The role of standards and standardisation processes in the EU's Artificial Intelligence (AI) Act

What role do standards play in the AI Act?

The European Commission's proposal for an Artificial Intelligence (AI) Act is in many ways structurally derived from the EU's New Legislative Framework (NLF) for products, which relies on harmonised standards. Manufacturers ('providers') of AI systems will be heavily incentivised to follow harmonised standards because of the presumption of conformity established in Article 40 of the AI Act.

The European Standardisation Organisations (ESOs) will be responsible for setting these standards to ensure the consistent and clear application of technical rules across the EU (Article 40, AIA). However, the particularities and novelties of artificial intelligence systems are very different from the products traditionally covered by the NLF, raising specific and significant challenges for the use of standards for regulating AI systems.

Whilst harmonised standards are important for facilitating providers' uniform technical compliance with certain EU requirements, the draft AI Act should not delegate any decisions to standards bodies which may impact on key political and legal points. ESOs are private, bureaucratic organisations which are dominated by industry actors (including several multi-national corporations whose interests do not fully align with EU values). They are inaccessible to those without the resources to learn the processes and finance their involvement. Furthermore, ESOs lack representation from and meaningful engagement with civil society (especially at the national level), data protection regulators, accessibility experts, consumer rights groups and other relevant and/or impacted stakeholders. As ANEC asserts:

"The way the AI Act envisages the role of standards amounts to a de facto regulation by private bodies ... and thus a serious lack of democratic accountability."²

What would an approach to standardisation which respects and protects fundamental rights look like?

Harmonised standards must not be used to take decisions that require democratic scrutiny or legislative interpretation. Such decisions, with potentially severe implications on people's rights and freedoms, need to remain within the remit of the democratic process, supported by experts in areas such as equality and non-discrimination as well as in the socio-technical impacts of technology and data. Standardisation processes must be clearly ringfenced so that they cannot be misused to set standards which lower or circumvent existing human rights safeguards, thereby facilitating the development of technologies that are not aligned to EU values.³

The standards permitted under the AI Act must therefore be limited to ESOs' area of expertise, which is to develop technical standards which describe how to implement the decisions made by the EU's co-legislators. In order to achieve this, the requirements set in the Act should be sufficiently detailed as to avoid political or legal ambiguity.

1 The European Commission retains the right to adopt common specifications in respect of the requirements for high-risk AI systems (Chapter II, Title III, AIA) by means of implementing acts, where harmonised standards referred to in Article 40 do not exist or where the Commission considers that the relevant harmonised standards are insufficient or that there is a need to address specific safety or fundamental right concerns (Article 41, AIA).
2 https://www.beuc.eu/publications/beuc-x-2021-088_regulating_ai_to_protect_the_consumer.pdf
Fundamental rights, however, are clearly beyond the expertise and remit of ESOs and should not be subject to technical standardisation. Standards should also be subject to regular update mechanisms in order to include developments in technology which may pose additional or novel risks. Under the European Commission’s new Standardisation Strategy, standards should drive a free, open, accessible and secure internet, with a monitoring website to enable scrutiny and accountability.⁴ Publicly-available standardisation roadmaps, national hubs and ex post compliance tools can also support the proper application of standards.⁵

The joint civil society recommendation for obligations on users (i.e. deployers) of AI systems is an essential counterpart to the standards established in the AI Act. Placing obligations on users to conduct Fundamental Rights Impact Assessments (FRIAs) is necessary to ensure a comprehensive approach. This is because many of the risks and harms relating to AI systems arise in specific contexts of use and therefore cannot be fully foreseen by providers. Mandatory FRIAs by users are thus necessitated by the Act’s reliance on standards.

We recognise, but do not engage with here, the broader issue of standardisation and the need for horizontal reform of standardisation processes at EU level,⁶ particularly with regard to their application to other socio-technical areas of legislation similar to AI which equally do not lend themselves to NLF/technical standardisation processes.

Harmonised standards for the AI Act under Article 40 (Chapter 5, Title III), specifically, should:

- Enable providers to apply ‘clear, unambiguous and replicable’⁷ standards which embed security, privacy, data protection and accessibility by design and by default, and which are fully compliant with EU values and fundamental rights, for example by removing the presumption of conformity in Article 42.1 and by better setting the legal and political elements of Risk Management in Article 9;
- Explicitly limit the harmonised standards established in Art. 40 (for Title III, Chapter 2, Requirements for high-risk AI) to the technical aspects for which ESOs are responsible (meaning those relating to technical performance, documentation and processes, as well as procedural aspects where needed to sufficiently interpret the AI Act, and not those which may interpret fundamental rights, EU values or other aspects outside of the ESOs’ mandate, for example as is currently risked in Article 10.2.(f) on bias);
- Ensure that standards address the needs of all members of society via a universal design approach, and that accessibility becomes a cornerstone of the EU’s AI policy and development approach;
- Guarantee that relevant authorities, such data protection authorities, civil society organisations, accessibility experts, SMEs and environmental, consumer and social stakeholders are represented and enabled to effectively participate in AI standardisation and specification setting processes and bodies at European and national level;
- Ensure that harmonisation under the AIA is without prejudice to existing or future national laws relating to transparency; access to information; accessibility; non-discrimination and equality; and other relevant rights, in order to ensure that harmonisation is not misused or extended beyond the specific scope of the AIA; and
- Address issues of interoperability, transparency and the role of CE markings.

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⁴ [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13099-Standardisation-strategy_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13099-Standardisation-strategy_en)
⁵ [https://oxcaigq.ox.ac.uk/publications/harmonising-artificial-intelligence/](https://oxcaigq.ox.ac.uk/publications/harmonising-artificial-intelligence/)