

ENNHRI response to the Digital Package and Omnibus Consultation

Simplification measures must retain fundamental rights protections

Introduction

The European Network of National Human Rights Institutions ([ENNHRI](#)), which represents over 50 [National Human Rights Institutions](#) (NHRIs) across Europe, has taken note of the European Commission's ("the Commission") consultation on the upcoming Digital Omnibus, in particular the targeted adjustments of the Artificial Intelligence Act (AI Act). While ENNHRI welcomes this opportunity to contribute to a discussion on the simplification of the digital package, in particular efforts to enhance predictability and effectiveness of the application of the AI Act, we also emphasise that it is vital to maintain the fundamental rights protections set out in the regulation. The AI Act was designed to promote innovation and most critically to address urgent risks to safety, fundamental rights, and trust in AI. Therefore, any lowering of fundamental rights protections would undermine the purpose and credibility of the regulation, and negatively impact the credibility of the EU as a global leader in rights-based governance of AI, in line with the EU fundamental values set out in Article 2 of the Treaty on European Union (TEU).

ENNHRI has been active throughout the AI Act negotiation process, and has consistently called for strong and effective fundamental rights safeguards. This includes ENNHRI's [Common Position](#) on the EU Artificial Intelligence Act, the [Joint Equinet and ENNHRI Statement on the EU Artificial Intelligence Act Trilogue](#), and [ENNHRI submission on the European Commission's White Paper on Artificial Intelligence](#).

NHRIs are recognised by the Commission as part of checks and balances at the national level, and as key actors to advance the implementation of the EU Charter of Fundamental Rights ("the Charter"). The importance and role of independent and effective NHRIs has been explicitly acknowledged by the Commission in its [annual report on rule of law in the EU](#) and its [revised Strategy on the effective implementation of the EU Charter of Fundamental Rights](#) and subsequent annual reports on the Charter. Further, many NHRIs have been designated as authorities protecting fundamental rights under Article 77 of the AI Act.

To avoid any adjustments to the AI Act negatively impacting the protection of fundamental rights as enshrined in the Charter, ENNHRI recommends that the EU:

- Ensure that the next phase of the legislative process is undertaken transparently and on the basis of adequate stakeholder consultation and a solid evidence base.
- Maintain the obligation to undertake fundamental rights impact assessments for high risk AI systems.
- Safeguard the powers of authorities protecting fundamental rights.
- Uphold the AI Act's wider approach to regulating high-risk AI systems, particularly regarding the right to an effective remedy.

1. The EU should ensure that the Digital Omnibus process is transparent, undertaken on the basis of adequate stakeholder consultation and solid evidence

ENNHRI highlights concerns that the call for evidence regarding the Digital Omnibus indicates that no impact assessment is foreseen for this proposal. ENNHRI recalls the Commission's responsibility to ensure transparent, timely and meaningful public consultations on EU law and policymaking processes and to conduct human rights impact assessments of EU legislation and policies, in consultation with relevant human rights actors, including NHRIs. This is to ensure compliance of EU legislation with the EU Treaties as per Article 2 TEU and the Charter, and in line with the European Commission's own Better Regulation guidelines, which include stakeholder consultation as "an essential element of policy preparation and review" and which requires impact assessments for initiatives expected to have significant economic, social or economic impacts. The Digital Omnibus is a comprehensive package, covering areas from data legislation to cybersecurity and privacy rules, and therefore warrants careful impact assessment.

ENNHRI has consistently called for meaningful public consultations and impact assessments within EU legislative processes, including in submissions to the Commission on the [Mid-Term Review of the EU Charter Strategy](#) and to the [EU 2024 Rule of Law Report](#). Accordingly, ENNHRI welcomes this opportunity to provide feedback on the Digital Omnibus but cautions against the proposal of significant changes to the AI Act without a solid evidence base gathered through a full impact assessment. Further, ENNHRI recalls that the AI Act only entered into force on 1 August 2024, and most obligations will not apply until 2 August 2026. It is not possible to meaningfully assess the impact or application of an instrument when its implementation is still ongoing. ENNHRI also notes that changes to the AI Act could undermine not only the ongoing

implementation but also the ability of the instrument to create legal certainty for deployers, providers and rightsholders.

2. The EU should maintain the obligation to undertake fundamental rights impact assessments for high-risk AI systems

ENNHRI highlights that Article 27 of the AI Act, which requires Fundamental Rights Impact Assessments (FRIAs) for high-risk AI systems, is essential because it operationalises the EU's foundational commitment to human dignity, equality, freedom, and the rule of law as enshrined in Article 2 TEU and the Charter. By obliging deployers of high-risk AI to proactively assess and mitigate potential impacts on fundamental rights, Article 27 turns the AI Act's principles into concrete preventive action. It ensures that technological innovation aligns with the Charter's protections for individuals and communities, rather than undermining them. Weakening or removing Article 27 would risk creating a gap between the EU's treaty-based principles and its regulatory practice, potentially undermining the EU's credibility as a global leader in rights-based governance of AI.

Previously, ENNHRI's [statement on FRIAs](#) welcomed their inclusion in the AI Act under Article 27. At the same time, ENNHRI highlighted how effective FRIAs should reflect a fundamental rights based approach and provided a list of ten recommendations to the Commission on how to achieve this. These recommendations include the need for meaningful public consultation and stakeholder engagement throughout the FRIA development and process, guidance on conducting FRIAs, and the importance of requiring that individuals or teams performing FRIAs have relevant fundamental rights expertise.

While the implementation of Article 27 can and should be strengthened, ENNHRI underscores the critical importance of FRIAs and a fundamental rights-based approach to AI governance. This provision plays a crucial role in ensuring a systematic examination of the potential risks that AI systems may pose to fundamental rights. ENNHRI therefore calls on the European Commission to preserve Article 27 and avoid any proposals that would weaken this provision or narrow its scope.

3. The EU should safeguard the powers of authorities protecting fundamental rights

The AI Act formally integrates fundamental rights bodies into the oversight and enforcement framework for AI systems under Article 77 AI Act. It assigns them specific powers, including the

power to request and access data and documentation when necessary for effectively fulfilling their mandates within the limits of their jurisdiction (Article 77(1)). They may make a reasoned request to the Market Surveillance Authorities (MSAs) to organise testing (Article 77(3)). Moreover, MSAs will need to inform Article 77 authorities and cooperate with them when risks to fundamental rights are identified (Article 79(2)).

These powers for fundamental rights authorities are vital to ensure that transparency and oversight can turn the AI Act's principles into enforceable reality, helping prevent harm from opaque "black-box" systems, promoting accountability among providers, ensuring consistent enforcement across EU Member States, and building public trust in AI regulation. ENNHRI urges the Commission to maintain the integrity of Article 77 and to refrain from making any adjustments that would limit the powers or role of Article 77 authorities. Moreover, it calls on the Commission to ensure that bodies designated under Article 77, including NHRIs, are fully independent and provided with sufficient resources to carry out their tasks effectively.

4. The EU should uphold the AI Act's wider approach to regulating high-risk AI systems, particularly regarding the right to an effective remedy

ENNHRI calls on the Commission to uphold the AI Act's wider approach to ensuring fundamental rights protections, especially regarding regulating high-risk AI systems. These include provisions on the right to an effective remedy under Article 85, which allows for the right to lodge a complaint with MSAs, and Article 86 on the right to an explanation of individual decision-making. Further, ENNHRI highlights that the registration of high-risk AI systems, as laid down in Article 49, is an important basis for achieving transparency and should also be fully maintained. It allows society to understand for what purpose and within what context AI is used and to what extent they are or can be affected by it.