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Omnibus aligning product legislation with the digital age



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Executive Summary

CEN and CENELEC support the European Commission's efforts to harmonize criteria for issuing common specifications. This is in principle positive, but it is crucial that the process is done in a way that ensures the involvement of a broad range of stakeholders, from societal stakeholders to Member States and industry (the actors who will later enforce and follow the specifications to gain access to the internal market). It is also important that there is a clear framework for the Commission's competences and for the possible withdrawal of common specifications. CEN and CENELEC urge the EC to follow the consistency set in recent legislative negotiations and continue to use the Machinery Regulation as blueprint for all future articles on common specifications, including in this proposed Omnibus.

CEN and CENELEC Position on Common Specifications

A reliance on European Commission (EC) common specifications could undermine the New Legislative Framework. Harmonized standards should remain the preferred choice, while resorting to common specifications should be only considered in narrowly defined and duly justified cases. There are some clear advantages to using harmonized standards for compliance with EU legislation over common specifications.

Firstly, there is a clear framework with well-defined rules for the development of harmonized standards established by Regulation 1025/2012. CEN and CENELEC have been developing harmonized standards in an open and transparent process for many years and those relying on the development of harmonized standards have experience of this process. While EC has announced the intention to have a fallback option that would enable them to adopt common specifications, they have not provided an explanation of what would be their proposed process of development or the resources that would be required.

In the Staff Working Document accompanying the Omnibus, the impact assessment does not include an estimate of the cost to the EC of developing a common specification, which in likelihood would require considerable resources, both in terms of time and finances.

Secondly, the European Standardization System (ESS) relies on diverse expertise in industry, academia, and other relevant sectors that are needed to develop a harmonized standard. These experts are appointed by national standardization bodies and national committees and represent the views of the country under the national delegation principle of CEN and CENELEC. This ensures a broad base of knowledge, and a variety of interests are represented from all parts of Europe. The development of common specifications will be entirely within the remit of the EC, and they will have the ultimate say in who is involved in the development without having the same access to the wide range of expertise that is in the ESS.

Finally, while CEN and CENELEC understand concerns around the timely delivery of harmonized standards, it is not yet clear whether common specifications could be developed faster, without sacrificing the access of all interested parties, or the time needed to ensure all relevant technical details are considered. ESOs, with encouragement from the EC, has developed procedures to ensure the involvement of a wide variety of stakeholder groups, including industry, public authorities, SMEs and societal interests in standardization. It is still unclear how the development of common specifications will achieve faster development without negatively impacting the inclusivity, technical expertise and industrial acceptance of the final deliverable.

The Need for A Consistent Fallback Solution Across Legislation

CEN and CENELEC acknowledges the EC's intention to be able to develop common specifications if the standardization system cannot deliver the necessary harmonized standards. CEN and CENELEC emphasizes the following about Common Specifications:

- That they remain a fallback solution to be used when all other options have been exhausted.
- Their application should be consistent across jurisdictions.
- The design should involve relevant stakeholders - especially the affected industry and societal actors - and be based on international standards.
- There should be clear rules on when the EC is authorized to create common specifications and when these should be withdrawn (especially as soon as a harmonized standard is available or if a Member State objects).
- Like harmonized standards referenced in OJEU, common specifications should be voluntary and give presumption of conformity.

CEN and CENELEC support Article 20 of the Machinery Regulation (Annex I) as a framework for the use of Common Specifications. This article is preferred by a wide range of stakeholders because it clearly defines the above points. This article has also been the basis for similar articles in a wide range of recent legislation, such as the Provisional Agreement on the Toy Safety Regulation. CEN and CENELEC would also prefer Article 14 of the Toy Safety Regulation over the current Omnibus proposal. Unfortunately, the Omnibus proposal removes several important guarantees for involvement, withdrawal and changes the decision-making procedure. The proposal gives the EC wider margin to interpret when to use Common Specifications.

The EC justifies the need for increased control in the staff working document accompanying the omnibus. Regrettably, it omits the EC's role in the problems of slow publication, the cost of developing common specifications and fails to assess alternative solutions. It also ignores that industry has repeatedly rejected common specifications as an appropriate solution to facilitate market access.

The omnibus proposal aims for uniform changes across legislation but does not do so consistently (e.g. the Cyber Resilience Regulation is omitted). This creates unnecessary burdens for businesses, as many products are subject to multiple sets of regulations. This means the introduction of common specifications are not uniform across legislation. The European Standardization Strategy emphasises the need to avoid fragmentation: “To avoid a fragmentation of sectoral approaches, the Commission will work towards a horizontal approach in terms of criteria and processes for when and under which conditions the Commission could be empowered to develop common specifications via implementing acts, in those cases where the relevant legislation provides for this.”

CEN and CENELEC therefore urges the EC to follow the consistency set in recent legislative negotiations and continue to use the Machinery Regulation as blueprint for all future articles on common specifications.

Leveraging the Existing Public-Private Partnership to Improve the Timely Availability of Standards

CEN and CENELEC realise that part of the need to have common specifications as a fallback solution is due to concerns about the timely availability of harmonized standards. CEN and CENELEC believe that the best way to improve the timeliness of deliverables is for both actors in the public-private partnership to take concrete actions for improvements, framed by the upcoming Revision of Regulation 1025/2012.

Since our creation as ESOs, CEN and CENELEC and our Members have been constantly evolving, adapting our offer to address the latest developments, while maintaining our core values of openness, transparency, consensus and inclusiveness.

Both organizations are currently working on new solutions such as Online Standards Development (online-authoring) and SMART (machine-readable) Standards, to meet the evolving needs of the European market and regulatory context. We are also reviewing our standards development processes and actively developing solutions that accelerate the timely availability of deliverables while upholding its integrity.

The EC, in turn, should consider actions that could contribute to timely availability of harmonized standards, which would be considerably less time consuming than setting up a parallel system to develop common specifications. The EC could include greater flexibility within standardization requests, creating more balance between qualitative legal requirements and the need to ensure that harmonized standards represent the state-of-the-art innovation and technical expertise. The EC should also commit to a shorter processing time for citation of new harmonized standards into the Official Journal of the EU, accompanied by the introduction of concrete KPIs that would increase accountability and transparency. More details on these proposals can be found in Annex 3 of our response to the Evaluation of the Standardization Regulation.

CEN and CENELEC wish to contribute to the creation of a more agile and inclusive ESS to meet today's complex challenges. To find solutions to these common challenges, we commit to work together with the European Commission for an advanced European Standardization System, including by ensuring the timely availability of harmonized standards.

CEN and CENELEC Position on Provisions on Digitalisation and the Digital Product Passport

CEN and CENELEC welcomes the provisions in the Omnibus IV that integrates conformity-related information, such as the EU Declaration of Conformity, into a digital format, provided through open and user-friendly channels. This is an important step towards increased digitisation and more effective product compliance.

To ensure coherence and avoid unnecessary burdens, CEN and CENELEC emphasise the importance of coordinating the implementation of the DPP with the forthcoming revision of the New Legislative Framework (NLF). The Omnibus IV on digitisation and common proposes using the DPP as a tool for companies' self-documentation. It is imperative that the Omnibus IV does not create parallel structures that risk undermining the more comprehensive approach envisaged in the upcoming revision of the New Legislative Framework.

A consistent and harmonized framework is crucial to avoid fragmentation, ensure interoperability and build a truly European DPP ecosystem. In this context, it is essential that the CE marking continues to serve as a clear, legally secure, and trusted indication of conformity. The CE mark and the DPP should complement each other without creating unnecessary administrative burdens, especially for SMEs.

CEN and CENELEC therefore call on the Commission to ensure full alignment between the Omnibus IV, the DPP, and a revised NLF. Future legislation should harmonize the use of the DPP across all European product safety legislation and establish a DPP ecosystem based on European and international standards. A coherent framework on the use of the DPP and the CE Marking can strengthen the internal market, enhance product safety, and promote innovation without creating additional complexity.

Annex 1: Machinery Regulation Article 20

Presumption of conformity of products within the scope of this Regulation

1. A product within the scope of this Regulation which is in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the essential health and safety requirements set out in Annex III covered by those standards or parts thereof.

2. The Commission shall, as provided in Article 10(1) of Regulation (EU) No 1025/2012, request one or more European standardisation organisations to draft harmonised standards for the essential health and safety requirements set out in Annex III.

3. The Commission may adopt implementing acts establishing common specifications covering technical requirements that provide a means to comply with the essential health and safety requirements set out in Annex III for products within the scope of this Regulation.

Those implementing acts shall only be adopted where the following conditions are fulfilled:

(a) the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more European standardisation organisations to draft a harmonised standard for the essential health and safety requirements set out in Annex III and:

(i) the request has not been accepted; or

(ii) the harmonised standards addressing that request are not delivered within the deadline set in accordance with Article 10(1) of Regulation (EU) No 1025/2012; or (iii)

the harmonised standards do not comply with the request; and

(b) no reference to harmonised standards covering the relevant essential health and safety requirements set out in Annex III has been published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 and no such reference is expected to be published within a reasonable period.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(3).

4. Before preparing the draft implementing act referred to in paragraph 3, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 3 have been fulfilled.

5. When preparing the draft implementing act referred to in paragraph 3, the Commission shall take into account the views of relevant bodies or the expert group and shall duly consult all relevant stakeholders.

6. A product within the scope of this Regulation which is in conformity with the common specifications established by implementing acts referred to in paragraph 3, or parts thereof, shall be presumed to be in conformity with the essential health and safety requirements set out in Annex III covered by those common specifications or parts thereof.

7. Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess the harmonised standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal the implementing acts referred to in paragraph 3, or parts thereof which cover the same essential health and safety requirements as those covered by that harmonised standard.

8. When a Member State considers that a common specification does not entirely satisfy the essential health and safety requirements set out in Annex III, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question

About CEN and CENELEC

CEN (European Committee for Standardization) and CENELEC (European Committee for Electrotechnical Standardization) are recognized by the European Union (EU) and the European Free Trade Association (EFTA) as European Standardization Organizations responsible for developing standards at European level, as per European Regulation 1025/2012. The members are the National Standards Bodies (CEN) and National Electrotechnical Committees (CENELEC) from 34 European countries. European Standards (ENs) and other standardization deliverables are adopted by CEN and CENELEC, are accepted and recognized in all of these countries. These standards contribute to enhancing safety, improving quality, facilitating cross-border trade and strengthening of the European Single Market. They are developed through a process of collaboration among experts nominated by business and industry, research institutions, consumer and environmental organizations, trade unions and other societal stakeholders. CEN and CENLEC work to promote the international alignment of standards in the framework of technical cooperation agreements with ISO (International Organization for Standardization) and the IEC (International Electrotechnical Commission).



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