

## **KAN position paper**

# **Accelerated standardisation processes at CEN/CENELEC: European Agile Specifications**

**Presumption of conformity only for full standards**

**March 2026**

## 1. Core positions

KAN takes the view that only full standards should give rise to the presumption of conformity, as they are the only ones subject to all the established fundamental principles based on the WTO criteria for standardisation. Consequently, only these standards possess the legitimacy required for the special role intended for them within the framework of conformity assessment procedures and thus under Union law<sup>1</sup>.

In KAN's view, the European Agile Specification (EAS) must not give rise to a presumption of conformity. Standardisation documents may only give rise to a presumption of conformity if

- accelerated processes do not compromise their quality and legitimacy,
- they continue to enjoy a high level of acceptance by drawing on the broad expertise of all relevant stakeholders, for which sufficient time must be allowed in the drafting and public enquiry process,
- genuine consensus is reached during their development, as this is the only way to ensure that important societal interests, such as those relating to occupational safety and health, are adequately taken into account,
- efforts to make their development process more flexible do not lead to further constraints on the opportunities for interested parties to participate, as limited participation and dispensing with a public enquiry reduce their legitimacy and prevent feedback at an early stage regarding technical and practical problems.

In the event that harmonised standards are not available immediately, no further action is required. The legal acts under the New Legislative Framework (NLF) provide that economic operators may refer to other technical specifications and standards, and demonstrate this to the market surveillance authorities or the notified body by means of the technical documentation in line with the available conformity assessment procedures. While the presumption of conformity conferred by the application of a harmonised standard and the resulting reversal of the burden of proof are desirable, they are not a prerequisite for the functioning of the NLF.

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<sup>1</sup> Court of Justice of the European Union (CJEU), Judgment of 27 October 2016 – C-613/14, James Elliot Construction Ltd./Irish Asphalt Ltd.

## 2. Background

EAS is a new type of document developed by CEN/CENELEC to permit a swifter response to new market-related, technological and regulatory requirements. The aim is for technical specifications to be made available within short space of development time.

CEN/CENELEC has presented the EAS to the European Commission as an alternative for harmonised European standards in order to accelerate standardisation processes. The background to this proposal is that with the instrument of common specifications<sup>2</sup>, the Commission has already created the option of a fallback solution for the event that harmonised standards are inadequate or do not exist at all. The Commission is also considering drawing on outcomes produced by standardisation organisations beyond those already established in Europe. The EAS is to serve as an alternative standardisation product developed by the Technical Committees (TCs) and Working Groups (WGs) within the existing European standardisation system, and is to be able to give rise to the presumption of conformity.

### **Development process planned by CEN/CENELEC**

The aim of the development process envisaged by CEN/CENELEC is for an EAS to be developed in accordance with the principles of openness, transparency and balanced participation, despite the accelerated process. The national standards bodies are to ensure compliance with these principles.

An EAS is to serve as an intermediate step towards a full European standard. The procedure for their development differs from the normal standardisation process in that an EAS is to be published as soon as it is deemed to be safe, stable and "good enough" to be released. It is then to undergo a cycle of continual improvement until it is either transposed into a European standard by way of the normal procedure, or withdrawn.

Development of an EAS is to be based on a normal new work item proposal (NWIP). The responsible TC is to vote within four weeks on whether interest exists in principle in addressing the topic. Consistent with the principle of national

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<sup>2</sup> KAN Position paper on the European Commission instrument of common specifications, October 2024 ([www.kan.de/fileadmin/Redaktion/Dokumente/Basisdokumente/en/EU/KAN\\_position\\_paper\\_Common\\_Specifications.pdf](http://www.kan.de/fileadmin/Redaktion/Dokumente/Basisdokumente/en/EU/KAN_position_paper_Common_Specifications.pdf)) and KAN Position statement on the Omnibus IV package, August 2025 ([www.kan.de/fileadmin/Redaktion/Dokumente/Basisdokumente/en/Deu/2025-08\\_Stellungnahme\\_Omnibus\\_Common\\_Specifications-en.pdf](http://www.kan.de/fileadmin/Redaktion/Dokumente/Basisdokumente/en/Deu/2025-08_Stellungnahme_Omnibus_Common_Specifications-en.pdf)).

delegation, the national standardisation organisations are to be involved in voting, conduct consultations at national level and delegate experts to the working group.

Plans are for the draft to be developed in the responsible working group, optionally even before the work item proposal has been voted upon. The outcome of the development process is to be open at the outset of development: the final form of publication is to be determined only in the course of the process. It is also envisaged that a smaller group (a drafting team) within the WG will prepare an initial draft. Once sufficient progress has been made on the draft and it meets with the support of the WG, the latter is to decide whether to publish the document as an EAS. To this end, a consensus is to be sought within the WG, but with no obligation for a consensus actually to be reached (consensus-driven development process).

The vote in the TC on the draft for publication is to be held within four weeks. Should the result of the vote be positive, the EAS is to be published; should it be negative, the document is to be returned for revision to the WG, which should then consider the TC's comments. Unlike the normal standardisation procedure, provision is not made for a public enquiry.

The EAS is to be announced and published in English by the national standardisation organisations. Translations are to be possible, but must not delay the development and publication process. No obligation is to exist for the EAS to be adopted at national level. An EAS must not contradict an existing European standard, but no requirement exists that national standards conflicting with it be withdrawn.

Once an EAS has been published, the TC is to decide whether it should be revised and republished as an EAS or transposed into a full EN standard by way of the usual procedure. Each EAS is to be reviewed at least every three years for its market relevance and potential for further development into a European standard.

The EAS pilot phase has already started. The new process is being tested in practice in selected TCs in order to gain experience and receive feedback at an early stage. CEN/CENELEC's aim is to assess the clarity, efficiency and added value of the process and of the EAS itself, and to identify any need for adjustment.

### 3. KAN's position

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. KAN considers these principles to be indispensable as they ensure the legitimacy and acceptance of standardisation.

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, which is accompanied by increasingly short deadlines for the development of supporting standards. Against this backdrop, the efforts of CEN/CENELEC are understandable. In KAN's view, however, the proven fundamental principles that are essential to standardisation must not be watered down. Furthermore, the dynamic nature of the standardisation system increases its complexity and makes it more difficult for societal stakeholders, which includes those in occupational safety and health, to participate.

#### Compliance with the principles of standardisation

An important foundation for the legitimacy of standardisation work lies in the rules governing the composition of the committees responsible for the work, the opportunity for stakeholders to participate in the standardisation process, and the procedures through which working documents are approved for publication. These rules build trust in the results and strengthen their acceptance in practice.

CEN/CENELEC state that an EAS should be drawn up in accordance with the principles of openness, transparency and balanced participation and within defined rules in order to ensure a consensus-driven development process despite the accelerated process. However, no obligation exists for an EAS to be developed in accordance with the WTO criteria<sup>3</sup> for the development, adoption and application of standards.

From KAN's perspective, it is crucial that the introduction of EAS not lead to an erosion of the proven fundamental principles of standardisation, particularly not when standards are to be assigned such a prominent role in EU law. Accelerated

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<sup>3</sup> Committee on Technical Barriers to Trade. Second triennial review of the operation and implementation of the agreement on technical barriers to trade. G/TBT/9, 13 November 2000. Annex 4 p. 24-26 ([https://docs.wto.org/dol2fe/Pages/FE\\_Search/ExportFile.aspx?id=4879&filename=Q/G/TBT/9.pdf](https://docs.wto.org/dol2fe/Pages/FE_Search/ExportFile.aspx?id=4879&filename=Q/G/TBT/9.pdf)).

procedures must not compromise transparency, balanced participation and comprehensive consensus-building.

## **Acceleration must not compromise quality and legitimacy**

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.

Unlike the normal standardisation process, in which a standard is published only once full consensus has been reached and following a comprehensive review, an EAS can be published as soon as the TC deems it to be safe, stable and "good enough" to be released.

From KAN's perspective, this approach entails considerable risks. It is left solely to the TC to determine whether a standardisation document is safe, stable and "good enough" to be released, and can therefore be published as an EAS. Moving away from the established approval processes for standards may result in important interests not being adequately taken into account and may undermine the legitimacy of standardisation work. 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.

## **Consensus-building must be mandatory**

Development of standards on the basis of consensus is a central pillar of the European standardisation system and a particularly valuable element for the legitimacy of the regulatory system in the Single Market. It ensures that all stakeholders and interested parties are involved in the process and that the results meet with broad acceptance.

In the case of EASs, however, this principle is watered down: the documents are not intended to be developed on the basis of consensus. The aim is simply to seek consensus within the respective working group, without any obligation to actually reach a consensus (consensus-driven development process). This is immediately followed by the vote in the relevant TC.

In the absence of a broad consensus, a risk exists that important societal interests, including those relating to occupational safety and health, will not be given adequate consideration. Furthermore, an EAS may be published despite low levels

of approval or participation in the vote. From KAN's point of view, the vote in the TC therefore does not constitute a sufficient control mechanism capable of ensuring the quality and acceptance of the document.

## **Ensuring stakeholder participation**

A further essential principle of the European standardisation system is the broad participation of all stakeholders and interested parties in the development of technical standards. This principle ensures that the results are technically sound and socially accepted and enables knowledge gained in the field to be transferred to the standardisation process. KAN urges that the current efforts to make the standardisation system more flexible must not lead to stakeholders' opportunities to participate being constrained any further.

In the case of alternative standardisation products such as the EAS, a risk exists in that the accelerated procedures will significantly constrain stakeholder participation. This would not only undermine the democratic processes and the acceptance of standardisation work but also diminish the quality of the standards' content.

No provision is made for a public enquiry during the development of an EAS. KAN emphasises that a public enquiry creates transparency and strengthens confidence in the standardisation process. It provides an opportunity to identify technical and practical issues prior to publication and thereby helps to improve the content. Furthermore, it ensures the participation of all interested parties and contributes to balanced outcomes. Finally, a public enquiry also strengthens acceptance of the standards in industry and wider society within the Single Market. KAN points out that taking stakeholders' feedback into account only during a subsequent revision of the EAS is not sufficient. Such an opportunity for feedback does not replace a public enquiry prior to publication.

## **Presumption of conformity only for full standards**

As a possible alternative to harmonised standards, EASs are also intended to be able to give rise to the presumption of conformity. The opportunities for stakeholders to influence the process are hampered by shortened procedures, the associated time pressure and the absence of a public enquiry. Moreover, unlike in the normal standardisation process, an EAS is to be published as soon as the individuals involved in its development consider it to be safe, stable and sufficiently robust. This contravenes the fundamental principles for the development of standards. In KAN's view, documents that only meet these criteria cannot be considered to be of assured quality or to possess sufficient legitimacy to give rise to a presumption of conformity. This equally applies to Technical Specifications (TS) and Technical Reports (TR).

In the event that harmonised standards are not available immediately, no further action is required. The legal acts under the NLF provide that economic operators may refer to other technical specifications and standards, and demonstrate this to the market surveillance authorities or the notified body by means of the technical documentation in line with the available conformity assessment procedures. While the presumption of conformity conferred by the application of a harmonised standard and the resulting reversal of the burden of proof are desirable, they are not a prerequisite for the functioning of the NLF.

KAN therefore advocates that only full standards be eligible for giving rise to a presumption of conformity, as only these guarantee full compliance with the standardisation principles.

## 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.

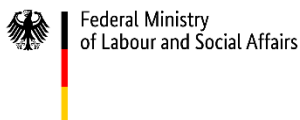
KAN's activities therefore include the monitoring of standardisation activity where it impacts upon occupational safety and health, and also the associated legislative activity in Europe, and drawing attention to needs for action. It is in KAN's interests that regulations and directives set out suitable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