KAN Kommission Arbeitsschutz und Normung

Position paper

The European Commission Instrument of Common Specifications

October 2024

1 Key messages

- The process for development, adoption and publication of common specifications should be governed by a single, binding, horizontal act.
- Common specifications should be developed and adopted in accordance with clear, legally binding criteria and within a transparent process.
- All stakeholders, including societal interest groups such as that for occupational safety and health, should be involved in the process.
- The European Commission should make use of the instrument of common specifications only in exceptional cases.

2 Background

The European Commission has recently been empowered in several EU directives and regulations to use a further instrument. These are the "common specifications". Article 3 (28) of the Artificial Intelligence Act[1] defines common specifications legally as:

> "[…] a set of technical specifications as defined in Article 2, point (4) of Regulation (EU) No 1025/2012 [Standardisation Regulation[2]], providing means to comply with certain requirements established under this Regulation".

Common specifications thus supplement harmonised standards as an instrument for the purpose of harmonising product requirements.

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1 Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202401689&qid=1727080578913).

2 Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R1025&qid=1728476212963).

Yet, no horizontal legal framework has been in place setting out generic provisions concerning the essential requirements for common specifications and the process for their development and adoption. Instead, the process has become established for them to be enshrined in individual acts. As a result, common specifications are currently provided for in acts such as the following:

- Regulation (EU) 2023/1230 on machinery (Machinery Regulation)[3]
- Regulation on horizontal cybersecurity requirements for products with digital elements (Cyber Resilience Act)[4]
- Regulation (EU) 2024/1689 laying down harmonised rules on artificial intelligence (Artificial Intelligence Act)[5]

Note: Implementing acts termed common specifications are already referred to in the Medical Devices Regulation (MDR)[6] and the In Vitro Diagnostic Medical Devices Regulation (IVDR)[7]. These implementing acts are based on explicit requirements set out in these two acts.[8] In these cases, standardisation mandates were not

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[3] Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023R1230).

[4] Regulation of the European Parliament and of the Council on horizontal cybersecurity requirements for products with digital elements and amending Regulation (EU) 2019/1020, final compromise text as approved by the European Parliament on 12 March 2024 (https://www.europarl.europa.eu/doceo/document/TA-9-2024-0130_EN.pdf).

[5] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202401689&qid=1727080578913).

[6] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745).

[7] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0746).

[8] Cf. Article 17 (5) and Article 1 (2) in conjunction with Article 9 (1) of the MDR and Article 9 (1) of the IVDR in conjunction with Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022 laying down common specifications for certain class D in vitro diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R1107).

issued to CEN/CENELEC, as the legislation provided for independent development of technical specifications by the European Commission from the outset.[9]

2.1 Essential conditions for empowerment

Common specifications are to be solely an "exceptional fall back solution"[10] by the European Commission. Implementing acts may therefore be adopted only if several conditions are met:

- 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 and:
  - the request has not been accepted; or
  - 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
  - the harmonised standards do not comply with the request; and
- no reference to harmonised standards 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.[11]

Further conditions or means of application specific to individual acts may also apply (see also 2.1).[12]

In view of the role of harmonised standards, this option is regarded by the Commission as a fall back solution which is intended to ensure that the public interest is served in cases where harmonised standards do not exist or are

[9] For further information on Common Specifications in the MDR and IVDR, refer to the Medical Device Coordination Group Document, "Guidance on standardisation for medical devices" (https://health.ec.europa.eu/document/download/59ac4cb0-f187-4ca2-814d-82c42cde5408_en?filename=md_mdcg_2021_5_en.pdf&prefLang=en), pp. 22 f.

[10] Cf. Recital 45 of the Machinery Regulation or Recital 121 of the Artificial Intelligence Act.

[11] Cf. Article 41 (1) of the Artificial Intelligence Act or Article 20 (3) of the Machinery Regulation.

[12] Cf. Article 41 (1) (a) (iii) of the Artificial Intelligence Act.

inadequate. In the 2022 EU Strategy on Standardisation[13], the Commission stated that it was working towards a horizontal approach in terms of criteria and processes for when and under which conditions it could be empowered to adopt common specifications where provided for in the relevant legislation. The horizontal approach is intended to avoid fragmentation of the sectoral approaches.

2.2 Development and adoption of common specifications

The individual acts contain no indication of how the European Commission may develop the specific, technically demanding common specifications and how the necessary expertise can be ensured.

Several means exist for the Commission to produce an initial draft of common specifications. Firstly, the Commission could develop common specifications itself within its own services in cases where a harmonised standard is inadequate. Secondly, the Joint Research Centre (JRC) could be tasked with development. Thirdly, contracts can also be concluded with independent service providers.

Before the Commission adopts the common specifications, Commission expert groups[14] are consulted and the draft legislation is published for comment by the general public on the 'Have your say' portal[15].

The act is then adopted, in the form of an implementing act, in the comitology procedure. The Commission - and in special cases also the Council - is empowered to adopt implementing acts to ensure that EU legislation is applied and implemented uniformly. Implementing acts also have the purpose of addressing topical developments that would otherwise necessitate revision of legislation that has already been adopted. However, for an implementing act to be adopted, provisions to this effect must be set out in the act concerned. The specific objectives and requirements of this instrument are also defined in the process. In addition, implementing acts can be adopted only in areas where harmonised conditions for implementation are necessary. One such area is the protection of people's safety and health. As part of the comitology procedure, a group of experts

[13] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions: "An EU Strategy on Standardisation – Setting global standards in support of a resilient, green and digital EU single market" (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52022DC0031), p. 6.

[14] Cf. also https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups-explained?lang=en.

[15] https://have-your-say.ec.europa.eu/index_en.

comprising representatives of the Member States is consulted during the drafting of implementing acts.[16]

2.3 Repealing of common specifications

General provisions for the repealing of common specifications do not exist; only specific rules in individual acts. Where a harmonised standard is developed and proposed to the Commission for listing, the Commission reviews it in accordance with the provisions of the EU Standardisation Regulation. Upon publication of the harmonised standard in the Official Journal of the European Union, the common specifications that cover the same requirements of the regulation or directive are fully or partially repealed by the Commission.[17]

Furthermore, when a Member State considers that an implementing act does not entirely satisfy the requirements of the relevant regulation or directive, it may inform the Commission by submitting a detailed explanation. The Commission evaluates the detailed explanation and may amend the common specifications if required.[18]

3 Position of KAN

As the voice of the German occupational safety and health interests in standardisation and in consideration of the above explanations, the position adopted by KAN is as follows:

3.1 Definition of a horizontal legal framework

The legal framework for the adoption of common specifications is currently defined in the relevant sector-specific individual acts. The relevant provisions are therefore considered and negotiated for each individual act. This results in the requirements for the adoption of common specifications potentially differing from one act to

[16] Further information on implementing acts: https://www.kan.de/en/publications/kanbrief/2/23/the-implementing-act-an-instrument-for-harmonized-implementation-of-eu-legislation.

[17] Cf. Article 41 (4) of the Artificial Intelligence Act, Article 20 (7) of the Machinery Regulation, Article 27 (6) of the Cyber Resilience Act.

[18] Cf. Article 41 (6) of the Artificial Intelligence Act, Article 20 (8) of the Machinery Regulation, Article 27 (7) of the Cyber Resilience Act.

another.[19] It further leads to fragmentation and incoherence of the body of standards and regulations.

To prevent this, the process for the drafting, adoption and publishing of common specifications should therefore be governed by a **single horizontal act** that is binding for all Single Market legislation.

This act should include **additional provisions for the repealing and validity** of common specifications and **conflicts between items of legislation**.

Such an act would also define the essential cases of application in a binding manner. **Extensions specific to individual acts could thus be limited to exceptional cases**.

3.2 Transparency of the process

Rules on the composition of the responsible committees, how the affected parties can participate in the standardisation work and which procedures are used to release the working documents for publication are an important basis for the legitimation of standardisation work. Transparency of these provisions builds trust.

Common specifications provide a fall back solution for cases where European standardisation organisations fail to submit harmonised standards despite receiving a standardisation mandate, or where the existing standards are inadequate.

KAN therefore considers it essential that common specifications be developed and adopted on the basis of **clear, legally binding criteria** and within a **transparent process**.

3.3 Involvement of stakeholders

KAN acknowledges that the process for adopting implementing acts allows for some degree of stakeholder involvement, such as by publication of the draft in the 'Have your say' portal. However, common specifications are – as a fall back solution to harmonised standards – a technically challenging regulatory matter. For the stakeholders to be able to make substantiated comments to the drafts, an in-depth analysis and further expert input is required. The period of four weeks envisaged for this entire process appears to be too short.

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[19] For example, Article 41 of the Artificial Intelligence Act expands some of the conditions for empowerment described under 1.1. Subject to the further conditions being met, this also enables the Commission to take advantage of the instrument of the Common Specifications when "the relevant harmonised standards insufficiently address fundamental rights concerns".

KAN therefore proposes, in particular, **the possibility to comment** on the draft implementing act in the 'Have your say' portal **be extended to at least twelve weeks**, as part of the process for adoption of common specifications.

Furthermore, it has not yet been clearly defined how the required technical expertise will be ensured during drafting of the implementing act.

In KAN's view, not only should all the Commission's relevant committees and expert groups be consulted at the earliest opportunity, but also external experts. **Participation by all stakeholders**, including societal interests such as occupational safety and health, must be ensured.

3.4 Common specifications as the last resort

KAN welcomes the Commission's acknowledgement of the fundamental primacy of harmonised European standards in its own declaration that common specifications represent merely a "exceptional fall back solution". Yet, however, this primacy is stated only in accompanying documents[20] and in the recitals[21] of the acts concerned.

KAN therefore proposes that the statement of this primacy **be enshrined in a legally binding manner, possibly in a horizontal act**.

Furthermore, as defined in the Standardisation Regulation[22], harmonised European standards have the following advantages over common specifications:

- The process of their development within the European standards organisations is transparent.
- All stakeholders, including societal interests such as occupational safety and health, are able to participate in standardisation, thereby enabling the broadest possible technical expertise to be ensured.

[20] Cf. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions: "An EU Strategy on Standardisation – Setting global standards in support of a resilient, green and digital EU single market" (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52022DC0031), p. 5.

[21] Cf. Recital 121 of the Artificial Intelligence Act, Recital 45 of the Machinery Regulation, Recital 84 of the Cyber Resilience Act.

[22] Article 2 (1) (c) of the Standardisation Regulation.

- Standards are developed by consensus by means of a bottom-up approach; consequently, those who use the standards are directly involved in their development.

- Trust in the final product is build.

KAN shares the view that the instrument of common specifications **should be used only as a fall back solution**.

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 pool their interests and discuss them with DIN (German Institute for Standardization). KAN analyses standards and other outcomes of the work of the standards bodies, and where applicable other organizations developing standards, that have a direct or indirect impact upon safety and health at work.

KAN's activities therefore include the monitoring of standardization 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 standardization mandates.

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

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