Brussels, 17 December 2025

From delay to delivery: making the development of harmonised European standards smarter & faster

Executive Summary

Orgalim calls for a number of important, yet targeted improvements to the European standardisation system while maintaining the proven New Approach. The improvements aim at accelerating speed in standardisation development processes while preserving quality, market relevance and consensus and at incentivising experts to participate in this strategically important activity. The proposed solution is not to replace, but rather to upgrade, the current framework for faster, smarter delivery of standards and ensuring a high degree of international alignment which is of critical importance for Europe's competitiveness.

This position paper outlines a number of concrete proposals to improve the European standardisation system and make the upcoming revision of the Regulation a success.

In particular, Orgalim believes it is important to:

a) **Maintain the essential principles of the standardisation system (voluntary nature, stakeholder participation, market relevance, coherence with the NLF)**

b) **Increase speed and accelerate standardisation processes while maintaining quality, consensus & market relevance by:**

   1. Nominating a **central process owner** for the Standardisation Requests & citations
   2. Setting **binding timelines** for standardisation request(s) & citation(s)
   3. Establishing **clear definitions** of standardisation deliverables & conditions for their use
   4. Setting **clear criteria** for standardisation organisations & consortia
   5. **Shortening & improving the drafting phase** with the help of leaner and digitised processes
   6. Simplifying the **revision of existing hENs**
   7. Smoothening processes for **Formal Objections**
   8. NOT imposing **penalties for delays** in the drafting stage

c) **Preserve close alignment with international standards to ensure state-of- the-art requirements by:**

   1. Increasing coordination on strategic priorities at all levels
   2. Establishing a data collection system to assess where hENs originate and how they align with international standards

d) **Make it more attractive for experts to participate in (harmonised) standardisation processes by**

   1. Making standardisation an attractive area of work
   2. Introducing tax incentives for companies involved in standardisation processes and funding for SMEs

e) **Find a sound, financially viable, and sustainable solution regarding accessibility**

I. Introduction

The revision of Regulation 1025/2012 on European Standardisation (hereafter called "the Regulation") offers the opportunity to improve and upgrade the system that has been put in place for the request, development and citation of harmonised European standards (hENs). As a strong supporter of the standardisation system, Orgalim is eager to contribute to this revision process and has developed a number of specific proposals to tackle the issues that concern our industries the most.

While we acknowledge the need for structural changes and improvements, we also strongly believe that the foundations on which the system is based, e.g. the New Approach, are solid and should not be undermined by the revision of the Regulation in any way. The New Approach is key for Internal Market integration because it harmonises essential requirements for products across the EU, allowing goods to move freely without technical barriers while leaving detailed technical solutions to voluntary European standards. This flexible framework enables innovation and competition, as manufacturers can choose how to meet the essential requirements. The Regulation must continue to support this approach by providing the legal basis for the development of the hEN that give presumption of conformity, thereby building trust in the system.

This paper focuses primarily on hENs. Nevertheless, it is important to note that the vast majority of standards created at international or European level are not part of the hEN framework, which accounts for approximately 3,600 standards[1] across all sectors.

II. Specific proposals for a successful revision of the Standardisation Regulation

a. Maintain the essential principles of the standardisation system

The revision of the Regulation should ensure that the provisions contained are developed according to high standards of openness, fairness, accountability and effectiveness. This will improve compliance and ensure that the law serves the public interest well. In particular, the following essential principles must be maintained:

- **Voluntary nature:** The **voluntary nature** of the application of hENs by manufacturers is an essential pillar of the standardisation system and should be maintained.

- **Stakeholder participation**: Interested stakeholders must be able to **participate** in the development of hENs and of any other type of technical specifications in order to ensure the indispensible trust required by the system to work.

- **Market relevance**: The **market relevance** of hEN remains a fundamental element for successful implementation due to the technical nature of hEN and other technical specifications and their application in products that are sold in the EU Single Market.

- **Balanced approach**: It follows that a **balance** must be struck **between** the legitimate interest of the legislator in achieving **legal certainty** and the equally legitimate need of economic operators, market surveillance authorities and civil society at large to have high-quality hEN available within a reasonable timeframe.

- **Coherence with the NLF and the Market Surveillance Regulation:** The **coherence** of the Regulation with the New Legislative Framework (comprised of a regulation and a decision) and the Market Surveillance Regulation must be safeguarded. These acts together provide a robust framework for placing safe products on the EU Single

[1] Figure from the European Commission's Communication "An EU Strategy on Standardisation – Setting global standards in support of a resilient , green and digital EU single market" (COM/2022/31 final)

Market. Orgalim supports the proposal of the European Commission to tackle these three elements in a package known as the **European Product Act,** that will provide full regulatory consistency under a coherent legal framework.

- **The number of European Standardisation Organisations (ESOs) should remain unchanged**: A proliferation of ESOs would dilute the ability of industry to provide valuable input, particularly as we face a shortage of experts in the standardisation field. It is essential not to create scope overlap among the National Standardisation Bodies or between ESOs.

b. Increase speed and accelerate standardisation processes while maintaining quality, consensus & market relevance

		Baseline (before the Regulation) determined in the evaluation study		After the Regulation (assessed in 2024)
Phase	**Subphase**	**Low estimate**	**High estimate**	
Phase A: adoption & notification of standardisation request	Standardisation requests adopted by the European Commission	0.8 year (9 months)	0.8 year (9 months)	**1.7 years**
Phase B: Delivery of the standard	Acceptance of standard request by the ESOs	0.7 years (5 months)	0.7 years (5 months)	**0.1 year (1 month)**
	Drafting stage	2.7 years	5 years	**3.1 years**
Phase C: Submission and publication	ESO submission to the European Commission	5.4 years	5.4 years	**0.3 years (3 months)**
	Citation time in the OJEU	Not available	Not available	**0.9 years (11 months)**
Total		9.6 years	11.9 years	**6.1 years**

Figure 1: Pre/post Regulation 1025/2012 comparison of average duration of standard development at the request of the Commission.Source: Evaluation Study of the Regulation 1025/2012 on European Standardisation, Section 4.1.1.1, p.28.

HENs need to be developed in a timely manner to be relevant and serve their purpose in conformity assessments. However, according to the evaluation report from 2024, it takes an average of 6.1 years to develop a hEN from the drafting of the Standardisation Request (SReq) until its citation in the EU`s Official Journal (OJEU). Clearly, this timeframe is too long, especially in new and emerging areas of technology where lifecycles are short and innovation happens quickly.

Also, a shorter development timeline for standards will make the system more attractive for experts to contribute. Speed, however, cannot come at the expense of substance. Quality and consensus must be maintained to avoid a potential loss of relevance of standards.

To speed up standardisation processes while maintaining quality, consensus, and market relevance Orgalim proposes the following changes:

1. Nominate a central process owner for Standardisation Requests & citations

Nominating a central process owner responsible for the drafting of SReqs would reduce complexity, streamline processes and help coordinate the input of all stakeholders involved. In addition, the owner could be tasked to assess and evaluate in how far the developed standard(s) fulfil(s) the SReq. The new role of process owner could be taken on either by a **European agency** or by a **centralised office within the Commission**, similar to the European AI Office. A process owner would be particularly beneficial whenever more than one Directorate General of the Commission is involved so as to guarantee a consistent and coherent process. The process owner should not have the power to influence, formulate or develop

specifications and requirements itself, nor direct decision-making in favour of one party, or the ability of pursuing its own interest.

The responsibilities of the process owner should be strictly limited to the following tasks:

- validation of criteria;
- drafting & managing SReqs;
- overseeing the development of Common Specifications;
- reviewing existing Common Specifications; and
- assessing existing technical rules for their suitability.

2. Set binding timelines for Standardisation Request(s) & citation(s)

As shown in Figure 1, the drafting of a hEN takes up only half of the overall time needed, while the other half is spent on drafting the SReqs and citing the standard in the OJEU. The Commission has a central role to play in both phases and should abide by clear and binding timelines. They should present concrete justifications when delays happen in these steps and clearly define new deadlines so that all stakeholders know what to expect. Increased transparency in these phases and predictable listing of hENs in the Official Journal will improve plannability and help industry implement the hEN in their products efficiently.

- **Orgalim proposes a binding timeline of 9-12 months for the drafting of the SReqs.**

At the same time, faster citations should not shorten the transition periods that remain critical for industry to implement the hEN requirements in practice.

3. Establish clear definitions of standardisation deliverables & conditions for their use

Orgalim is committed to the system of using hENs for providing presumption of conformity with essential requirements enshrined in EU legislation. **hENs must remain the first option and ultimate goal** of any activity intended to provide technical requirements in support of EU legislation.

To accommodate the need in certain exceptional cases for faster development of technical requirements, Orgalim proposes the use of **other European standardisation deliverables being developed by the ESOs**. Technical Specifications could act as a temporary solution during the hEN development to rapidly support EU legislation while meeting the SReq deadlines. These Technical Specifications have the added value of being developed within the existing framework for the development of standards and with the final aim of being replaced by hEN. We consider the newly introduced "**European Agile Specifications**" by CEN and CENELEC as a positive effort to provide such a deliverable.

In recent years the Commission has begun to include the possibility of developing Common Specifications in addition to or as substitutes for hENs in product legislation. **Orgalim warns against such alternative routes, which constitute a serious deviation from the NLF and a reduction of transparency and inclusiveness, pillars of the European Standardisation System.**

The provision of Common Specifications in legislation:

- must remain a **fall-back option** to be used only under the specific conditions outlined in Annex II of the Regulation[2] on openness, consensus and transparency; and

- should be replaced as soon as the relevant hEN is available.

Finally, it is important to note that the development of Common Specifications is not necessarily faster than standard development and that it may take away already scarce resources from the main route, thus undermining the standardisation process. There is also a potential risk that some stakeholders may intentionally delay or obstruct standardisation to promote the use of common specifications if they percieve advantages in following that route.

As an alternative to Common Specifications, if the publication of hENs is delayed due to difficulties in meeting the legal requirements introduced by the Commission as a result of the James Elliot case, policymakers could refer to lists of available state-of-the-art European or international standards. The Technical Committee responsible for developing the hEN would establish such list, which would then be endorsed by the relevant Administrative Cooperation Group (AdCo) as a "good enough" temporary alternative. Manufacturers could then use these lists to demonstrate compliance, while waiting for the hENs to be finalised and cited in the OJEU.

4. Set clear criteria for standardisation organisations & consortia

Other standardisation organisations and consortia are often mentioned as entities that could support in the development of such Common Specifications. Should that happen, it is important that:

- these entities are fit for purpose and respect the criteria listed in Annex II of the Regulation[3] on requirements for the identification of ICT technical specifications on openness, consensus and transparency;
- there are clear, transparent criteria for stakeholder participation;
- there are no entry barriers for stakeholders' participation, such as membership fees.

It should be noted that ESOs already carry out an analysis of what is available in other standardisation organisations before drafting a new standard and, when possible, use this as a starting point. In this way the contribution of consortia is welcome, so long as the input is channelled through the ESOs thus ensuring a seamless integration in the existing framework.

5. Shorten & improve the drafting phase with the help of leaner and digitised processes

A number of changes should be considered to shorten and improve the drafting stage. These changes fall mostly, but not exclusively, under the responsibility of the ESOs. The ESOs have already taken welcome steps to modernise and simplify the development of standards, as shown, for instance, by the actions agreed in the EC-ESOs Task Force on "Timely European standards for a green and digital, single and global market".

In addition, Orgalim calls for the adoption of the following additional measures:

- **Continue the digitalisation** of the standard development and consensus building processes in the Technical Committees (TCs). The use of digital tools can be used to speed up the revisions and support the inclusion of experts through remote participation in TC meetings.

[2] See Annex II of Regulation 1025/2012 on requirements for the identification of ICT technical specifications on openness, consensus and transparency

[3] See Annex II of Regulation 1025/2012 on requirements for the identification of ICT technical specifications on openness, consensus and transparency

- **Provide better project management support to TCs,** including mechanisms for quick conflict resolution and assistance to ensure standards meet publication requirements.
- **Remove translation periods** from the standards drafting process. This could save up to 8 weeks in time. The English version is the only one that is relevant during the drafting stage.
- **Shorter voting periods,** for example:
    - the voting period for New Work Item Proposals (NWIPs) could be shortened from 8 to 4 weeks;
    - the Enquiry phase could pass from 12 to 8 weeks; and
    - the Formal Vote from 8 to 4 weeks.
    - altogether, these changes could save up to 12 weeks.
- **Start standardisation activities already on the basis of the draft EU legal act and a preliminary SReq**. This will give a headstart to the standardisation work that will need to take place once the legal act is adopted and the final SReq is approved. This would allow preparatory work to begin in parallel with legislative drafting, ensuring that standardisation efforts are not delayed post-adoption. The process should be less linear and entail more interaction between industry, ESOs, and policy makers along the way.

Should the Commission decide to continue to rely on third-party support (eg. HAS consultants) for the evaluation of the hEN drafts, and should this preliminary evaluation be conducted during the drafting stage, the process needs to be improved, simplified and made more efficient. Based on the existing system relying on HAS consultants, these elements should be improved:

- Encourage early involvement in the standardisation process of both the consultant and the Commission Desk Officer in charge of the assessment of the standard.
- Increase the budgets for consultants to be able to attend more standardisation meetings and shorten processes to request consultants' participation (the current system demands to make the request 5 weeks in advance).
- Maintain the same consultant throughout the entire standardisation process for each standard deliverable, and where possible, also for related standard deliverables, such as amendments and multi-part standards. It should be possible to substitute the consultant no more than once during the draft development and only if strictly necessary.
- Strengthen accountability and improve communication by allowing the TCs to know the identity of the consultant assigned to a project as early as possible.
- Improve communications by allowing consultants to give feedback rather than limiting themselves to highlight the clauses that are not in line with the legal requirements.

Orgalim believes that the above improvements to the drafting stage should **not** be enshrined in the revised Regulation as this would not be beneficial to developing an agile system that is able to evolve and adapt. Rather, the changes should be agreed upon and implemented by the organisations involved, as part of the Public -Private-Partnership (PPP).

6. Simplify the revision of existing hENs

The revision of existing standards, especially when it concerns minor changes to the content of a standard, should be simplified in order to speed up development and citation. It should be possible to amend single parts of multi-part standards without reopening the entire series in order to amend specific clauses. Being forced to revise the entire standard when only targeted amendments are needed constitutes an unnecessary burden without any benefits.

Citing the latest available hEN in the OJEU is a key priority to ensure that products placed on the market are state of the art, in line with NLF principles. As explained in the report of Work Stream 4 of the High-Level Forum on European Standardisation[4], we have identified anecdotal cases in which updating a hEN with the latest version or generation coming from ISO took up to 10 years. A more structural analysis of these aspects should be undertaken to get a better understanding of the size of the issue (further elaborated in point c.1 below).

Moreover, when updating hENs which have been developed before the introduction of the new processes to identify legally relevant parts, consideration should be given to the fact that the revision may be more complex as it has to encompass the new legal requirements. In the case of revising existing hENs, as well as developing new hENs, sufficient transition periods are necessary for industry to comply with the requirements.

7. Smoother processes for Formal Objections

The Commission should consider that restricting or withdrawing the presumption of conformity according to Article 11 of the Regulation is a drastic measure that should only be a last-resort option when it is evident that a hEN fails to adequately fulfil the relevant and covered essential requirements rather than as a shortcut to participation in the standardisation process. Using such a measure carefully and prioritising technical consideration and constructive dialogue between experts would improve the procedure and the quality of decisions made.

Currently, Formal Objections can occasionally be adopted without sufficient exchange between stakeholders, especially ESOs and the party submitting the Formal Objection, to discuss technical details before broader discussions in the relevant expert groups. 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.

For the same reason, market surveillance authorities should be encouraged to actively participate in national and European standardisation committees and present their concerns to these groups before submitting a Formal Objection. This could spare significant resources and time that are otherwise spent when a Formal Objection is raised while still reaching a satisfactory resolution.

8. No penalties should be imposed for delays in the drafting stage

Drafting is the most delicate phase for a standard and determines whether it will be developed in a high-quality, market-driven, consensual ways. Changes to this phase are only acceptable if they do not compromise any of these three fundamental elements. For this reason:

- **Orgalim strongly objects to the possibility of setting penalties whenever a hEN is not being delivered within the timeline set by the SReq**

A punitive approach would excessively skew the system towards speed, thus risking neglect of quality and consensus. Also, this phase is often related to the development of international standards. Changes should therefore be made in line with the Vienna and Frankfurt Agreements and must in no way jeopardise alignment with international standards.

[4] For further information see "Alignment between European and International standards – Final report elaborated by workstream 4".

c. Preserve close alignment with international standards to ensure state-of-the-art requirements

In the vast majority of cases, hENs are not developed in a vacuum but start from another 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) thanks to the Vienna and Frankfurt Agreements that govern technical cooperation between ISO and CEN and IEC and CENELEC, respectively. These agreements give Europe a special status in ISO and IEC and support the ambition of European experts to anchor European requirements in international standards.

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. **Close international alignment is therefore crucial for the global competitiveness of the European economy**. Standards developed at international level are also considered to reflect the stateof-the-art of technology.

For all these reasons, efforts to decouple from the international system are detrimental to the economy. Whilst we understand that the "international first" principle may not always be applicable when it comes to hENs, we are concerned by the fact that burdensome requirements are making it extremely difficult today to use international standards as the basis for hENs, even when this would make sense.

In order to maintain the EU's leading position as a standards setter in the areas where it continues to be a front-runner (e.g. machinery) and to build a strong position in the development of standards for new technologies, the EU should pursue the following measures:

1. Increase coordination at all levels on the strategic priorities at all levels

Europe must adopt a more coordinated approach to strengthen its role in global standardisation. This requires systematic monitoring of international standardisation priorities and initiatives, alignment of strategic priorities at the international level, and sustained engagement with third countries to embed standardisation objectives in trade agreements. Acting as an integrated system—comprising Member States, ESOs, National Standardisation Bodies (NSBs) and National Committees (NCs), and standardisation experts—Europe should work collectively to secure a leading position in areas that are critical to economic security. The "process owner" mentioned in section b2 could play a role in coordinating activities in line with EU industrial policy priorities.

2. Establish a data collection system to assess where hENs originate and how they align with international standards

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 hENs originated, the degree of alignment with international standards, or how many homegrown hENs become international standards. Before discussing decoupling or developing standards independently of the international standardisation activities, it is important to understand the extent to which hEN currently contain elements that have been developed in international fora.

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. For this reason, we call on the Commission to take up the recommendations developed

by Work Stream 4 of the High-Level Forum on European standardisation[5] 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.

d. Make it more attractive for experts to participate in (harmonised) standardisation processes

1. Make standardisation an attractive area of work

Today, the development of standards is a cumbersome, complex, and lengthy process. When the product under development is a hEN, the process is burdened further by legal requirements, unrealistic timelines and low approval rates. All of this discourages the involvement and commitment of experts. A possible future decoupling from international standards could render harmonised standardisation even less attractive, as stakeholders may shift their focus to global fora instead.

Experts developing hENs aim to meet legislative requirements and ensure safe products worldwide, but the process must be better organised and simplified to maintain standardisation as an attractive area of work.

- **Orgalim calls on the Commission to keep requirements manageable and ensure that assessments are consistent and pragmatic.**

Implementing the improvements mentioned above will bring greater clarity and transparency, reduce Formal Objections, improve adoption rates, and build trust— thereby creating a better environment for standards development. **At the same time, we urge ESOs to continue providing training for experts and simplifying internal processes.** They should provide their TCs with legal expertise on how to address the requirements stemming from SReqs.

2. Introduce tax incentives for companies involved in standardisation processes and funding for SMEs

International and European standardisation systems rely on voluntary contributions from technical experts, mainly industry, but also consumers, trade unions, NGOs and academia. Today, Europe faces a generational challenge in replacing long-serving experts, alongside growing global competition in standardisation. Higher participation and growing influence by other countries underline the need for financial incentives to strengthen EU involvement. Orgalim supports the Council's May 2024[6] call for a stronger EU strategy and greater business participation in international standardisation. Tax incentives could help fund industry-driven projects, reduce costs, and encourage engagement. Coordinating such incentives at EU level would maximise impact and avoid conflicting policies.

Building on existing programmes, the establishment of additional funding mechanisms should be explored to support participation in standardisation work at national and international levels. This could include targeted financial support to reduce barriers for experts contributing to EN or ISO/IEC projects, with Member States contributions complemented by European-level funding. Such an approach will improve inclusiveness and access while ensuring efficient use of resources.

[5] For further information see "Alignment between European and International standards – Final report elaborated by workstream 4".
[6] Council conclusions on "A Single Market for the benefit of all", 24 May 2024

e. Accessibility: finding a sound, financially viable, and sustainable solution

Orgalim is concerned how to continue financing the system following the ruling on the "Right to Know" Case (C-588/21), considering the costs associated with developing and maintaining high-quality standards, which are currently in large part sustained by industry[7], and the strong alignment of hENs with international standards developed by ISO and IEC, whose original content is protected by copyright. A solution must be found to be able to finance free access to the legally relevant content of the standards in a sustainable way. Such cost should be seen as an investment in the competitiveness of European industries, which will continue to benefit from the alignment between European and international standardisation, and in the preservation of the NLF. Failure to properly compensate copyright owners may lead, among other things, to a stark separation of hENs from international standardisation, de facto turning the Single Market into a silo; or – in the worst-case scenario – to the collapse of the NLF framework.

III. Summary & Outlook

The revision of Regulation 1025/2012 on European standardisation presents a unique opportunity to enhance and modernise the framework governing the requests for, development, and citation of harmonised European standards (hENs). Orgalim, as a committed advocate of the standardisation system, stands ready to actively support this process. The proposals outlined above address the most pressing challenges facing our industries, with the aim of ensuring that the revised Regulation continues to foster innovation, competitiveness and trust across the European market.

[7] A Commission Staff Working Document estimated the contribution of industry experts at around €1 billion each year between 2013 and 2015 to participate in, and contribute to, voluntary standardisation work.

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 over €2,750 billion, manufacturing one-third of all European exports and providing over 11 million direct jobs. Orgalim is registered under the European Union Transparency Register – ID number: 20210641335-88.

Orgalim aisbl
Arts 56
Avenue des Arts 56,
1000 Brussels, Belgium

+32 2 206 68 83
secretariat@orgalim.eu
www.orgalim.eu
VAT BE 0414 341 438