EUROPEAN
COMMISSION

Brussels, 28.10.2019
COM(2019) 486 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

The annual Union work programme for European standardisation for 2020

EN   **EN**

1   Introduction

The annual Union **work programme** for European standardisation[1] (work programme) for 2020 identifies priorities for European standardisation. It sets out the specific objectives and policies for European standards and standardisation deliverables in the coming period and lists the type of actions the Commission intends to take[2]. These actions on European standardisation are embedded in Union policies, such as the digital and single markets, energy efficiency & climate and international trade. Standards support these policies to ensure that European products and services are competitive worldwide and reflect state-of-the-art safety, security, health and environmental considerations.

The work programme also outlines the actions that the Commission intends to initiate during 2020 to improve the governance, inclusiveness and international impact of the European standardisation system (ESS).

The work programme has no budgetary impact over and above what is already set out in the Draft Budget 2020.

2   Priorities for European standardisation

Standards have an important economic impact, and companies and consumers in the single market feel their benefits every day. A well-functioning standardisation system helps Europe to safeguard its advantage as first mover and to keep pace with changes and opportunities created by market developments. At the same time, standards guarantee a high level of safety, health, consumer and environmental aspects to protect European citizens.

Standards play an enabling role by offering manufacturers a stable basis for investing in new technologies and the digitisation of manufacturing processes.

This section outlines requests for developing and/or revising harmonised[3] European standards in support of Union's legislation and reviews the Commission's broader strategic priorities for European standardisation. The Commission will closely monitor the work programmes of the European standardisation organisations to ensure that the requests discussed below are duly developed and the Commission's strategic priorities are considered.

2.1   *Harmonised European standards in support of EU legislation*

The European standardisation system is based on a public-private partnership between the Commission and the standardisation community. Its uniqueness lies in the use of harmonised European standards. These standards are developed (or revised as the case may be) on the basis of a request by the Commission to apply Union harmonisation legislation[4]. When

---

[1] Article 8 of Regulation (EU) No 1025/2012.
[2] For a more comprehensive list of actions, see the annex to this Communication.
[3] Not excluding European standards ensuring compliance with the general safety requirements under Directive 2001/95/EC on general product safety.
[4] see Article 10 of Regulation (EU) No 1025/2012.

adopted, the standards become part of Union law, and when used, they provide manufacturers across the single market with a presumption that their products are in conformity with the requirements of Union legislation.

This provides important legal certainty and stability to users of harmonised standards. It reduces costs for manufacturers, which is in turn important for investors, and allows small and medium-sized businesses to place products in compliance with Union legislation on the market without additional costs. It also increases the public responsibility of the regulators who must oversee these harmonised standards appropriately. In 2020, the Commission intends to request that harmonised standards supporting EU legislation be developed and/or revised in several key areas such as the protection of environment and the single market for goods.

The Commission will ask for the development of standards for the recycling and the reuse of plastic fishing gear[5]. These harmonised standards will support the implementation of Directive 2019/904 on the reduction of the impact of certain plastic products on the environment.

Pursuant to the objectives of the Regulation (EU) 2017/1369 on energy labelling and of the Directive 2009/125/EC on ecodesign requirements the Commission will propose the development of standards to measure the energy performance of electrical motors, water heaters washing machines and household washer-dryers. These standards will support the implementing legal acts[6] related with the specific product categories.

One of the key initiatives in this context will be the update by the European standardisation organisations of the current harmonised standards, which the Commission intends to request in order to reflect the requirements of Directive 2013/29/EU on pyrotechnic articles and the latest developments in technology[7]. This update will increase the safety of pyrotechnic articles and the quality of conformity assessments of such articles by aligning the existing standards in this field with current legislative and safety requirements and with the latest technologies.

In the medical area, in line with the requirements of the Basic Safety Standard, Council Directive 2013/59/Euratom, the Commission intends to request harmonised standards for the design, manufacturing, the installation, use and performance verification of radionuclide calibrators[8]. These standards will improve the dose optimisation process by verification of the administered activity to patients using radionuclide calibrators.

Further, the Commission intends to ask the European standardisation organisations to revise the harmonised standards used in support of Directive 2014/34/EU relating to equipment and protective systems intended for use in potentially explosive atmospheres in order to reflect the technological updates[9].

---

[5] see actions and measures related to fishing gear in European Strategy for Plastics in a Circular Economy - COM(2018) 28 final and action 13 in the annex to this Communication.
[6] see details in actions 1 to 3 in the annex to this Communication.
[7] see action 7 in the annex to this Communication.
[8] see action 8 in the annex to this Communication.
[9] see action 6 in the annex to this Communication.

The newly adopted Regulation (EU) 2019/1009 on fertilisers extends its scope from fertilisers made from mined or chemically produced, inorganic materials to fertilisers made from recycled or organic materials. Harmonisation of analytical test methods for verifying the conformity of fertilising products from secondary raw material will enable common inspection and testing practices for conformity to legal requirements, facilitating trade in the single market[10].

In the context of the Regulation(EC) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals the Commission intents to ask the European standardisation organisations for the development of migration limits of the restricted substances (polycyclic aromatic hydrocarbons) in rubber and plastic material used in consumer articles[11].

A common technical language is required for the appropriate functioning of the harmonisation system created in or by means of the construction products Regulation (EU) 305/2011. The Commission intends to ask for the development of a series of standards in this regard[12].

Given the impact of the conformity bodies in the internal market and in particular on SMEs it is important to ensure that accreditation and conformity assessment have the same stringency in all Member States. Therefore, the Commission will ask for the development of harmonised standards[13] in support of the accreditation Regulation (EC) 765/2008 and of the market surveillance Regulation (EC) 1221/2009.

Last but not least, harmonised standards will be needed to support the compliance with the accessibility requirements for products and services set by Directive (EU) 2019/882[14]. These standards will help to harmonise the approaches that manufacturers and service providers currently use to comply with requirements whenever they produce/provide products and services with specific accessibility features, thus enabling persons with disabilities to have better access to products and services in the internal market.

2.2 Strategic priorities for the European standardisation system

The Commission intends to continue its cooperation with its partners in the European standardisation system in strategically important fields to ensure that the standards developed support its broad policy priorities for a fully functioning single market.

Artificial intelligence (AI) will have a broad impact on the economy and the whole of society. In 2018 the Commission recognised the importance of AI for the single market in its Communication 'Artificial Intelligence for Europe'[15]. The Communication sets out a European initiative on AI as part of the digital single market and emphasises its importance for the Union's industries in the competitive global market. Standardisation helps to address the challenges this key technology brings, particularly in terms of safety, liability and ethical

---

[10] see action 5 in the annex to this Communication.
[11] see action 4 in the annex to this Communication.
[12] see action 9 in the annex to this Communication.
[13] See action 11 in the annex to this Communication.
[14] see action 12 in the annex to this Communication.
[15] COM(2018) 237.

considerations. Developing standards which reflect the European perspective for the operation of AI-based systems should be an important priority for the European standardisation organisations.

Standardisation is important for developing the Internet of things (IoT), as security, safety, reliability and interoperability are crucial in a world that revolves around smart devices. Hence, the European standardisation organisations should focus on developing standards to enhance security protocols, anticipate and reduce cyberattacks and ensure the interoperability of different IoT networks.

Protecting technologies from cyber-threats through cybersecurity is a precondition before they can be implemented and used. This is important because of the protection of privacy but also because of the protection of critical European infrastructure such as energy production plants and transmission and telecommunication networks. The 'EU Cybersecurity Act'[16] establishes a European cybersecurity certification framework for ICT products, services and processes. Standardisation plays an important role in the new framework. The Commission is therefore expecting close cooperation on cybersecurity matters between the European standardisation organisations and the EU Agency for Cybersecurity, ENISA[17] to help further complete the European single market, respond to the fast-changing and demanding realm of privacy and raise the level of cybersecurity in the EU in general.

The Commission has adopted a Recommendation on a 'European Electronic Health Record exchange format'[18]. The Recommendation supports the digital transformation of healthcare in the EU by seeking to unlock the flow of health data across borders and supporting Members States in their efforts to ensure that people can securely access and exchange their health data wherever they are in the EU. This technology will allow people to access their health data quickly and share it with healthcare professionals, for instance, when consulting a specialist or receiving emergency treatment in another EU country.

The European standardisation organisations should support the implementation of the recommended format for the exchange of European electronic health records by developing state-of-the-art standards to protect health data and ensure the security of network and information systems on which such electronic health record systems rely. This will help to avoid data breaches and minimise the risks of security incidents.

The Communication 'On the road to automated mobility: An EU strategy for mobility of the future'[19] was adopted in 2018, highlighting that connected and automated mobility is likely to transform the way people move and the way vehicles are used, sold and owned. It will also open up new areas for business development and pave the way for new mobility services in a changing energy market. Whether such a mobility transition is successful depends on the performance, affordability and sustainability of the new system. The role of standardisation is to support the interoperability and interconnectivity between the different subsystems, i.e. vehicle, road and energy systems. The European standardisation organisations should work closely with the automotive industry, the energy providers and the ICT sector to develop

---

[16] COM(2017) 477 final.
[17] European Union Agency for Network and Information Security.
[18] C(2019)800 of 6 February 2019.
[19] COM(2018) 283 final.

standards related to the interoperability of cooperative systems spanning all vehicle classes, across borders and brands, and supporting the standardisation of communication protocols for multi-brand platooning is particularly important.

Similarly, the development of standards for digitisation, automation and cybersecurity is crucial for the rail sector. Such standards[20] will facilitate the integration of the different rail subsystems in a multimodal transport system and will secure its potential weak points or components from unauthorised access.

The steel industry has achieved significant reductions in greenhouse gas emissions in the past decades by improving energy efficiency and deploying new technologies. However, the current processes have reached their limits and there is a need to develop new technologies to reduce greenhouse gas emissions further in order to reach the targets of the 2030 climate & energy framework and the 2050 long-term strategy. Taking due account of standards at the research stage of new innovative production processes will help to ensure a smooth transition to a low-carbon economy. In addition, European standards can support a harmonised implementation of innovative steel production technologies in the single market.

The European defence industrial development programme (EDIDP)[21] aimed at supporting the competitiveness and innovation capacity of the Union's defence industry. It is a pilot programme of the European Defence Fund (EDF), which will provide financial incentives for Member States to engage in joint research on defence equipment and technologies in the EU under the next multiannual financial framework (2021-2027). As part of the European Defence Action Plan, EDIDP is intended to provide the European defence industry with financial support during the development phase of new products and technologies in selected areas. The EDIDP work programme for 2020-2021 was adopted on 19 March 2019 and the calls for proposals for 2019 were published on 4 April 2019. Increased cooperation between the Member States on defence creates economies of scale by reducing the cost of producing and purchasing military material. Standards should support this cooperation by offering a common nomenclature for designing, developing and procuring the relevant material.

3   International cooperation

The meeting of July 2018 between Presidents Juncker and Trump and the ensuing Joint Statement[22] that explicitly mentions cooperation on standards as a priority to increase trade and growth in both regions led to the establishment of an EU-US Executive Working Group (EWG), where cooperation in standardisation is among the priority subjects discussed.

The 21st EU-China Summit of 9 April 2019[23] gave new impetus to the relations between the two trade partners. Standardisation is now closely monitored as a key indicator for the opening of China's market, in particular the aspects of an access of EU companies/subsidiaries to Chinese standardisation processes and the rate of China's adoption of international standards. To more effectively promote European standards, a systematic

---

[20] see action 10 in the annex to this Communication.
[21] Regulation (EU) 2018/1092.
[22] STATEMENT/18/4687.
[23] https://www.consilium.europa.eu/media/39020/euchina-joint-statement-9april2019.pdf.

mapping of the Chinese standardisation landscape will be developed. In this context, the EU-China Working Group on 'Standardisation' represents an important platform for dialogue and cooperation.

Standardisation is always an essential part of the Technical Barriers to Trade (TBT) chapter of every free trade agreement (FTA) negotiated and will remain so in the future. The EU-Singapore FTA enters into force early 2020, and the negotiations on FTAs with Australia, New Zealand, Indonesia and Mercosur will continue, underlying the EU's openness to the global arena in its pursuit to boost European competitiveness, jobs, and growth.

4   Public-private partnership

4.1   Governance

A timely delivery of high-quality standards remains the Commission's priority. In that regard, harmonised standards should receive specific attention in order to meet the recent jurisprudence of the Court of Justice. As part of European law, harmonised standards must fulfill the defined criteria of quality in terms of both form and technical substance.

In particular, the quality of the harmonised standards, which provide for the legal effect of presumption of conformity, require specific attention from both sides. Against this background, on 22 November 2018, the Commission adopted the Communication on 'Harmonised standards: Enhancing transparency and legal certainty for a fully functioning Single Market'[24]. The Communication provides an overview of the functioning of the European standardisation system and defines specific actions that the Commission will undertake to support the implementation of the European Standardisation Regulation[25].

In this respect, the Commission, after consultation, will also issue a guidance document on the practical aspects of implementing the European Standardisation Regulation, paying particular attention to the division of roles and responsibilities in the process of developing harmonised standards and paying close attention to the efficiency, inclusiveness and speed of standardisation processes. In that guidance document, the Commission will take into account the recent jurisprudence and particular conditions required to comply with the European Standardisation Regulation and improve the standardisation process in practice. Following these steps, the Commission will continue to reassess its procedures in discussion with all the stakeholders involved.

The Commission recommends that the European standardisation organisations take due account of the guidance document, particularly with regard to the timely provision of all documents needed to assess draft harmonised standards allowing for a smooth progress of the assessment process.

---

[24] COM(2018) 764.
[25] Regulation (EU) No 1025/2012.

The Commission will continue to support the governance process through all relevant means available to it, namely through the Committee on Standards (CoS), the Multi-Stakeholder Platform (MSP) on ICT standardisation and the structural dialogues with the European standardisation organisations. In this context, the Commission encourages the European standardisation organisations to actively participate in these platforms in order to help continue shaping European industrial and digital policies.

4.2   *Inclusiveness*

Inclusiveness and transparency are the key features of the European standardisation system. The Commission will therefore continue to support the involvement of stakeholders representing SMEs, consumers, environmental interests and trade unions in the standardisation process (referred to as the Annex[26] III organisations[27]).

Financial support to the organisations representing SMEs, social and societal interests at European level has paved the way for gradually involving their members in the standardisation activities. Nonetheless, there are still certain challenges to their effective participation in the standardisation process.

The Commission will closely monitor how the European standardisation organisations implement the requirements of effective participation of the Annex III organisations, pursuant to Article 5 of the European Standardisation Regulation.

The European standardisation organisations CEN and CENELEC and the international standardisation organisations are based on the national delegation principle. As a rule, the participation of experts in the elaboration of standards is expected to be open to everybody. The Commission calls upon the Annex III organisations to include, in their annual reports, any incident where stakeholders requested but did not manage to participate in the standardisation activities; this reporting should also include the international level (ISO, IEC).

4.3   *Financing European standardisation*

The current Framework Partnership Agreements, which provide the legal frameworks for Union funding to European standardisation organisations, will end in December 2020. The future financing of European standardisation is a part of the "Single Market Programme"[28]. The impact of this programme will be assessed through mid-term and final evaluations and by continuous monitoring of a set of high-level key performance indicators. The indicator adopted for European standardisation is the 'Share of implementation of European standards as national standards by Member States in total amount of active European standards'.

---

[26] Annex III of the European Standardisation Regulation (EU)1025/2012.
[27] Small Business Standards (SBS), the European consumer voice in standardisation (ANEC), the European Trade Union Confederation (ETUC) and the European Environmental Citizens' Organisation for Standardisation (ECOS).
[28] COM(2018) 441 final.

Study on the economic and societal impact of standardisation

European standards are indispensable instruments for the proper functioning of the single market. Among other things, they support economic growth by removing the barriers for placing innovative, competitive products and services in existing markets and by expanding the trade to new ones. However, their potential and actual effects and functions remain under-examined and call for a more detailed understanding.

Against this background, following the invitation from the Council and in line with the Joint Initiative on Standardisation, the Commission is launching a study in 2019 on the functions and effects of European standards and standardisation in the EU. The results of the study will be available by 2021.