

Submission for Sweden's position ahead of EU negotiations – proposal for Omnibus IV on digitalisation and common specifications

The Council's proposal is set out in full in section 9. The Swedish Implementation Council's proposals in summary are:

- The Swedish Implementation Council considers that the Commission's proposal for Omnibus IV regarding common specifications comes at an inopportune time, as it risks pre-empting the planned revision of the Standardisation Regulation and creating regulatory uncertainty for companies.
- The Council supports the ambition to reduce the administrative burden for Swedish companies, but stresses that this must not be at the expense of the quality, transparency and broad acceptance of the well-established standardisation system. The Swedish Implementation Council therefore proposes that the Government should work to:
 - preserving the consensus-based standardisation system as the basis for European competitiveness
 - ensure that common specifications do not undermine this well-functioning system for European industry
 - prioritise the global competitiveness of Swedish companies through continued links to international standards
 - avoid regulatory fragmentation that could make it more difficult for Swedish export companies.

1. Task of the Swedish Implementation Council

The Swedish Implementation Council is tasked with assisting the Government in its efforts to strengthen the competitiveness of Swedish companies by avoiding implementation above the minimum level and counteracting unjustified regulatory burdens, as well as reducing administrative costs and other compliance costs in connection with the implementation of EU regulations in Swedish law. The Implementation Council's work must be based on a company perspective.

The Implementation Council is to submit documentation and recommendations to the Government, partly as a contribution to Swedish positions in negotiations and partly on how EU legal acts can be implemented in Swedish law in a way that is not more far-reaching from a business perspective than what the legal acts require.

The Implementation Council's work is based on problem descriptions that have been communicated to the Council, mainly from industry organisations and their member companies. During the work on the documentation, contacts are also made with others who are familiar with the respective subject area, such as government agencies. In the light of the information gathered and in the context of the overall objective of the act in question, the Council makes a weighted and independent assessment of how the business perspective can be effectively addressed in each case.

In preparing this opinion, the Council has mainly used documentation received in contacts with, among others, Teknikföretagen and the Confederation of Swedish Enterprise.

2. EU legislative proposal concerned

Commission proposal for a Directive COM(2025)503 and Regulation COM(2025)504 on the digitalisation and adaptation of common specifications, as part of the Omnibus IV proposal.

3. Objective and purpose of the proposal

The overall objective of the Omnibus IV proposal is to reduce the administrative burden on businesses and strengthen the EU's competitiveness. The proposal for common specifications aims to address the problem that it takes too long for standardisation organisations to establish harmonised standards that manufacturers can use to demonstrate compliance with EU legislation. According to the Commission, the common specifications should be a uniform and legally recognised alternative that can be used in the absence or inadequacy of harmonised standards.

4. Where in the process is the proposal?

The Omnibus IV proposal was presented by the European Commission on 21 May 2025 and is currently being prepared under the ordinary legislative procedure. Negotiations between the European Parliament and the Council are expected to start in the second half of 2025, with the possible final adoption of the act in 2026.

5. Responsible ministry

The Ministry of Climate and Enterprise and the Ministry of Foreign Affairs.

6. Problem description from a Swedish business perspective

The EU Harmonised Standards System (hENs) comprises over 3 600 technical specifications which, once cited in the Official Journal of the EU, confer a presumption of conformity and thus market access throughout the Union. The development of these standards takes place through extensive cooperation between industry, authorities, experts and civil society within the framework of the three European standardisation organisations (CEN, CENELEC and ETSI). 28% of CEN's and 67% of CENELEC's harmonised standards are based on ISO and IEC respectively, but currently 117 ISO/IEC standards are missing that have not yet been submitted to the Commission for publication in the Official Journal of the European Union. This means that companies do not always have access to up-to-date standards to rely on, which disrupts the functioning of the internal market and hinders product development, innovation and market access.

The Commission proposes to adopt technical specifications in the form of implementing acts under the advisory procedure. These powers are envisaged for situations where harmonised standards do not exist, where existing European standards are not fit for purpose, or when there is an urgent need.

According to stakeholders consulted by the Implementation Council, increased intervention by the European Commission in the standardisation process risks undermining the parallel development of European and international standards, thereby weakening the connection between European and global markets. Moreover, such intervention could reduce the process's flexibility and its adaptability to emerging technologies and policy objectives.¹

7. The Swedish Implementation Council's Analysis

Industries and companies concerned

According to a study commissioned by the Nordic standardisation bodies, 69 per cent of exporting companies state that standards simplify their export of goods and services. In the manufacturing industry – which, according to Statistics Sweden, accounts for just over 60 percent of Sweden's goods exports – 97 percent of companies report that they use standards. According to the aforementioned report, standards account for as much as 39% of labour productivity growth and 28% of GDP growth in the Nordic region during the period 1976–2014.²

Consequences for Swedish companies

The proposal introduces Common Specifications (CS) as a legally recognised alternative to harmonised standards, a time-limited solution with the aim of providing companies with a clear and legally certain path to market in the

¹ Additional challenges have arisen following the European Court of Justice's ruling in case C-588/21 P ("Malamud"), which has created uncertainty about copyright and the financing of standards. There are now 62 pending requests for open access to hENs, covering around 10 000 standards and representing an investment cost of EUR 10 billion. National standardisation bodies are at risk of revenue loss of EUR 50-100 million, representing 10-20% of their budgets. If hENs are made freely available without remuneration, the ISO/IEC risks no longer allowing its standards to be used as the basis for European standards, which would weaken the link with international rules and further undermine the EU's competitiveness.

² [Menon Economics. \(2018\). Nordic Market Study: The Influence of Standards on the Nordic Economies \(Menon Publication No. 31/2018\)](#). Menon Economics. (2023). [Macroeconomic benefits of standardisation: Evidence from six Northern European countries \(Menon Publication No. 43/2023\)](#).

absence of harmonised standards or when they are insufficient.³ The Commission stresses that the process of common specifications is less bureaucratic, which is considered important when delays in the standardisation system threaten innovation and competitiveness, but has not clarified how these specifications will be developed in an inclusive and transparent manner for the companies concerned or how broad acceptance will be achieved. In its documentation, the European Commission assesses that common specifications can reduce compliance costs by an average of €4,000 per product compared to the absence of harmonised standards and certification is required.⁴ However, this figure is reported without available documentation regarding the calculation method or documentation, which makes it difficult to evaluate its reliability.

Despite the potential benefits of CS, the Implementation Council, based on our consultations with industry experts, assesses that there are decisive objections to the proposal. The Council considers that CS should be strictly used as an exception when harmonised standards (hENs) are absent or insufficient, and should not be a permanent option. There is a real risk that CS undermines the consensus-based, inclusive and market-driven standardisation model. Since the CS is not developed within the framework of the recognised European standardisation organisations and the COM has not described in more detail how industry and expertise should be involved in the development of the CS, there is a risk that the process lacks transparency, broad participation from relevant stakeholders and sufficient technical expertise. This could lead to reduced acceptance, lower technical quality and poorer adaptation to actual technological developments, which in turn could make it more difficult for Swedish and European companies to compete on equal terms.⁵

³ These CSs have already been used in over 10 pieces of legislation and are now proposed to be included in a further 16 directives and regulations.

⁴ [SWD\(2025\) 130 final](#)

⁵ Cf. with Håkan Jonsson, Comments on Dr Tim Rühl's article "Technical Standardization and Innovation in a Changing Geopolitical Landscape" in [Swedish Entrepreneurship Forum \(2023:01\)](#): Standardization must be integrated into the strategic political framework, but the technical content must not be politicized. Policies should set the framework of the system, while industry should design the technical specifications. Excessive politicisation threatens interoperability, technology neutrality and market acceptance. Europe's strength is an industry-driven, consensus-based process in which standards are developed bottom-up by industry experts and standardisation bodies such as CEN and CENELEC.

8. Possible alternative solutions to make the proposal less intrusive

There are other examples of EU legal acts that allow the Commission to develop common specifications, but to a more limited extent. For example, the new Machinery Regulation (EU 2023/1230) allows the Commission to establish common specifications, but only if the Commission has first requested standardisation organisations for a harmonised standard to be developed and this request has been rejected, or if the requested standard is not delivered on time or is not fit for purpose. In addition, those implementing acts must be produced under the stricter scrutiny procedure, and it is explicitly stated in the Machinery Regulation that when preparing draft implementing acts, the Commission must take into account the views of relevant bodies or expert groups and duly consult all interested parties. The Council considers that it is of value to adhere to these already adopted working methods for the development of CS rather than to develop new mechanisms, especially as a broader review of the standardisation regulation is announced in the near future.

In addition to the structural shortcomings described above, the Council also finds grounds to object to the timing of the proposal. In light of the announced revision of the Standardisation Regulation (EU 1025/2012) planned for 2025, for which a public consultation was carried out from 2 May to 25 July 2024, the proposal for Omnibus IV may appear premature and risks pre-empting the wider reform initiated by the Commission itself. At the same time, the Commission plans to present the review as part of a broader package covering the entire New Legislative Framework (NLF) structure, including market surveillance and accreditation. Negotiating the Omnibus proposal at this stage risks creating regulatory fragmentation and unpredictability, which directly counteracts the companies' need for regulatory stability. The proposal therefore risks complicating rather than simplifying the activities of companies, which is in direct contradiction to the Commission's stated objective of reducing the administrative burden by at least 25% for large companies and 35% for SMEs.

9. The Implementation Council's input for the Swedish position in the ongoing EU negotiations

In light of the above procedural challenges, it is particularly important that Sweden's position ensures that the ongoing Omnibus proposal neither

anticipates the upcoming revision of the Standardisation Regulation nor creates unnecessary regulatory uncertainty. According to the EU Competitiveness Compass 2025, the upcoming review aims to streamline and accelerate standardisation processes, strengthen stakeholder involvement, and increase the flexibility and adaptability of the system. Based on the Implementation Council's consultations with industry experts, the Council assesses that the Commission's proposal in Omnibus IV may entail risks of counteracting these objectives, which in turn could lead to increased technical barriers to trade and a deterioration in the innovation and competitiveness of European companies. In view of the identified challenges, the Implementation Council believes that the Government should take into account the following proposals in the Swedish position in future EU negotiations:

- **Precedence of harmonised standards:**
EU legislation should clearly establish that harmonised standards (hENs) are the primary tool for complying with legal requirements and that common specifications (CSs) should only be used as an exceptional instrument in the absence of hENs. In order to avoid regulatory uncertainty and discretionary decision-making, the activation of the CS should be limited to objectively ascertainable situations where harmonised standards do not exist. To ensure this arrangement, a clear legal provision should be introduced, corresponding to Article 20(3) of the Machinery Regulation (EU 2023/1230), which establishes hEN as a general rule.

Furthermore, consideration could be given to limiting the activation of CS to situations where documented delays exceed 24 months, and always preceding such a procedure with a thorough analysis of possible deviations from ISO/IEC standards, in order to ensure continued global interoperability. In this context, the Commission should justify why it is not possible to wait for the finalisation of a harmonised standard.

- **Review, phase-out and transition period:**
The Implementation Council welcomes the introduction of a mandatory review of the CS every five years, to ensure their continued relevance, as well as an automatic phase-out mechanism once the corresponding hEN has been published. It may be appropriate for the transition period from CS to the corresponding

hEN to be at least 24 months, in order to give industry a reasonable amount of time to adapt and thus prevent market fragmentation.

- **International harmonisation and competitiveness:**

The introduction of the CS should be designed in such a way that consistency with international ISO/IEC standards continues to be a priority to ensure the global competitiveness of European companies. As European standards are often developed in cooperation with international standardisation bodies, deviations risk creating additional costs and hindering trade for export-dependent sectors. Consideration should therefore be given to introducing a binding requirement that at least 95% of the content of the CS must comply with ISO/IEC standards, where possible, and that this is clearly stated in the legislation.

Finally, the Implementation Council notes that the digitalisation proposals in the Omnibus IV package – such as the digitalisation of the EU Declaration of Conformity (DoC), the electronic provision of user manuals and the introduction of mandatory digital contact points – are technologically mature reforms that have broad acceptance by industry and offer tangible efficiency gains and cost savings. It is unfortunate that these initiatives have been linked to the issue of common specifications, as this risks delaying the implementation of measures that already have technical and operational viability. The Council considers that the digitalisation proposals in Omnibus IV should be dealt with as a separate legal act, so that they can be dealt with swiftly and without being subject to the more complex and lengthy negotiations on the future design of the standardisation system in the context of the upcoming revision of the Standardisation Regulation.

The Swedish Implementation Council would also like to state the following: in the upcoming revision of the Standardisation Regulation, it is important to ensure that small companies have the opportunity to participate in the work of developing harmonised standards and to facilitate their access to these standards.

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Decided by the Swedish Implementation Council on 7 August 2025.

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