

A detailed close-up photograph of a mechanical watch movement. The image features several interlocking gears of different sizes, some with a polished gold finish and others with a blue metal finish. The gears are set against a background of blue metal plates and components. The lighting is bright, highlighting the intricate details and textures of the mechanical parts.

Bitkom's position on the «Omnibus IV» Proposal for Common Specifications and Digitalisation

2025 August

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Bitkom read the Commission's «Proposal for a [Directive/Regulation] [...] as regards the digitalisation and alignment of common specifications» with great interest and would like to provide input. Shortly summarized, we believe:

- **Common Specification should be designed as a clearly limited fallback option in alignment of Art. 20 of the Machinery Regulation and developed with industry involvement.**
- **The proposal contains good steps towards digitalisation, but would offer a chance to introduce additional changes, such as e-labelling, digital contacts only and digital safety information.**

1. Regarding Common Specifications

We understand the Commission's intention to provide timely technical guidance to industry and an alternative to harmonised standards should deadlocks arise in the work with the European Standardisation Organisations (ESOs). However, we believe the Commission significantly underestimates the **negative impact on European competitiveness** of a broad introduction of common specifications (CSs).

Firstly, the development of high-quality, widely accepted standards requires **open, transparent, and inclusive** processes. The proposal misses a description on how wide participation, especially from industry stakeholders, and a consensus-based approach, essential to achieve this quality, is ensured for the development of common specifications.

Secondly, common specifications effectively decouple EU regulations from **international standards**, which increases the cost of placing products on non-EU markets and reduces the global competitiveness of European companies.

In light of this, we find the current approach to common specifications unacceptable and urge the Commission to consider the following improvements to the proposal:

Align the proposal with Regulation (EU) 2023/1230 (Machinery Regulation)

The Machinery Regulation contains several important points:

- It ensures CSs are a fallback solution, by defining the conditions on when they can be adopted;
- it clearly stipulates that CSs are withdrawn as soon as hENs are available;

- it uses the Examination Procedure, rather than the proposed Advisory Procedure, which ensures quality assurance and allows member states to intervene on behalf of national stakeholders, which ensures especially SME's voice in the process.

We therefore strongly suggest using Art. 20 of the Machinery regulation as a blueprint for introducing common specifications across the NLF.

We also propose enshrining two principles of Art. 20 of the Machinery Regulation into the legislative text via the following amendments:

1. **Safeguard direct stakeholder participation through expert groups:** Bitkom has serious doubts that the provisions for an implementing act alone, as laid down in Regulation (EU) No 182/2011, are suitable for the development of CSs. To ensure that CS reflect the state-of-the-art and can be efficiently implemented in real products & services, the CS shall be created in an expert group following tried and tested examples such as the CRA expert group. These expert groups allow direct participation of all stakeholders via an open application system, including affected industries.

Suggested Amendment to Art. 20 (5):

*5. When preparing the draft implementing act referred to in paragraph 3, the Commission shall **work with** relevant bodies **and** the expert group and shall duly consult all relevant stakeholders.*

2. **Set appropriate transitional periods when repealing CS:** Depending on the industry and product, Bitkom members have development cycles of up to four years. Efficiently switching from an established common specification to a freshly published harmonised standard therefore takes time. A repeal of the implementing act of a CS in favour of a harmonised standard needs to occur with an appropriate transitional period in consultation with the expert group. During the transitional period, both CS and harmonised standards should provide presumption of conformity.

Suggested Amendment to Art. 20 (7):

*7. [...] 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 **with appropriate transitional periods.***

Introducing Common Specification as a Fallback Option Only

To keep CSs as a fallback only, a phrasing such as «there is a need to address an urgent concern» in condition (c) of the commission's proposal should be avoided. Such a phrasing allows an overly broad application, while a definition and limitation of cases when CS can be developed set clearer expectations for ESOs and industry and legitimizes common specifications, ensuring larger industry acceptance. In addition, the scope of condition (b) should be clarified to better explain under which circumstances it applies.

Consider Provisional Specifications

We ask the Commission to reassess the required resources to accurately reflect the impact of common specifications regarding two aspects:

1. **Lack of experts:** The standardisation system is already facing a shortage of technical experts. Creating parallel structures to develop high-quality CSs diverts scarce resources, slowing down both processes.
2. **Cost considerations:** The Commission's staff working document¹ bases calculations of savings on a scenario where no harmonised standards exist. However, the analysis should also account additional costs: (1) the cost of changing requirements that come with a later publishing of harmonised standards, and (2) the cost of non-alignment with international standards, which creates barriers to international trade.

If the Commission's goal in introducing CS is to accelerate the development of standards by reducing participation or bypassing consensus, **we recommend that this approach is used by ESOs instead**. Rather than introducing CS, the ESOs could develop temporary «provisional specifications» that would later be refined and adopted as full harmonised standards. This solution would achieve the desired speed while relying on the same expert networks used for hENs, and would minimise the costs and disruptions associated with transitioning to a harmonised standard at a later stage. Additionally, Bitkom trusts that the ESOs will be able to integrate international standards in the Provisional Specifications, mitigating the cost of non-alignment.

2. Regarding Digitalisation

We support the Commission's goal to advance digitalisation, and we strongly welcome the introduction of digital instructions. However, we would like to note that the current proposal offers limited added value, as it primarily formalises existing industry practices regarding digital communication with notified bodies and market surveillance authorities.

We encourage the Commission to consider additional measures that could significantly enhance the benefits of the proposal:

1. **E-labelling:** The proposal misses the opportunity to allow electronic labelling for regulatory information, a step well-suited to the digital age that would lower compliance costs for manufacturers and offer greater flexibility in product design.
2. **Digital contact only:** Since communication with market surveillance authorities and notified bodies is now entirely electronic, the requirement to print a postal address is outdated. Printing both postal and electronic address imposes *additional* obligations on manufacturers, rather than reducing them.

¹ COMMISSION STAFF WORKING DOCUMENT accompanying the proposals

Updating the postal address and fitting it on products or packaging creates an unnecessary administrative and logistical burden.

3. **Digital safety information:** We believe end users are fully capable of accessing safety information in digital form. Limiting digitalisation to user instructions alone does not meaningfully reduce costs, as manufacturers must still print safety information—including updates and translations—for a significant range of products. Moreover, switching to digital formats offers environmental advantages over paper documentation.

Bitkom represents more than 2,200 companies from the digital economy. They generate an annual turnover of 200 billion euros in Germany and employ more than 2 million people. Among the members are 1,000 small and medium-sized businesses, over 500 start-ups and almost all global players. These companies provide services in software, IT, telecommunications or the internet, produce hardware and consumer electronics, work in digital media, create content, operate platforms or are in other ways affiliated with the digital economy. 82 percent of the members' headquarters are in Germany, 8 percent in the rest of the EU and 7 percent in the US. 3 percent are from other regions of the world. Bitkom promotes and drives the digital transformation of the German economy and advocates for citizens to participate in and benefit from digitalisation. At the heart of Bitkom's concerns are ensuring a strong European digital policy and a fully integrated digital single market, as well as making Germany a key driver of digital change in Europe and the world.

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WG Standardisation and WG Product Safety and Market Access

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Appendix: Proposal for Common Specifications following Art. 20 of the Machinery Regulation

Presumption of conformity of products within the scope of this Regulation

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 **work with** relevant bodies **and** 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 **with appropriate transitional periods**.

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.