



Common specifications as a fallback option

DIN Position paper on the Omnibus IV Simplification Package, specifically the proposal for a Directive as regards the digitalisation and alignment of common specifications

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- Harmonized European standards should remain the preferred solution for the technical concretization of legal requirements. Common specifications should only serve as a fallback option in exceptional cases.
- Many questions regarding the implementation of common specifications, in particular with regard to their development process, remain unanswered and should be addressed by the Commission. The stringent criteria set for developing harmonized standards should also be applied to common specifications.
- Clear guidelines on when the Commission may resort to common specifications and when they should be withdrawn are needed.
- In order to achieve a uniform approach to common specification across all product regulation, the legal text agreed within the framework of the Machinery Directive should be used in the Omnibus IV.
- Future legislation should harmonize legislation for the digital product passport, introduce it across European product safety legislation, and support the digital transformation of public authorities.

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As a national standards body and German member of the European standardization organization CEN, DIN is pleased to have the opportunity to comment on the draft for the Omnibus Directive aligning product legislation with the digital age (Omnibus IV), which, among other things, plans the broad introduction of common specifications (CS) across large parts of European product regulation.

We realise, that part of the need to have CS as a fallback option is due to concerns about the timely availability of harmonised European standards (hEN). We would therefore like to preface our comments by stating 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. CEN, CENELEC and their national members 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. Furthermore, we are working on solutions to accelerate the timely availability of deliverables while upholding the integrity of the European standardization system.

With this in mind, we would like to provide the following background information and recommendations on the planned Omnibus IV:

Harmonized European Standards as default, Common Specifications as a fallback option

Harmonized European standards are a success story that have initially enabled the unique European internal market. They should remain the preferred choice, while resorting to common specifications should be only considered in narrowly defined and duly justified cases. We therefore welcome the EU Commission's repeated statements that CS should only be a fallback option in exceptional cases. This is especially important because:

- CS increase the burden for compliance and guidance, especially for small and medium-sized enterprises (SME). SME would have to stay informed about another type of regulatory document, integrate it into their quality management and actively advocate opportunities to participate in the development process of CS. CS thus counteract the Commission's efforts to improve access to technical rules for SMEs, currently being pursued e.g. with the revision of Regulation 1025/2012.
- CS run the risk of not being coherent with the uniform European body of standards.
- CS lack the international connectivity that hENs or other deliverables by the European Standardization Organizations offer and that is an important advantage for the export-orientated European economy.

Additionally, a distinction is needed between technological areas where speed is essential in delivering a standard, and other fields of technology, where timely rather than speedy availability of a standard is perfectly acceptable to meet market requirements.

DIN recommends: Against this background, it is important that the wording of the Omnibus IV regulation reflects the restricted use of common specifications to exceptional cases.

Comparison of harmonized European standards and common specifications

Directly comparing hEN and CS highlights the benefits of hEN and underscores the need for clearer understanding of the CS instrument and its development process:

	Harmonized European Standards (hEN)	Common specifications
Requirements for the development process	Well-defined rules and framework conditions (including requirements for transparency, consensus and broad participation) for development in accordance with EU Regulation 1025/2012	No legal requirements for the development process
Developed by	European standardization organizations (according to Annex I of EU Regulation 1025/2012)	Service provider commissioned by the Commission (depending on the individual case)
Inclusiveness	Involvement of all interested parties through the guidelines of CEN and CENELEC, based on the national delegation principle and on Articles 5-7 of EU Regulation 1025/2012	No specifications for stakeholder participation, the executing service provider probably decides who may participate in the development
International connectivity	Contractual connection to international standardization; providing a consistent set of standards across Europe and beyond	Content cannot be based on international standards and may conflict with them
Legal principle	Following the legal principle of the New Legislative Framework where the legislator sets essential requirements and refers to standards for their technical concretization	Not compliant with the New Legislative Framework ¹ , instead following the “Old Approach” with detailed technical regulation by the legislator
Market relevance	Relevant to the market and fit for purpose, as relevant market participants from all over Europe are actively involved in the development through the national delegation principle	Whether the content is relevant to the market or not depends on which service provider is selected for the development process
Compliance with antitrust law	Unobjectionable under antitrust law	Antitrust assessment dependent on the development process and stakeholder involvement
Co-determination rights of member states	Participation of member states in the issuing of standardization requests in the Committee on Standards (CoS) and for member states and the EU Parliament through formal objections	According to the proposed wording in Omnibus IV, member states only have a right of co-counseling via the comitology procedure; no right of co-decision for member states or the EU Parliament

¹ Common specifications are not compliant with Article 3 of Decision 768/2008/EC on a common framework for the marketing of products. Article 3(1) second subparagraph calls for an ex-ante assessment in view of the public interests which the legislation aims to protect. In view of the protection of those interests, the Article provides for only two options between which the legislator has to choose: (1) either it is sufficient – which it normally is – to set out the essential requirements and provide for recourse to harmonized standards or (2) detailed specifications have to be set out in the legislation concerned.

Requirements for the use and development process of common specifications

As of now, the development process of common specifications and what resources would be needed for drafting them remains unclear. Further, in the Staff Working Document accompanying the Omnibus IV proposal, the impact assessment does not provide an estimate of the cost to the European Commission for developing a common specification, which would likely demand significant resources, both in terms of time and finances.

As an alternative to CS, CEN and CENELEC already offer a wide range of deliverables, from hENs directly compliant with WTO/TBT principles to Technical Specifications, that fulfil the needs of a variety of stakeholders and provide timely compliance. These deliverables combine flexibility in consensus and time required for their delivery, allowing the European standardization organizations (ESOs) to quickly respond to new technologies and market needs. The Commission should clarify which current or future deliverables of the ESOs might best support legal requirements, thus rendering parallel standardization processes and the need for common specifications obsolete.

DIN recommends: *For CS to gain market acceptance, the same high requirements that the European Commission places on the development of hENs through the Standardization Regulation 1025/2012 must be applied to the development of CS. These include:*

- a. transparency in the development process;*
- b. broad public participation, in particular from industry, academia, societal actors, SMEs and representatives of consumer and environmental interests; and*
- c. the involvement of broad expertise from experts across Europe.*

Furthermore, there should be clear guidelines outlining when the European Commission is permitted to use common specifications and when these should be withdrawn, including:

- a. CS shall only be adopted when the Commission has requested one or more European standardization organizations to draft a hEN and*
 - i. no reference to hEN covering the respective essential requirements has been cited in the OJEU and no such reference is expected to be published within a reasonable period and*
 - ii. the request has not been accepted or the harmonised standard developed does not comply with the request.*
- b. CS shall be withdrawn as soon as a hEN on the same subject as the CS is cited in the OJEU or when a member state objects.*

As an alternative, the European standardization organizations already offer a wide range of products. The Commission should clarify which current or future deliverables of the ESOs might best support legal requirements.

A consistent instrument across different legislation

One of the objectives the Commission aims to achieve with this proposal is “to align the alternative option in legislative acts which do not provide for any alternative option to harmonised standards. The alternative option is to be implemented in a uniform manner as regards definition, legal effect, the conditions under which that alternative option may be adopted and adoption procedure” (page 2 of the Commissions proposal). To achieve this objective, the legal text of the Machinery Directive on CS offers the most suitable solution. During the revision of the Machinery Directive, there was a broad discussion

about the instrument of common specifications. The compromise reached in this context was broadly approved among stakeholders and subsequently adopted in other legal acts, such as the Artificial Intelligence Act and the Cyber Resilience Act. The extensive revision of requirements for common specifications in the omnibus package will lead to inconsistencies between this legislation and the ones targeted by the omnibus.

DIN recommends: *Avoid fragmenting the of the common specification instrument. The omnibus article should be harmonized with the wording of Article 20 of the Machinery Regulation (see annex), because:*

- a. The Machinery Regulation clearly outlines the requirements for developing common specifications as a fallback option. In contrast, the Omnibus presents this ambiguously and eliminates the necessity of issuing a standardization request to the ESOs in advance. It merely focuses on the lack of a hEN. This could result in common specifications without the European standardization bodies being able to take action beforehand, thus encouraging a parallel standardization process outside the European standardization system whilst endangering the coherence of the uniform European body of standards.*
- b. There is a repeal mechanism in the Machinery Regulation that is missing in the Omnibus.*
- c. In the Machinery Regulation, the Commission examines the positions of the relevant bodies and duly consults all relevant stakeholders. This procedure is not encompassed in the Omnibus proposal. However, broad participation in the development of common specifications is an essential prerequisite for their quality and acceptance on the market.*

Further developing the digital product passport

The obligatory use of the digital product passport (DPP) within the processes of European market surveillance is an important step towards reducing bureaucratic costs for member states and industry alike. DIN therefore welcomes the provisions of the Omnibus IV that require the utilization of the DPP in cases where Union legislation has already introduced a DPP as an important step. To automate as much of the necessary but bureaucratic processes behind European market surveillance, DIN recommends, that future legislative projects, like the revision of the New Legislative Framework (NLF), continue to build on the contributions of the Omnibus IV.

Specifically, the Omnibus IV will result in the centralization of information regarding product compliance only for certain products, but it will not fundamentally change the way in which data is handled within market surveillance authorities. This limits the overall benefits of the Omnibus IV. However, documents, like the Competitive Compass or the current Call for Evidence on the NLF, hint at the ultimate potential of the DPP: Automating as much of the bureaucracy behind European product safety regulation as possible and thus axing bureaucratic costs while making the Single Market safer. DIN therefore recommends that the Commission continues with its ambitious approach.

DIN recommends: *Future legislation should focus on harmonizing the utilization of the DPP across all European product safety legislation, creating a DPP-ecosystem based on common European standards, integrating the DPP into projects like the EU Business Wallet and supporting the digital transformation of member states market surveillance authorities².*

² For a more detailed analysis of potential contributions of the DPP to the NLF, please [see here](#).

About DIN

DIN, the German Institute for Standardization, is the independent platform for standardization in Germany and worldwide. Together with industry, scientific institutions, public authorities and civil society as a whole, DIN plays a major role in identifying future areas for standardization. By helping to shape the green and digital transformation, DIN makes an important contribution towards solving current challenges and enables new technologies, products and processes to establish themselves on the market and in society. More than 40,000 experts from industry, research, consumer protection and the public sector bring their expertise to work on standardization projects managed by DIN. The results of these efforts are market-oriented standards and specifications that promote global trade, encouraging rationalization, quality assurance and environmental protection as well as improving security and communication. For more information, go to <http://www.din.de/en>.

Annex: Article 20 of the current Machinery Regulation

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.