Ada Lovelace Institute

The future of regulation

Discussion paper

Inclusive AI governance

Civil society participation in standards development

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Contents

Executive summary

This discussion paper contributes to the conversation around European Union (EU) AI standards by clarifying the role technical standards will play in the AI governance framework created by the EU's Artificial Intelligence Act (the 'AI Act'), and how this may diverge from the expectations of EU policymakers.

In the AI Act, EU policymakers appear to rely on technical standards to provide the detailed guidance necessary for compliance with the Act's requirements for fundamental rights protections. However, standards development bodies seem to lack the expertise and legitimacy to make decisions about interpreting human rights law and other policy goals. This misalignment is important because it has the potential to leave fundamental rights and other public interests unprotected.

The research presented in this paper is not conclusive; it is based on the limited, publicly available information about the development of technical standards for the AI Act, as well as feedback from a small number of experts.

However, this information and feedback point to several policy strategies that may be helpful and necessary for the successful implementation of the AI Act. This paper can therefore inform the interinstitutional negotiations ('trilogues') on the AI Act and help the European Commission explore these policy strategies.

One approach is to boost civil society participation in the standardisation process, which would improve the diversity of viewpoints and representation of public interests. However, since this is unlikely to provide the political and legal guidance needed to interpret essential requirements, institutional innovations are also proposed.

This discussion paper may also help policymakers outside the EU to understand the feasibility of implementing AI policy through technical standards when developing their own AI regulations. For similar reasons, civil society organisations considering their positions on AI policy proposals may find it informative.

This paper begins by exploring the role of standards in the AI Act and whether the use of standards to implement the Act's essential requirements creates a regulatory gap in terms of the protection of fundamental rights. It goes on to explore the role of civil society organisations in addressing that gap, as well as other institutional innovations that might improve democratic control over essential requirements.

This is followed by conclusions and recommendations for adapting the EU's standardisation policy to the goals of the AI Act.

Information about this topic was gathered through legislative and policy analysis, as well as interviews with experts involved in standards development for the AI Act and civil society organisations with expertise relevant to the AI Act. A detailed description of the methodology appears at the end of the paper on page 57.

Recommendations and open questions for EU policymakers

Our analysis finds that EU standardisation policy and the AI Act create a regulatory gap. Lawmakers expect that technical standards will clarify and implement the Act's essential requirements. However, neither the legislative text, nor the technical standards implementing the legislation, are likely to answer the challenging legal and political questions raised by these essential requirements.

Although the European Commission's standardisation request to Joint Technical Committee 21 (JTC-21) says that adequate fundamental rights expertise and other public interests must be represented in the standards-setting process, most experts identified prohibitive barriers to meaningful civil society participation. These barriers include, but are not limited to: the time commitment, the opacity and complexity of the standardisation process and the dominance of industry voices in that process.

These findings suggest that EU policymakers should explore institutional innovations to fill the regulatory gap, as well as strategies to boost civil society participation.

This paper explores three strategies for EU policymakers to expand civil society participation in JTC-21:

- **Amend the Regulation on European Standardisation** to broaden the categories of Annex III organisations eligible for funding and mandated participation, increasing funding for organisations' participation in line with this.

- **Fund more individuals from civil society organisations** with the Commission's specialised StandICT grants, which provide funding for European standardisation experts to participate in standards development, including for participation in national delegations.

- **Create or fund a central hub to support civil society participation.** This would institutionalise activities already carried out by organisations such as the European Trade Union Confederation (ETUC) and the European Consumer Voice in Standardisation (ANEC) that aim to facilitate the contribution of subject-matter experts to standards-setting processes.

The European Commission should also consider institutional innovations to improve democratic control over essential requirements. These include the creation of:

- **Common specifications:** The Commission could leverage its right to develop common specifications, which would address the safety and fundamental rights concerns that are not captured by the technical standards that implement EU legislation (known as 'harmonised standards').

- **A benchmarking institute:** The proposed AI benchmarking institute could take up the questions that JTC-21 avoids or answers inadequately, complementing JTC-21's procedure- and documentation-oriented standards with more substantive standards.

Further questions

As originally conceived, the EU's New Legislative Framework (NLF) ensures political decisions remain within EU institutions and decisions made within European Standards Organisations (ESOs) are 'purely technical'.[1]

The Commission's Explanatory Memorandum implies this is true of the AI Act, describing harmonised standards as 'precise technical solutions'[2] for designing AI that complies with essential requirements. Yet, the AI Act effectively delegates political decisions to ESOs. This scenario is unlikely to ensure fundamental rights protections and related policy goals are realised.

This research therefore raises a broader question about the AI Act and the NLF – **what role do EU institutions expect standards to play in AI governance?**

Before voting on the AI Act, EU policymakers should ask the following questions:

- How far is the EU delegating political power to private entities?
- Which private entities are being empowered?
- Are amendments necessary to safeguard public interests?

These questions will be of particular importance for parliamentarians voting on the AI Act and other institutional players during the 'trilogue' negotiations.

1 European Commission (2015). *Vademecum on European Standardisation in support of Union Legislation and policies*, SWD(2015) 205 final, part 1, section 3.1. Available at: https://ec.europa.eu/docsroom/documents/13507/attachments/1/translations

2 European Commission (2021). *Proposal for a regulation of the European Parliament and of the Council on laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts (AI Act)*, COM(2021) 206 final section 5.2.3. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021PC0206

There may be a better solution that avoids relying on European standards at all. This path prompts bigger questions:

- Is a new political theory of AI governance necessary and, if so, what should it be?
- How could a governance framework be designed to effectively protect fundamental rights and better safeguard the public interest from conflicting corporate interests?
- How can it balance the incorporation of technical expertise with effective democratic control?

We hope this research will generate discussion among EU policymakers, civil society organisations and standards bodies, about how to expand civil society participation within standards development for the AI Act. For EU policymakers in particular, there are broader questions to consider around the role of standards in AI governance alongside this. Detailed analysis and next steps for policymakers can be found from page 42.

The requirements for high-risk systems, known as essential requirements, are phrased in highly general and vague terms in the legislative text of the AI Act.

Introduction

The Artificial Intelligence Act (AI Act)[3] represents the European Union's (EU's) proposed framework to regulate artificial intelligence broadly, beyond specific areas like medical devices. The European Commission's proposal is designed to achieve several overarching goals: the protection of EU values and citizens' fundamental rights, health and safety; fostering an innovative and globally competitive AI market; and setting global legal standards and norms.[4]

Fundamental rights protections are particularly prominent in the AI Act. In addition to contributing to the Commission's 'ultimate aim' of ensuring AI 'increas[es] human well-being', the Commission expects strong fundamental rights protections to promote uptake and growth of the AI market by fostering public trust in AI.[5]

Much of the legislation outlines substantive rules for the protection of fundamental rights and other public interests, along with requirements for demonstrating compliance with these substantive rules. These rules apply to AI identified in the legislation as 'high-risk', meaning it poses a significant risk to fundamental rights, health or safety.[6]

However, the requirements for high-risk systems, known as essential requirements, are phrased in highly general and vague terms in the legislative text of the AI Act. For example, a biometric identification system must feature an 'appropriate level of accuracy' to mitigate risks to fundamental rights.[7]

3 European Commission (2021). *Proposal for a regulation of the European Parliament and of the Council on laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts (Explanatory Memorandum),* COM(2021) 206 final. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021PC0206

4 European Commission (2021). *AI Act (proposal)*, Recitals 1, 5, 13, 32, 39, 43, and 78. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021PC0206; European Commission (2021). *Explanatory Memorandum*, sections 1.1, 1.2, 1.3, 2.2, 2.4 and 3.5; European Commission (2022). *A European approach to artificial intelligence.* Available at: https://digital-strategy.ec.europa.eu/en/policies/european-approach-artificial-intelligence

5 European Commission (2021). *Explanatory Memorandum*, section 1.1.

6 European Commission (2021). *Explanatory Memorandum*, section 1.1.

7 European Commission (2021). *AI Act (proposal)*, Article 15(1).

The Commission intends for standards development bodies to clarify essential requirements by operationalising them in technical standards for use by developers.

Ambiguous instructions for software design can 'conflict deeply with [. . .] [a] computer scientist's mindset',[8] which relies on precision and clarity. This may make it difficult for AI providers – people or entities who develop AI or have AI developed for use under their name or trademark – to interpret and operationalise essential requirements, resulting in insufficient protections for fundamental rights and other public interests.[9]

It appears that the Commission intends for standards development bodies to clarify essential requirements by operationalising them in technical standards for use by developers.[10] As in some other product safety legislation, the AI Act empowers the European Commission to request the development of technical standards by private standards development bodies to facilitate compliance with essential requirements.

This is seemingly based on the assumption that standards development bodies are equipped to grapple with questions about human rights and other public interests implicated by the AI Act.

However, standards development bodies typically rely on employees of large technology companies for their outputs and see minimal participation by civil society organisations and other stakeholders.[11] This means they are unlikely to benefit from the legal and policy expertise relevant to the AI Act's essential requirements.

This situation also creates the possibility that decisions will be made in companies' best interests, even when they conflict with the public interest.

8 Kroll, J. et al. (2017). 'Accountable Algorithms', *University of Pennsylvania Law Review*, p. 696. Available at: https://scholarship.law.upenn.edu/penn_law_review/vol165/iss3/3

9 European Commission (2021). *AI Act (proposal)*, Article 3(2). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021PC0206

10 European Commission (2021). *Explanatory Memorandum*, sections 2.1 and 2.3. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021PC0206

11 Büthe, T. and Mattli, W. (2011). *The New Global Rulers*, p. 139. Princeton: Princeton University Press.

> If neither the legislative text of the AI Act nor standards clarify how to comply with the AI Act's essential requirements for fundamental rights and other public interests, AI designers may not implement them effectively, leaving the public unprotected.

Whether this is the case is unclear. Little information about the development of standards for the AI Act is publicly available. AI is also a relatively new area in standards development, which makes it difficult to trace the impacts of AI standards on individuals and society, or to understand how AI experts approach these issues in standards development.

What are standards?

A standard is a document that 'describes the best way of doing something. It could be about making a product, managing a process, delivering a service or supplying materials – standards cover a huge range of activities'.[12]

A standard 'provides rules, guidelines or characteristics for activities or for their results, aimed at achieving the optimum degree of order in a given context. It can take many forms. Apart from product standards, other examples include: test methods, codes of practice, guideline standards and management systems standards'.[13]

Companies can access and license these documents through standards development bodies, which are intended for industry-wide use. For example, electronics companies have standardised the design of electric power plugs and sockets within entire countries and regions, enabling one to use a device manufactured by one company after plugging it into a socket manufactured by another.

12 International Organization for Standardization (ISO). *Standards*. Available at: https://www.iso.org/standards.html (Accessed: 16 March 2023)

13 ISO. *Deliverables*. Available at: https://www.iso.org/deliverables-all.html (Accessed: 16 March 2023)

If standards are to play a significant role in the EU's new approach to AI governance, research is needed about AI standards to assess the AI Act's suitability.

What is clear from research in other areas of standards development is that standards can create significant sociopolitical impacts, including fundamental rights impacts, and can be highly contested for political and economic reasons by different stakeholders.[14]

If standards are to play a significant role in the EU's new approach to AI governance, research is needed about AI standards to assess the AI Act's suitability. Several questions remain unanswered:

1. **Whether the AI Act creates a regulatory gap for the protection of fundamental rights and other public interests.** Will providers of AI systems find it difficult or impossible to comply with these requirements, given the ambiguity of the legislative text and the apparent lack of authoritative guidance from technical standards bodies?

2. **If there is a regulatory gap, is civil society participation in standardisation helpful or even necessary to fill it?** Civil society organisations with expertise in human rights law and other policy areas may be able to provide the non-technical expertise necessary to implement the AI Act's essential requirements in technical standards. They may also help to ensure the public interest is not disregarded in the pursuit of commercial interests.

3. Assuming there is a regulatory gap for the protection of fundamental rights and other public interests, and that civil society participation can fill this gap, **how can policymakers enhance the effective participation of civil society in the development of standards for the AI Act?** Few civil society organisations are able to participate in standards development and those that do find it difficult to influence the process. Policymakers may be able to provide them with additional resources and legislative support.

14 See, for example: Caeiro, C., Jones, K. and Taylor, E. (forthcoming). 'Technical Standards and Human Rights: The case of New IP', *Human Rights in a Changing World*. Washington, DC: Brookings Institution Press. Available at: https://oxil.uk/publications/2021-08-27-technical-standards-human-rights/Human_rights_and_technical_standards.pdf; Cath-Speth, C. (2021). *Changing Minds and Machines: A Case Study of Human Rights Advocacy in the Internet Engineering Task Force (IETF)*. Oxford Internet Institute. Available at: https://corinnecath.com/wp-content/uploads/2021/09/CathCorinne-Thesis-DphilInformationCommunicationSocialSciences.pdf; ten Oever, N. (2020). *Wired Norms*. Available at: https://nielstenoever.net/wp-content/uploads/2020/09/WiredNorms-NielstenOever.pdf

This research used legislative analysis and document review, as well as interviews with civil society organisations and participants in standards development.

Sources of information

Several types of information can shed light on these questions. This research used legislative analysis and document review, as well as interviews with civil society organisations and participants in standards development.

To understand whether a regulatory gap exists, the AI Act's text was analysed in conjunction with documentation related to other elements of the European standardisation system. Because the AI Act is part of a larger governance framework, it is not possible to identify a regulatory gap without considering whether it is filled by other policies.

Based on their experience, those involved in standards development are best placed to understand whether and how civil society organisations can provide missing legal and policy expertise in standards development for the AI Act.

Interviews with experts (i.e., interviewees) involved in the development of standards for the AI Act, as well as experts with experience in standards development more generally, helped to answer these questions.

Interviewees were mainly experts who are part of working groups of Joint Technical Committee 21 (JTC-21), which is responsible for developing standards to implement the AI Act. JTC-21 is a technical committee created by two of the three European Standards Organisations (ESOs): the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC), jointly referred to as CEN-CENELEC.

JTC-21 working group experts include both representatives of civil society organisations and technologists from industry and academia. Most experts are employees of companies, acting as delegates of the national members of CEN-CENELEC to JTC-21.

Civil society organisations shared insight into the barriers to and facilitators of their participation in standards development. Interviews, workshops and polls – with representatives of organisations both with and without experience in standards development – provided guidance on the resources, policies and norms that can promote or undermine their effective participation.

A major limitation to this research was the small number of interviewees and workshop participants. The names of JTC-21 experts are generally not publicly available, which made it difficult to identify potential interviewees. In the civil society workshop, few participants felt confident contributing actively due to a lack of familiarity with European standardisation and AI.

For more information about interviewees and workshop participants, and the methods used in this research, see page 57.

The AI Act's fundamental rights and other public interest protections may be ineffective, due to the discretion the legislative text apparently affords industry in their interpretation.

Does the AI Act create a regulatory gap?

The AI Act's fundamental rights and other public interest protections may be ineffective, due to the discretion the legislative text apparently affords industry in their interpretation.

Modelled on the New Legislative Framework (NLF), the AI Act is designed in a way that assumes standards development bodies will develop the crucial details of high-level rules for the protection of fundamental rights and other policy goals. In the absence of standards, those decisions generally fall to individual companies.

In theory, the NLF restricts political and legal decisions to EU institutions and allocates technical questions about the implementation of legislation to standards development bodies.

In practice, the legislation leaves open many questions about how to operationalise fundamental rights protections and other policy goals, which leaves highly political questions to standards development bodies or companies that generally lack the expertise and incentive to implement them effectively.

What is the New Legislative Framework?

Like other EU legislation regulating certain technologies, such as boats and explosives, the AI Act is modelled on the NLF. The European Commission and Parliament have published several detailed descriptions of the logic behind the NLF and how it works.[15]

15 European Commission (2015). *Vademecum on European Standardisation in support of Union legislation and policies*, SWD(2015) 205 final, part I. Available at: https://ec.europa.eu/docsroom/documents/13507/attachments/1/translations; European Commission (2016). The 'Blue Guide' on the implementation of EU products rules 2016, Official Journal of the European Union, C 272/1. Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC0726%2802%29&from=EN; European Commission (2022). The 'Blue Guide' on the implementation of EU product rules 2022, Official Journal of the European Union, C 247. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C:2022:247:TOC

NLF legislation features essential requirements, which 'define the results to be attained, or the hazards to be dealt with, [without] specify[ing] the technical solutions for doing so'.[16] The European Commission requests the development of technical standards, known as harmonised standards, by European Standards Organisations (ESOs) to operationalise essential requirements, providing the 'precise technical solution'[17] to achieve the desired result.

Harmonised standards help companies to comply with essential requirements by operationalising policy language in a way technologists can understand. Alternatively, a provider can develop their own technical solution 'in accordance with general engineering or scientific knowledge laid down in engineering and scientific literature',[18] or by using other technical standards.

While voluntary, the NLF incentivises the use of harmonised standards by offering additional legal certainty, known as a presumption of conformity. This means a Market Surveillance Authority must begin with an assumption that any product designed in line with a harmonised standard complies with the relevant essential requirements, making it more challenging to punish a provider for non-compliance. Though they do not completely shield a manufacturer from liability for failure to meet essential requirements, harmonised standards offer authoritative guidance for satisfying essential requirements that are approved by the European Commission.[19] The Commission creates a presumption of conformity by citing a potential harmonised standard in the *Official Journal of the European Union*.[20]

This regulatory framework was developed as an alternative to including technical specifications in legislation, as the EU's legislative process was too slow to meet industry needs.[21]

16 European Commission (2016). The 'Blue Guide' on the implementation of EU products rules 2016, Official Journal of the European Union, C 272/1. Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC0726%2802%29&from=EN
17 European Commission (2016). Blue Guide 2016, section 4.1.1.
18 European Commission (2016). Blue Guide 2016, section 4.1.1.
19 European Commission (2016). Blue Guide 2016, sections 1.1.3 and 1.4.
20 European Commission (2016). Blue Guide 2016, section 4.1.2.2.
21 European Commission (2016). Blue Guide 2016, section 1.1.1.

EU institutions explain that they maintain the boundary between political and purely technical decisions by defining essential requirements precisely in legislation.

However, EU institutions consider it imperative to draft NLF laws in a way that ensures all political decisions remain with them, and only technical decisions are made by ESOs.[22]

What do ideal essential requirements look like?

EU institutions explain that they maintain the boundary between political and purely technical decisions by defining essential requirements precisely in legislation.[23] Failure to define essential requirements precisely and preclude misinterpretation by ESOs would risk 'delegat[ing] political powers to the ESOs and their members',[24] which EU institutions aim to avoid.

For example, it is the European Parliament's responsibility to define the maximum permissible level of exposure to a hazard in legislation.[25]

Another element of the NLF that helps to minimise ambiguity is that essential requirements typically set health and safety standards for physical products with limited ranges of use.[26] For example, an essential requirement in an NLF law regulating watercraft specifies maximum decibel levels for noise emissions.[27]

Although there is little general information about how the Commission determines whether a harmonised standard satisfies essential requirements, this determination is apparently based on whether the standard or design reflects the 'state of the art'.[28] According to the Commission, the 'assessment of whether requirements have been met

22 European Commission (2015). *Vademecum on European Standardisation in support of Union Legislation and policies*, part 1, section 3.1. Available at: https://ec.europa.eu/docsroom/documents/13507/attachments/1/translations

23 European Commission (2015). *Vademecum*, part 1, section 3.1. European Parliament (2010). Resolution of 21 October 2010 on the future of European standardisation (2010/2051(INI)), Official Journal of the European Union, C 70 E/56, paragraph 15. Available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2012:070E:0056:0067:EN:PDF

24 European Commission (2015). *Vademecum*, part 1, section 3.1.

25 European Commission (2015). *Vademecum*, part 1, section 3.1.

26 European Commission. *Harmonised Standards.* Available at: https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards_en (Accessed: 22 February 2023)

27 European Parliament and Council of the European Union (2013). *Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC*, Annex I(C), Official Journal of the European Union. Available at: https://eur-lex.europa.eu/eli/dir/2013/53/oj

28 European Commission (2016). The 'Blue Guide' on the implementation of EU products rules 2016, Official Journal of the European Union, C 272/1. Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC0726%2802%29&from=EN

or not [is] based on the state of technical know-how at the moment the product is placed on the market'.[29]

What is the role of civil society organisations in standards development?

The Regulation on European Standardisation, which underpins the NLF, requires ESOs to include civil society organisations representing certain societal stakeholders in the development of harmonised standards.[30] This helps to ensure that the interests of people and groups affected by standards are taken into account during their development.

Annex III of the Regulation lists the categories of stakeholder groups that ESOs must consult in the standardisation process. So-called 'Annex III organisations' include those representing consumer rights, workers' rights, environmental protection and small and medium enterprises (SMEs).[31] The Regulation on European Standardisation also empowers the European Commission to fund their participation.[32] A recital justifies this funding and mandatory participation by describing civil society participation as 'necessary'[33] for the safety and wellbeing of EU citizens, given the broad impact standards can have on society.

Why the AI Act does not conform to the New Legislative Framework

While the AI Act is structured as an NLF law, it diverges from EU institutions' characterisations of the NLF in several consequential ways.

Essential requirements in the AI Act are ambiguous, potentially leaving them open to interpretation by ESOs. They are worded imprecisely, and sources of clarification outlined in the AI Act and elsewhere appear to be insufficient. Substantively, they cover

29 European Commission (2016). The 'Blue Guide' on the implementation of EU products rules 2016, Official Journal of the European Union, C 272/1. Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC0726%2802%29&from=EN

30 European Parliament and Council of the European Union (2012). *Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation*, Article 5. Available at: http://data.europa.eu/eli/reg/2012/1025/2015-10-07

31 European Parliament and Council of the European Union (2012). *Regulation (EU) No 1025/2012*, Article 5 and Annex III.

32 European Parliament and Council of the European Union (2012). *Regulation (EU) No 1025/2012*, Article 5.

33 European Parliament and Council of the European Union (2012). *Regulation (EU) No 1025/2012*, Recital 22.

Essential requirements in the AI Act are ambiguous, potentially leaving them open to interpretation by ESOs. They are worded imprecisely and sources of clarification outlined in the AI Act and elsewhere appear to be insufficient.

fundamental rights and other policy areas that are not as easily quantified and operationalised as safety standards.

Additional sources of clarification from public authorities and international standards are likely to be insufficient.

Finally, ESOs' existing stakeholder representation is unlikely to cover all affected public interests. This is inconsistent with the logic behind the inclusion of Annex III organisations, which is to represent interests affected by NLF legislation.

Unclear essential requirements

Essential requirements for high-risk AI systems appear in Title III, Chapter 2 of the AI Act.[34] High-risk systems are categories of AI deemed to pose a particularly high risk to human health, safety or fundamental rights, such as AI used in education, worker management, biometric surveillance and access to essential services.[35]

As in other NLF legislation, the AI Act's essential requirements address human health and safety. Unlike most NLF laws, they also broadly address fundamental rights and apply to technologies that affect other policy goals, like the administration of elections.[36]

Essential requirements in the AI Act tend to be worded ambiguously. According to Article 9, the overall level of risk to fundamental rights and health and safety following a risk mitigation process must be 'acceptable'.[37] Training datasets must be assembled using 'relevant design choices'.[38] High-risk systems must exhibit an 'appropriate level of accuracy, robustness and cybersecurity'.[39]

34 European Commission (2021). *AI Act (proposal)*, Annex VI(3). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021PC0206
35 European Commission (2021). *AI Act (proposal)*, Article 6 and Annex III; European Commission (2021). *Explanatory Memorandum*, section 5.2.3. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021PC0206
36 European Commission (2021). *AI Act (proposal)*, Annex III; European Commission (2021). *Explanatory Memorandum*, section 5.2.3.
37 European Commission (2021). *AI Act (proposal)*, Article 9(4).
38 European Commission (2021). *AI Act (proposal)*, Article 10(2)(a).
39 European Commission (2021). *AI Act (proposal)*, Article 15(1).

It is doubtful that any of the potential sources of clarification for ambiguous essential requirements will be sufficient to meet the needs of providers of high-risk systems.

> The ambiguity of essential requirements is inconsistent with the Commission's description of harmonised standards, which must be defined precisely to avoid delegating political power to ESOs.

For example, the Commission specifically uses the choice of a maximum hazard exposure level as an example of a political choice that must remain with lawmakers. In contrast, the AI Act leaves decisions about acceptable levels of risks related to fundamental rights to ESOs and providers.

Moreover, human rights law is far less amenable to quantification, and far more open to interpretation, than safety standards. This is likely to create new challenges for industry technologists trying to operationalise essential requirements.

Inadequate alternative sources of clarification

The AI Act and the EU's standardisation strategy potentially provide sources of clarification for ambiguous essential requirements, these include: references to the state of the art; European Commission and member state guidance; international standards; and stakeholder representation. However, it is doubtful that any of these sources will be sufficient to meet the needs of providers of high-risk systems. Each source is explored in detail below.

The state of the art

As in other NLF laws, the AI Act implies that the state of the art can help providers and ESOs understand how to comply with essential requirements. However, this is largely inapplicable where fundamental rights are concerned.

Article 9, which describes the risk management system used to determine the overall level of risk to fundamental rights permitted in a high-risk system, states that the designer should 'take into account

the generally acknowledged state of the art'.[40]

Similarly, Recital 49 explains that high-risk systems must 'meet an appropriate level of accuracy, robustness and cybersecurity in accordance with the generally acknowledged state of the art'.

The Commission sought to clarify the meaning of 'state of the art' in its draft standardisation request to CEN-CENELEC. Here they said the term 'should be understood as a developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience and which is accepted as good practice in technology. The state of the art does not necessarily imply the latest scientific research still in an experimental stage or with insufficient technological maturity.'[41]

More generally, the Commission's Explanatory Memorandum accompanying the AI Act proposal states that the 'precise technical solutions to achieve compliance with [essential] requirements may be provided by standards or [...] otherwise be developed in accordance with general engineering or scientific knowledge at the discretion of the provider of the AI system'.[42]

During a discussion at a panel event in 2021 hosted by the Center for Data Innovation with members of the European Parliament and others, a Microsoft representative confirmed that the Commission will accept design solutions to address essential requirements that are based on the state of the art.[43]

However, an allusion to the state of the art is unlikely to answer questions about what constitutes an acceptable level of risk to fundamental rights, or what constitutes an appropriate level of accuracy. Unlike the measurement of noise emissions with decibel levels, there is no agreed, one-dimensional metric for measuring risk to fundamental rights, and any metric that is developed will be highly contested.

40 European Commission (2021). *AI Act (proposal)*, Article 9(3). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021PC0206

41 European Commission (2022). *AI Act: Draft Standardisation Request*, No 1025/2012, Annex II. Available at: https://artificialintelligenceact.eu/wp-content/uploads/2022/12/AIA-%E2%80%93-COM-%E2%80%93-Draft-Standardisation-Request-5-December-2022.pdf

42 European Commission (2021). *Explanatory Memorandum*, section 5.2.3. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021PC0206

43 Center for Data Innovation (2021). 'What's Next on the EU's Proposed AI Law?' [Webinar]. Available at: https://www.youtube.com/watch?v=vdcSKXeiDAU&t=3335s

Whether a rule or practice violates human rights law tends to be context dependent and determinations typically involve balancing various rights and interests. Unlike hearing loss injuries, human rights violations usually cannot be easily quantified or reduced to either-or decisions to demarcate acceptable from unacceptable risk levels.

Furthermore, even if state of the art standards in human rights law and related policy areas existed, the lack of relevant legal and policy expertise in ESOs would make it difficult to identify them.

This means that the state of the art is unlikely to provide sufficient guidance for operationalising essential requirements related to fundamental rights.

Guidance from the European Commission and member states

The AI Act also envisions ways in which the European Commission and EU member states can provide authoritative interpretations of essential requirements directly to providers. These include common specifications; guidance from a European Artificial Intelligence Board; harmonised standards (HAS) consultants; regulatory sandboxes; and a dedicated communication channel.

However, few details are provided in the legislation or elsewhere about whether or how these resources will be provided. Without information about their implementation, it is difficult to predict whether any will be sufficient to clarify essential requirements. Based on the information available, this appears doubtful.

European Commission guidance

Several aspects of the AI Act and the EU's standardisation policy enable the Commission to provide guidance for interpreting essential requirements.

Article 41 of the AI Act empowers the Commission to essentially create its own harmonised standards, called common specifications, for providers to use if ESOs' harmonised standards are incomplete or insufficient. However, there are no publicly available plans in place to develop common specifications, so it is unlikely these will be available to industry when the AI Act comes into effect.

Article 58(c) describes the tasks of a newly established European Artificial Intelligence Board, part of which is to 'issue opinions, recommendations or written contributions on matters related to [...] technical specifications [...] regarding [essential] requirements'.

This language suggests that the Board could issue specifications that operationalise essential requirements like appropriate accuracy levels and acceptable levels of risk to fundamental rights for various types of high-risk systems.

While there are no detailed, publicly available plans in place for the Board, it is unlikely the Board would be sufficiently responsive to providers' questions while juggling advisory work with other administrative tasks.[44]

On 5 December 2022, the Commission issued a draft request to CEN-CENELEC to develop harmonised standards to support the AI Act.[45] This is the first formal step in the process of developing harmonised standards.

In line with its existing standardisation strategy, the European Commission can provide HAS consultants to ESOs during the standards development process to help interpret essential requirements.[46]

HAS consultants are private contractors from a consultancy firm who play two key roles in European standardisation. First, at certain stages of the standardisation process, they can provide feedback about whether existing drafts conform to an NLF law's essential requirements.[47] Second, they help the Commission to assess a standard to determine whether it should be cited in the *Official Journal*, creating a presumption of conformity.[48]

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44 European Commission (2021). *AI Act (proposal)*, Article 58. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021PC0206

45 European Commission (2022). *AI Act: Draft Standardisation Request,* No 1025/2012. Available at: https://artificialintelligenceact.eu/wp-content/uploads/2022/12/AIA-%E2%80%93-COM-%E2%80%93-Draft-Standardisation-Request-5-December-2022.pdf

46 Beltrão, A. and Legrand, T. (2018). 'HAS consultants assessment' [Presentation]. Available at: https://experts.cenelec.eu/media/Experts/Trainings/Harmonized%20Standard/has-consultants-assessment.pdf; European Committee for Standardization (CEN) (2021). *HAS assessment process*. Available at: https://boss.cen.eu/developingdeliverables/pages/en/pages/has_assessment_process/ (Accessed: 22 March 2023)

47 Beltrão, A. and Legrand, T. (2018); CEN (2021).

48 Beltrão, A. and Legrand, T. (2018). 'HAS consultants assessment' [Presentation]. Available at: https://experts.cenelec.eu/media/Experts/Trainings/Harmonized%20Standard/has-consultants-assessment.pdf; European Committee for Standardization (CEN) (2021). *HAS assessment process*. Available at: https://boss.cen.eu/developingdeliverables/pages/en/pages/has_assessment_process/ (Accessed: 22 March 2023)

However, it is questionable that private contractors can or should make such weighty decisions as to what constitutes an acceptable level of risk to fundamental rights, such as in the development of a biometric surveillance system used in the processing of asylum seekers.

It is unclear whether HAS consultants for AI Act standards would have expertise in human rights law or other policy goals, like the administration of elections. Calls for expressions of interest from consultants typically require a master's degree or experience in the relevant industrial sector, for example, but not in human rights law or other areas of public policy.[49]

Member state guidance

The AI Act also calls on EU member states to provide guidance for compliance. Articles 53 and 55 require or encourage member states to provide guidance or help through regulatory sandboxes (e.g. test beds) and 'dedicated channel[s] for communication' for smaller providers, respectively.[50]

However, as in the case of guidance from the Commission, the lack of detail makes it unclear how responsive this guidance will be to providers' needs.

International standards

Another potential source of clarification is international standards.

A large proportion of harmonised standards originates as international standards, later adopted by ESOs because of agreements between ESOs and their international counterparts to prioritise these standards.[51] This means that, if an international standard on a topic

49 See, for example: Ernst & Young. *Call for Expression: "Eco-design" (Directive 2009/125/EC & Several Regulations)*. Available at: https://assets.ey.com/content/dam/ey-sites/ey-com/en_be/topics/advisory/ey-has-eco-design.pdf (Accessed: 16 March 2023); Ernst & Young. *Would you like to become a Harmonised Standards Consultant?* Available at: https://www.ey.com/en_be/consulting/harmonised-standards-consultant (Accessed: 16 March 2023)

50 European Commission (2021). *AI Act (proposal)*, Articles 53(1) and 55(1)(c). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021PC0206

51 International Organization for Standardization (ISO) and CEN. *Agreement on Technical Co-operation between ISO and CEN (Vienna Agreement)*, section 4. Available at: https://boss.cen.eu/media/CEN/ref/vienna_agreement.pdf; ISO and CEN (2016). *Guidelines for the Implementation of the Agreement on Technical Cooperation between ISO and CEN*, 7th edition, p. 6, section 5.2 and Annex A.2.1. Available at: https://boss.cen.eu/media/CEN/ref/va_guidelines_implementation.pdf

An analysis of the AI Act's text reveals a possible regulatory gap. Without clear rules or authoritative guidance, it is unlikely that the Act's goal of protecting fundamental rights and other public interests will be realised.

already exists, an ESO generally cannot develop a conflicting standard on the same topic.

However, there is no indication that international standards currently under development will address the political facets of essential requirements.[52] Also, the lack of civil society participation suggests international standards are likely to suffer from similar shortcomings in terms of legal and policy expertise and will not provide the necessary guidance for AI Act compliance.[53]

Stakeholder representation

Stakeholder representation within ESOs could potentially facilitate the interpretation of essential requirements for fundamental rights and other public interests.

However, Annex III organisations include only those representing consumer rights, workers' rights, environmental interests and SMEs. These represent merely a fraction of the fundamental rights and other public interests implicated by the AI Act.

Nevertheless, civil society participation in the development of harmonised standards is likely to be the most promising strategy to fill the AI Act's apparent regulatory gap. It appears this is the only source of non-technical expertise with a record (discussed below) of providing advice about the protection of fundamental rights and other public interests to ESOs.

As such, policymakers would benefit from a better understanding of civil society organisations' current and future roles in European standardisation. In particular, it is important to understand whether rules governing their participation must be updated to accommodate an expanded remit in the development of harmonised standards for the AI Act.

52 ISO. *Standards by ISO/IEC JTC 1/SC 42: Artificial Intelligence*. Available at: https://www.iso.org/committee/6794475/x/catalogue/p/0/u/1/w/0/d/0 (Accessed: 16 March 2023)

53 ISO. *ISO/IEC JTC 1/SC 42 – About: Liaisons*. Available at: https://www.iso.org/committee/6794475.html (Accessed: 16 March 2023)

Open questions

An analysis of the AI Act's text reveals a possible regulatory gap. Although a core goal of the Act is to protect fundamental rights and other public interests beyond health and safety, it does not guarantee that clear rules or authoritative guidance will be available to providers to ensure this goal is realised.

This leaves open the questions of whether civil society participation in European standardisation could fill the gap and, if so, how policymakers can bolster this participation.

This research exposed high barriers to effective participation by civil society organisations in the standards-setting process, as well as several existing and potential facilitators of participation.

Experts' views on civil society participation

Interviews and reviewed documents exposed high barriers to effective participation by civil society organisations, as well as several existing and potential facilitators of participation.

While interviews with standardisation experts revealed perceived benefits to civil society participation, these generally did not include the interpretation of legislation or human rights law. This is largely due to Joint Technical Committee 21's (JTC-21) avoidance of these topics.

For more information on the methodology, as well as a list of experts who were interviewed, see page 57.

High barriers to effective civil society participation

Civil society representatives both with and without experience in European standardisation identified several significant barriers to effective participation. These include restrictive eligibility criteria for existing opportunities, burdensome time commitments, an inability to navigate complicated standardisation processes, industry dominance and a lack of awareness and interest.

Limited opportunities for civil society participation

Opportunities for participation by civil society organisations in JTC-21 are limited. These include participating as an Annex III organisation, a CEN-CENELEC liaison organisation, and direct or indirect participation through a National Standardisation Body (NSB). Even when an organisation qualifies for one of these opportunities, formal and practical impediments prevent it from wielding significant influence.

Barriers to effective participation by civil society organisations include restrictive eligibility criteria, the time commitment, the complex process, industry dominance and a lack of awareness and interest.

Participation as a liaison organisation

CEN-CENELEC conditions for liaison participation prevent most civil society organisations with expertise relevant to the AI Act's fundamental rights protections and policy goals from participating in JTC-21.

An organisation can apply to CEN-CENELEC for permission to participate in JTC-21 as a liaison organisation to represent interests affected by its standardisation activities.[54]

One eligibility criterion is that the organisation must have representatives in at least four CEN-CENELEC NSB member states, and those representatives must be businesses or organisations, rather than individuals.[55]

In a survey of workshop participants whose organisations have relevant expertise but are not involved in JTC-21, less than a quarter satisfied this requirement.

Interviewees, including both technologists and civil society representatives, could name only one liaison organisation currently involved in JTC-21. It is called ForHumanity and specialises in the independent auditing of AI and autonomous systems.[56] Few if any other liaison organisations represent non-commercial interests.[57]

Participation as an Annex III organisation

Few civil society organisations receive funding from the European Commission for participation in European standardisation.

As discussed above, the European Commission funds the participation of civil society groups representing consumer and labour rights, as well as environmental interests, and requires ESOs to include them in standardisation activities.[58] They are called Annex III organisations because the categories of organisations eligible

54 CEN. *European Partners: Liaison Organizations*. Available at: https://standards.cencenelec.eu/dyn/www/f?p=205:42:0::::FSP_ORG_ID,FSP_LANG_ID:,25&cs=1BBDD38C5C889B115AE5CD7D931EFA3BD (Accessed: 16 March 2023)

55 CEN-CENELEC (2021). *Guide 25: The concept of Cooperation with European Organizations and other stakeholders, Edition 3*, section 2.3. Available at: https://www.cencenelec.eu/media/Guides/CEN-CLC/cenclcguide25.pdf . NB As part of a student-led non-profit organisation, the author of this report applied unsuccessfully for liaison status in 2021.

56 See: ForHumanity. Available at: https://forhumanity.center/

57 CEN. *European Partners: Liaison Organizations*.

58 European Parliament and Council of the European Union (2012). *Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation*, Article 5. Available at: http://data.europa.eu/eli/reg/2012/1025/2015-10-07

for funding are listed in Annex III of the Regulation on European Standardisation.

However, the eligibility conditions are restrictive and the Commission funds only one organisation per stakeholder category. In the workshop held for civil society organisations, none met the eligibility requirement of having mandates from organisations in at least two-thirds of EU member states.

In theory, each Annex III organisation represents the views of their national counterparts. For example, the European Trade Union Confederation (ETUC) collects and represents the views of national trade unions in standardisation activities, including JTC-21 work. However, Annex III organisations find it challenging to interest their national counterparts in education and research on standards, according to interviewees Philippe Saint-Aubin, a JTC-21 expert working on behalf of ETUC, and Chiara Giovannini of ANEC, who represent their respective Annex III organisations in standards development.

Participation as a National Standardisation Body (NSB)
While eligibility criteria for participation in NSBs may be less strict, civil society organisations find it difficult to influence national standardisation activities.

At the national level, civil society organisations usually have opportunities to participate directly or indirectly in JTC-21 activities through their NSB's mirror committee or through public comments. A mirror committee exists to gather national stakeholders' views about the activities of a European or international technical committee, such as JTC-21.

Though the rules of NSBs vary, a civil society organisation generally has an opportunity to contribute feedback in a mirror committee and can potentially act as an NSB's delegate to JTC-21.[59] A delegate represents the positions of an NSB in standardisation activities, as NSBs make up the membership of CEN-CENELEC.

However, it can be difficult for civil society organisations to join and wield influence in an NSB mirror committee.

59 CEN-CENELEC. (2015). *Guide 20, Edition 4*, section 2. Available at: https://www.cencenelec.eu/media/Guides/CEN-CLC/cenclcguide20.pdf

Interviewee Chiara Giovannini of ANEC, an Annex III organisation representing consumer rights, finds that the consumer voice is 'frequently absent and disregarded' in NSBs. Contributions from Giovannini's national counterparts in NSBs have been disregarded because, by missing meetings, the organisations lost good standing, in accordance with the NSB's rules.

Even when they are able to participate, civil society representatives are usually vastly outnumbered and outvoted by company representatives. It was because of civil society's 'weak' representation in NSBs, relative to industry, that the European Parliament recognised the need for financial and political support for what are now known as Annex III organisations.[60]

NSBs also offer members of the public – including civil society representatives – the opportunity to read and comment on draft standards after registering for an account on the NSB's website.[61] This is possible during a limited period of time, after a CEN-CENELEC technical committee has completed a draft standard, and before all suggested amendments are considered in the comment resolution stage.

NSBs can consider public comments and decide whether to submit them to the CEN-CENELEC technical committee for consideration in the comment resolution stage. While most or all AI-related standards are not yet available for public review and comment, this option appears to be used rarely in all standardisation categories.

Giovannini also points to a lack of dedicated funds for civil society participation in NSBs as a barrier.

60 European Parliament (2010). Resolution of 21 October 2010 on the future of European standardisation (2010/2051(INI)), Official Journal of the European Union, C 70 E/56, paragraph 33. Available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2012:070E:0056:0067:EN:PDF

61 See, for example: British Standards Institution. *Healthcare: Latest standards activities*. Available at: https://standardsdevelopment.bsigroup.com/categories/006 (Accessed: 16 March 2023)

Time commitment

As a time-intensive process, European standardisation excludes many organisations that cannot afford to commit full-time personnel.

The development of a European or international standard generally requires between two and five years, according to interviewees David Filip, of the Organization for Standardization (ISO), and Philippe Saint-Aubin, who both participate in JTC-21's work. New areas like AI require closer to five years.

Saint-Aubin, a representative of the ETUC, an Annex III organisation, finds that each standard requires between two and ten hours per month for meetings, comments and reading. Earlier stages require less time, while the more significant comment resolution stage, during which proposed changes to a draft standard are negotiated and resolved, requires closer to ten hours.

Saint-Aubin judges that standardisation is too time-consuming for most trade unionists, who are already 'overbooked'. Interviewee Mary Towers, of the Trades Union Congress (TUC) in Britain, confirms this view, finding it difficult to juggle standardisation work with her many other responsibilities.

Participation in standardisation must also be continuous to be effective. In the experiences of civil society representatives interviewed, it was essential to attend every, or nearly every, meeting of a working group developing a standard to maintain the credibility necessary to influence the group.

According to Saint-Aubin, it is important to begin contributing as early as possible, during less critical stages of the process, to develop the standing necessary to influence the more important later stages; otherwise, their views will be disregarded. Early and continuous participation gives other experts confidence that one can be trusted to bring a valuable perspective to the process.

On a practical level, Mary Towers describes how, given the complexity of standards development, missing a single meeting or joining halfway through can also cause a civil society representative without extensive experience to feel confused about the proposal under consideration.

Additionally, a technical committee typically develops multiple standards at any given time, causing even Annex III organisations to refrain from contributing to many of them.

As such, Saint-Aubin reports that, despite their funding from the European Commission, even Annex III organisations lack the human resources necessary to participate in every working group of a technical committee. An organisation would likely require more than one full-time expert to participate actively in the development of all AI standards relevant to its mission.

Moreover, organisations like the ETUC are responsible for participating in standards development in areas outside of AI.

A small survey of civil society representatives not participating in JTC-21 activities, but whose organisations have expertise relevant to the AI Act's fundamental rights protections, revealed that none were certain their organisations could make this time commitment. Most were certain their organisations could not spare this much time, and only one was unsure. This time commitment was also the most frequently listed barrier to their potential participation in a question with open answers.

Opacity and complexity

The opacity and complexity of the standards development process can be particularly challenging to those without extensive experience**.** Mary Towers finds standards development to be 'distant' and 'difficult to navigate'. Even jargon is 'a real barrier' that can make the process 'inaccessible'.

Lack of awareness and interest

A lack of awareness and interest in standards development emerged as another key challenge for civil society representation.

Mary Towers has the impression that there is low awareness among trade unionists about the relevance of standards to their work. This is likely to be because standards development happens outside of their workplaces and does not fall within the realm of most workers' immediate experiences.

Philippe Saint-Aubin finds that national trade unions are interested in standards that impact workers more tangibly, such as those dealing with health and safety or human resources, and do not prioritise AI standards.

A consumer rights representative from the Annex III organisation ANEC has found it difficult to interest a coalition of civil society groups specialising in AI policy in standards development. Chiara Giovannini attempted to solicit feedback from the fifteen organisations in the coalition about how to reword ambiguous essential requirements, due to concerns about how they would be interpreted by ESOs, but received no feedback.

Industry dominance

Civil society representatives often find themselves unable to influence final decisions made in standards development because they are vastly outnumbered by industry representatives. This is problematic because industry preferences can conflict with the public interest.

Most experts in CEN-CENELEC working groups are employees of large companies, sent as delegates to represent NSBs. This is because few organisations, besides large companies, have the resources to pay full-time staff to work on standardisation, according to David Filip. When industry and civil society opinions diverge, industry views take precedence.

Decisions made by industry representatives can undermine the public interests civil society organisations aim to promote. For example, in European standardisation, Chiara Giovannini of ANEC finds that industry representatives tend to interpret ambiguous essential requirements in line with existing industry practices, even when these practices are inconsistent with the spirit of the legislation.

In the development of an international standard that defined maximum surface temperatures for household appliances, Giovannini found that industry representatives preferred to codify existing norms, despite rigorous empirical evidence that ANEC had gathered from scientific experts in burns hospitals demonstrating that these norms were unsafe. She believes this was because it would be more expensive to use alternative or thicker materials to prevent burns.

Giovannini also participated in the development of a European standard that the European Commission declined to reference in the *Official Journal* due to its failure to meet accessibility requirements.

Part of the standard addressed the degree of colour contrast featured in lift button panels and was intended to implement an EU Directive on lifts and lift safety components.[62] Those drafting the standard were primarily representatives of five dominant lift manufacturers in Europe, and they chose a colour contrast level that was deemed too low for visually impaired people.

Civil society representatives have little recourse in these situations. While delegates of NSBs – who are almost always industry representatives – have voting rights in CEN and CENELEC, civil society organisations do not.[63] Giovannini finds influencing a vote on a standard to be even more challenging than influencing the content of a standard.

While Annex III organisations have the right to appeal a decision, Giovannini finds that the process is too labour-intensive to exercise it as often as ANEC otherwise would.

NSBs may give civil society organisations voting rights when developing views for the NSB to bring to ESO technical committees, but industry votes usually or always outnumber them, according to Giovannini.

This lack of influence is reflected in standards' content. After contributing feedback to a 60-page standard, Saint-Aubin found that the ETUC's suggestions appeared in only one footnote. He says that this work can be disappointing. Giovannini recalls six years of ANEC contributions to the development of one standard, which resulted in the modification of only one line.

62 European Parliament and Council of the European Union (2014). Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts, Official Journal of the European Union. Available at: http://data.europa.eu/eli/dir/2014/33/oj

63 European Parliament and Council of the European Union (2012). Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, Official Journal of the European Union, Recital 23. Available at: http://data.europa.eu/eli/reg/2012/1025/2015-10-07; CEN-CENELEC (2021). *Guide 25: The concept of Cooperation with European Organizations and other stakeholders, Edition 3*, section 1.2.1. Available at: https://www.cencenelec.eu/media/Guides/CEN-CLC/cenclcguide25.pdf

Civil society organisations identified three facilitators of their participation in JTC-21. These include a central resource for information to facilitate ad hoc participation, funding and education.

At the same time, according to David Filip, who participates in JTC-21's work, even industry actors and technologists are 'lucky' if their contributions appear in one-to-three lines of a final product, given the intensive editing process involved.

Facilitators of civil society participation

Civil society organisations also shared views about what does or would facilitate their participation in JTC-21, or European standardisation generally. These include a central resource for information to facilitate ad hoc participation, funding and education.

Central resource for information

By acting as a hub for information and activity, Annex III organisations facilitate participation of national civil society organisations in standards development.

Mary Towers of the TUC in Britain participates in a standardisation committee for trade unions, as well as an AI taskforce, both organised by the ETUC, an Annex III organisation.[64] ETUC representatives share information and documents related to standardisation activities at the European and international levels via email, giving members of the committee and taskforce opportunities to provide feedback without participating in standardisation directly. This enables Towers to participate when she has enough time to do so.

In addition to gathering the perspectives of national organisations, Annex III organisations can also funnel positions *to* national organisations.

Chiara Giovannini describes ANEC as a hub of information used by national consumer rights advocates participating in NSB activities. ANEC provides research and positions to national counterparts that would like to participate in NSB activity but lack the resources to do so independently.

64 The author also participates in the ETUC AI taskforce.

Funding

Many interviewees identified funding as a vital resource for expanding civil society participation in European standardisation.

Giovanni points out that sufficient funding can enable organisations to set up specialised departments on standards development, hire experts to attend more meetings, organise lobbying campaigns and commission scientific studies to provide empirical evidence.

Likewise, Philippe Saint-Aubin, an expert working on behalf of the ETUC, thinks additional funding would be useful for organisations to hire more experts to participate, and Mary Towers identified funding as a critical resource.

> Given how crucial it is, Giovannini also argues that policymakers must choose to either significantly increase funding for civil society participation to represent the public interest adequately in standardisation or refrain from implementing public policy through standards.

Education and training

Raising awareness of the relevance of AI standards to civil society organisations, as well as training them to participate in European standardisation, is also likely to be essential in promoting effective civil society participation.

According to Philippe Saint-Aubin, even with more funding for civil society participation, organisations would still be hampered by a lack of potential experts. While national trade union members could potentially supply these experts to represent labour interests, they do not prioritise standardisation. This means few trade unionists are willing and able to navigate the AI standards development process.

Improving diversity of viewpoints was seen by JTC-21 experts as a key benefit of civil society participation in the standards-setting process.

Those without extensive experience and training that do venture into standards development often stop participating because of confusion about the process. Saint-Aubin thinks more education is needed about the importance of standards to workers, as is training in the procedures of standards development.

Similarly, Mary Towers identifies a need for more education about the relevance of standards within trade union affiliates, as well as training in the process of standards development. After organising a training session with ETUC representatives, Towers found that several of her colleagues became interested enough in standards development to attend a workshop about the design of the Alan Turing Institute's AI Standards Hub.[65]

The value of civil society participation

Interviews with JTC-21 experts, most of whom are technologists, focused on the benefit civil society organisations bring to AI standards development, as well as the costs. There was a particular focus on whether civil society organisations can support JTC-21 to interpret ambiguous key terms from essential requirements that relate to the protection of fundamental rights and other public interests.

> While most participants found inclusivity to be helpful by providing otherwise missing perspectives and information, the interpretation of ambiguous essential requirements was not identified as a benefit.

65 Alan Turing Institute. *AI Standards Hub*. Available at: https://aistandardshub.org/ (Accessed: 24 March 2023)

Providing diversity of viewpoints and building consensus

Standardisation experts generally found civil society participation in standards development beneficial or even essential.

David Filip, the convenor of a working group on AI trustworthiness in the ISO, has found Philippe Saint-Aubin's contributions to various standardisation activities valuable.

Filip noticed that the ETUC representative shaped the working group's agenda. Saint-Aubin contributed to the development of a roadmap for the group's standardisation activities and highlighted opportunities to promote the 8th UN Sustainable Development Goal (SDG), which focuses on decent work and economic growth.[66]

This is relevant because the ISO encourages the development of standards that help users address SDGs, and others in Filip's working group tend to focus mainly on the 9th SDG, which addresses industry, innovation and infrastructure.[67]

Based on these experiences, Filip thinks it is important to have a more 'representative' and 'balanced' standardisation process, because 'the stakes are too high' in the field of AI to exclude non-industry voices.

He finds that having the right team in place from the beginning of a standardisation project is the most important factor in the project's success, and that a more inclusive group with civil society representation can help the group to see an issue from every angle.

While chairing a working group in the Institute of Electrical and Electronics Engineers (IEEE) that is developing a standard for algorithmic bias considerations, Ansgar Koene, who represents the British Standards Institution (BSI) in JTC-21, has noticed civil society representatives and others with non-technical backgrounds making unique contributions to high-level thought and planning.

66 United Nations Development Programme (UNDP). *What are the Sustainable Development Goals?* Available at: https://www.undp.org/sustainable-development-goals (Accessed: 22 February 2023)

67 UNDP. *What are the Sustainable Development Goals?*; ISO. *Sustainable Development Goals*. Available at: https://www.iso.org/sdgs.html (Accessed: 22 February 2023)

While interviewees find high-level civil society feedback to be valuable, they do not seek input about interpreting legislative terms or human rights law in JTC-21 activities.

Participants without computer science backgrounds sparked the idea for annexes covering cultural dimensions of bias and different jurisdictions' legal approaches, which would otherwise not have been included. The annex on varying cultural norms is intended to help providers adjust risk assessments for bias in different cultural contexts.

Participants with social science backgrounds led the stakeholder identification activities, helping Koene's group to identify stakeholders beyond the more obvious categories of people with specific legal protections.

Koene finds civil society input particularly useful for the 'cultural dimensions' of standards development and identifying sensitivities. He says that lived experience shared by civil society representatives can be the most valuable input.

Adam Leon Smith, another BSI representative in JTC-21, who also gained experience in international AI standardisation prior to JTC-21, finds civil society participation beneficial when the participants have relevant subject-matter expertise. For example, he would find it helpful to have an expert in homelessness involved in the development of a standard related to banking, given the particular challenges this group might face, but not necessarily an expert in voting rights.

Another benefit of civil society participation, according to David Filip, is that it helps to build a more durable consensus. If a standard is developed to reflect the views of all affected interests, it is less likely that excluded interests will identify and object to shortcomings at a later stage.

Even when standards developers focus only on implementing legislation, rather than interpreting it, Chiara Giovannini of ANEC finds broad stakeholder participation beneficial. For example, a standard for record-keeping procedures may not require experts to interpret human rights law directly, but decisions they make can indirectly affect a person's human rights, such as the right to an effective remedy. In these cases, it is useful to have civil society representatives present to spot issues and make recommendations.

There were few perceived downsides to participation by civil society organisations. While David Filip finds that greater inclusivity increases the amount of time needed to reach a consensus, he judges that its benefits outweigh the time costs.

Avoiding legislative interpretation

Interviewees report that JTC-21 working group experts tend to avoid making more granular decisions about interpreting ambiguous legislative terms pertaining to fundamental rights and related public interests. Experts, including both technologists and civil society representatives, feel that these decisions should be made primarily by lawmakers. As a result, they do not seek this input from civil society representatives.

Ansgar Koene observes that JTC-21 working group experts 'dance around' questions raised by the interpretation of terms like 'appropriate level of accuracy'. His sense is that experts feel they 'do not have the right' to make these decisions, as the issues are too 'sensitive', and JTC-21 has not been authorised to define societal norms.

Instead, his working group and others in JTC-21 focus on procedures and documentation that will enable public authorities to assess a system's compliance with policies they have made, such as thresholds they have set for accuracy or risk levels. These standards will instruct a provider about which steps to take, or which boxes to tick, to demonstrate that issues like fundamental rights have been considered fully, and how to document these steps. They will not specify thresholds or benchmarks to meet.

Adam Leon Smith witnessed a similar tendency in the development of an international standard on algorithmic bias. Although this standard does not implement legislation, the committee frequently discussed whether or how to address fairness. Ultimately it avoided defining fairness because there was too much cultural variation in its meaning.

From David Filip's perspective, there are two major challenges to standardising human rights protections.

The first challenge is that human rights risks in AI are multi-dimensional, making it infeasible to develop a single metric to measure risk to fundamental rights. In contrast, product safety standards developed for most New Legislative Framework (NLF) legislation typically address one-dimensional risks to human life or physical injuries.

Where fundamental rights are concerned, multiple rights may be implicated by AI. A developer may need to make difficult legal assessments about a design feature that protects one right but interferes

with another right. Legal balancing tests and similar analyses normally fall within the purview of a constitutional court or legislature, which have the expertise and legitimacy to make such determinations.

According to Filip, a technical committee can determine how to minimise the number of workers killed by machinery, for example, but not which degree of privacy intrusion is acceptable to prevent a worker from being injured. This is an 'unsolvable problem' for which JTC-21 cannot and will not take responsibility.

The second challenge is that the standardisation of risk management for a product depends on the sequential development of several interdependent standards.

For example, Filip's ISO working group on trustworthiness first defines qualitative characteristics of trustworthiness in standards, such as robustness, and then determines how to measure them in subsequent standards. From his perspective, only after these steps are complete does it make sense to require a certain threshold of a characteristic in law.

Equivalent preliminary standards would be necessary to develop the standards envisioned in the AI Act. However, that work has not yet been completed, and will not be complete before the AI Act goes into effect, in 2023 or 2024.

Similarly, James Davenport, a representative of the BSI, thinks that, in the absence of operationalised definitions of risks to human rights that are produced by lawmakers or otherwise socially accepted, JTC-21 cannot develop standards for acceptable levels of risk.

Davenport illustrates this point with the hypothetical example of avoiding gender-based discrimination resulting from the use of hiring software (a type of high-risk AI system). He points out that no UK or EU law specifies whether the output of a shortlisting programme should be a list in which there are equal numbers of applicants with each gender, the proportion of each gender reflects the original applicant pool, or some other pattern.

Yet 'no answer is not good enough for a computer programme', says Davenport; they 'need to have an answer'. He thinks it is 'not reasonable' for policymakers to ask something of standards development bodies that policymakers have not done themselves.

Without operationalised definitions of risk to fundamental rights, questions about what constitutes acceptable or appropriate levels are 'not scientifically sound', according to Davenport. For this reason, he thinks that it is not helpful to have civil society organisations available to help interpret these provisions of the AI Act.

On the other hand, Davenport is confident that JTC-21 can deliver process-oriented standards. Representatives of Annex III organisations hold similar views.

Philippe Saint-Aubin, an ETUC expert, states that 'nobody wants standards to replace law and policy', so standards development organisations aim to avoid specifying what should be covered in national laws. Rather than creating substantive rules that overlap with regulation, Saint-Aubin encourages the incorporation of social dialogue in international standards affecting workers' rights. This is because different national trade unions may have different views, and some workers may end up in a worse position with a uniform set of rules.

The European Commission and Parliament should explore strategies to increase the representation of civil society organisations in the standards-setting process.

How to fill the regulatory gap: analysis and next steps for policymakers

Summary of the research findings

An analysis of the AI Act and documents pertaining to EU standardisation policy suggests that the AI Act does create a regulatory gap. Neither the legislative text, nor harmonised standards implementing the legislation, are likely to answer challenging legal and political questions raised by essential requirements.

Little information is available about most other potential sources of authoritative interpretations of essential requirements, but the evidence suggests they will be inadequate to meet providers' needs.

Although Joint Technical Committee 21 (JTC-21) aims to avoid interpreting the AI Act's essential requirements for fundamental rights and related public interests when developing standards, most of the standardisation experts interviewed value inclusive civil society representation. Their expertise can provide otherwise missing viewpoints and knowledge and facilitate consensus-building.

However, civil society organisations face significant barriers to effective participation in JTC-21 and standards development generally. While there are several opportunities for direct civil society participation in JTC-21, most civil society organisations are ineligible to take advantage of them, and those that do face major barriers to participating effectively.

Challenges include the size and inflexibility of the time commitment, the opacity and complexity of the standardisation process, disempowerment by industry dominance in the standardisation process and a lack of awareness about the relevance of European and AI standards. Though eligibility criteria for public comments can be less restrictive, this option limits participation to a narrow window of time, and civil society groups appear to be unaware of or uninterested in it.

Feedback from civil society representatives suggests several resources could increase the amount and effectiveness of their participation in standards development. These include education about the relevance of standards to organisations' missions, training in how to participate and funding for participants.

However, even with increased civil society participation in JTC-21, the ambiguity of the AI Act's essential requirements for fundamental rights protections and other public interests limits the types of standards deliverables JTC-21 can produce.

This means JTC-21's harmonised standards are unlikely to clarify how providers can comply with the AI Act's essential requirements for the protection of fundamental rights and related public interests. This leaves challenging political and legal questions to providers.

These findings suggest that EU policymakers should explore strategies to boost civil society participation, while also exploring institutional innovations to fill the regulatory gap.

Expanding civil society participation in JTC-21

The European Commission and Parliament can explore several strategies to bolster civil society participation in JTC-21. These include increasing the number and diversity of Annex III organisations, expanding eligibility criteria for Commission grants to individuals and creating or incentivising the creation of a civil society hub.

This could increase JTC-21's viewpoint diversity and balance the relative representation of public and commercial interests.

Why increase civil society participation?

There are several reasons why the European Commission and Parliament should develop strategies to boost the number and effectiveness of civil society organisations in JTC-21.

First, civil society representatives with expertise in human rights law and public policy provide valuable input, even if that input does not involve interpreting legislation or human rights law.

Civil society participation in standards-setting provides increased diversity of viewpoints and can create more balanced decision-making.

They can provide missing perspectives and information, such as different cultural perspectives on ethical questions or lived experience, which Ansgar Koene, who represents the BSI in JTC-21, found useful in the development of a standard on algorithmic bias considerations.

As an ANEC representative pointed out, they can identify and make recommendations for indirect human rights impacts, such as the ways in which record-keeping practices can impact the enforcement of human rights protections.

Second, a more equal balance of civil society representatives and employees of large companies could avert decisions made in companies' interests that conflict with the public interest.

JTC-21 may be less likely to design standards in line with existing industry practice when empirical evidence shows that alternative interpretations produce better outcomes for the public (although nothing suggests that this is currently a problem in JTC-21). Whereas a lone ANEC representative may be unable to influence a working group dominated by industry representatives who have voting rights, as Chiara Giovannini of ANEC has found, a coalition of civil society representatives may be more successful.

Even if expanded participation may prolong the consensus-building process, the benefits for increasing the quality of the standard will likely outweigh the time cost, according to JTC-21 participant David Filip. This is particularly relevant where harmonised standards are concerned; the Commission frequently declines to cite potential harmonised standards in the *Official Journal* since harmonised standards (HAS) consultants find they do not conform to essential requirements.[68]

How can civil society representation be increased?

In light of these benefits, the European Commission and Parliament should explore strategies to increase the representation of civil society organisations in JTC-21.

68 European Commission (2022). *Report on the implementation of the Regulation (EU) No 1025/2012 from 2016 to 2020*, COM(2022) 30 final, section 2.7.1. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52022DC0030

Several options have emerged from this research, including:

- broadening the categories of Annex III organisations eligible for funding and mandated participation by amending the regulation on European Standardisation, and increasing funding for organisations' participation in line with this
- funding more individuals from civil society organisations with the Commission's specialised StandICT grants, including for participation in national delegations
- exploring ideas for the creation of a central hub to support civil society participation.

Amend the regulation on European Standardisation

Annex III of the Regulation on European Standardisation lists the types of civil society organisations eligible for EU funding and mandated involvement in European standardisation. Currently the list includes groups representing consumer, environmental, small and medium enterprises (SMEs) and social interests, with social interests defined as employees' and workers' rights.[69]

Parliament could amend the Regulation to add new categories of stakeholder groups to Annex III.[70] Categories could correspond to each of the fundamental rights and policy areas implicated by the AI Act's essential requirements and high-risk systems, such as privacy and surveillance, fair elections and the right to an education.

The logic behind the Regulation on European Standardisation arguably demands this amendment. The Regulation justifies the participation of Annex III organisations by standards' 'broad impact on society',[71] making it 'necessary [to strengthen] the role and the input of societal stakeholders'.[72]

69 European Parliament and Council of the European Union (2012). Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, Official Journal of the European Union, Recital 17 and Annex III. Available at: http://data.europa.eu/eli/reg/2012/1025/2015-10-07

70 Although Annex III can be amended in a delegated act by the Commission alone, a delegated act can only be used to change the eligibility criteria of a stakeholder category, but not add new categories. See: European Parliament and Council of the European Union (2012). Regulation on European standardisation, Article 20(b).

71 European Parliament and Council of the European Union (2012). Regulation on European standardisation, Recital 22.

72 European Parliament and Council of the European Union (2012). Regulation on European standardisation, Recital 22.

Yet the shortlist of Annex III organisations was created a decade ago, when New Legislative Framework (NLF) laws dealt mainly with single-use manufactured products, and essential requirements dealt mainly with health and safety.

Given that the AI Act will expand the scope of standards' societal impacts on fundamental rights generally, as well as a variety of new policy areas, the breadth of interests represented by Annex III organisations should expand correspondingly. Otherwise, stakeholder input would reflect only a narrow portion of standards' societal impacts.

Consequently, the European standardisation system would privilege environmental interests over students' interests in the development of standards for AI used in education, for instance, which would not prioritise the interests most affected.

Amending Annex III would mitigate some of the challenges to effective civil society participation identified in this research. It would create new funding opportunities, particularly for organisations that wish to hire experts to focus on standards development full-time, as civil society representatives often struggle to meet the demanding time commitment along with their other responsibilities.

Increasing the number of potential Annex III organisations could also help to balance the numbers of experts representing public and company interests. Another outcome might be an increase in more ad hoc participation by creating new hubs for civil society activity.

One Annex III organisation, the European Trade Union Confederation (ETUC), solicits feedback from national trade unions and some civil society organisations and experts focused on labour rights to inform its work in European and international standardisation. Another, ANEC, feeds information to national consumer rights groups that wish to participate in National Standardisation Bodies (NSBs).

New Annex III organisations could play these roles for different interests impacted by the AI Act. As a result, harmonised standards developed by JTC-21 would be more likely to successfully implement the AI Act's essential requirements.

Expand StandICT grant eligibility

Through the StandICT.eu Fellowship Programme, the European Commission provides funding for European standardisation experts to participate in standards development. Funds can be used for travel expenses or time to participate in or prepare for meetings.

While the most recent call for applications welcomes those with expertise in some areas relevant to the AI Act's essential requirements, such as data governance, privacy and justice, it does not reference fundamental rights generally.[73]

With its influence, the Commission could encourage the programme to expand eligibility criteria to include those who have expertise in additional fundamental rights and policy areas.

Additionally, the StandICT website states that funds are only available for international standardisation activities, suggesting they are available for work in the International Organization for Standardization (ISO) but not in CEN-CENELEC. However, funds can be granted for work in CEN-CENELEC and other standardisation organisations. This should be clarified so that civil society organisations wishing to participate in JTC-21 or NSB mirror committees know they can apply for funding.

Dedicated civil society hub

The European Commission could also create or fund a hub for civil society participation in European standardisation. This hub could institutionalise activities already carried out by the ETUC and ANEC that enable organisations and experts to contribute to European standardisation when they otherwise could not. Its design could be based on best practices derived from other central resources created for standardisation.

A civil society hub could be designed to mitigate several of the challenges to effective civil society participation.

73 StandICT.eu (2022). *StandICT.eu 2023 - 7th Open Call*. Available at: https://www.standict.eu/standicteu-2023-7th-open-call (Accessed: 22 March 2023)

Through outreach to civil society organisations focusing on fundamental rights and public interests beyond health and safety, the hub could make organisations aware of the relevance of European standardisation to their organisations' missions. This would mitigate a major challenge to civil society participation, which is that most organisations are unaware of its importance, according to interviews with civil society representatives.

The hub could provide training and continued support on procedures, terminology, English language translations and other aspects of the standardisation process that tend to intimidate or frustrate the efforts of newcomers and ad hoc participants. This would mitigate problems observed by Mary Towers of the Trades Union Congress (TUC) and Philippe Saint-Aubin, an ETUC expert, in the chapter on 'Experts' views on civil society participation' (see pages 34-36).

It could also provide technical expertise to enable those without technical backgrounds to better understand standards' contents, reducing another barrier to effective civil society participation.

To facilitate ad hoc participation by organisations excluded by the time requirements, one or more point persons in the hub could collect and represent civil society views continuously throughout the standardisation process.

When designing the hub, the Commission could look to the successes and failures of other attempts to create central resources for participation in standards development.

One of these is the European Multi-Stakeholder Platform on ICT Standardisation, which is established by the Commission.[74] The Multi-Stakeholder Platform appoints very few civil society members, most of which are Annex III organisations.[75]

74 European Commission (2022). *European Multi-Stakeholder Platform on ICT Standardisation*. Available at: https://digital-strategy.ec.europa.eu/en/policies/multi-stakeholder-platform-ict-standardisation (Accessed: 22 March 2023)

75 European Commission (2022). *Register of Commission Expert Groups and Other Similar Entities: European Multi-Stakeholders Platform on ICT Standardisation (E02758)*. Available at: https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?do=groupDetail.groupDetail&groupID=2758 (Accessed: 22 March 2023)

Another example is the Alan Turing Institute's AI Standards Hub. Although the Hub is new, one of its stated aims is to educate and train stakeholders, including civil society, in international standards development.[76] The Commission may be able to learn about best practices and pitfalls to avoid.

Summary of strategies for increasing civil society participation

While some policymakers or industry representatives may object to these policies, arguing that they would require additional EU funding or improper interference with private entities, improved civil society representation can help to ensure essential requirements uphold fundamental rights and other public interests.

> According to Chiara Giovannini of ANEC, if policymakers wish to implement public policy through standards while relying on civil society to represent the public interest, then civil society participation must be funded adequately; otherwise, policymakers must disentangle standards from public policy.

Even with these changes, JTC-21's understandable reluctance to make political decisions on standards could create a fatal flaw in the AI Act's regulatory strategy, necessitating deeper reforms to the standards development process.

Institutional innovations for democratic control over essential requirements

If the AI Act continues to rely on a decades-old regulatory framework designed for product safety legislation, the European Commission and Parliament should explore possibilities for institutional innovations that adapt the NLF to the AI Act.

76 Ostmann, F. and McGarr, T. (2022). 'Introduction to the AI Standards Hub' [Presentation]. Available at: https://jtc1info.org/wp-content/uploads/2022/06/01_07_Tim_Florian_AI-Standards-Hub-intro.pdf

The European Commission and Parliament should explore institutional innovations that adapt the NLF to the AI Act.

As things stand, the AI Act's harmonised standards will not fulfil their intended function, which is to clarify for providers how to design AI in accordance with requirements about fundamental rights and other public interests. Neither the legislation nor other sources of clarification are likely to deliver this information.

Lacking authoritative interpretations of essential requirements, providers will face legal uncertainty in their attempts to comply with the AI Act. This would both negate the purpose of the NLF and endanger fundamental rights and other public interests.

Institutional innovations designed to answer tricky political and legal questions could fill this regulatory gap, while also creating opportunities for stronger democratic control and the inclusion of more legal and policy expertise in standardisation. This would be likely to result in the more successful implementation of the AI Act's public interest protections.

Why are institutional innovations required?

Preliminary interviews with JTC-21 experts revealed that they are generally unwilling to develop harmonised standards for essential requirements that involve political judgements, due to a perceived lack of legitimacy.

This aligns with EU institutions' views on the NLF, according to which 'essential requirements [...] should be defined precisely in order to avoid misinterpretation on the part of the ESOs or leaving them to make political choices'.[77] It is imperative to avoid the risk of 'delegat[ing] political powers to the ESOs'.[78]

Though the AI Act includes other potential sources of clarification for essential requirements, there is uncertainty about whether they will meet providers' needs.

A new European Artificial Intelligence Board will be empowered to provide advice about the implementation of the AI Act, including

77 European Commission (2015). *Vademecum on European Standardisation in support of Union legislation and policies*, SWD(2015) 205 final, part 1, section 3.1. Available at: https://ec.europa.eu/docsroom/documents/13507/attachments/1/translations

78 European Commission (2015). *Vademecum*, section 3.1.

technical specifications related to essential requirements.[79] However, the high-level outline of the Board's responsibilities in the proposal does not guarantee that the Board will fill the gaps left by JTC-21.

Even if the Board attempts to provide this guidance, it will juggle this task with other responsibilities, such as the coordination of member states enforcement and administration of regulatory sandboxes.[80] Whether the Board will have the resources and vision necessary to carry out all of these tasks effectively remains to be seen.

Additionally, the Commission can clarify essential requirements by issuing common specifications. Common specifications are implementing acts – a type of streamlined EU legislation – that are functionally equivalent to harmonised standards. They are permissible when harmonised standards are absent or insufficient to implement the AI Act.[81]

Finally, while HAS consultants may be on hand to clarify legislative terms and legal matters for JTC-21, this will not fill the regulatory gap if JTC-21 continues to avoid political questions. Were JTC-21 to reverse its position, this would raise concerns about the legitimacy of its decisions.

For the NLF to work with the AI Act, providers will need additional sources of authoritative guidance for essential requirements that have sufficient democratic or political legitimacy.

How could institutional innovations be implemented?

The European Commission can explore the possibilities of common specifications and a benchmarking institute to provide missing guidance in the implementation of the AI Act. These mechanisms could also create opportunities to build effective democratic control or oversight into the EU's AI governance policy, along with sufficient legal and policy expertise.

79 European Commission (2021). *AI Act (proposal)*, Article 58(c). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021PC0206

80 European Commission (2021). *AI Act (proposal)*, Article 58.

81 European Commission (2021). *AI Act (proposal)*, Article 41.

Common specifications

> The European Commission could use the AI Act as an opportunity to create a novel standardisation process that incorporates sufficient legal and policy expertise, while allowing for more democratic control.

Redesigning procedures for common specifications in a way that ensures civil society organisations and other experts are consulted more widely than in ESOs would be one way to do this.

Choosing the route of common specifications was seemingly ruled out when the Commission issued a draft request for harmonised standards in December 2022. Article 3 of this request compels CEN-CENELEC to ensure the appropriate involvement of 'civil society organisations, and the gathering of relevant expertise in the area of fundamental rights' in its standardisation processes. It remains to be seen how CEN-CENELEC will achieve this, but they will be required to provide relevant evidence in their final report.

If relevant safety and fundamental right protections are deemed inadequate in the harmonised standards, the Commission should withhold, and possibly leverage, the right to use common specifications instead. This process should gather the views of relevant bodies or expert groups that are not necessarily tied to an industrial sector. It could consult civil society organisations with expertise in a larger proportion of the legal and policy areas implicated by the AI Act's essential requirements.

The Commission could also explore the possibility of regularly consulting organisations that engage the public in policymaking when developing common specifications. This would introduce a higher degree of democratic control than would otherwise exist in decision-making by political appointees and civil servants or private contractors.

Though representatives of EU member states will have the opportunity to vote on the adoption of common specifications, national representatives in similar decision-making processes are

usually not elected officials. Instead, they tend to represent trade and economy ministries.[82]

Given that common specifications take the form of implementing acts, the public can potentially provide feedback via the Commission's 'Have your say' website, which would create new opportunities for ad hoc civil society participation in standardisation.[83] This could expand participation by organisations like the TUC that are effectively excluded by the time commitments typically required for standards development.

Benchmarking institution

The European Commission could explore similar ideas in a more targeted benchmarking institution.

This institution could take up the questions that JTC-21 avoids, complementing JTC-21's procedure- and documentation-oriented standards with more substantive standards. It could provide guidance about questions like how to measure risk to fundamental rights, and which thresholds are 'acceptable' or 'appropriate'.

The European Parliament's Committee on Industry, Research and Energy has proposed amendments that would prompt the European Artificial Intelligence Board to either design an independent benchmarking institution or house a benchmarking authority within the Board.[84]

At least one JTC-21 expert, Ansgar Koene, felt that a benchmarking authority could answer the more political questions about compliance with essential requirements left open by the committee's focus on procedure and documentation.

82 See, for example: European Commission (2020). *Committee on Standards: Summary record of the 21st Meeting Held on 8 November 2020*, p.3. Available at: https://ec.europa.eu/transparency/comitology-register/screen/documents/073077/1/consult?lang=en

83 European Commission. *Welcome to Have your say*. Available at: https://ec.europa.eu/info/law/better-regulation/have-your-say_en (Accessed: 22 March 2023)

84 European Parliament (2022). *Draft opinion of the Committee on Industry, Research and Energy for the Committee on the Internal Market and Consumer Protection and the Committee on Civil Liberties, Justice and Home Affairs on the proposal for a regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts,* COM(2021)0206 – C9-0146/2021 – 2021/0106(COD), Amendments 8, 58, and 100. Available at: https://www.europarl.europa.eu/doceo/document/ITRE-PA-719801_EN.pdf

Summary of institutional innovations

Common specifications and a benchmarking institution are only two examples of institutional innovations the European Commission and Parliament can explore to fill the regulatory gap created by the AI Act's NLF. Regardless of the particular strategy chosen, institutional innovations that modernise the NLF are probably necessary to ensure JTC-21 and providers have access to otherwise absent authoritative guidance on the interpretation of essential requirements.

EU institutions can take advantage of this modernisation by promoting more effective civil society participation. This would help to ensure essential requirements are interpreted in accordance with the views of experts in human rights law and relevant policy areas.

They can also use the opportunity to create new forms of democratic control over a rulemaking process that is currently dominated by private actors, which is arguably necessary to legitimise decisions in standards-setting that are more overtly political.

The suggestions in this discussion paper may prompt further questions for EU policymakers. Most importantly, what role do EU institutions expect standards to play in AI governance?

Further questions

These conclusions and suggestions are tentative, given how limited public information is about Joint Technical Committee 21 (JTC-21) experts and activities, and consequently, how difficult it is to gather empirical evidence through interviews and other means. This gives rise to its own questions:

Do EU institutions have a responsibility to publicise (or require CEN-CENELEC to publicise) JTC-21's activities, given how crucial they are to a landmark piece of legislation that directly implicates fundamental rights and other public interests?

For those who are or could be involved in the development of EU standards, including JTC-21 participants and civil society organisations, this paper raises questions about the role of civil society in the development of the AI Act. There are many approaches that would facilitate their involvement – this would support the protection of fundamental rights and therefore fulfil one of the primary goals of the AI Act.

> This research also raises broader questions about the AI Act and EU's New Legislative Framework (NLF) – what role do EU institutions expect standards to play in AI governance?

As originally conceived, the NLF ensures political decisions remain within EU institutions, and decisions made within European Standards Organisations (ESOs) are 'purely technical'.[85] The Commission's Explanatory Memorandum implies this is true of the AI Act, describing harmonised standards as 'precise technical solutions'[86] for designing AI that complies with essential requirements.

85 European Commission (2015). *Vademecum on European Standardisation in support of Union legislation and policies*, SWD(2015) 205 final, part 1, section 3.1. Available at: https://ec.europa.eu/docsroom/documents/13507/attachments/1/translations

86 European Commission (2021). *Explanatory Memorandum*, section 5.2.3. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021PC0206

However, the AI Act effectively delegates political decisions to ESOs, who are unequipped to make these decisions, leaving them to individual providers. This scenario is unlikely to ensure fundamental rights protections and related policy goals are realised. Nevertheless, the choice of the NLF for the AI Act implies that Parliament does not wish to make these granular decisions for industry.

Before voting on the AI Act, the European Parliament must understand the degree to which it is delegating consequential political power to private entities, which private entities are being empowered and whether amendments are necessary to safeguard public interests.

Parliament must also consider whether the NLF is suitable for AI governance and the protection of fundamental rights and other public interests. Rather than reforming European standardisation and the decades-old NLF to accommodate the AI Act, policymakers could avoid relying on European standards at all.

This raises broader questions for EU policymakers:

- Is a new political theory of AI governance necessary and, if so, what should it be?
- How could a governance framework be designed to effectively protect fundamental rights and better safeguard the public interest from conflicting corporate interests?
- How can it balance the incorporation of technical expertise with effective democratic control?

Legislative and policy analysis, interviews with JTC-21 working group experts and a workshop with civil society representatives were used to gather evidence for this paper.

Methodology

Several strategies were used to determine whether a regulatory gap exists in the AI Act, whether the gap can be filled by civil society participation in Joint Technical Committee 21 (JTC-21) and how to bolster civil society participation.

Legislative analysis and other policy analysis was used to determine whether a regulatory gap exists in the AI Act, particularly where the protection of fundamental rights and other public interests are concerned.

Interviews with JTC-21 working group experts and others with experience in standardisation were intended to clarify whether they consider it helpful or crucial to have civil society representatives involved in the interpretation and operationalisation of the AI Act's essential requirements.

The goal behind interviews with civil society representatives experienced in European or AI standardisation was to understand what facilitates or hinders their effective participation. This information informed a workshop with civil society organisations lacking this experience, in order to understand what would be necessary for them to participate effectively.

Additional information was gathered through document review.

Legislative and policy analysis

An analysis of the AI Act's text was carried out to reveal whether the legislation creates a regulatory gap, by depending on European Standards Organisations (ESOs) to operationalise ambiguously worded protections of fundamental rights and other public interests.

The legislation was analysed in conjunction with other sources and descriptions of EU standardisation policy, such as the Regulation on European Standardisation and the Commission's *Blue Guide*.

Semi-structured interviews with Joint Technical Committee 21 experts

Interviews with participants in JTC-21, the ESO technical committee responsible for AI Act standards, were designed to elucidate how the committee goes about interpreting the Act's essential requirements concerning fundamental rights and policy areas like election administration.

The goal was to understand whether JTC-21 working group experts will struggle to implement essential requirements in harmonised standards, and the degree to which civil society participation can help.

Although the European Commission's first standardisation request to JTC-21 is not yet finalised, the recently formed committee has begun preliminary work in anticipation of the first standardisation request. Experts include both representatives of civil society organisations and technologists from industry and academia.

Questions in semi-structured interviews with standardisation experts were built, in part, around understanding how experts plan to operationalise essential requirements related to fundamental rights and issues like election administration.

They asked, for example, about how working groups within the committee are approaching terms like 'appropriate level of accuracy', whether they have the legal and policy expertise needed to interpret and operationalise them, and what role civil society organisations play or have played in similar standards development.

Interviews with civil society representatives also focused on the barriers to and facilitators of their participation.

Interviews were held in the spring of 2022 through Zoom and Microsoft Teams, with follow-up questions sent by email.

Interviewees

The target group for interviews was JTC-21 working group experts and those with experience in European standardisation or AI standards development.

Because the names of JTC-21 participants are not publicly available, most interviewees were identified through news articles, websites and LinkedIn profiles after searching for variations of 'JTC-21'. Several interviewees were referred to the author of this paper by another interviewee or were already known to her.

Interviewees included:

- James Davenport, a computer science and mathematics professor at the University of Bath, and a representative of the British Standards Institution (BSI), the United Kingdom's National Standardisation Body (NSB), in JTC-21.

- David Filip, who focuses on global standardisation strategy for the Huawei Ireland Research Centre. He is a JTC-21 participant who also convenes a working group focused on trustworthiness in AI in the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC).

- Chiara Giovannini, a Deputy Secretary General and Senior Manager of Policy & Innovation at the European Consumer Voice in Standardisation (ANEC). She has experience in European and international standardisation.

- Ansgar Koene, the Global AI Ethics and Regulatory Leader at Ernst & Young. He represents the BSI in JTC-21, in which he convenes a working group on conformity assessment. He also chairs a working group in the Institute of Electrical and Electronics Engineers that is developing a standard on algorithmic bias considerations.

- Adam Leon Smith, the Chief Technology Officer of Dragonfly, who represents the BSI in JTC-21. He has experience in international AI standards development.

- Philippe Saint-Aubin, a JTC-21 expert working on behalf of the European Trade Union Confederation (ETUC), who has experience in AI standards development in the ISO and IEC.

- Mary Towers, an employment rights policy expert with the Trades Union Congress. She has represented her organisation in international standards development, with guidance from the ETUC.

Limitations

There were several limitations to these interviews. The number of interviewees was limited by the fact that the identities of JTC-21 participants are not publicly available. Of the experts whose names are publicly available, most declined interview requests.

Most NSBs did not respond to emails asking for referrals to their JTC-21 representatives. Most interviewees were based in the UK or Brussels, as most experts were referred or introduced to the interviewer by other interviewees.

Also, JTC-21 activity had only recently begun, and had done so before the European Commission finalised its first standardisation request. This means experts had relatively few experiences to draw from and were not certain about the exact scope of the work they would be asked to do.

Finally, because so few civil society groups are involved in JTC-21 and European standardisation broadly, the number of civil society representatives interviewed was necessarily small.

Workshop with civil society representatives

The views of civil society representatives that are not involved in European standardisation, but whose organisations' missions will be impacted by essential requirements, were gathered in a workshop.

Held online as part of RightsCon on 9 June 2022, the workshop both informed participants about the relationship between the fundamental rights, the AI Act and European standardisation, and also elicited feedback from participants about their organisations' abilities to engage effectively with JTC-21.

Questions were designed to understand what would be necessary or helpful for these organisations to participate in JTC-21 and were based on information gleaned in interviews and document review.

For example, one question asked participants whether they could meet the average time commitment for the development of a harmonised standard, which was information derived from interviews, with the options of 'yes', 'no' and 'not sure'. Another asked which organisations

satisfied the eligibility criteria for CEN-CENELEC liaison organisation status, which was information derived from document review.

Answers were submitted through two Mentimeter polls. One poll was directed to European civil society organisations, and another to other participants. Only the former is referenced in this paper.

Participants

Participants from at least one civil society organisation in each CEN-CENELEC member country (which includes countries that are not EU member states) were invited to the workshop. Representatives of organisations with expertise in each high-risk category were invited, as were representatives with organisations in fundamental rights more broadly. Invitations were also sent to organisations specialising in technology policy and human rights.

For example, representatives of anti-poverty organisations were invited to share their perspective on access to essential public services, a high-risk AI category.

Participants included an expert in the use of automation in the administration of justice; a policy analyst and a human rights lawyer from organisations specialising in human rights and technology policy; a representative of an organisation specialising in the use of technology to document human rights violations; and a representative of an organisation that promotes media freedom. Several participants contributed anonymously.

Additional RightsCon participants joined the workshop, which took the total number of participants to 25.

Limitations

There were several limitations to the workshop.

Although most invitees were from organisations that did not specialise in technology policy, most of the participants that accepted invitations were from such organisations. Those lacking familiarity with AI or technology policy generally tended not to reply, or to reply saying that

they felt uncomfortable discussing a topic outside of their area of expertise.

Those that did join attended on the condition that they would listen rather than actively contribute.

Though 25 participants attended the workshop, less than half answered questions in the Mentimeter polls and contributed to group discussions.

Document review

Additional information about European standardisation was gathered through the review of documents, such as publications from the European Commission and CEN-CENELEC rules of procedure.

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About the Ada Lovelace Institute

The Ada Lovelace Institute was established by the Nuffield Foundation in early 2018, in collaboration with the Alan Turing Institute, the Royal Society, the British Academy, the Royal Statistical Society, the Wellcome Trust, Luminate, techUK and the Nuffield Council on Bioethics.

The mission of the Ada Lovelace Institute is to ensure that data and AI work for people and society. We believe that a world where data and AI work for people and society is a world in which the opportunities, benefits and privileges generated by data and AI are justly and equitably distributed and experienced.

We recognise the power asymmetries that exist in ethical and legal debates around the development of data-driven technologies, and will represent people in those conversations. We focus not on the types of technologies we want to build, but on the types of societies we want to build.

Through research, policy and practice, we aim to ensure that the transformative power of data and AI is used and harnessed in ways that maximise social wellbeing and put technology at the service of humanity.

We are funded by the Nuffield Foundation, an independent charitable trust with a mission to advance social well-being. The Foundation funds research that informs social policy, primarily in education, welfare and justice. It also provides opportunities for young people to develop skills and confidence in STEM and research. In addition to the Ada Lovelace Institute, the Foundation is also the founder and co-funder of the Nuffield Council on Bioethics and the Nuffield Family Justice Observatory.

Find out more:

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