The integrity of the European standardisation system is its strength, as it ensures the coherence of a set of standards. The involvement of fora and consortia in the system should not lead to the establishment of contradictory standards or competing specifications, nor should it hinder the participation of SMEs (the costs of participating in fora are high, and the decision-making criteria are not always democratic). Moreover, certain fora and consortia may be dominated by actors from outside the European Union. Therefore, the setting of standards should be restricted, as far as possible, to the currently recognised European standardisation organisations, and advantage should be taken of the many possibilities offered by those organisations as regards the drafting of documents using an accelerated consensus-based process that involves all stakeholders from all EU Member States (e.g. by organising thematic conferences).

The application of the specifications of fora/consortia should be permissible in strictly defined cases (e.g. in public procurement procedures in places where no standards exist), while maintaining the same requirements regarding: consensus, openness, voluntary participation, transparency, etc., as well as European standardisation organisations.

- 6) There is no reference to the latest technologies, such as nanotechnology, biotechnology or nuclear technology.

## **AMENDMENTS**

The Committee on Industry, Research and Energy calls on the Committee on the Internal Market and Consumer Protection, as the committee responsible, to incorporate the following amendments in its report:

### **Amendment 1**

## Proposal for a regulation

### Recital 2

#### *Text proposed by the Commission*

(2) European standardisation also helps to boost the competitiveness of enterprises by facilitating in particular the free movement of goods and services, network interoperability, means of communication, technological development and innovation. Standards produce significant positive economic effects, for example by promoting economic interpenetration on the internal market and encouraging the development of new and improved products or markets and improved supply conditions. Standards thus normally increase competition and lower output and sales costs, benefiting economies as a whole. Standards may maintain and enhance quality, provide information and ensure interoperability and compatibility, thereby increasing value for consumers.

#### *Amendment*

(2) European standardisation also helps to boost the competitiveness of enterprises by facilitating in particular the free movement of goods and services, network interoperability, means of communication, technological development and innovation. ***European standardisation strengthens the competitiveness of business when coordinated with the international standardisation system.*** Standards produce significant positive economic effects, for example by promoting economic interpenetration on the internal market and encouraging the development of new and improved products or markets and improved supply conditions. Standards thus normally increase competition and lower output and sales costs, benefiting economies as a whole. Standards may maintain and enhance quality, provide information and ensure interoperability and compatibility, thereby increasing value for consumers.

## Amendment 2

### Proposal for a Regulation

#### Recital 3

#### *Text proposed by the Commission*

(3) European standards should continue to be adopted by the European standardisation ***bodies***, namely European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) and the European Telecommunications Standards Institute (ETSI).

#### *Amendment*

(3) ***The European standardisation system should continue to be run by and for stakeholders in line with the principles of cohesion, transparency, openness, consensus, independence from special interests, market adequacy, effectiveness and national representation in the decision-making process, and*** European standards should continue to be adopted by the European standardisation ***organisations***, namely the European

Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) and the European Telecommunications Standards Institute (ETSI).

*Justification*

*This recalls the current situation.*

**Amendment 3**

**Proposal for a regulation**

**Recital 4**

*Text proposed by the Commission*

(4) European standards play a very important role within the internal market, **mainly** through the presumption of conformity of products to be made available on the market with the essential requirements of those products laid down in Union harmonisation legislation.

*Amendment*

(4) European standards play a very important role within the internal market, **for example** through the presumption of conformity of products to be made available on the market with the essential requirements of those products laid down in Union harmonisation legislation.

*Justification*

*A large proportion of European standards (70%) do not directly support EU policy or legislation, which makes the text slightly misleading.*

**Amendment 4**

**Proposal for a regulation**

**Recital 8**

*Text proposed by the Commission*

(8) **The** development of voluntary standards on services should be market-driven whereby the needs of the economic operators and stakeholders directly or indirectly affected by the standard prevail and should take into account the public interest and be based on consensus. They should primarily focus on services linked to products and processes.

*Amendment*

(8) **Services activities often correspond to national specificities. Therefore the** development of voluntary standards on services should **address well-defined and carefully assessed areas. It should** be market-driven whereby the needs of the economic operators and stakeholders directly or indirectly affected by the standard prevail and should take into

account the public interest and be based on consensus. They should primarily focus on services linked to products and processes.

*Within the scope of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications<sup>1</sup>, standardisation is only permitted on a subsidiarity basis.*

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<sup>1</sup> OJ L 255, 30.9.2005, p. 22.

### *Justification*

*Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications aims to ensure that (professional) qualifications in the Union are of a high quality and thus constitutes a definitive set of rules for the further development of mutual recognition procedures which must be given priority in terms of validity.*

## **Amendment 5**

### **Proposal for a Regulation**

#### **Recital 10**

##### *Text proposed by the Commission*

(10) Within the Union, national standards are adopted by national standardisation **bodies** which could lead to conflicting standards and technical impediments in the internal market. Therefore, it is necessary for the internal market and for the effectiveness of standardisation within the Union to confirm the existing regular exchange of information between the national standardisation **bodies**, the European standardisation **bodies** and the Commission, about current and future standardisation work. This exchange of information should be aligned with Annex 3 to Agreement on Technical Barriers to Trade approved by Council Decision No 80/271/EEC of 10 December 1979 concerning the conclusion of the Multilateral Agreements resulting from the

##### *Amendment*

(10) Within the Union, national standards are adopted by national standardisation **entities** which could lead to conflicting standards and technical impediments in the **EU** internal market. Therefore, it is necessary for the **EU** internal market and for the effectiveness of standardisation within the Union to confirm the existing regular exchange of information between the national standardisation **entities**, the European standardisation **organisations** and the Commission, about current and future standardisation work, **and also about regulations on the standstill principle concerning their application to national standardisation entities under European standardisation organisations.** This exchange of information should be aligned with Annex 3 to Agreement on

1973 to 1979 trade negotiations.

Technical Barriers to Trade approved by Council Decision No 80/271/EEC of 10 December 1979 concerning the conclusion of the Multilateral Agreements resulting from the 1973 to 1979 trade negotiations.

### *Justification*

*The absence of the standstill principle (Articles 4 and 7 of Directive 98/34/EC). Standstill is an excellent instrument that enables technical obstacles to trade to be avoided and which also supports technical harmonisation at EU level.*

## **Amendment 6**

### **Proposal for a regulation**

#### **Recital 12**

##### *Text proposed by the Commission*

(12) *Standards* can contribute to helping European policy address the major societal challenges such as climate change, sustainable resource use, ageing, and innovation in general. By driving the development of European or international standards for goods and technologies in these expanding markets, Europe could create a competitive advantage for its companies and facilitate trade.

##### *Amendment*

(12) ***When standards are mainly market-driven tools that are used voluntarily by stakeholders, they*** can contribute to helping European policy address the major societal challenges such as climate change, sustainable resource use, ageing, and innovation in general. By driving the development of European or international standards for goods and technologies in these expanding markets, Europe could create a competitive advantage for its companies and facilitate trade.

## **Amendment 7**

### **Proposal for a regulation**

#### **Recital 13**

##### *Text proposed by the Commission*

(13) Standards are important tools for undertakings and especially small and medium-sized enterprises (hereinafter 'SME') which, however, are not adequately involved in the standardisation system so that the risk exists that standards do not take into account the needs and concerns of

##### *Amendment*

(13) Standards are important tools for undertakings and especially small and medium-sized enterprises (hereinafter 'SME') which, however, are ***sometimes under-represented and*** not adequately involved in the standardisation system so that the risk exists that standards do not



SME. Consequently, it is essential to improve their representation and participation in the standardisation process, particularly in the technical committees.

take into account the *appropriate* needs and concerns of SME *nor their potential for contributing innovative technologies*. *Standardisation rules should encourage SMEs to actively contribute their innovative technology solutions to innovative standardisation efforts*. Consequently, it is essential to improve their representation and participation in the standardisation process *in all stages of the process*, particularly in the technical committees.

## Amendment 8

### Proposal for a Regulation

#### Recital 14

##### *Text proposed by the Commission*

(14) European standards are of vital interest for the competitiveness of SMEs which, however, are *in general* under-represented in standardisation activities, in particular at European level. Thus, this Regulation should ensure an appropriate representation of SME in the European standardisation process *by an entity with appropriate qualifications*.

##### *Amendment*

(14) European standards are of vital interest for the competitiveness of SMEs which, however, are under-represented *in a number of areas* in standardisation activities, in particular at European level. Thus the Regulation should ensure an appropriate representation of SME in the European standardisation process. *Granting SMEs effective membership of the European Standardisation Organisations, including voting rights is expected to have a positive impact on the involvement and participation of SMEs in standardisation*.

##### *Justification*

*Stakeholders, including SMEs, participate in European standardisation at national level, where they deal with similar firms and local governments and are able to work in their native language. The national consensus, obtained with the participation of SMEs, is then submitted to the appropriate technical committees at EU level by a delegate from the national entity (the principle of national representation).*

## Amendment 9

### Proposal for a regulation

#### Recital 15

*Text proposed by the Commission*

(15) Standards can have a broad impact on society, in particular on the safety and well-being of citizens, the efficiency of networks, the environment, accessibility and other public policy fields. Therefore, it is necessary to ensure that the role and the input of societal stakeholders in the elaboration of standards is strengthened, through the support of organisations representing the interests of consumers, the environment and societal stakeholders.

*Amendment*

(15) Standards can have a broad impact on society, in particular on the safety and well-being of citizens, the efficiency of networks, the environment, accessibility and other public policy fields. Therefore, it is necessary to ensure that the role and the input of societal stakeholders in the elaboration of standards is strengthened, through the support of organisations representing the interests of consumers, the environment and societal stakeholders.  
***Granting those organisations effective membership in the European Standardisation Organisations, including voting rights, will have a positive impact on the quality of standards.***

**Amendment 10**

**Proposal for a regulation  
Recital 16**

*Text proposed by the Commission*

(16) Standards should ***as far as possible*** take into account environmental impacts throughout the life cycle of products and services. Important and publicly available tools for evaluating such impacts throughout the life cycle have been developed by the Commission's Joint Research Centre.

*Amendment*

(16) Standards should take into account environmental impacts throughout the life cycle of products and services. Important and publicly available tools for evaluating such impacts throughout the life cycle have been developed by the Commission's Joint Research Centre.

**Amendment 11**

**Proposal for a regulation  
Recital 17**

*Text proposed by the Commission*

(17) The viability of the cooperation between the Commission and the European standardisation system depends on careful

*Amendment*

(17) The viability of the cooperation between the Commission and the European standardisation system depends on careful

planning of future requests for the development of standards. This planning could be improved, in particular through the input of interested parties. Since Directive 98/34/EC already provides for the possibility to request the European standardisation bodies to elaborate European standards, it is appropriate to put in place a better and more transparent planning in an annual work programme which should contain an overview of all requests for standards which the Commission intends to submit to European standardisation bodies.

planning of future requests for the development of standards. This planning could be improved, in particular through the input of interested parties, ***by introducing mechanisms for collecting opinions and facilitating the exchange of information among all interested parties.*** Since Directive 98/34/EC already provides for the possibility to request the European standardisation bodies to elaborate European standards, it is appropriate to put in place a better and more transparent planning in an annual work programme which should contain an overview of all requests for standards which the Commission intends to submit to European standardisation bodies.

## Amendment 12

### Proposal for a Regulation

#### Recital 19

##### *Text proposed by the Commission*

(19) Public authorities should make best use of the full range of relevant standards when procuring hardware, software and information technology services, for example by selecting standards which can be implemented by all interested suppliers, allowing for more competition and reduced risk of lock-in. Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors and 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 specify that technical specifications in public procurement should be formulated by reference to national standards transposing European

##### *Amendment*

(19) Public authorities should make best use of the full range of relevant standards ***and technical specifications*** when procuring hardware, software and information technology services, for example by selecting standards ***and technical specifications*** which can be implemented by all interested suppliers, allowing for more competition and reduced risk of lock-in. Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors and 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 specify that technical specifications in public procurement

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, or equivalent. **Standards** in the field of information and communication technologies, however, are often developed by other standard developing organisations and do not fall in any of the categories of standards and approvals laid down in Directives 2004/17/EC and 2004/18/EC. Therefore, it is necessary to provide for the possibility that technical specifications for public procurement could refer to **standards** in the field of information and communication technologies, in order to respond to the fast evolution in the field of information and communication technologies, facilitate the provision of cross-border services, encourage competition and promote interoperability and innovation.

should be formulated by reference 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, or equivalent. **Technical specifications** in the field of information and communication technologies, however, are often developed by other standard developing organisations and do not fall in any of the categories of standards and approvals laid down in Directives 2004/17/EC and 2004/18/EC. Therefore, it is necessary to provide for the possibility that technical specifications for public procurement could refer to **technical specifications** in the field of information and communication technologies, in order to respond to the fast evolution in the field of information and communication technologies, facilitate the provision of cross-border services, encourage competition and promote interoperability and innovation.

### *Justification*

*Standards are defined according to the region in which they originate or the method by which they are developed, not according to the industrial sector.*

## **Amendment 13**

### **Proposal for a Regulation** **Recital 20**

#### *Text proposed by the Commission*

(20) Some **standards** in the field of information and communication technologies are not developed according to the criteria set out in Annex 3 of the

#### *Amendment*

(20) Some **technical specifications** in the field of information and communication technologies are not developed according to the criteria set out in Annex 3 of the

Agreement on Technical Barriers to Trade. Therefore, this Regulation should lay down a procedure for the selection of the **standards** in the field of information and communication technologies that could be used in public procurement, involving a broad consultation of a large spectrum of stakeholders, including the European standardisation bodies, enterprises and public authorities. This Regulation should also lay down requirements, in the form of a list of attributes, for such **standards** and their associated standardisation processes. These attributes should ensure that public policy objectives and societal needs are respected, and should be founded on the criteria developed within the World Trade Organisation for international standardisation **organisations**.

Agreement on Technical Barriers to Trade. Therefore, this Regulation should lay down a procedure for the selection of the **technical specifications** in the field of information and communication technologies that could be used in public procurement, involving a broad consultation of a large spectrum of stakeholders, including the European standardisation bodies, enterprises and public authorities. This Regulation should also lay down requirements, in the form of a list of attributes, for such **technical specifications** and their associated standardisation processes. These attributes should ensure that public policy objectives and societal needs are respected, and should be founded on the criteria developed within the World Trade Organisation for international standardisation.

#### *Justification*

*Standards are defined according to the region in which they originate or the method by which they are developed, not according to the industrial sector.*

### **Amendment 14**

#### **Proposal for a Regulation**

##### **Recital 21**

###### *Text proposed by the Commission*

(21) In order to further innovation and competition **between standardised solutions**, the recognition of a particular technical specification should not disqualify a **competing** technical specification from being recognised in accordance with the provisions of this Regulation. Any recognition should be subject to the attributes being fulfilled and to the technical specification having achieved a **minimum** level of market acceptance. **Market acceptance should not be interpreted as having been widely**

###### *Amendment*

(21) In order to further innovation and competition, the recognition of a particular technical specification should not disqualify a technical specification from being recognised in accordance with the provisions of this Regulation. Any recognition should be subject to the attributes being fulfilled and to the technical specification having achieved a **significant** level of market acceptance.

*implemented in the market.*

*Justification*

*Standardised solutions should not contradict each other. A set of standards should be cohesive. Standardised technical solutions ought to give equal opportunities to enterprises so that they may be competitive as far as their designs or services are concerned. For consumers, standardised technical solutions ought to act as a clear indicator of what to buy.*

**Amendment 15**

**Proposal for a Regulation**

**Recital 22**

*Text proposed by the Commission*

(22) The selected *standards* in the field of information and communication technologies could contribute to the implementation of Decision No 922/2009/EC of the European Parliament and of the Council of 16 September 2009 on interoperability solutions for European public administrations (ISA) which establishes, for the period 2010-2015, a programme on interoperability solutions for European public administrations and institutions and bodies of the Union, providing common and shared solutions facilitating interoperability.

*Amendment*

(22) The selected *technical specifications* in the field of information and communication technologies could contribute to the implementation of Decision No 922/2009/EC of the European Parliament and of the Council of 16 September 2009 on interoperability solutions for European public administrations (ISA) which establishes, for the period 2010-2015, a programme on interoperability solutions for European public administrations and institutions and bodies of the Union, providing common and shared solutions facilitating interoperability.

*Justification*

*Standards are defined according to the region in which they originate or the method by which they are developed, not according to the industrial sector.*

**Amendment 16**

**Proposal for a Regulation**

**Recital 23**

*Text proposed by the Commission*

(23) Situations may arise in the field of information and communication

*Amendment*

(23) Situations may arise in the field of information and communication

technologies where it is appropriate to encourage the use of, or require, compliance with specified standards at Union level in order to ensure interoperability in the single market and to improve freedom of choice for users. In other circumstances, it may also happen that specified European standards no longer meet consumers' needs or are hampering technological development. For these reasons, Directive 2002/21/EC of the European Parliament and the Council of 7 March 2002 on a common regulatory framework for electronic communications networks and services enables the Commission, where necessary, to request European standardisation bodies to draw up standards, to establish a list of standards and/or specifications published in the Official Journal of the European Union with the view to encourage their use, ***or to make their implementation compulsory***, or to remove standards and/or specifications from that list.

technologies where it is appropriate to encourage the use of, or require, compliance with specified standards at Union level in order to ensure interoperability in the single market and to improve freedom of choice for users. In other circumstances, it may also happen that specified European standards no longer meet consumers' needs or are hampering technological development. For these reasons, Directive 2002/21/EC of the European Parliament and the Council of 7 March 2002 on a common regulatory framework for electronic communications networks and services enables the Commission, where necessary, to request European standardisation bodies to draw up standards, to establish a list of standards and/or specifications published in the Official Journal of the European Union with the view to encourage their use or to remove standards and/or specifications from that list.

#### *Justification*

*The standards are not binding; they are, and should remain, voluntary.*

### **Amendment 17**

#### **Proposal for a regulation**

##### **Recital 29**

#### *Text proposed by the Commission*

(29) The financing of standardisation activities should also be capable of covering preliminary or ancillary activities in connection with the establishment of standards or other standardisation products. This is necessary primarily for work involving research, the preparation of preliminary documents for legislation, inter-laboratory tests and the validation or evaluation of standards. The promotion of standardisation at European and

#### *Amendment*

(29) The financing of standardisation activities should also be capable of covering preliminary or ancillary activities in connection with the establishment of standards or other standardisation products. This is necessary primarily for work involving research, the preparation of preliminary documents for legislation, inter-laboratory tests and the validation or evaluation of standards. The promotion of standardisation at European and

international level should also continue through programmes relating to the technical assistance to, and cooperation with, third countries. With a view to improving market access and boosting the competitiveness of enterprises in the Union, it should be possible to give grants to *other bodies* through calls for proposals or, where necessary, by awarding contracts.

international level should also continue through programmes relating to the technical assistance to, and cooperation with, third countries. With a view to improving market access and boosting the competitiveness of enterprises in the Union, it should be possible to give grants to *those entities carrying out the abovementioned activities* through calls for proposals or, where necessary, by awarding contracts.

#### *Justification*

*It is important that it is only national and European Standardization organizations that validate and revise European standards. Otherwise it is not possible to ensure the necessary involvement of SMEs, NGOs etc. At the same time the risk of creating parallel systems are imminent if other organizations are allowed to validate and revise standards.*

### **Amendment 18**

#### **Proposal for a Regulation Recital 36**

##### *Text proposed by the Commission*

(36) The advisory procedure should be used for the implementing decisions with respect to the objections to harmonised standards which the Commission considers justified and where the references to the harmonised standard concerned were not yet published in the Official Journal of the European Union, given that the relevant standard did not yet lead to the presumption of conformity with the essential requirements set out in the applicable Union harmonisation legislation.

##### *Amendment*

(36) The advisory procedure should be used for the implementing decisions with respect to the objections to *the annual European standardisation work programme and to* harmonised standards which the Commission considers justified and where the references to the harmonised standard concerned were not yet published in the Official Journal of the European Union, given that the relevant standard did not yet lead to the presumption of conformity with the essential requirements set out in the applicable Union harmonisation legislation.

#### *Justification*

*The Member States should be consulted over the standardisation work programme.*



## Amendment 19

### Proposal for a Regulation Recital 37

#### *Text proposed by the Commission*

(37) The examination procedure should be used for the implementing decisions with respect to the objections to harmonised standards which the Commission considers justified and where the references to the harmonised standard concerned were already published in the Official Journal of the European Union, given that such **a decision** could have consequences on the presumption of conformity with the applicable essential requirements.

#### *Amendment*

(37) The examination procedure should be used ***in relation to all standardisation notifications with European standardisation organisations, recognition of technical specifications in the areas of information and communication technology, nanotechnology, biotechnology and nuclear technology***, for the implementing decisions with respect to the objections to harmonised standards which the Commission considers justified and where the references to the harmonised standard concerned were already published in the Official Journal of the European Union, given that such ***decisions*** could have consequences on the presumption of conformity with the applicable essential requirements.

#### *Justification*

*The procedure for recognising technical specifications in the field of new technologies should have provision for Member States to make comments.*

## Amendment 20

### Proposal for a regulation Article 1

#### *Text proposed by the Commission*

This Regulation establishes rules with regard to the cooperation between European standardisation bodies, national standardisation bodies and the Commission, the establishment of European standards and European standardisation deliverables for products and for services in support of Union legislation and policies, the recognition of

#### *Amendment*

This Regulation establishes rules with regard to the cooperation between European standardisation bodies, national standardisation bodies and the Commission, the establishment of European standards and European standardisation deliverables for products and for services in support of Union legislation and policies, the recognition of

technical specifications in the field of information and communication technologies (hereinafter “ICT”) **and** financing of European standardisation.

technical specifications in the field of information and communication technologies (hereinafter “ICT”), financing of European standardisation **and the conditions for a balanced representation of European stakeholder organisations.**

## Amendment 21

### Proposal for a regulation

#### Article 2 – point 1 – introductory part

*Text proposed by the Commission*

(1) ‘standard’ means a technical specification for repeated or continuous application, with which compliance is not compulsory, and which is one of the following:

*Amendment*

(1) ‘standard’ means a technical specification, **approved by a recognised standard-setting body**, for repeated or continuous application, with which compliance is not compulsory, and which is one of the following:

## Amendment 22

### Proposal for a regulation

#### Article 2 – point 1 – point c

*Text proposed by the Commission*

(c) ‘harmonised standard’ means a European standard adopted on the basis of a request made by the Commission for the application of Union **harmonisation** legislation;

*Amendment*

(c) ‘harmonised standard’ means a European standard adopted on the basis of a request made by the Commission for the application of Union legislation **and the references for which are published in the Official Journal of the European Union;**

## Amendment 23

### Proposal for a Regulation

#### Article 2 – paragraph 1 – point e

*Text proposed by the Commission*

**(e) ‘ICT standard’ means a standard in the field of information and**

*Amendment*

**deleted**

*communication technologies.*

*Justification*

*Standards are defined according to the region in which they originate or the method by which they are developed, not according to the industrial sector. Furthermore, there is a lack of clarity as to the true meaning of the term 'ICT standard' in this definition.*

**Amendment 24**

**Proposal for a Regulation**

**Article 2 – paragraph 3**

*Text proposed by the Commission*

(3) 'draft standard' means a document containing ***the text of the technical specifications concerning a given subject, which is being considered for adoption in accordance with the relevant standards procedure, as that document stands after the preparatory work and as circulated for public comment or scrutiny;***

*Amendment*

(3) 'draft standard' means a document containing ***a proposed standard that has been submitted for an opinion, for a vote or for approval;***

*Justification*

*A definition from the appropriate European standard should be applied.*

**Amendment 25**

**Proposal for a Regulation**

**Article 2 – paragraph 4 – first part**

*Text proposed by the Commission*

(4) 'technical specification' means a ***specification contained in*** a document which lays down one of the following:

*Amendment*

(4) 'technical specification' means a document ***setting the technical requirements that a product, process or service must fulfil,*** which lays down one of the following:

*Justification*

*Adopted as EN 45020.*

## **Amendment 26**

### **Proposal for a Regulation**

#### **Article 2 - paragraph 8 a (new)**

*Text proposed by the Commission*

*Amendment*

***(8a) 'standstill principle' means that national standardisation entities refrain from further work on projects that are already underway;***

*Justification*

*This definition appears in Articles 4 and 7 of Directive 98/34/EC.*

## **Amendment 27**

### **Proposal for a regulation**

#### **Article 3 – paragraph 5**

*Text proposed by the Commission*

*Amendment*

***5. National standardisation bodies may not object to the inclusion of a subject for standardisation in the work programme of a European standardisation body.*** ***deleted***

*Justification*

*National standardisation bodies, which are members of European standardisation bodies, should be free to object to the inclusion of a subject for standardisation in the work programme. It is this freedom that guarantees both the voluntary nature of standardisation and the actual market relevance of a standardisation mandate given by the European Commission.*

## **Amendment 28**

### **Proposal for a Regulation**

#### **Article 3 - paragraph 5 a (new)**

*Text proposed by the Commission*

*Amendment*

***5a. While a European standard is being drawn up, or following its approval, national standards entities shall not be able to undertake any actions that could***

*have a negative impact on the goal of harmonisation and, in particular, they may not publish – within a given area – a new or updated national standard that is not fully consistent with the existing European standard.*

*Justification*

*This provision would fulfil the criteria of the standstill principle moved from Directive 98/34/EC.*

**Amendment 29**

**Proposal for a regulation**

**Article 4 – paragraph 3 – point a**

*Text proposed by the Commission*

(a) the publication of draft standards in such a way that parties established in other Member States have the opportunity to submit comments;

*Amendment*

(a) the publication of draft standards in such a way that parties established in other Member States have the opportunity to submit comments. *If translation is needed, it should be carried out at the expense of the interested party;*

**Amendment 30**

**Proposal for a regulation**

**Article 5 – title**

*Text proposed by the Commission*

Stakeholder Participation in European standardisation

*Amendment*

Stakeholder participation in European standardisation *and facilitation of access to standards*

**Amendment 31**

**Proposal for a regulation**

**Article 5 – paragraph 1 – introductory part**

*Text proposed by the Commission*

1. European standardisation bodies shall

*Amendment*

1. European standardisation bodies shall

**ensure** an appropriate representation of small and medium-sized enterprises (hereinafter 'SME'), consumer organisations and environmental and social stakeholders, in particular **through the** organisations referred to in Annex III, at the policy development level and at least at the following stages of the development of European standards or European standardisation deliverables:

**encourage, facilitate and support** an appropriate representation the small and medium-sized enterprises (hereinafter 'SME'), consumer organisations and environmental and social stakeholders, in particular **by facilitating** organizations referred to in Annex III, at the policy development level and at least at the following stages of the development of European standards or European standardisation deliverables:

## Amendment 32

### Proposal for a regulation Article 5 – paragraph 1 a (new)

*Text proposed by the Commission*

*Amendment*

***1a. Standards should be conceived and adapted so as to take account of SMEs' characteristics and the SME environment, especially in the case of small craft businesses and microbusinesses, thus enabling them to have improved and less expensive access to standards.***

## Amendment 33

### Proposal for a regulation Article 5 – paragraph 1 b (new)

*Text proposed by the Commission*

*Amendment*

***1b. In order to ensure user access to the European standards established in support of EU legislation and policies, it is necessary to envisage differential systems for establishing prices and the introduction of special fees and discounted standards packages, especially for SMEs, microbusinesses and craft businesses.***

## Amendment 34

### Proposal for a regulation Article 5 – paragraph 2

#### *Text proposed by the Commission*

2. European standardisation bodies shall **ensure** an appropriate representation, at technical level, of undertakings, research centres and universities and other legal entities, in standardisation activities concerning an emerging area with significant policy or technical innovation implications, if the legal entities concerned participated in a project that is related to that area and that is funded by the Union under a multiannual framework programme for activities in the area of research and technological development.

#### *Amendment*

2. European standardisation bodies shall **enable** an appropriate representation, at technical level, of undertakings, research centres and universities, **market surveillance bodies in the Member States** and other legal entities, in standardisation activities concerning an emerging area with significant policy or technical innovation implications, if the legal entities concerned participated in a project that is related to that area and that is funded by the Union under a multiannual framework programme for activities in the area of research and technological development.

#### *Justification*

*‘Appropriate representation’ is a vague phrase that combined with the demanding obligation of ensuring the representation potentially could block the whole standardization system. The standardization organization can only do their best to try to involve stakeholders but if they won’t participate it should not block the system. At the same time the Members States market surveillance bodies should get involved in the standardization process and ensure quality and knowledge in the process.*

## Amendment 35

### Proposal for a regulation

#### Article 6 — paragraph 1

#### *Text proposed by the Commission*

1. The Commission shall adopt an annual European standardisation work programme **which** shall indicate the European standards and European standardisation deliverables that it intends to request from the European standardisation bodies in accordance with Article 7.

#### *Amendment*

1. The Commission shall adopt, **after consultation with the European Standardisation Organisations and relevant stakeholders, for instance those referred to in Annex III and national standardisation organisations**, an annual European standardisation work programme, **and shall inform them of its publication. The work programme** shall

indicate the European standards and European standardisation deliverables that it intends to request from the European standardisation bodies in accordance with Article 7.

## Amendment 36

### Proposal for a regulation Article 7 – paragraph 1

#### *Text proposed by the Commission*

1. The Commission may request one or several European standardisation bodies to draft a European standard or European standardisation deliverable within a set deadline. They shall be market-driven, take into account the public interest and based on consensus.

#### *Amendment*

1. The Commission may request one or several European standardisation bodies to draft a European standard or European standardisation deliverable within a set deadline. They shall be market-driven, take into account the public interest and based on consensus. ***The Commission shall consult and inform the relevant stakeholders, including all interested parties of requests made in accordance with paragraph 1.***

## Amendment 37

### Proposal for a regulation Article 7 – paragraph 2

#### *Text proposed by the Commission*

2. The relevant European standardisation body shall indicate, within ***one month*** following its receipt, if it accepts the request referred to in paragraph 1.

#### *Amendment*

2. The relevant European standardisation body shall indicate, within ***two months*** following its receipt, if it accepts the request referred to in paragraph 1.

## Amendment 38

### Proposal for a Regulation Article 7 – paragraph 3

#### *Text proposed by the Commission*

3. The Commission shall inform the relevant European standardisation ***body***,

#### *Amendment*

3. The Commission shall inform the relevant European standardisation



within **three months** following the receipt of the acceptance referred to in paragraph 2, about the award of a grant for drafting a European standard or European standardisation deliverable.

**organisation**, within **one month** following the receipt of the acceptance referred to in paragraph 2, about the award of a grant for drafting a European standard or European standardisation deliverable.

#### *Justification*

*The explanatory memorandum points out that the time taken to draw up standards is an issue that ought to be addressed. The optimisation of processes ought to affect all interested parties. Therefore, it is proposed that the time taken to reach a decision on granting subsidies should be reduced to one month (the same amount of time that European standardisation organisations have to reach a decision on accepting an application).*

### **Amendment 39**

#### **Proposal for a regulation Article 8 – paragraph 4**

##### *Text proposed by the Commission*

4. The decision referred to in paragraph 2(a) of this Article shall be adopted in accordance with the advisory procedure referred to in Article 18(2).

##### *Amendment*

4. This decision referred to in paragraph 2(a) of this Article shall be adopted in accordance with the advisory procedure referred to in Article 18(2), ***after consultation with the monitoring committee for the corresponding directive for the sector.***

### **Amendment 40**

#### **Proposal for a regulation Article 8 – paragraph 5**

##### *Text proposed by the Commission*

5. The decision referred to in paragraph 2(b) of this Article shall be adopted in accordance with the examination procedure referred to in Article 18(3).

##### *Amendment*

5. The decision referred to in paragraph 2(b) of this Article shall be adopted in accordance with the examination procedure referred to in Article 18(3), ***after consultation with the monitoring committee for the corresponding directive for the sector.***

## Amendment 41

### Proposal for a Regulation Chapter IV — title

*Text proposed by the Commission*

*Amendment*

***Standards in the field of ICT***

***Technical specifications in the field of ICT***

*Justification*

*Standards are defined according to the region in which they originate or the method by which they are developed, not according to the industrial sector. Furthermore, there is a lack of clarity as to the meaning of the term 'ICT technical specifications' in the definition of a standard.*

## Amendment 42

### Proposal for a regulation Article 9

*Text proposed by the Commission*

*Amendment*

Either on proposal from a public authority referred to in Directive 2004/18/EC or on its own initiative the Commission may decide to recognise technical specifications which are not national, European or international standards and meet the requirements set out in Annex II, ***as ICT standards.***

Either on proposal from a public authority referred to in Directive 2004/18/EC or on its own initiative the Commission, ***after consultation with representatives of all interested stakeholders, including the European standardisation bodies,*** may decide to recognise technical specifications ***in the field of ICT*** which are not national, European or international standards and meet the requirements set out in Annex II, ***for use in public procurement and policies to ensure interoperability in ICT.*** ***When evaluating conformity of technical specifications with the requirements laid down in Annex II, the Commission shall take due account of the opinion of consulted stakeholders, including of European standardisation bodies.***

## Amendment 43

## Proposal for a regulation

### Article 11 – paragraph 1 – point e

#### *Text proposed by the Commission*

(e) the translation, **where required**, of European standards or European standardisation deliverables used in support of Union policies and legislation into the official Union languages other than the working languages of the European standardisation bodies or, in duly justified cases into languages other than the official Union languages,

#### *Amendment*

(e) the translation of European standards or European standardisation deliverables used in support of Union policies and legislation into the official Union languages other than the working languages of the European standardisation bodies or, in duly justified cases into languages other than the official Union languages,

## Amendment 44

## Proposal for a regulation

### Article 11 – paragraph 1 – point f

#### *Text proposed by the Commission*

(f) the drawing up of information to explain, interpret and simplify European standards or European standardisation deliverables, including the drawing up of user guides, best practice information and awareness-building actions;

#### *Amendment*

(f) the drawing up of information to explain, interpret and simplify European standards or European standardisation deliverables, including the drawing up of user guides, **summaries of standards**, best practice information, awareness-building actions **and training modules**;

*(The wrong numbering in the French version of the Commission proposal should be corrected.)*

## Amendment 45

## Proposal for a regulation

### Article 13 – paragraph 4 – point b

#### *Text proposed by the Commission*

(b) SME, consumer organisations and environmental and social stakeholders are appropriately represented in European standardisation work, as referred to in Article 5(1).

#### *Amendment*

(b) SME, consumer organisations and environmental and social stakeholders are appropriately represented in European standardisation work, as referred to in Article 5(1), **provided that relevant experts from those stakeholders are available and**

*willing to participate.*

*Justification*

*The standardization organization can only do their best to try to involve stakeholders but if they won't participate it should not block the system.*

**Amendment 46**

**Proposal for a regulation**

**Article 13 – paragraph 4 a (new)**

*Text proposed by the Commission*

*Amendment*

***4a. In order to allow SMEs to benefit fully from the understanding and application of the European harmonised standards, the financing granted to the European Standardisation Bodies for the purposes of translation shall cover a significant portion of the total cost incurred and the translation funding procedures shall be simplified. Grants awarded for the translation activities referred to in point (e) of Article 11(1) shall take the form of lump sums per translated page to be paid in advance and upon evidence being provided that European standards are effectively translated.***

**Amendment 47**

**Proposal for a regulation**

**Article 16 – point a**

*Text proposed by the Commission*

*Amendment*

***(a) update the list of European standardisation bodies set out in Annex I;***

***deleted***

## Amendment 48

### Proposal for a Regulation Article 16 - point b

#### *Text proposed by the Commission*

(b) adapt the criteria for recognising **standards** in the field of ICT set out in Annex II to technical developments;

#### *Amendment*

(b) adapt the criteria for recognising **technical specifications** in the field of ICT set out in Annex II to technical developments;

#### *Justification*

*In order to ensure terminological coherence with the proposed definitions.*

## Amendment 49

### Proposal for a regulation Article 17 – paragraph 2

#### *Text proposed by the Commission*

2. The delegation of power referred to in Article 16 shall be conferred on the Commission for **an indeterminate period of time** from 1 January 2013.

#### *Amendment*

2. The delegation of power referred to in Article 16 shall be conferred on the Commission for **five years** from 1 January 2013. **The Commission shall submit a report on the powers delegated no later than six months before the closure of the five-year period. The delegation of power shall be renewed automatically for identical periods unless it is revoked by the European Parliament or the Council.**

## Amendment 50

### Proposal for a regulation Article 17 – paragraph 3

#### *Text proposed by the Commission*

3. The delegation of powers referred to in Article 16 may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the powers specified in

#### *Amendment*

3. The delegation of powers referred to in Article 16 may be revoked at any time by the European Parliament or by the Council. **The institution which initiated the internal decision-making procedure with**

that decision. It shall take effect the day following the publication of the Decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of the delegated acts already in force.

*regard to revoking the delegation of powers shall make every effort to inform the Commission, within a reasonable time-frame prior to adoption of a final decision, indicating the delegated powers liable to be revoked and the potential grounds for revocation.*

A decision of revocation shall put an end to the delegation of the powers specified in that decision. It shall take effect the day following the publication of the Decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of the delegated acts already in force.

## Amendment 51

### Proposal for a regulation Article 18 – paragraph 1

#### *Text proposed by the Commission*

1. The Commission shall be assisted by a committee. That **committee** shall be a committee within the meaning of Regulation (EU) No 182/2011.

#### *Amendment*

1. The Commission shall be assisted by a committee. That **Committee** shall be a committee within the meaning of Regulation (EU) No 182/2011. ***The Committee shall meet at least two times per year with European and national standardisation organisations and Member States.***

#### *Justification*

*The decisions are fundamental for the standardization system that is why the European standardization organizations and the Member States have to be involved.*

## Amendment 52

### Proposal for a regulation Article 19 – paragraph 1 – introductory part

#### *Text proposed by the Commission*

1. The European Standardisation Bodies shall send **an** annual report on the

#### *Amendment*

1. The European Standardisation Bodies shall send ***a short and concise*** annual

implementation of this Regulation to the Commission. It shall contain **detailed** information on the following:

report on the implementation of this Regulation to the Commission. It shall contain information on the following:

#### *Justification*

*The word 'detailed' is used in the English version, which may create more red tape without helping in terms of implementation. The report should instead be targeted and relatively concise.*

### **Amendment 53**

#### **Proposal for a regulation Article 19 – paragraph 3**

##### *Text proposed by the Commission*

3. By 31 December 2015 and every **five** years thereafter, the Commission shall present a report to the European Parliament and the Council on the implementation of this Regulation. This report shall contain an evaluation of the relevance of the standardisation activities receiving Union financing in the light of the requirements of policies and legislation of the Union.

##### *Amendment*

3. By 31 December 2015 and every **three** years thereafter, the Commission shall present a report to the European Parliament and the Council on the implementation of this Regulation. This report shall contain an evaluation of the relevance of the standardisation activities receiving Union financing in the light of the requirements of policies and legislation of the Union.

### **Amendment 54**

#### **Proposal for a regulation Annex II – point 2 – point c – point ii**

##### *Text proposed by the Commission*

(ii) information on (new) standardisation activities was widely announced through suitable and accessible means.

##### *Amendment*

(ii) information on (new) standardisation activities was **publicly and** widely announced through suitable and accessible means.

### **Amendment 55**

#### **Proposal for a regulation Annex II – point 2 – point c a (new)**

*Text proposed by the Commission*

*Amendment*

- (ca) appropriate representation:*
- (i) the technical specifications were developed with the participation of all interested parties;*
- (ii) representation of all categories of stakeholders was balanced.*

## **Amendment 56**

### **Proposal for a regulation Annex III – point a – introductory part**

*Text proposed by the Commission*

*Amendment*

(a) A European organisation representing SME in European standardisation activities which:

(a) A European **horizontal** organisation **solely** representing **craft businesses and** SMEs in European standardisation activities which:

*(The wrong numbering in the French version of the Commission proposal should be corrected.)*

## **Amendment 57**

### **Proposal for a regulation Annex III – point a – introductory part**

*Text proposed by the Commission*

*Amendment*

(a) A European organisation representing SME in European standardisation activities which:

(a) A European **horizontal** organisation representing **crafts and** SME in European standardisation activities which:



## PROCEDURE

<b>Title</b>	European standardisation
<b>References</b>	COM(2011)0315 – C7-0150/2011 – 2011/0150(COD)
<b>Committee responsible</b> Date announced in plenary	IMCO 23.6.2011
<b>Committee(s) asked for opinion(s)</b> Date announced in plenary	ITRE 23.6.2011
<b>Rapporteur(s)</b> Date appointed	Adam Gierek 28.6.2011
<b>Discussed in committee</b>	5.10.2011                      20.12.2011
<b>Date adopted</b>	28.2.2012
<b>Result of final vote</b>	+:                      38 –:                      5 0:                      2
<b>Members present for the final vote</b>	Gabriele Albertini, Josefa Andrés Barea, Zigmantas Balčytis, Bendt Bendtsen, Maria Da Graça Carvalho, Jürgen Creutzmann, Pilar del Castillo Vera, Gaston Franco, Adam Gierek, Norbert Glante, András Gyürk, Fiona Hall, Edit Herczog, Kent Johansson, Romana Jordan, Krišjānis Kariņš, Philippe Lamberts, Bogdan Kazimierz Marcinkiewicz, Judith A. Merkies, Angelika Niebler, Jaroslav Paška, Aldo Patriciello, Vittorio Prodi, Miloslav Ransdorf, Teresa Riera Madurell, Jens Rohde, Paul Rübig, Francisco Sosa Wagner, Konrad Szymański, Patrizia Toia, Evžen Tošenovský, Claude Turmes, Alejo Vidal-Quadras
<b>Substitute(s) present for the final vote</b>	Maria Badia i Cutchet, Satu Hassi, Jolanta Emilia Hibner, Yannick Jadot, Seán Kelly, Alajos Mészáros, Vladko Todorov Panayotov, Mario Pirillo, Pavel Poc, Vladimír Remek, Jean Roatta, Hannu Takkula