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Harmonised Standards and Conformity Assessments in the AI Act: Strengthening Independent and Participatory Oversight

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ABOUT THIS PAPER

The position paper "Harmonised Standards and Conformity Assessments in the AI Act: Strengthening Independent and Participatory Oversight" was developed following the Weizenbaum Forum *"An Ecosystem for AI Accountability? Between Evaluation, Audit and Certification"* and reflects the Institute's ongoing interdisciplinary research on technological evaluation and governance of AI systems. In addition to its research-based objectives, this paper serves as a complementary contribution to the Weizenbaum Institute's official statement[1] on the draft bill for the national implementation of the EU Artificial Intelligence Act (AIA) issued by the Federal Ministry for Digital Transformation and Government Modernisation (BMDS).[2] It thereby underscores its interdisciplinary expertise in shaping responsible AI regulation.

1 Weizenbaum-Institut, Stellungnahme zum Referentenentwurf eines Gesetzes zur Durchführung der VO (EU) 2024, 1689.

2 Entwurf eines Gesetzes zur Durchführung der Verordnung (EU) 2024/1689 des Europäischen Parlaments und des Rates vom 13. Juni 2024 zur Festlegung harmonisierter Vorschriften für künstliche Intelligenz und zur Änderung der Verordnungen (EG) Nr. 300/2008 (Gesetz zur Durchführung der KI-Verordnung).

Weizenbaum Policy Paper

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Abstract

Adopted by the European Union in 2024, the Artificial Intelligence Act (AIA) constitutes a landmark framework for the regulation of AI systems within the EU's internal market. While recognising its significance for fostering accountability and trustworthy AI, this position paper focuses on two central mechanisms for its effective implementation: (1) technical standardisation and (2) conformity assessments. It argues that, in their current formulation, both mechanisms risk an excessive reliance on private governance, thereby constraining democratic oversight and the effective protection of fundamental rights.

The AIA implements its legal obligations through technical standardisation under Article 40, delegating detailed requirements to the European standardisation organisations. Compliance with these harmonised standards creates a presumption of conformity, giving companies strong incentives to follow them. Although the AIA introduces broader stakeholder consultation via the AI Board and Advisory Forum, participation remains non-binding, allowing large corporations to dominate standard-setting and raising concerns about democratic legitimacy and fundamental rights protection.

Under Article 43, conformity assessments verify whether high-risk AI systems meet AIA requirements before market entry. Most rely on internal self-assessment; external control is only required in very limited cases. While this reduces administrative burdens, it also risks weakening oversight, transparency, and protection of fundamental rights.

Contents

1 Introduction

As a horizontal regulatory framework, the AIA establishes obligations for providers, deployers, importers, and distributors of AI systems, with a particular focus on those AI-systems classified as "high-risk". Although we acknowledge the important legislative progress achieved with the AIA, we also identify shortcomings regarding its enforceability, democratic oversight and legitimacy, and capacity to ensure effective protection of fundamental rights. This position paper focuses specifically on two critical areas of the AIA that are key to its effective implementation: the role of technical standardisation and conformity assessments. These two mechanisms define both the substance of the AIA requirements and the manner in which compliance is verified. However, in their current form, both are characterized by inadequate transparency and democratic control.

In Section 1 we identify the legal architecture and the deficiencies of both the technical standardisation (1.2) and the conformity assessments (1.3) under the AIA, demonstrating a structural deficit in democratic oversight. Based on these analyses, the Weizenbaum Institute identifies five recommendations to ensure that the AIA's implementation achieves its trustworthiness and accountability goals to ensure and enforce continued compliance as AI systems, respectively, their functionalities can change, e.g. due to system updates or varying operational environments. Section 2 presents five concrete recommendations to address these gaps through: (2.1) mandatory third-party audits, (2.2) participatory oversight mechanisms, (2.3.) periodic re-auditing, (2.4) accessible redress mechanisms, and (2.5) participatory standardisation. We conclude with a short summary.

1.1 Identifying the Accountability Gap in the AI Act

In what follows, we highlight the legal architecture, current practice, and the deficiencies in creating oversight, one of four accountability goals[3], especially focusing on standardisation and conformity assessment procedures. We argue that these mechanisms reveal structural deficiencies in the Act: the risk of privatising accountability and the lack of third-party-audit mechanisms under the AIA, resulting in an imbalance in the distribution of democratic oversight.

3 Claudio Novelli, Mariarosaria Taddeo, and Luciano Floridi. "Accountability in artificial intelligence: What it is and how it works". In: Ai & Society 39.4 (2024), pp. 1871–1882.

1.2 Current Standardisation Practice and Its Limitations

Legal Framework: Harmonised Standards as Quasi-Normative Technical Standardisation (Art. 40 AIA)

The AI Act is based on the New Legislative Framework (NLF), which relies on co-regulation to concretise legal obligations into technical standards. Instead of specifying technical details in legislation, the AIA defines essential requirements and leaves the task of concretisation to the European standardisation organisations CEN and CENELEC through their joint committee, JTC21, in cooperation with national bodies such as DIN and DKE in Germany. Therefore, the AIA delegates much of the substantive definitions to harmonised technical standards developed by private standardisation bodies.[4] Harmonised standards provide legal certainty. Once adopted by the Commission, compliance with these standards creates a presumption of conformity with the AIA. As Ebers[5] explains it, companies can, in theory, develop their own technical solutions; the administrative difficulties and additional costs involved usually lead them to follow standards. Recognising these effects, the European Court of Justice (ECJ) has ruled that harmonised standards form "part of EU law" and must be developed and published in accordance with the rule of law.[6] Although harmonised standards are relatively unknown in digital law, they are a well-established tool in product safety law. Harmonised standards translate the AIA's general legal requirements into detailed technical procedures, ensuring consistency and flexibility across sectors. However, harmonised standards do not have any legal status, as European standardisation organizations are not democratically legitimate.[7] Despite of that, technical standards will create considerable incentives for compliance in practice. The source of their incentive effect lies in the presumption of conformity regulated in Article 40(1) of the AIA, according to which compliance with the legal requirements is presumed in favour of those subject to the standard if and to the extent that they adhere to the standards laid down in the harmonised standards when designing and controlling a high-risk AI system.[8] The awarding of standardisation mandates is governed in accordance with Art. 40(2) subpara. 1 sentence 1 AIA in conjunction with Art. 10 Regulation (EU) 1025/2012[9] in its basic features by the requirements known from product safety law, but is supplemented

4 Sandra Wachter. "Limitations and Loopholes in the EU AI Act and AI Liability Directives: What This Means for the European Union, the United States, and beyond Special Issue: Yale Information Society Project Digital Public Sphere Series". In: Yale Journal of Law and Technology 26.3 (2024), pp. 671–718. (Visited on 08/06/2025).

5 Ebers, Martin: When Guidance Becomes Overreach: How the forthcoming Code of Practice Threatens to Undermine the EU's AI Act, VerfBlog, 2025/4/08, https://verfassungsblog.de/when-guidance-becomes-overreach-gpai-codeofpractice-aiact/.

6 Ibid.

7 Ibid.

8 Gerdemann: Harmonisierte Normen und ihre Bedeutung für die Zukunft der KI (MMR 2024, 614).

9 Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council Text with EEA relevance.

and specified in Art. 40(2) of the AIA. The additional procedural requirements of the AIA consistently reflect the need for more democratic legitimacy because the regulation of high-risk AI systems is very relevant to fundamental rights entails compared to traditional product safety law. Thus, before issuing a standardisation mandate, the European Artificial Intelligence Board (the 'Board') pursuant to Art. 64 AIA must be consulted with the delegated representatives of the Member States, and the Advisory Forum established pursuant to Art. 67 AIA. Art. 67(2) AIA states that the membership of the advisory forum shall represent a balanced selection of stakeholders, including industry, start-ups, SMEs, civil society and academia. The membership of the advisory forum shall be balanced with regard to commercial and non-commercial interests and, within the category of commercial interests, with regard to SMEs and other undertakings.[10] Article 40(3) of the AIA also sets out various substantive objectives for the development of harmonised standards. It rules that the participants in the standardisation process shall seek to promote investment and innovation in AI, through increasing legal certainty, as well as the competitiveness and growth of the Union market, to contribute to strengthening global cooperation on standardisation and taking into account existing international standards in the field of AI that are consistent with Union values, fundamental rights and interests, and to enhance multi-stakeholder governance ensuring a balanced representation of interests and the effective participation of all relevant stakeholders in accordance with Articles 5, 6, and 7 of Regulation (EU) No 1025/2012. In these Articles the representation of interests and the effective multi-stakeholder governance is nonetheless no binding prerequisite of the standardisation process. Art. 5 states that national standardisation bodies shall encourage and facilitate the access for all stakeholders. Whereas this might have worked for the standardisation process in regards to product safety law, the regulation of high-risk AI systems is due to its fast development and socio-technical consequences in need of a broader and mandatory inclusion of stakeholder participation.

In May 2023, the EU Commission issued the mandate to develop the harmonised standards in accordance with Article 10 of the Regulation (EU) No 1025/2012.[11] With the standardisation mandate, the Commission pursued the goal of preparing the necessary technical environment for the implementation of the AI Regulation as early as possible. However, the fact that the AIA was not yet in force at that time also meant that the Commission was not required to comply with the participatory procedural rules set out in Article 40(2) and (3) when issuing the standardisation mandate. But even if these rules had already been in force at the time of the standardisation mandate, their wording remains non-binding. This is because Article 40(3) stipulates that *"the participants in the standardisation process shall seek (...) taking into account existing international standards in the field of AI that are consistent with Union values, fundamental rights and interests, and to enhance multi-stakeholder governance ensuring a balanced representation of interests and the effective participation of all relevant stakeholders*

10 Gerdemann: Harmonisierte Normen und ihre Bedeutung für die Zukunft der KI (MMR 2024, 614).

11 C(2023)3215 – Standardisation request M/593, COMMISSION IMPLEMENTING DECISION of 22.5.2023 on a standardisation request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation in support of Union policy on artificial intelligence

in accordance with Articles 5, 6, and 7 of Regulation (EU) No 1025/2012." CEN and CENELEC were obliged to ensure that the outcome of standardisation is consistent with EU law, in particular with the fundamental rights and values of the European Union, the public interest and data protection, and that there is appropriate stakeholder participation, including SMEs, consumer organisations and trade unions.[12] In practice, however Gerdemann[13] argues, the picture already familiar from product safety law is emerging in the relevant committees, whereby primarily resource-rich international companies are actively involved in the technically challenging standardisation process.

Standards are developed in processes that suffer from significant transparency and accountability limitations. Civil society organisations and academic experts are generally underrepresented and often only hold observer status, thus lack meaningful participation rights, and governance remains largely dominated by big industrial stakeholders.[14] These standards effectively define how compliance with the AIA's essential requirements is operationalised. As the European Commission states itself, the AIA sets result-oriented requirements and obligations but leaves the concrete technical solutions and operationalisation to industry-driven standards and codes of practice that are flexible to be adapted to different use cases and to enable new technological solutions.[15] While this approach allows for flexibility and technological adaptability, it also raises concerns regarding democratic legitimacy, transparency, and regulatory sufficiency. Wachter notes that the lack of participatory parity undermines the democratic legitimacy of these standards, which acquire quasi-normative status under EU law, even though they are developed outside public law processes.[16] Providers may also choose alternative technical specifications under Article 43(1)(2) AIA, but doing so creates greater legal uncertainty for the developers and providers and requires additional justification.

Given that these standards profoundly shape the interpretation of fundamental rights obligations this privatised norm-setting process raises constitutional and democratic concerns. From a legal perspective, delegating effective norm creation to private actors with insufficient public oversight may infringe principles of legality, proportionality, and democratic legitimacy. Ebers underlines that this form of delegated legislation through harmonised standards is problematic, primarily because of the lack of democratic legitimacy. Standardisation requires a series of legal and ethical decisions to be made, which necessitate a democratic discourse involving the whole of society, in which stakeholders should be adequately involved. European standardisation involves the delegation of legislative powers to private organisations. To Ebers this is problematic due to the lack of participation rights for the

12 See Article 2 and recitals 5, 8(1) and (2), 14(2), 14(4) and 15(2), 15(1) of the Implementing Decision.

13 Gerdemann: Harmonisierte Normen und ihre Bedeutung für die Zukunft der KI (MMR 2024, 614). In German.

14 Wachter, "Limitations and Loopholes in the EU AI Act and AI Liability Directives".

15 European Commission. Artificial Intelligence – Questions and Answers. https://ec. europa.eu/commission/presscorner/detail/en/qanda_21_1683. Published 1 August 2024, accessed 3 November 2025. url: https://ec.europa.eu/commission/presscorner/ detail/en/qanda_21_1683.

16 Wachter, "Limitations and Loopholes in the EU AI Act and AI Liability Directives".

Council and Parliament, the limited influence of relevant interest groups and insufficient judicial control (no validity check of harmonised standards by the ECJ).[17]

Neither the European Parliament nor the Member States can veto the harmonised standards commissioned by the European Commission. Even the Commission has only limited influence. Veale and Zuiderveen Borgesius[18] therefore state: "Consequently, standardisation is arguably where the real rulemaking in the AI Act will occur."[15] This concern has not only been underlined by academia but also by civil society. The European consumer protection organisations, ANEC and BEUC, also emphasise that the current EU standardisation system lacks democratic legitimacy and adequate inclusion of public interest stakeholders. In its 2023 position paper, the ANEC and BEUC both highlight that "the standardisation process is currently dominated by industrial actors and suffers from a lack of transparency, accessibility and effective representation of civil society, SMEs and consumer interests"[19]. Particularly in areas such as artificial intelligence, where technical standards effectively operationalise legal norms, this imbalance can lead to a systemic underrepresentation of fundamental rights considerations and public accountability.

1.3 The Role and Inadequacy of Conformity Assessments

Article 43 AIA requires that the majority of high-risk AI systems undergo conformity assessments through internal checks conducted by the providers themselves. While this approach aims to reduce administrative burden, this reliance on self-certification contradicts basic principles of independent oversight, particularly in light of the systemic risks posed by not only high-risk AI systems, but AI systems in general, in critical domains such as education, employment, migration policy, jurisdiction and law enforcement.

Conformity assessments verify whether high-risk AI systems comply with the AIA's obligations before market entry.[20] In most cases, these checks are conducted internally by providers, while third-party evaluation and continuous monitoring are required only in limited sectors. The conformity assessment procedure to be applied depends on the type of high-risk AI system. The conformity assessment of high-risk AI systems listed in Annex I of the AIA is carried out in accordance with Art. 43(3) AIA, in accordance with the legal acts from the New Legislative Framework specified therein. These regularly provide for third-party

17 Ebers; Martin/ Streitbörger; Chiara; Die Regulierung von Hochrisiko-KI-Systemen in der KI-Verordnung; RDI 9/2024; 393 (398).

18 Michael Veale and Frederik Zuiderveen Borgesius. "Demystifying the Draft EU Artificial Intelligence Act". In: Computer Law Review International 22.4 (2021), pp. 97–112. url: https://ssrn.com/abstract=3896852.

19 ANEC and BEUC. For a 'Standardisation Governance Act': Recommendations to adapt Regulation (EU) 1025/2012. Tech. rep. Position paper; accessed via https://www.beuc. eu / sites / default / files / publications / BEUC - X - 2024 - 001 _ For _ a _ standardisation _ governance_act.pdf on 24 July 2025. ANEC – The European consumer voice in standardisation; BEUC – The European Consumer Organisation, 2024.

20 Markus Fuderer. "Doppelte Konformitätsbewertung bei KI-basierten Medizinprodukten". In: (2022). in German, pp. 121–126.

conformity assessment. In exceptional cases, internal conformity assessment is permitted if certain technical requirements are met. With regard to high-risk AI systems listed in Annex III, point 1 of the AIA, there is a choice, provided that harmonised standards are available: internal control in accordance with Annex VI or control by an external body. Only for high-risk AI systems for remote biometric identification used by law enforcement, immigration or asylum authorities or by EU institutions, bodies, offices or agencies does the AIA stipulate in Art. 74(8) and (9) that the market surveillance authorities shall assume the function of the notifying authority. High-risk AI systems listed in Annex III, points 2-8, are subject to an internal conformity assessment (Article 43(2) AIA) in accordance with Annex VI. This list of high-risk AI systems that are used in areas that are particularly sensitive in terms of fundamental rights. This self-assessment model reduces administrative burden but raises questions about independence and effectiveness in detecting risks to fundamental rights and public trust, especially when systems are operated over a longer period of time.

Lessons from Social Media and High-Risk AI Domains

Evidence from prior deployments of high-risk AI tools underscores the limitations of internal auditing. There are several cases where civil society audits or journalists revealed significant risks that internal controls had failed to address. For instance, the Rotterdam welfare fraud system disproportionately targeted low-income individuals[21], and very recently, Workday's AI-based screening system was conditionally certified to have had a disparate impact based on race, age, and disability[22]. In neither of these cases did internal evaluations or audits detect or disclose the respective harms. These examples are part of a much broader oversight ecosystem in which external actors, rather than providers themselves, uncovered systemic harms.

A similar trajectory can be observed in the history of social media accountability and regulation. For years, platform providers restricted or denied researchers access to APIs and independent evaluations, leaving fundamental questions about societal impact unaddressed. A history of restricted and opaque access to platform data motivated the Digital Services Act (DSA)'s vetted-researcher access regime in Art. 40(4) and 40(12), which seek to replace ad-hoc goodwill with transparent, standardised procedures.[23] We are now witnessing a similar dynamic with commercial generative AI systems, where a lack of transparency and access

21 Eva Constantaras et al. "Inside the Suspicion Machine". en-US. in: Wired (2023). Visited on Aug 26th 2025. issn: 1059-1028. url: https://www.wired.com/story/welfare-state-algorithms/ (visited on 07/24/2023).

22 Guy Brenner, Jonathan Slowik, and Dixie Morrison. AI Bias Lawsuit Against Workday Reaches Next Stage as Court Grants Conditional Certification of ADEA Claim. Law and the Workplace Blog, Proskauer Rose LLP. 2025. url: https://www.lawandtheworkplace. com/2025/06/ai-bias-lawsuit-against-workday-reaches-next-stage-as-court-grants-conditional-certification-of-adea-claim/ (visited on 10/21/2025).

23 L K Seiling et al. Data Access for Researchers under the Digital Services Act: From Policy to Practice. Weizenbaum Policy Paper 14. Berlin: Weizenbaum Institute, 2025.

hinders meaningful scrutiny and oversight.[24] Recent debates around the EU's General-Purpose AI (GPAI) Code of Practice point in the same direction, namely, the need for an external assessment as a default.[25] Without external audit mechanisms as now implemented in the DSA, the AIA risks repeating past failures seen in high-risk AI-decision-systems and social media governance. This record highlights the necessity of binding third-party audits to complement or replace provider-led conformity assessments.

External control, e.g. in the form of third-party audits, does not provide an absolute guarantee that evaluated systems are entirely safe, secure, or devoid of deficiencies. However, their independent and impartial nature, combined with the specialised expertise of auditing entities, significantly contributes to minimising associated risks.

2 Recommendations for Democratic AI Accountability

Recommendation 1: Mandatory Independent Audits by Third Parties

In the national context of each member state, mandatory third-party audits would help the providers get external reviews on their AI-developments and also enhance the effectiveness of the supervisory and notifying authorities of each member state. We follow the definition of AI audits by Raji et al. (2023) as "a process through which an auditor evaluates an AI system or product according to a specific set of criteria and provides findings and recommendations to the auditee, to the public, or to another actor, such as to a regulatory agency or as evidence in a legal proceeding"[26]. We understand that the purpose of AI audits is "to discover and mitigate potential risk, harms, and breaches of standards"[27]. The boundaries of "third-party" and "independent" audits remain debated: some define independence narrowly, excluding any financial relationship, while others accept paid external audits as legitimate if conflicts of interest are adequately managed. In this paper, we use the term third parties to include stakeholders – such as academia, affected communities, journalists, and accredited conformity

24 David Hartmann et al. "Addressing the Regulatory Gap: Moving towards an EU AI Audit Ecosystem beyond the AI Act by Including Civil Society". In: AI and Ethics 5.4 (2025), pp. 3617–3638. issn: 2730-5961. doi: 10.1007/s43681-024-00595-3. (Visited on 08/06/2025).

25 The Future Society. Closing the Gap: Five Recommendations for Improving the Third Draft of the EU Code of Practice for General-Purpose AI. Policy brief. 2025. url: https: //thefuturesociety.org/copthirddraft/ (visited on 09/02/2025).

26 Inioluwa Deborah Raji, Sasha Constanza Chock, and J Buolamwini. "Change from the outside: towards credible third-party audits of AI systems". In: Missing links in AI governance 5 (2023).

27 Matti Minkkinen, Anniina Niukkanen, and Matti Mäntymäki. "What about Investors? ESG Analyses as Tools for Ethics-Based AI Auditing". In: AI & SOCIETY (2022). doi: 10.1007/s00146-022-01415-0.

assessment bodies – who are not part of the audited entity and who operate without dependency relationships that could compromise their impartiality.

External audit reports could provide actionable insights and assessments of AI systems, thereby enhancing the capacity for risk-based monitoring and intervention. In the absence of such audits, providers themselves and also national authorities may lack the tools to assess compliance or evaluate broader systemic impacts. Art. 43(6) AIA empowers the Commission "to adopt delegated acts in accordance with Article 97 in order to amend paragraphs 1 and 2 of this Article (Art. 43 AIA) in order to subject high-risk AI systems referred to in points 2 to 8 of Annex III to the conformity assessment procedure referred to in Annex VII or parts thereof."

We therefore recommend the German Federal Government take the following actions to strengthen transparency and regulatory credibility:

- **Advocate for a Delegated Act at EU level:** Advocate at the European level, particularly within the Council of the European Union, for the European Commission to adopt a delegated act under the AI Act (according to Art. 97(1) AIA) that establishes binding requirements for external third-party audits for all high-risk AI systems, especially referred to in points 2 to 8 of Annex III, not only ex-post but ex-ante.
- **Promote External Auditing within the AI Board:** Use Germany's seat in the AI Board[28] to actively propose and support the development of common specifications or guidance that recommend third-party audits for all high-risk AI systems. Germany should push for the systematic inclusion of independent external oversight mechanisms such as third-party audits, particularly in sectors involving fundamental rights.

Recommendation 2: Participatory Audits and Inclusion of Affected Communities

Incorporating participatory methods into the oversight architecture of the AIA would strengthen both its democratic legitimacy and its capacity to discover harms. As recent research shows, participation is only weakly embedded in the AIA itself.[29] The AIA does not explicitly require stakeholder participation in key obligations such as risk management (Art. 9) or fundamental rights impact assessments (Art. 27). Article 27(1) of the AIA stipulates that, prior to the commissioning of a high-risk AI system in accordance with Article 6 (2) AIA, operators that are public-law bodies or private bodies providing public services, and operators

28 European Commission. AI Board. https://digital-strategy.ec.europa.eu/en/policies/ai-board. Last updated 22 October 2025, accessed 3 November 2025. 2025. url: https://digital-strategy.ec.europa.eu/en/policies/ai-board.

29 Chiara Ullstein et al. "Participatory AI and the EU AI Act". In: Proceedings of the Eighth AAAI/ACM Conference on AI, Ethics, and Society (AIES 2025). New York, NY: Association for the Advancement of Artificial Intelligence, 2025, pp. 2550–2557.

of high-risk AI systems as defined in Annex III, point 5(b) or (c), must carry out an assessment of the potential impact of the use of such a system on fundamental rights. According to Recital 96, the aim of this fundamental rights impact assessment is to ensure that operators of high-risk AI systems that may affect people's rights assess these risks in advance and proactively determine measures, such as compliance structures, to be taken in the event that these risks materialise. Recital 96 mentions the sectors of education, healthcare, social services, housing and the administration of justice. The results of the fundamental rights impact assessment are to be submitted to the respective national market surveillance authorities. The impact assessment of high-risk AI systems referred to in Article 6(2) in conjunction with Annex III of the AIA is carried out exclusively by the operators addressed in Article 27(1) of the AIA, and the results are reviewed by the market surveillance authorities. The external control or assistance in the impact assessment is not linked to the affected parties or their perspectives, which raises concerns about how effectively such assessments can be evaluated.[30] The high-risk AI systems listed in Annex III of the AIA cover biometrics, education and training, employment, human resources management, access to self-employment and basic private and public services, law enforcement, migration, asylum and border control, and the administration of justice and democratic processes. The impact assessment includes listing categories of individuals who could be affected by the use of a specific system and identifying the risks of harm. However, if the operators referred to in Article 27(1) AIA included the perspective of those affected in their assessment, they could potentially better identify the risks of harm.[31]

The analysis[32] identifies multiple points of entry for participatory practices — ranging from data governance to resilience testing — that could operationalise inclusion and accountability in practice. Projects such as We-Audit[33], participatory research for low-resourced languages[34], and the Action-Oriented AI Policy Toolkit[35] demonstrate how community-led and activist-driven audits can surface harms, biases, and risks not visible to purely technical assessments. Embedding such approaches would ensure that the AIA's oversight structure includes perspectives of affected communities, particularly those systematically marginalised or disproportionately impacted.

30 Ullstein et al., "Participatory AI and the EU AI Act".

31 Ibid.

32 Ibid.

33 Wesley Hanwen Deng et al. "WeAudit: Scaffolding User Auditors and AI Practitioners in Auditing Generative AI". in: arXiv preprint arXiv:2501.01397 (2025).

34 Wilhelmina Nekoto et al. "Participatory Research for Low-resourced Machine Translation: A Case Study in African Languages". In: Findings of the Association for Computational Linguistics: EMNLP 2020. Ed. by Trevor Cohn, Yulan He, and Yang Liu. Online: Association for Computational Linguistics, 2020, pp. 2144–2160. doi: 10.18653/v1/2020.findings-emnlp.195. url: https://aclanthology.org/2020.findings-emnlp.195/.

35 PM Krafft et al. "An action-oriented AI policy toolkit for technology audits by com-munity advocates and activists". In: Proceedings of the 2021 ACM conference on fairness, accountability, and transparency. 2021, pp. 772–781.

We therefore recommend:

- **Fund Participatory Pilots:** Fund participatory audit pilots and institutionalise engagement with civil society organisations.
- **Promote Participatory Audits on a National level:** Promote participatory audits for AI systems, that are not classified as high-risk AI systems but nevertheless have greater socio-technical consequences and eventually fundamental rights impact.

Recommendation 3: Periodic Re-Auditing and Life-cycle Monitoring

AI systems evolve continuously after deployment — through learning, user interaction, environmental changes, and retraining. High-risk examples include hate speech detection systems, where new slurs, coded language, or implicit hate emerge dynamically[36], as well as credit scoring or automated loan approval systems, which adapt to shifting market conditions or behavioural patterns[37]. In such cases, static, one-time audits are insufficient to ensure long-term compliance and accountability. As in other regulatory domains — such as vehicle safety inspections — continuous or periodic reassessment is a very important factor to maintain trust and safety over time.[38]

The Weizenbaum Institute, therefore, emphasises the need for mandatory external re-auditing or continuous monitoring to account for data drift, unintended outcomes, and model recalibration. A systematic external re-auditing framework could help ensure that changes in system behaviour over time are subject to appropriate scrutiny.

We recommend:

- **Establish a central audit register** that collects and archives audit documentation: Such an audit register, which collects information about the outcome of the audits,

36 David Hartmann et al. "Lost in Moderation: How Commercial Content Moderation APIs Over- and Under-Moderate Group-Targeted Hate Speech and Linguistic Variations". In: Proceedings of the 2025 CHI Conference on Human Factors in Computing Systems. CHI '25. Association for Computing Machinery, 2025. isbn: 9798400713941. doi: 10.1145/3706598.3713998. url: https://doi.org/10.1145/3706598.3713998; Manuel Tonneau et al. "HateDay: Insights from a Global Hate Speech Dataset Representative of a Day on Twitter". In: Proceedings of the 63rd Annual Meeting of the Association for Computational Linguistics (Volume 1: Long Papers). Ed. by Wanxiang Che et al. Vienna, Austria: Association for Computational Linguistics, 2025, pp. 2297–2321. isbn: 979-8-89176-251-0. doi: 10.18653/v1/2025.acl-long.115. url: https://aclanthology.org/2025.acl-long.115/.

37 Jiaqi Qian et al. "Managing dataset shift by adversarial validation for credit scoring". In: arXiv preprint arXiv:2112.10078 (2021). url: https://arxiv.org/abs/2112.10078; Ilias Nikolaidis, Athanasios Tsakonas, and Michael N. Vrahatis. "Credit Scoring with Drift Adaptation Using Local Regions of Competence". In: Computational Economics 59.4 (2022), pp. 1317–1336. doi: 10.1007/s43069-022-00177-1. url https://link.springer.com/ article/10.1007/s43069-022-00177-1.

38 Tina B. Lassiter and Kenneth R. Fleischmann. "Something Fast and Cheap" or "A Core Element of Building Trust"? - AI Auditing Professionals' Perspectives on Trust in AI". in: Proc. ACM Hum.-Comput. Interact. 8.CSCW2 (2024). doi: 10.1145/3686963. url: https://doi.org/10.1145/3686963.

should be accessible to oversight authorities, affected persons, and, where appropriate, the public, while ensuring that personal data is protected.

Recommendation 4: Enforcing Rights and Redress Mechanisms

The Weizenbaum Institute welcomes the inclusion of Articles 85 and 86 AIA, which recognise the rights of affected persons to lodge complaints and seek redress. These provisions are crucial for ensuring that the obligations imposed on AI providers and deployers translate into tangible protection for individuals. However, the practical enforcement of these rights depends heavily on the institutional and procedural infrastructure established at the national level. Without accessible mechanisms, legal empowerment risks remaining merely formal.

Civil society organisations play a central role in bridging this gap. Initiatives such as HateAid illustrate how actors can operationalise digital rights enforcement by supporting victims, coordinating legal action, and raising public awareness. To ensure that affected individuals can effectively exercise their rights under the AIA, similar models of civil society engagement should be funded and expanded. Sustainable funding structures are essential to guarantee independent legal support, enable strategic litigation, and foster public trust in AI governance. Such measures would help establish a comprehensive enforcement ecosystem in which regulatory oversight, civil society participation, and judicial mechanisms interact effectively, ensuring that the rights guaranteed by the AIA are not only declared, but practically enforceable.

Furthermore, Article 77 AIA introduces the possibility of collective redress actions by qualified entities, allowing multiple individuals with similar legal claims to bring joint proceedings against a defendant. This mechanism is particularly relevant in the context of high-risk AI systems, which can produce widespread harms, such as discriminatory profiling or algorithmic exclusion, affecting large groups of people. Collective procedures improve access to justice, increase efficiency and cost-effectiveness, and can provide systemic remedies that go beyond individual compensation.

We recommend the Federal German Government to:

- **Provide public funding** for civil society organisations and ombudsperson offices that assist affected individuals to strengthen legal certainty and ensure reliable procedural channels for combating damage related to AI systems.

Recommendation 5: Strengthening Civil Society and Academic Representation in European Standardisation Processes

The Weizenbaum Institute recommends a reform of the EU standardisation process to ensure that normative standards reflect the plurality of European fundamental rights, including consumer protection, non-discrimination and social and ecological fairness. This must include structural funding for civil society participation, clearer legislation that mandates inclusiveness, and a rebalancing of influence within standardisation bodies, because there are insufficient opportunities for interest groups to participate in the development of harmonised standards, as shown above.

In practice, European interest groups have only limited rights of participation. They have no voting rights, but can only request access to documents, submit suggestions and proposals, and provide comments and technical opinions. European interest groups can only appeal against decisions made by standardisation organisations under very narrow conditions. In addition, there are a number of practical obstacles that make it difficult for interest groups to participate. Civil rights associations, trade unions and environmental and consumer associations usually have no experience or technical expertise in the field of European standardisation. They may not even be represented at the EU level.[39]

Despite their technical sophistication, existing standards exhibit several critical limitations: Many of the current standardisation processes show structural weaknesses that limit their ability to ensure accountable and rights-based AI governance. First, they tend to lack contextual sensitivity. Standards often focus narrowly on technical system behaviour without considering the socio-technical settings in which AI systems are deployed, such as criminal justice, welfare, or education. Second, fundamental rights are insufficiently integrated. Core rights such as non-discrimination, fair trial, and access to information are often only indirectly referenced or embedded in fragmented ways. Third, most standards follow a static audit logic that concentrates on one-time, pre-deployment assessments rather than continuous, adaptive evaluations as systems evolve in practice.

To rectify this imbalance, we recommend the German Federal Government to:

- **Promote the institutionalisation and funding of academia and civil society representation** on the EU Level within the standardisation processes, for example by improving access and exploring options for stronger procedural roles.

39 Ebers: Standardisierung Künstlicher Intelligenz und KI-Verordnungsvorschlag RDi 2021, 588., In German.

3 Towards Independent and Participatory Oversight

Building on these analyses, the Weizenbaum Institute identifies five recommendations to ensure that the AIA's implementation achieves its goals of trustworthiness and accountability:

1. Third-party audits for high-risk AI systems where internal conformity assessment is insufficient, complemented by transparent publication of audit outcomes.
2. Participatory oversight mechanisms that integrate perspectives of affected communities and civil society organisations into system evaluation and fundamental rights impact assessments.
3. Periodic re-auditing and lifecycle monitoring to ensure continued compliance as AI systems change through retraining, as well as implementation and deployment changes.
4. Accessible complaint and redress mechanisms supported by public funding and collective action tools to enable effective enforcement of individual and group rights.
5. Promote the institutionalisation and funding of academia and civil society representation on the EU Level within the standardisation processes, for example by improving access and exploring options for stronger procedural roles.

4 Conclusion

The German Federal Government has a critical responsibility to advocate at the European level, particularly within the Council of the European Union, for the European Commission to adopt a delegated act under the AI Act that establishes binding requirements for external third-party audits in high-risk AI areas, as internal controls and assessments are often insufficient, and risks of conflict of interest are high. Moreover, it should ensure that the implementation of the AIA aligns with constitutional principles of legality, transparency, accountability, and participation. This includes not only faithfully transposing the AIA into national law, where possible, but also leveraging available discretion to enhance protections, build inclusive institutions, and promote democratic oversight.

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The Weizenbaum Institute is a joint project funded by the German Federal Ministry of Research, Technology and Space (BMFTR) and the State of Berlin. It conducts interdisciplinary and basic research on the digital transformation of society and provides evidence- and value-based options for action in order to shape digitalization in a sustainable, self-determined and responsible manner.