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## Orgalim key recommendations on European standardisation

### Introduction

Orgalim represents Europe's technology industries, encompassing 770,000 companies in the mechanical engineering, electrical and electronics, ICT, and metal technology sectors. Together, these industries form the EU's largest manufacturing sector, generating an annual turnover of €2,819 billion, producing one third of all European exports, and providing 11.9 million direct jobs. Collectively, our industries develop and manufacture the products, systems, and services essential for a prosperous and sustainable future.

The [Orgalim policy agenda for a European high-tech manufacturing base](#) identifies six key areas policymakers should prioritise during the 2024-2029 legislative cycle in order to unleash Europe's high-tech manufacturing potential and make our net-zero future a reality:

- Reduce the regulatory burden
- Regain global leadership in research and innovation
- Recommit to the single market
- Make digital legislation effective for manufacturing industries
- Remove trade barriers
- Ensure a competitive and secure energy supply

This paper will provide the technology industries' key recommendations for the European standardisation system – a crucial component in maintaining the single market. Effective harmonisation of standards can facilitate seamless trade, foster innovation, and maintain high quality and safety levels across products and services.

### Recommendations

The European Standardisation System (ESS) has significantly evolved over the years, increasing stakeholder involvement and financial investment. From its foundation, the system has expanded to include over 200,000 technical experts and stakeholders, ensuring broad-based input into the standardisation process. Financially, the system is heavily dependent on the significant contribution of industry experts, the cost of which is estimated to amount to around €1 billion each year

to participate in, and contribute to, voluntary standardisation work<sup>1</sup>. When it comes to standards in support of legislation, the European Commission has stabilised funding at approximately €20 million annually<sup>2</sup> to support these activities.

Over the past ten years, the ESS has witnessed substantial changes on different levels. The legal cases brought before the European Court of Justice (ECJ) have been pivotal in driving operational changes within the system. Meanwhile, broader geopolitical developments have also significantly impacted the system. These include the increased engagement of other regions in the international standardisation scene, making it harder to achieve the adoption of EU-specific amendments at international level; the increased technical complexity of standardisation subjects due to new technology elements; the changing geopolitical situation; erosion of trust from the Commission in EU industry's ability or commitment to develop safe products – proved by the increase number of requests to involve third party certification bodies and by considering more and more specific Commission delegated acts; the loss of competitiveness among European industries which limits resources for standardisation activities; and the generational turnover of technical experts. Collectively, these factors, coupled with complexities introduced by new processes (e.g. HAS consultants' approvals) and a high volume of (often horizontal) legislation covering new subjects requiring standards, have created an exceptionally challenging framework for the development of harmonised European standards (hENs) within the EU, resulting in negative consequences for the entire system. Harmonised European standards are technical specifications that are particularly helpful in ensuring compliance with mandatory legal requirements. If their reference is cited in the OJEU, they provide presumption of conformity with EU legislation. However, when there are delays in the approval process, or when developed standards are rejected, the system is weakened. Orgalim would like to propose a reset of the conversation, starting from a more constructive relationship between all players involved. The key question to answer should be: what is the most efficient approach to achieve the best harmonised European standards for EU citizens and industry, in a timely manner?

In response to this question, these are Orgalim's recommendations:

- **Clarify the implications of the legal status of harmonised standards**
- **Ensure a balanced system for the request, development and citation of harmonised European standards**
- **Maintain alignment with international standardisation**
- **Support experts in standardisation activities**
- **Develop a coordinated and consistent data collection system**

## Clarify the implications of the legal status of harmonised European standards

Since the judgement on the James Elliott case<sup>3</sup>, the status of harmonised European standards has been at the centre of much debate. On the basis of that ruling, the Commission initiated substantive changes in the processes leading to the development and citation of harmonised European standards, but there was never a full disclosure of the reasoning and legal analysis that brought the Commission to the conclusion that the measures put forward were justified and required. On the other hand, the business and standardisation community has perceived a tightening of the inspection procedures, which is felt to be disproportionate – particularly because there has been a lack of transparent communication about the reasons for this. Increased transparency will improve trust in the system and among all the stakeholders involved.

Eight years later, a new judgement on Case C-588/21 P confirms that harmonised European standards providing legal effect "form part of EU law". However, the judgement does not contain any further explanation as to how harmonised standards should be part of EU law, nor does it provide detailed information as regards their practical implementation. Orgalim believes that these details require further analysis and evaluation. **To improve transparency and trust in the**

<sup>1</sup> [Report](#) from the Commission to the European Parliament and the Council on the Implementation of the Regulation (EU) No 1025/2012 from 2013 to 2015

<sup>2</sup> <https://www.cencenelec.eu/european-standardization/cen-and-cenelec/>

<sup>3</sup> Judgement of the Court (James Elliott) of 27 October 2016 ([Case C-613/14](#))

system, we call on the Commission to provide clarification on how they intend to achieve this status; notably when it comes to the development of these standards, taking into consideration the other findings of the court which confirm that “compliance with harmonised standards is not compulsory” and that “development of those standards is entrusted to a body governed by private law”.

Ultimately, the aim should be to clearly formulate the Commission's expectations of what the changes will entail from a working perspective, its understanding of the responsibilities in detail and the reasoning behind the measures put forward to ensure the review processes.

In our view the general structure provided by the New Legislative Framework must be respected: while the underlying regulations specify *what* the requirements are, the harmonised standards give the technical solutions as to *how* these requirements can be fulfilled. To maintain an environment that supports innovation and technical developments the voluntary nature of standards must be protected. Furthermore, we believe that the assessment of the standard, before its reference is published in the Official Journal, should be related only to formal aspects and its completeness and consistency with the standardisation request. A full review of the content of the standard is outside the scope of such an assessment<sup>4</sup>.

## Ensure a balanced system for the request, development and citation of harmonised European standards

Orgalim understands and agrees that standards providing presumption of conformity with EU legislation must abide by the legislative requirements included in the legislation and that these elements must be verified. We also acknowledge that some recent changes in the development of harmonised European standards have improved clarity; for example the use of a correspondence table in Annex Z to identify which part of the standard responds to which essential requirement in the legislation. However, **we believe that the proportionality principle should be applied and that checks can be successfully carried out without the current administrative burden.** This will ensure that the system effectively fulfils its primary objective: ensuring product safety by responding to the essential health and safety requirements, taking into account the state of the art. Orgalim does not challenge the responsibility of the Commission to ensure that the standards developed address the requirements in the legislation. Our concerns lie with the fact that the system currently requires overly prescriptive checks which do not improve the safety or clarity of the standard itself and cause substantial delays in the publication of the references in the Official Journal<sup>5</sup>. These delays are ultimately detrimental to the safeguarding of consumers, workers and the environment because they impact the implementation of technical requirements that could mitigate certain risks, and should be avoided at all costs – especially when the reasons for the delays are lengthy legalistic procedures not aimed at improving the content of the standard. They also risk widening the gap between EU and international standards, potentially leaving harmonised European standards lagging behind the latest advances, such as in the case of the EN 60204-1<sup>6</sup>. The bottom line is to focus on the main objectives of EU legislation instead of getting lost in legal details.

**Orgalim calls on the Commission to strike a balance between legalistic procedures and efficiency with a view to ensuring the sustainability of the system and the timely placing of state of the art products on the EU market. One**

<sup>4</sup> Legal Opinion on the European System of Harmonised Standards, Commissioned by the German Federal Ministry for Economic Affairs and Energy (“BMWi”), August 2020; p. 25-32.

<sup>5</sup> The current harmonised standards providing safety requirements for construction machines still rely on a 2006 version. There has been an approximately ten year drafting process, which has been rejected by HAS consultants twice —first in 2020 and again in early 2024. These rejections were due to different reasons, as two consultants were involved, each with different interpretations.

<sup>6</sup> The latest version of international standard IEC 60204-1, Safety of Machinery – Electrical equipment of machines – Part 1: General requirements is from 2021. The corresponding harmonised European standard EN 60204-1 is from 2018 and it was cited in the OJEU in 2020, based on the previous IEC version, dated from 2016.

option could be for the Commission to require HAS consultants to submit their assessments to the Commission before their comments are addressed by the Technical Committees (TCs). In this way, the Commission could discard non-safety-related comments that would unnecessarily delay the approval of the standard.

Another challenging issue is the fact that the **final approval of the standard by the Commission happens after that standard has already been published by the European Standardisation Organisations (ESOs) as a European standard**. This creates confusion and is detrimental to the overall system, as manufacturers face a dilemma between using an outdated standard that is cited or a revised, state of the art version that is not cited, often due to reasons unrelated to user safety. **We call for this problem to be addressed; for example by allowing for corrigenda to the European standard so that it can be quickly republished without delaying the implementation of new safety provisions.**

Finally, the Commission should consider that limiting the presumption of conformity or requesting the revision of a standard according to Article 11 of Regulation (EU) 1025/2012 should only be a last resort option when it is evident that a hEN fails to adequately fulfil the essential requirements for which it is harmonised. Using this option carefully and prioritising technical consideration and constructive dialogue would improve the procedure as a whole while addressing any necessary adjustments. Currently Formal Objections can occasionally be adopted without a timely and sufficient exchange between stakeholders, such as ESOs and the party submitting the Formal Objection, to discuss technical details. Dedicated opportunities for technical exchanges with sectoral technical experts should be part of the procedure, in line with what is already foreseen by the Regulation.

Some examples of the current overly prescriptive approach include:

- **Granular Standardisation Requests (SReqs) with unrealistic deadlines for adoption of the standards.** Regulation 1025/2012 only requires the Commission to outline the policy objectives, the requirements to be met and a deadline for adoption, without further details. Deadlines for adoption should be defined, taking into consideration the complexity of the subject, existing (or lack of) technical standards in the same area, necessary procedural steps within ESO's and the Commission, and overall feasibility. Unrealistic deadlines put the system under stress, discouraging experts from participating in the process. SReqs should be developed concurrently with the regulations they are designed to cover. This ensures reasonable timeframes and provides TC experts with visibility and the opportunity to prioritise their work based on the regulation's application date.
- **Inflexible assessment of the standards.** The current system is overly prescriptive and lacks flexibility to allow for the technical needs of each specific standard. While it is positive that the updated checklist is now the same for all players involved (HAS consultants, TCs and the Commission), the fact that all boxes must be ticked for the standard to be positively reviewed and adopted is extremely challenging. The HAS consultant reviews lack consistency and new aspects for consideration are often introduced too late in the process. Unlike any other step in the European Standardisation System (ESS), the HAS consultant revision consists of one person deciding whether the standard has passed the assessment. This individual decision-making power goes against the democratic and inclusive principles which are part of the ESS. We believe HAS consultants should provide input to the work of the TCs as early as possible and should take into due consideration their views and explanations, acknowledging the careful consensual process that they have followed in developing the standard. It is also highly detrimental to the whole system that one HAS consultant can reverse a previously positive assessment from another HAS consultant, leading to a never-ending development phase. We encourage the evaluation of the overall HAS system for a smooth assessment of standards in the future.
- **Citation of the standards in Official Journal.** Overall, the time needed by the Commission to validate the standard once this has already been adopted by the ESOs and has received a positive evaluation by the HAS consultants remains too long. In this context, the decision to move the publication of the cited standards from the C to the L series adds a further administrative burden, since documents published in the L series must be approved by the college of commissioners and Regulation 1025/2012 does not specifically require this. In

addition, the added value of using the L series is debatable. It also prevents the listing of all harmonised European standards under one EU regulation. Users have to laboriously search for and organise the references of harmonised standards that give rise to the presumption of conformity for a provision from a series of legal acts. User-friendliness should be given due priority in the publication of references.

## Maintain alignment with international standardisation

Harmonised European standards are, in the vast majority of cases, not developed in a vacuum, but start from an existing or draft standard. Very often, these standards originate from international IEC/ISO standards that are transposed with or without amendments into European standards (ENs). For the industries represented by Orgalim, including both large and small companies trading internationally, the alignment between European and international standards is of the utmost importance. It ensures interoperability, simplifies product design and contributes to the removal of trade barriers. International connectivity is also crucial for the global competitiveness of the European economy. Efforts to decouple from international markets are detrimental to the economy. While we understand that 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 even when this would make sense. **We call for a thorough assessment of the current levels of alignment, the benefits connected to it and the risks associated with decoupling (please refer to the point below for further information on this).** For the same reasons, we are also concerned by the implications that the recent ECJ judgement on case C-588/21 P will have on the use of international standards as the basis for hENs in the future. Lastly, transition periods for new, amended or superseded hENs should be of adaptable length depending on the technical content of the standard as well as international transition periods, to allow efficient transitions and avoid discrepancies between international and regional versions of the standard. **To determine the appropriate length of transition periods, the ESOs should be consulted where necessary.** The current practice of blanket 18 month transition periods does not adequately reflect the technical reality of updating product designs.

## Support experts in standardisation activities

As mentioned above, both international and European standardisation systems rely heavily on the voluntary contribution of technical experts, primarily from industry but also importantly from other stakeholders such as consumers, trade unions, environmental NGOs and academia. Currently this system is facing a generational challenge in the turnover of European experts.

In addition to the problem of recruiting experts, there is also competition between political systems. In this context, a rapid increase in both participation and dominance in international standardisation from competing countries can be observed. Among other factors, financial incentives and support for experts actively involved in this area could help strengthen European participation in international standardisation. **Orgalim therefore fully supports the Council conclusion from May 2024<sup>7</sup> highlighting the need to further develop the EU’s strategic approach to international standardisation and emphasising the importance of supporting greater participation of the EU business community in the development of standards at an international level.** Orgalim has previously concluded<sup>8</sup> that one way to allocate money to industry-driven projects and achieve greater participation is through tax incentives. Tax incentives have the potential benefits of decreasing both tax levels and transaction costs since the money stays where it was first generated, and such incentives could also be considered when participating in international standardisation. Tax incentives also provide equal access and predictability for recipients, thus encouraging their participation in further standardisation

<sup>7</sup> Council conclusions on “[A Single Market for the benefit of all](#)”, 24 May 2024

<sup>8</sup> [Orgalim key recommendations on investments](#), June 2024

activities. National tax incentives should be coordinated at EU level to increase impact and avoid contradictory policy goals.

Beyond this generalised issue, the development of standards requested by the Commission in response to legislation poses an additional challenge in that more and more experts are discouraged from participating in these activities due to the burdensome legalistic and overly prescriptive requirements, the unrealistic timelines and the low rate of approval of the standards. A potential future decoupling from international standards would be likely to exacerbate this problem as organisations and experts might decide to focus their engagement on international forums.

Standardisation experts involved in the development of harmonised European standards are knowledgeable individuals who strive to develop technical documents that respond to the essential requirements in legislation and facilitate the manufacturing of products which are safe to be used all over the world. While this is, and should remain, the main focus of standardisation activities, in recent years the process of developing harmonised European standards has become more and more burdensome, requiring extensive efforts to be spent on administrative tasks that have little to do with the quality of the technical content of the standard.

**Orgalim calls on ESOs to continue providing training to help experts in the fulfilment of their administrative tasks. At the same time, we call on the Commission to keep the administrative requirements to a manageable level and to ensure that HAS assessments are coherent and consistent across the board to increase predictability.** This would improve the working experience of the TCs by reducing objections and comments by HAS consultants and increasing the adoption rate of standards. Increased clarity and transparency in the system will also contribute to strengthening trust among all stakeholders involved, thus creating a more suitable environment for the development of standards.

In addition, **Orgalim calls for the reinforcement of the consensus-based approach in standardisation. We warn against alternative routes such as the development of common specifications, which constitute a serious deviation from the NLF and significantly reduce transparency and access.** When including common specification provisions in legislation as a fall-back option, we call for a consistent approach where the wording of Article 20 of the Machinery Regulation (EU) 2023/1230 is used as the blueprint.

## Develop a coordinated and consistent data collection system

As mentioned in the point concerning alignment between European and international standards, it is not possible to discuss harmonised European standards without taking into consideration the broader standardisation landscape. Yet, the EU does not currently have a streamlined framework for the collection and reporting of standardisation data which can help to measure and track trends showing where harmonised European standards originated, the degree of alignment with international standards, or how many homegrown harmonised European standards become international standards. Orgalim believes that a proper framework for the collection and reporting of this data would benefit the European Standardisation System by providing concrete information on the state of play and helping to prioritise areas or topics where EU resources are needed. This is also one of the conclusions stemming from a High Level Forum workstream coordinated by Orgalim and involving a broad range of stakeholders. **We call on the Commission to take up the recommendation of the HLF that are currently under adoption and establish a research project to develop a framework for collection and reporting of data. The project should be publicly funded and allow for the engagement of all stakeholders in an inclusive and transparent development process.**

## Link to Orgalim publications

### Orgalim Policy Agenda and key recommendations for the upcoming EU legislative period 2024-2029

- [Orgalim Policy Agenda](#) for a European high-tech manufacturing base for the 2024-2029 legislative cycle
- [Orgalim key recommendations on the single market](#) for the 2024-2029 legislative cycle
- [Orgalim key recommendations on the circular economy](#) for the 2024-2029 legislative cycle
- [Orgalim key recommendations on investments](#) for the 2024-2029 legislative cycle
- [Orgalim key recommendations on digital policy](#) for the 2024-2029 legislative cycle
- [Orgalim key recommendations on energy and climate](#) for the 2024-2029 legislative cycle
- Other Orgalim key recommendations for the 2024-2029 legislative cycle will soon be available on the [Orgalim website](#).

### Others

- Joint letter on [deepening the EU Single Market and renewing the dynamic of European integration](#)
- Joint statement: [Europe Must Maintain Industry Know-How For Its Standardisation System to Succeed](#)
- [Orgalim response to the European Commission call for evidence for an evaluation of the regulation on European standardisation](#)
- Orgalim position on [enhancing EU manufacturing competitiveness with a future-proof approach to placing products on the single market](#)
- Orgalim position on [securing Europe's industrial competitiveness](#)
- Orgalim position on the [Machinery proposal – mandatory third party certification is a step backwards](#)
- Orgalim case studies: [Technology in Action](#)
- Orgalim common specifications: [Internal Market: Criteria for common specifications | Orgalim](#)

Orgalim represents Europe's technology industries, comprised of 770,000 innovative companies spanning the mechanical engineering, electrical engineering, electronics, ICT and metal technology branches. Together they represent the EU's largest manufacturing sector, generating annual turnover of €2,835 billion, manufacturing one-third of all European exports and providing 11.7 million direct jobs. Orgalim is registered under the European Union Transparency Register – ID number: 20210641335-88.



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