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 (Text with EEA relevance)

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

(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 Committee[(1)],

Acting in accordance with the ordinary legislative procedure[(2)],

Whereas:

(1) The primary objective of standardisation is the definition of voluntary technical or quality specifications with which current or future products, production processes or services may comply. Standardisation can cover various issues, such as standardisation of different grades or sizes of a particular product or technical specifications in product or services markets where compatibility and interoperability with other products or systems are essential.

(2) 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 founding

principles'). In accordance with the founding principles, it is important that all relevant interested parties, including public authorities and small and medium-sized enterprises (SMEs), are appropriately involved in the national and European standardisation process. National standardisation bodies should also encourage and facilitate the participation of stakeholders.

(3) European standardisation also helps to boost the competitiveness of enterprises by facilitating in particular the free movement of goods and services, network interoperability, means of communication, technological development and innovation. European standardisation reinforces the global competitiveness of European industry especially when established in coordination with the international standardisation bodies, namely the International Organisation for Standardisation (ISO), the International Electrotechnical Commission (IEC) and the International Telecommunication Union (ITU). Standards produce significant positive economic effects, for example by promoting economic interpenetration on the internal market and encouraging the development of new and improved products or markets and improved supply conditions. Standards thus normally increase competition and lower output and sales costs, benefiting economies as a whole and consumers in particular. Standards may maintain and enhance quality, provide information and ensure interoperability and compatibility, thereby increasing safety and value for consumers.

(4) European standards are adopted by the European standardisation organisations, namely CEN, Cenelec and ETSI.

(5) European standards play a very important role within the internal market, for instance through the use of harmonised standards in the presumption of conformity of products to be made available on the market with the essential requirements relating to those products laid down in the relevant Union harmonisation legislation. Those requirements should be precisely defined in order to avoid misinterpretation on the part of the European standardisation organisations.

(6) Standardisation plays an increasingly important role in international trade and the opening-up of markets. The Union should seek to promote cooperation between European standardisation organisations and international standardisation bodies. The Union should also promote bilateral approaches with third countries to coordinate standardisation efforts and promote European standards, for instance when negotiating agreements or by seconding standardisation experts to third countries. Furthermore the Union should encourage contact between European standardisation organisations and private forums and consortia, while maintaining the primacy of European standardisation.

(7) European standardisation is governed by a specific legal framework consisting of three different legal acts, namely Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services[(3)], Decision No 1673/2006/EC of the European Parliament and of the Council of 24 October 2006 on the financing of European standardisation[(4)] and Council Decision 87/95/EEC of 22 December 1986 on standardisation in the field of information

technology and telecommunications[5]. However, the current legal framework is no longer up to date with developments in European standardisation over recent decades. Therefore, the current legal framework should be simplified and adapted in order to cover new aspects of standardisation to reflect those latest developments and future challenges in European standardisation. That relates in particular to the increased development of standards for services and the evolution of standardisation deliverables other than formal standards.

(8) The European Parliament's Resolution of 21 October 2010 on the future of European standardisation[6], as well as the report of the Expert Panel for the Review of the European Standardization System (Express) of February 2010 entitled 'Standardization for a competitive and innovative Europe: a vision for 2020', have set out an important number of strategic recommendations regarding the review of the European standardisation system.

(9) In order to ensure the effectiveness of standards and standardisation as policy tools for the Union, it is necessary to have an effective and efficient standardisation system which provides a flexible and transparent platform for consensus building between all participants and which is financially viable.

(10) Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market[7] establishes general provisions facilitating the exercise of the freedom of establishment for service providers and the free movement of services, while maintaining a high quality of services. It obliges the Member States to encourage, in cooperation with the Commission, the development of voluntary European standards with the aim of facilitating compatibility between services supplied by providers in different Member States, the provision of information to the recipient and the quality of service provision. However, Directive 98/34/EC only applies to standards for products while standards for services are not expressly covered by it. Furthermore, the delineation between services and goods is becoming less relevant in the reality of the internal market. In practice, it is not always possible to clearly distinguish standards for products from standards for services. Many standards for products have a service component while standards for services often also partly relate to products. Thus, it is necessary to adapt the current legal framework to these new circumstances by extending its scope to standards for services.

(11) Like other standards, standards for services are voluntary and should be market-driven, whereby the needs of the economic operators and stakeholders directly or indirectly affected by such standards prevail, and should take into account the public interest and be based on the founding principles, including consensus. They should primarily focus on services linked to products and processes.

(12) The legal framework allowing the Commission to request one or several European standardisation organisations to draft a European standard or European standardisation deliverable for services should be applied while fully respecting the distribution of competences between the Union and the Member States as laid down in the Treaties. This concerns in particular Articles 14, 151, 152, 153, 165, 166 and 168 of the Treaty on the Functioning of the European Union (TFEU) and Protocol (No 26) on Services

of General Interest annexed to the Treaty on European Union (TEU) and to the TFEU in accordance with which it remains the exclusive competence of the Member States to define the fundamental principles of their social security, vocational training and health systems and to shape the framework conditions for the management, financing, organisation and delivery of the services supplied within those systems, including - without prejudice to Article 168(4) TFEU and to Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications[(8)] - the definition of requirements, quality and safety standards applicable to them. The Commission should not, by means of such a request, affect the right to negotiate, conclude and enforce collective agreements and to take industrial action in accordance with national law and practices which respect Union law.

(13) The European standardisation organisations are subject to competition law to the extent that they can be considered to be an undertaking or an association of undertakings within the meaning of Articles 101 and 102 TFEU.

(14) Within the Union, national standards are adopted by national standardisation bodies which could lead to conflicting standards and technical impediments in the internal market. Therefore, it is necessary for the internal market and for the effectiveness of standardisation within the Union to confirm the existing regular exchange of information between the national standardisation bodies, the European standardisation organisations and the Commission, about their current and future standardisation activities as well as the standstill principle applicable to the national standardisation bodies within the framework of the European standardisation organisations which provides for the withdrawal of national standards after the publication of a new European standard. The national standardisation bodies and European standardisation organisations should also observe the provisions on exchange of information in Annex 3 to the Agreement on Technical Barriers to Trade[(9)].

(15) The Member States' obligation to notify the Commission of their national standardisation bodies should not require the adoption of a specific national legislation for the purposes of recognition of those bodies.

(16) The regular exchange of information between the national standardisation bodies, the European standardisation organisations and the Commission should not prevent national standardisation bodies from complying with other obligations and commitments, and in particular with Annex 3 to the Agreement on Technical Barriers to Trade.

(17) The representation of societal interests and societal stakeholders in European standardisation activities refers to the activities of organisations and parties representing interests of greater societal relevance, for instance environmental, consumer interests or employee interests. However, the representation of social interests and social stakeholders in European standardisation activities refers particularly to the activities of organisations and parties representing employees and workers' basic rights, for instance trade unions.

(18) In order to speed up the decision-making process, national standardisation bodies and European standardisation organisations should facilitate accessible information on

their activities through the promotion of the use of information and communication technologies (ICT) in their respective standardisation systems, for example by providing to all relevant stakeholders an easy-to-use online consultation mechanism for the submission of comments on draft standards and by organising virtual meetings, including by means of web conferencing or video conferencing, of technical committees.

(19) Standards can contribute to helping Union policy address the major societal challenges such as climate change, sustainable resource use, innovation, ageing population, integration of people with disabilities, consumer protection, workers' safety and working conditions. By driving the development of European or international standards for goods and technologies in the expanding markets in those areas, the Union could create a competitive advantage for its enterprises and facilitate trade, in particular for SMEs, which account for a large part of European enterprises.

(20) Standards are important tools for the competitiveness of undertakings and especially SMEs, whose participation in the standardisation process is important for technological progress in the Union. Therefore it is necessary that the standardisation framework encourage SMEs to actively participate in and provide their innovative technology solutions to standardisation efforts. This includes improving their participation at national level where they can be more effective due to lower costs and lack of linguistic barriers. Consequently this Regulation should improve representation and participation of SMEs in both national and European technical committees and should facilitate their effective access to and awareness of standards.

(21) European standards are of vital interest for the competitiveness of SMEs which, however, are in some cases under-represented in European standardisation activities. Thus, this Regulation should encourage and facilitate appropriate representation and participation of SMEs in the European standardisation process by an entity that is effectively in contact with, and duly representative of, SMEs and organisations representing SMEs at national level.

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

(23) The obligation of the European standardisation organisations to encourage and facilitate representation and effective participation of all relevant stakeholders does not entail any voting rights for these stakeholders unless such voting rights are prescribed by the internal rules of procedure of the European standardisation organisations.

(24) The European standardisation system should also fully take into account the United Nations Convention on the Rights of Persons with Disabilities[10]. It is therefore important that organisations representing the interests of consumers sufficiently represent and include the interests of people with disabilities. In addition, the