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Joint Industry recommendations for effective Harmonised Standardisation

Reminder: Joint Industry [letter to Council Presidency](#)

This paper provides tangible recommendations to remove bottlenecks in harmonised standardisation. In view of the upcoming standardisation strategy, a constructive dialogue to find synergies will be necessary to fulfil the strategic value of standardisation, as highlighted in the European Commission's updated Industrial Strategy, and the delivery of stakeholder know-how on technical solutions.

We welcome the [recommendations](#) made by seventeen EU delegations on “EU industry competitiveness and effective harmonised standardisation” at the Competitiveness Council on 27 May 2021, and any concrete steps by the European Commission to enhance the processes for harmonised standardisation, as suggested in the updated Industrial Strategy.

We are convinced that for the well-functioning of the European standardisation system, including harmonised standardisation, industry must remain a key stakeholder, bringing in competence and experience to the said system. Therefore, we believe it is essential that the following roles and principles be kept in mind:

1. The European Commission has the legal responsibility to ensure that the laws of the European Union can be effectively and consistently applied. This includes the Regulation on Standards, (EU) 1025/2012, which culminates in the citation of harmonised standards in the Official Journal of the EU.

2. Stakeholders in the European Standardisation Organisations (ESOs) have the expertise in drafting standards that are understandable to the target audience, workable in everyday practice, focused on EU legislation and considered adequate to give presumption of conformity to specific requirements. To that extent, implementing acts, codes of conduct as well as legislative and other related technical specifications published by the European Commission should be avoided wherever they are intended to replace standards and only be used cautiously in reference to topics for which standardisation is not appropriate.

3. The ESOs have dedicated agreements with international Standards Developing Organisations (SDOs), notably the Vienna and Frankfurt Agreements. Development of

European standards for safety and performance based on the expertise at international level results in significant benefits for European stakeholders and helps reduce regulatory divergence.

While we remain convinced that the European Commission's interpretation of Regulation (EU) 1025/2012 following the court rulings should be reassessed¹, based on our members' experience, and in a spirit of cooperation and to support endeavours to fix harmonised standardisation, we provide the following remarks and recommendations.

Flexibility in Standardisation Requests

Quick adaptation of standards to market innovation and stakeholders' needs requires flexibility in several aspects. As such, we recommend:

- **Accommodating updates of harmonised standards:** Any standardisation request must accommodate updates with respect to both revisions of harmonised standards already listed and initial editions of standards not yet listed in the Official Journal of the EU, especially relevant for new fields of technology. Such flexibility can be arranged for by frequent updates of the standardisation request or by flexibility built in such requests.
- **Flexible Annual Working Programme:** Similar flexibility is needed for new standardisation projects beyond the confirmed Annual Work programme.
- **Synchronising the lifetime of standardisation requests with the legal act:** The lifetime of a standardisation request should be as far as possible synchronised with the legal act it aims to support and should cover the continuous maintenance of the set of standards listed in the Official Journal of the EU.

Clear and reliable criteria for the assessment of harmonised standards

In general, we recognise that the Annex ZZ/Annex A is a useful tool for users of a standard to check which legal requirements are covered. However, the current requirements to Annexes ZZ/Annex A are too detailed and risk to delay the development of standards for formal reasons, especially in sectors where (majority or exclusively) international (ISO and IEC) standards are used. To strike a fair balance between formal and effective finalisation of standards, we recommend:

- **Aligning with international requirements:** Structuring technical standards according to the requirements of EU Regulation only 1) widens the gap between International and European standards, 2) increases product development costs to European manufacturers and potentially prices to end-users, and 3) delays the placing on the market of state-of-the-art products in the EU, which will result in a loss of technology leadership of European industry.
- **Agreeing in general terms on legal and technical criteria for standard assessment:** It would be of added value to jointly agree between the European Commission and ESOs on the criteria and limits of the legal scrutiny and on ESO's room to manoeuvre on the technical content for experts.
- **Synchronising terms and definitions across all New Approach Regulations/Directives:** Experts are confronted to contradicting definitions and terms

¹ See the legal [Opinion](#) on the European System of Harmonised Standards Commissioned by the German Federal Ministry for Economic Affairs and Energy ("BMWi");

in different EU legislation. As some standards are used to comply with more than one piece of legislation, a synchronisation of definitions would promote consistency in standardisation processes.

- **Defining of legally relevant terms:** Current requirements in certain sectoral standardisation requests prevent the normative body of a harmonised standard to “define any legally relevant terms not defined in those Regulations”. While we concur that EU law prevails over technical standard, the European Commission should provide the standardisation project teams as early as possible with a reliable and comprehensive list of legally relevant terms which should not be defined in standards. ESOs would then be enabled to define technically relevant terms in line with EU legislation where necessary.
- **Removing requirements to map clauses in the standard to individual clauses in legislation:** Compliance with a standard can only be claimed when complying with all technical requirements in that standard. It is sufficient to indicate which Essential Requirements of the Regulations are covered when complying with all clauses of a harmonised standard.
- **Improving legal support for experts:** Technical experts working in Technical Committees (TC) cannot be expected to have the legal expertise to write an Annex ZZ/A which passes the HAS consultant’s assessment without findings. Therefore, the ESOs or the European Commission should make available legal experts to assist standards writers to navigate the legal complexities of European legislation in the respective Technical Committees.

Transparent communication between experts, HAS consultants and the European Commission

Extremely detailed assessments by the HAS consultant are followed by quality checks conducted by Ernst & Young (managing the consultant system), further technical checks by the legal staff and desk officers of the European Commission and more administrative steps before the approved standard can be referenced in the Official Journal of the EU. It is a matter of urgency to limit third-party intervention to where it is most needed, to open a transparent and early discussion mechanism and to achieve reasonable levels of performance, quality, and efficiency. We recommend:

- **Establishing clear and transparent guidelines:** Inconsistent interpretations between different HAS consultants (even within the same standardisation project) and the Commission desk officers should be avoided, as well as changes of interpretations over time of one consultant (or the successor of a consultant). This needs to be addressed, e.g., through clear, transparent, guidelines.
- **Introducing an early feedback process and regular consultations with experts:** HAS consultant’s feedback should come as concrete and as early as possible along the process: in the standards development process and at the stage of formal vote in the Technical Committees. Special attention should be paid to the process at the stage of formal vote, where the final HAS consultant assessment is decisive for a positive outcome. For non-compliant assessments at this stage, a feedback mechanism should be established which allows an official confirmation from the HAS consultant that remaining problems are being settled by final modifications as offered from the Technical Committee. Such a mechanism would save time and resources for all involved stakeholders. No standard should be “finally rejected” as this doesn’t neither help the Commission nor manufacturers.
- **Strengthening qualification requirements of consultants:** Qualification of HAS consultants must include domain-specific technical knowledge.

- **Avoiding disruption due to budget negotiations:** EU standardisation processes must not be disrupted by EU budget discussions. The European Commission's consultants must remain operational to accompany the standardisation processes. We commend the efforts of the European Commission to allocate and keep up the needed funding for the HAS consultant services contract.
- **Introducing a monitoring system for the entire standards assessment process:** Transparency on the standard assessment at each milestone in the standardisation process improves predictability for all parties involved and helps managing resources better. Establishing a monitoring system for the entire process (from start to citation), including an obligation to provide stakeholders with regular updates about the current state-of-affairs, would be helpful.

Short processing time for citation of harmonised standards in the OJEU

The slow citation of harmonised standards in the Official Journal of the EU increases financial and administrative burden for stakeholders and demotivates experts, including those from industry, from participating in European standardisation. Timely citation of standards is crucial to ensure legal certainty for product and services providers. We recommend:

- **Applying a time limit for the citation of standards:** There should be an overall time limit within which a standard is listed. This would include not only deadlines for the ESOs but also for the European Commission to check harmonised standards for citation in the Official Journal of the EU within a reasonable, pre-defined, timeline.