Raising standards for consumers

The Consumer Voice in Europe

FOR A 'STANDARDISATION GOVERNANCE ACT'

ANEC and BEUC recommendations to adapt Regulation (EU) 1025/2012

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Why it matters to consumers

Standards are everywhere: from our smartphone chargers, the eco-design of our washing machines, the safety of our ovens, the security of our electronic devices and much more. Over the past decades, standards have contributed to making products placed on the EU market safer, more accessible and easier to use, more secure, more interoperable and more sustainable. In many cases, standards enable cost savings that benefit consumers, while also increasing consumer protection and welfare.

However, the European Standardisation System suffers from several shortcomings that can adversely affect the ambitions of standards, such as mitigating damage to the environment or the protection of consumers. The current European Standardisation System does not allow the views of civil society to be sufficiently heard in the process while tackling an ever-growing number of issues that sometimes hold key societal implications.

Additionally, as the current legislative work on the EU's AI Act has shown, the borderline between what must be stipulated in EU legislation and what can be delegated to standardisation bodies is blurred. This situation is particularly problematic when standards are used to support EU legislation that aims to protect consumers, including their fundamental rights. The purpose of ANEC's and BEUC's joint recommendations is to create a system where no delegation of lawmaking takes place, and where societal stakeholders are not only present but can have an impact in shaping standards.

Summary

In its 2022 Standardisation Strategy[1], the European Commission explains that standards "are at the core of the EU's Single Market". In particular, harmonised standards allow companies to demonstrate compliance with EU law. Thus, they facilitate the implementation of EU laws on health, safety and security. In this respect, harmonised standards are instrumental in helping ensure that products placed on the EU market do not harm consumers. Over the past three decades, the European Standardisation System has delivered more than 3,600 harmonised standards.[2]

Nevertheless, the European Standardisation System is not flawless and proves to be ill-equipped to deal with newer challenges, such as the risks to consumers from the use of artificial intelligence. This paper provides recommendations to be considered in the evaluation of Regulation 1025/2012[3] on European standardisation.

In essence, ANEC and BEUC believe the Regulation needs to be amended to address emerging economic and societal issues and renamed into "Standardisation Governance Act". Such a new name would better reflect the strategic importance of European standardisation and offer a clear distribution of roles.

[1] European Commission, "An EU Strategy on Standardisation - Setting global standards in support of a resilient, green and digital EU single market", COM(2022), 2 February 2022.
[2] Ibid.
3 REGULATION (EU) No 1025/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2012 on European standardisation.

This paper addresses *harmonised* standards, due to their special status in Europe, but the recommendations on civil society participation cover European standards at large.

Summary of the recommendations

Regulation (EU) 1025/2012 should be amended to set out the principles and limits of standardisation

- Define domains where standardisation shall not be used to underpin EU legislation, such as the definition of ethical values, or the definition of fundamental rights.
- Ensure that all New Legislative Framework (NLF) legislation is substantive enough to be the basis for harmonised standards and that there is no room for misinterpretation or too much discretion of interpretation by the European Standardisation Organisations (ESOs).
- Establish a specific assessment by the European Commission's Regulatory Scrutiny Board in case of an NLF-based legislative proposal to ensure it does not delegate lawmaking to standards-setting bodies.

Regulation (EU) 1025/2012 should reflect the special status of harmonised standards as "part of EU law"

- Noting the legal effect of harmonised standards, give the European Commission the right to indicate in a standardisation request whether the standards shall be drafted exclusively within the European Standardisation System or in association with international standardisation organisations (most notably ISO/IEC), especially within the context of protecting European values and ensuring the inclusiveness of the process.[4]
- Replace the Harmonised Standards (HAS) consultant system with a newly created Standardisation Scrutiny Board within the European Commission, with not only technical expertise but also expertise in a wide range of relevant disciplines. The Standardisation Scrutiny Board would support the European Commission in assessing whether the draft harmonised standards comply with EU law.
- Clarify that it is primarily the role of the European Commission, based on the assessment of the Standardisation Scrutiny Board, to decide whether draft harmonised standards are in line with the initial standardisation request, EU law and the EU Charter of Fundamental Rights, and that the provisions of the Regulation were followed in their drafting.
- Establish free accessibility to the text of harmonised standards.

The presence and rights of societal stakeholders in standardisation should be reinforced

- At the national level, together with Member States:
    - Harmonise the conditions for the participation of civil society organisations and remove all barriers to participation possible (e.g., free access to participate in standardisation activities, removal of accessibility barriers for persons with disabilities).
    - Designate national stakeholder organisations, supported by adequate public funding.

[4] Adoption of international (ISO, IEC etc.) standards would still be possible subject to review and if necessary, revision (creation of a European version) within the European Standardisation System.

- Improve visibility of and facilitate commenting on draft standards during the public enquiry stage.

- At the European and international level:
  - Reinforce European stakeholder organisations' rights within European Standardisation Organisations, including a right to take the chair of a technical committee.
  - Provide European stakeholder organisations with a level of public funding that allows them to undertake fully and effectively the tasks set out in Article 5 of the Regulation, including consequent participation in standardisation at the international level.
  - Create the possibility for the European Commission to list in each standardisation request additional civil society organisations that shall have direct and free access to the standardisation work on the condition that they contribute actively.
  - Include in Regulation 1025/2012 requirements that set out conditions under which CEN-CENELEC can ask ISO/IEC to lead on standardisation work - for example, requiring the automatic participation in the international technical body of European stakeholder organisations (Annex III organisations) and other relevant civil society organisations listed in the standardisation request.

Introduction: The limits of the European Standardisation System

When assessing the relevance and limits of the current European Standardisation System, we will focus on the elaboration of harmonised standards. Harmonised standards are of a special kind. The specificity of harmonised standards is that the European Commission requests them to support the implementation of EU legislation. Once their references are published in the Official Journal of the EU,[5] harmonised standards provide the businesses that comply with them a presumption of conformity with the law. In other words, products that conform to harmonised standards are presumed compliant with EU legislation. Manufacturers are not obliged to rely on harmonised standards, but they have a strong incentive to do so as harmonised standards often represent the easiest and most cost-effective path to prove compliance.

Harmonised standards are instrumental in the New Legislative Framework (NLF). As per the NLF approach, the EU legislation lays down a set of essential requirements that products must meet, while European Standardisation Organisations (ESOs) draft the harmonised standards that will support compliance with these legal requirements. This is a well-established division of labour: policy and legislation for the EU institutions, and technical work for the ESOs. The ESOs are three specific organisations named in Annex I to Regulation 1025/2012: CEN, CENELEC and ETSI.[6]

The NLF has been central to the creation of the Single Market, from which consumers have benefited and continue to benefit. It has facilitated the removal of barriers to trade within the EU, including technical barriers. Equally important is the traditional contribution of the NLF to the protection of the health and safety of consumers. Numerous pieces of safety

[5] The reference of the harmonised standard is published, not the text of the standard which is copyrighted.
[6] ETSI is in charge of standardising telecommunications. CENELEC prepares standards in the electrotechnical domain. CEN standardises virtually everything else. However, the frontiers between the three ESOs have become blurred, which gives rise to more joint work, especially between CEN and CENELEC. The latter share a common secretariat and have similar working methods, while ETSI's organisation differs.

legislation follow the NLF approach, such as the Toy Safety Directive[7] and the Machinery Regulation[8].

However, the NLF approach, which already fails sometimes to offer the levels of protection or welfare expected by the consumer,[9] shows additional flaws when used to support EU digital policies.

Firstly, the scope and limits of standardisation have been put to the test in recent years and the EU's proposal for an Artificial Intelligence Act (AI Act) is to date the best illustration of this problem. The European Commission chose the NLF approach for the AI Act, meaning that ESOs[10] are tasked with specifying the technical requirements to implement the future Regulation. One of the objectives of the AI Act is to ensure that AI systems placed on the EU market are safe and respect fundamental rights and Union values. Thus, there is an acknowledgement that AI systems can impact fundamental rights. Biased decisions[11] and lack of transparency,[12] for instance, are two common problems when it comes to AI systems. Many requirements of the AI Act are vaguely drafted.[13] For instance, Article 10 of the AI Act proposal stipulates that data governance and management practices shall concern "examination in view of possible biases" but without defining what constitutes bias. Another example is the requirement of transparency (Article 13 of the proposal), according to which high-risk AI systems' operation shall be "sufficiently transparent to enable users to interpret the system's output and use it appropriately". The AI Act does not further specify this sentence. These requirements will still be translated into technical standards. This means that ESOs are left with a very big margin of interpretation of legal requirements.

The particular case of the AI Act raises the more general question of the limits between law and standards. The European Commission's Vademecum states that "in issuing a standardisation request, the Commission does not delegate political powers to the ESOs and their members, but recognises their specific technical roles in the process".[14] In other words, the European Commission should not mandate decisions to the ESOs that go beyond developing technical requirements and processes that interpret the law. Regulation 1025/2012 states that "those requirements should be precisely defined in order to avoid misinterpretation on the part of the European standardisation organisations".[15] Nothing is said however on what to do if there is still a considerable margin of interpretation, as is the case with the AI Act.

Secondly, the very legal nature of harmonised standards is an ongoing discussion. In 2016, the Court of Justice of the EU stated in the *James Elliott* case that a harmonised standard "forms part of EU law" due to its special role in the implementation of EU legislation. The conclusions from James Elliott are not yet reflected in Regulation 1025/2012, for instance in terms of free accessibility to the text of harmonised standards.

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[7] DIRECTIVE 2009/48/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 June 2009 on the safety of toys.
[8] REGULATION (EU) 2023/1230 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC.
[9] Hans-W. Micklitz, "The Role of Standards in Future EU Digital Policy Legislation – A Consumer Perspective", July 2023, study commissioned by ANEC and BEUC, page 12.
[10] At the European level, the European Commission tasked CEN and CENELEC with the drafting of such standards. CEN/CENELEC started the work with a strong influence from international standardisation, especially standards developed by ISO/IEC.
[11] Martin Ebers, "Standardizing AI - The Case of the European Commission's Proposal for an Artificial Intelligence Act", The Cambridge Handbook of Artificial Intelligence: Global Perspectives on Law and Ethics, 6 August 2021, available at SSRN: https://ssrn.com/abstract=3900378, also see as an illustrative case Matt Burgess, "This Algorithm Could Ruin Your Life", WIRED, 6 March 2023, last consulted on 31 July 2023.
[12] Ibid, also see EDPB, "Berlin SA Berlin SA imposes 300 000 euro fine against bank after lack of transparency over automated rejection of credit card application", 31 May 2023, last consulted on 31 July 2023.
[13] Ibid.
[14] European Commission, *Vademecum on European Standardisation in support of Union Legislation and policies*, PART I, 27 October 2015, page 9.
[15] Recital 5.

Thirdly, the composition of the technical bodies that draft harmonised standards is a problem. Standardisation bodies are private structures, despite the crucial role they play in the EU Single Market. Their funding stems from the sale of copyrighted standards (especially at the national level), membership fees and public authorities (especially at the European level). In all fields, most experts come from industry, given the economic interest of industry in the use of standards and, particularly, in gaining the presumption of conformity from the application of harmonised standards. Although Regulation 1025/2012 requires ESOs to encourage and facilitate stakeholder participation,[16] more than a decade after its adoption, the inclusiveness of the system is still far from being a reality in practice. Civil society's participation is marginal, and its views are often disregarded. Having facilitated "access" (that is, openness) is not the same as having "effective participation" (that is, inclusiveness). Participation needs not only to be simply possible and passively supported, but actively encouraged and effectively enabled in line with Regulation 1025/2012. This continued imbalance between the influence of civil society in the process, compared with the much stronger position of industry, raises questions as to whether standardisation has the legitimacy to address issues that could significantly affect the application of fundamental rights and the welfare of our societies, especially in the digital sphere.

All these elements call for the amendment of Regulation 1025/2012.[17]

1. Defining the principles and limits of standardisation

In many ways, the European Standardisation System is not equipped to cater for the protection of fundamental rights. The rationale behind this is straightforward: it was never meant to be the role of ESOs to deal with fundamental rights.

However, the line between a purely technical matter and a legal one can be fine. The AI Act illustrates this very well (see the Introduction). The European Standardisation System is not - and will never be - fully shielded from having to address societal issues. Thus, it needs to embed a series of safeguards to:

- Define areas where standardisation shall not be used to underpin EU legislation.
- Define a principle according to which legal requirements must be sufficiently clear and detailed in order to use the NLF approach.

1.1. Domains where standardisation shall not be used to underpin EU legislation

The current version of Regulation 1025/2012 does not set any limits to the domains that standardisation may cover. As explained above, this is problematic as standardisation organisations do not have sufficient democratic legitimacy, nor expertise, to set standards for everything in our society.

We recommend introducing a new article addressing the domains where standardisation must not be used to underpin EU legislation under Article 10. Such an article could draw inspiration from DIN 820-1:2022, a standard issued by the German National Standardisation Body (DIN) to define the principles of standardisation.

Regulation 1025/2012 should state that harmonised standards shall not address:

- The definition or legal interpretation of ethical values
- The definition or legal interpretation of rights enshrined in the EU Charter of Fundamental Rights

[16] Article 5.
[17] Throughout this paper, we will regularly mention the AI Act to exemplify specific points. However, the scope of our conclusions is general and does not limit itself to this particular legislation.

- Matters of religion or ideology
- The domain of social partners

In principle, even non-harmonised standards should not cover those domains because they are issues that should be discussed within a democratic and sovereign process. However, it is particularly important to rule out the use of harmonised standards for these domains due to their special status in the Single Market.

Furthermore, the European Commission and ESOs shall not promote or support international standardisation work covering such domains.

ANEC and BEUC recommendations:

- Introduce a new article on the domains where harmonised standards shall not be used.

1.2. Conditions for legislation to follow the NLF approach

Beyond setting limits to what is standardisable, it is essential to strengthen the conditions under which harmonised standards can be requested to avoid delegation of lawmaking. In other words, Regulation 1025/2012 should contain more stringent conditions for legislation to follow the NLF approach.

As mentioned in the introduction, the AI Act illustrates perfectly how NLF-based legislation can lack legal clarity on key concepts, such as bias, which means that ESOs (CEN and CENELEC in this case) will need to fill the gaps. Not only is there a risk of delegation of political power to standards-setting bodies but delegation in relation to interpreting fundamental rights.

First, an amendment of Regulation 1025/2012 needs to introduce an evaluation that the NLF is the right basis for a given field. Naturally, all the domains that were mentioned in the previous section (1.1) cannot be covered by harmonised standards. This would mean, for instance, that general principles in the fields of consumer protection or fundamental rights could not be the basis for harmonised standards as they would entail the legal interpretation of a fundamental right. This should be part of the assessment that any NLF-based proposal must undergo.

Secondly, Regulation 1025/2012 should also include safeguards to ensure that the legislation is substantive enough in case it follows the NLF approach. Thus, what appears in the last sentence of Recital 5 of Regulation 1025/2012 should become a binding provision: **"For legislation to be the basis for harmonised standards, its requirements shall be precisely defined in order to avoid misinterpretation on the part of the European standardisation organisations."**

An entity should be in charge of checking these conditions are met, even before a proposal is issued. The Regulatory Scrutiny Board is an existing independent body that provides quality control and support for Commission impact assessments and evaluations. It intervenes at an early stage in the legislative process, precisely when the conditions for NLF use should be checked. Regulation 1025/2012 should upgrade its role and task it with the responsibility of assessing whether the NLF is a suitable basis for a legislative proposal and whether there is a risk of delegation of lawmaking. The Regulatory Scrutiny Board would provide the European Commission with an opinion, which would be the outcome of such evaluation.

ANEC and BEUC recommendations:

- Introduce a binding provision in Regulation 1025/2012 to state that, in case legislation foresees reliance on harmonised standards, its requirements shall be

precisely defined in order to avoid misinterpretation and delegation of legislative power to ESOs.

- Entrust the Regulatory Scrutiny Board with the task of evaluating: 1) that the field covered is suitable for an NLF-based legislative proposal and; 2) that the proposal for legislation is specific enough to serve as the legal basis for harmonised standards.

In essence, Regulation 1025/2012 should include the following main principles:

✓ Not everything is standardisable via harmonised standards.

✓ Legislators are in charge of lawmaking and no delegation of legislative power to ESOs must take place in the making of harmonised standards.

The amended Regulation should also better reflect the special role that harmonised standards play in the Single Market. If harmonised standards can indeed be drafted, as concluded by the Regulatory Scrutiny Board, how should the drafting take place? The second chapter of this paper delves into this matter.

2. Consequences of harmonised standards being "part of EU law" (James Elliott CJEU ruling)

In 2016, the Court of Justice of the EU gave its *James Elliott* judgment,[18] in which it concluded that a harmonised standard "forms part of EU law". The Court referred to the presumption of conformity with the law that the application of a harmonised standard triggers. Harmonised standards, though voluntary, are "by their nature measures implementing or applying an act of EU law". [19]

Thus, the Court acknowledged the key role that harmonised standards play in the legal framework of the Single Market. Harmonised standards have a specific role and impact and hence require close scrutiny.

However, this does not mean that harmonised standards can or should add requirements to the legislation (they are not on equal footing with a Regulation or a Directive). They are simply implementing measures developed by experts in technical bodies.

2.1. Alignment with international standards or homegrown European standards?

Nowadays, a significant portion of the European catalogue of standards corresponds to a transposition of international standards, often in identical terms. Indeed, more than 34% of CEN's catalogue is made up of deliverables that are identical adoptions of ISO deliverables (although the percentage varies across the multitude of sectors that CEN and ISO cover).[20] For CENELEC, this figure is much higher: 74% of its catalogue is made up of adoptions identical to IEC deliverables.[21] In other words, nearly three-quarters of the deliverables adopted by CENELEC are copies of international standards. In CENELEC, the influence of international standards is most important in two fields: electro-technology and digital society.[22]

Such statistics can be explained by the agreements between CEN and ISO, on the one hand, and CENELEC and IEC, on the other hand. Those are called respectively the Vienna Agreement and the Frankfurt Agreement. These agreements follow the spirit of the WTO Agreement on Technical Barriers to Trade (TBT), whereby international standards are to

[18] ECJ C-613/14 - *James Elliott Construction*, ECLI:EU:C:2016:63.
[19] Ibid.
[20] CEN-CENELEC, *Global Outreach Report*, January 2023.
[21] Ibid.
[22] Ibid.

be preferred to regional or national standards. The idea is that standards should foster international trade and not hinder it.

Harmonised standards are often developed at the international level in the context of these Vienna and Frankfurt agreements. In the CENELEC catalogue of *harmonised standards*, 721 references are identical to IEC publications, 194 are based on IEC publications, while 399 have no reference to IEC publications. In other words, the vast majority of harmonised standards produced by CENELEC were actually drafted by IEC.[23] In CEN, this figure tends to be lower, with a little more than a quarter of produced harmonised standards drafted by ISO.[24]

In the current European Standardisation System, the European Commission does not have a say on whether CEN and CENELEC should mandatorily take the lead for the development of harmonised standards. CEN and CENELEC have full latitude to entrust ISO or IEC with the drafting of standards requested by the European Commission.

It is possible for CEN and CENELEC to develop a standard in cooperation with ISO and IEC but with CEN or CENELEC as the leading parties, meaning that the actual drafting takes place within CEN or CENELEC. However, often the reverse option is chosen, ISO and IEC are in the lead: the principle of "international first". In some fields, this raises the question of the alignment of international standardisation with EU values.

For harmonised standards, the European Commission should have the option to indicate whether a standard should be exclusively drafted within ESOs as part of the standardisation request. Article 10 of Regulation 1025/2012 should be amended accordingly.

ANEC and BEUC recommendations:

- Amend Article 10 to give the European Commission the right to indicate in a standardisation request whether the standards shall be drafted exclusively within the European Standardisation System or in association with ISO/IEC.

2.2. Establishing a Standardisation Scrutiny Board

Article 10 paragraph 5 of Regulation 1025/2012 states that "[…] The Commission together with the European standardisation organisations shall assess the compliance of the documents drafted by the European standardisation organisation with its initial request". Paragraph 6 continues: "Where a harmonised standard satisfies the requirements which it aims to cover and which are set out in the corresponding Union harmonisation legislation, the Commission shall publish a reference of such harmonised standard without delay in the Official Journal of the European Union".

Following the ruling of the CJEU in James Elliott,[25] the European Commission interpreted Article 10 paragraphs 5 and 6 of Regulation 1025/2012 in such a way that it exercises closer scrutiny on the draft harmonised standards. The European Commission is supported by the Harmonised Standards consultants (HAS consultants) to check whether the draft harmonised standard complies with the requirements of the standardisation request and the EU legislation. The Commission took over the management of the HAS consultants after James Elliott. In the past, such consultants used to be managed by CEN and CENELEC under a different name ("New Approach consultants"). The HAS consultants are hired by a private consultancy and usually are technical experts.[26] Their role is not defined in Regulation 1025/2012 and is not subject to any kind of public scrutiny.

[23] CEN-CENELEC, *CEN-CENELEC in Figures*, 2023 Q2, available at https://www.cencenelec.eu/stats/CEN_CENELEC_in_figures_quarter.htm
[24] Ibid.
[25] ECJ C-613/14 - *James Elliott Construction*, ECLI:EU:C:2016:63.
[26] Hans-W. Micklitz, "The Role of Standards in Future EU Digital Policy Legislation – A Consumer Perspective", July 2023, study commissioned by ANEC and BEUC, page 74.

A recent Commission report[27] shows that HAS consultants issued a positive assessment for less than a third of draft harmonised standards. The consultants deemed two-thirds of draft harmonised standards not to be fit for purpose due to non-compliance with EU law. Such a low percentage of positive assessments questions the claims that the European Standardisation System, as it stands today, is delivering. The corrective actions needed in case of a negative assessment unquestionably lead to delay, especially in the eventual presumption of conformity. We note that the European Commission and the ESOs have taken steps in this direction through a "high-level task force". Nevertheless, it is too soon to judge the results of the task force's work as its discussions ended only in July 2023.

The HAS consultant system may have a certain value in ensuring adequacy between standards and law, but the system is unfit to address today's challenges and is not in line with the principle of democratic scrutiny. Harmonised standards are used in a wide range of sectors with strong societal implications: eco-design, environmental protection, cybersecurity, health etc. It is not an easy task to ensure that the draft harmonised standards properly support the legislation that will rely on them for its implementation. In this respect, the role of the HAS consultants is pivotal.

We recommend replacing the current HAS system with a Standardisation Scrutiny Board within the European Commission. The Standardisation Scrutiny Board would be composed of a wide range of expertise, not only technical expertise but also legal expertise (including fundamental rights to ensure that those are not defined in the standard), as well as experience and knowledge from a broad range of fields: sociology, accessibility, gender studies, consumer and social issues etc. The diversity of profiles would ensure that harmonised standards adequately respond to societal needs, in line with the standardisation request and EU law.

The Standardisation Scrutiny Board should look not only at the content of the draft harmonised standards but also at the drafting process. More precisely, it should assess whether there was a balanced representation of interests in the making of the harmonised standards, including -but not only- if there was civil society participation. For instance, if a specific company had an excessive weight in the discussion, this could be a ground for issuing a negative assessment on a draft harmonised standard.

Additionally, the Standardisation Scrutiny Board should also take appeals within the ESOs against a standard into consideration. Such appeals can be made in the ESOs by Annex III organisations representing specific societal interests, ANEC in the case of consumers (see 3.2). The grounds for such appeals may contain valuable information on whether a proposed harmonised standard is fit for purpose.

The assessment of draft harmonised standards, including the specific grounds for positive or negative assessment, should be made public. Thus, the existing opaque system would be replaced with more transparency.

ANEC and BEUC recommendations:

- Revise Article 10 paragraph 5 of Regulation 1025/2012 to specify that a Standardisation Scrutiny Board shall assist the Commission in assessing the compliance of draft harmonised standards with the standardisation request and EU law.
- The Standardisation Scrutiny Board would replace the current HAS consultant system.

[27] REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on the implementation of the Regulation (EU) No 1025/2012 from 2016 to 2020, 2 February 2022. Extract: "Across all sectors, only 27,58% of the HAS assessments came out as positive, mainly due to inadequacy with EU law, showing that more work is to be invested in the development process of standards – e.g. within the technical committees – so that the work is more aligned with the policy and legal requirements."

- Add a new paragraph to Article 10 to specify that the assessment of draft harmonised standards by the Standardisation Scrutiny Board shall be made publicly available.

2.3. Final responsibility for compliance with EU law

Article 10 should clearly indicate that the final responsibility for compliance with EU law and the EU Charter of Fundamental Rights lies with the European Commission. This is the logical conclusion considering standards are part of EU law. It also better reflects the current situation, where *de facto* the European Commission already assumes this responsibility - with the support of the HAS consultants. However, such an important matter cannot merely be left to the interpretation of Regulation 1025/2012, it has to be stated in the Regulation itself.

ANEC and BEUC recommendations:

- Revise Article 10 paragraph 5 of Regulation 1025/2012 to clarify that the European Commission has the final responsibility for compliance of harmonised standards with EU law and the EU Charter of Fundamental Rights.

2.4. Public access to the text of harmonised standards

Standards, including harmonised standards, are copyrighted. The European Commission only publishes the references in the Official Journal of the EU, not the full text of the standards.

Concretely, this also means that the drafting process is subject to this strict copyright, apart from when the draft is at the public enquiry stage[28] but such access is often subject to a fee (see 3.1). Even if standardisation experts wished to consult civil society organisations during drafting, they could do so only by asking specific questions. They cannot circulate the draft deliverables for comments, even to very specific organisations. The copyright prevents this from happening, meaning that civil society organisations need to actively participate in the standardisation work to have access to the draft deliverables. In the following section (3), we will explain why such participation is often difficult. This situation is striking in the case of AI standards, which touch upon issues such as non-discrimination, transparency and societal risks.

Additionally, the copyrighting of standards can also make it harder for a civil society organisation, such as a consumer organisation, to unveil and prove evidence of wrongdoing. Access to the text of harmonised standards could enable a consumer organisation to notice that a product that benefited from the presumption of conformity is in fact non-compliant with the harmonised standard. This would mean that the product should not have been placed on the market. Likewise, this could facilitate the enforcement of EU legislation by market surveillance authorities. In the academic world, free access could allow researchers to study the content of harmonised standards and carry out independent research on products and systems.

In a nutshell, granting free access to the text of the harmonised standard could facilitate the crucial role of a wide range of actors in testing products and identifying flaws in the market. Above all, such copyright protection is a paradox if harmonised standards are indeed part of EU law. It is a well-established principle, since the time of Hammurabi,[29] that citizens must be able to consult the laws that govern them.

[28] Around 12 weeks for draft European standards.
[29] Hans-W. Micklitz, "The Role of Standards in Future EU Digital Policy Legislation – A Consumer Perspective", July 2023, study commissioned by ANEC and BEUC, page 164, and see https://en.wikipedia.org/wiki/Hammurabi.

Advocate General Medina's recent Opinion[30] goes in the very same direction in the case Public.Resource.Org and Right to Know v Commission and Others. The Advocate General explains that Harmonised Technical Standards (HTS) must be freely available without charge: "[F]or the purposes of EU law in general and of the access to EU law in particular, the fact remains that HTS form part of EU law and, given their indispensable role in the implementation of mandatory EU secondary legislation and their legal effects, they should, in principle, not benefit from copyright protection." The Court of Justice of the EU is expected to give a judgment in 2024.

This matter of accessibility to standards deserves an article in Regulation 1025/2012. Due to their special nature and role in the EU legal order, the texts of harmonised standards should be freely accessible.

Such free availability of harmonised standards will have an impact on the business model of National Standardisation Bodies. The latter rely indeed on the income from the sale of copyrighted standards for their day-to-day activities. It is for the European Commission and National Standardisation Bodies to find together a viable financial model, keeping in mind that National Standardisation Bodies do technical work that benefits the general public interest.

ANEC and BEUC recommendations:

- Establish in Regulation 1025/2012 that the texts of the adopted harmonised standards shall be freely accessible.

2.5. Participation of public authorities in the drafting of harmonised standards

During the past decades, growing competition for national resources has seen public authorities tend to disengage from standardisation activities, although standards are strongly connected to public interest goals (e.g., health, safety). Public authorities have relevant knowledge, including means of industry wrongdoing, from their market surveillance work. They have a lot to share on how to close loopholes in standards which disadvantage consumers.

Their participation in the making of harmonised standards could contribute to making EU law more enforceable, as they could provide input so that it is easier for market surveillance authorities to check compliance with legal requirements.

Thus, Member States shall not merely encourage the participation of public authorities, as mentioned in current Article 7, but public authorities - especially market surveillance authorities - shall mandatorily participate in the drafting of harmonised standards. We recommend revising Article 7 as follows:

- When harmonised standards are developed, national public authorities **shall participate** in corresponding national standardisation activities, including in national mirror committees.
- The European Commission **shall also participate** in the drafting of harmonised standards. The purpose here is to have Commission officials directly follow the discussions by attending the meetings of the technical bodies in charge of drafting the harmonised standard(s).

In the case of the AI Act and Cyber Resilience Act, we welcome the stronger involvement of the European Commission in standardisation activities. This should become the rule for all harmonised standards.

[30] Opinion of Advocate General Medina in Case T-185/19 *Public.Resource.Org*, ECLI:EU:T:2021:445, Appeal Case before the Court of Justice C-588/21, where Advocate General Medina concluded that harmonised standards must be freely available without charge because of their particular legal nature as acts that form part of EU law.

ANEC and BEUC recommendations:

- Revise Article 7 to make the involvement of national and European public authorities mandatory when harmonised standards are being developed or revised.

3. Reinforcing the presence and rights of societal stakeholders in standardisation

Due to the importance of harmonised standards for society, the place of civil society organisations in the European Standardisation System is instrumental. Such participation is key in all kinds of fields to bring another perspective to the table (e.g., consumer viewpoint, including vulnerable consumers) and additional or complementary expertise. Societal stakeholders can help increase the quality of the deliverables by ensuring that the needs of all consumers, workers and citizens are addressed adequately by the standard.

Regulation 1025/2012 contains a requirement of inclusiveness (Article 5):

> *"European standardisation organisation shall encourage and facilitate an appropriate representation and effective participation of all relevant stakeholders, including SMEs, consumer organisations and environmental and social stakeholders in their standardisation activities. They shall in particular encourage and facilitate such representation and participation through the European stakeholder organisations […]".*

Some European stakeholder organisations represent specific categories of interest and receive financing from the European Commission. They are known as "Annex III organisations" because the categories and conditions to be the representative European stakeholder organisation are laid down in Annex III to the Regulation. ANEC, which represents consumers in standardisation activities, is one of the four Annex III organisations.

Despite this requirement of inclusiveness, a strong majority of experts still come from the industry, and civil society actors have little influence in the process. Harmonised standards are no exception to the rule. Their drafting is first and foremost a discussion among businesses. The lack of civil society participation is due to a combination of factors: insufficient funding, barriers to entry, and lack of awareness.

Therefore, we recommend amending Regulation 1025/2012 to strengthen civil society participation at all levels: national, European and international.

3.1. Civil society participation at the national level: starting a virtuous circle

The national level plays an important role because of the national delegation principle. CEN and CENELEC, two of the three ESOs, are founded on this principle. The CEN members are National Standardisation Bodies (NSBs) while the CENELEC members are National (Electrotechnical) Committees (NCs). In many European countries, NSBs and NCs are the same entity. [31] An expert cannot directly take part in the drafting of standards at CEN and CENELEC. Experts need to be nominated by an NSB and contribute to the European standardisation work on its behalf. By contrast, companies and not-for-profit organisations can be direct members of ETSI. Nevertheless, in all three ESOs, the adoption of European Standards (EN's) is decided at the national level, by a weighted vote of the national members of CEN-CENELEC and the National Standards Organisations (NSOs) in ETSI. Since Regulation (EU) 2022/2480 entered into force on 9 July 2023, the decision on whether to

[31] For simplification purposes, the rest of the document will only refer to National Standardisation Bodies (NSBs).

adopt an EN responding to a Standardisation Request is limited to NSBs, NCs and NSOs in EEA countries.

ISO and IEC, two international standardisation bodies, are based on this national delegation principle too, just like CEN and CENELEC. This means that reinforcing civil society participation at the national level (within NSBs) can have a virtuous effect at both the European and international levels.

There is currently a very high degree of fragmentation in the way civil society participation is facilitated and supported across the European Union. The rights of civil society organisations to participate, and whether or not they have to pay to do so, vary considerably in the EU, as indeed does the level of political support at the national level. Participation in standardisation work is already very resource-intensive for these organisations; it is time-consuming and requires expertise in specific domains. Therefore, there should not be additional barriers to entry for civil society organisations, including no fees to pay to NSBs. Overall, barriers to civil society organisations to participate should be removed.

We therefore recommend creating a new article on the access of civil society organisations to NSBs. Civil society organisations should benefit from free participation in their activities. Member States and NSBs should explore innovative financing mechanisms whereby industry indirectly finances the participation of civil society organisations (e.g., through a common fund).

Additionally, each Member State should designate a specific consumer organisation as a national stakeholder organisation and provide adequate funding for its participation in the work of the NSB(s). These stakeholder organisations should be chosen after a national call for proposals.

Consumer participation - through the selected national stakeholder organisation - could take place within a consumer council or consumer network linked to the NSB. Such a system already exists in some countries and proves effective in enhancing the consumer voice in standardisation. For instance, in Germany, consumer organisations participate in the standardisation process at the national level through the DIN Consumer Council within the German NSB, DIN.

For other civil society organisations - which are not recognised stakeholder organisations - Member States should consider a targeted approach (e.g. where they provide funding to cover expenses to take part in the standardisation work). Such organisations should be non-governmental, non-profit-making and independent of industry, commercial, and business or other conflicting interests. This targeted approach could also be considered for academics, as they have the potential to bring a distinct but complementary viewpoint to the table.

In addition, inclusiveness should be facilitated at the national level during the public enquiry stage. Such public enquiry can take place for national, European or international standards. During the public enquiry, draft standards are publicly available, and any interested parties should have the opportunity to send comments to an NSB. NSBs should then take these comments into account when forming their position on the draft standard.

However, current practices at the national level show that public enquiry is not always "public". The opportunity to comment on drafts is not necessarily publicised to the general public in a visible way and some NSBs require interested parties to pay a fee to access the text of the draft standard. There is a need to harmonise the public enquiry practices across countries, at least for draft harmonised standards. As a general rule, NSBs should publicise the opening of a public enquiry (e.g., website, newsletter etc.), including by specifying the topics that the draft standard tackles. Access to the draft standard should then be free of charge and NSBs should make it as straightforward as possible for any interested parties to comment on the draft standard. Finally, a good practice consists of inviting the

commenters to the national meetings where such comments are going to be resolved. Thus, commenters, including civil society stakeholders, can defend their views.

Additionally, the European Commission itself should contribute to making draft harmonised standards under public enquiry more visible. For instance, it should publish those draft harmonised standards on its "Have your say" (Better Regulation) portal and invite interested parties to comment via an NSB.

ANEC and BEUC recommendations:

- Create a new article on the access of civil society to national standardisation, including introducing the principle of free access to standardisation activities.
- Create an obligation for Member States to designate national stakeholder organisations and provide them with sufficient funding.
- For consumer representation, consider broadening the system of Consumer Councils/Committees across Europe.
- Introduce in the new article an obligation for NSBs to: 1) publicise on their websites and other relevant communication channels draft standards that are at the public enquiry stage; and 2) grant access to those draft standards free of charge and allow any interested parties to comment. As a best practice, NSBs should invite commenters to the meeting where their comments will be considered so that they have an opportunity to defend them.

3.2. European level: consolidating the status of stakeholder organisations

At the European level, the status of stakeholder organisations (Annex III organisations) has been instrumental in carrying the voice of societal interests. For instance, ANEC has been leading the work on the revision of the harmonised standards[32] that cover the safety of electrical household appliances (toasters, vacuum cleaners etc.) ANEC's contribution to this work has been essential in establishing harmonised standards that foresee the safe use of electrical household appliances by children, older people and persons with disabilities, and affect millions of appliances sold in Europe annually.

Stakeholder organisations (Annex III organisations) have direct access to the work of CEN and CENELEC, they do not need to be nominated by an NSB. The reasoning behind this direct access is that civil society organisations were so under-represented in the process (including at the national level) that specific societal interests needed to be represented directly at the European level.

This line of reasoning is particularly relevant in the digital sector where skills are scarcer. Companies are competing for talent, and civil society organisations - often with far fewer resources - struggle to find the right expertise to be represented in standardisation initiatives. One example is AI, where it proves difficult for a civil organisation to find individuals: 1) with AI expertise; 2) willing to represent the civil society perspective; and 3) with knowledge of standardisation. These experts exist but they are few and far between and, therefore, it is logical for civil society organisations to pool this expertise at the European level instead of trying to create or find it in every country. This is why the status of European stakeholder organisations is more relevant than ever.

However, the current status of European stakeholder organisations provides limited rights to stakeholder organisations, meaning that their voices are often ignored. Additionally, the funding they receive is insufficient to:

- Cover all topics that are relevant to their constituencies.

[32] The EN 60335 series.

- Hire enough qualified experts, especially in digital domains where there is competition to find those skills.
- Contribute to the work not only at the European level but also international level, especially as many European standards are direct adoptions of international standards (see 2.1).

The status of stakeholder organisations (Annex III organisations) needs to be strengthened to ensure that they can make their voice heard.

A first step in this direction would be to name them explicitly as permanent "designated beneficiaries" in Annex III to Regulation 1025/2012, hence providing them with stability. In the current system, Annex I to Regulation 1025/2012 names the ESOs explicitly. The Annex III organisations are mentioned collectively as designated beneficiaries in Regulation (EU) 2021/690[33], which implements the Single Market Programme 2021-2027, but it remains unclear whether this recognition will continue automatically into the next Programme. There is no such doubt in the case of the ESOs.

Secondly, we recommend expanding stakeholder organisations' rights within the ESOs. An amendment to Regulation 1025/2012 should create a list of rights in Article 5. European stakeholder organisations shall be entitled to:

- Unimpeded and free access to standardisation activities
- Free access to all draft standards
- The ability to chair any technical body
- Discuss and comment on proposals of their choice
- A formalised right of opinion (as used in CEN-CENELEC)
- Have the right of appeal against the development or drafting of any European Standard or European standardisation deliverable at any stage
- Have the right of appeal against adoption as a European Standard or European standardisation deliverable of a standard originating elsewhere
- A right to be consulted when the European Parliament and Member States raise an objection against a harmonised standard pursuant to Article 11

Thirdly, European stakeholder organisations need adequate funding to support their work, especially in fields relating to new technologies. With such funding, European stakeholder organisations can hire specific expertise in those fields. European stakeholder organisations also need to be able to increase the frequency of the standardisation meetings they can attend, which also takes up more resources.

In the case of the AI Act, the Joint Technical Committee 21 of CEN-CENELEC is in charge of drafting the standards. Five working groups have been established, each of which involves sub-groups (task groups) dedicated to specific work items. In practice, there can be a couple of meetings per week for each working group. On top of this, experts must read and comment on the standardisation work, which represents additional hours spent every week. An organisation would easily need three full-time AI experts[34] to follow the drafting of standards only for the AI Act. And this is only one EU legislative text among the many fields relevant to consumers. This example illustrates the increased needs in terms of funding and expertise.

Thus, we recommend introducing a new paragraph in Article 16 of Regulation 1025/2012 to state that the European Commission shall ensure an adequate level of funding so that

[33] Regulation (EU) 2021/690 of the European Parliament and of the Council of 28 April 2021 establishing a programme for the internal market, competitiveness of enterprises, including small and medium-sized enterprises, the area of plants, animals, food and feed, and European statistics (Single Market Programme).
[34] ANEC's estimates based on the number of working groups, task groups and meetings.

civil society organisations can effectively fulfil their role and function in the elaboration of harmonised standards, especially in light of the scope and depth of the Annual Union Work Programme for European standardisation.

Additionally, an amended Regulation 1025/2012 should establish the involvement of European stakeholder organisations (Annex III organisations) in the assessment of draft harmonised standards, alongside ESOs and the European Commission -the latter being supported by the Standardisation Scrutiny Board. Annex III organisations have often closely followed the discussions that led to the draft harmonised standard. Thus, they are very well-placed to spot any misalignment with the standardisation request or EU legislation. Furthermore, the involvement of societal stakeholders in the assessment of draft harmonised standards would help restore the deficits faced by Annex III organisations when international standards are adopted as harmonised European standards. As explained in the following section, civil society participation at the international level is even scarcer, despite many harmonised standards being drafted by ISO or IEC. Annex III organisations should have a say before such an international standard is officially turned into a harmonised standard, thus making up for their absence in the drafting process.

Consequently, paragraph 5 of Article 10 should be amended as follows: "[…] The Commission together with the European standardisation organisations **and European stakeholder organisations** shall assess the compliance of the documents drafted by the European standardisation organisations with its initial request." The next sentence would specify that the Standardisation Scrutiny Board shall support the European Commission in carrying out this task (see 2.2).

Besides Annex III organisations, other civil society entities could bring valuable input to the drafting of a harmonised standard but currently cannot have direct access to the technical work at the European level. This is the case, for instance, if an organisation does not have a network of members and hence cannot qualify for the liaison partner status to contribute to the work at CEN and CENELEC. Such civil society organisations would have to take part in the work at the national level but as mentioned earlier, there are obstacles to participation and their voice is likely to be diluted. The downside to this situation is that standardisation bodies are missing out on the technical and legal expertise that such organisations could bring to the drafting of harmonised standards.

The list of such entities can be endless, depending on the harmonised standard at stake. Thus, we recommend adopting a targeted approach, whereby the European Commission would undertake a mapping of the respective civil society organisations with expertise in the field of the standard and explicitly list in the standardisation request the civil society organisations that should have direct and free access to the work on the harmonised standard. The European Commission should consult these organisations on its intent to include them in the future standardisation request and on the content of the standardisation request. Article 10 should be revised to cater for this possibility.

Article 10 should also set out the conditions that these organisations should fulfil. First, they should be non-governmental, non-profit-making and independent of industry, commercial, and business or other conflicting interests. These organisations could be identified from the EU Transparency Register. Secondly, if they agree to be listed in the standardisation request, those organisations should actively contribute to the standardisation work (attending meetings, drafting comments etc.)

ANEC and BEUC recommendations:

- Name the European stakeholder organisations (Annex III organisations) as "designated beneficiaries" in Regulation 1025/2012.
- Strengthen European stakeholder organisations' rights in Article 5.
- Revise Article 16 to establish that the European Commission shall ensure an adequate level of funding to European stakeholder organisations especially in light

of the scope and depth of the Annual Union Work Programme for European Standardisation.

- Revise Article 10 to specify that Annex III organisations should be involved in the assessment of the compliance of draft harmonised standards with the standardisation request.
- Create in Article 10 the possibility for the European Commission to list in a standardisation request the civil society organisations that should have direct and free access to the drafting of harmonised standards on condition that they participate actively.

3.3. Closing the civil society gap at the international level

An amendment of Regulation 1025/2012 needs to address the international level too because of its contribution to the European Standardisation System. As explained above (2.1), international standards are very often identically transposed into European standards.

The problem is that civil society participation is even scarcer at the international level which is not subject to a principle of inclusiveness (no equivalent to Article 5). Efforts to strengthen civil society participation at the national or European levels will not fully deliver unless the Vienna and Frankfurt Agreements are tackled at the same time.

We recommend introducing in Regulation 1025/2012 the possibility for the European Commission to set conditions in the standardisation request under which ISO or IEC lead can be used. The main purpose of this should be to ensure the participation of Annex III organisations at the international level. When Work Items are developed in ISO/IEC, the inclusion of Annex III organisations at the international level should be automatic.

Additionally, Annex III organisations should have the right to access the text of ISO/IEC standards on which harmonised European standards are to be based. In the current system, Annex III organisations often cannot comment on the suitability of an international standard to be turned into a harmonised standard simply because they do not have access to the text of the international standard.

To this effect, Regulation 1025/2012 should contain a new article dedicated to the interaction between the European Standardisation System and international standardisation with a particular focus on the participation of Annex III organisations.

ANEC and BEUC recommendations:

- Include in Regulation 1025/2012 requirements regarding the conditions under which ISO or IEC lead can be used, in particular the inclusion of European stakeholder organisations (Annex III organisations) when Work Items are developed at the international level.

3.4. The final touches to balanced representation

Finally, we recommend complementing the "Standardisation Governance Act" (amending Regulation 1025/2012) with additional measures to foster a balanced representation.

First, there is a need for more transparency on the ongoing standardisation work. There needs to be harmonisation of the basic information that standardisation bodies present on their web pages. Everyone should be able to find easily, and in an accessible format:

- The list of technical committees and working groups, or other relevant technical bodies
- For each working group, the titles of the ongoing work items with a short summary of the topic and the status of the work

- The contact details of the staff in charge of the technical body in case anyone wishes to have more information or join the work
- Names of organisations, including companies, that take part in the activities of the national mirror committee.

Secondly, another topic to explore is translation, including automatic translation of technical work. One additional barrier to civil society participation, even at the national level, is the language of the documents (English in most cases). This means that experts who want to take part in the work in NSBs still need a high level of English because it is the language in which most documents are drafted. The intelligent translation of documents could further foster the participation of a broader range of profiles.

ANEC and BEUC recommendations:

- Revise Article 3 of Regulation 1025/2012 to further harmonise the information publicly available on the standardisation bodies and their work.
- Explore translation as a way to engage more technical experts, especially at the national level.

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