

Position statement

Omnibus IV package: Proposals for a regulation and a directive as regards digitalisation and common specifications

August 2025

KAN, the Commission for Occupational Health and Safety and Standardization, welcomes the opportunity to comment on the European Commission's proposals in the Omnibus IV package for a regulation and a directive as regards digitalisation and common specifications.

As part of its Omnibus IV package, the European Commission proposes to introduce the instrument of common specifications into numerous other items of Single Market legislation. Common specifications are European implementing acts that are intended to serve as an exceptional fallback solution for the European Commission in cases where standardisation mandates have been issued but the European standardisation organisations fail to develop harmonised standards, fail to deliver them on time, or present standards that are inadequate.

Primacy of harmonised European standards

The European Commission recognises the primacy of harmonised European standards by explicitly referring to common specifications in accompanying documents and recitals as an "exceptional fallback solution". From KAN's perspective, this primacy is of key importance and should also be enshrined in the enacting terms of the Omnibus proposals.

KAN emphasises that harmonised European standards should have primacy over alternative solutions, such as common specifications, where these are under consideration. KAN regards this primacy as essential, as harmonised European standards offer decisive advantages over common specifications:

- A transparent development process within the European standardisation organisations
- Broad participation of all stakeholders, including societal stakeholders such as occupational safety and health representatives, by which comprehensive technical expertise can be assured

- Consensus-based development in line with the bottom-up principle, in which the users of the standards are actively involved in their development
- Creation of trust in the final product and broad acceptance of it, owing to processes being transparent and participatory

Against this background, common specifications should be used only in exceptional cases. Where the Commission does resort to common specifications, it must do so on the basis of clear, legally binding criteria and as part of a transparent process for their development and adoption. The involvement of all relevant stakeholders – in particular societal stakeholders – in this process must be ensured at an early stage.

Criteria for the adoption of common specifications

KAN views the Omnibus proposals with great concern, as they make provision for expanding the scenarios in which the Commission may make use of the instrument of common specifications. The cases proposed for their application are more far-reaching than those in previous legislation, such as the Machinery Regulation (EU) 2023/1230.

Of particular concern is the possibility of common specifications being adopted in cases where “[...] the Commission considers that there is a need to address an urgent concern with regard to non-compliant [products or product components]”. Application in such a case, based solely on urgency and lacking objective and verifiable criteria for action by the Commission, must be emphatically rejected. Rather, recourse to common specifications must be strictly limited to exceptional cases in which the European standardisation organisations fail to deliver harmonised standards to deadline or at all, or deliver standards that fail to satisfy the terms of the mandate. Such a limitation is provided for in the Machinery Regulation.

The Omnibus proposals also fail to make the adoption of common specifications conditional upon a standardisation mandate being issued in the first instance to the European standardisation organisations; their focus lies solely on the absence of harmonised European standards. This could lead to the Commission adopting common specifications without first involving the European standardisation organisations. This would undermine the systematic distinction between legislative responsibility and technical standardisation, which is one of the foundations of the New Legislative Framework (NLF). KAN considers the emergence of such a parallel structure and dilution of the NLF to be unacceptable.

The provisions described in the Omnibus proposals deviate not only from those already set out in the Machinery Regulation, but also and in a similar way from the provisions on common specifications contained in Regulation (EU) 2024/1689 on

artificial intelligence (the AI Act) and in Regulation (EU) 2024/2847 on horizontal cybersecurity requirements for products with digital elements (the Cyber Resilience Act). This is of questionable alignment with the reasons for and objectives of the Omnibus proposals formulated by the Commission, which state the following with respect to the common specifications:

"[...] Several current legislative acts already contain an alternative option to provide businesses with legal predictability and prove compliance with EU law, to cater for such situations. The present proposal's objective 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.*"

Should the criteria for adoption set out in the Omnibus proposals be incorporated into numerous other items of Single Market legislation, a risk exists of large-scale inconsistencies between the individual product regulations in the Single Market. KAN therefore calls for the narrowly formulated criteria for application of common specifications set out in the Machinery Regulation to be adopted and retained, to ensure their consistent application in the Single Market and prevent further fragmentation and incoherence in the regulatory framework.

Procedures for development and adoption

Rules governing the composition of the committees responsible for standardisation work, means of participation in standardisation work by the stakeholders, and the processes by which working documents are approved for publication lend fundamental legitimacy to standardisation work. This transparency creates confidence in the results and strengthens their acceptance in the field.

Common specifications should be used only in cases where, despite standardisation mandates having been issued, the European standardisation organisations fail to deliver harmonised standards, or present standards that are deemed inadequate. KAN therefore considers it essential that common specifications be developed and adopted in accordance with clear, legally binding criteria and within a transparent process.

At present, it is not sufficiently clear how common specifications are to be developed by the Commission and how transparency and broad acceptance can be ensured in the process. KAN therefore calls on the European Commission to make the development process precise and publicly transparent.

The implementing acts for establishing common specifications are adopted in accordance with the comitology procedure laid down in Regulation (EU) No

182/2011 (the Comitology Regulation). The Omnibus proposals now provide for the advisory procedure under Article 4 of the Comitology Regulation to be applied in this context. This conflicts with previous arrangements, such as those of the Machinery Regulation, which provide for the examination procedure of Article 5 of the Comitology Regulation to be applied. Why the Commission's proposals deviate from the existing provision is unclear. KAN strongly advocates retaining the examination procedure, as this ensures a greater right of scrutiny over the implementing powers.

A further critical point is the absence in the Omnibus proposals of a mechanism for repeal or amendment of common specifications. Such a mechanism is necessary to enable reversion to normal standardisation work. The European standardisation system and the New Legislative Framework, with its clear distinction between legislative responsibility and technical standardisation, has proved to be a viable basis for the regulatory system in the Single Market. KAN therefore calls for a repeal mechanism to be included in the Omnibus proposals, modelled on the provisions in the Machinery Regulation concerning common specifications.

Involvement of stakeholders

A key principle of the European standardisation system is the broad participation of all stakeholders and affected parties in the development of technical standards. This principle ensures that the results are technically sound, socially acceptable and relevant to the field. KAN warns that common specifications must not be allowed to become an instrument that undermines the standardisation system and its established participation processes.

Particularly critical is the lack of clarity at this stage of how the necessary technical expertise for common specifications is to be ensured. Since common specifications are to be used as a fallback alternative to harmonised standards and as a result will affect technically demanding regulatory subject matter, sound and broadly based technical expertise is essential.

The comitology procedure applicable to implementing acts makes no provision for the involvement of societal stakeholders. The Machinery Regulation contains approaches for involving relevant committees and Commission expert groups, but these approaches are not present in the Omnibus proposals. In KAN's view, however, even the provisions in the Machinery Regulation are inadequate. External experts and all affected parties, including societal stakeholders such as the social partners and occupational safety and health representatives, must be involved systematically and at the earliest possible stage, and clear provisions to ensure this must be established. Mandatory consultation of stakeholders should be part of the development process itself.

In order to ensure wider participation in the process for adoption of common specifications, the draft implementing acts should be published for comment on the Have Your Say website. Given the complexity of the subject matter, stakeholders must also conduct in-depth analyses and solicit technical expertise from within their own circles. The current standard four-week deadline for comments on implementing acts would seem far too short for this purpose. KAN therefore proposes that the comment period for these implementing acts on the Have Your Say website be extended to twelve weeks, in order to ensure wider participation by qualified parties from among the stakeholders.

Specification of a horizontal legislative framework

At present, the legislative conditions for the adoption of common specifications are set out in the respective sector-specific legal acts. Consequently, the criteria for adoption of common specifications are reconsidered and renegotiated in the course of the legislative procedures for the respective individual legal acts. As a result, the provisions of the Machinery Regulation are already fragmenting in part to those of the AI Act or the Cyber Resilience Act.

The Omnibus proposals exacerbate this problem, as they have been drafted with significant deviations from those of previous arrangements, to the further detriment of consistency. KAN therefore sees an urgent need for common specifications to be enshrined horizontally in a single legal act, such as in a revision of the Standardisation Regulation (EU) No 1025/2012, rather than being addressed on a sector-by-sector basis in individual legal acts.

Such a legal act should not only lay down the procedure for developing, adopting and publishing common specifications, but should also include provisions on their validity and repeal and on possible conflicts with existing standards. It could also clearly define the essential cases for application and ensure that these are extended for a specific sector only in justified individual cases.

Finally, KAN emphasises that common specifications should be used only in clearly defined exceptional cases, and should under no circumstances undermine the proven European standardisation system. Maintaining the primacy of harmonised European standards, a transparent and participatory development and adoption process and a coherent legal framework are indispensable for the functioning of the Single Market and the acceptance of technical regulations. Many questions and ambiguities remain unanswered and unresolved, particularly with regard to the development of common specifications.

KAN therefore recommends that the European Commission reconsider the proposed provisions for common specifications set out in the Omnibus package: these must

not lead to the undermining of key elements of the NLF and the proven fundamental principles of the European standardisation system.

About KAN

In the Commission for Occupational Health and Safety and Standardization (KAN), the German representatives of employers, employees, the federal and state governments and the German Social Accident Insurance Institutions channel their interests and discuss them with DIN (German Institute for Standardization). KAN analyses standards and other outcomes of the work of standards organisations, and where applicable other bodies developing standards, that have a direct or indirect impact upon safety and health at work.

KAN's activities therefore include the monitoring of standardisation activity where it impacts upon occupational safety and health, and also the associated legislative activity in Europe, and drawing attention to needs for action. It is in KAN's interests that regulations and directives set out suitable and coherent statutory provisions and lead to corresponding standardisation mandates.

KAN is registered in the EU Transparency Register with the number **90520343621-73**.

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