




| Basic information | |
|---|---------------------|
| <p>2011/0150(COD)</p> <p>COD - Ordinary legislative procedure (ex-codecision procedure) Regulation</p> | Procedure completed |
| <p>European standardisation</p> <p>Repealing Decision 1673/2006/EC 2005/0157(COD) Amending Directive 95/16/EC 1992/0394(COD) Amending Directive 97/23/EC 1993/0462(COD) Amending Directive 98/34/EC 1996/0300(COD) Amending Directive 2004/22/EC 2000/0233(COD) Amending Directive 2007/23/EC 2005/0194(COD) Amending Directive 2009/23/EC 2007/0164(COD) Amending Directive 2009/105/EC 2008/0076(COD) Amended by 2021/0170(COD) Amended by 2022/0021(COD) See also 2016/2274(INI)</p> <p>Subject</p> <p>2.10.03 Standardisation, EC/EU standards and trade mark, certification, compliance</p> | |




| Key players | | | |
|--|--|--|------------------|
| European Parliament | Committee responsible | Rapporteur | Appointed |
| | IMCO Internal Market and Consumer Protection | COMI Lara (PPE) | 11/07/2011 |
| | | Shadow rapporteur | |
| | | SCHALDEMOSE Christel (S&D) | |
| | | MANDERS Antonius (ALDE) | |
| | | RÜHLE Heide (Verts/ALE) | |
| | KOŽUŠNÍK Edvard (ECR) | | |
| | DE JONG Dennis (GUE/NGL) | | |
| | SALVINI Matteo (EFD) | | |
| | Committee for opinion | Rapporteur for opinion | Appointed |
| INTA International Trade | PROUST Franck (PPE) | 11/10/2011 | |
| EMPL Employment and Social Affairs | The committee decided not to give an opinion. | | |
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| | <div style="border: 1px solid red; display: inline-block; padding: 2px;">ENVI</div> Environment, Public Health and Food Safety | The committee decided not to give an opinion. | |
| | <div style="border: 1px solid red; display: inline-block; padding: 2px;">ITRE</div> Industry, Research and Energy | GIEREK Adam (S&D) | 28/06/2011 |
| Council of the European Union | Council configuration | | Meetings |
| | Employment, Social Policy, Health and Consumer Affairs | | 3188 |
| | Competitiveness (Internal Market, Industry, Research and Space) | | 3133 |
| | Competitiveness (Internal Market, Industry, Research and Space) | | 3113 |
| European Commission | Commission DG | | Commissioner |
| | Economic and Financial Affairs | | REHN Olli |
| European Economic and Social Committee | | | |

| Key events | | | |
|------------|---|--|---------|
| Date | Event | Reference | Summary |
| 01/06/2011 | Legislative proposal published | COM(2011)0315  | Summary |
| 23/06/2011 | Committee referral announced in Parliament, 1st reading | | |
| 29/09/2011 | Debate in Council | | Summary |
| 05/12/2011 | Debate in Council | | Summary |
| 21/03/2012 | Vote in committee, 1st reading | | |
| 07/05/2012 | Committee report tabled for plenary, 1st reading | A7-0069/2012 | Summary |
| 10/09/2012 | Debate in Parliament |  | |
| 11/09/2012 | Decision by Parliament, 1st reading | T7-0311/2012 | Summary |
| 11/09/2012 | Results of vote in Parliament |  | |
| 04/10/2012 | Act adopted by Council after Parliament's 1st reading | | |
| 25/10/2012 | Final act signed | | |
| 25/10/2012 | End of procedure in Parliament | | |
| 14/11/2012 | Final act published in Official Journal | | |

| Technical information | |
|----------------------------|--|
| Procedure reference | 2011/0150(COD) |
| Procedure type | COD - Ordinary legislative procedure (ex-codecision procedure) |

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| Procedure subtype | Legislation |
| Legislative instrument | Regulation |
| Amendments and repeals | Repealing Decision 1673/2006/EC 2005/0157(COD) Amending Directive 95/16/EC 1992/0394(COD) Amending Directive 97/23/EC 1993/0462(COD) Amending Directive 98/34/EC 1996/0300(COD) Amending Directive 2004/22/EC 2000/0233(COD) Amending Directive 2007/23/EC 2005/0194(COD) Amending Directive 2009/23/EC 2007/0164(COD) Amending Directive 2009/105/EC 2008/0076(COD) Amended by 2021/0170(COD) Amended by 2022/0021(COD) See also 2016/2274(INI) |
| Legal basis | Treaty on the Functioning of the European Union TFEU 114-p1 |
| Other legal basis | Rules of Procedure EP 165 |
| Mandatory consultation of other institutions | European Economic and Social Committee |
| Stage reached in procedure | Procedure completed |
| Committee dossier | IMCO/7/06240 |

| Documentation gateway | | | | |
|---|--|------------------------------|-------------------------|-------------------------|
| European Parliament | | | | |
| Document type | Committee | Reference | Date | Summary |
| Committee draft report | | PE478.420 | 04/01/2012 | |
| Committee opinion | INTA | PE478.355 | 01/02/2012 | |
| Amendments tabled in committee | | PE480.857 | 29/02/2012 | |
| Committee opinion | ITRE | PE476.047 | 01/03/2012 | |
| Committee report tabled for plenary, 1st reading/single reading | | A7-0069/2012 | 07/05/2012 | Summary |
| Text adopted by Parliament, 1st reading/single reading | | T7-0311/2012 | 11/09/2012 | Summary |
| Council of the EU | | | | |
| Document type | Reference | Date | Summary | |
| Draft final act | 00032/2012/LEX | 25/10/2012 | | |
| European Commission | | | | |
| Document type | Reference | Date | Summary | |
| Legislative proposal | COM(2011)0315  | 01/06/2011 | Summary | |
| Document attached to the procedure | SEC(2011)0671  | 01/06/2011 | | |
| Document attached to the procedure | SEC(2011)0672  | 01/06/2011 | | |

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|--|--|------------|-------------------------|
| Commission response to text adopted in plenary | SP(2012)665 | 11/10/2012 | |
| Follow-up document | COM(2015)0198  | 13/05/2015 | Summary |
| Commission working document (SWD) | SWD(2015)0205 | 27/10/2015 | Summary |
| Follow-up document | COM(2016)0212  | 01/06/2016 | Summary |
| Follow-up document | SWD(2016)0126  | 01/06/2016 | |
| Follow-up document | COM(2022)0030  | 02/02/2022 | |

National parliaments

| Document type | Parliament /Chamber | Reference | Date | Summary |
|---------------|-------------------------------|---------------|------------|---------|
| Contribution | PT_PARLIAMENT | COM(2011)0315 | 20/09/2011 | |
| Contribution | IT_SENATE | COM(2011)0315 | 05/10/2011 | |

Additional information

| Source | Document | Date |
|----------------------|----------|------|
| National parliaments | IPEX | |
| European Commission | EUR-Lex | |

Final act

| | |
|--|-------------------------|
| Regulation 2012/1025 OJ L 316 14.11.2012, p. 0012 | Summary |
|--|-------------------------|

European standardisation

2011/0150(COD) - 05/12/2011

The Council took note of information provided by the Presidency on the progress made on a draft regulation aimed at modernising European standardisation.

The basis for discussions on the future reform was put forward by the Commission in the communication "[A strategic vision for European standards](#)" and the [draft regulation on European standardisation](#).

A first ministerial debate on the reform of the standardisation system in Europe took place on 29 September 2011. Ministers expressed broad support for increasing the role of European standards, to benefit the EU economy, and agreed on the need to shape a standardisation model that would be adaptable to ever-changing conditions by making it more flexible.

European standardisation

2011/0150(COD) - 07/05/2012 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Internal Market and Consumer Protection adopted the report by Lara COMI (PPE, IT) on the proposal for a regulation of the European Parliament and of the Council on European Standardisation and amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/105/EC and 2009/23/EC of the European Parliament and of the Council.

The committee recommends that the European Parliament's position in first reading following the ordinary legislative procedure should amend the Commission proposal as follows:

European standards: Members specify that this means a standard adopted by one of the European Standardisation Organisations, which shall be implemented through its publication as an identical national standard, with the obligation for National Standardisation Organisations to withdraw any existing and conflicting national standards.

Technical specification: the characteristics required of a product include levels of environmental protection and public health.

Participation and balanced representation of stakeholders: Members want European Standardisation Organisations to encourage and facilitate appropriate representation and participation of all relevant stakeholders, such as public authorities, including market surveillance authorities, SMEs, organisations representing the interests of consumers, including people with disabilities, environmental and social stakeholders, including social partners, in particular, through the stakeholder organisations, referred to in Annex III, at the policy development level and at least at the certain stages of the development of European standards or European standardisation deliverables.

Access of SMEs to standards: the report stresses SMEs participation in the standardisation process is essential for technological progress in the Union. It makes a series of amendments to encourage SME participation in standardization activities, particularly at national level and to facilitate their effective access to standards. It provides that National Standardisation Organisations shall exchange best practices aiming to enhance the participation of SMEs in standardisation activities and to increase and facilitate the use of standards.

Ensuring the participation of public authorities: noting that in most Member States public authorities show a limited interest in participating in the standards development process, Members want the Regulation to ensure that public authorities take part in all national technical committees mirroring the development of standards mandated by the Commission. The participation of national authorities is particularly crucial for the proper functioning of legislation in the areas covered by the 'New Approach', and for the avoidance of ex-post objections to harmonised standards.

Objection to harmonised standard: as the European Parliament is on an equal footing with the Council in the ordinary legislative procedure, the European Parliament must have the right to object to a harmonised standard.

Recognition and use of technical specifications in the field of ICT: the Union should encourage contact between standardisation bodies and forums and consortia drafting technical specifications especially in the field of information and communication technologies (ICT), while avoiding the creation of a system which competes with standardisation.

Either on proposal from a Member State or on its own initiative the Commission may decide, after consultation with the European Standardisation Organisations and all relevant stakeholders, including the European multi-stakeholder platform on ICT standardisation as set up by the Commission, to reference ICT technical specifications which are not national, European or international standards and meet the requirements set out in Annex II. The report supports the introduction of a new system allowing the use, in particular in the field of public procurement, of specifications developed by other organisations.

Improving and accelerating the European standard-setting process through more transparency and consultation: Members consider that it is essential for European standards to be developed within a reasonable period of time. Before issuing a request, the Commission shall within a reasonable deadline consult the European Standardisation Organisations, all relevant stakeholders, especially those referred to in Annex III, and the committees of national experts set up by the corresponding sectoral directive where such a directive exists as well as notify all interested parties registered in the European Transparency register.

As standards are primarily a market tool, it is necessary to ensure a high level of cooperation between the European Standardisation Organisations and the Commission in the establishment of its annual European standardisation work programme in order to ensure that the standards that the Commission intends to request from the European Standardisation Organisations are market-driven.

Better consultation between the Commission and the European Standardisation Organisations is also necessary prior to the issue of a request for new standardisation work.

Accordingly, the committee within the meaning of Regulation (EU) No 182/2011 shall meet at least twice per year with the European and National Standardisation Organisations. Furthermore, the Commission may invite the organisations referred to in Annexes I, Ia and III, and other relevant stakeholders, as observers, to the meetings of the committee.

Joint Research Centre: the Commission's Joint Research Centre shall contribute to the preparation of the European standardization work programme and participate in the activities of the European Standardisation Organisations providing scientific input, in its areas of expertise, to ensure that standards take into account economic competitiveness and social needs such as environmental sustainability and safety and security concerns.

Use of ICT: in order to accelerate the standardisation process and facilitate the participation of all interested parties in that process, European and National Standardisation Organisations should make best use, in their working methods, of information and communication technologies.

Review: the Commission shall consider the need for additional measures to simplify the financing of European standardisation and reduce the administrative burden for the European Standardisation Organisations. It shall present its conclusions in a report to be submitted to the European Parliament and to the Council by 1 January 2015, and shall submit, if appropriate, a legislative proposal for the amendment of this Regulation.

European standardisation

2011/0150(COD) - 11/09/2012 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 639 votes to 18 with 17 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on European Standardisation and amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/105/EC and 2009/23/EC of the European Parliament and of the Council.

Parliament adopted its position in first reading following the ordinary legislative procedure. The amendments adopted in plenary are the result of a compromise negotiated between Parliament and Council. They amend the Commission proposal as follows:

Objectives: the compromise text stipulates that the Regulation aims to ensure: (i) the effectiveness and efficiency of standards and standardisation as policy tools for the Union through cooperation between European standardisation organisations, national standardisation bodies, Member States and the Commission; (ii) the establishment of European standards and European standardisation deliverables for products and for services in support of Union legislation and policies, (iii) the identification of ICT technical specifications eligible for referencing, (iv) the financing of European standardisation and (v) stakeholder participation in European standardisation.

European standard: the text clarifies that the term means a technical specification, adopted by a recognised standardisation body.

Technical specification: the characteristics required of a product include levels of environmental protection and public health.

Transparency of work programmes of standardisation bodies: during the preparation of a harmonised standard or after its approval, national standardisation bodies shall not take any action which could prejudice the harmonisation intended and, in particular, shall not publish in the field in question a new or revised national standard which is not completely in line with an existing harmonised standard. After publication of a new harmonised standard, all conflicting national standards shall be withdrawn within a reasonable deadline.

When a national standardisation body receives comments indicating that the draft standard would have a negative impact on the internal market, it shall consult the European standardisation organisations and the Commission before adopting it.

Participation and balanced representation of stakeholders: European standardisation organisations shall encourage and facilitate an appropriate representation and effective participation of all relevant stakeholders, including SMEs, consumer organisations and environmental and social stakeholders in their standardisation activities.

Access of SMEs to standards: the compromise text introduces a series of amendments, which aim to encourage and facilitate the access of SMEs to standards and standards development processes in order to reach a higher level of participation in the standardisation system. National standardisation bodies shall exchange best practices aiming to enhance the participation of SMEs in standardisation activities.

Participation of public authorities in European standardisation: Member States shall, where appropriate, encourage participation of public authorities, including market surveillance authorities, in national standardisation activities aimed at the development or revision of standards requested by the Commission.

Cooperation with research facilities: the Commission's research facilities shall contribute to the preparation of the annual Union work programme for European standardisation and provide European standardisation organisations with scientific input, in their areas of expertise, to ensure that European standards take into account economic competitiveness and societal needs such as environmental sustainability and safety and security concerns.

Formal objections to harmonised standards: as the European Parliament is on an equal footing with the Council in the ordinary legislative procedure, the European Parliament must have the right to object to a harmonised standard.

Notification of stakeholder organisations: the Commission shall establish a notification system for all stakeholders, including European standardisation organisations and European stakeholder organisations receiving Union financing in accordance with this Regulation in order to ensure proper consultation and market relevance prior to: (i) adopting the annual Union work programme for European standardisation; (ii) adopting standardisation requests; (iii) taking a decision on formal objections to harmonised standards.

Identification of ICT technical specifications eligible for referencing: either on proposal from a Member State or on its own initiative the Commission may decide to identify ICT technical specifications that are not national, European or international standards, but meet the requirements set out in Annex II, which may be referenced, primarily to enable interoperability, in public procurement.

Delegated acts: the Commission shall be empowered to adopt delegated acts concerning amendments to the Annexes, in order to: (i) update the list of European standardisation organisations set out in Annex I to take into account changes in their name or structure; (ii) adapt the criteria for European stakeholder organisations set out in Annex III to this Regulation to further developments as regards their non-profit making nature and representativeness.

The power to adopt delegated acts shall be conferred on the Commission for a period of five years from 1 January 2013 (which may be tacitly extended for an identical period).

Review: 2 years after the date of entry into force of the Regulation, the Commission shall evaluate the impact of the procedure established by Article 10 of the Regulation on the timeframe for issuing standardisation requests. It shall present its conclusions in a report to the European Parliament and to the Council. Where appropriate, that report shall be accompanied by a legislative proposal to amend the Regulation.

European standardisation

2011/0150(COD) - 01/06/2011 - Legislative proposal

PURPOSE: to define the general framework for European Standardisation.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

BACKGROUND: standards and standardisation are very effective policy tools for the EU. They are used as policy instruments to ensure, inter alia, the functioning of the single market of products, the interoperability of networks and systems, in particular in the field of ICT, a high level of consumer and environmental protection, and more innovation and social inclusion.

This proposal addresses three major problems:

1. In a rapidly changing world and society, especially in sectors characterised by very short product lives and development cycles, standards must keep pace with rapid technological development. Some stakeholders argue that the entire process of creating European standards developed at the request of the Commission is **too slow**.
2. SMEs encounter a series of problems with respect to standards and standardisation. One of the most important problems, according to many stakeholders, is that **SMEs are in general under-represented** in standardisation activities, in particular at European level.
3. In the field of ICT, many standards ensuring interoperability are not elaborated by the ESOs but by other organisations that develop standards (hereinafter "global fora and consortia"). Concrete examples are Internet and World Wide Web related standards. At the moment, referring to "Fora and Consortia Standards" in public procurement which is subject to Directive 2004/18/CE is only possible in exceptional circumstances.

To respond rapidly to evolving needs in all areas, a comprehensive, inclusive, efficient and technically up-to-date European standardisation system will be required.

In its [Europe 2020 strategy](#) for smart, sustainable and inclusive growth, the Commission highlighted the necessity to improve the method of standard setting and the use of standards in Europe.

On 21 October 2010, the European Parliament adopted a [report](#) on the future of European standardisation which indicated that the review of European standardisation should preserve its many successful elements, remedy its deficiencies and strike the right balance between the European, national and international dimensions.

In its communication of 13 April 2011 on the '[Single market Act: Twelve levers to boost growth and confidence](#)', the Commission included among its twelve key priority actions to be adopted by the EU institutions before the end of 2012 the extension of the European standardisation system to services.

IMPACT ASSESSMENT: the Commission accepted a combination of different options:

Options 1.A (deadlines on the delivery of European standards) and **1.C** (transparent and simplified procedures for harmonised standards and other European standards requested by the Commission),

Option 2.C (strengthen the position of organisations representing SMEs and societal stakeholders within the ESOs by providing for the possibility of an operating grant) and 3.B (referencing of "Fora and Consortia Standards" in public procurement) meet the criteria of effectiveness, efficiency and consistency. Therefore, these 4 options constitute the basis of this proposal.

LEGAL BASIS: Article 114 of the Treaty on the Functioning of the European Union (TFEU).

CONTENT: this proposal replaces a part of Directive 98/34/EC and repeals Decisions No 1673/2006/EC and 87/95/EEC. It aims to establish rules with regard to: (i) the cooperation between European standardisation bodies, national standardisation bodies and the Commission; (ii) the establishment of European standards and European standardisation deliverables for products and for services in support of Union legislation and policies; (iii) the recognition of technical specifications in the field of information and communication technologies (ICT) and; (iv) financing of European standardisation.

The main elements of the proposal are as follows:

- **Enhanced cooperation:** the cooperation between national standardisation bodies will become more transparent.
- **International standards:** the use of standards developed by other organisations in the field of information and communication technologies will be possible in public procurement, provided that these standards comply with a set of criteria based on the WTO principles for international standardisation processes, in domains where there are no European standards, where European standards have not gained market uptake or where these standards have become obsolete.
- **Planning:** the planning will be improved: the Commission will establish an annual Work Programme, which will identify priorities for European standardisation and the mandates required.
- **Representation of SMEs:** SMEs and societal stakeholders should be better represented in European standardisation, and the financial support to organisations representing SMEs and societal stakeholders will be ensured.
- **Simplification:** a reduction of the administrative burden imposed on the Commission and the ESOs, for example by the possibility of a robust simplification of lump sums, clearly disconnected from any verification of actual costs of implementation. This proposal constitutes a further shift towards a performance-based system, based on the definition of agreed indicators and objectives (outputs and outcomes).

- **Service standards:** although European standards are already widely used for transport and logistics, postal services and electronic communications networks and services, the voluntary European standards have played a less prominent role in supporting the completion of the single market for services. This proposal therefore includes service standards within its scope in order to enable the Commission to issue mandates requesting the development of European service standards and to finance a part of the cost of this development.

BUDGETARY IMPLICATIONS: the proposal relates to **the extension of an existing action**. It should be noted that the amounts set out in this legislative financial statement do not prejudice the forthcoming Commission proposal for the post-2013 multi-annual financial framework. Budgetary appropriations allocated to this action will be proposed by the Commission in the annual budgetary procedure. Consequently, this financial statement is limited to one year (**2013**). The implication on operational appropriations is estimated at **EUR 27 million in commitment appropriations**.

DELEGATED ACTS: this proposal contains provisions to empower the Commission to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union.

European standardisation

2011/0150(COD) - 29/09/2011

The Council **exchanged views** on a strategy to modernise European standardisation. It instructed its preparatory bodies to pursue the examination.

The debate was structured around key questions put forward by the Presidency on the basis of the two proposals submitted by the Commission:

- the [communication](#) " A strategic vision for European standards";
- a draft regulation on European standardisation (*refer to the summary dated 1 June 2011*).

Delegations expressed **broad support for increasing the role of European standards** to benefit the EU economy and to strengthen the single market and consumer protection.

They agreed on the need to shape a standardisation model adaptable to ever-changing conditions by making it more flexible.

Most delegations:

- highlighted the need to **speed up the process for adopting European standards** without this being detrimental to their quality and consistency;
- outlined the important role that the use of information and communication technologies (ICT) standards developed by global ICT fora and consortia can play in public procurement policies;
- expressed convergent views on the importance of a greater involvement of stakeholders in the standardisation process and particularly of the small and medium-sized enterprises (**SMEs**).

More transparency and **better accessibility to standards** were also mentioned as an important aspect of the reform.

It should be recalled that the new strategic vision put forward by the Commission contains a list of 29 legislative and non-legislative actions and 5 axes of action: (i) industrial policy and innovation; (ii) inclusive standard-setting; (iii) standards on services; (iv) ICT fora and consortia standards, and (v) European standards in the global market.

European standardisation

2011/0150(COD) - 01/06/2016 - Follow-up document

The Commission presents a report on the implementation of Regulation (EU) No 1025/2012 from 2013 to 2015.

The report assesses the performance of the European Standardisation System (ESS) including the implementation of the Regulation since its entry into force in 2013, in terms of effectiveness, efficiency, coherence, relevance and EU added value. It includes:

- analysis of the implementation of the Regulation, through the reports provided by the European standardisation organisations (ESOs) and the Annex III organisations concerning the years 2013 and 2014;
- an evaluation of the relevance of standardisation activities receiving Union financing;
- an assessment of opportunities for simplifying the financing of European standardisation and reducing the administrative burden.

Bearing in mind the importance of standardisation as a way to harmonise the single market and of its impact on the competitiveness of the EU economy, this evaluation is linked to the Commission's Regulatory Fitness and Performance Programme ([REFIT](#)).

Effectiveness: the report notes that the Regulation has **increased the contribution of standards and European standardisation to a better functioning of the internal market**, stimulating growth and innovation and fostering the competitiveness of EU enterprises, especially SMEs.

Steps have been taken to improve the transparency of the development of the Commission's standardisation requests in support of EU legislations and policies and the participation of SMEs and underrepresented stakeholders. The Regulation also **facilitates the exploitation of the potential of innovative ICT technologies** and contributes to the realisation of the single market.

In the ICT domain, **the Multi-Stakeholder Platform (MSP)** generates the ICT Rolling Plan as a collaborative tool to bring together the Commission and the ICT standardisation stakeholders – EU and global- and to increase their coordination and cooperation.

Efficiency: the report notes that the current data **does not allow for a complete and comprehensive analysis** of the efficiency of the ESS, as they are influenced by the activities supported by the Commission within the new framework of the Regulation.

Following the invitation from the Council to analyse the impact of standardisation on the economy, and taking into account the interest of all the parties, the Commission envisages launching a study in good time to analyse the results **in the next report**, which should be in 2020.

Next steps: the report stresses that the Regulation has brought significant improvements in the ESS due to: (i) the timely availability of standards requested by the Commission, (ii) the early involvement of stakeholders, (iii) the creation of consensus around the standardisation requests under preparation, and (iv) the improvement in the quality and detail of the requests issued.

Overall, **no major problem in the application of the Regulation had been identified, but there are some areas that could be improved, e.g.:**

- the need to take better advantage of the early identification of standardisation needs and failures in the early launch of standardisation activities;
- overcoming barriers for SMEs to taking part in standardisation and/or in applying standards;
- remedying gaps in Commission communication on the standardisation process;
- the need for information for all the stakeholders on the standardisation work ongoing or planned;
- complex procedures including reporting obligations and number of steps/actors involved;
- remedying gaps in communication between the Commission and the ESOs during the standardisation process;
- the lack of alignment between the Commission and standardisers in the phase during which there are compliance checks;
- dealing with conflicting national standards remaining;
- different layers in standardisation and the need to adapt the approach to different requirements;
- identification of needs in sectors not covered by standardisation (e.g. services);
- the need for better patents declaration framework.

The Commission will consider how to best tackle these matters, in particular through the **Joint Initiative on Standardisation** (presented in the context of the [single market strategy](#)) that aims at promoting the coherent implementation of the Regulation through non-legislative actions in co-operation with the main actors of the ESS.

The Joint Initiative on Standardisation will also explore how the gap between research/innovation priorities and European standardisation could be analysed in a more systematic and forward-looking way and more effectively bridged.

In conclusion, **the Commission feels that there is no justification for revising the Regulation at this time**. It will revisit the situation five years after completion of the present evaluation, in the context of the report that it will present to the Council and to the European Parliament on the implementation of the Regulation.

European standardisation

2011/0150(COD) - 25/10/2012 - Final act

PURPOSE: to modernise and improve the European standardisation system.

LEGISLATIVE ACT: Regulation (EU) No 1025/2012 of the European Parliament and of the Council on European standardisation, 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, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council.

CONTENT: following an agreement with the European Parliament at first reading, the Council adopted a Regulation that seeks to simplify and **adapt the legislative framework** to cover new aspects to reflect the latest developments and future challenges in European standardisation.

The [European Parliament's resolution of 21 October 2010](#) on the future of European standardisation already contained a large number of strategic recommendations concerning the revision of the European standardisation system.

European standardisation is organised by and for the stakeholders concerned based on national representation [the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec)] and direct participation (the European Telecommunications Standards Institute (ETSI)), and is founded on the principles recognised by the World Trade Organisation (WTO) in the field of standardisation, namely coherence, transparency, openness, consensus, voluntary application, independence from special interests and efficiency.

The Regulation lays down rules governing: (i) cooperation between European standardisation organisations, national standardisation bodies, Member States and the Commission; (ii) the establishment of European standards and European standardisation deliverables for products and for services in support of Union legislation and policies; (iii) the identification of information and communication technology (ICT) technical specifications eligible for referencing; (iv) the financing of European standardisation and (v) stakeholder participation in European standardisation

The main innovation introduced in the Regulation are as follows:

Standards in respect of services: the new Regulation covers the means by which voluntary standards for services may be drawn up. Currently, this is only the case for products.

Levels of environmental and public health protection must also be included among the required characteristics of a product or service.

Broader participation in the standards setting process:

- European standardisation organisations shall encourage and **facilitate an appropriate representation and effective participation of all relevant stakeholders, including SMEs**, consumer organisations and environmental and social stakeholders in their standardisation activities.
- National standardisation bodies shall encourage and **facilitate the access of SMEs to standards** and standards development processes. The Regulation encourages the exchange of best practices between national standardisation bodies to enhance the participation of SMEs in standardisation activities and to increase and facilitate the use of standards by SMEs.
- Member States shall, where appropriate, encourage **participation of public authorities**, including market surveillance authorities, in national standardisation activities aimed at the development or revision of standards requested by the Commission.

Recognition and use of technical specifications in the ICT field: Public authorities should make best use of the full range of relevant technical specifications when procuring hardware, software and information technology services.

Contracting authorities will be able to refer to ICT technical specifications, in order to respond to the fast evolution in the field of ICT.

The technical specifications have market acceptance and their implementations do not hamper interoperability with the implementations of existing European or international standards.

The Union's annual standardisation work programme: the Commission shall adopt the Union's annual work programme in the area of European standardisation which will lay down the strategic priorities for European standardisation, bearing in mind the Union's long-term growth strategies.

The Commission shall establish **a notification system for all stakeholders**, including European standardisation organisations and European stakeholder organisations receiving Union financing in accordance with this Regulation in order to ensure proper consultation and market relevance prior to: (i) adopting the annual Union work programme for European standardisation referred to in Article 8(1); (ii) adopting standardisation requests; and (iii) taking a decision on formal objections to harmonised standards.

Objections to harmonised standards: given that Parliament participates on an equal footing with the Council in the ordinary legislative procedure, the European Parliament shall also have the right to object to a harmonised standard.

Review: by 2 January 2015, the Commission shall evaluate the impact of the procedure established by Article 10 of this Regulation on the timeframe for issuing standardisation requests. The Commission shall present its conclusions in a report to the European Parliament and to the Council. Where appropriate, that report shall be accompanied by a legislative proposal to amend this Regulation.

ENTRY INTO FORCE: 04/12/2012.

APPLICATION: from 01/01/2013.

DELEGATED ACTS: the Commission may adopt delegated acts in order to update the list of European standardisation organisations and to adapt the criteria for organisations representing SMEs and societal stakeholders to further developments as regards their non-profit making nature and representativity. The power to adopt delegated acts shall be conferred on the Commission for **a period of five years from 1 January 2013** (a period that may be tacitly extended for periods of an identical duration, **unless the European Parliament or the Council opposes such extension not later than three months before the end of each period**). **The European Parliament or the Council may express their objection to a delegated act within a period of two months of its notification** (this period may be extended by two months at the initiative of Parliament or the Council). If Parliament or the Council express objections, the delegated act does not enter into force.

European standardisation

2011/0150(COD) - 13/05/2015 - Follow-up document

The Commission presents a report on the impact of the procedures established by Article 10 of Regulation (EU) No 1025/2012 on European standardisation on the timeframe for issuing standardisation requests (Standardisation Regulation.).

To recall, the main feature of the European standardisation system is that the Commission may request the European standardisation organisations (ESOs) to draw up a European standard or a European standardisation deliverable for products or for services in order to support Union legislation and policies. Around 20% of all European standards and European standardisation deliverables are the result of such Commission requests, while the remaining 80% stem directly from proposals by industry or other standardisation stakeholders.

The report describes the previous regime for standardisation requests as established by Directives 83/189/EEC, and later by 98/34/EC, noting that it was restricted to product standardisation. It also covers the effects of the new Regulation.

Implementing act: the Standardisation Regulation establishes revised rules. The main change is that, under Article 10(2), the Committee on Standards is consulted applying the examination procedure described in Article 5 of Regulation (EU) No 182/2011 5. Therefore, the opinion of the Committee is binding and the Commission adopts a standardisation request as an implementing act subsequently. The previous regime had maintained the informal status of standardisation requests and consultations.

Increase speed: the [Communication on "A strategic vision for European standards"](#) sets an improved speed of the European standardisation as a strategic objective. For standardisation requested by the Commission, the calculation of speed includes the overall time taken by the Commission itself during the preparation of a standardisation request. Thus, there is an increased need for efficient cooperation between the ESOs, the Commission, Member State experts and stakeholders under the new rules in order to ensure that the full sequence of steps in the workflow can be completed in due time. Therefore, the **consultation of Member States in the Committee on Standards does not create a delay in the process** compared to the previous

practice when considering the total amount of time spent in the preparation process of a standardisation request. Only a negative opinion of the Committee on Standards would cause an extra delay of several months.

Statistical analysis: the average number of standardisation requests during years 2006-2013 (issued under the old regime) was 20 requests per year. In 2014, the first year of issuing requests under the new regime, the number is estimated to be nine requests.

The scope of standardisation requests has widened from product standardisation to service standardisation, and requests supporting the Union's general policies have been made possible. However, the **number of standardisation requests is expected to drop in 2014 by 50%** from the average number during the last years of the old regime. In addition to a downward trend since 2012 in the number of requests (due to the maturity of the New Approach sectors) the other two main reasons for this drop could be:

- the increased formality of the process, together with the compulsory annual planning and more specific requirements on the content of a standardisation request, and
- the fact that standardisation requests are no longer used to initiate actions like standardisation related studies, which do not directly lead to the adoption of European standards or European standardisation deliverables.

Pertinent factors: the report notes the following

- the relatively short period of experience concerning standardisation requests issued on the basis of Article 10 of the Standardisation Regulation;
- transparent and proper planning of standardisation requests and informal consultation process with the ESOs, the Member States and all relevant stakeholders are of key importance before issuing standardisation requests;
- the Commission is updating its internal guidance concerning how to plan, to draft and to consult standardisation requests;
- preliminary and ancillary work in relation to European standardisation, like feasibility studies, where no specific European standards or European standardisation deliverables are requested by the Commission can be initiated together with the ESOs without requests.

Conclusion: since there has been a short time-frame since the application of the Regulation, there has not been enough time to gain sufficient experience with the application of the new rules to draw definitive conclusion about whether the new rules will result in a permanent and unacceptable increase in the length of procedures for standardisation requests. Thus, there is **not enough data to substantiate the need for a legislative proposal** to amend Article 10 of the Standardisation Regulation at this stage. The Commission will revisit the situation by the end of 2015, in the context of the implementation report.

European standardisation

2011/0150(COD) - 27/10/2015 - Follow-up document

This Commission Staff Working Document concerns the Vademecum on European standardisation.

To recall, [Regulation \(EU\) No 1025/2012](#) on European standardisation is the legal basis for the Commission's requests to the European Standardisation Organisations (ESOs) to draw up European standards or European standardisation deliverables in support of Union legislation and policies.

The document consists of three parts relating to standardisation requests:

Part I on the role of the Commission's standardisation requests to the European standardisation organisations: the objective of this document is to ensure a **common understanding of the role of Commission's standardisation requests** ('mandates') to the ESOs and the role and responsibilities of the various actors in planning, preparing and executing these requests.

This part concentrates in particular on:

- the concept of a standardisation request;
- the conditions for issuing a standardisation request;
- a standardisation request as an implementing act, implications of non-compliance with a standardisation request;
- the validity of a standardisation request;
- revisions to European standards supporting Union legislation.

It is addressed to all actors of the European standardisation system (ESS) and in particular to Commission officials, public authorities in the Member States and EFTA countries, the ESOs, the national standardisation bodies (NSBs) and all stakeholders in European standardisation.

Conclusions: the document concludes that during the standardisation work and after the ESOs have adopted the deliverables, the Commission must respect, in its guidance and assessment, the requirements of relevant sectoral legislation or policy and as given in its request. Should the relevant Union legislation or policy evolve during execution of a request having effect to standardisation needs, the Commission should amend the request in line with Article 10(1) and (2) of Regulation (EU) No 1025/2012.

Part II on the preparation and adoption of the Commission's standardisation requests: this document clarifies the principles to be followed in the drafting and adoption of Commission standardisation requests to European standardisation organisations.

It is addressed to Commission officials and is structured as follows:

- guidance on preparation and adoption procedures;

- generic drafting guidance;
- the **model structure** for a request;
- some basic information on the execution phase.

Conclusions: on the issue of **timing**, in some cases, a standardisation request is intended to support the application of Union legislation or policy that is still under consideration in the Council and in the European Parliament on the basis of a Commission proposal. The preparation work should start while these discussions are ongoing, or even before. By submitting a standardisation request to examination procedure in the Committee on Standards or adopting it before the new legislation is formally approved by the legislator or published in the Official Journal, the Commission can **save time in carrying out the standardisation work and implementing the legislation**. However, it should evaluate carefully case by case whether this is possible or advisable.

An optimistic minimum lead time from the launch of inter-service consultation (ISC) procedures until final notification of the ESO(s) is at least **four months**.

Part III on guidelines for the ESOs' execution of standardisation requests: this document sets out guidelines for the execution of standardisation requests which have been accepted by the European standardisation organisations (ESOs). It is addressed to the ESOs and their technical bodies or equivalent drafting entities and should be applied consistently during execution of all requests. The approach taken and the underlying principles are aimed at:

- enabling efficient and timely drafting and adoption of standardisation requests and thus prompt availability of European standards or European standardisation;
- promoting effective project planning, transparent reporting and efficient follow-up during the execution of requests;
- ensuring transparent access to requested-work programmes;
- setting conditions for amending requested-work programmes;
- promoting transparent, market-relevant and SME-friendly harmonised standards and standardisation processes taking account of the public interest.

Conclusions: the ESOs should inform the Commission if they intend to **withdraw** a harmonised European standard referred to in the Official Journal on the basis that it no longer reflects the 'state of the art' or has become obsolete and they do not intend to revise it or publish a new harmonised standard to supersede it.