

## SBS comments on the adoption of the Omnibus Regulation and Directive Aligning product legislation with the digital age (Omnibus IV package)

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SBS welcomes the opportunity to provide feedback on the European Commission proposals for a Regulation and a Directive aligning product legislation with the digital age (Omnibus IV package).

The Omnibus IV package tackles two areas of primary importance to SBS and to all European SMEs: the drafting of common specifications by the European Commission as a possible alternative to harmonised standards for providing compliance with European legislation and the shift towards a stronger digitalisation of the Single Market.

### Common specifications

SBS acknowledges the Commission proposal to adopt common specifications via implementing acts. In this sense, the Omnibus IV package extends the number of pieces of EU legislation that include provisions allowing common specifications, following on a trend already started in the last few years.

SBS understands the need for a fall-back option when requested harmonised standards (hENs) are not delivered by the European standardisation organisations (ESOs). However, a few main areas of concern remain:

- In the absence of an established ad-hoc process for the development of common specifications, the references to Comitology procedure under Regulation 182/2011 for the approval of implementing acts do not give sufficient guarantees in terms of stakeholder involvement. In fact, Regulation 182/2011 does not set rules about which stakeholders can participate in the drafting of an implementing act, nor does it lay down requirements in terms of consultation of stakeholders such as SMEs.

- Unlike Regulation 1025/2012 on European standardisation, which explicitly recognises SMEs representatives and promotes their active participation in standardisation, the Comitology Regulation includes no obligation to consult them in the development of implementing acts. Using comitology to adopt common specifications therefore risks bypassing the inclusive framework established by Regulation 1025/2012.
- Consequently, there is insufficient clarity on the mechanism and transparency for the gathering of input by stakeholders in the development of the specifications. It is crucial to ensure a fully inclusive drafting process for common specifications that duly involves relevant stakeholders and particularly the stakeholder representatives identified by Regulation 1025/2012 on European standardisation (i.e.: Annex III organisations). Any fallback option such as common specifications must guarantee the same level of access granted to stakeholders and their representatives present under Regulation 1025/2012 and its Annex III. Furthermore, a full and genuine consensus principle must be preserved: Only a carefully balanced compromise between different interests can produce high-quality, widely accepted standards.
- There is still a lack of clarity on the criteria to trigger the process of development of common specifications. In its proposal, the Commission mentions cases where “*no harmonised standards exist or where they are insufficient*” or where “*there is an urgent need*”. It is quite evident that this wording does not provide adequate clarity and certainty. Obvious questions remain open, including:
  - Does “*no harmonised standards exist*” include cases where harmonised standards are under development but with delays? If so, what amount of delay triggers the process?
  - How is the fact that the candidate hENs might be “*insufficient*” established? Would one negative assessment by the so-called HAS consultants be enough?
  - What does constitute “*an urgent need*” for the Commission to trigger the process? How is the need assessed? Would there be consultation or input from stakeholders?

Next to these areas of concern, SBS also reiterates its belief that in any case common specifications should only be considered as a last resort measure. The primacy of stakeholder-driven harmonised standards must be preserved as the main way to facilitate compliance and provide presumption of conformity.

With regards to the wording proposed by the Commission in the Omnibus package to add the clause allowing for common specifications in the different, SBS suggests an alternative. This is to use instead a wording based on [Art.20 of Regulation 1230/2023 \(“Machinery Regulation”\)](#). This article, in different clauses and paragraphs, provides strong improvements in terms of clarity regarding the three aforementioned areas of concern. Specifically, Articles 20.3 and 20.4 give

some needed clarification regarding the procedure and the fora to be consulted for the development of common specifications, and Article 20.5 clearly prescribes that “*The Commission (...) shall duly consult all relevant stakeholders*”.

## Digitalisation of the Single Market

SBS strongly supports a shift towards the digitalisation of the Single Market, provided it reflects the needs and specificities of SMEs and microenterprises, for instance with regards to digital literacy and time and personnel constraints. Digital instructions and declarations of conformity can reduce administrative burdens and compliance costs for SMEs. However, the transition to digital formats involves initial investments in IT infrastructure and staff training, which may be challenging for smaller businesses with limited resources. Therefore, while long-term benefits are anticipated, short-term costs must be considered.

Practical measures should be put in place to ensure an inclusive a gradual transition towards a full digitalisation of the Single Market. Some of these measures might include:

- The “once only” principle should be adopted: once a declaration or instruction is uploaded to an EU portal, it should be valid for all authorities and distributors.
- Also, longer transition periods for micro and small enterprises before digital-only solutions become mandatory. Similarly, a transition period allowing continued availability of paper-based options, upon request, should be foreseen.
- SME-targeted guidance and training;
- Support for upskilling and reskilling. In this sense, it is crucial to strengthen the cooperation with VET institutions and allocate funding to facilitate collaboration between digital SMEs and more “traditional” SMEs;
- Funding opportunities for SMEs to take up and implement digital tools in their activity both at national and European level (eg. vouchers for microenterprises and smaller SMEs to acquire software or hire external providers to ensure compliance with legislation).

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Small Business Standards (SBS) is the European association representing and supporting small and medium-sized companies (SMEs) in the standardisation process, both at European and international levels.

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