



EUROPEAN UNION

THE EUROPEAN PARLIAMENT

THE COUNCIL

Strasbourg, 14 December 2022
(OR. en)

2022/0021(COD)
LEX 2209

PE-CONS 58/1/22
REV 1

COMPET 801
MI 750
IND 414
RECH 548
ENT 143
MAP 34
TELECOM 411
CODEC 1544

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AMENDING
REGULATION (EU) NO 1025/2012 AS REGARDS DECISIONS OF EUROPEAN
STANDARDISATION ORGANISATIONS CONCERNING EUROPEAN STANDARDS AND
EUROPEAN STANDARDISATION DELIVERABLES

REGULATION (EU) 2022/...
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 14 December 2022

amending Regulation (EU) No 1025/2012

as regards 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 Committee¹,

Acting in accordance with the ordinary legislative procedure²,

¹ OJ C 323, 26.8.2022, p. 43.

² Position of the European Parliament of 22 November 2022 (not yet published in the Official Journal) and decision of the Council of 8 December 2022.

Whereas:

- (1) Regulation (EU) No 1025/2012 of the European Parliament and of the Council¹ 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 more European standardisation organisations to draft a European standard or European standardisation deliverable.
- (3) European standards and European standardisation deliverables play an important role in the internal market and consumer protection. Standards not only determine the technical aspects of products and services, but they also play an important role for workers, consumers and the environment. For example, harmonised standards can be used to confer a presumption that products to be made available on the market are in conformity with the essential requirements laid down in the relevant Union harmonisation legislation for those products, while ensuring the quality and safety of products and services for consumers and protecting the environment.

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, 14.11.2012, p. 12).

- (4) In the past, practices in the European standardisation organisations as regards their internal governance and decision-making procedures have changed. As a result of those changes, the European standardisation organisations have increased their cooperation with international and European stakeholders. Such cooperation is welcome as it contributes to a transparent, open and impartial standardisation process built on consensus. Nevertheless, when European standardisation organisations execute standardisation requests in support of Union legislation and policies, it is essential that their internal decisions take into account the interests, policy objectives and values of the Union, as well as public interests in general.
- (5) In line with Articles 5 and 6 of Regulation (EU) No 1025/2012, sound procedures and a balanced representation of relevant stakeholders' interests, including those stakeholders representing inter alia SMEs and environmental, social and consumer interests, are essential, and therefore should be ensured. The views of, and the input from, all relevant stakeholders should be taken into account in European standardisation organisations. Furthermore, the views expressed in the national consultations conducted by national standardisation bodies should be taken into account when taking decisions on European standards and European standardisation deliverables requested under Article 10(1) of Regulation (EU) No 1025/2012.

- (6) National standardisation bodies play an essential role in the standardisation system, both at Union level, in accordance with Regulation (EU) No 1025/2012, and at Member State level. National standardisation bodies are therefore best placed to ensure 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 the 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, without affecting the important role played by the broader stakeholder base in preparing effective standards that respond to public interest and market needs.

- (7) The decision-making bodies of the European standardisation organisations are open for participation not only by national standardisation bodies, but also, inter alia, by national standardisation organisations of acceding countries, candidate countries and other countries which have formally become members of the European standardisation organisations in question and have concluded an agreement with the Union to ensure regulatory convergence. In order to avoid excluding those organisations from participating in the work of the 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. Participation by the national standardisation organisations of third countries in the work of the European standardisation organisations should not prevent the adoption of any decision concerning European standards and European standardisation deliverables requested by the Commission where such decision has the support of the national standardisation bodies from Member States and EEA countries only.

- (8) In order for the requirement that 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 be taken exclusively by representatives of national standardisations bodies to be effective, it is necessary to provide that the Commission should only make such requests to a European standardisation organisation that complies with that requirement.
- (9) Standardisation procedures entail decisions that require specific work streams, which should be deemed to constitute separate work items. Such work items are initiated in order either to develop a new, or to revise, merge, amend or correct an existing European standard or European standardisation deliverable.
- (10) Regulation (EU) No 1025/2012 should therefore be amended accordingly.
- (11) In order to allow the European standardisation organisations to adapt, where necessary, their internal rules of procedure to comply with 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) paragraph 1 is replaced by the following:

- ‘1. The Commission may, within the limitations of the competences laid down in the Treaties, request that one or more 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. European standards and European standardisation deliverables shall be market-driven, take into account the public interest as well as the policy objectives clearly stated in the Commission’s request and be based on consensus. The Commission shall determine the requirements as to the content to be met by the requested document and a deadline for its adoption.’;

(2) the following paragraph is inserted:

‘2a. Without prejudice to other advisory opinions, 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 and refusal of standardisation requests;
- (b) decisions on the acceptance of new work items that are needed for the fulfilment of the standardisation request; and
- (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 ... [6 months after 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 Strasbourg,

For the European Parliament
The President

For the Council
The President