

## ZVEI-Position – Open public consultation on the proposal for a revision of regulation 1025/2012

ZVEI believes that Regulation 1025/2012 is a core pillar of the 'New Approach', it goes hand in hand with the New Legislative Framework (NLF). The NLF creates a uniform and reliable set of rules that facilitates the free movement of goods and ensures fair competition while guaranteeing high standards for safety and other product requirements. The 'New Approach' and the NLF have provided the EU with a proven framework for product regulation for over four decades. This proven framework combines binding basic legal requirements for safety, security and other product requirements with a technology-neutral design by focusing on those basic requirements in legislation and enabling implementation via voluntarily applicable harmonised European standards (hEN).

We are committed to maintain the essential requirements of the Standardisation Regulation, as these basic rules are essential for the standardisation system in Europe. In view of developments in recent years, precise clarifications are needed in the following areas. This is because the European Standardisation System (ESS) has undergone significant changes following the CJEU judgement on "James Elliott" and the introduction of the current HAS system. Areas for clarification and improvement are:

### Alignment between international and European standards

A major added value of standardisation is the industry-oriented and market-driven approach. The Electro and Digital Industry is a very export driven and global acting industry. Therefore, the approach of a public private partnership must be retained and the alignment between European and international standards must be strengthened. It ensures interoperability, simplifies product design and contributes to the removal of trade barriers. While we understand the "international first" principle may not always be applicable when it comes to hENs, we are concerned by the fact that current burdensome requirements are making it extremely difficult to use international standards as the basis for hENs. We believe the established process for creating hENs and the sometimes considerable delays during this process must be structurally eliminated (see proposals below) to ensure a better alignment between European and international standardisation following the Frankfurt and Vienna Agreements.

### Speeding up the European standardisation process

The evaluation study of the Regulation (EU) 1025/2012 on European standardisation showed that the development and delivery of harmonised European standards takes more than six years – about 3 years for drafting the standards and another 3 years for formal processes like the adoption of the standardisation request, ESO submission to the Commission and about a year for the citation in the OJEU. ZVEI shares the conclusion that this is too long. Therefore, all three phases of the standardisation process (Standardisation Request – Drafting – Evaluation/Listing) should be improved to speed up the process:

#### **Standardisation Request:**

Industry needs planning certainty. Standardisation requests (SReq) must be drafted clearly to avoid misunderstandings and lengthy discussions. European SReqs should provide the framework and name the essential (safety, security and other) requirements that must be fulfilled. There should be also a clear distinction between product requirements and organisational / process requirements. However, they should leave the technical freedom to the standard developing organisations (SDOs) within these conditions.

The duration of a standardisation request should also be synchronised with the legal act it is intended to support. Appropriate transition periods for the application of EU regulations and the deadlines for the development of hENs should be defined based on relevant criteria, such as the criticality of the products, the

existence of relevant standards, the number of standards to be developed or the formal processes at the ESOs or the Commission. The early publication of draft standardisation request, for example basic requirements in a draft version, helps to gain time. With those preliminary standardisation requests the experts in the technical committees in the ESO could start their work. In case standards are not delivered in time, a fast and unbureaucratic extension of the standardisation request without changing the scope / content would be extremely helpful.

The technical definitions and descriptions should be clarified (in most cases) in the SReq phase by the EU COM to avoid delays in the standards development process at the ESOs later on.

For subjects of a broader and / or convergent technology, SReqs should reach adequate contribution by all ESOs and their relevant TCs.

#### **Standards development:**

The processes for ESOs should be reviewed with experts to streamline and digitise every step. There must be no breaking points between the different actors to ensure a smooth digital process at the different stages. The consequent and consistent use of digital and AI supported tools (e.g. for translation) is key to speed up the process. If deadlines are exceeded a consistent action of the steering groups is needed.

In case of urgent standardisation needs, accelerated procedures and fast development should be established. This should include all relevant parties: Commission, ESOs and consultants. If these procedures are used, it is important to clearly define the conditions, procedures and rules for the development, use and withdrawal—across all relevant legislations. These accelerated procedures must be subject to the same principles and requirements as hENs (e.g. consensus, transparency, reliability, predictability, openness to / inclusion of all relevant stakeholders, reflection of state of the art) and should eventually lead to harmonised European standards via the regular standardisation process.

#### **Evaluation/Listing:**

According to the evaluation study, more than 2/3 of draft harmonised standards received a negative assessment by HAS consultants between 2018-2022. This is a situation which is not acceptable for all involved parties. We need a critical scrutiny and realignment of the HAS process with the involvement of industry. We support the CEN/CLC innovative process with the aim of an early involvement of consultants. But it is essential to clearly define the roles, rights and obligations of the consultants to ensure an effective and fast process. Consultants should focus on strategic objectives of the SReq only. The change of a HAS consultant in the process often leads to delays and conflicting interpretations and should not happen.

Processes of Commission and ESOs for submission and listing of standards need to be reviewed. Increased transparency in these stages and ensuring predictable, regular listings of hENs in the Official Journal will improve plannability and help industry implement hENs in their products efficiently and on-time.

Adequate transition periods that are defined during listing of amended or superseded hEN are essential for European industry as they bring legal certainty and can allow for an efficient transition to new standards. Depending on complexity and safety relevance, a sufficient transition time is essential for an effective implementation for legal requirements. While 12 months can be sufficient for minor changes, longer transition periods of up to 48 months are sometimes necessary for shifts in requirements that entail complex changes in the design of products.

## **European Standardisation System with the European Standardisation Organisations should be kept**

The current ESS with three ESOs (CEN/CENELEC/ETSI) should be retained as it ensures the link with national and international SDOs and gives companies, especially small and medium-sized enterprises, and their experts a clear point of contact. Nevertheless, the current system should be better equipped, and the processes need to be streamlined and fully digitised. Additional SDOs generate a risk of non-transparency and further dilution of the scarce experts and would hence lead to a less inclusive system.

We reject the idea of introducing minimum quotas in TCs for certain stakeholder groups and highlight the importance of the national delegation principle as this ensures a low-threshold approach for all stakeholders. A

more useful approach to activate experts could be the financial support for participation in standardisation (see section: support of engagement of experts).

In order to take into account the development of standards outside the traditional standardisation (e.g. industry or open-source consortia), we advocate to define requirements and mechanisms together with experts from industry to adopt such content more quickly. An option to quickly adopt existing Industry standards would be the PAS submitter process as successfully used in ISO/IEC JTC1.

If the Commission accepts other SDOs than the three established ESOs it must be ensured that the same principles and rules apply to all SDOs (e.g. consensus, transparency, reliability, predictability, openness to / inclusion of all relevant stakeholders, reflection of state of the art).

We strictly reject the creation of completely new structures that are detached from industrial practice (e.g. an EU agency) - this would lead to a decoupling with international standardisation and would not solve any of the existing problems.

## Legal nature of hENs and the significance of the presumption of conformity

The ‘presumption of conformity’ of harmonised European standards is a valuable asset that should be retained to save time and costs for companies and other stakeholder as market surveillance organisations. For this purpose, it is important that hENs cover the ‘state of the art’. A process for a common and regular re-evaluation of hENs would be useful. The legal nature of hENs shall be clarified. From ZVEI point of view, it must be clear, that the use of hENs must always be voluntary.

The relevance of the current HAS model should be questioned. It was designed in response to a specific court case (James Elliott case) largely concerning the construction sector where hEN application is required rather than voluntary and HAS model has significantly contributed to the difficulties facing the current system of hEN development. Its application to the fully harmonised areas (like electrotechnology) needs to be reassessed.

Finally, the definition of hENs as part of EU law should revised and the validity of copyright on their content should be legally confirmed.

## Consistent approach for the use of common specifications

ZVEI believes in the established stakeholder-driven European and international standardisation system. In recent legislations the EU Commission has introduced the possibility to draft common specifications in the absence of harmonised European standards. ZVEI is convinced that common specifications must only ever be a fall-back solution.

If common specifications are used, it is important to clearly define the conditions, procedures, and rules for the development, use and withdrawal of common specifications – across all relevant legislations. Common specifications must be subject to the same principles, requirements and assessments as hENs (e.g. consensus, transparency, reliability, predictability, openness to / inclusion of all relevant stakeholders, reflection of state of the art).

The proposal of the European Commission via the Omnibus IV package regarding the alignment of common specifications does not specify or fulfil any (of these) criteria but rather gives the European Commission a blanket check to act without clearly defined criteria. Therefore, we strongly advocate to use the wording of Art. 20 of the Machinery Regulation 2023/1230 as a blueprint, which defines a clear framework for the development, use and withdrawal of common specifications. As soon as hENs are available, they should supersede the common specifications.

## Support of engagement of experts

Both international and European standardisation systems rely on voluntary contributions from technical experts—mainly industry, but also consumers, trade unions, NGOs and academia. At the international level we see a rapidly increasing participation of experts from other regions in the world. One way to increase the involvement of European experts in international standardisation bodies could be financial support, e.g. via tax incentives for companies (similar to R&D allowances).

## European Product Act

The Market Surveillance Regulation and the New Legislative Framework (NLF) had already been merged into a single legal act in the past and were only temporarily split into two legal acts due to an urgent need for adjustment, particularly with regard to “fulfillment service providers”. From the industry's point of view, a renewed merger of these two legal acts would be expressly welcomed. The Standardisation Regulation, on the other hand, has a broader and more differentiated scope. Among other things, it regulates services and cooperation with European standardisation organisations. It should therefore continue to exist as a separate regulation in the future.

The industry is therefore clearly in favor of combining the New Legislative Framework (NLF) and the Market Surveillance Regulation in a single legal act and continuing to regulate the Standardisation Regulation separately.

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