

Reply by the European Commission to the inquiry from the European Ombudsman regarding how the European Commission ensures transparency and accountability in the adoption of harmonised standards related to artificial intelligence in the context of the AI Act.

Complaint ref. 2025/1974/MIK

I. BACKGROUND/SUMMARY OF THE FACTS/HISTORY

The present inquiry follows a complaint against the European Commission from Corporate Europe Observatory (hereafter ‘the complainant’), a civil society organisation concerned with the transparency and inclusiveness of the process related to the adoption of harmonised standards for the artificial intelligence Act (AI Act), with whom the Commission has already been in contact in the past.

On 19 December 2024, as the complainant was finalising a report on the AI standardisation process, the Commission was asked to provide written input on several questions. On 8 January 2025, the Commission provided a reply which was directly attached by the complainant in their online publication. On 15 January 2025, at the request of the complainant, the Commission met with two of their representatives to continue the discussion around the AI standardisation process, and answer remaining questions, in particular on the transparency rules that apply to the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC) and the diversity of experts profiles in the Joint Technical Committee 21 (JTC 21), the committee in charge of developing harmonised standards for the AI Act.

On 12 May 2025, the complainant sent to the Commission a research paper they had commissioned from an external lawyer, arguing that the standardisation process must follow rule of law principles from the Treaty of the European Union (TEU) and the Charter, especially transparency and participatory rights. The same day, the complainant requested access to documents pursuant to Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (hereafter ‘Regulation (EC) No 1049/2001’)¹. The complainant requested access to the affiliation of experts participating in CEN/CENELEC/JTC21 as well as the agendas and minutes of meetings of CEN/CENELEC/JTC21 Working Group 2. In its reply of 28 August 2025, the Commission services responded that “*DG CONNECT does not receive agendas and minutes directly and does not have access to or hold documents that indicate the affiliation of the experts*”². The complainant was informed that, in accordance with Article 7(2) of Regulation (EC) No 1049/2001, it was entitled to make a confirmatory application requesting the Commission to review this position. No confirmatory application was received by the Commission.

II. THE COMPLAINT TO THE EUROPEAN OMBUDSMAN

¹ See [Ares\(2025\)3812438](#)

² See EASE 2025/2608, [Ares\(2025\)6997268](#)

In their complaint to the European Ombudsman, the complainant claims that “*the European Commission does not comply with the rule of law principles including transparency, openness, and accountability when developing harmonised standards*” for the AI Act. The complainant argues that:

- following the *James Elliott Construction* ruling, harmonised standards are considered part of EU law and therefore should be subject to the rule of law principles;
- following the *Public.Resources.Org* case, “*both principles - openness and transparency – must apply to harmonised standards*”.
- “*the fact that the Commission oversees and plays a central role in the process means that the Commission has a duty to ensure that the process complies with the rule of law and democracy*”
- “*there is a clear overriding public interest in knowing the affiliations of the experts involved in drafting rules that have legal effect in the EU and will have an impact on fundamental rights*”
- “*AI standard-setting remains heavily unbalanced and dominated by a few large companies*”

The complainant concludes that “*the Commission should introduce transparency and balanced composition rules similar to those governing expert groups*”. According to the complainant, this entails that:

- “*the Commission should make public the affiliation of experts involved in developing harmonised standards;*
- *the Commission should ensure that consultants publicly declare their interests and disclose the clients they are representing;*
- *the minutes and working documents of joint technical committees and working groups should be made public;*
- *[...] the Commission should further improve the balanced representation of societal interests in standard-setting.”*

In its complaint, the complainant informed the Ombudsman of its email exchanges with the Commission. The complainant did not mention that they had an in-person meeting with Commission representatives after receiving the Commission’s written input, nor that the complainant, before filing the complaint, had submitted a request for access to documents.

III. EUROPEAN OMBUDSMAN’S INQUIRY

The European Ombudsman decided to open an inquiry concerning how the European Commission ensures transparency, inclusiveness, and accountability in the adoption of harmonised standards for artificial intelligence.

In its letter to the President of the European Commission, the European Ombudsman acknowledges the reply from the European Commission to the complainant but considers that the reply “*has not yet fully addressed all the issues raised*”. In particular, the European Ombudsman notes that the responsibility of the European Commission in the standardisation process should be put in perspective with recent case law.

As part of its investigation, the Ombudsman asked detailed questions to the Commission about (a) the Commission’s role in reviewing the process of developing harmonised standards on AI and its outcomes, (b) the transparency of the process, and (c) the inclusiveness of the standardisation process.

IV. THE REPLY OF THE EUROPEAN COMMISSION

Harmonised standards are European standards developed by recognised European Standardisation Organisation (hereafter ‘the ESOs’): CEN, CENELEC and ETSI. They are developed following a standardisation request from the European Commission to one or several ESOs. Once developed, harmonised standards are reviewed by the Commission and, if they are positively assessed, the Commission adopts a Decision to publish the reference of the harmonised standards in the Official Journal of the European Union (OJEU). When they rely on harmonised standards cited in the OJEU, product manufacturers are automatically deemed compliant with the corresponding EU legislation: this legal effect of cited harmonised standards is called ‘presumption of conformity’.

Harmonised standards have regularly been used to support EU legislation. Since 1985, the ‘New Approach’ restricted the content of legislation to ‘essential requirements’ leaving the technical details to European harmonised standards. The development of European standardisation policy, including Regulation (EU) 1025/2012 on European standardisation³ (hereafter ‘Regulation (EU) 1025/2012’), helped support this approach by organising the legal interface for using standards as a tool for EU policy and legislation. Therefore, the process of development and adoption of harmonised standards for the AI Act is part of a larger process of standard-making for European legislation (hereafter ‘the standardisation process’). Article 10 of Regulation (EU) 1025/2012 outlines the Commission’s key role in the standardisation process, including the issuance of standardisation requests and the evaluation of the conformity of standards with these requests. However, the standards themselves are developed by standardisation organisations and the Commission representatives act as observers and counsellors in the standardisation work.

As regard artificial intelligence, two European standardisation organisations, CEN and CENELEC, established in June 2021 a Joint Technical Committee, called JTC 21, dedicated to developing AI standards, including harmonised standards for the AI Act. Since the start of

³ Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council Text with EEA relevance, <https://eur-lex.europa.eu/eli/reg/2012/1025/oj/eng>

JTC 21 activities, the Commission has been following closely the development of AI standards. The Commission formally issued a standardisation request to CEN-CENELEC, first in 2023⁴, ahead of the adoption of the AI Act, and then an amended version in 2025⁵, to cover the requirements for high-risk AI systems (Articles 10 to 15, 17 and 43 AI Act). To ensure the timely delivery of harmonised standards and the quality of the end result, the Commission has been actively involved in JTC 21 activities, participating in plenary, working group, and task group meetings, advising on legal aspects and reviewing draft standards.

Furthermore, the Commission has always been open to reply to the questions and enquiries of civil society and external stakeholder groups regarding the process of development of harmonised standards for the AI Act. This is reflected in the reply sent to the complainant's questions and the opportunity given to them to discuss directly with Commission staff of the AI Office.

In response to the questions raised by the Ombudsman in the inquiry of 26 September 2025, the Commission first would like to underline its commitment to compliance with all established EU law making standards. The harmonised standards at issue are still in development and therefore not cited in the OJEU. Once the harmonised standards for the AI Act are finalised by the ESOs, they will be assessed by the Commission; if they are considered as satisfactorily, reflecting the content of the legal provisions which they are supposed to address, the reference to them will be published in the OJEU. This process, which is usual for EU safety legislation, ensures proper safeguards and control on the final outcome of the overall process.

On the specific questions, the Commission provides the following replies:

- 1. How can the Commission's statement about the lack of its responsibility for the process and its outcomes be reconciled with the *James Elliott Construction* ruling, in which the Court of Justice held that the Commission must subject the work of the ESOs to "detailed monitoring" and confirm "the compliance of the final drafts of the harmonised standards, prior to their publication in the 'C' series of the Official Journal of the European Union"⁶?**

The Commission notes that the quote mentioned by the Ombudsman in its inquiry, and which

⁴ Commission Implementing Decision on a standardisation request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation in support of Union policy on artificial intelligence, ref. C(2023)3215, [https://ec.europa.eu/transparency/documents-register/detail?ref=C\(2023\)3215&lang=en](https://ec.europa.eu/transparency/documents-register/detail?ref=C(2023)3215&lang=en)

⁵ Commission Implementing Decision on a standardisation request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation as regards high-risk AI-systems in support of Regulation (EU) 2024/1689 of the European Parliament and of the Council and repealing Implementing Decision C(2023)3215, ref. C(2025)3871, [https://ec.europa.eu/transparency/documents-register/detail?ref=C\(2025\)3871&lang=en](https://ec.europa.eu/transparency/documents-register/detail?ref=C(2025)3871&lang=en)

⁶ Judgment of the Court of Justice of 27 October 2016, *James Elliott Construction Limited*, Case C613/14, paragraph 45, <https://curia.europa.eu/juris/document/document.jsf?text=&docid=184891&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=26431641>

was used by Corporate Europe Observatory in the complaint, is incomplete. Although the Commission's reply to the complainant indeed states that the Commission is not responsible for the technical content produced by the ESOs, it also recognises that the Commission is “*empowered to review standards once they are drafted, to decide to endorse them or not*”.

The Commission fully recognises that it has several key responsibilities in the standardisation process and would like to confirm its responsibility in ensuring a “*detailed monitoring*” of the standardisation process, as well as its responsibility in assessing “*the compliance of the final drafts of the harmonised standards, prior to their publication in the Official Journal of the European Union*”, with the relevant legislation and/or standardisation requests.

The *James Elliott Construction* ruling emphasised the importance of the Commission in ensuring that harmonised standards effectively integrate into the EU legal framework while supporting the internal market legislation. It also highlighted the Commission's responsibility to oversee the standardisation process and ensure compliance with EU principles. The ruling stressed the importance of control mechanisms, which had already been foreseen by Articles 10 and 11 of Regulation (EU) 1025/2012. Therefore, the Commission recognises its central role *ex ante*, *ex durante* and *ex post* the development of harmonised standards.

As regards its role *ex ante* the development of harmonised standards, the Commission is empowered to issue standardisation requests to the ESOs, pursuant to Article 10(1) of Regulation (EU) 1025/2012.

As regards its role *ex durante* the development of harmonised standards, the Commission duly monitors the process. The general reporting obligations of the ESOs are listed in Article 24(1) of Regulation (EU) 1025/2012, pursuant to which the ESOs shall send an annual report to the Commission, including detailed information on the application of obligations related to the transparency of standards (Article 4) and the stakeholder participation in European standardisation (Article 5). Specifically for the AI Act, the standardisation request includes an obligation to report to the Commission every 6 months on the execution of the standardisation request, including a description of how CEN and CENELEC have “*facilitated an appropriate representation and effective participation of the relevant stakeholders, including small and medium-sized enterprises and societal stakeholders*”⁷.

Once draft standards are finalised by the ESOs, the Commission is responsible for the evaluation of harmonised standards and the subsequent reference of harmonised standards in the OJEU, pursuant to Article 10(5) of Regulation (EU) 1025/2012. The evaluation of harmonised standards conducted by the Commission prior to their reference ensures that harmonised standards fully meet the intended objectives as set out in secondary sectorial legislation. The *James Elliott Construction* ruling underscored the final responsibility of the Commission in quality control and due diligence as regards harmonised standards.

As regard the *ex post* control of harmonised standards, Article 11(1)(b) of Regulation (EU) 1025/2012 empowers the European Parliament and Member States to trigger the procedure

⁷ Ibid, Article 3(4)(a)&(b)

for formal objection if a harmonised standard does not entirely satisfy the essential requirements, once the reference to a standard is published in the OJEU. In this case, the Commission has the competence to decide to maintain, to maintain with restriction, or to withdraw from the OJEU the reference to the standard concerned.

However, the Commission would like to note that the drafting of harmonised standards and their technical content is a competence of the ESOs. Standardisation, per se, is a private, independently operating activity, market driven and consensus-based. In the standardisation process, the Commission's focus is to ensure legal certainty. This means that the Commission shall ensure that harmonised standards are procedurally developed according to underlying EU law and that their content aligns with the essential requirements set out in sectoral secondary legislation. However, provided that these objectives are fulfilled, the Commission is not empowered to interfere in the drafting of the standards on substance (technical content). In its reply of 8 January 2025, the Commission aimed at underlining the fact that, while being subject to the monitoring of the Commission, the development process of harmonised standards was mainly under the responsibility of ESOs from the acceptance of a standardisation request until the delivery of harmonised standards to the Commission.

Subsequently to the *James Elliott Construction* ruling, the Commission took a number of steps to improve the standardisation process, including the development of a Vademecum on European standardisation, the revision of the template for standardisation requests, a guidance document for Commission officials on the verification of conditions for the publication of references of harmonised standards in the OJEU, and a change in the publication method of referencing of harmonised standards in the OJEU⁸. The Commission has also enhanced its oversight of the drafting process, as reflected in the strong involvement of Commission representatives in JTC 21. The Commission is constantly looking to improve its processes for reviewing and assessing harmonised standards to avoid legal challenges, including ensuring that harmonised standards address the essential requirements of EU legislation.

2. How does the Commission generally ensure that its monitoring is sufficiently 'detailed' within the meaning of the above-mentioned ruling? Does the Commission ensure that ESOs apply the Commission's Vademecum on European Standardisation⁹? For instance, has the Commission nominated "observers and counsellors in the standardisation work", as mentioned in the Vademecum¹⁰? If so, which departments of the Commission do they represent and what is their role?

The Commission has several EU officials registered as 'European Counsellors'¹¹ in JTC 21.

⁸ Whereas previously harmonised standards were cited in the C series (Communication) of the OJEU, today they are referenced in the L series (Legislation).

⁹ Commission Staff Working Document - Vademecum on European Standardisation in support of Union Legislation and policies, SWD(2015) 205 final, https://single-market-economy.ec.europa.eu/single-market/goods/european-standards/vademecum-european-standardisation_en

¹⁰ As foreseen in its Vademecum, *ibid.*, Part 1, point 4.2.2., p. 12.

¹¹ European Counsellors are invited to participate in Technical Committees or Subcommittees of CEN and CENELEC as observers and without voting rights. Previously, DG CNECT has collaborated with the Joint

These Commission's representatives are in charge of following the discussions and monitoring the ongoing work on harmonised standards for the AI Act. Currently, seven Commission's representatives from DG CNECT are registered as "*observers and counsellors in the standardisation work*" in JTC 21. Five of them¹² are in DG CNECT.A2, the unit in charge of "Regulation and Compliance" at the AI Office, supervising the implementation of the AI Act. DG CNECT.A2 is therefore actively involved in the discussions happening in JTC 21, participating in plenary meetings, working group meetings, and other task group meetings, monitoring closely the development of all harmonised standards for the AI Act.

The role of the Commission's representatives when they participate as 'European Counsellors' in JTC 21 is mainly to ensure that the harmonised standards and standardisation deliverables are aligned with the objectives of the AI Act. By participating in standardisation meetings and helping standardisation experts from JTC 21 understand the content of the regulation, the Commission's representatives help ensure that the development of harmonised standards remains aligned with legal provisions. This continuous participation as observers helps the Commission to identify early-on quality issues that would have prevented standards from meeting publication requirements and would have led to rejections or the need for further revisions if they were to be presented for citation to the OJEU¹³. However, the Commission's representatives do not take part in the drafting of harmonised standards for the AI Act.

Commission's representatives in JTC 21 also help ensure that the ESOs do apply the Commission's Vademecum on European Standardisation. This notably happens through regular and active participation in transversal discussions held in the "Strategic Advisory Group", the "Technical Coherence Forum" and the "Inclusiveness Task Group", all hosted in JTC 21/ Working Group 1.

3. How will the Commission review the substance of harmonised standards concerning AI? In particular, which departments of the Commission will be involved in this review, what criteria will they apply, and how? Does the Commission have in-house expertise to perform this review and what will be the standard of review applied?

The Commission plans to duly review the harmonised standards that will be offered for

Research Centre (JRC) to monitor the development of harmonised standards for the AI Act. JRC representatives were considered by CEN and CENELEC as 'European Institutional Stakeholder'. The role of European Counsellors and European International Stakeholders are described in CEN-CENELEC Guide 25 on 'The concept of Cooperation with European Organizations and other stakeholders'.

<https://www.cencenelec.eu/media/Guides/CEN-CLC/cenclguide25.pdf>

¹² The remaining two are in DG CNECT.H2 (cybersecurity and digital privacy policy) and DG.CNECT.DDG2.01.002 (coordination of standardisation activities related to digital technologies) and less actively involved.

¹³ This was a common situation when the Commission was relying on external HAS consultants. See Commission Staff Working Document Evaluation of Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, Section 3.1.1, <https://webgate.ec.europa.eu/circabc-ewpp/d/d/workspace/SpacesStore/947923b2-99c1-4630-af61-76590ac1806f/download>

citation in the OJEU to give presumption of conformity to the AI Act. The Commission will notably assess whether the harmonised standards offer a guaranteed level of protection with regard to the essential requirements established by the legislation and that they comply with the technical obligations set out in the standardisation request.

The Commission has decided to rely on in-house expertise for the assessment of the standards supporting the implementation of the AI Act¹⁴. The AI Office possesses with CNECT.A2 and CNECT.A3 in-house technical expertise related to AI, as well as expertise in standardisation processes. The AI Office can also count on the support and expertise of the Joint Research Centre (JRC). The Commission organised in February 2025 a full-scale stock review exercise of all draft harmonised standards for the AI Act. A dozen officials from across different CNECT unit¹⁵ and the JRC were mobilised to review and comment on the draft harmonised standards. Through this exercise, the Commission has gained experience and confirmed that it has the necessary expertise to perform this review.

For the final review of harmonised standards, the Commission will base its assessment on the checklist developed for HAS consultants¹⁶, a set of agreed criteria between CEN-CENELEC and the Commission, intended to guide the HAS consultants in their review. These criteria were already used for the interim review in February 2025.

The checklist ensures that the harmonised standards are aligned with EU legislation by including criteria stating that the harmonised standard's requirements should be coherent with EU legislation¹⁷ and that the harmonised standard should avoid interpreting or unsuitably repeating legal requirements¹⁸. The checklist also includes criteria on the quality of the harmonised standards' requirements, including criteria that states that the standard should be written in a clear way to leave no room for arbitrary choices¹⁹, that the tests should be reproducible and appropriate to ensure that they should be applied to demonstrate compliance with the legal requirements in an objectively verifiable manner²⁰, or that the requirements should be on product design and product properties, not set to an economic operator and its competence or resources²¹.

4. How will the Commission address any deficiencies that it identifies in harmonised standards delivered by CEN and CENELEC? In particular, will the Commission consider issuing its own 'common specifications'²² to replace deficient harmonised standards?

¹⁴ [The Commission can also rely on harmonised standards assessment consultants \(hereafter 'HAS consultants'\) to do the necessary quality checks to inform the decision related to the citation of harmonised standards in the OJEU, notably when it considers it does not have the necessary expertise for the assessment.](#)

¹⁵ CNECT.A2; CNECT.A3 and DG.CNECT.DDG2.01.002.

¹⁶ Checklist for standards in response to a standardization request and to be offered for citation in the OJEU, https://boss.cen.eu/media/BOSS%20CEN/formtemp/checklist_hens.docx

¹⁷ Ibid, Criteria 1.2.13

¹⁸ Ibid, Criteria 1.2.15 and 1.2.16

¹⁹ Ibid, Criteria 1.2.14

²⁰ Ibid, Criteria 1.2.17

²¹ Ibid, Criteria 1.2.18

²² Under Article 41 of the AI Act.

The Commission is mindful of the value of the standardisation process in developing technical specifications which reflect the state of the art and the consensus by industry and societal players. Therefore, the Commission remains fully committed to supporting the work of JTC 21 *ex-durante* to ensure that AI system providers will be able to rely on harmonised standards to demonstrate their compliance to the AI Act.

However, the Commission is aware and concerned by the delay in the development of harmonised standards for the AI Act and have urged CEN and CENELEC to take action to remedy the challenges being faced within JTC 21. Hence the Commission is considering alternative measures which may help providers of high-risk AI systems to comply with the essential requirements of the AI Act while being mindful that such alternatives need to be available by the time of entry into application of the legal obligations.

At this stage, the Commission is not planning to develop common specifications as per the meaning of Article 41 AI Act. However, the Commission could issue guidance to fill the gaps caused by the delay of the standardisation work.

Once the harmonised standards are developed by CEN-CENELEC, and in the case where they are deemed not to satisfy the requirements which they aim to cover following an assessment by the Commission, the Commission will reconsider whether to develop common specifications as per the meaning of Article 41 AI Act.

5. Has the Commission performed any interim reviews of the preliminary results of CEN and CENELEC's work?

As indicated in the reply to question 3 above, the Commission did indeed conduct a full-scale stock review exercise in February 2025 of all draft harmonised standards, based on the assessment criteria of the HAS consultants' checklist. This exercise was beneficial to experts in JTC 21 since it permitted to highlight the remaining gaps and clarify the expectations from the Commission. The exercise was also beneficial for the Commission itself to accumulate experience in the organisation of such review. During the review, the Commission found a number of issues with the draft standards. Main issues concerned the level of granularity of technical requirements, the interplay between harmonised standards and the structure and scope of harmonised standards.

Additionally, the Commission has provided guidance on whether some existing international standards could suffice for giving presumption of conformity to certain legal requirements of the AI Act. Notably, the Commission has assessed the fitness of ISO/IEC 42001:2023 to cover the requirement on the quality management system (Article 17 AI Act). The Commission concluded that there were foundational differences in the understanding of the concept of 'risk' and in the overall objective of the respective management systems in ISO/IEC 42001:2023 and the AI Act and ruled the international standard to be unsuitable for meeting the regulatory requirements and objectives of Article 17 AI Act.

6. What are the confidentiality rules applied by CEN and CENELEC in the process of developing harmonised standards on AI?

As regards the confidentiality rules that apply to the content produced by CEN-CENELEC, CEN-CENELEC have Internal Regulations which are public documents that explain their way of working. Internal Regulations Part 2²³ contains CEN-CENELEC's copyright policy²⁴ and document availability policy²⁵. Further to the copyright policy, the exploitation rights in experts' contributions are assigned to CEN-CENELEC for the benefit of its members, i.e. the national standardisation bodies. However, the copyright policy states that the original copyright holder is not precluded from continuing to exploit their own contribution for their own purposes "*provided that such exploitation does not adversely affect the exploitation of the common work*". CEN-CENELEC Guide 10²⁶ further explains the copyright of CEN-CENELEC's content and the distribution and sale through CEN-CENELEC's members. Further to the document availability policy "*CEN and/or CENELEC working documents should not be made available outside the bodies cooperating in CEN and/or CENELEC work*". Internal Regulations Part 3²⁷ states that the copyright policy should follow ISO/IEC Directives²⁸. The copyright policy of ISO/IEC, followed by CEN-CENELEC, clarifies that publications, documents, text, figures, images or other content that are submitted to the ISO/IEC standards development process may be copyright protected.

As regards the confidentiality rules that apply to the individual experts registered in CEN-CENELEC, the Code of conduct²⁹ which is presented at the start of each standardisation meeting and which each individual standardisation expert is expected to respect, states that "*delegates experts and observers are committed to respecting others and the professional culture of European standardization within CEN/CENELEC*". This includes "*revealing neither the identity nor the affiliation of other participants when using information received but not included in official minutes without prior consent*".

7. What are the transparency practices applied by CEN and CENELEC in the process of developing harmonised standards on AI? Please share with the Ombudsman references to information published by CEN and CENELEC regarding the process in question.

CEN and CENELEC are private law organisations which follow their own internal policies and regulations. In the case of JTC 21, additional efforts have been made to inform the public and stakeholders about activities related to the development of harmonised standards for the AI Act. A summary of these transparency practices is provided by CEN-CENELEC as a reply to the Ombudsman inquiry and can be found in Annex 1.

²³ CEN-CENELEC, Internal Regulation Part 2 – Common Rules For Standardization Work, January 2025, https://boss.cen.eu/media/BOSS_CEN/ref/ir2_e.pdf

²⁴ Ibid, Section 9

²⁵ Ibid, Section 10

²⁶ CEN-CENELEC Guide 10, Policy on the distribution, sale and copyright of CEN and CENELEC Content, Edition 5, January 2025, <https://www.cencenelec.eu/media/Guides/CEN-CLC/cencleguide10.pdf>

²⁷ CEN-CENELEC, Internal Regulation Part 3, Principles and rules for the structure and drafting of CEN and CENELEC documents, July 2022, Section 32, https://boss.cen.eu/media/BOSS_CENELEC/ref/ir3_e.pdf

²⁸ Declaration for participants in ISO activities, <https://www.iso.org/declaration-for-participants-in-iso-activities.html>

²⁹ Code of Conduct for delegates, experts and observers participating in the technical work of CEN/CENELEC, https://boss.cen.eu/media/oitflkv2/code_conduct_experts.pdf

In addition to CEN-CENELEC internal regulations, the ESOs are also bound by European legislation, notably transparency obligations from Article 3, Article 4 and Annex II(3)(c) of Regulation (EU) 1025/2012. These include the obligation to establish a work programme to be shared on the ESOs' website and the obligation to send any draft national standard, European standard or European standardisation deliverable to the Commission upon request. The basic cooperation agreement between the Standardisation Organisations and the Commission which is established in the 'General Guidelines for the Cooperation between CEN, CENELEC and ETSI and the European Commission'³⁰, published in the Official Journal in 2003, also reiterates the principles of openness and transparency from the World Trade Organisation's Technical Barrier to Trade Principles for the Development of International Standards³¹.

8. What are the Commission's views on the complainant's argument that there is an overriding public interest in disclosure of information about the membership of JTC 21, the interest(s) they represent and their ongoing work, given the impact of the standards on fundamental rights and the legal status of the standards?

DG CONNECT did not hold any documents that contained information about the membership of JTC 21 and its ongoing work at the time of the complainant's access to documents request.³² On 28 August 2025, the complainant was informed that the '[...] CEN/CENELEC/JTC21 meetings are managed by CEN-CENELEC. DG CONNECT does not receive agendas and minutes directly and does not have access to or holds documents that indicate the affiliation of the experts.'

The documents related to the JTC 21 originate with and are held by CEN/CENELEC on the organisation's internal platform. On the platform, the only information available about the affiliation of the experts is the national standardisation body that appointed them; other affiliations are not accessible.

That said, the Commission notes that in the *Public.Resource.Org and Right to Know*³³, the Court underscored the importance of the rule of law and the principle of free access to EU law as enshrined in Article 2 of the Treaty of the European Union (TEU) and ruled that there is an overriding public interest, within the meaning of the last clause of Article 4(2) of Regulation No 1049/2001, justifying the disclosure of the requested harmonised standards which form

³⁰ General Guidelines for the Cooperation between CEN, Cenelec and ETSI and the European Commission and the European Free Trade Association, 28 March 2003, <https://op.europa.eu/en/publication-detail/-/publication/7b4b103b-d0f5-47e3-80ff-664537e81e80>

³¹ World Trade Organisation, Technical Barriers to Trade – Principles for the Development of International Standards, Guides and Recommendations, https://www.wto.org/english/tratop_e/tbt_e/principles_standards_tbt_e.htm
[Ares\(2025\)6997268](#)

³³ Judgment of the Court of Justice of 5 March 2024, *Public.Resource.Org Inc. v Commission*, Case C588/21 P, <https://curia.europa.eu/juris/document/document.jsf?text=&docid=283443&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=26696941>

part of EU law due to their legal effects. This means that the Commission has an obligation to disclose standards that form part of EU law

However, it is important to note that, as long as a reference of a harmonised standard is not published in the OJEU, compliance with the harmonised standard, or parts thereof, does not give presumption of conformity with the essential or other requirements it aims to cover, and thus does not produce legal effects. Therefore, the harmonised standards developed by the ESOs are to be considered to form part of EU law only after the references to these harmonised standards have been published in the OJEU. During their development and prior to their reference in the OJEU, the regime of access to harmonised standards should not be affected by the *Public.Resource.Org and Right to Know* ruling. As of the writing of this reply to the Ombudsman inquiry, no harmonised standards following a standardisation request for the AI Act has been cited in the OJEU for this legislation, and the development of harmonised standards for the AI Act is still ongoing.

Similar to draft standards, supporting documents like experts contributions, minutes or agendas of meetings should not be considered to form part of EU law, therefore there cannot be an overriding public interest in their disclosure pursuant to the *Public.Resource.Org and Right to Know* ruling. On the contrary, unless there is an overriding public interest in disclosure, the Commission shall refuse access to documents where disclosure would undermine the protection of commercial interests and intellectual property pursuant to the last clause of Article 4(2) of Regulation (EC) 1049/2001. Since disclosure of the preparatory content to draft standards would harm the commercial interests of CEN-CENELEC, the Commission must refuse access to it pursuant to Article 4(2) first indent of Regulation (EC) 1049/2001.

As far as the impact of these standards on fundamental rights is concerned, in addition to the responsibilities of the Commission *ex ante*, *ex durante* and *ex post* the development process to ensure that harmonised standards can guarantee an adequate level of protection, it is to be noted that Member States and the European Parliament are also empowered to raise formal objections to harmonised standards pursuant to Article 11 of Regulation (EU) 1025/2012 when they consider that a harmonised standard does not entirely satisfy the requirements of the relevant Union harmonisation legislation which it aims to cover.

Furthermore, there is the possibility for any stakeholder to review the draft harmonised standards and raise their comments to the ESOs during the ‘Public Enquiry process’.

9. How many members of the JTC 21 represent industry, private consultancies, other private entities, public authorities, civil society organisations and academic institutions? Please share with the Ombudsman any statistical data in this regard.

The Commission does not hold official statistical data as regard the participation of industry, private consultancies, other private entities, public authorities, civil society organisations and academic institutions in the development of harmonised standards for the AI Act. A list of members can be found in the JTC 21 main folder on the online platform³⁴. However, this list does not include the members' professional affiliation.

On 14 March 2025, the task group Inclusiveness launched a questionnaire aiming to provide statistical information on diversity in JTC 21's working groups based on a selection of criteria such as nationality, gender, and interests represented. The results from this questionnaire, which can be found on CEN-CENELEC's online platform, show that civil society organisations, public authorities, academics and independents represent more than half of the experts in JTC 21.

In their complaint, the complainant claims that CEN-CENELEC is "*dominated by industry*", and that specifically in JTC 21, "*large tech companies, Big Tech firms in particular, are overrepresented*". It is here important to note that the standardisation work required to translate legal requirements into technical specifications requires highly technical profiles and industry expertise. In addition, the main users of harmonised standards are private-sector organisations which seek in the compliance with harmonised standards the benefit of presumption of conformity which gives them legal certainty as regard their obligations in secondary legislation. The role of the industry is therefore central in the standardisation process and it appears reasonable that such industrial stakeholder participate actively in the development of standards.

Nevertheless, the Commission would like to reiterate that the inclusivity and diversity of the standardisation process is one of its key priorities. The obligations regarding the inclusiveness of the process are stated in Article 5 of Regulation (EU) 1025/2012 and additional provision for access of SMEs to standards are stated in Article 6. For harmonised standards on AI specifically, the standardisation request contains reporting obligations, notably including a description of how CEN and CENELEC have "*facilitated an appropriate representation and effective participation of the relevant stakeholders*"³⁵. The Commission has also strongly encouraged on multiple occasions national public authorities to participate in JTC 21, in particular through the Committee on Standards and the subgroup of the AI Board dedicated to

³⁴ The online platform is owned by CEN and the International Standardisation Organisation (ISO) and access to JTC 21 folders is managed by CEN-CENELEC. Documents are therefore only accessible through a personal login and password. As agreed with CEN-CENELEC, only a limited number of Commission's representative can have access to the platform. In the case of AI standardisation, five colleagues from DG CNECT.A2 have access to CEN-CENELEC JTC 21 folders, as well as a few colleagues from other units and the Joint Research Centre (JRC).

³⁵ Ibid, Article 3(4)(a)

standardisation. It has also funded specific activities through action grants to facilitate the participations of civil society stakeholders and SMEs³⁶.

10. Please provide the list of the Annex III organisations that participate in the standardisation process concerning AI.

All four Annex III organisations³⁷ have representatives following the work on AI standards in JTC 21. These include:

- Small Business Standards (SBS), representing SME stakeholders (Annex III(1));
- the European Association for the Coordination of Consumer Representation in Standardisation (ANEC), representing consumer stakeholders (Annex III(2));
- the Environmental Coalition on Standards (ECOS), representing environmental stakeholders (Annex III(3));
- the European Trade Union Confederation (ETUC), representing social stakeholders (Annex III(4)).

Some of these organisations hold leadership positions in JTC 21. SBS holds the convenorship of JTC 21 Working group 2 on “Operational aspects”, hosting notably the development of the standards on “AI Risk Management”, “Quality management system” and “Conformity Assessment”, some of the main harmonised standards covering the standardisation request for the AI Act.

ETUC is the leader of the task force Inclusiveness, hosted by JTC 21 Working Group 1. ETUC is also active in several working groups, participating in technical discussions around harmonised standards for the AI Act.

ANEC is very active in JTC 21, with experts present in all working groups to follow the development of main harmonised standards. ANEC also recently created of a new “AI and consumers Task Force”, with a kick-off meeting organised in April 2025 in Brussels, where Commission representatives from the AI Office attended.

ECOS is less active in AI standardisation, seemingly monitoring the work on harmonised standards without participating actively in technical discussions.

Apart from Annex III organisations, several civil society organisations participate actively to the development process of harmonised standards for the AI Act, such as 5Rights, Equinet and Algorithm Audit.

11. How has the Vademecum on European Standardisation helped Annex III

³⁶ <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/projects-details/43252476/101140954/SMP>

³⁷ Annex III organisations are stakeholder organisations meeting the criteria laid down in Annex III to Regulation (EU) 1025/2012 on European standardisation.

organisations overcome obstacles to their effective participation in the standardisation process?

Annex III are directly consulted by the Commission regarding different steps of the standardisation process, including before submitting a standardisation request.

In addition, the EU budget directly finances Annex III organisations through grants. These organisations, alongside the ESOs, receive EU funding via Framework Partnership Agreements in the form of operating or action grants.

In their participation to the overall standardisation process, including but not limited to AI, Annex III organisations face costs for operations, member coordination, and dissemination, as well as costs for compliance with the reporting obligations arising from Article 24 of Regulation (EU) 1025/2024. However, according to the Evaluation of Regulation (EU) 1025/2012 conducted by the European Commission and published in June 2025, these costs are mostly offset by EU funding³⁸.

The European Commission annually provides on average for all standardisation activities, including but not limited to AI, operating grants amounting to €1.37 million to ANEC, €833,000 to ECOS, and €366,000 to ETUC, while SBS received €1.65 million in action grants. Overall, EU funding to Annex III organisations has grown from 2015 to 2023³⁹. This increase in funding follows the increasing workload faced by Annex III organisations given the adoption of new legislation relying on harmonised standards⁴⁰.

The activities financed through EU funding include participation in technical work, contribution to policy work and awareness raising and dissemination activities. All these activities have increased over time, including the participation of Annex III organisations in technical discussions within CEN and CENELEC's technical committees, working groups and other groups⁴¹.

However, it is worth noting that, despite increased engagement, Annex III organisations still face challenges in contributing to international standards and perceive fragmented national-level participation as detrimental to their impact at EU level. Main difficulties arise from the long duration of processes and the associated cost of participation, governance models of ESOs and NSBs, and a lack of awareness and skills in standardisation⁴².

12. Please share more information about the composition and work of the task force on inclusivity.

³⁸ Commission Staff Working Document Evaluation of Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, Section 4.1.2.1, <https://webgate.ec.europa.eu/circabc-ewpp/d/d/workspace/SpacesStore/947923b2-99c1-4630-af61-76590ac1806f/download>

³⁹ Ibid.

⁴⁰ Ibid.

⁴¹ Ibid, Section 3.1.2

⁴² Ibid, Section 4.1.1.6

JTC 21 created a dedicated Inclusiveness task group in January 2023 following a joint initiative of SBS and ETUC. The task group, initially hosted in JTC 21 Working Group 2 on Operational aspects, was transferred to Working Group 1, the Strategic Advisory Group, since inclusiveness is transversal to all the work of JTC 21. The task group has been chaired by a representative from ETUC since the beginning, with a representative from ANEC being recently appointed as a co-chair. SBS, some civil society organisation, a few industry representatives, as well as the Commission, are active participants to the monthly task group meetings.

Since its creation, the task group has helped issue several⁴³ editions of the ‘AI Standardisation Inclusiveness Newsletter’, available to the general public on ETUC’s website⁴⁴. The newsletter distributes updated information on the landscape of AI standardisation activities in European and international standardisation organisations, including JTC 21 and ISO/IEC SC 42.

Following the questionnaire on diversity in JTC 21 mentioned in question 9, the task group has proposed several measures to improve the inclusiveness of the standardisation process. These measures can be found with the results from the questionnaire on CEN-CENELEC’s online platform.

13. Could the Commission take a position on the complainant’s suggestion to introduce rules for ESOs based on the rules for the Commission’s expert groups concerning the composition of groups, conflicts of interest, and transparency⁴⁵?

The Commission’s expert groups are of different nature than standardisation groups. Expert groups support the Commission in the preparation of legislative proposals and policy initiatives and help inform policy decisions when in-house expertise is insufficient. Expert groups are subject to strict rules, which are unsuitable in the context of standardisation. Experts must notably declare that no conflict of interest exists and that they will inform the Commission if any such conflict should arise in the course of their duties. If applied to JTC 21, this obligation would prevent industry stakeholders who are themselves providers of AI systems in the meaning of Article 3(1) AI Act to participate, depriving the standardisation process of much needed technical industry expertise. As regard the disclosure of the composition of groups or the content they produce, the impact on CEN-CENELEC’s business model would have to be assessed.

The Commission would like to emphasise that the ESOs are private law entities and that their organisational structure and rules of procedure are internal matters. As indicated through the replies to the previous questions, it is to be noted that safeguards are already in place to ensure that the outcome of the standardisation process is compliant with EU law.

⁴³ At the time of writing, 10 editions

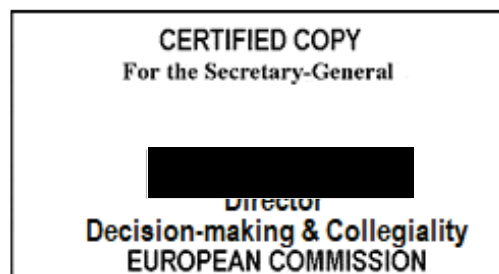
⁴⁴ Artificial Intelligence Standardisation Inclusiveness Newsletter, <https://www.etuc.org/en/artificial-intelligence-standardisation-inclusiveness-newsletter>

⁴⁵ [https://ec.europa.eu/transparency/documents-register/detail?ref=C\(2016\)3301&lang=en](https://ec.europa.eu/transparency/documents-register/detail?ref=C(2016)3301&lang=en)

V. CONCLUSION

Transparency, inclusiveness and accountability are key priorities for the Commission. The Commission monitors closely the development of harmonised standards for the AI Act and will review thoroughly the outcome of the standardisation process in view of the reference of these harmonised standards in the OJEU.

For the Commission
Henna VIRKKUNEN
Executive Vice-President



List of enclosures:

- Annex 1: Reply from CEN-CENELEC on the transparency and confidentiality rules or policies applicable to the work of CEN and CENELEC on the harmonised standards on AI

QUESTION : “transparency and confidentiality rules or policies applicable to the work of CEN and CENELEC on the harmonised standards on AI,”

RESPONSE:

The rules on transparency and confidentiality of the work of CEN and CENELEC are found mainly in the “*Internal Regulations – Part 2: Common Rules for Standardization Work*” (“IR-Part 2” – see enclosed copy)¹. The IR-Part 2 describe the organizational structures, the policies and the procedures to be followed for the standardization work of CEN and CENELEC.

The following provision is relevant as regards the confidentiality of documents:

- Section 10 deals with the Document availability policy. Section 10.5 states that “*CEN and/or CENELEC working documents should not be made available outside the bodies cooperating in CEN and/or CENELEC work*”.

The following provisions are also relevant as regards the transparency of the process:

- Section 11.2 deals with the Preparation of European Standards. Section 11.2.1.1 states that “*The elaboration of a European Standard includes a public enquiry, followed by a Formal Vote (see 11.2.3) of CEN and/or CENELEC Members and final ratification.*” Section 11.2.2 describes the “*CEN and/or CENELEC Enquiry*” procedure. Essentially, when the draft standard is finalized, it goes up to public enquiry open to all interested parties, via the members.

For the sake of completeness, it should be noted that once a standard is adopted, its content can (in principle) only be reproduced and disseminated in accordance with the “*CEN & CENELEC Guide 10 - Policy on the distribution, sale and copyright of CEN and CENELEC Content*” (see enclosed copy), subject however to the decision of the CJEU in relation to the public access to certain standards².

CEN and CENELEC would like to stress that since the beginning of the work on the harmonised standards on AI, significant efforts have been made, beyond what was customary for other standards, to inform the public and stakeholders about the ongoing work, especially as regards the aspect of inclusiveness of AI standards. This effort includes the following websites and newsletters:

- The website of the JTC 21: <https://jtc21.eu/>, and a LinkedIn group: <https://www.linkedin.com/groups/8793224/>
- A newsletter dedicated to inclusiveness coordinated by ETUC, the European Trade Union Confederation, available on subscription (with ca. 500 subscribers at this point), as well as online here:
 - o on the website of ETIC: <https://www.etuc.org/en/artificial-intelligence-standardisation-inclusiveness-newsletter>
 - o on the website of JTC 21: <https://jtc21.eu/newsletter/>
 - o in the aforementioned LinkedIn group

¹ These Internal Regulations are publicly available on the CEN and CENELEC BOSS (Business Operations Support System) websites: <https://boss.cenelec.eu/reference-material/refdocs/pages/> and <https://boss.cen.eu/reference-material/refdocs/pages/>

² Judgment of the Court of Justice of 5 March 2024, Public.Resource.Org Inc. v Commission, Case C-588/21 P, <https://curia.europa.eu/juris/document/document.jsf?text=&docid=283443&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=26696941>

- Information on the CEN and CENELEC website: <https://www.cencenelec.eu/news-events/news/2024/brief-news/2024-07-26-inclusiveness-in-ai-standardization/>