



Supplementary Paper to  
BusinessEurope's Regulation 1025  
Public Consultation Response



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## Key Messages

- 1. The ESS is a very cost-effective system for the EU budget as EU financing composes only 0.53% of contributions.**
- 2. Industry is predominant backer and financer of the ESS- funding up to 95% of activity. For every 100 EUR invested more than 99 EUR comes from private/public actors.**
- 3. Regulation 1025 in many areas is fit-for-purpose however it is clear that inefficiencies exist which we believe may be exacerbated by the implementation of ECJ rulings.**
- 4. Regulation 1025 should be amended in a targeted manner to address these specific inefficiencies and prevent destabilisation of the European Standardisation System and the International First principle while safeguarding copyrights.**

As a supplement to our answers to the 1025 Questionnaire we would like to further elaborate on our key points and present in general some basic economic assumptions that guide our overall logic. However, we would like to note that the framing of many of the questions in the survey can be interpreted in extremely different ways with 'leading questions' that can cause many respondents that may agree on issues to give completely different answers. Ultimately, we have serious concerns that the way this questionnaire is structured may be indicative of a pre-formed conclusion and does not follow the principles of better regulation. Un-numbered question preventing direct cross-referencing, sections with important implications remaining conditional on negative answers, insufficient 'free boxes' to elaborate on sections, all seem to point to a process and design that has been ill-thought out.



## Economic Assumptions of Standardisation

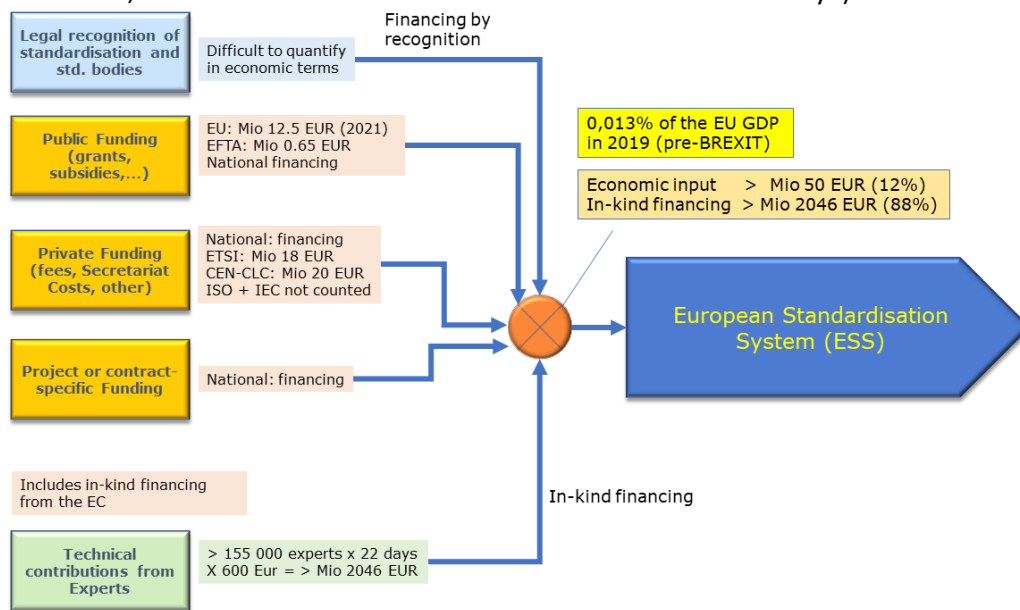
1. Figure 1: Impact Assessment to the Proposal for Regulation 1025/2012 (2011)

<b>Estimated annual costs of working groups of creation of new standards (euros)</b>	
	3 year process
Experts costs (1 meeting /6 days/month*10 experts*600 euro)	432,000
Laboratory costs	400,000
Travel costs	86,400
<b>Total</b>	<b>918,400</b>
Number of working groups (CEN/CENELEC)	1,704
Estimated active working groups (35%of total existing wg)	596
Cost 35% working groups CEN/CENELEC	547,733,760
Cost ETSI (estimated of the basis of number of deliverables)	2,306,247,411

Number of annual deliverables (CEN/CENELEC/ETSI)	3,069
<b>Total costs</b>	<b>2,853,981,171</b>
<b>Cost per deliverable</b>	<b>929,938</b>



**Figure 2: Overall Quantification of Inputs to the ESS** (Study on the Functions and Effects of European Standards and Standardisation in the EU and EFTA Member States, EY Commissioned by DG GROW, November 2021. Hereafter referenced as ‘DG Grow study’ )



**Figure 3: Value of Recognition for Standards:** (Study on the Functions and Effects of European Standards and Standardisation in the EU and EFTA Member States, EY Commissioned by DG GROW, November 2021)

A: Percentage of standards	B: Percentage of sales	Approximate value of the standard (B/A)
70 (non-cited European standards)	50	0.7
30 (cited European standards)	50	1.7

*‘The professionals interviewed from European NSBs estimated that one-third of the total standards – both harmonised standards and other standards cited in legislation – represent more than 50% of the total sales of standards. This suggests that each standard cited in legislation and public policies has an approximate relative value that is 2.3–2.4 times higher than the value of a standard that is not cited in public policies.’*



## A Targeted Revision to Regulation 1025 is Needed.

Considering the judicialisation of standards and increasing legal challenges we believe it is necessary to conduct a targeted amending of the regulation and create legal certainty without having to rely on implementation measures. The revision should consist of a targeted amendment that contains various modifications to parts of 1025 that we see are suffering from poor implementation to the detriment of Industry.

Regulation 1025 is quite clear under Art 10.1 That European Standards and European Standardisation deliverables are to be market-driven and take into account public objectives alongside the policy goals of the Commission. This in our view means that Regulation 1025 first and foremost must guarantee the uptake of standards by companies, in compliance with essential requirements of the legislation that protects public interest. If we are currently in a situation where this is failing to occur, then this demands legal change to rectify.

On the other hand we also do reinforce the point made by the Fit4Future Platform's opinion on Standardisation which under recommendation #1 suggests restraint in a full revision of 1025. As the opinion states: the objective of any evaluation should be based on the assessment if standardisation is efficient and effective in proportion to the needs of all involved stakeholders.

Broadly Regulation 1025 has been very successful for the single market. In theory it provides a solid and future-proof foundation for the ESS. Yet as demonstrated over the past years, the calls for focusing on implementation and further refinement of guidelines has not proven itself a solution.

However, when contemplating what to revise in 1025 it is important to properly delineate issues of the Regulation itself, such as specific Articles or recitals and issues arising from the implementation and 'secondary' effects of regulation 1025.

As an example of this we do not see a need to question the logic of Regulation 1025 on the 'added value' section of the Questionnaire. 1025's Recitals 1-6 these are quite clear with the intent of improving the state of the single market and promoting the safe and free movement of goods and services. Yet if in the Regulation's application and implementation there is a breakdown, such as a backlog of citation of hENs, this will be detrimental to the questions on added value.

Regulation 1025 Recital 5 correctly underpins the importance of hENs and the presumption of conformity in the internal market. On the basis of this recognition in the Regulation we note the findings for DG Grow<sup>1</sup> For facilitating product compliance, the main motivator to use a hEN is to

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<sup>1</sup> Study on the Functions and Effects of European Standards and Standardisation in the EU and EFTA Member States, DG Grow, 2021.



comply with EU legislation. Furthermore, a majority of companies see clear competitive advantages in having conformity assessments use European Standards. An important caveat is that when it comes to self-assessment or notified body assessments and companies have an option to choose, broadly 54% use self-assessment and 45.5% use notified bodies<sup>2</sup>. In our view this clearly challenges any narrative (which was particularly notable in the AI Act debate) that companies overwhelmingly prefer self-certification as a means to avoid what is perceived as more stringent checks by third bodies. (Although we do acknowledge these preferences may change per sector, but even at a sectoral break-down the discrepancies were no larger than roughly 10%) But we stress that this emerges when companies are given the option and are not mandated.

Overall, by maintaining a clear link between the presumption of conformity and hENs, Regulation 1025 continues to give legal certainty and benefits to companies. Yet as the 2010 Impact Assessment to Regulation 1025 pointed out, these benefits are not inherent to any referencing of EU legislation. The mere existence of standards is trade-enhancing due to their cost decreasing effect and reduction of information asymmetries. The impact of standards on GDP have shown the economic benefits and that a positive relation between more EU standards and productivity does exist albeit there is a lower productivity benefit from hENs specifically (DG Grow, 2021).

As the 2021 Study shows: a one percentage point growth increase in the stock of European standards is associated with an increase in EU and EFTA gross value added of approximately EUR 8.4 billion in the succeeding year. With this in mind it is an unquestionable fact that the ESS needs to remain a system that can deliver while remaining attractive and incentivising so the experts continue participating in it.

## Industry as Main Financers of the ESS.

Any review of regulation 1025 must consider the fact that industry is the predominant financer of Standardisation. 1025's Impact Assessment gives the estimate that 93-95% of activity is industry financed and that the rough estimate for the creation of standards in the ESOs in 2009 was 3 billion EUR, with one standard estimated at 1 Million EUR.

With this view, standardisation is defacto an exercise in 'Free Riding' as not only does industry pay for the majority of costs but the largest benefits of standardisation comes from firms who are not undertaking the cost of development themselves. This is demonstrated in the 2021 DG Grow study indicating that the productivity gains from standards are the largest in sectors who buy inputs from sectors that apply European standards.

DG Grow's 2021 study estimates that in 2020, EN development was still between 780K- 1 Million EUR. And EN development can be 200-300% of the cost of other deliverables. Input-wise, it was estimated by the same study that there are over 155,000 experts in standardisation participating

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<sup>2</sup> Study on the Functions and Effects of European Standards and Standardisation in the EU and EFTA Member States, DG Grow, 2021.



in ESO work, representing 0.1% of all employees in the EU. The estimated economic value of these workers implies a figure of 2.5 billion EUR. (See figure 2)

The study continued by calculating that EU financing into the ESS is marginal at 0.53% of contributions to the ESS, with the implication being that for every 100 EUR invested in the ESS, less than 1 EUR is from the EU and more than 99EUR from the other private/public actors.

Furthermore, Regulation 1025's relationship to the wider New Legislative Framework cannot be ignored and its value-add here is significant. The ESS as a whole seems to contribute to 2.1% of the EU's GDP (346.6 billion EUR for 2023) whereas it adds another 0.2% to GDP via the infrastructure of testing, inspection, and certification in Europe.

Based off these calculations it is a safe assumption to say the ESS under Regulation 1025 is very cost-effective for the EU budget in providing a crucial service as a means to implement EU legislation.

This cost-effectiveness must be maintained when considering a targeted amendment. Anything that up-ends this relationship jeopardises the ecosystem that has allowed the ESS to be competitive.

## Implications of ECJ Case (Case C-588/21 P) 'Right to Know'

A big concern over the cost-effectiveness for us is related to the ECJ ruling in 'Right to Know/Malamud' and what the implications of the implementation of this verdict will be.

As of May 30, 2024 we understand that there are 62 pending requests for access to hENs which would include around 10,000 European and International Standards representing a rough investment cost of 10 billion EUR on behalf of industry and other financiers in creating those standards.

The Impact Assessment to Regulation 1025 did some preliminary calculations at the time, finding that the sales of standards in Europe was estimated to be over 230 million EUR and that roughly 1/3 of total standards (hENs and others cited in legislation) represent more than 50% of the total sales of standards.

Making hENs free<sup>3</sup> brings loss of revenue up to 10-20% of NSB operating budget. This is estimated as equivalent to a total loss across Europe to 50-100 million EUR. NSBs remain quite adamant that work on hENs is only possible if cost is compensated either by the Commission or Member States and this possible compensation package was estimated in 2010 to be around 180k-6mill EUR depending on the NSB.

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<sup>3</sup> We await the final format of implementation of the ruling. An important clarification is that the Impact Assessment specifically calculated the implications of being unable to sell hENs. It did not calculate situations such as 'read-only' access.





Aside from the question of 'freely accessible' the implementation of the ruling brought again attention to the issue of copyright. On this the 1025 Impact Assessment again provides a stark reminder of possible implications as NSBs warned already that: *'Attempts on the part of NSBs to provide free access to hENs based on ISO/IEC standards would result in copyright infringement, may result in legal action, and may lead ISO/IEC to no longer make their standards available for adoption as European standards. This could lead to significant disconnection between European and International standardisation, with negative consequences at both levels'*

Thus a key issues to be resolved in the implementation of the Right to Know Case is that there is no legal basis for compensation/financing for these standards. It may be prudent to consider establishing such a basis in a targeted Amendment to Regulation 1025 under a revised Article 15.2.A and Article 17.

*As a recital suggestion: **Standards are copyright protected. The cost of developing standards is mainly carried by private businesses and the revenues from the sales of the standards are used to finance the European standardisation system. Legislators using standards in support of legislation should fairly compensate the copyright holders if these standards are made available.***

If Regulation 1025 will wish to continue having an impact on facilitating the free movement of goods and services in the internal market, while also ensuring that the EU is able to compete at the international level then the issue of 'who pays' when hENs will be made free to access must be resolved as well as ensuring copyright is respected vis-à-vis international obligations

## Speed & Development

While the matter of compensation and copyright are critical components for the future of the ESS one of the long-standing issues also suitable to some form of targeted Amendment is over development time. The below sections go into more detail about the various roadblocks and inefficiencies we have seen forming in the development process. It is important, as mentioned above, to delineate problems of implementation and from the Articles of 1025 themselves though.

In a general sense, the creation of 1025 has correlated with a shorter development of standards. Prior to 1025 the entire process could 'easily take 3 years and often much longer' (Impact Assessment to Regulation 1025, pg 12) with examples given of 10 or even 15 years for the development of certain hENs. However it must be noted that when looking at development time for hENs in 2003 which took 8 years to develop, shortening this to 3 by 2008 is a good achievement and a testament to the soft-law changes that the ESOs were able to make to address issues of speed, prior to the creation of Regulation 1025. However, It may be that rather



than taking full credit for shortening citation timing 1025 encoded the best practices and efforts that were being done by the ESOs prior to 2012.

Modern-day development seems to suggest that this 3 year period remains roughly stable and that there is an inherent ‘stickiness’ to the development time-frame as CEN/CENELEC figures from 2022 to 2024 indicate: the average development time for EN/HDs is around 2.65 years for non-Frankfurt/Vienna and 2.5 years for Frankfurt/Vienna EN/HDs. (However these numbers are higher when looking at individual CEN or CENELEC time to publication)

**Tables from 1025 Implementation Report 2022 Chapter 2.7.2**

<b>Median (and average) time (days) between ESO’s adoption and delivery to the Commission</b>	<b>2018</b>	<b>2019</b>	<b>2020</b>	<b>Total</b>
<b>CEN</b>	75 (115)	105 (199)	70 (91)	83 (141)
<b>CENELEC</b>	218 (424)	189 (1374)	82 (481)	186 (822)
<b>ETSI</b>	29 (27)	49 (58)	20 (29)	28 (38)
<b>Total</b>	109 (224)	117 (683)	75 (251)	100 (407)

	<b>2018</b>	<b>2019</b>	<b>2020</b>	<b>2021</b>
<b>Median (and average) time (days) between delivery to the Commission and citation in the OJEU</b>	238 (298)	292 (322)	228 (231)	108 (121)

## Political Interference/Interpretation Issues on Standardisation Request Development

We believe it is very important the Regulation 1025 is left flexible in prescribing timelines as it is impossible to put a blanket number on how long the standardisation of certain subjects should take. As was noted in the 1025 Impact Assessment deadlines could lead to increased costs possibly up to 150-200K EUR if a 2 year deadline was mandated, with industry having to shoulder 142-190K EUR of said cost.

Article 10 of Regulation 1025 is sufficient in outlining the general expectations of the request. But it is important to differentiate processes per Standardisation Request. As some standardisation requests such as the Cyber Resiliency Act or under the Radio Equipment Directive delegated acts have issues that Regulation 1025 would never be able to address in regard to the feasibility of the request, or worse when they have been issued with heavy political pressures We especially are worried that in some instances the ESOs feel 'pressured' by the Commission into accepting Standardisation Requests that are not feasible in the timeframe requested- with the Cyber Resiliency Act as an anecdotal example.



For example, the situation in 2022 for the RED delegated regulation was such that a 30 month total transition time was given until August 2024, with a SR being issued alongside the Delegated Regulation in March 2022. The initial plan was for industry to have a 10 month window to adopt to the changes following a 20 month period of standardisation work. However due to delays in drafting at the TC, predicted HAS consultant availability, and limited resources of notified bodies, there was a serious risk that the as a result there would be no hEN available to industry to make use of in that 10 month period that was envisioned. This would have forced unnecessary and costly usage of notified bodies by default. However further complications related to a negative HAS opinion occurring during the same time as a final vote have put the future of this into question and potentially wasting the past years of work on the standards.

Another example also of the RED is its interplay with the AI Act. Under the AI Act, Article 6.1 states that an AI system can become high-risk if it is used as a safety component or is a product itself under sectoral EU legislation and is required to undergo a third-party conformity assessment. This implies that an AI product that benefits from the presumption of conformity granted to it by Harmonised European Standards under respective EU sectoral legislation would allow the product to avoid being classified as high-risk and the costs related to this classification. However, the Commission under the RED believes that the AI system would be high-risk under the AI Act irrespective of the existence or application of harmonised standards. This interpretation on the usage of standards is damaging and should not be used to justify further scope expansion of what is High-Risk AI under other sectoral EU legislation. This would further undermine competitiveness and incentive to develop sectoral hENs for products that would integrate AI, which in turn would undermine one of the main goals of the AI Act which was to increase trusted AI uptake. The notion that the legal requirement for third-party assessment exists ignoring the possibility of using harmonised standards set the grounds for a future legal challenge.

The situations above are examples of how important it is that regular constructive dialogue is held between all stakeholders and that 1025 is left flexible in elaborating timelines. OR that some sort of emergency procedure in a targeted AM to Regulation 1025 is formalised to allow for these interactions.

We have also noted with concern the increasing marginalisation of ETSI as an ESO when it comes to receiving Standardisation Requests. Depriving Standardisation Request access to the expertise at ETSI on political or personal grounds is a disservice to European industry and competitiveness. The introduction of the targeted amendment to 1025 that addressed governance issues should be enough to satisfy political concerns.

## Implications of the ‘James Elliott’ C-613/14 Ruling on the ESS:

Despite the work being done to speed up the process of standards as indicated with the decreases in administrative/procedural time related to delivery and citation, we believe that inefficiencies remain namely stemming from the implementation and interpretation of the ECJ’s Judgement in ‘James Elliott’ ruling prompting the Commission to change the development process for hENS and the introduction of the ‘HAS’ Consultancy system. This in our view



contributed to a slower citation process as well as a gradual undermining of the principles of the New Approach.

The HAS system as it stands poses a highly inefficient and unsuitable system for citation, one of the key roadblocks of this system is that it puts a contractual limit on the amount of time that the consultant can spend, the 2018 contracts cite 2 hours<sup>4</sup> per week. As we explain in a section further down this sort of imposition of time constraints/deadlines can lead to increased costs for stakeholders.

But HAS consultants should not be seen as the sole creator of the problem, they were simply introduced as an attempted solution to the legal issues posed by the James Elliott ruling. Companies participating in standards do benefit from having expert assistance in guiding the standardisation work, but we must differentiate between expertise that helps craft and comply with essential requirements and expertise related to the legal certainty for citation.

The findings of the European Court of Auditors<sup>5</sup> regarding the Commission’s use of external consultants finds that their general usage does not fully maximise value for money and the Commission has a number of failures in monitoring, managing, and mitigating the risks of overdependence, concentration of suppliers, and possible conflicts of interest. While the ECA was not focusing on the HAS system we do note anecdotally that there are inefficiencies. Most notably this is characterised by the 2021 Budget debacle, where the EU Budget for HAS consultants supposed to last until January 2022 ran out already in October 2021. This effectively froze all HAS assessment work, created a backlog for citation, and further undermined the cooperative spirit in the ESS.

We would ask that a basic cost analysis be conducted on the basis of the backlog that was created by this budgetary discretion. Furthermore if due to the backlog any of the pending hENS have become outdated with the state of the art which incurs additional cost. Regulation 1025 establishes no legal grounds for such a roadblock to citation nor should it.

## Cost of Non-Citation

Utilising the data from the various studies done we would like to give a rough estimate of the monetary cost that is hidden in some of the recent figures that have been presented since 2020. Using the baseline assumption that 1 million EUR is the cost of 1 deliverable.

### Study on the Implementation of Regulation 1025/2012, 2020

**Table 8: Number of Offered References**

	2018	2019
CEN	447	233
CENELEC	111	141
ETSI	7	11
Total	565	385

<sup>4</sup> [https://www.ey.com/en\\_be/consulting/harmonised-standards-consultant](https://www.ey.com/en_be/consulting/harmonised-standards-consultant)

<sup>5</sup> [https://www.eca.europa.eu/Lists/ECADocuments/SR22\\_17/SR\\_External\\_consultants\\_EN.pdf](https://www.eca.europa.eu/Lists/ECADocuments/SR22_17/SR_External_consultants_EN.pdf)



**Table 9: Annual OJ Publication Independently when a reference was offered to EC**

	2018	2019
Normal publication	335	151
Publication with restriction	5	5
<b>Total</b>	<b>340</b>	<b>156</b>

From the two tables a trend was developing that offered references were decreasing while the number of standards being published also decreased. With publication rate dropping from 60% in 2019 to 40%

**Table 10 HAS Statistics**

	2018	2019
Average number of days the consultants use per draft standard assessed	1.89	2.83
Percentage of positive assessments carried out at formal vote stage out of total references submitted <sup>16</sup>	43.57%	37.18

We see an increasing trend of negative HAS assessments as well as an increased trend of working hours for 2018-2019, As of December 2021 the positivity rate by HAS consultants was 27.58% due to ‘inadequacy with EU law<sup>6</sup>’ we see the trend continuing in a negative direction. However we do raise the fact that this has been contested as stated in the ETSI TC report on the RED<sup>7</sup>.

<sup>6</sup> Report on the implementation of the Regulation (EU) No 1025/2012 from 2016 to 2020, 2022.

<sup>7</sup> *there have been other factors that have led to unfavourable reviews. Widespread concern was also expressed by TC chairs over the consistency of decisions and inflexibility of the EC in assessing candidate harmonised standards, and there was frustration at the growing number of standards that are rejected or cited with restrictions. Many examples of inconsistency of decisions from standard to standard were cited, leading to frustration and delays in the publication of standards. Such delays cost standards writers time, and hence money, but also leave the EU market with incomplete documentation, thereby adding further costs to industry and leading to uncertainty in the quality of products being placed on the market. The EC is empowered to introduce delegated acts on existing legislation, such as the RED, providing it carries out a thorough impact assessment. Recent experience demonstrates that, even after the (sometimes controversial) public debate and publication of such an impact assessment, the corresponding actions, such as the publication a delegated act or the issuance of a Standardisation request, the actual impact on industry (both cost and time to make changes) and the market more widely is often wildly underestimated. Pg 7 - [Study into the challenges of developing harmonised standards in the context of future changes to the environment in which products are being developed and operated. ETSI, 2022](#)*



And that the Commission itself is allegedly avoiding HAS consultancy procedures for certain Standardisation Requests.

We are concerned that the 2018 and 2019 publication data in the OJ indicated a decreasing trend from 60% to 40% which would be contrary to Regulation 1025's objective of speed and timeliness. We would request a more-in-depth study in how the HAS system has been functioning as the Commission's Final Report 2020 study on the implementation of Regulation 1025 was unable to extrapolate much data due to how new the process was at the time.

Looking<sup>8</sup> further shows:

Year/Period	Description	Number of hENs in backlog	Cost in EUR (Millions)	Notes
March 2017	Unprocessed hENs submitted by ESOs	596	596	Backlog of hENs up to March 2017
December 9, 2021	Reduction of backlog	7 (2 from 2018, 5 from 2019)	7	

In relation to the evaluation's question if the time taken to develop harmonised standards is consistent with bringing innovation to the market this is highly dependant on the hEN. We unfortunately have instances where the state of the art has developed at the international level but European companies cannot take advantage of this as the hEN is outdated. And this poses a risk to consumer safety as well as losses to companies.

For example for a certain product type that has current outdated listing, the additional cost to close the gap for one company with state of the art for a single project costs 83K EUR with an additional 680 hours of effort required. If this cost assumption is held across all hENs (which in reality is unknown to us) and we assume 20% (which is also dubious) of the 235 hENs that CEN/CENELEC state are not cited are outdated to state of the art we come to a cost of 3.9 million EUR and 31,960 additional hours for one company.

From a consumer safety perspective an analysis<sup>9</sup> of RAPEX notifications shows that thanks to standards, 52% of the total notifications explicitly referred to standards resulting in 14,625 products being identified as dangerous. Another 34% had indirect standards references, meaning that for RAPEX, standards contributed to 86% of all notifications and protecting up to 26.4 billion EUR of consumers costs.

<sup>8</sup> Data in the table below is collected from Section 2.71- Report on the implementation of the Regulation (EU) No 1025/2012 from 2016 to 2020, 2022.

<sup>9</sup> Study on the Functions and Effects of European Standards and Standardisation in the EU and EFTA Member States, DG Grow, 2021.



Year/Period	Description
As of December 2021	3312 requests for hEN Assessments
	2944 requests processed
	368 requests non-eligible

Year/Period	Description	Cost in EUR
2018-2020	1247 hENs submitted	1.247 billion EUR
	1009 new hENs	1 billion EUR
	238 resubmissions	

Year/Period	Description	Cost in EUR
By December 2021	576 hENs Cited	576 million EUR
	17 in process of citation	17 million EUR
	371 rejected	371 million EUR
	45 pending	45 million EUR

Year/Period	Description	Cost in EUR
Q 1 2024 <sup>10</sup> (excluding ETSI)	3379 hENs cited	3.379 billion EUR
	235 hENs not cited	235 million EUR

**We can conclude then that of the 2018-2020 1 billion EUR invested into new HENs, roughly 50% of the money saw a direct return on investment by the end of December 2021.** (the return being citation and presumption of conformity)

## Stakeholder Participation & Inclusiveness

Regarding stakeholder participation, it is important that a baseline is established to determine what is inclusive and what those metrics look like. For example, is the aim to have simply an Annex III representative in every TC? Or only in TC's deemed 'critical'? Without such metrics we don't think that any changes made to accommodate participation concerns will be considered 'enough' by certain stakeholders.

We recall that in the past BusinessEurope criticised the new 1025 for not being inclusive of industry enough and called for Industry to be given an Annex III status. Industry cannot be represented by ESOs as it is not their role to develop standards. ESOs facilitate the process through supporting industry development by providing: the process, tools, nexus of trust, authority and appropriate legal status while upholding Regulation 1025/2012. Industry cannot

<sup>10</sup> [CEN/CENELEC in Figures 2024 Q1](#)



be represented by any current Annex III members. This is since three members represent consumers, environment and social aspects of development. The other represents SMEs, this is unfortunate as we feel that one stakeholder who specifically represents SMEs cannot represent the interests of all industry stakeholders in the development of standards.

Industry stakeholders are not fully involved in the initial mandate standard setting phase: planning and preparation. In the planning phase, it is not sufficient to consult industry only via the annual union work programme as this does not contain the political goals or technical requirements for each item. Under Art 10(2) of Regulation 1025/2012 it permits consultation of stakeholder organisations receiving Union financing or those in the Annex III committee. Industry is represented in neither of these categories and so is not involved in the preparation stage. Under Art 12, Industry stakeholders are only notified when published to all on the notification website. Industry stakeholders could be better involved if included during the drafting work and initial consultation phase alongside the organizations receiving Union financing. This is not by any means prohibited by Regulation 1025/2012; on the contrary consultation of sectorial experts is encouraged under Art 10(2).

For example, following the ECJ's decision in 'Right to Know' and despite industry being the main financial backer of the ESS, industry alongside academia were the last stakeholders to learn of the implementation plans by the Commission. Member States as well as Annex III organisations were informed via the Committee on Standards. Yet Industry and academia were not given any such consideration as a 'whole.' While a later update was provided to the High-Level Forum, membership to the forum is limited and not encompassing a wide base of industrial players.

## Conclusion:

With the above arguments in mind the European Standardisation System is at a crossroads. The role standards play in compliance, how we finance standards, how we pool expertise, the effects of hENS on users, all of these require careful evaluation and consideration. In doing so we must avoid reverting to the 'Old Approach' style of legislation which directly undermines the European investment climate and hinders our ability to be competitive.

In conducting this evaluation, a choice must be made then on the wider relationship Regulation 1025 has with the New Legislative Framework. Would a revision that promotes industry and Europe's interests be served by merely translating jurisprudence into a new framework? Or rather more challengingly do we need to rethink the legal basis of 1025 so that it is best fit.