

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<sup>(1)</sup>,

Acting in accordance with the ordinary legislative procedure<sup>(2)</sup>,

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

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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<sup>(3)</sup>, Decision No 1673/2006/EC of the European Parliament and of the Council of 24 October 2006 on the financing of European standardisation<sup>(4)</sup> and Council Decision 87/95/EEC of 22 December 1986 on standardisation in the field of information

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technology and telecommunications<sup>(5)</sup>. 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<sup>(6)</sup>, 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<sup>(7)</sup> 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

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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<sup>(8)</sup> - 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<sup>(9)</sup>.
- (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

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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<sup>(10)</sup>. It is therefore important that organisations representing the interests of consumers sufficiently represent and include the interests of people with disabilities. In addition, the

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participation of people with disabilities in the standardisation process should be facilitated by all available means.

- (25) Due to the importance of standardisation as a tool to support Union legislation and policies and in order to avoid *ex-post* objections to and modifications of harmonised standards, it is important that public authorities participate in standardisation at all stages of the development of those standards where they may be involved and especially in the areas covered by Union harmonisation legislation for products.
- (26) Standards should take into account environmental impacts throughout the life cycle of products and services. Important and publicly available tools for evaluating such impacts throughout the life cycle have been developed by the Commission's Joint Research Centre (JRC). Thus, this Regulation should ensure that the JRC can play an active role in the European standardisation system.
- (27) The viability of the cooperation between the Commission and the European standardisation system depends on careful planning of future requests for the development of standards. This planning could be improved, in particular through the input of interested parties, including national market surveillance authorities, by introducing mechanisms for collecting opinions and facilitating the exchange of information among all interested parties. Since Directive 98/34/EC already provides for the possibility to request the European standardisation organisations to develop European standards, it is appropriate to put in place a better and more transparent planning in an annual work programme which should contain an overview of all requests for standards which the Commission intends to submit to European standardisation organisations. It is necessary to ensure a high level of cooperation between the European standardisation organisations and the European stakeholder organisations receiving Union financing in accordance with this Regulation and the Commission in the establishment of its annual Union work programme for standardisation and in the preparation of requests for standards in order to analyse the market relevance of the proposed subject matter and the policy objectives set by the legislator, and to allow the European standardisation organisations to respond more quickly to the requested standardisation activities.
- (28) Before bringing a matter regarding requests for European standards or European standardisation deliverables, or objections to a harmonised standard before the committee set up by this Regulation, the Commission should consult experts of the Member States, for instance through the involvement of committees set up by the corresponding Union legislation or by other forms of consultation of sectoral experts, where such committees do not exist.
- (29) Several directives harmonising the conditions for the marketing of products specify that the Commission may request the adoption, by the European standardisation organisations, of harmonised standards on the basis of which conformity with the applicable essential requirements is presumed. However, many of those directives contain a wide variety of provisions on objections to these standards when the latter do not, or do not entirely, cover all applicable requirements. Diverging provisions which lead to uncertainty for economic operators and European standardisation organisations

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are in particular contained in Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment<sup>(11)</sup>, Council Directive 93/15/EEC of 5 April 1993 on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil uses<sup>(12)</sup>, Directive 94/9/EC of the European Parliament and the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres<sup>(13)</sup>, Directive 94/25/EC of the European Parliament and of the Council of 16 June 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft<sup>(14)</sup>, European Parliament and Council Directive 95/16/EC of 29 June 1995 on the approximation of the laws of the Member States relating to lifts<sup>(15)</sup>, Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment<sup>(16)</sup>, Directive 2004/22/EC of the European Parliament and of the Council of 31 March 2004 on measuring instruments<sup>(17)</sup>, Directive 2007/23/EC of the European Parliament and of the Council of 23 May 2007 on the placing on the market of pyrotechnic articles<sup>(18)</sup>, Directive 2009/23/EC of the European Parliament and of the Council of 23 April 2009 on non-automatic weighing instruments<sup>(19)</sup> and Directive 2009/105/EC of the European Parliament and of the Council of 16 September 2009 relating to simple pressure vessels<sup>(20)</sup>. Therefore, it is necessary to include in this Regulation the uniform procedure provided for in Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products<sup>(21)</sup>, delete the relevant provisions in those Directives and extend to the European Parliament the right to object to a harmonised standard in accordance with this Regulation.

- (30) Public authorities should make best use of the full range of relevant technical specifications when procuring hardware, software and information technology services, for example by selecting technical specifications which can be implemented by all interested suppliers, allowing for more competition and reduced risk of lock-in. Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors<sup>(22)</sup>, Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts<sup>(23)</sup>, Directive 2009/81/EC of the European Parliament and of the Council of 13 July 2009 on the coordination of procedures for the award of certain works contracts, supply contracts and service contracts by contracting authorities or entities in the fields of defence and security<sup>(24)</sup> and Commission Regulation (EC, Euratom) No 2342/2002 of 23 December 2002 laying down detailed rules for the implementation of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities<sup>(25)</sup> specify that technical specifications in public procurement should be formulated by reference to national standards transposing European standards, European technical approvals, common technical specifications, international standards, other technical reference systems established by the European standardisation organisations or - when these do not exist

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- to national standards, national technical approvals or national technical specifications relating to the design, calculation and execution of the works and use of the products, or equivalent. ICT technical specifications, however, are often developed by other standard developing organisations and do not fall in any of the categories of standards and approvals laid down in Directives 2004/17/EC, 2004/18/EC or 2009/81/EC or Regulation (EC, Euratom) No 2342/2002. Therefore, it is necessary to provide for the possibility that technical specifications for public procurement could refer to ICT technical specifications, in order to respond to the fast evolution in the field of ICT, facilitate the provision of cross-border services, encourage competition and promote interoperability and innovation.

- (31) Technical specifications not adopted by European standardisation organisations do not hold an equivalent status to European standards. Some ICT technical specifications are not developed in accordance with the founding principles. Therefore, this Regulation should lay down a procedure for the identification of ICT technical specifications that could be referenced in public procurement, involving a broad consultation of a large spectrum of stakeholders, including the European standardisation organisations, enterprises and public authorities. This Regulation should also lay down requirements, in the form of a list of criteria, for such technical specifications and their associated development processes. The requirements for the identification of ICT technical specifications should ensure that public policy objectives and societal needs are respected, and should be based on the founding principles.
- (32) In order to further innovation and competition, the identification of a particular technical specification should not disqualify a competing technical specification from being identified in accordance with the provisions of this Regulation. Any identification should be subject to the criteria being fulfilled and to the technical specification having achieved a significant level of market acceptance.
- (33) The identified ICT technical specifications could contribute to the implementation of Decision No 922/2009/EC of the European Parliament and of the Council of 16 September 2009 on interoperability solutions for European public administrations (ISA)<sup>(26)</sup> which establishes, for the period 2010-2015, a programme on interoperability solutions for European public administrations and institutions and bodies of the Union, providing common and shared solutions facilitating interoperability.
- (34) Situations may arise in the field of ICT where it is appropriate to encourage the use of, or require compliance, with relevant standards at Union level in order to ensure interoperability in the single market and to improve freedom of choice for users. In other circumstances, it may also happen that specified European standards no longer meet consumers' needs or are hampering technological development. For these reasons, Directive 2002/21/EC of the European Parliament and of the Council of 7 March 2002 on a common regulatory framework for electronic communications networks and services<sup>(27)</sup> enables the Commission, where necessary, to request European standardisation organisations to draw up standards, to establish and publish in the *Official Journal of the European Union* a list of standards or specifications with the



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view to encourage their use, or to make their implementation compulsory, or to remove standards or specifications from that list.

- (35) This Regulation should not prevent European standardisation organisations from continuing to develop standards in the field of ICT and to increase their cooperation with other standard developing bodies, especially in the field of ICT, in order to ensure coherence and avoid fragmentation or duplication during implementation of standards and specifications.
- (36) The procedure for identification of ICT technical specifications provided for in this Regulation should not undermine the coherence of the European standardisation system. Therefore, this Regulation should also lay down the conditions under which it can be considered that a technical specification does not conflict with other European standards.
- (37) Before identifying ICT technical specifications which may be eligible for referencing in public procurement, the Multi Stakeholder Platform established by the Commission Decision of 28 November 2011<sup>(28)</sup> should be used as a forum for consultation of European and national stakeholders, European standardisation organisations and Member States in order to ensure legitimacy of the process.
- (38) Decision No 1673/2006/EC establishes the rules concerning the contribution of the Union to the financing of European standardisation in order to ensure that European standards and other European standardisation deliverables are developed and revised in support of the objectives, legislation and policies of the Union. It is appropriate, for the purpose of administrative and budgetary simplification, to incorporate the provisions of that Decision into this Regulation and to use wherever possible the least burdensome procedures.
- (39) In view of the very broad field of involvement of European standardisation in support of Union legislation and policies and the different types of standardisation activity, it is necessary to provide for different financing arrangements. This mainly concerns grants without calls for proposals to the European standardisation organisations and national standardisation bodies in accordance with the second subparagraph of Article 110(1) of Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities<sup>(29)</sup> and point (d) of Article 168(1) of Regulation (EC, Euratom) No 2342/2002. Furthermore, the same provisions should apply to those bodies which, whilst not recognised as European standardisation organisations in this Regulation, have been mandated in a basic act and have been entrusted with carrying out preliminary work in support of European standardisation in cooperation with the European standardisation organisations.
- (40) Inasmuch as European standardisation organisations provide ongoing support for Union activities, they should have effective and efficient central secretariats. The Commission should therefore be allowed to provide grants to those organisations that are pursuing an objective of general European interest without applying, in the case of operating grants, the principle of annual reduction provided for in Article 113(2) of Regulation (EC, Euratom) No 1605/2002.

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- (41) Decision No 1639/2006/EC of the European Parliament and of the Council of 24 October 2006 establishing a Competitiveness and Innovation Framework Programme (2007 to 2013)<sup>(30)</sup>, Decision No 1926/2006/EC of the European Parliament and of the Council of 18 December 2006 establishing a programme of Community action in the field of consumer policy (2007-2013)<sup>(31)</sup> and Regulation (EC) No 614/2007 of the European Parliament and of the Council of 23 May 2007 concerning the Financial Instrument for the Environment (LIFE+)<sup>(32)</sup> already provide for the possibility of financial support of European organisations representing SMEs, consumers and environmental interests in standardisation, while specific grants are paid to European organisations representing social interests in standardisation. The financing under Decision No 1639/2006/EC, Decision No 1926/2006/EC and Regulation (EC) No 614/2007 will end on 31 December 2013. It is essential for the development of European standardisation to continue fostering and encouraging the active participation of European organisations representing SMEs, consumers and environmental and social interests. Such organisations pursue an aim of general European interest and constitute, by virtue of the specific mandate that national non-profit organisations have given them, a European network representing non-profit organisations active in the Member States and promoting principles and policies consistent with the objectives of the Treaties. Because of the context in which they operate and their statutory objectives, European organisations representing SMEs, consumers and environmental and social interests in European standardisation have a permanent role which is essential for Union objectives and policies. Therefore, the Commission should be in a position to continue providing grants to those organisations without applying, in the case of operating grants, the principle of annual reduction provided for in Article 113(2) of Regulation (EC, Euratom) No 1605/2002.
- (42) The financing of standardisation activities should also be capable of covering preliminary or ancillary activities in connection with the establishment of European standards or European standardisation deliverables for products and for services. This is necessary primarily for work involving research, the preparation of preliminary documents for legislation, inter-laboratory tests and the validation or evaluation of standards. The promotion of standardisation at European and international level should also continue through programmes relating to the technical assistance to, and cooperation with, third countries. With a view to improving market access and boosting the competitiveness of enterprises in the Union, it should be possible to give grants to other bodies through calls for proposals or, where necessary, by awarding contracts.
- (43) Union financing should seek to establish European standards or European standardisation deliverables for products and for services, to facilitate their use by enterprises through the enhanced support for their translation into the various official Union languages, in order to allow SMEs to fully benefit from the understanding and application of the European standards, to strengthen the cohesion of the European standardisation system and to ensure fair and transparent access to European standards for all market players throughout the Union. This is especially important in cases where the use of standards enables compliance with relevant Union legislation.

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- (44) In order to ensure the effective application of this Regulation, there should be the possibility of using the requisite expertise, particularly with regard to auditing and financial management, as well as administrative support resources capable of facilitating implementation, and of evaluating on a regular basis the relevance of the activities receiving Union financing in order to ensure their usefulness and impact.
- (45) Appropriate measures should also be taken to avoid fraud and irregularities and to recover funds unduly paid in accordance with Council Regulations (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities financial interests<sup>(33)</sup> and (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities<sup>(34)</sup> and Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF)<sup>(35)</sup>.
- (46) 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 acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amendments to the Annexes to this Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (47) The committee set up by this Regulation should assist the Commission in all matters related to the implementation of this Regulation, having due regard for the views of sectoral experts.
- (48) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers<sup>(36)</sup>.
- (49) The advisory procedure should be used for the adoption of implementing acts with respect to the objections to harmonised standards and where the references to the harmonised standard concerned have not yet been published in the *Official Journal of the European Union*, given that the relevant standard has not yet led to the presumption of conformity with the essential requirements set out in the applicable Union harmonisation legislation.
- (50) The examination procedure should be used for each standardisation request submitted to European standardisation organisations and the adoption of implementing acts with respect to the objections to harmonised standards and where the references to the harmonised standard concerned have already been published in the *Official Journal*

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*of the European Union*, given that such decision could have consequences on the presumption of conformity with the applicable essential requirements.

- (51) In order to achieve the main objectives of this Regulation and to facilitate speedy decision-making procedures as well as reducing the overall development time for standards, use should be made as far as possible of the procedural measures provided for in Regulation (EU) No 182/2011, which enables the chair of the relevant committee to lay down a time limit within which the committee should deliver its opinion, according to the urgency of the matter. Moreover, where justified, it should be possible for the opinion of the committee to be obtained by written procedure, and silence on the part of the committee member should be regarded as tacit agreement.
- (52) Since the objectives of this Regulation, namely to ensure 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, the establishment of European standards and European standardisation deliverables for products and for services in support of Union legislation and policies, the identification of ICT technical specifications eligible for referencing, the financing of European standardisation and stakeholder participation in European standardisation cannot be sufficiently achieved by the Member States and can, therefore, by reason of their effect, be better achieved at the Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 TEU. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (53) Directives 89/686/EEC, 93/15/EEC, 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 should therefore be amended accordingly.
- (54) Decision No 1673/2006/EC and Decision 87/95/EEC should be repealed,

HAVE ADOPTED THIS REGULATION:

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- (1) [OJ C 376, 22.12.2011, p. 69.](#)
- (2) Position of the European Parliament of 11 September 2012 (not yet published in the Official Journal) and decision of the Council of 4 October 2012.
- (3) [OJ L 204, 21.7.1998, p. 37.](#)
- (4) [OJ L 315, 15.11.2006, p. 9.](#)
- (5) [OJ L 36, 7.2.1987, p. 31.](#)
- (6) [OJ C 70 E, 8.3.2012, p. 56.](#)
- (7) [OJ L 376, 27.12.2006, p. 36.](#)
- (8) [OJ L 255, 30.9.2005, p. 22.](#)
- (9) Approved by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994) ([OJ L 336, 23.12.1994, p. 1.](#))
- (10) Approved by Council Decision 2010/48/EC of 26 November 2009 concerning the conclusion, by the European Community, of the United Nations Convention on the Rights of Persons with Disabilities ([OJ L 23, 27.1.2010, p. 35.](#))
- (11) [OJ L 399, 30.12.1989, p. 18.](#)
- (12) [OJ L 121, 15.5.1993, p. 20.](#)
- (13) [OJ L 100, 19.4.1994, p. 1.](#)
- (14) [OJ L 164, 30.6.1994, p. 15.](#)
- (15) [OJ L 213, 7.9.1995, p. 1.](#)
- (16) [OJ L 181, 9.7.1997, p. 1.](#)
- (17) [OJ L 135, 30.4.2004, p. 1.](#)
- (18) [OJ L 154, 14.6.2007, p. 1.](#)
- (19) [OJ L 122, 16.5.2009, p. 6.](#)
- (20) [OJ L 264, 8.10.2009, p. 12.](#)
- (21) [OJ L 218, 13.8.2008, p. 82.](#)
- (22) [OJ L 134, 30.4.2004, p. 1.](#)
- (23) [OJ L 134, 30.4.2004, p. 114.](#)
- (24) [OJ L 216, 20.8.2009, p. 76.](#)
- (25) [OJ L 357, 31.12.2002, p. 1.](#)
- (26) [OJ L 260, 3.10.2009, p. 20.](#)
- (27) [OJ L 108, 24.4.2002, p. 33.](#)
- (28) [OJ C 349, 30.11.2011, p. 4.](#)
- (29) [OJ L 248, 16.9.2002, p. 1.](#)
- (30) [OJ L 310, 9.11.2006, p. 15.](#)
- (31) [OJ L 404, 30.12.2006, p. 39.](#)
- (32) [OJ L 149, 9.6.2007, p. 1.](#)
- (33) [OJ L 312, 23.12.1995, p. 1.](#)
- (34) [OJ L 292, 15.11.1996, p. 2.](#)
- (35) [OJ L 136, 31.5.1999, p. 1.](#)
- (36) [OJ L 55, 28.2.2011, p. 13.](#)

**Status:**

Point in time view as at 31/01/2020.

**Changes to legislation:**

There are currently no known outstanding effects for the Regulation (EU) No 1025/2012 of the European Parliament and of the Council, Introductory Text.