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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**amending Regulation (EU) No 1025/2012 as regards the decisions of European
standardisation organisations concerning European standards and European
standardisation deliverables**

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

The European standardisation organisations (ESOs) are private organisations, which have a special role within the European standardisation system. As set out in Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012¹, European standardisation is organised by and for the stakeholders concerned, based on national representation (in the European Committee for standardisation, CEN, and the European Committee for Electrotechnical Standardisation, CENELEC) and on direct member participation (in the European Telecommunications Standards Institute, ETSI). When a request for standardisation is made by the Commission, the European standardisation organisations (as defined in Regulation (EU) No 1025/2012) are the only bodies that can issue standards and standardisation deliverables. They do so in line with specific procedures set out in Article 10 of Regulation (EU) No 1025/2012 of the “Standardisation Regulation”. The Standardisation Regulation also provides that the European Union may support the European standardisation organisations financially.

The European standardisation organisations are defined in Article 2, point 8 and Annex I to the Standardisation Regulation. There are three European standardisation organisations: CEN, CENELEC and ETSI. They have an exclusive role to carry out standardisation work requested by the Commission in support of EU legislation and policies.

This is mainly due to historic reasons. In the 1980s, when the current European standardisation organisations were set up and their role in delivering standards was established, the system was mostly centred on stakeholders of the European Union.

Today, the situation is different and the ESOs’ internal governance, decision-making procedures and their membership structure have gone through multiple changes. The European standardisation organisations now cooperate with a wide range of stakeholders, including from third countries, and allow them to participate not only in the technical work but also in their internal policy- and decision-making. Such cooperation is welcome; however, when the European standardisation organisations should focus on supporting EU legislation and policies, safeguards are needed to ensure sound procedure and a balanced representation of stakeholders’ interests, in line with the strategic priorities and legislative needs. In particular, this applies to internal decisions to develop standards and standardisation deliverables, as requested by the Commission on the basis of Article 10(1) of the Standardisation Regulation. These internal decisions can cover issues such as decisions on the acceptance of standardisation requests, on the acceptance of new work items, and on the adoption, revision or withdrawal of European standardisation deliverables. In these cases, particularly when the European standardisation organisations support the application of EU legislation and develop standards that are crucial to the EU general public and to companies, the internal governance of the European standardisation organisations must duly take into

¹ Regulation (EU) 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 316/12 of 14.11.2012).

account the views of all European stakeholders (including small and medium enterprises and civil society organisations). This is even more pertinent given that some European standardisation organisations are mainly composed by economic operators who have voting rights and the participation of civil society organisations and public authorities is limited in some cases.

Greater clarification is therefore needed to ensure that the whole internal decision-making process in issuing standards and standardisation deliverables, requested by the Commission on the basis of Article 10(1) of the Standardisation Regulation, is in line with what the EU institutions expect from a standards-developing body officially recognised as a European standards organisation.

Requiring a certain representation and decision-making power of national standardisation bodies as regards standards requested by the Commission would put in place sufficient checks and balances so to ensure consistency with EU legislation and policies.

- **Consistency with existing policy provisions in the policy area**

The Commission announced that it would propose an amendment to Regulation (EU) No 1025/2012 in its initiative Updating the 2020 *new industry* strategy (COM(2021)350)² together with a standardisation strategy, which is presented together with this proposal.

- **Consistency with other Union policies**

The proposed legislative amendment is in line with the political importance of standards, as highlighted in other key Commission initiatives, such as Shaping Europe's digital future (COM(2020)67³), the Global Gateway (JOIN(2021)30⁴), or the Council's statement welcoming 'the Commission's intention to develop a strategy for standardisation to strengthen the European standardisation system and its governance' (Council conclusions of 09.06.2020⁵).

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

The legal basis for the initiative is Article 114 of the Treaty on the Functioning of the European Union.

- **Subsidiarity (for action where the ESOs do not have exclusive competence)**

The question of subsidiarity is not an issue. This initiative is to amend an EU Regulation governing the European standardisation system. It aims specifically to safeguard good governance principles in the delivery of standards requested by the Commission under Article 10(1) of the Standardisation Regulation. This initiative will reinforce the role of national representatives (i.e. national standardisation bodies) in the system.

- **Proportionality**

The proposed amendment to Regulation (EU) No 1025/2012 is very limited and targeted to the work of the European standardisation organisations following a request from the

² <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2021:350:FIN>

³ <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:52020DC0067>

⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=JOIN%3A2021%3A30%3AFIN>

⁵ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020XG0616%2801%29>

Commission. These requests follow a public policy mandate and, therefore, it is important to ensure good governance principles in line with EU decision making. The proposal complies with the proportionality principle because it does not go beyond what is necessary in order to achieve the objectives of ensuring that national representation/participation for the development of European standards and standardisation deliverables, based on a request under Article 10 of Regulation (EU) No 1025/2012, is guaranteed at every stage of the process.

- **Choice of the instrument**

Regulation amending a Regulation.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Stakeholder consultations**

The Commission has carried out a targeted consultation with the stakeholders on this matter (notably the European standardisation organisations, national standardisation bodies, EU Member States, and industrial and civil society stakeholders). These stakeholders were given the opportunity to express their views and provide input to the Commission's work.

During the consultation on the roadmap for the standardisation strategy, stakeholders provided valuable feedback on the governance and on transparency in the European standardisation system in the Commission's Better Regulation portal⁶. The Commission received similar feedback through the reports issued by the European stakeholder organisations under Article 24(2) of the Standardisation Regulation.

- **Impact assessment**

The Commission did not carry out an impact assessment (IA) for this initiative. The proposed initiative regards administrative decisions within the European standardisation organisations following requests from the Commission based on a policy or legal need. These administrative decisions cover governance/administrative decisions for Union policies. The impact of these administrative decisions are limited to identifiable stakeholders. In conclusion, there was no need for an IA and the related public consultation as the amendment would be/is limited in scope, targeted and provides technical amendments to the existing legislation regarding the issue of governance.

4. BUDGETARY IMPLICATIONS

The proposal does not have a budgetary impact for the EU institutions.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

The proposal is to amend only two articles.

To enable the European Standardisation Organisations – where necessary – to adapt their internal rules of procedure, the amendment provides for a transition period of six months before entering into force.

⁶ https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13099-Standardisation-strategy_en

The Commission will assist the European standardisation organisations to help them amend their internal rules for decision making regarding standards and standardisation deliverables requested by the Commission under Article 10(1) of the Standardisation Regulation.

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amending Regulation (EU) No 1025/2012 as regards the decisions of European standardisation organisations concerning European standards and European standardisation deliverables

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee⁷,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Regulation (EU) No 1025/2012 of the European Parliament and of the Council⁸ establishes rules with regard to the establishment of European standards and European standardisation deliverables for products and for services in support of Union legislation and policies.
- (2) In accordance with Article 10 of Regulation (EU) No 1025/2012 the Commission may request one or several European standardisation organisations to draft a European standard or European standardisation deliverable.
- (3) European standards and European standardisation deliverables play an important role for the internal market. For instance, harmonised standards may be used to confer a presumption that products to be made available on the market are in conformity with the essential requirements that are laid down in the relevant Union harmonisation legislation for those products when they comply with the harmonised standards.
- (4) In the past years, the practices in the European standardisation organisations as regards their internal governance and decision-making procedures have changed. As a result, the European standardisation organisations have increased their co-operation with international and European stakeholders. Such cooperation is welcome as it

⁷ OJ C ..., ..., p.

⁸ Regulation (EU) 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).

contributes to the transparent, open, impartial and consensus-built standardisation process. However, when European standardisation organisations execute standardisation requests to support Union legislation and policies, unrestricted participation of any stakeholder in their internal decision-making may lead to decisions that do not entirely take into account the interests, policy objectives, and values of the Union as well as public interests in general.

- (5) National standardisation bodies play an essential role in the standardisation system, both, at the Union level, in accordance with Regulation (EU) No 1025/2012, and at the level of Member States. National standardisation bodies are therefore best placed to make sure that the interests, policy objectives and values of the Union as well as public interests in general are duly taken into account in European standardisation organisations. It is therefore necessary to strengthen their role in decision-making bodies of the European standardisation organisations when those bodies take decisions concerning European standards and European standardisation deliverables requested by the Commission under Article 10(1) of Regulation (EU) No 1025/2012.
- (6) The decision-making bodies of the European standardisation organisations are open to participation not only by national standardisation bodies, but also by national standardisation organisations of acceding countries, candidate countries and potential candidates to the Union, among others. In order to avoid excluding those organisations from participation in the work of decision-making bodies concerned, it is only necessary to provide that the decisions in those bodies concerning European standards and European standardisation deliverables requested under Article 10(1) of Regulation (EU) No 1025/2012 be taken exclusively by representatives of national standardisation bodies, without imposing any other requirements on the work of the decision-making bodies of the European standardisation organisations.
- (7) In order for the requirement for decisions in the decision-making bodies of European standardisation organisations concerning European standards and European standardisation deliverables requested by the Commission under Article 10(1) of Regulation (EU) No 1025/2012 to be taken exclusively by representatives of national standardisation bodies to be effective, it is necessary to provide that the Commission may only make such requests to a European standardisation organisation that complies with that requirement.
- (8) Regulation (EU) No 1025/2012 should therefore be amended accordingly.
- (9) In order to allow the European standardisation organisations to adapt, where necessary, their internal rules of procedure to the requirements of this Regulation, its application should be deferred,

HAVE ADOPTED THIS REGULATION:

Article 1

Article 10 of Regulation (EU) No 1025/2012 is amended as follows:

- (1) in paragraph 1, the first sentence is replaced by the following:

‘The Commission may within the limitations of the competences laid down in the Treaties, request that one or several European standardisation organisations draft a European standard or European standardisation deliverable within a set deadline, provided that the European standardisation organisation concerned complies with paragraph 2a.’;

- (2) the following paragraph 2a is inserted:

‘2a. Each European standardisation organisation shall ensure that the following decisions concerning European standards and European standardisation deliverables referred to in paragraph 1 are taken exclusively by representatives of the national standardisation bodies within the competent decision-making body of that organisation:

- (a) decisions on the acceptance, refusal and execution of standardisation requests;
- (b) decisions on the acceptance of new work items;
- (c) decisions on the adoption, revision and withdrawal of European standards or European standardisation deliverables.’.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from ... [OP: please insert the date – 6 months from the date of entry into force of this Regulation].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President