ENNHRI calls on the European Commission to ensure effective Fundamental Rights Impact Assessments (FRIAs) under the EU AI Act

10 key recommendations for Fundamental Rights Impact Assessments

Given their designation as authorities protecting fundamental rights under Article 77 of the AI Act and their broad human rights mandate to monitor fundamental rights compliance, including with the EU Charter on Fundamental Rights, National Human Rights Institutions (NHRIs) are particularly well-placed to advise on one of the EU Artificial Intelligence Act's (AI Act) key provisions for fundamental rights protection: Fundamental Rights Impact Assessments (FRIAs).

ENNHRI welcomes the inclusion of FRIAs in the AI Act under Article 27, as well as the requirement for the AI Office to develop a template questionnaire to facilitate deployers[1] in complying with their obligation to perform FRIAs.

Effective FRIAs for AI should reflect a fundamental rights-based approach. To achieve this, ENNHRI recommends that the Commission should:

1. Include meaningful public consultation in the development of the template questionnaire
2. Develop guidance on conducting FRIAs to complement and apply the template questionnaire required by the AI Act under Article 27(5).
3. Require that individuals or teams performing FRIAs have relevant fundamental rights expertise, or request relevant assistance.
4. Underline that the primary purpose of FRIAs should be the prevention of fundamental rights violations.
5. Require that the methodology and benchmarks for assessment are grounded in human rights standards.
6. Promote policy coherence with existing international standards and other EU regulations.
7. Require meaningful transparency and effective remedy.
8. Recommend that FRIAs address collective and societal-level harms.
9. Require meaningful stakeholder engagement throughout the FRIA process.
10. Ensure the FRIA process is understood as iterative, covering the entire AI lifecycle.

[1] A 'deployer' means a natural or legal person, public authority, agency or other body using an AI system under its authority except where the AI system is used in the course of a personal non-professional activity – AI Act Article 3(4).

Background: ENNHRI and NHRIs

ENNHRI, the European Network of National Human Rights Institutions, consists of nearly 50 National Human Rights Institutions (NHRIs) across Europe. NHRIs are independent national authorities established by constitution or law to protect and promote human rights in accordance with the United Nations Paris Principles and the Council of Europe Committee of Ministers Recommendation 2021/1.

NHRIs are recognised by the European Commission ("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 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.

Since the conception of the AI Act, ENNHRI 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.

Article 77 Authorities Protecting Fundamental Rights

The specific characteristics of AI may create challenges for authorities protecting fundamental rights, such as NHRIs, when monitoring or assessing the potential impacts of AI on fundamental rights. These include opacity, complexity, lack of transparency, and large-scale cross-border deployment. To address this, the AI Act introduces specific powers for these authorities (referred to as Article 77 bodies), and cooperation mechanisms between these authorities and market surveillance authorities (MSA). These specific powers include 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 MSA to organise

testing (Article 77(3)). Moreover, MSAs will need to inform Article 77 bodies and cooperate with them when risks to fundamental rights are identified (Article 79(2))[2].

To date, at least 15 NHRIs in 15 EU Members States have already been designated as Article 77 bodies (in Austria, Belgium, Croatia, Czechia, Denmark, Greece, Ireland, Latvia, Lithuania, Netherlands, Bulgaria, Cyprus, Finland, Malta and Spain). This number is expected to grow, as Member States are required to keep the list up to date, implying further bodies can be added to the list, and while not all Member States have complied with the Article 77(2) deadline identifying their Article 77(1) bodies.

Recommendations on the development of the FRIA template questionnaire

1. Meaningful public consultation in the development of the template questionnaire

ENNHRI recommends that the Commission consult relevant stakeholders, including NHRIs, in the development of the template questionnaire under Article 27(5) of the AI Act. This would reflect a human rights-based approach to the application of FRIAs under the AI Act and also reflects the fact that stakeholder engagement is essential in performing FRIAs (further below under 9). Further, such engagement could enhance the cost-effectiveness of the process by facilitating early provision of expertise from fundamental rights bodies, which have both technical knowledge and information concerning affected rightsholders. A public consultation could serve as an effective way to achieve this, ensuring that a broad range of perspectives is considered. Incorporating their input early on would strengthen the questionnaire's ability to guide meaningful FRIAs.

2. Develop guidance on conducting FRIAs to complement the template

ENNHRI recommends that the Commission should consider publishing more elaborate guidelines on performing FRIAs, similar to the approach taken with prohibited practices under the AI Act. Such guidelines would enhance legal certainty, particularly in managing private sector expectations. For example, clarification could be provided regarding which entities fall under the scope of FRIA obligations, especially in relation to private entities providing public services and deployers of certain high-risk AI systems listed in an annex to the AI Act, such as banking or

[2] See also Article 73(7): "Upon receiving a notification related to a serious incident referred to in Article 3, point (49)(c), the relevant market surveillance authority shall inform the national public authorities or bodies referred to in Article 77(1))".

insurance entities. High-quality guidance from the Commission would not only improve fundamental rights protection, but also ensure alignment with EU standards, fostering consistent application of the AI Act across Member States. Moreover, the Commission could use this opportunity to clarify the scope and nature of oversight necessary for FRIAs, in line with the principle of effectiveness enshrined in Article 24(3) of the Treaty on European Union (TEU) and Article 13(1) TEU, ensuring that Member States implement and enforce FRIA obligations consistently across the EU. ENNHRI also recommends including practical guidance about what different fundamental rights entail and examples of how AI systems in different areas may interfere with these rights. This guidance could include: 1) process and methodology guidance to support proper implementation; and 2) annexes and tools to further assist providers in meeting their obligations.

Recommendations on how to ensure effective FRIAs

3. Require the inclusion of fundamental rights expertise

Ensuring that FRIAs for AI systems are performed with fundamental rights expertise is essential. While these assessments may, depending on the complexity and potential impact of the system, be carried out by an individual or by teams, in all cases, there must be adequate fundamental rights expertise informing the assessment. Therefore, ENNHRI recommends the Commission to include this in the FRIA template.

Under Article 27(1)(c), deployers must identify the categories of natural persons and groups likely to be affected by an AI system in a given context. Furthermore, Article 27(1)(d) obliges them to assess the specific risks of harm these groups may face. ENNHRI reiterates that specific expertise is required to identify fundamental rights harms, to assess their impact, and to determine the relevant affected groups. Performing an effective assessment ideally requires an interdisciplinary team including legal and fundamental rights expertise, particularly for high-impact or complex systems, which can be complemented by select input from bodies named under Article 77 AI Act, as well as other fundamental rights experts from NHRIs, academia, or civil society, to ensure a comprehensive evaluation of fundamental rights impacts.

A concern arises (also discussed further below under 5) that FRIAs might be delegated solely to data protection officers for efficiency reasons, including in light of their role to carry out data protection impact assessments (DPIAs) under the General Data Protection Regulation (GDPR). While data protection expertise is critical for understanding AI system-related risks, the AI Act requires that negative impacts of AI systems across a broad range of fundamental rights are

considered which should be reflected in the expertise of the team conducting the FRIA assessment.

4. Primarily assess whether AI use is necessary and proportionate to fundamental rights risks

The primary purpose of FRIAs should be to prevent fundamental rights violations. This means that, in addition to putting in place effective prevention and mitigation measures, deployers need to evaluate whether it is necessary to have recourse to AI systems in the first place, taking into account the severity of risks to fundamental rights. To facilitate that analysis, the template questionnaire could, for example, include the so-called "zero questions" elaborated upon in the human rights impact assessment methodology (HUDERIA) developed by the Council of Europe's Committee on AI and negotiated on by the European Commission. These questions would require deployers to assess whether the AI system is the most appropriate solution, whether non-automated alternatives were considered, and the consequences of not using the AI system. If an AI system is found to be incompatible with fundamental rights or fails to serve its intended purpose (anymore), it should not be deployed. EU Member States already apply this principle in practice; for instance, the Rotterdam IAMA determined that a fraud detection system should not be used due to doubts about whether it could achieve the required level of transparency and legality.

ENNHRI recalls that addressing fundamental rights risks requires integrating prevention, training, monitoring and mitigation into the planning and budgeting process from the very conception of an AI system. Allocating sufficient resources early on ensures compliance and safeguards fundamental rights effectively. This should be considered when evaluating the "zero question," ensuring that the potential costs of addressing risks, such as bias detection and mitigation, are factored in early on to make informed decisions.

5. Methodology and benchmarks for assessment

The benchmark for the assessment of negative impacts on fundamental rights should be explicitly grounded in the EU Charter for Fundamental Rights and the European Convention on Human Rights, and should factor in relevant case law from the European Court of Human Rights and the Court of Justice of the European Union.

ENNHRI recommends that the methodology for assessing impacts on fundamental rights under the AI Act should be aligned with the UNGPs, which is the international authoritative framework on human rights risk and impact management. Importantly, the UNGPs clarify that the main

purpose of human rights risk management is the prevention of negative impacts and that any prioritisation of impacts for prevention and mitigation efforts should be based in a prior assessment of the severity of negative impacts to people.[3]

6. Policy coherence with existing international standards and other EU regulations

ENNHRI underlines the importance of ensuring consideration of coherence between DPIAs under the GDPR and FRIAs under the AI Act. While DPIAs can provide a useful complement to FRIAs, they cannot replace them due to the different nature and purpose of the assessments, as is noted under Article 27(4) of the AI Act. Furthermore, ENNHRI emphasises that existing international standards such as the UN Guiding Principles on Business and Human Rights (UNGPs) and the OECD Guidelines for Multinational Enterprises setting expectations for businesses in the areas of human rights risk and impact assessment need to be taken into account for FRIAs. This is important for EU policy coherence given that the UNGPs and the OECD Guidelines are mentioned in, and have informed to a large degree, other cross-sectoral EU regulations in the area of corporate sustainability, such as the Corporate Sustainability Due Diligence Directive (CSDDD) and the Corporate Sustainability Reporting Directive (CSRD).

7. Require meaningful transparency and effective remedy

ENNHRI emphasises the importance of requiring meaningful transparency and effective remedy. Without access to key FRIA findings, individuals may be unable to assess potential harm, formulate grievances, or seek redress, undermining the right to an effective remedy. Article 47 of the EU Charter of Fundamental Rights guarantees the right to an effective remedy and a fair trial. According to established case law of the Court of Justice of the European Union and the European Court of Human Rights, an effective remedy requires that those affected by a decision have meaningful access to the relevant information necessary to challenge it.[4] A meaningful level of transparency can be ensured through the publication of FRIA findings in publicly accessible registers.

---

[3] The UN Guiding Principles on Business and Human Rights (UNGPs) primarily refers to scale, scope and remediability as severity criteria that can be used to prioritise prevention and mitigation efforts. While the likelihood variable can be used, it should play a less salient role than severity. For example, a very severe risk with low likelihood should still be prioritised for action.

[4] Kadi II, Joined Cases C-584/10 P, C-593/10 P & C-595/10 P at paras. 98–137 (in particular, paragraphs 98 and 100 and the case-law cited) See also jurisprudence from the ECtHR: Guide on Article 13 - Right to an effective remedy

Article 27(1)(f) of the AI Act mandates that deployers include in the FRIA the measures to be taken in the event of risks materialising, including internal governance arrangements and complaint mechanisms. For these mechanisms to function effectively, affected persons must have a minimum level of transparency regarding the AI system in question.[5]

FRIA databases could serve as a source of inspiration for providers across Europe and would be conducive to legal certainty and access to remedy. Where legal constraints, such as trade secrets, national security, or other recognised exceptions apply, they should be interpreted narrowly and in line with European and national access-to-information frameworks.[6] The most comprehensive possible versions of the FRIA should still be made publicly available, ensuring that the right to an effective remedy remains practical and not merely theoretical.

8. Address collective and societal-level harms

ENNHRI recommends reflection in the Commission's template that FRIAs should integrate an assessment of AI's impact on interests with a collective and societal scope, such as risks to democracy and environment, which extend beyond individual concerns and align with the AI Act's overarching principles.

Under Article 27(1)(d) of the AI Act, the issue of potential collective harm is acknowledged, as it requires deployers to assess specific risks likely to affect categories of natural persons or groups of persons. The reference to "groups of persons" signals attention to both collective and societal-level harms. While the Article's wording focuses on collective impacts, broader societal harms also warrant consideration. Recital 5 recognises that AI can generate risks and cause harm to public interests and fundamental rights, including societal harm. Similarly, the definition of systemic risk in Article 3 includes negative effects on society as a whole, particularly when harms propagate at scale. Recital 27 further emphasises the importance of monitoring and assessing long-term societal impacts, including effects on democracy. These provisions underline the need for FRIAs to go beyond individual harm and collective risks to also assess broader societal consequences. For example, in the context of social media, AI-driven algorithms can contribute to the polarisation of voters by filtering and promoting extreme viewpoints over moderate ones,

[5] Recital 93 states that deployers of high-risk AI systems play a critical role in informing natural persons. This information should include the intended purpose and the type of decisions a high-risk AI system makes. The deployer should also inform the natural persons about their right to an explanation provided under this Regulation.
[6] See for example the Council of Europe Convention on Access to Official Documents, and Article 42 of the European Charter of Fundamental Rights which establishes the right of access to EU institutions documents.

distorting political realities and undermining citizens' ability to make informed decisions in democratic elections. While individual harm from such algorithmic content control may not be immediately visible, the cumulative societal impact over time can be devastating to democracy, as it distorts public opinion, undermines political pluralism, and limits freedom of expression.

9. Meaningful stakeholder engagement throughout the FRIA process

Stakeholder engagement, including of potentially affected individuals and groups, is essential in performing FRIAs. This is recognised in Recital 96 of the AI Act which highlights the importance of including relevant stakeholders, including representatives of groups of persons likely to be affected by the AI system, independent experts, and civil society organisations. To properly assess these risks, FRIAs must integrate an iterative stakeholder engagement process,[7] with heightened attention to the need to meaningfully involve individuals and groups at risk of vulnerability or marginalisation, including socio-economically disadvantaged people. This approach aligns with Article 18 of the UNGPs, which establishes stakeholder consultation as a cross-cutting element of human rights due diligence. Furthermore, it is also reflected in the human rights impact assessment methodology developed by the Council of Europe's Committee on AI (HUDERIA), which was negotiated on by the European Commission. For more practical guidance, the *stakeholder engagement guidance on HRIA of digital activities* developed by the Danish Institute for Human Rights further illustrates good practices for meaningful stakeholder engagement.

10. An iterative FRIA process, covering the entire AI lifecycle

ENNHRI underlines the importance of highlighting that FRIAs should be caried out periodically during the entire lifecycle of the AI system, and not just prior to putting it into use. This is in line with Article 27(2) which states that "If, during the use of the high-risk AI system, the deployer considers that any of the elements listed in paragraph 1 has changed or is no longer up to date, the deployer shall take the necessary steps to update the information". Moreover, this view of FRIAs as a continuous iterative process is consistent with the general risk management approach adopted in the AI Act, as outlined in Article 9(2): "The risk management system shall be understood as a continuous iterative process planned and run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic review and updating".

Co-funded by
the European Union

[7] See also Recital 93 of the AI Act, which underscores that risks arising from AI systems are not limited to their design but also stem from their use, hence the need for an iterative approach to stakeholder engagement.