

KAN Position statement

European Commission public consultation on the revision of Regulation (EU) No 1025/2012 on European standardisation

December 2025

1. Underpinning the Single Market: European standardisation

Regulation (EU) No 1025/2012 forms the central framework for the development of European standards. These standards play a crucial role in the harmonisation of products, services and processes within Europe. They thus contribute decisively to the functioning of the Single Market and to strengthening the European Union's competitiveness. The principle of clear demarcation between legislative responsibility and technical standardisation has proved to be a reliable basis for the European regulatory system.

Proven principles ensure quality and acceptance

The European standardisation system's efficacy has been demonstrated by its implementation in practice. It is based on such principles as transparency, the comprehensive participation of all stakeholders and interested parties and the development of standards by consensus. For standardisation to meet with acceptance, it is also important for the objects of standardisation to be limited to those for which a need for harmonisation exists. The regulation governs cooperation between organisations and institutions involved in European standardisation and ensures that these principles are observed and developed further. KAN considers these principles to be indispensable.

Adapting to new challenges

At the same time, the European standardisation system is facing new challenges: the growing pace of technology and innovation cycles, intensifying global competition and the continually widening spectrum of EU legislation. A revision of the regulation should therefore aim to increase the flexibility and efficiency of the standardisation system whilst at the same time retaining the proven and fundamental principles of standardisation.

2. Participation of societal stakeholders

An essential asset of the European standardisation system is the participation of societal stakeholders. These stakeholders, which include those in occupational safety and health, contribute their technical expertise to standardisation activity and enable knowledge gained in the field to be transferred to it. KAN therefore welcomes the European Commission's objective of improving inclusiveness and balanced stakeholder representation in the course of the revision.

Barriers to effective participation: KAN's demands

Major obstacles preventing societal stakeholders from participating effectively in the standardisation process still exist, however. These stakeholders, which include those in occupational safety and health, consider it essential that groups who have no commercial interest in a subject of standardisation but are affected by the content of the standard should have opportunities to participate in its development free of charge, and that the documents should be readily accessible and freely available.

KAN further welcomes the following measures envisaged by the European Commission:

- Assurance by the European standardisation organisations of a minimum level of participation of all affected societal stakeholders in the standards committees and technical committees that are co-funded by the European Union
- Establishing stronger voting rights for societal stakeholders in the standardisation process
- Enhanced transparency with regard to all stakeholders involved in the development of standards, including harmonised standards
- Greater facilitation of stakeholders' active participation in the standardisation process: simplified guidelines and easier access to information for societal stakeholders support the identification of relevant standards and promote understanding and thus also opportunities for participation in the standardisation process.

In addition, KAN proposes that consideration be given to the introduction of veto rights for societal stakeholders where they are particularly affected by the content of standards.

Finally, KAN points out that the current efforts to make the standardisation system more flexible must not lead to societal stakeholders' opportunities to participate being constrained.

Annex III organisations: progress and limitations

Financial support as provided for in Annex III to Regulation (EU) No 1025/2012 has enabled small and medium-sized enterprises and societal stakeholder groups such as consumers, trade unions and environmental protection organisations to exert greater influence in the standardisation process. KAN also points out, however, that the Annex III organizations are limited in their ability to participate in the numerous meetings of standards committees and working groups potentially relevant to them. In addition, depending upon a standard's content, further parts of civil society may be affected by it that cannot be assigned to the current Annex III organisations.

Relevance of the social partners' interests

Article 5 (1) of Regulation (EU) No 1025/2012 provides for the participation of a range of stakeholders, including SMEs, consumer organisations and societal stakeholders. The legally safeguarded interests of the social partners should be regarded as an essential societal interest in this context. In KAN's view, greater emphasis should be placed on this aspect during the revision process, both in the recitals and in the enacting terms of the regulation.

3. Acceleration of the standardisation process

KAN recognises that swift development of standards is desirable. Accelerating the standardisation process must not, however, lead to any compromise in the quality of the standards' content. In order for standards to meet with acceptance in industry, the research community and wider society, they must be based on the broad expertise of a large number of diverse stakeholders. In this context, it must be ensured that sufficient time is allocated for the steps needed to put the standardisation principles into effect, including broad participation and development on the basis of consensus.

Deadlines and quality assurance in the standardisation process

Particular caution is required regarding the introduction of additional deadlines for individual process steps. Tight schedules must not compromise the quality of the results. Decisions on the duration of standards development work, including in fast-track procedures, should remain the responsibility of the standards committees themselves. Decisions concerning the content of standards and the procedure for their development must likewise remain the prerogative of the standards committees.

Simplified procedures only with retention of rights to participate

Whereas simplified procedures are certainly advantageous for purely formal amendments to standards, such as the updating of dated references, they are not suitable for changes to the standards' content. Where measures for simplification are adopted, it must be ensured that the fundamental principles of standardisation continue to be observed and the broad participation of all stakeholders and interested parties guaranteed. Simplified processes must not lead to opportunities for participation being restricted.

3.1. Common specifications and alternative European standardisation products

In recent years, scope for introducing common specifications has been enshrined by the European Commission in certain Single Market regulations. With the recently published Omnibus IV package, this instrument has been extended to a large number of further Single Market regulations. These implementing acts are intended to serve as an exceptional fallback solution for the 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 deemed inadequate.

KAN's position on common specifications

KAN has already commented¹ on common specifications on several occasions and has formulated the following demands:

- Primacy of harmonised European standards
- Use of common specifications only as a last resort
- Strict criteria for the adoption of common specifications: in particular, that they should not be adopted for vague reasons or reasons of urgency ("urgent concerns")
- A transparent and participatory process with clear, legally binding criteria and timely involvement of all relevant stakeholders, including those in occupational safety and health
- A coherent legal framework with harmonised rules for validity, withdrawal and procedures
- A mechanism for reintegrating common specifications into the European standardisation system

¹ Refer also to the KAN position paper on the European Commission's common specifications instrument (www.kan.de/fileadmin/Redaktion/Dokumente/Basisdokumente/en/EU/KAN_position_paper_Common_Specifications.pdf) and the KAN position statement on the IVth Omnibus Package: Proposals for a Regulation and a Directive on digitalisation and common specifications (www.kan.de/fileadmin/Redaktion/Dokumente/Basisdokumente/en/Deu/2025-08_Stellungnahme_Omnibus_Common_Specifications-en.pdf).

Critical assessment of alternative standardisation products

KAN also takes a highly critical view of the Commission possibly resorting to alternative standardisation products in order to make the standardisation system more flexible.

Alternative standardisation products present a fundamental risk that the shortened procedures envisaged for them will considerably restrict the participation of societal stakeholders. Not only would this impact negatively on democratic processes and the acceptance of standardisation, it would also reduce the quality of the results in terms of content. This equally applies to the alternative standardisation products of the kind currently being developed by CEN-CENELEC, such as the European Agile Specifications (EASs).

Consensus-based development of standards is a central and particularly valuable element of the regulatory system in the European Single Market. This asset must not be jeopardised. KAN therefore demands that only standards in the strict sense should be able to give rise to a presumption of conformity, as they alone guarantee full compliance with the principles of standardisation. Where harmonised standards are not immediately available, no further measures are required: All legal acts of the New Legislative Framework make provision for economic operators to be able to make use of other available technical specifications and standards in such cases and state this in their technical documentation, in accordance with the relevant conformity assessment procedure. Although the reversal of the burden of proof achieved by the presumption of conformity is desirable, it is not an imperative requirement for the New Legislative Framework to function.

3.2. Recourse to other standardisation organisations and standardisation products

In order to make the standardisation system more flexible, the Commission is also considering awarding standardisation mandates to organisations beyond the existing European standardisation organisations or making use of standardisation products from other organisations. In KAN's view, this should be viewed critically, as any widening of the existing arrangement must be subject to societal stakeholders being granted at least the same rights and opportunities for participation and public involvement that they enjoy in the European standardisation system. Recourse to standardisation organisations and products outside Europe carries the risk that the participation of societal stakeholders cannot be guaranteed.

KAN therefore calls for standardisation mandates issued to bodies other than the existing European standardisation organisations to contain strictly defined

conditions ensuring that development is conducted in observance of the European standardisation principles and does not present obstacles to participation by the societal stakeholders.

Detailed review of other standardisation products

Before external standardisation products are adopted, a careful review of their content is also necessary. A decision to adopt such a product should be the responsibility of the standards committees with responsibility for the relevant subject area.

Critical monitoring of open call procedures

Facilitation of possible “open call procedures” must also be monitored critically. Standardisation mandates may be awarded only to organisations that comply with all basic principles of European standardisation activity, such as inclusiveness, transparency, and consensus-based and public consultation procedures. In particular, they must guarantee societal stakeholders, such as those in occupational safety and health, the same opportunities to participate in the development of standards.

3.3. Widening of Annex I of the regulation

One proposal by the Commission for increasing the standardisation system’s flexibility is for the list of European standardisation organisations contained in Annex I of Regulation (EU) No 1025/2012 to be regularly reviewed. In KAN’s view, adding further organisations to the list poses considerable risks for societal stakeholders, such as those in occupational safety and health.

Ensuring the participation of societal stakeholders

At present, the participation of societal stakeholders is enshrined solely for the existing European standardisation organisations. Should further organisations be added to the list, it must be ensured that they satisfy the same conditions for comprehensive and effective participation as those guaranteed for and practised by the existing European standardisation organisations.

Avoidance of further strain on resources

Furthermore, extension of the European standardisation organisations must under no circumstances place additional strain on the human, administrative and financial resources of the societal stakeholders. Their ability to participate in the numerous standards committee meetings relevant to them is already limited. So as not to restrict opportunities for participation further, structures and processes must remain transparent and clear.

Clear and comprehensible criteria for additional organisations

Finally, the inclusion of further organisations in the list of European standardisation organisations must be based entirely on clear, publicly comprehensible criteria and requirements.

3.4. Procedure for requesting, evaluating and publishing harmonised standards

From KAN's perspective, the entire procedure for requesting, evaluating and publishing harmonised standards should be presented more transparently to make it more readily comprehensible to experts and users involved in standardisation, without necessarily simplifying the procedure itself.

Proven cooperation in SRAHGs

With regard to the requesting of harmonised standards, dialogue in the Standardisation Request Ad-Hoc Groups (SRAHGs) between the bodies involved in standardisation and with the participation of the European Commission has proved beneficial. KAN is therefore committed to this being maintained on the same scale.

Increasing the efficiency and transparency of the review and listing process

To accelerate the standardisation process, particular attention must continue to be paid to the time frame for the review and listing of harmonised standards. KAN's view of the system of HAS Consultants, which was introduced for the reviewing of harmonised standards, is that it still lacks the required efficiency and requires additional human and structural resources. High formal requirements slow the process down further.

Conversely, measures to increase transparency and the compliance rate could accelerate the process. Communication with the affected standards committees during the ongoing process should be facilitated: for example, optional feedback loops could be set up at defined milestones, such as after completion of the draft stages. However, care must be taken to ensure that the neutrality of the HAS Consultants is maintained.

Overall, assessment of standards by HAS consultants must be made more effective, with closer consultation of the respective standards committees, and significantly more transparent. In addition, standards that have passed the assessment process must be listed in the Official Journal of the EU more quickly than to date.

4. Digitalisation of the development process

Digitalisation of the standards development process is an important step by which efficiency and transparency can be promoted. In KAN's view, however, care must be taken to ensure that digitalisation measures facilitate the process without limiting, much less hindering, the opportunities for participation. Furthermore, digital measures must not lead to a decline in the quality of standardisation documents. The work of standards committees requires intensive efforts to reach a consensus; the option of face-to-face meetings in person must therefore be retained.

In addition, harmonised standards must follow strict structures and formats to ensure their readability and suitability for automated processing. These requirements are, for the most part, already in place, but require continual coordination with the international standardisation organisations ISO, IEC and ITU to ensure global coherence and acceptance.

5. Adoption of international standards

In its 2022 EU Standardisation Strategy, the European Commission emphasises that the European Union must strengthen its role as a global standard-setter and play a pioneering role in setting international standards. In this process, it must be ensured that standardisation continues to be based on consensus, and follow democratic principles. This includes adequate participation by all stakeholders in occupational safety and health. KAN also takes the view that a high level of protection must be assured for vulnerable groups such as workers.

Focus on key technologies

In KAN's view, the European Commission's goal of establishing the European Union as a global standard-setter should be reassessed in the light of limited resources and depending on market relevance. In the interests of influence being stronger and more coordinated, consideration should be given to whether it would be advantageous to focus on individual key technologies and core areas. This would also be consistent with the goal of improving opportunities for societal stakeholders to participate at international level.

Clear quality criteria and rigorous assessment

The adoption of international standards into the European body of standards must be based on clear quality criteria. It is imperative to ensure that the standards are compatible with the existing European legal framework and the national regulations of the Member States. Standards that conflict with these requirements or encroach into areas that enjoy constitutional protection, such as the collective bargaining

autonomy of the social partners or internal company organisation, must not be adopted.

International standards should be selected and adopted only where they are strategically desirable and address existing deficits. Furthermore, no standard should be adopted without the involvement of the relevant European standards committees and their close expert scrutiny of the non-European standard concerned. Where occupational safety and health concerns are affected, a standard may be adopted only if competent committees exist at European level.

The Vienna Agreement and the Frankfurt Agreement already provide for cooperation between ISO and CEN and between IEC and CENELEC. If the European standardisation organisations reject the development of a standard within this framework, international standards must not be given an alternative path of entry into the European body of standards.

6. Role of market surveillance and formal objections

Finally, KAN believes that the role of market surveillance in standardisation should be strengthened. This would enable formal objections to be avoided proactively and confidence in standardisation to be increased.

Furthermore, the process for submitting and examining formal objections, as laid down in Article 11 of Regulation (EU) No 1025/2012, should be reviewed with a view to it possibly being streamlined and thereby accelerated.

About KAN

In the Commission for Occupational Health and Safety and Standardisation (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.

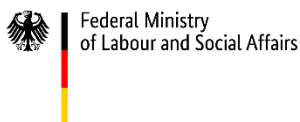
KAN's activities therefore include the monitoring of standardisation activity where it impacts upon occupational safety and health, and also the associated legislative activity in Europe, and drawing attention to needs for action. It is in KAN's interests that regulations and directives set out suitable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