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signed by Mr Jordi AYET PUIGARNAU, Director

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To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of  
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PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND  
SOCIAL COMMITTEE Harmonised standards: Enhancing transparency  
and legal certainty for a fully functioning Single Market

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Delegations will find attached document COM(2018) 764 final.

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Brussels, 22.11.2018  
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**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN  
PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL  
COMMITTEE**

**Harmonised standards: Enhancing transparency and legal certainty for a fully  
functioning Single Market**

The Commission has presented today a first response to the request of the European Council in March 2018 to assess the state-of-play, as well as the remaining barriers and opportunities for a fully functioning Single Market.<sup>1</sup>

Standardisation plays an important role in this assessment considering, in particular, its role in eliminating technical barriers to trade. Standards help to ensure that complementary products and services are interoperable, facilitate the introduction of innovative products and ultimately build trust of European consumers in the quality of products and services offered in the Union. In the context of rapidly evolving technological developments, the digitisation of the European economy and newly emerging economic trends and growth models, standardisation plays a key role in ensuring that the development of the Single Market is future-proof and that European consumers and businesses reap the benefits from such changes<sup>2</sup>.

European standards replace potentially conflicting national standards in all Member States of the Union and so, facilitate market access for those that use them. In this way, standards contribute to a continuous deepening of the Single Market. By promoting a close alignment of European and international standards, the European Union promotes best practices and increases synergies in global value chains. This enhances trade flows and opportunities for European businesses to scale up their activities.

A European standardisation system that functions well contributes to overall economic growth, supports innovation and global competitiveness of the European industry. It also helps to ensure that the levels of safety, health and consumer and environmental protection set out in Union legislation are met in practice<sup>3</sup>. European industry is transforming rapidly through the adoption of a wide range of innovative solutions and digital technologies. Traditional sectors of the economy are also concerned by this trend. All have needs that require standardisation responses, supported by advanced European standards and developed by a modern and agile European standardisation system.

This Communication provides an overview of the functioning of the European standardisation system and takes stock of the initiatives launched in recent years to support the implementation of the Standardisation Regulation, also in the light of the relevant case law of the Court of Justice of the European Union. The Communication explains the actions taken recently by the Commission to further improve the system and also includes specific actions that the Commission will take in the immediate future in order to enhance the efficiency, transparency and legal certainty for the actors involved in the development of harmonised standards. This Communication is relevant in the context of harmonised standards, that is, European standards adopted on a basis of a request made by the Commission for the application of Union harmonisation legislation.<sup>4</sup>

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 standards. These standards become part of Union law and, when used, provide manufacturers across the Single Market with a presumption of conformity with the requirements of Union

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<sup>1</sup> COM(2018) 772.

<sup>2</sup> For instance, further development of the circular economy in the Union requires the setting up of high quality standards for secondary raw materials such as plastics or waste-based fertilisers.

<sup>3</sup> Harmonised standards also cover social inclusion issues, such as accessibility. The European Accessibility Act uses standards to provide presumption of conformity.

<sup>4</sup> It is not applicable to other types of standards, i.e. international standards, European (non-harmonised) standards, national standards, technical specifications etc.

legislation. This provides important legal certainty to users of harmonised standards and is particularly important for small and medium-sized enterprises as it allows them to place products in compliance with Union legislation on the market without additional costs. The so-called ‘New Legislative Framework’ has been designed as a flexible and market-driven system built around consensus by industry, small and medium-sized enterprises and other key stakeholders, while ensuring that products conforming with harmonised standards comply with Union legislation.

The use of harmonised standards offers legal certainty and stability to users, which reduces costs for manufacturers. This in turn is important for investors but it also creates increased public responsibility on the regulators, who must oversee these harmonised standards appropriately.

Since it entered into force in 2013, Regulation 1025/2012 (hereafter ‘the Standardisation Regulation’)<sup>5</sup> has provided the main legal framework for the European standardisation system including the division of responsibilities and obligations of the actors involved. Certain improvements to the practical implementation of this framework need to be made swiftly, notably in light of the case of law of the Court of Justice of the European Union.

## **1. FUNCTIONING OF THE EUROPEAN STANDARDISATION SYSTEM**

Harmonised standards are developed by one of the three European Standardisation Organisations<sup>6</sup> on the basis of an official request from the Commission (‘standardisation request’), in order to support the implementation of Union legislation. These standardisation requests define what is expected from the European Standardisation Organisations. In particular, they specify which harmonised standards need to be produced, and by when. The Commission develops the standardisation requests in an inclusive and transparent process together with Member States.

The Commission and the European Standardisation Organisations ensure that the process of developing harmonised standards is based on consensus and is transparent and inclusive. In particular, the Commission closely monitors whether the input of small and medium-sized enterprises and stakeholders representing all parts of society, such as consumers, workers and environmental interests, is taken into account in the process as their contribution enhances the quality of the standards. Once the European Standardisation Organisations have developed a harmonised standard, the Commission assesses whether it complies with the requirements of corresponding Union legislation and the original standardisation request. If the Commission concludes that the standard is in compliance with the request and Union legislation, it will decide to publish its reference in the Official Journal of the European Union. As a result, and following a Commission decision to publish the reference in the Official Journal, the standard will produce legal effects under the relevant Union legislation.

Products manufactured in compliance with harmonised standards benefit from a presumption of conformity with the corresponding legislative requirements<sup>7</sup>. By using the harmonised

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<sup>5</sup> OJ L 316, 14.11.2012, p. 12–33.

<sup>6</sup> The European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC), and the European Telecommunications Standards Institute (ETSI).

<sup>7</sup> There are many other acts of Union legislation that mirror the system laid down in Regulation (EU) 1025/2012 such as Regulation (EU) 305/2011 (Construction Products Regulation), Directive 2001/95/EC (General Product Safety Directive). For ease of reference, they are not examined separately in this Communication. However, the general considerations addressed in this Communication also apply to these acts.

standards, the manufacturer may benefit from a simplified conformity assessment process. In this way, harmonised standards reduce the financial and administrative burden for manufacturers, particularly small and medium-sized enterprises, and increase legal certainty as regards the compliance of products with the Union legislation. That legal effect and certainty are crucial for small and medium-sized enterprises as it allows them to manufacture state-of-the-art products in a competitive way<sup>8</sup>.

The Commission must therefore pay particular attention to the content of the harmonised standards. The Court of Justice of the European Union has further reinforced this requirement in its recent case law, in particular by the Case C-613/14 'James Elliott Construction Limited vs. Irish Asphalt Limited'<sup>9</sup>. Through this judgment, the Court clarified the role and legal status of harmonised standards by concluding that harmonised standards 'form part of EU law', even though they are developed by independent private organisations and their use remains voluntary.

In addition, the Court reiterated the Commission's responsibility in the process of initiating, managing and monitoring of harmonised standards. The Commission has thus the obligation to follow the development process of harmonised standards thoroughly and to assess whether they comply with the requirements set out in harmonised Union legislation and/or standardisation requests in order to ensure that harmonised standards fully comply with the applicable legislation. This does not only include the technical aspects of standards but also other elements of the European Standardisation Regulation, such as whether their development process has been inclusive. It is the Commission's intention to fulfil these obligations in a manner which is as swift and efficient as possible.

## **2. IMPLEMENTING THE STANDARDISATION REGULATION AND THE RELEVANT CASE LAW**

Following the entry into force of the Standardisation Regulation in 2013<sup>10</sup> and several judgments of the Court of Justice of the European Union, the Commission has launched a number of initiatives to support the implementation of the legal framework and to improve how the European standardisation system functions in practice.

In accordance with the Standardisation Regulation<sup>11</sup>, the Commission has adopted Annual Union Work Programmes for European standardisation, highlighting the importance of harmonised standards, their legal effect (presumption of conformity), and their quality and timeliness. In addition to planning the work on the development of harmonised standards, these programmes have also put forward specific proposals to improve the governance of the European standardisation system, such as prioritising the European Union financial contribution to the European Standardisation Organisations on direct technical support to the development of harmonised standards. Moreover, the Commission has also given clear directions to the European Standardisation Organisations in the Annual Union Work Programmes, to strengthen the involvement of small and medium-sized enterprises and societal stakeholders in the European standardisation process.

The Commission has also taken several initiatives to make its standardisation policy more transparent and accessible. To ensure that the Standardisation Regulation is implemented correctly, the Commission's services have provided guidance on the role, development,

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<sup>8</sup> The construction product sector is subject to important deviations from general practices in standardisation.

<sup>9</sup> See also e.g. case T-474/15 Global Garden Products and C-630/16 Anstar.

<sup>10</sup> Replacing the standardisation provisions of Directive 98/34/EEC.

<sup>11</sup> Article 8 of Regulation (EU) 1025/2012

adoption and execution of standardisation requests in a 2015 'Vademecum on European standardisation'<sup>12</sup>. This document was prepared in full partnership and cooperation with the European Standardisation Organisations, small and medium-sized enterprises and societal stakeholders, together with Member States and industry. The Commission has also developed a common template for publishing the references of harmonised standards in the Official Journal of the European Union as well as a 2016 guidance document on the 'Verification of conditions for the publication of references of harmonised standards in the Official Journal'<sup>13</sup>.

In line with the 2015 Single Market Strategy<sup>14</sup> and the Standardisation Package<sup>15</sup> adopted on 1 June 2016, the Commission has set out a shared vision for European standardisation in its Joint Initiative on Standardisation (the “Joint Initiative”), supported by a broad range of stakeholders and all Member States. The aim of the Joint Initiative is to ensure the Union’s sustained efforts to modernise the European standardisation system so as to maintain its attractiveness, to keep pace with developments, such as digitisation, within an agile, flexible, and inclusive framework and to speed up and better prioritise standard setting to respond in a timely way to market and users' needs. Specific actions of the Joint Initiative are dedicated to raise awareness and to improve the development and implementation of harmonised standards. The Joint Initiative also looks at the role of standards in addressing the challenges of the digital transformation of the economy. This digital transformation of the economy creates the need to accelerate the transformation of the European standardisation to make it fit for current and future challenges, in particular in an area such as Internet of Things, big data, advanced manufacturing, robotics, 3D printing, blockchain technologies and artificial intelligence. A modern, agile and inclusive European standardisation system which can react quickly to new developments will help to speed up the diffusion of these new technologies.

In 2017, the Commission and the European Standardisation Organisations reached an agreement on a joint Action Plan to address the issue of harmonised standards which are not cited in the Official Journal following a negative assessment by the Commission. This issue was raised by the REFIT Platform<sup>16</sup> and by several stakeholders, as it impacts the sound functioning of the European standardisation system. To respond to this concern, the Commission has prioritised the rapid decrease of the backlog of such harmonised standards, in cooperation with the European Standardisation Organisations. Dealing with the remaining backlog remains a priority for the Commission.

***First Action:*** *The Commission will use its best endeavours to eliminate the remaining backlog as rapidly as possible.*

To ensure the timeliness and the efficiency of the citation of compliant harmonised standards in the Official Journal, it is useful to identify emerging issues as early as possible in the development process. The Commission has set up a framework of consultants for such purposes. The consultants provide Commission services with technical assistance in assessing draft harmonised standards, thereby contributing to strengthening further the Commission control of the consistency of harmonised standards with the relevant legislation.

To enhance coordination within the public-private standardisation partnership, the Commission and the European Standardisation Organisations have held regular structural

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<sup>12</sup>SWD(2015)205 final of 27.10.2015, [http://ec.europa.eu/growth/single-market/european-standards/vademecum\\_en](http://ec.europa.eu/growth/single-market/european-standards/vademecum_en)

<sup>13</sup> <http://www.cc.cec/Ares/ext/documentInfoDetails.do?documentId=080166e5ae43cdde>

<sup>14</sup> COM(2015) 550 final

<sup>15</sup> COM(2016) 358 final

<sup>16</sup> REFIT Platform opinion XXII.2.b.

dialogues. These dialogues have focused on technical and policy aspects of European standardisation, including on matters related to the quality of harmonised standards and the impact they have on businesses, markets and consumers.

To promote a stronger involvement of co-legislators in the process of priority-setting for European standardisation, the Commission organised in June 2018 an inter-institutional dialogue. The dialogue included high-level representatives of European Union institutions, standardisation organisations, businesses (including small and medium-sized enterprises) and other relevant stakeholders, such as consumers, workers and environmental organisations. It focused on priority issues relevant to the process of developing harmonised standards and future priorities in this area, such as the digitisation and the booming collaborative economy.

The inter-institutional dialogue and the discussions with the key actors in the European standardisation system have highlighted the need to further enhance legal certainty to ensure that the Union legislative framework for standardisation is interpreted uniformly, in particular in light of the Standardisation Regulation, the case law of the Court of Justice of the European Union and the guidance documents.

### **3. FURTHER ACTIONS TO ENHANCE TRANSPARENCY, REINFORCE LEGAL CERTAINTY AND SPEED OF ADOPTION**

While significant progress has been made, the Commission recognises that the efforts to improve the functioning of the European standardisation system need to be sustained. To this end, the Commission will take a set of dedicated, immediate actions to further enhance the transparency and efficiency of the European standardisation process. This will reinforce the legal certainty for stakeholders and users and clarify the roles and responsibilities of the different actors.

The Commission is reviewing its internal decision making processes with a view to streamlining the procedures for publishing the references to harmonised standards in the Official Journal<sup>17</sup>. This review is based on best practices within the framework of the Commission's internal rules of procedure and will ensure a co-ordinated, timely and thorough preparation of the necessary decisions.

***Second Action:*** *The Commission is reviewing its internal decision making processes with a view to streamlining the procedures for publishing the references to harmonised standards in the Official Journal.*

In order to further clarify the roles and responsibilities of the different actors during all stages of the harmonised standards development, the Commission will prepare a guidance document.

This guidance, complementing existing documents<sup>18</sup> will in particular explain the substantive and procedural aspects of the new format of the standardisation request which the Commission is developing with the aim of ensuring greater transparency and predictability in the development of the standards. It will also clarify the role of the Commission and its expert consultants. Finally, it will provide additional guidance to improve the consistency and speed of the assessment procedure of harmonised standards across the all relevant sectors.

***Third Action:*** *The Commission will elaborate over the next months in consultation with stakeholders, a guidance document on practical aspects of implementing the Standardisation*

<sup>17</sup> As of 1 December 2018, these Decisions will be taken by accelerated written procedure by the Commission.

<sup>18</sup> Vademecum on standardisation, the Blue Guide etc.

*Regulation, paying particular attention to the division of roles and responsibilities in the development process of harmonised standards as well as to efficiency and speed.*

In order to ensure better upstream coordination in the process of assessing harmonised standards, which the European Standardisation Organisations are in the process of developing, the Commission will continue to rely on the scientific input of the Joint Research Centre and, at the same time, will reinforce its liaison with the technical committees in charge of developing standards through the recently introduced system of expert consultants. The goal will be to maximise the speed, quality and accuracy of the assessments to improve the quality of the process and to ensure that the references to harmonised standards are published as quickly as possible in the Official Journal. Measures will include:

- reinforcing links between the relevant Commission services in charge of harmonised legislation and the technical committees in charge of developing harmonised standards;
- expanding the pool of expert consultants and their skills-sets to ensure the expertise required for high-quality assessments and the resilience of the system;
- refining the structure of the work procedures and task allocation to expert consultants;
- focussing on continuous quality review of the consultants' input; including training programmes for expert consultants;
- enhancing the horizontal coherence of the assessments by applying streamlined guidance across all sectors;
- appropriate management of possible conflicts of interest.

***Fourth Action:*** *The Commission will reinforce, on an on-going basis, the system of consultants to support swift and robust assessments of harmonised standards and timely citation in the Official Journal of the European Union.*

## CONCLUSION

The European standardisation system has been instrumental for the development of the Single Market. The presumption of conformity with the relevant Union legislation provides important legal certainty to all standard users and small and medium-sized companies in particular. The Standardisation Regulation, which came into force in 2013, introduced a new division of roles and responsibilities of the actors in the system based on a public private partnership. It also established a strong framework for inclusiveness requirements, allowing interests of small and medium-sized enterprises, consumers and workers, as well as environmental interests to be taken into consideration in the standardisation process. The joint objective of all partners in the European standardisation system is to ensure that the Standardisation Regulation and other relevant Union laws are implemented as effectively as possible.

The Commission is entrusted with the responsibility for the assessment of European harmonised standards. The Commission also needs to ensure that these standards are compatible with the requirements of the relevant harmonised Union legislation. The case law of the Court of Justice of the European Union has confirmed the importance of this responsibility and highlighted its legal implications.

While the current system is functional, the Commission recognises that further improvement is necessary. The four actions outlined above will be initiated immediately in order to achieve



further progress with regard to inclusiveness, legal certainty, predictability and the rapid delivery of the benefits of harmonised standards for the Single Market. Innovation and the protection of citizens and the environment are also key objectives in this context. The Commission will continue to work with all relevant partners to ensure the continued success of European standardisation as a cornerstone of a fully functioning Single Market.