

20 July 2022

COMMON SPECIFICATIONS

KEY MESSAGES



- 1** The European Commission's Standardisation Strategy must not undermine the New Legislative Framework for products by creating a parallel system via the Commission's reliance on common specifications instead of standards.
- 2** Common specifications should be seen as a time-limited 'fallback option' until harmonised standards are available. Their use should be permitted only under strict, finite, and clear criteria; reinforcing that they are not to be used as a complete replacement for harmonised standards.
- 3** If common specifications must be issued, it is critical they follow standards and the appropriate scrutiny process is applied, as outlined in Regulation (EU) 1025/2012, in order to maintain consistency.
- 4** The horizontal approach of the European Standardisation Strategy requires more clarification and precision to create legal certainty both with EU legislation and international criteria.



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CONTEXT

European-wide harmonised standards are a proven method for assisting regulators and driving practical innovation that is embedded in the market. For this to remain it is critical the fundamental principles of the New Legislative Framework (NLF) – the maintaining of the separation of essential requirements from technical realisation – are upheld. Such an approach avoids overly prescriptive technical requirements or disproportionate verification schemes in the legislation, ensuring the technical design aspect leads to compliance in implementation. If Europe is unable to maintain this balance, we fear it risks decoupling from the global market and triggering a loss of market access as a result.

While BusinessEurope welcomes in principle the Commission's European Standardisation Strategy, it is crucial the strategy does not undermine the NLF and create a parallel system via the Commission's reliance on common specifications.

LEGAL FRAMEWORK

Whereas harmonised European standards are governed by Regulation (EU) 1025/2012, the usage of common specifications has become more prominent in recent EU legislation¹ and upcoming Commission proposals.² The Commission in essence sees the utilisation of common specifications as a 'fallback' or 'safety net' option when harmonised standards do not exist, or existing ones are seen as insufficient.

The process for the Commission to initiate the creation of common specifications are set via implementing acts and under the following conditions:

- When there is no reference to harmonised standards published in the Official Journal of the European Union, or an existing standard must be revised.

¹ Regulation (EU) 2017/745 on medical devices, Regulation (EU) 2019/881, Cybersecurity Act.

² Artificial Intelligence (COM/2021/206), Machinery Products (COM(2021)202), Data Act (COM(2022)0068)



- Upon submitting a standardisation request to the European standardisation organisations for a new harmonised standard and:
 - The request has been denied,
 - A significant delay in establishing the standard occurs,
 - Or the Commission deems the standard unsatisfactory with the requirements of the EU legislation in question or the standard failed to comply with the Commission's initial standardisation request.
- The Commission furthermore must adhere to the standard rules regarding implementing acts but must also inform the Committee of Standards established by Regulation (EU) 1025/2012.
- In the case a common specification was adopted, and a harmonised European standard becomes available the Commission must assess if the standard is adequate and should be published subsequently resulting in the repealing of the common specification.

COMMENTS

Broadly this alternative approach should be avoided unless adhering to the strict criteria outlined below.

In addressing this issue BusinessEurope reiterates that transparency and inclusiveness of public-private partnership in the wider European Standardisation Strategy is a key factor to the economic success of the European Union. Thus, it is pivotal that common specifications *follow* standards and are appropriately scrutinised. When common specifications are being chosen this should be done by the Committee on Standards as specified under Regulation (EU) 1025/2012 therefore creating consistency with existing procedure.

In the following, BusinessEurope presents its recommendations for a way forward on clarifying the horizontal approach cited in the European Standardisation Strategy. Furthermore, we suggest key criteria that affirm when common specifications should be used. Ultimately common specifications must avoid the creation of a parallel system, nor should they contribute to the existing bottlenecks and backlog within the European Standardisation System³. Additionally, it is paramount common specifications ensure that continued alignment with technical requirements in international standards is maintained.

³ [BusinessEurope paper - Standardisation Strategy Roadmap](#), 9 August 2021



1. Clear criteria for common specifications

- a. BusinessEurope supports the Commission's intention to create binding and clear criteria for the commissioning or application of common specifications. In doing so, the following accumulative criteria should be considered:
 - i. There is no reference to harmonised standards published in the Official Journal of the European Union according to Regulation (EU) 1025/2012.
 - ii. The Commission has requested one or more European standardisation organisations to draft a harmonised standard and there are undue delays in the standardisation procedure, or the request has not been accepted without good reason by any of the European standardisation organisations or a European standardisation organisation has delivered a standard that does not entirely correspond with the request of the Commission (not taking insignificant or trivial disparities into account; nor discrepancies which objectively prove to be an improvement) after the standardisation organisation was given a reasonable period of time to adjust such standard after having been made aware of the disparity between the request and the deliverable.
 - iii. When references of a harmonised standard are published in the Official Journal of the European Union, the conflicting implementing acts shall be repealed.
- b. BusinessEurope suggests that along with the preconditions to justify the usage of common specifications, additional factors must be accounted for:
 - i. Clear deadlines and time limits that detail exactly when a common specification will become valid and when it will be withdrawn.
 - ii. The Commission must ensure funding is not diverted from the European standardisation organisations in the pursuit of developing common specifications.

2. Adequate expertise is essential

- a. Common specifications will require specific technical know-how on the state of the art, which is largely unavailable in the Commission and which has a limited expert pool to draw on. This may lead to a lack of experience and participation of qualified experts in the creation of common specifications consequently resulting in them being technically unfeasible or practical and ultimately unsuitable for application.



- b. The European Commission must take the lead in developing common specifications while ensuring necessary expertise is available even going so far as to integrate additional expertise when needed – thus further investment in the participation of experts at the technical level is needed.

3. Appropriate scrutiny procedure for common specifications

- a. Common specifications must be subject to the same principles and requirements as harmonised standards as without them the Commission's intent to be transparent and inclusive will fail.
- b. A review process for common specifications must be carried out in the Committee on Standards as part of the comitology procedure, akin to the procedure for harmonised standards. The Commission should be able to adopt the final implementing act only after a positive vote has been given by the Committee.

4. Clear terminology is key

Terminology and definitions are fundamental. We recommend that the term 'common specification' is used consistently and uniformly in the legislation that may foresee these common specifications.

5. Alignment of criteria across legislations and Internationally

- a. If the Commission applies common specifications this must be done in a harmonised manner. Upcoming legislative proposals and revisions of existing regulations must be consistent in their application of the criteria for common specifications.
- b. Considering the interconnectedness of European standardisation organisations to international standardisation bodies, the development of common specifications may lead to misalignment with the technical solutions proposed at the international level. An overuse of common specifications may undermine existing agreements, such as the Frankfurt and Vienna Agreements, between European and international standardisation organisations which ensure the alignment of technical requirements that are essential for the global competitiveness of European industry. It will be imperative common specifications are in line with the wider global initiatives if they are to be usable.

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