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**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND
THE COUNCIL**

**Article 25 Report to the European Parliament and the Council 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**

1. INTRODUCTION

According to Article 25 of Regulation (EU) No 1025/2012 on European standardisation (hereinafter the Standardisation Regulation)¹:

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.

This is the report drafted to respond to such Article 25.

2. EUROPEAN STANDARDS AND EUROPEAN STANDARDISATION DELIVERABLES SUPPORTING UNION LEGISLATION AND POLICIES

2.1. European standardisation organisations

Since the 1980's the European standardisation organisations (ESOs) have played an important and widely recognised role in harmonising national standards in EU/EFTA countries and in supporting the creation of the Single Market. This recognition was first confirmed by Directive 83/189/EEC², then by the General Guidelines for Co-operation between the Commission and the ESOs, signed in 1984 and revised in 2003³.

The European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) and the European Telecommunications Standards Institute (ETSI) are the European standardisation organisations (ESOs) recognised by the Standardisation Regulation. They adopt, on a voluntary basis, European standards and European standardisation deliverables to define voluntary technical or quality specifications with which current or future products, production processes or services may comply.

The main feature of the European standardisation system is that the Commission may request the 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. The legal basis used to be the Directive 98/34/EC and the co-operation agreement with the ESOs while, nowadays, is the Standardisation Regulation. Around 20% of all European standards and European standardisation deliverables are the result of such Commission requests, while the remaining 80% are stemming directly from proposals by industry or other standardisation stakeholders.

¹ Regulation (EC) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 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, OJ L 316, 14.11.2012, p. 12-33.

² Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations - the Directive 98/34/EC is a codification of the Directive 83/189/EEC and its amendments, OJ L 204, 21.7.1998

³ OJ C 91 of 16.4.2003

2.2. A standardisation request before the Standardisation Regulation

Article 6 of Directive 83/189/EEC (later replaced by Directive 98/34/EC⁴) allowed the Commission to submit “*proposals aimed at eliminating existing or foreseeable barriers to trade*” and within this context “*request the European standards institutions to draw up a European standard within a given time limit*”. Before issuing such standardisation requests, the Commission needed to consult the Article 5 Standing Committee (98/34 Committee) consisting of representatives appointed by the Member States. This was the only regulated requirement.

The regime for standardisation requests as established by Directives 83/189/EEC, and later by 98/34/EC, was restricted only to product standardisation. It did not specifically set forth either the content of such request or its legal format, and did not explain how the ESOs or other stakeholders should be consulted during its preparation.

A draft standardisation request was submitted in three languages (DE/EN/FR) to the Standing Committee for its opinion, usually after it was discussed in the relevant sectorial Committee, or Working Party established on the basis of the relevant sectorial legislation, and after consultation with the ESOs and other relevant stakeholders.

The Standing Committee had an advisory status only and its opinion was not binding for the Commission. The consultation was done either in a meeting or using a written procedure taking 4 to 6 weeks to allow submission of comments by the members of the Committee. The Commission then independently finalised the request on the basis of the comments received and communicated the final request to the ESOs 2 to 5 months after the consultation. No deadline was usually given to the ESOs to respond to a request for standards.

Standardisation requests were not only used to ask for the development of standards but also to initiate feasibility studies or other pre-normative work not directly leading to the adoption of European standards.

2.3. A standardisation request as an Implementing Act

The Standardisation Regulation establishes revised rules with regard to the request of European standards and European standardisation deliverables for products and for services in support of Union legislation and policies. The main change is that, according to its Article 10(2), the Committee under Article 22 (Committee on Standards) is consulted applying the examination procedure described in Article 5 of Regulation (EU) No 182/2011⁵. Therefore, the opinion of the Committee is binding and a standardisation request is subsequently adopted by the Commission as an Implementing Act (Commission Implementing Decision).

In its proposal for a Regulation on European standardisation COM(2011)315⁶ the Commission had proposed to maintain the informal status of standardisation requests as well as the consultation described in Directive 98/34/EC. The co-legislator however decided differently: when issuing standardisation requests, the Member States should maintain control

⁴ OJ L 204, 21.7.1998, p.37

⁵ Regulation of the European Parliament and of the Council laying down the rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers OJ L 55, 28.2.2011, p. 13

⁶ COM(2011)315 final, 1.6.2011

on the Commission's implementing powers via the examination procedure of Regulation (EU) No 182/2011.

In order to address any concern about the impact of the new examination procedure on the time required to issue a request for standardisation, Article 25 requires that the Commission evaluates it by 2 January 2015.

3. ANALYSIS

3.1. Impact of the Standardisation Regulation

Although the overall planning, preparation, consultation and adoption process as provided for in Article 8, Article 10(1)-(2) and Article 12 are quite different from the process set out by Directive 98/34/EC, the changes have been so far manageable.

Indeed, even before the Standardisation Regulation was applicable, the Commission had already decided on its own commitments for planning future requests (via action plans or rolling plans) and for making this information publicly available, while it had defined principles for consultation of the ESOs, the Member States' sectorial experts and all relevant stakeholders before consulting the Member States in the 98/34 Committee.

The Standardisation Regulation mainly enforced the previously non-regulated practices. The Article 12 Notification System is the only major novelty, allowing public access to all draft requests. The Standardisation Regulation, however, sets higher standards for the Commission when using European standardisation as a policy tool to support Union policies.

In short, the Standardisation Regulation creates the following direct and indirect consequences:

- According to Article 8 the Commission must define its plans regarding new standardisation requests in the annual Union work programme for European standardisation. This means that the normal timespan for preparing requests is generally longer than 12 months, independently from the means of consulting the Committee on Standards at the end of the process.
- According to Article 10(2) sectorial experts of the Member States, the ESOs and the European stakeholder organisations receiving Union financing in accordance with the Standardisation Regulation must be consulted during the preparation phase of a standardisation request. This was usually already done before but not systematically and without legal obligations.
- According to Article 12, during the preparation phase, the Commission must make draft requests available to all stakeholders, even to those not referenced in Article 10(2), using the online Notification System.
- According to the rules and procedures of the Committee on Standards, the chair of the Committee must inform the Committee, before it provides its opinion, of the opinions of the sectorial experts of the Member States during the preparation phase.
- According to Article 10(3) the ESOs must indicate within one month after they have received a request, whether they accept it. This requirement leads to a need for an effective and continuous communication between the Commission and the ESOs during the preparation phase of a request.

- Finally, because a standardisation request is issued as an Implementing Act after intensive consultations, planning and discussions, such request should be accepted (or rejected) unconditionally by the ESOs, i.e. selecting and accepting only some parts of a request is no longer possible. In the past it was common that Commission requests were conditionally or only partly accepted by the ESOs on the basis of available financial resources or of other interests, as the ESOs members were often consulted only after officially receiving the final request.

The Communication on “A strategic vision for European standards: Moving forward to enhance and accelerate the sustainable growth of the European economy by 2020”⁷, which was adopted by the Commission in conjunction with the proposal for a Regulation on European standardisation, sets improved speed of the European standardisation as one of the strategic objectives. For standardisation requested by the Commission, the calculation of speed includes also the overall time consumed 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 required steps in the workflow can be completed in due time.

Therefore, the consultation of the Member States in the Committee on Standards does not create a bottle neck or a delay in the process compared to the previous practice⁸, on the basis of the experiences available so far, when considering the total amount of time spent in the preparation process of a standardisation request.

This applies on the condition that the planning phase and the consultation of the ESOs, the Member States’ sectorial experts and all relevant stakeholders are done properly, ensuring a positive opinion of the Committee on Standards as well. A positive opinion also implies that the Commission draft request submitted to the examination procedure is adopted without any modifications or with some minor adaptation only allowing a faster notification to the ESOs.

Compared to the old practice, only a negative opinion of the Committee on Standards would cause an extra delay of several months.

However, regarding standardisation initiatives under the Directive 2001/95/EC on general product safety⁹ (subject to the regulatory procedure with scrutiny), Regulation (EU) No 1025/2012 indeed added an additional layer of formal Commission decision pursuant to Comitology rules because after adoption of the safety requirements to be met by European standards by means of a Commission Decision in accordance with Directive 2001/95/EC, the corresponding standardisation request needs to be adopted again by a further Commission Decision in accordance with the Standardisation Regulation (subject to the examination procedure). The Commission has already spotted the problem and the on-going proposal for a consumer product safety regulation¹⁰ aims to simplify the procedure and align it with Regulation (EU) No 1025/2012.

⁷ COM(2011)311 final, 1.6.2011

⁸ The minimum time allowed to consult the Committee is two weeks. In practise 4 to 6 weeks is given.

⁹ OJ L 11, 15.1.2002, p. 4

¹⁰ COM(2013)78 final

In addition to this, Article 10 of the Standardisation Regulation clearly excludes preliminary or ancillary work in connection with European standardisation, like feasibility studies, because such actions never directly lead to the adoption of European standards or European standardisation deliverables within the meaning of Article 10(1). In the old regime such actions were initiated by the Commission using standardisation requests, but under the Standardisation Regulation this is no longer possible, and this new practice allows for a shorter timeframe to start or to prepare such actions.

3.2. Statistical analysis

The Commission's internal statistics covering years 2006-2014 indicate that 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** (see Table 1).

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:

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

Table 1 – Number of standardisation request, including amendments, during 2006-2014

Consultation regime	Year	Number of issued requests
Directive 98/34/EC (Article 6(4) point e)	2006	24
	2007	20
	2008	18
	2009	21
	2010	20
	2011	19
	2012	23
	2013	16 ^{*)}
Regulation (EU) No 1025/2012 (Article 10(2))	2014	9 ^{**)}
^{*)} All these requests issued in 2013 where consulted already in 2012 in the 98/34 Committee ^{**)} This is an estimate on the basis of information available in October 2014: the sample consists of one adopted request and 8 requests already submitted or near of submission to the Committee on Standards to consult its opinion.		

To be noted that the Commission started recording more systematically the “starting date” of the preparation process only in 2009. This starting date, however, represents the first contact between a Commission Directorate-General preparing a request and the Chair of the Committee (the 98/34 Committee and later the Committee on Standards) at the moment when the real preparation of a request is about to start or has already been started. Due to this uncertainty in recording this date should then be regarded as an estimate.

The Commission statistics covering years 2009-2013 indicate an average preparation time of **363 calendar days** (around 12 months) for requests issued under the old regime (sample size is only 40 because the starting date was recorded only for 40% of 2009-2013 requests). Estimates for 2014 indicate an average preparation time of **420 calendar days** (around 13,5 months) for requests estimated to be issued under the new regime (sample size nine, see Table 2).

Limited availability and the quality of data prevent drawing any definite conclusions. However this possible recorded increase, if confirmed, could be the result of the more formal administrative framework for the development of standardisation requests requiring a highly efficient cooperation between the involved actors.

Table 2 – Average preparation times for requests under the old and new regimes

Consultation regime	Issuing year	Number of requests considered	Average time from the starting date of the preparation to the notification to the ESOs
Directive 98/34/EC (Article 6(4) point e)	2009 ... 2013	40	363 calendar days (12 months) ^{*)} (standard deviation 179 calendar days)
Regulation (EU) No 1025/2012 (Article 10(2))	2014	9 ^{**)}	420 calendar days (13,5 months) (standard deviation 170 calendar days)
<p>^{*)} In its report COM(1998)291 final¹¹ the Commission estimated that the average preparation time was 8 to 14 months during that time.</p> <p>^{**)} The number of requests to be issued by the end of 2014 is an estimate. In this estimated data the notification to the ESOs should take place three weeks after the examination procedure in the Committee on Standards.</p>			

4. CONCLUSIONS

Considering:

- the relatively short period of experience concerning standardisation requests issued on the basis of Article 10 of the Standardisation Regulation;
- that 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;
- that the Commission is updating its internal guidance concerning how to plan, to draft and to consult standardisation requests;
- that 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;

the Commission concludes that while the new rules under Article 10 of the Standardisation Regulation increase the need for efficient cooperation between the involved actors, the short

¹¹ COM(1998)291 final of 13.5.1998, Report from the Commission to the Council and the European Parliament on "Efficiency and accountability of European Standardisation under the New Approach"

timeframe to gain experience with the new processes does not allow to draw a final 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 report that it will present to the Council and to the European Parliament on the implementation of the Standardisation Regulation, under its Article 24(3).