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Anonymous

Only organisation details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published as received. Your name will not be published. Please do not include any personal data in the contribution itself if you want to remain anonymous.

Public

Organisation details and respondent details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published. Your name will also be published.

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D Involvement in standardisation

17 How familiar are you with the European Standardisation System (ESS) and standardisation practices in general?

Maximum 1 selection(s)

- No or limited knowledge
- Moderate knowledge
- Expert knowledge

18 What is your involvement in European standardisation?

Select all that apply

- My organisation uses harmonised standards
- My organisation uses other types of European standardisation deliverables
- I participate in technical work on standardisation
- I represent the interests of organisations involved in standardisation
- My organisation is active in education and/or research relating to standardisation
- Other

22 In your organisation, what is the estimated yearly number of full-time equivalent (FTE) staff participating in standardisation activities?

3

23 How much of your organisation's yearly budget is invested to participate in standardisation activities?

Please provide an estimate in monetary terms (preferably in EUR).

0.8

25 In how many standardisation projects (e.g. working groups or technical committees) are you involved in simultaneously?

- 1
- 2-4
- 5-10
- 11+

26 What are the main reasons you or your organisation participate in standardisation work?

We are a non-profit with the mission is to help accelerate the writing of AI safety standards. (Standards seen in a broad sense, it also includes Codes and Guidelines)

27 Do you or your organisation receive EU funding to participate in standardisation activities?

- Yes
- No
- Don't know

28 Does your organisation want to play a more active role in the European standardisation system?

- Yes, my organisation thinks that it can benefit from participating more actively in European standardisation.
- No, my organisation does not think this is necessary.
- Don't know

30 Do you consider investment in standardisation (via direct participation and/or financial support) by the following actors to be sufficient?

	More than Sufficient	Sufficient	Insufficient	Don't know
Member States	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
European Commission	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Industry	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Academia & research & technology organisations (RTOs)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Civil society	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

31 In your opinion, in which of these areas has the Standardisation Regulation been effective in its contributions?

You can select multiple choices

- Supporting a fast delivery of harmonised standards.
- Supporting a fast delivery of European standards.
- Supporting a fast delivery of other standardisation deliverables
- Guaranteeing that standards are easily available and accessible.
- Ensuring a balanced stakeholder participation in the development of European standards.
-

Supporting the EU's role as a global standard-setter.

- Contributing to the international competitiveness of EU businesses.
- Other

E Speed and responsiveness to innovation

The results of the evaluation of the Standardisation Regulation highlight slow, complex processes, delays due to lengthy quality assessments, limited digitisation, and insufficient flexibility in finding alternatives when (harmonised) standards are not available in a timely manner.

The Commission aims to make the standardisation process faster and more flexible. In this section, we invite you to share your experience with the speed of delivering harmonised standards and suggest the most effective ways to improve it.

33 Have you experienced situations where harmonised standards were unavailable or delayed in their availability?

- Yes
- No
- Don't know

34 Have you encountered situations where other European standards or standardisation deliverables were unavailable or delayed?

- Yes
- No
- Don't know

35 How often have you experienced the unavailability or delayed availability of harmonised standards? How did your organisation adapt to these challenges? Please share specific examples, including in terms of quantifiable financial costs on your organisation.

Once: delays in availability of harmonised (JTC21) standards for AI Act.

We have adapted by spending more time and resources on helping to write the JTC21 standards than originally budgeted.

36 How often have you experienced the unavailability or delayed availability of other European standards or standardisation deliverables? How did your organisation

adapt to these situations? Please share specific examples, including in terms of quantifiable financial costs on your organisation.

Once: delays in availability of supporting JTC21 standards for AI Act. These non-harmonised standards projects are getting delayed in JTC21, and in general lack resources to complete, because of priorities in finishing the harmonised standards.

37 Please share your views on the following approaches to improve speed and flexibility of standardisation processes.

	Level of agreement	Expected benefits for me /my organisation	Expected costs for me /my organisation
There should be stronger mechanisms, such as mandatory deadlines paired with penalties, to enforce timely delivery of requested (harmonised) standards.	Strongly agree	Very high	Very low
There should be more flexibility in the way (harmonised) standards are developed and delivered, including dedicated and simplified formats and procedures for (harmonised) standards requested to support EU law; use of alternative types of standardisation deliverables instead of standards; recourse to other standardisation bodies; open calls procedures for obtaining standards.	Strongly agree	Very high	Low
There should be fast-track procedures to develop and deliver priority standards.	Strongly agree	High	Low
The Commission's procedures for the request, evaluation and citation of (harmonised) standards should be simplified.	Somewhat disagree	Low	Very low
When standards or other standardisation deliverables are requested by the Commission, there should be strict, transparent and enforceable deadlines to be followed.	Somewhat disagree	Moderate	Low
Simplified procedures and consolidation of texts by default should be applied when existing standards are amended.	Strongly disagree	Low	Moderate
The procedures for drafting or editing a standard should be fully digitised. For example, information exchange during the drafting process should only take place in a digital format.	Strongly disagree	Moderate	Low
There should be more and earlier involvement from Commission experts throughout the standardisation process to ensure that draft standards meet all legal requirements.	Strongly agree	High	Low
There should be better use of existing standards developed outside the European Standardisation System, provided they are appropriately adapted to meet essential requirements and subject to a set of criteria (e.g. inclusiveness, transparency).	Somewhat agree	Moderate	Low

<p>When using standards from recognised international standardisation bodies such as ISO, IEC and ITU, there should be a faster adaptation, adoption and take-up in the EU system.</p>	<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Very low	<input type="checkbox"/> Low
<p>The Commission should have the option to request the development of new standards by actors beyond the existing European Standardisation Organisations, provided that they work in an inclusive manner with balanced participation of relevant European stakeholders.</p>	<input type="checkbox"/> Strongly agree	<input type="checkbox"/> Very high	<input type="checkbox"/> Low
<p>All (harmonised) standards should follow the same strict template and format to improve readability (including machine-readability) and understanding of its main components.</p>	<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Very low	<input type="checkbox"/> High

38

What measures could be implemented when there are no harmonised standards or when such standards are delayed or unavailable at the time of applicability of the legislation they are supporting? For example: common specifications, interim solutions, use of previous standards.

Common specifications, codes of practice, or guidance documents can be written to fill the gap.

The delaying of the entry into force of the corresponding legislation is also a measure that can be considered, but we prefer more refined approaches, e.g. where the entry into force of obligations to provide information to the regulator is not delayed, but where a grace period is created where the regulator will not yet impose fines.

The EU could also start specific projects (via normal innovation subsidies, or via special channels) to encourage parties or consortia to write and publish technical information (e.g. documents defining metrics, quality criteria, safety criteria, or state of the art practices) or voluntary consortium-written standards related to the legislation, information that could be usefully pointed to by the regulator, in order to inform parties affected by the legislation.

39

What measures could be implemented when there are no other European standards or when such standards are delayed or unavailable at the time of applicability of the legislation they are supporting? For example: use of implementing acts, interim solutions, use of previous standards.

Non-harmonised European standards cannot offer a presumption of conformity, so the lack of timely availability of such documents is less of an issue.

Common specifications, codes of practice, or guidance documents can be written to fill the gap.

The EU could also start specific projects (via normal innovation subsidies, or via special channels) to encourage parties or consortia to write and publish technical information (e.g. documents defining metrics, quality criteria, safety criteria, or state of the art practices) or voluntary consortium-written standards related to the legislation, information that could be usefully pointed to by the regulator, in order to inform parties affected by the legislation.

40 Please share your views on the following approaches related to the role of the European Standardisation Organisation (ESOs).

	Agreement	Expected benefits for me /my organisation	Expected costs for me /my organisation
The list of European Standardisation Organisations in Annex I of the Regulation should be reviewed regularly to verify if the ESOs still fulfil the conditions to have this status, and/or to add new ESOs.	Strongly agree	High	Low
There should be a set of clear criteria that standardisation organisations must meet to be recognised as an ESO.	Strongly agree	Very high	Low
The standardisation framework should be opened to allow other organisations or consortia to respond to specific standardisation requests alongside the recognised ESOs, provided they meet a set of pre-defined criteria, such as inclusiveness, ensuring the quality of their work.	Strongly agree	High	Low

41 What other measures do you propose to improve speed and responsiveness to innovation of the development of European standards?

Main recommendation: The recent Evaluation of Regulation (EU) 1025/2012 mentioned at the top of this survey considers two approaches: either creating more incentives for CEN and CENELEC, or extending the list of standards organisations that can be given a standards request. We strongly encourage the latter approach for any Standards Request related to digital or green legislation.

We recommend that Standards Requests are given to new organisation(s), which are specifically new and different by using a new and different standards writing process, one that is better tailored to fulfilling standards requests in a speedy and inclusive way. We propose specific details for this new process in the document attached to this contribution. Our proposed process significantly departs from the basic structure of the CEN and CENELEC process, and therefore also from that of the ISO/IEC process that it largely copies.

As an alternative measure to creating and relying on entirely new organisations, it would also be possible for the new legislation to require that, when new harmonised standard(s) to support new legislation in these fields, the EC simply starts a special-purpose project using the new process we propose. The recent project to develop GPAI Codes of Practice for the EU AI Act is an example of how this approach can be successful.

The updating of existing harmonised standards has also been a problem, where CEN-CENELEC stakeholders have refused (with a majority vote against such a proposal) to start projects to update or amend existing harmonised standards that contained out of date information. We recommend that a mechanism is created so that, if such a majority vote against updating a standard cited in the Official Journal of the EU, happens, in CEN-CENELEC or ISO/IEC or another standards organisation, it becomes possible and legitimate to assign the work to update the standard to another organisation or project, operating under different process rules.

The main driver of the above recommendation to develop harmonised standards outside of CEN-CENELEC is our negative assessment of the capacity for change that the standards system ecosystem nominally led by these two organisations has. We see a clear lack of capacity for meaningful change no matter how many positive incentives (e.g. deadlines with penalties) or positive incentives (e.g. more funding for these organisations and for stakeholder participation) were to be applied. The barriers to change are not only located inside CEN and CENELEC, their business models, organisational structures, and organisational cultures: they are equally present in the business models and the organisational cultures of the participating National Bodies, and in the way (mostly copied from ISO/IEC processes and ISO/IEC organisational culture) in which their standards writing is organised.

This assessment is based not only on public facts, but also based on many events we have seen happening close-up inside the standards process, events that we cannot share here because of the confidentiality of the process. Working on standards for the EU AI Act inside JTC21, we have seen many events that have been detrimental to timeliness, quality, and inclusiveness. We have seen an organisational culture that has utterly lacked the ability to attract and retain the volunteer expertise and manpower needed to do the actual standards writing, to run the complex bureaucratic processes required by the rules, and to create an organisational environment where the stakeholders present trust and understand each other well enough to be able to productively work together, and come to a well-informed and well-reasoned technical consensus.

The CEN-CENELEC and ISO-IEC standards writing models can work great for industries where all incumbents actually embrace the idea that their field should be regulated more, or where all incumbents embrace the idea of jointly transitioning the market towards products that are safer or greener in some way. These conditions do not apply in digital and green spaces. For example, when it comes to the EU AI Act it is well known that there are stakeholders who would rather not be regulated at all, as well as stakeholders who would not mind at all to

see a delay in enforcement of the EU AI Act because the standards will be late.

When the pre-condition that regulatory initiatives are broadly embraced by all stakeholders does not apply, and it does not apply in the digital and green spaces, we recommend assigning the standards request to a different organisation or a special purpose project, one that will explicitly admit that it operates under rules which are different than used in CEN-CENELEC or ISO/IEC.

F Inclusiveness of the standardisation process

Regarding achieving a balanced stakeholder participation in standardisation work, several barriers remain, in particular the lack of financial support and incentives for EU SMEs, startups, civil society and academia. Some organisations may lack the awareness, skills and resources to participate effectively, and are therefore underrepresented in the standardisation process. This is particularly acute in complex technical domains where working with standards requires scarce specialist knowledge.

In this section, we ask you to assess which measures you deem most relevant to improve an inclusive stakeholders' participation.

42 To what extent do you agree that standardisation activities are conducted in an inclusive manner, with balanced participation of all relevant stakeholders?

	Response
At national level, managed by national standardisation bodies.	Somewhat disagree
At European level, managed by European standardisation organisations:	Somewhat disagree
At international level, managed by international standardisation bodies:	Somewhat disagree

43 How familiar are you with current or planned standardisation projects concerning European standards or other European standardisation deliverables that affect your organisation?

(e.g. the launch of a new working group)

- Fully aware
- Partly aware
- Neutral
- Partly unaware
- Fully unaware
- Don't know

44 Please share your views on the following potential measures to improve inclusiveness and stakeholder participation.

Proposed measure	Level of agreement	Expected benefit for me /my organisation
Measures such as financial support or free access are needed to better support participation of experts representing SMEs in technical committees.	Strongly agree	High
Measures such as financial support or free access are needed to better support participation of experts representing civil society in technical committees.	Strongly agree	High
Increased capacity building available for European experts interested in participating in standardisation activities. This could include training courses on how to participate in standardisation work or awareness building on financing opportunities.	Somewhat agree	High
Increased transparency regarding the stakeholders involved in technical committees and working groups developing (harmonised) standards.	Strongly agree	Moderate
An obligation on ESOs and NSBs to ensure a minimum share of specific stakeholder interest in standardisation bodies and technical committees co-financed by the EU. For example, this could include a minimum share of SME representatives and balanced voting rights.	Strongly agree	Moderate
Voting rights for SMEs, consumers and other societal stakeholders (Annex III) in the standardisation process.	Strongly agree	Moderate
Accessible, simplified guidance to SMEs and other stakeholders to help new entrants find, understand and engage with standards. This could include tools like an AI-based standardisation assistant or a dedicated FAQ page.	Strongly agree	Moderate

45 What additional measures would you propose to improve inclusiveness and ensure balanced participation in standardisation?

The complexity and labor-intensive nature of the CEN-CENELEC standards process, as it exists on paper and as it is run in practice, stand in the way of better inclusiveness and balanced representation. In the document attached to this contribution, we propose a better process.

Many industry stakeholders inside and outside of the EU have gambled that, if they do not volunteer to add manpower and field-specific expertise to the CEN-CENELEC JTC21 standards writing process in support of the AI Act, these standards will be late and they can then lobby the legislator to delay enforcement of the AI Act. This gambling strategy has in fact been paying off for them and this is not the first harmonised standards writing process where such a strategy has paid off for stakeholders.

Unless something is very visibly done to change the likely success of this strategy going forward, standards writing will continue to suffer from a lack of participation. See our attached proposal for what could be visibly done in terms of the standards process.

G Access to standards

Case law confirms that harmonised standards are part of EU law, and that the principles of transparency and accessibility apply. Requirements in the current framework to encourage and facilitate access to standards have proven insufficient. Ensuring accessibility – especially for citizens, public authorities and SMEs – is therefore a matter of legal compliance and fair competition.

In this section, we ask you to share your views on how to improve access to harmonised standards.

46 To what extent do you agree with the following statements concerning your experience with access to harmonised standards?

	Response
It is difficult to identify the legally relevant content of a harmonised standard which is needed for presumption of conformity. <i>Legally relevant content is the specific content from the standard that provides the technical details on how the legal requirements of EU legislation can be implemented.</i>	Neutral
Harmonised standards are too long and complex.	Strongly disagree
It is easy to find which harmonised standard(s) best fit to my/my organisation's needs.	Somewhat agree
Harmonised standards sufficiently reflect the state of the art.	Neutral
Having more options of standards to choose from would be beneficial.	Strongly disagree

47 Please share your views on the following statements related to potential measures to improve access to standards.

Potential measures	Level of agreement	Expected benefits for me /my organisation	Expected costs for me /my organisation
The legally relevant content of standards should be published and freely accessible by default.	Strongly agree	Very high	Very low
Free access to a simplified summary of a standard's content would be useful.	Somewhat agree	Moderate	Very low
Accessing only the legally relevant content of harmonised standards in the OJEU is sufficient for my work.	Strongly disagree	Low	Moderate
Access to standards supporting EU law in one's own language is important.	Somewhat disagree	Low	Very low

H EU's role in global standard-setting

While the EU has traditionally had a strong footprint in international standardisation activities, other countries and regions have become increasingly assertive and are using standards to give their industries a competitive advantage. In this section, we want you to share which measures you deem most relevant to strengthen the EU's role in global standard-setting.

48 To what extent do you agree that, in your field of expertise, the EU has a strong influence on standardisation internationally?

- Strongly agree
- Somewhat agree
- Neutral
- Somewhat disagree
- Strongly disagree
- Don't know

49 Please indicate your thoughts on the following potential measures to strengthening the EU's role in international and global standard-setting.

Potential measure	Level of agreement	Expected benefits for me /my organisation	Expected costs for me /my organisation
Measures such as financial support and capacity building are needed to improve participation of experts representing SMEs or civil society from the EU in technical committees at the international level.	Somewhat agree	Low	Very low
The EU should introduce a systematic monitoring action on new and on-going international standardisation activities and an intervention system to better protect EU values in international standardisation when needed.	Somewhat agree	Moderate	Very low
The EU should prioritise financial support and other types of incentives to European stakeholders active in developing standards in emerging technologies.	Somewhat agree	Moderate	Very low
There should be measures to increase cooperation and coordination between European stakeholders in international standards organisations.	Strongly agree	Moderate	Very low
The EU should build structural alliances with like-minded partners at the international level to amplify its values and strategic goals.	Somewhat agree	Moderate	Low

50 What aspects should be evaluated when considering the legislative use of international standards at EU level? (several options)

- None, international standards should be taken up in support of EU legislation whenever possible
- Alignment with EU values, notably its Charter of Fundamental Rights
- Impact on international competitiveness of EU companies
- Compatibility with EU policy objectives, including strategic autonomy, health, safety and performance requirements, green and digital transition
- Inclusiveness of the development process of the international standard
- Reflecting the recognised technological and legal state of the art in the EU
- Other

52 What other measures do you propose to strengthen the EU's influence in international and global standardisation?

53 Do you think the Commission or another EU entity should be more or less involved in the following activities when carried out at international level?

	Response
Prioritisation of key standardisation projects	No Change
Support for pre-normative research	More
Assessment of proposed harmonised standards	More
Coordination of EU participation in international standardisation	No change
Collaboration with international partners on standardisation	More
Promotion of skills and education in standardisation	More
Active and direct participation in standardisation activities	No change

I Final Remarks

54

You have reached the end of this questionnaire. If, in your opinion, specific points have not been sufficiently covered or were even left out, please provide any further comments or additional information here:

For the first sub-question of Q37 'There should be stronger mechanisms, such as mandatory deadlines paired with penalties, to enforce timely delivery of requested (harmonised) standards.': while we agree stronger mechanisms are needed, we also believe that it would be inappropriate to pressure CEN-CENELEC standardisation project officers (who are typically non-remunerated volunteers) by creating fines for projects missing deadlines, because this would be pressuring CEN-CENELEC to disregard the quality and inclusiveness safeguards in its working group process, safeguards that prioritize unanimity or consensus over speed. See e.g. CEN internal regulations part 2, section 11.2.1.6 where it is defined that 'every effort shall be made to reach a unanimous agreement on the drafts for submission', where this 'every effort' definitely includes having a longer discussion if there is still a chance that stakeholders can converge based on longer discussion.

Applying pressure to CEN-CENELEC officers to violate well-defined rules and well-established interpretations of such rules (well-established interpretations shared with ISO/IEC) is entirely inappropriate, and has (in the case of JTC21) already been corrosive to the legitimacy of both CEN-CENELEC and the EC.

If the legislator desires hard deadlines to be upheld, then the appropriate action is to assign the standardisation request with a hard deadline to an organisation or project that is operating under different rules, rules create more options for handling a lack of agreement, and for handling situations where there is no time for a fully inclusive discussion of all issues with all stakeholders. See the attachment for a proposal for such a process.

55 Would you be interested in participating in a targeted consultation?

- Yes
- No

56 If you would be willing to be contacted for a targeted consultation, please leave your email address below:

koen@holtmansystemsresearch.nl

57 You may upload any additional documents (e.g. position papers) to support your contribution to this consultation.

Please note that any uploaded material will be published alongside your response to the questionnaire which is the essential input to this public consultation. The document is an optional complement and serves as additional background reading to better understand your position.

Only files of the type pdf,txt,doc,docx,odt,rtf are allowed

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