VDMA Response

Technical Affairs & Standardisation

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VDMA Response
to the Call for Evidence for the Revision of Regulation (EU) No. 1025/2012

Introduction

VDMA represents more than 3'600 German and European companies in the mechanical and plant engineering sector, making it the most significant industrial association in Europe. As an umbrella organisation comprising 36 specialised associations, VDMA covers the entire value chain of the capital goods industry – from individual components to complete systems, from system suppliers to service providers, and from interconnected machinery to self-organising logistics.

VDMA funds and staffs the Mechanical Engineering Standards Committee (NAM) within DIN German Institute for Standardisation, which was established on 11 March 1949. NAM is responsible for national, European, and international standardisation activities in the field of mechanical engineering. Similarly, the DIN Standards Committee for Machine Tools (NWM), which closely cooperates with NAM, is also affiliated with VDMA. In the 2024 business year, NAM managed 14 CEN/TC secretariats as well as 17 ISO/TC and ISO/SC secretariats respectively. Currently, 3'029 experts from 1'725 companies are actively involved in 329 different committees. Over more than 70 years, the close organisational integration of NAM within VDMA and its specialised associations has proven to be a guarantee for high-quality standardisation work. Moreover, NAM plays a vital role in promoting European interests in international standardisation and contributes significantly to the global market success of the European mechanical engineering industry.

Harmonised standards have always played a crucial role in mechanical engineering. Under the Machinery Directive 2006/42/EC, approximately 810 harmonised standards' references are currently listed in the Official Journal of the European Union. Consequently, VDMA views recent developments in the European standardisation system with great concern and has a fundamental interest in ensuring that the current challenges and structural issues are effectively addressed.

Contributions to the Call for Evidence

Harmonised standards (hEN) are and must remain the primary instrument for presumption of conformity within the EU's harmonised legislation. They are developed by experts through transparent, consensus-based processes and reflect the state of the art in technology. Their legal function of providing a presumption of conformity when their reference is cited in the Official Journal of the European Union must be clearly defined and consistently applied across all relevant legal acts; previous discussions and results have stated that Article 20 of the Machinery Regulation (EU) 2023/1230 will serve as the harmonisation template, hence this should serve as the basis.

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Common Specifications (CS) should only be used as a fall-back mechanism in exceptional cases, such as when

- hEN are not available due to non-acceptance of Standardisation Requests by the European Standardisation Organisations (ESOs); or
- significant delays in the drafting process of hEN; or
- lack of requirements in hEN.

However, delays in the citation process or negative HAS assessments alone should not justify the development of CS. The use of CS must be governed by clear, horizontal criteria that ensure inclusiveness, coherence, transparency, and alignment with international best practices.
CS also present an opportunity to open the European standardisation system to other rule-makers, such as consortia in the ICT sector. However, any such involvement must comply with the principles outlined in Annex II of Regulation (EU) No. 1025/2012 and be integrated into the ESO-led processes to preserve the integrity and international compatibility of the European system while maintaining a level-playing field for hEN and CS.

To ensure legal certainty and effective governance, the following measures are essential:

- **Stakeholder involvement** must be assured as part of the inclusiveness when drafting CS.
- The hEN's **voluntary nature** needs to be legally stated. This also applies to CS in cases where hEN are missing.
- **Horizontal criteria** must be established for when and how CS may be developed. The how becomes even more important when opening the system to other standards setting organisations. Furthermore, it is essential to define
    - the characteristics of CS including their review cycles and
    - withdrawal procedures once an equivalent initially intended harmonised standard becomes available.
- A **dedicated process owner**, potentially a new Agency or Directorate General, should be responsible for organising the drafting process of Standardisation Requests and CS and for ensuring compliance with the defined criteria.
- A **uniform template for Standardisation Requests** as well as agreed timelines are needed for both hEN and possible CS to ensure clarity, consistency, and sufficient detail for both the European Commission and stakeholders.
- The **role, responsibilities, and decision-making criteria of HAS Consultants** must be clearly defined and embedded in the legal framework to ensure transparency and proportionality in the assessment process.
- **Early engagement** of standardisation bodies through preliminary (policy-based) Standardisation Requests should be enabled once legislative texts reach a stable stage in trilogue negotiations.
- **A leaner standardisation process** could reduce the drafting time for hEN by a few months in comparison to the situation at present. Options on which process steps could be parallelised and/or moved to somewhere else in the process should be evaluated and assessed.
- Involvement of **various standardisation setting organisations** leads to divergence in the processes, to administrative hurdles between the organisations and to a high level of complexity of the entire system for the experts. Instead, the complexity must be reduced by harmonising structures and processes or through consolidation.
- Due to the **increasing shortage of experts** and the increasingly horizontal topics, consortia must be linked to standardisation in the future without circumventing and undermining the actual standardisation processes and structures. It must be ensured that the work results of consortia can find their way into standardisation and that the respective experts can participate at a low threshold.

VDMA strongly supports a revision of Regulation (EU) No. 1025/2012 to address these issues and ensure that the European standardisation system remains efficient, inclusive, and internationally aligned. Harmonised standards must continue to be the backbone of EU product legislation, with Common Specifications serving only as a carefully governed exception.