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Delivering on the Promise of the Fundamental Rights Impact Assessments in the EU AI Act: Intersectionality and Vulnerability

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Abstract

The purpose of this paper is to analyse the adequacy of the fundamental rights impact assessment (FRIA) model as a means of safeguarding human rights in the context of high-risk systems in the EU AI Act. With Article 27 AI Act as the baseline context we analyse the 'genre' of impact assessments. The fundamental rights referenced in the AI Act are linked to relevant provisions of the EU Charter of Fundamental Rights (CFR). It is argued that, in addition to the 23 rights identified by the AI Act, the use of AI has the potential to impact all substantive CFR rights, albeit not to an equal measure. Drawing on this analysis the paper highlights limitations in the conceptualisation of FRIAs that will compromise their capacity to identify and mitigate the fundamental rights impacts. As issues pertaining to direct horizontal effect might emerge in litigation, the paper concludes by arguing that meaningful FRIAs will preferably require recourse to frameworks unconventional in EU law, such as intersectionality and the vulnerable subject theory.

Keywords: AI Act, fundamental rights, AI ethics, impact assessments, intersectionality, vulnerability.

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1. Introduction

In June 2024, the EU Council adopted the long-awaited Regulation laying down harmonised rules on artificial intelligence for the 27 Member States, known as the AI Act.[1] The AI Act represents a landmark regulatory initiative that, despite being confined to the EU jurisdiction, is poised to shape global AI governance through what is often referred to as the 'Brussels effect'.[2] Specifically, Article 2(1) stipulates that its scope extends beyond companies merely placing AI systems on the EU market or deploying them within EU borders, but also to those located in a third country 'where the output produced by the AI system is used in the Union'. This extraterritorial reach suggests the Act's potential to establish *de facto* global standards in AI regulation, compelling non-EU companies to align with its provisions to maintain market access.

The EU has chosen to adopt a risk-based approach resembling some of its product safety legislation.[3] Consequently, the EU legislator has introduced different levels of risk. AI systems associated with unacceptable levels of risk, e.g., ones using subliminal techniques distorting a person's behaviour to cause physical or psychological harm or 'social scoring' for general purposes done by public authorities, have been banned by Article 5(1) . Conversely, high-risk AI systems will be subject to compliance with strict mandatory requirements. Article 6 distinguishes two types of high-risk AI systems: 1) AI systems placed on the market as products or as safety components of products (Article 6(1)); and 2) AI systems with fundamental rights implications (Article 6(2) read in conjunction with Article 6(3)). Therefore, potential impact on fundamental rights plays a crucial role in distinguishing AI systems as high risk within the AI Act. This is confirmed in Article 6(3) which introduces a derogation whereby a system referred to in Annex III is not high risk 'where it does not pose a significant risk of harm to the health, safety or fundamental rights of natural persons'. These high-risk use cases are enumerated in Annex III AI Act (subject to modifications by the European Commission). Examples include the use of AI in student assessment, employee

[1] Parliament and Council Regulation (EU) 2024/1689, OJ L, 2024/1689.

[2] This concept refers to the EU's capacity to set *de facto* global standards, particularly in areas such as data protection and technology regulation, where companies and third countries often align with EU rules to retain access to its market. Anu Bradford, *The Brussels Effect: How the European Union Rules the World* (Oxford University Press, 2020). See also Charlotte Siegmann and Markus Anderljung, 'The Brussels Effect and Artificial Intelligence: How EU Regulation Will Impact the Global AI Market' (Centre of Governance of AI, 2022) available at <http://arxiv.org/abs/2208.12645> accessed 21 October 2024; Oskar J Gstrein, 'European AI Regulation: Brussels Effect versus Human Dignity?' (2022) 18(4) Zeitschrift für europarechtliche Studien 755. NB Marco Almada and Anca Radu, 'The Brussels Side-Effect: How the AI Act Can Reduce the Global Reach of EU Policy' (2024) 25(4) German Law Journal 646.

[3] Jerome De Cooman, 'Humpty Dumpty and High-Risk AI Systems: The Ratione Materia Dimension of the Proposal for an EU Artificial Intelligence Act' (2022) 6(1) Market and Competition Law Review 49; Johann Laux, Sandra Wachter and Brent Mittelstadt, 'Trustworthy Artificial Intelligence and the European Union AI Act: On the Conflation of Trustworthiness and Acceptability of Risk' (2024) 18(1) Regulation & Governance 3.

recruitment and promotion, credit rating evaluation, migration, asylum and border control management, and the judiciary.

This paper evaluates the scope of fundamental rights protection in high-risk AI systems regulated by Article 6(2) and listed in Annex III. It argues that while the AI Act's foundational framework marks significant progress, its tools – especially the fundamental rights impact assessments (FRIAs) mandated for high-risk AI – face serious limitations in effectively protecting the rights enshrined in the EU Charter of Fundamental Rights (CFR). Not only does the wording of the AI Act potentially underestimate the full spectrum of rights at risk, but it also fails to guarantee meaningful enforcement of the protected rights. To address these limitations, the paper suggests incorporating intersectionality and vulnerability theory into FRIA practices, arguing that these perspectives could better capture the nuanced impacts of high-risk AI on diverse groups and contexts.

2. Fundamental Rights Impacts Assessments as a Distinct Feature of AI Governance in the EU

Among many other control and compliance measures demanded of high-risk AI systems is the requirement, laid down in Article 27, to carry out an *ex ante* FRIA to be submitted – as a rule – to the market surveillance authority (Article 27(3)). Therefore, it appears that in non-contentious scenarios not requiring litigation, the judgement regarding compliance with the CFR and the balancing of various fundamental rights will be made by the market surveillance authorities.

A FRIA will be mandatory for many deployers of high-risk AI systems regulated by Article 6(2) with exceptions enumerated in Article 27(1). Notably, the requirement to conduct a FRIA does not apply to deployers of AI systems used in critical infrastructure, i.e. systems intended to be used as safety components in the management and operation of critical digital infrastructure, road traffic, or in the supply of water, gas, heating or electricity (Point 2 Annex III), and to private employers who do not provide any public services.[4]

The remainder of Annex III refers to the following AI uses: biometrics; education and vocational training; employment, workers' management and access to self-employment; access to and enjoyment of essential private services and essential public services and benefits; law enforcement, in so far as their use is permitted under relevant EU or national law; migration, asylum and border control management; and administration of justice and democratic processes. Many of these AI uses are reserved exclusively for the public sector or public services which, however, the

[4] Article 27(1) AI Act reads that those obliged to carry out a fundamental rights impact assessment are bodies governed by public law, or are private entities providing public services, and deployers of high-risk AI systems referred to in points 5(b) and (c) of Annex III. Thus, employers only fall within this category if they are public bodies or provide public services.

government may outsource to private bodies. Other examples of Annex III AI applications by private bodies include evaluation of creditworthiness of natural persons or establishing their credit score, as well as risk assessment and pricing in relation to life and health insurance.

Furthermore, while many private sector applications may not be formally required to conduct a FRIA, they are nevertheless under a distinct but complementary obligation to assess risks to fundamental rights as part of the overall risk management system required for high-risk AI systems, in accordance with Article 9 AI Act. In this context, the interplay between the developer's (provider's) obligation to conduct such assessments and the deployer's FRIA obligations is critical: both play a role in safeguarding fundamental rights at different stages of the value chain. Moreover, providers are not only expected to conduct these assessments, but also to share the results with deployers under Article 13(3). Another potential point of intersection might arise if FRIAs are incorporated into public procurement requirements, which may lead to further consideration by private sector providers.

The FRIA shall be conducted prior to the first use, unless any considerations change during the use of the AI system (Article 27(2)). Article 27(1) gives some limited guidance on the content of the fundamental rights impact assessments, which shall consist of:

a) a description of the deployer's processes in which the high-risk AI system will be used in line with its intended purpose;
b) a description of the period of time within which, and the frequency with which, each high-risk AI system is intended to be used;
c) the categories of natural persons and groups likely to be affected by its use in the specific context;
d) the specific risks of harm likely to have an impact on the categories of natural persons or groups of persons, taking into account the information given by the provider;
e) a description of the implementation of human oversight measures, according to the instructions for use;
f) the measures to be taken in the case of the materialisation of the risks, including the arrangements for internal governance and complaint mechanisms.

The FRIA envisaged in the AI Act bears some resemblances to the data protection impact assessments (DPIAs) required by Article 35 General Data Protection Regulation (GDPR).[5] Therefore, Article 27(4) AI Act provides that if any obligations

[5] Felix Bieker and others, 'A Process for Data Protection Impact Assessment Under the European General Data Protection Regulation' in Stefan Schiffner and others (eds), *Privacy Technologies and Policy*, vol 9857 (Springer International Publishing, 2016), available at <https://link.springer.com/chapter/10.1007/978-3-319-44760-5_2> accessed 28 July 2025; Reuben Binns, 'Data Protection Impact Assessments: A Meta-Regulatory Approach' (2017) 7(1)

have already been met through the GDPR or the Data Protection Law Enforcement Directive 2016/680, these impact assessments may be carried out jointly. Importantly, while the AI Act itself was not accompanied by a standardised template of a fundamental rights impact assessment, Article 27(5) provides that a template for a questionnaire, including through an automated tool, will be developed by the AI Office.

Importantly, the FRIAs, as regulated by Article 27, are outside the scope of Article 99 which regulates penalties for breach of the AI Act, i.e. there are no explicit sanctions for non-compliance with Article 27 contained within the Act, which might also be considered as a weakness of this provision.

Impact assessments related to various fundamental rights are a commonly used methodology, including in EU law, where there exist different types of impact assessments. EU measures expected to have significant economic, social or environmental impacts, such as legislative proposals, are typically preceded by a regulatory impact assessment which also considers the impact on fundamental rights.[6] This is an internal procedure that is subject to various guidelines, and to scrutiny of an independent body called the Regulatory Scrutiny Board.

More recently, we are also seeing impact assessments as a requirement under various legislation, whether EU or national, placed on private companies or public bodies, such as will be the case with the FRIA in the AI Act. Examples in the EU include the above-mentioned DPIAs required under the GDPR, and environmental impact assessments required under the Environmental Impact Assessment Directive 2011/92/EU (as amended by 2014/52/EU). Indeed, drawing parallels with environmental, privacy and algorithmic impact assessments, Wernick argues that the FRIA required by the AI Act can be understood not as a wholly novel instrument but as a replicable legal design pattern, albeit one that is characterised by core procedural tensions: epistemic uncertainty, conflicting stakeholder interests and the temporality of risk mitigation.[7] Additionally, some jurisdictions may require a gender or disability impact assessment or – broadly – an equality impact assessment (e.g. in Ireland).

International Data Privacy Law 22; Katerina Demetzou, 'Data Protection Impact Assessment: A Tool for Accountability and the Unclarified Concept of "High Risk" in the General Data Protection Regulation' (2019) 35(6) Computer Law & Security Review 105342.

[6] Andrea Renda, *Impact Assessment in the EU: The State of the Art and the Art of the State* (Centre of European Policy Studies, 2006); Helen Toner, 'Impact Assessments and Fundamental Rights Protection in EU Law' (2006) 31(3) European Law Review 316; Alberto Alemanno, 'A Meeting of Minds on Impact Assessment' (2011) 17(3) European Public Law 485; Jacopo Torriti, 'Impact Assessment in the EU: A Tool for Better Regulation, Less Regulation or Less Bad Regulation?' (2007) 10(2) Journal of Risk Research 239.

[7] Alina Wernick, 'Impact Assessment as a Legal Design Pattern—A 'Timeless Way' of Managing Future Risks?' (2024) 3(2) Digital Society 29.

Some impact assessment methodologies, such as environmental impact assessments, are well researched and developed.[8] However, many of these methodologies focus on assessing the impact on one isolated right, or a group of related rights. Conversely, by introducing the duty to conduct a fundamental rights impact assessment, the EU is laying down a requirement of a comprehensive review, presumably taking account of all the fundamental rights that may potentially be affected in varied contexts and impacting differently situated individuals, by a given AI system. A fundamental rights impact assessment will, thus, become a new distinct feature of AI governance in the EU.

3. From the Human Rights Impact Assessment Model to the AI Act Fundamental Rights Impact Assessment

The FRIA bears a significant resemblance to the established practice of conducting human rights impact assessments (HRIA) for business and human rights.[9] However, notwithstanding the similarities, the FRIA is distinct in many ways, not least in relation to the terminology of fundamental rights and human rights. This distinction between 'human' and 'fundamental' rights originates from the differing legal frameworks that safeguard them. While the term 'human rights' has been in use in international frameworks, and notably the UN, the latter has been the norm in certain influential European jurisdictions, such as Germany. Consequently, the EU has embraced the term 'fundamental rights' to denote its own framework represented by the CFR. The difference is more than merely semantic insofar as using the terms 'human' or 'fundamental' rights points in the direction of relevant legal instruments and enforcement mechanisms. Despite these differences, however, the substance of the protected rights remains largely similar in the context of EU law.[10]

The concept of a HRIA was first introduced as early as the 1990s,[11] and it was popularised following the UN Human Rights Council's endorsement of the 2011 Guiding Principles on Business and Human Rights (UNGPs). These principles

[8] John Glasson and Riki Therivel, *Introduction to Environmental Impact Assessment* (Routledge, 2013).

[9] James Harrison, 'Human Rights Measurement: Reflections on the Current Practice and Future Potential of Human Rights Impact Assessment' (2011) 3(2) Journal of Human Rights Practice 162; Deanna Kemp and Frank Vanclay, 'Human Rights and Impact Assessment: Clarifying the Connections in Practice' (2013) 31(2) Impact Assessment and Project Appraisal 86; Richard Boele and Christine Crispin, 'What Direction for Human Rights Impact Assessments?' (2013) 31(2) Impact Assessment and Project Appraisal 128.

[10] Available at <https://fra.europa.eu/en/content/what-are-fundamental-rights> accessed 22 October 2024.

[11] Larry Gostin and Jonathan M Mann, 'Towards the Development of a Human Rights Impact Assessment for the Formulation and Evaluation of Health Policies' (1994) 1(1) Health and Human Rights 58.

implemented the 'Protect, Respect and Remedy' Framework[12] and stressed the specific human rights obligations of business enterprises, namely their responsibility to respect human rights principles.

Recognising the relevance of the 'Protect, Respect and Remedy' Framework for digital technologies, including AI, the UN's B-Tech Project has developed a roadmap and set of tools to implement the UNGPs specifically in the context of digital technologies. Led by the UN Human Rights Office and developed in consultation with key stakeholders,[13] it aims to produce guidance notes, good practice case studies, commentary on shared dilemmas and policy recommendations clarifying the implementation of the UNGPs in the context of digital technologies. Importantly, the B-Tech Project addresses the risks of generative AI and the UN's expectations towards tech companies developing generative AI.

In fact, the B-Tech Project offers a taxonomy of generative AI harms based on the Universal Declaration of Human Rights (UDHR).[14] Many of the identified risks pertain to UDHR rights which directly correspond to the fundamental rights enshrined in the CFR.[15] Examples include the right to life (Article 3 UDHR and Article 2 CFR), prohibition of torture and cruel, inhumane or degrading treatment (Article 5 UDHR and Article 4 CFR), equality (Article 7 UDHR and Article 20 CFR), non-discrimination (Article 2 UDHR and Article 21 CFR), private and family life (Article 12 UDHR and Article 7 CFR), intellectual property (Article 27(2) UDHR and Article 17(2) CFR), freedom of thought, conscience and religion (Article 18 UDHR and Article 10 CFR), freedom of expression and information (Article 19 UDHR and Article 11 CFR), the right to vote and be elected (Article 21 UDHR and – to some extent – Articles 39 and 40 CFR).

Therefore, while stemming from a different human rights framework than the CFR, the UN B-Tech Project may constitute a source of inspiration for the enforcement of the AI Act. This aligns with a proposal from Mantelero, who in 2018 recognised the potential of the HRIA model in AI governance,[16] albeit with the caveat that the HRIA

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[12] Report of the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, John Ruggie 'Protect, Respect and Remedy: A Framework for Business and Human Rights' (A/HRC/8/5 2008), available at <https://digitallibrary.un.org/record/625292?ln=en&v=pdf> accessed 22 October 2024. See Nora Götzmann, 'Introduction to the Handbook on Human Rights Impact Assessment: Principles, Methods and Approaches', in *Handbook on human rights impact assessment* (Edward Elgar Publishing 2019); Nora Götzmann, 'Human Rights Impact Assessment of Business Activities: Key Criteria for Establishing a Meaningful Practice' (2017) 2(1) Business and Human Rights Journal 87.

[13] Available at <https://www.ohchr.org/en/business-and-human-rights/b-tech-project> accessed 15 October 2024.

[14] Universal Declaration of Human Rights (adopted 10 December 1948 UNGA Res 217 A(III) (UDHR).

[15] Charter of Fundamental Rights of the European Union [2016] OJ C 202/389.

[16] Alessandro Mantelero, 'AI and Big Data: A Blueprint for a Human Rights, Social and Ethical Impact Assessment' (2018) 34(4) Computer Law & Security Review 754; Alessandro Mantelero,

in the context of AI is distinct from the traditional HRIA.[17] In particular, he noted that such an approach would enable recourse to existing tools, whether developed in connection with the UNGPs or designed by other institutions. Recent legislative initiatives in the EU also show a growing interest in implementing the HRIA model in additional domains of activity.

Perhaps the most significant example is the Corporate Sustainability Due Diligence Directive adopted on the same day as the AI Act.[18] The Directive lays down a new obligation for companies operating within the EU to identify, prevent and mitigate 'adverse impacts' on human rights and the environment throughout their global value chains.[19] In this vein, the term 'adverse human rights impact' is defined, in Article 3(1)(c) of the Directive, as compromising human rights enshrined in international instruments listed in the Annex to the Corporate Sustainability Due Diligence Directive. Highlighting the complementarity between EU fundamental rights obligations and those required by UN conventions, the Annex includes 16 specific rights stemming from the International Covenant on Civil and Political Rights (ICCPR)[20] and the International Covenant on Economic, Social and Cultural Rights (ICESPR).[21] It also includes the core conventions of the International Labour Organization (ILO), e.g. the Right to Organise and Collective Bargaining Convention[22] or the Equal Remuneration Convention.[23] The same logic applies to 'adverse environmental impacts' (Article 3(1)(b) of the Corporate Sustainability Due Diligence Directive) where 16 prohibitions and obligations have been identified based on various

'Human Rights Impact Assessment and AI' in Alessandro Mantelero (ed), *Beyond Data: Human Rights, Ethical and Social Impact Assessment in AI* (TMC Asser Press 2022) <https://doi.org/10.1007/978-94-6265-531-7_2> accessed 28 February 2024; Alessandro Mantelero and Maria Samantha Esposito, 'An Evidence-Based Methodology for Human Rights Impact Assessment (HRIA) in the Development of AI Data-Intensive Systems' (2021) 41 Computer Law & Security Review 105561.

[17] See also Alessandro Mantelero, 'The Fundamental Rights Impact Assessment (FRIA) in the AI Act: Roots, Legal Obligations and Key Elements for a Model Template' (2024) 54 Computer Law & Security Review 106020.

[18] Council and Parliament Directive (EU) 2024/1760 on corporate sustainability due diligence and amending Directive (EU) 2019/1937 and Regulation (EU) 2023/2859, OJ L, 2024/1760.

[19] Christopher Patz, 'The EU's Draft Corporate Sustainability Due Diligence Directive: A First Assessment' (2022) 7(2) Business and Human Rights Journal 291; Livia Ventura, 'Corporate Sustainability Due Diligence and the New Boundaries of the Firms in the European Union' (2023) 34(2) European Business Law Review 239; Nicolas Bueno and others, 'The EU Directive on Corporate Sustainability Due Diligence (CSDDD): The Final Political Compromise' (2024) 9(2) Business and Human Rights Journal 294.

[20] International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976) 999 UNTS 171 (ICCPR).

[21] International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 23 March 1976) 993 UNTS 3 (ICESPR).

[22] ILO, Right to Organise and Collective Bargaining Convention, 1949 (No 98).

[23] ILO, Equal Remuneration Convention, 1951 (No 100).

environmental instruments, such as the World Heritage Convention,[24] the Convention on Biological Diversity,[25] the Stockholm Convention on Persistent Organic Pollutants,[26] etc. Thus, the adoption of the Corporate Sustainability Due Diligence Directive highlights the complementarity of these requirements and exemplifies growing awareness of the need to incorporate global human rights frameworks into the EU legal order.

4. Which Fundamental Rights might Fall into the Scope of the EU AI Act

The preamble to the AI Act acknowledges that an important metric for classifying AI systems as high risk is 'the extent of the adverse impact caused by the AI system on fundamental rights protected by the Charter' (Recital 48). While fundamental rights are recognised as general principles of EU law, there is not a single uniform source of fundamental rights protection in the EU.[27] Article 6 of the Treaty on the European Union (TEU) lists three such sources: 1) constitutional traditions common to the Member States; 2) the European Convention for the Protection of Human Rights and Fundamental Freedom (ECHR), to which all the EU Member States are parties; and 3) the CFR. The latter instrument, declared in 2000 and binding since 2009, is chronologically the latest addition to EU fundamental rights protection framework and remains considerably under-used in litigation. It has, nevertheless, gradually been gaining in prominence as a fundamental rights protection instrument.[28]

Indeed, when referring to fundamental rights protection in AI governance, the EU AI Act has largely followed the language of the CFR, which has been referred to on many occasions. The Preamble to the AI Act, in Recital 48, specifically mentions 17 rights, which were also included in the European Commission's Proposal for the AI Act. While other CFR rights also enjoy protection under the AI Act and should be incorporated into the FRIA, it appears that the Commission expects certain rights to be more directly impacted by the AI Act. These translate into 23 Charter Articles, as presented in the table overleaf:

[24] Convention Concerning the Protection of the World Cultural and Natural Heritage, 1037 UNTS 151, 27 UST 37, 11 ILM 1358 (1972).
[25] The Convention on Biological Diversity of 5 June 1992 (1760 UNTS 69).
[26] Stockholm Convention on Persistent Organic Pollutants, 22 May 2001, 2256 UNTS 119; 40 ILM 532 (2001).
[27] Eleanor Spaventa, 'Should We "Harmonize" Fundamental Rights in the EU? Some Reflections about Minimum Standards and Fundamental Rights Protection in the EU Composite Constitutional System' (2018) 55(4) Common Market Law Review 997; Elise Muir, 'Fundamental Rights: An Unsettling EU Competence' (2014) 15 Human Rights Review 25.
[28] Daniel Sarmiento, 'Who's Afraid of the Charter? The Court of Justice, National Courts and the New Framework of Fundamental Rights Protection in Europe' (2013) 50(5) Common Market Law Review 1267.

Table 1. Fundamental rights identified in Recital 48 to the AI Act and corresponding Articles of the CFR

Right to human dignity	Article 1 CFR
Respect for private and family life	Article 7 CFR
Protection of personal data	Article 8 CFR
Freedom of expression and information	Article 11 CFR
Freedom of assembly and association	Article 12 CFR
Non-discrimination	Article 21 CFR
Right to education	Article 14 CFR
Consumer protection	Article 38 CFR
Workers' rights	Articles 15, 27−32 CFR
Rights of persons with disabilities	Article 26 CFR
Gender equality	Article 23 CFR
Intellectual property rights	Article 17(1) CFR
Right to an effective remedy and to a fair trial	Article 47 CFR
Right of defence and the presumption of innocence	Article 48 CFR
Right to good administration	Article 41 CFR
Children's rights	Article 24 CFR
Environmental protection	Article 37 CFR

Specific CFR rights can be linked to specific provisions of the AI Act in various ways which will be addressed in the examples below. For instance, regarding AI's impact on the right to education (Article 14 CFR), AI systems used to determine admission to educational and vocational training institutions or assess the appropriate level of education that an individual will receive, and those used to evaluate learning outcomes or detect prohibited behaviour in testing, are considered high risk and have been included in Annex III to the AI Act. Furthermore, Article 5(1) AI Act bans the use of AI systems that infer emotions in education except when justified by medical or safety reasons. Another example is Article 12(1) CFR (freedom of assembly and association), which clarifies that this applies 'at all levels, in particular in political, trade union and civic matters, which implies the right of everyone to form and to join trade unions'.

The potential impact of AI on this right has been recognised in Article 5 AI Act which prohibits certain types of AI uses. Accordingly, the prohibition of using biometric categorisation systems that categorise individually natural persons based on their biometric data to deduce or infer their race, political opinions, trade union membership, religious or philosophical beliefs, sex life or sexual orientation (Article 5(1)(g)) is grounded, *inter alia*, in Article 12(1) CFR. Other fundamental rights that potentially overlap in this prohibition are the protection of personal data (Article 8

CFR), non-discrimination (Article 21 CFR), equality (Article 20 CFR), including gender equality (Article 23 CFR), the right to private and family life (Article 7 CFR) and freedom of thought, conscience and religion (Article 10 CFR).

However, the list of fundamental rights, as identified in Recital 48 of the Preamble to the AI Act, is incomplete, as other fundamental rights protected by the CFR, which have not been explicitly mentioned in the AI Act, may also be impacted by the new legislation. In the above example of the ban on using biometric data to infer certain personal characteristics, relevant CFR provisions not included in the AI Act are the right to equality (Article 20 CFR) and the freedom of thought, conscience and religion (Article 10 CFR). Another example of CFR rights that have not been included in Recital 48 – and yet fall within the scope of the AI Act – are the right to asylum (Article 18 CFR) and protection in the event of removal, expulsion or extradition (Article 19 CFR).

Annex III to the AI Act lists those AI systems that in the context of migration, asylum and border control management are to be classified as high risk. This classification is made with the understanding that the use of AI in these areas is contingent upon approval by the EU and/or individual Member States. However, empirical evidence suggests that AI-based technologies are already being deployed in migration-related contexts globally.[29] These include AI tools used as polygraphs, AI systems used to assess individuals seeking to enter an EU Member State, those used to assist in assessing applications for asylum or visa and associated complaints, as well as the use of AI for identification or document verification in border control management.

Moreover, further analysis conducted reveals that the AI Act may potentially impact nearly all the substantive rights included in the CFR, whether directly or indirectly.[30] Furthermore, it appears that certain CFR rights may also potentially be used as defences against too stringent EU interference. This applies particularly to the freedom to conduct a business (Article 16 CFR). Indeed, by prohibiting certain types of AI uses and introducing stringent monitoring mechanisms for those considered high risk, the EU is a considerable interference with the freedom to conduct business

On a general note, the CFR rights will in most instances likely pose some limits to the use of AI, like in the above example of the ban on using biometric data to infer certain personal characteristics. As fundamental rights are of relevance to high-risk AI, the placing on the market of AI systems listed in Annex III to the AI Act will require a

[29] Petra Molnar, 'Technology on the Margins: AI and Global Migration Management from a Human Rights Perspective' (2019) 8(2) Cambridge International Law Journal 305; Ana Beduschi, 'International Migration Management in the Age of Artificial Intelligence' (2021) 9(3) Migration Studies 576.

[30] The CFR consists of 54 Articles in total, but the final four Articles, laid down in Chapter VII, constitute the so-called horizontal provisions that do not contain substantive individual rights. These are found in Articles 1−50 CFR.

balancing act employing the principle of proportionality, with specific rights, or multiple specific rights placed on one end of the scale.[31]

5. FRIAs: Delivering Human Rights Protections in High-risk Systems?

FRIAs are intended to provide fundamental and far-reaching safeguards for the human rights of individuals across the EU whenever high-risk systems are to be deployed. They do so by assessing and mitigating the potential and actual human rights impacts of AI systems deployment, within the parameters of the AI Act. As such, they carry the weight of political and ethical expectation that they will protect and promote the equal dignity and rights of all individuals in the context of the development of this transformative technology. While the FRIA proposed in the AI Act is a discrete entity, as noted earlier, it shares some elements of HRIAs, particularly those developed in response to the UNGPs, and the cautions and challenges analysed over the 20 years of HRIA operationalisation provide important pointers for FRIA development. Lessons from evaluations of the effectiveness of HRIAs are therefore significant in this context since they highlight challenges of process and substance that will also likely arise in the context of the planned FRIA.[32] The challenges are (1) technical, i.e., relating to the processes, methodologies and technical rationality of the genre of the impact assessment; (2) conceptual, i.e., relating to the FRIA's individualistic and discrete conceptualisation of human rights; and (3) political i.e., relating to the processes by which public trust in FRIAs can be created, earned and maintained.[33]

5.1 Technical Challenges: Indicators and Processes

Human rights impact assessments function within the context of internationally recognised human rights standards, with the FRIA referencing the CFR, and must adhere to these standards in all phases of the development and implementation of the impact assessment. Moreover, this expectation applies both to the substance,

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[31] See further Wolf Sauter, 'Proportionality in EU Law: A Balancing Act?' (2013) 15 Cambridge Yearbook of European legal studies 439; Tor-Inge Harbo, 'The Function of the Proportionality Principle in EU Law' (2010) 16(2) European Law Journal 158; Filippo Fontanelli, 'The Mythology of Proportionality in Judgments of the Court of Justice of the European Union on Internet and Fundamental Rights' (2016) 36(3) Oxford Journal of Legal Studies 630.

[32] Nora Götzmann (ed), *Handbook on Human Rights Impact Assessment* (Edward Elgar, 2019). See especially Nora Götzmann, 'Introduction to the Handbook on Human Rights Impact Assessment: Principles, Methods and Approaches, in Götzmann, op. cit., 2−30, Kendyl Salcito, 'Company-commissioned HRIA: Concepts, Practice, Limitations and Opportunities', in Götzmann, op.cit., 32−48 and Margaret Wachenfeld, Elin Wrzoncki and Luis F. de Angulo, 'Sector-wide Impact Assessment: A "Big Picture" Approach to Addressing Human Rights Impacts' in Götzmann, op.cit., 85−100.

[33] Susan Joyce, 'Challenges and Strategies for Meaningful Rights-holder Participation in Company-commissioned HRIA' in Götzmann (n 32) 287−301, Roper Cleland, 'Understanding Conflict for HRIA' in Götzmann (n 32) 302–318 and Rebecca DeWinter-Schmitt and Kendyl Salcito, 'The Need for a Multidisciplinary HRIA Team: Learning and Collaboration Across Fields of Impact Assessment', in Götzmann (n 32) 319−335.

including benchmarks, indicators and assessment tools, and to the process of devising, agreeing and implementing the impact assessments.

The challenges of identifying appropriate benchmarks, indicators and assessment tools for the HRIA are well understood in the context of the UNGPs.[34] Among the challenges are those associated with utilising quantitative methods to assess compliance with human rights instruments.[35] Indeed, commenting on the FRIA process under the AI Act, Malgieri and Santos already noted the relevance of what they contend is 'a foundational disagreement between business scholars affirming that anything can be quantified and human rights scholars who are reluctant to quantifications of human rights or value'.[36]

Providing a partial response to this difficulty, the Office of the High Commissioner of Human Rights (OHCHR) recommends using both quantitative and qualitative indicators to establish the human rights impacts of business activity. Its recommended methodology institutes a two-phase approach: first, establishing the normative content of the relevant rights, and secondly, assessing the implementation according to structural, process and outcome indicators.

Notwithstanding this more comprehensive approach, however, the OHCHR also notes that 'indicators are tools that add value to assessments with a strong qualitative dimension; they do not replace them'.[37] Adding to the complexity, the *Danish Institute of Human Rights Human Rights Impact Assessments Guidance and Toolbox*[38] notes that the nature, scope and severity of the actual and potential human rights impacts need to be evaluated when performing a human rights impact assessment. It notes further that the indicators must be capable of capturing a range of diverse, qualitative dimensions, including the attributes of the rights affected. In addition, they need to be sufficiently nuanced to enable such evaluations in each discrete context, and in relation to each particular individual. Moreover, establishing the measures adequate to determining the nature, scope and scale of human rights impacts on discrete individuals and groups is complex and often contested. So too is

[34] James Harrison and Sharifah Sekalala, 'Addressing the Compliance Gap? UN Initiatives to Benchmark the Human Rights Performance of States and Corporations' (2015) 41(5) Review of International Studies 925.
[35] Johan J Graafland, Sylvester CW Eijffinger and H SmidJohan, 'Benchmarking of Corporate Social Responsibility: Methodological Problems and Robustness' (2004) 53(1–2) Journal of Business Ethics 137.
[36] Gianclaudio Malgieri and Cristiana Santos, 'Assessing the (Severity of) Impacts on Fundamental Rights' (2025) 56 Computer Law & Security Review 56 106113, 2.
[37] Cathrine Bloch Veiberg, Gabriela Factor and Jacqueline R. Tedaldi, 'Measuring human rights: Practice and trends in the use of indicators for HRIA' in Nora Götzmann (ed), *Handbook on Human Rights Impact Assessment* (Edward Elgar, 2019); UN Guiding Principles; Office of the United Nations High Commissioner for Human Rights (2012), Human Rights Indicators: A Guide to Measurement and Implementation, Geneva and New York: OHCHR, HR/PUB/12/5, 21.
[38] The Danish Institute for Human Rights, *Human Rights Impact Assessments Guidance and Toolbox* (Copenhagen, 2020), available at <https://www.humanrights.dk/tools/human-rights-impact-assessment-guidance-toolbox> accessed 14 June 2025.

the determination of the relative weight to be given to each of the categories of nature, scope and scale.[39] In this context there are also frequent challenges of data collection and data disaggregation, as well as difficulties of establishing the normative content of relevant rights as they are embedded in specific social, cultural and political contexts, and as they are experienced by discrete groups or communities, and of baseline development.[40]

In addition to determining appropriate indicators and measures to assess the impact of a particular business on human rights, the processes by which HRIAs are developed are expected to conform to human rights principles. This has many dimensions, but of particular importance is meaningful participation of all stakeholders in all stages of the design and implementation of the human rights impact assessment. As Götzmann argues, 'meaningful participation in the impact assessment process can be as important as the outcomes'.[41]

Impact assessments can be company-commissioned, company-led, sector-wide or community-based, and each scenario poses particular challenges for the meaningful involvement of all relevant stakeholders. As noted by Götzmann, it is vital that 'rights-holders are considered to be active agents in the impact assessment process',[42] and that the model of participation is expansive, in terms of 'questioning and broadening the points in time at which participation occurs; the level of information sharing involved in participation and consultation activities; and empowerment and capacity building of individuals to participate in the impact assessment'.[43] Meaningful stakeholder participation will also need to address and mitigate forms of political exclusion based on particular or intersectional vulnerabilities.[44]

Commenting on the genre of human rights impact assessments, Rosga and Satterthwaite note a further limitation, arguing that human rights indicators such as are utilised in these impact assessments are prone to 'Goodhart's Law', whereby a

[39] Ibid, especially 62–80.
[40] Ibid, especially 139–141; Cathrine Bloch Veiberg, Gabriela Factor and Jacqueline R. Tedaldi, 'Measuring Business Impacts on Human Rights: Practice and Trends in the Use of Indicators for HRIA', in Götzmann (n 37) 336–353, and Nora Götzmann, 'The Concept of Accountability in HRIA', in Götzmann (n 37) 373–389.
[41] Götzmann (n 37) 8 quoting Gabrielle Watson, Irit Tamir and Brianna Kemp, 'Human Rights Impact Assessment in Practice: Oxfam's Application of a Community-based Approach' (2013) 31(2) Impact Assessment and Project Appraisal 118–127.
[42] Ibid, 8.
[43] Ibid.
[44] See for example Tara M. Collins, 'Children's Rights in HRIA: Marginalized or Mainstreamed?' in Götzmann (n 37) 119−134,Cathal Doyle, 'Indigenous Peoples' Rights: Is HRIA an Enabler for Free, Prior and Informed Consent?' in Götzmann (n 37) 135−153, and Bonita Meyersfeld, 'The Rights of Women and Girls in HRIA: The Importance of Gendered Impact Assessment' in Götzmann (n 37) 154–170.

measure becomes a target, and thus ceases to be a good measure.[45] Consequently, the gap between what is reported and the true level of enjoyment of human rights widens. Moreover, Kemp and Vanclay refer to the 'immaturity' of the framework for assessing human rights impacts, noting the many conceptual and operational challenges that human rights raise for impact assessment methodologies.[46] Thus, while not a direct comparator for the FRIA proposed in the AI Act, more than two decades of experience of developing and implementing HRIAs in different contexts has nonetheless highlighted technical challenges that are likely to be relevant for the FRIA, particularly as its methodology and template are developed.

The AI Act's requirement that FRIAs be carried out in specific circumstances has generated a number of recent scholarly contributions that have offered some insights into the conceptual foundations, methodological structure, and operational metrics of the FRIA, with a focus on the importance of a person's context to their enjoyment of human rights. Of particular relevance is Mantelero's model template for FRIA, tailored to meet the requirements of the AI Act while also applicable in broader national and international contexts. His template outlines the key components of an effective FRIA, including the contextual analysis of AI deployment, stakeholder mapping, identification of at-risk rights, and documentation of mitigation strategies. The model prioritises procedural rigour, transparency and adaptability to evolving technological and societal dynamics. We agree with Manetelero's assertion that the relevant parameters to be considered in the FRIA process 'are inevitably context-based and grounded on expert knowledge of fundamental rights',[47] and recognise this development as an important first step. Moreover, an adequate level of contextuality could, in our view, be achieved by incorporating concepts of intersectionality and vulnerability into the analysis, which we discuss below.

In a similar vein, Malgieri and Santos[48] have also developed a multi-metric framework to assess the severity of AI interferences with fundamental rights, and in so doing attend to some of the challenges highlighted above, and which are, to a degree, addressed in the *Danish Institute of Human Rights Human Rights Impact Assessments Guidance and Toolbox.* They introduce a spectrum model of rights interference, encompassing everything from minor inconveniences to egregious violations. Drawing on social meaning theory, perception studies and regulatory doctrine, they propose operational parameters for severity assessment – including intensity, duration, scale of impact and societal salience. These metrics allow for both *ex ante* and *ex post* evaluations, facilitating proactive mitigation as well as judicial redress. This too is a significant contribution in light of the divergence between harm and risk-

[45] Ann J. Rosga and Margaret L. Satterthwaite, 'The Trust in Indicators: Measuring Human Rights' (2009) 27(2) Berkeley Journal of International Law 253.
[46] Deanna Kemp and Frank Vanclay, 'Human Rights and Impact Assessment: Clarifying the Connections in Practice' (2013) 31(2) Impact Assessment and Project Appraisal 86, 91–92.
[47] Mantelero (n 17) 5.
[48] Malgieri and Santos (n 36).

based approaches in the FRIA and rights-based approaches employed in litigation before the CJEU, which will be discussed in more detail in the next section.

5.2 Conceptual Challenges: Intersectionality and Vulnerability

However, it will be important that the technical aspects of the FRIA are developed in a nuanced, transparent and robust manner, according to human rights principles, if they are to be adequate to the task of assessing the human rights impacts of AI systems deployed in high-risk arenas. We note that the methodology developed by Malgieri and Santos, if adopted, would go a significant way to address many of these concerns. In addition to addressing the technical complexities noted above, the FRIAs will also need to tackle some underlying conceptual limitations. In particular, FRIAs will need to be able to reckon with the interdependent and intersectional nature of human rights challenges as they arise through the deployment of AI.

Currently, FRIAs (like the HRIAs) tend to focus exclusively on individual (i.e., discrete) human rights. Yet some AI systems carry risks that cannot be sufficiently or adequately addressed or mitigated solely through the language of individual human rights. For example, the dissemination of false online content generated by AI to spread misinformation and manipulate public opinion will undoubtedly impact the freedom of thought, conscience and religion (Article 10 CFR) of some individuals. However, it may also have an impact on the wider society and on the functioning of democracy going beyond individual human rights, for example by influencing election results, and therefore indirectly it may also impact the right to vote and to stand as a candidate in elections (Articles 39 and 40 CFR). In these contexts, AI may have direct impacts on multiple specific rights of individuals.

In addition, an AI system may compromise not only multiple human rights of individuals, but also political frameworks within which individual human rights are embedded and advanced. As currently conceived, FRIAs operate on the level of individual discrete fundamental rights, and while it is possible to identify how an AI system may indirectly impact multiple CFR rights, nonetheless FRIAs as currently conceptualised do not have the capacity to assess the consequent impacts on the political frameworks within which individual rights are guaranteed.

FRIAs also struggle to address intersectionality, a factor that is particularly relevant in AI governance. A sociolegal concept, intersectionality conveys how multiple forms of inequality can be compounded to create overlapping systems of disadvantage that often defy traditional ways of conceptualising discrimination derived from discrete categories, such as gender, race or religion. As an analytic framework for evaluating societal relationships of power and privilege,[49] intersectionality is highly relevant in non-discrimination law, where relying on traditional, single grounds of discrimination sometimes fails to do justice to disadvantaged groups or individuals. The concept was

[49] Patricia Hill Collins and Sirma Bilge, *Intersectionality* (John Wiley & Sons 2020).

first theorised by Crenshaw,[50] who argued that some groups of rights-holders, for example women, are not a homogeneous category and thus may be exposed to discrimination arising from various sources. Götzmann explains this is 'not as simple as a person experiencing "double" discrimination, but instead multiple identity factors give rise to a specific position and experience of discrimination that warrants attention particular to that experience'.[51]

In the EU, however, to date the Court of Justice (CJEU) has refused to recognise discrimination on combined grounds. The CJEU was first confronted with this issue in C-443/15 *Parris*, which concerned the refusal to recognise a same-sex partner as eligible for a survivor's pension payable to a spouse. The CJEU ruled that the case at issue did not constitute discrimination on the grounds of age or sexual orientation.[52] In a similar vein, the CJEU has repeatedly refused to recognise dismissals of female Muslim workers who wore headscarves in the workplace as instances of discrimination on combined grounds of religion and gender. This matter arose in a series of cases, including C-157/15 *Achbita*, C-188/15 *Bougnaoui*, C-804/18 and C-341/19 *WABE and Müller*, C-344/20 *SCRL* and C-148/22 *OP v Commune d'Ans.*[53] Nonetheless, the overlaps of breaches of specific fundamental rights do occur, and Schiek argues that EU non-discrimination law can successfully be interpreted to encompass the concept of intersectionality by using a purposive interpretation.[54]

Thus, the incorporation of the concept of intersectionality into the FRIA model may be an invaluable contribution to its future efficacy, particularly in the context of AI, since it provides a comprehensive and dynamic lens through which AI's impact on fundamental rights can be understood, and thereby assessed. Without incorporating the contextual lens of intersectionality, some affected stakeholders who for various reasons cannot be classified into the traditional grounds of discrimination (for example, female Muslim employees, as was in the case in the 'headscarf' saga) might indeed not be adequately identified in the FRIA process.

Attention to intersectionality would allow for an assessment of impacts on subjects who experience overlapping and intersecting forms of discrimination. However, in the context of AI, different CFR rights might be impacted not by the AI technology itself, but rather by the context in which it is being used. This adds a layer of complexity to the nature of the fundamental rights assessments, and for which a focus on

[50] Kimberlé Crenshaw, 'Demarginalizing the Intersection of Race and Sex: A Black Feminist Critique of Antidiscrimination Doctrine, Feminist Theory and Antiracist Politics (1989) 140(1) University of Chicago Legal Forum 139.
[51] Götzmann (n 37).
[52] Shreya Atrey, 'Illuminating the CJEU's Blind Spot of Intersectional Discrimination in *Parris v Trinity College Dublin*' (2018) 47(2) Industrial Law Journal 278.
[53] Erica Howard, *Headscarves and the Court of Justice of the European Union: An Analysis of the Case Law* (Taylor & Francis, 2023).
[54] Dagmar Schiek, 'On Uses, Mis-Uses and Non-Uses of Intersectionality before the Court of Justice (EU)' (2018) 18(2) International Journal of Discrimination and the Law 82.

intersectionality alone may not be adequate. For example, there are serious human rights issues with the use of AI by vulnerable persons such as children, or the use of AI by others whose activity may have a direct or indirect impact on children. Article 24 of the CFR highlights the rights of the child, and these intersect in multiple ways with other fundamental rights. Children cannot be expected to behave like an average AI user and therefore warrant special protection, particularly where Article 24 CFR overlaps with other CFR rights.

In this context 'the vulnerable subject' theory may provide further conceptual and legal avenues for protection. Like intersectionality, the vulnerable subject theory departs from the notion of rigid grounds of discrimination but may also be more easily accessible within the framework of the AI Act. Pioneered by Martha Albertson Fineman[55] as an alternative theory that can address the limitations of traditional equality law, the vulnerable subject theory argues that dominant legal and political theories are centred around the so-called liberal subject, who 'is a competent social actor' exemplified by a reasonable adult. The vulnerable subject theory challenges this presumption by framing the universal human condition as a state of a constant possibility of harm, where 'individuals are anchored at each end of their lives by dependency and the absence of capacity'.[56]

In recent times, the vulnerable subject theory has to some extent been incorporated into the European human rights framework by the Council of Europe and the European Court of Human Rights (ECtHR), albeit the ECtHR interprets the term more narrowly than Martha Albertson Fineman, applying it specifically to marginalised groups.[57] Of particular interest to the AI context is the Human Rights, Democracy and Rule of Law Impact Assessment (HUDERIA) methodology developed under the auspices of the Council of Europe's Committee on Artificial Intelligence for evaluating the societal risks of AI systems.[58] HUDERIA aims to ensure that AI development and deployment upholds fundamental rights, democratic principles, and the rule of law, in alignment with international human rights standards. Importantly, vulnerability is embedded in this contextual risk assessment analysis at various stages of the process.

In the EU context, Article 5(1) AI Act prohibits the use of AI systems that exploit the vulnerabilities of a person or a group of people due to their age, disability and social or economic situation. This provision highlights the paramount importance of the context in which AI is used, which will translate into the task of appropriately

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[55] Martha Albertson Fineman and Anna Grear, *Vulnerability: Reflections on a New Ethical Foundation for Law and Politics* (Ashgate Publishing, 2013); Martha Albertson Fineman and Jonathan W. Fineman, *Vulnerability and the Legal Organization of Work* (Routledge, 2017).
[56] Martha Albertson Fineman, 'The Vulnerable Subject: Anchoring Equality in the Human Condition' in *Transcending the boundaries of law* (Routledge-Cavendish, 2010).
[57] Alexandra Timmer et al, 'The Potential and Pitfalls of the Vulnerability Concept for Human Rights (2021) 39(3) Netherlands Quarterly of Human Rights 190.
[58]Available at <https://www.coe.int/en/web/artificial-intelligence/huderia-risk-and-impact-assessment-of-ai-systems> accessed 17 June 2025.

identifying the categories of potentially affected persons in the process of conducting the FRIA in accordance with Article 27(1) AI Act.

While the CJEU has never been confronted with the vulnerable subject theory, EU law does offer some tools that would enable the Court to engage with it. It can be argued that the vulnerable subject theory is already reflected to some extent in non-discrimination law through protected grounds such as age or disability, where the law recognises that all individuals are, at some stage of their lives, particularly susceptible to harm as their mental or physical state is compromised. Importantly, the courts have in recent years extended the definition of disability beyond a permanent condition to also include a temporary incapacity, for example arising from a serious illness.[59]

While the CFR does not use the language of vulnerability, the vulnerable subject theory has infiltrated some secondary EU legislation such as consumer law, as well as criminal law. As explained by Waddington, the EU criminal law incorporates vulnerability through focus on the rights of victims of crime, as well as those of suspects and accused persons.[60] EU consumer law, which is of particular relevance as being closely linked to the AI Act through product safety, has introduced the notion of 'particularly vulnerable consumers' who, unlike 'average consumers', might not be able to make reasonable choices due to, for example, 'mental or physical infirmity, age or credulity'.[61] In this vein, Riefa makes the case for a paradigm shift in EU consumer law to better protect vulnerable consumers in the digital single market. She suggests reversing the traditional expectation that average consumers act as market arbiters, proposing instead that businesses should be responsible for ensuring fairness by design.[62] Riefa emphasises that consumer protection should not rely solely on consumers' ability to defend themselves, but should be proactively addressed by businesses and enforced by regulators.

5.3 Political Challenges: Participation and Power

The technical and conceptual issues that will likely limit the FRIA's capacity to address and mitigate the fundamental rights impacts of AI are many. Moreover, others are likely to emerge during the design and implementation of these instruments. In addition, the political and business contexts in which FRIAs will function are also relevant to their capacity to protect the fundamental rights of individuals when AI systems are identified as high risk, even though in practice they are primarily deployed by public bodies. In particular, since each impact assessment will require balancing different interests and rights the question of how the interests of stakeholders and citizens will be heard in the internal (behind-closed-doors?)

[59] See Joined cases C-335/11 and C-337/11 *Jette Ring and Lone Skouboe Werge*, EU:C:2013:222.
[60] Lisa Waddington, 'Exploring Vulnerability in EU Law: An Analysis of "Vulnerability" in EU Criminal Law and Consumer Protection Law' (2020) 45(6) European Law Review 779.
[61] Ibid.
[62] Christine Riefa, 'Protecting Vulnerable Consumers in the Digital Single Market' (2022) 33(4) European Business Law Review 607.

processes whereby the impacts on fundamental rights, understood in a comprehensive and intersectional manner, are assessed. As noted in section 5.1 above, stakeholder participation is vital for the legitimacy and efficacy of human rights impacts assessments. However, in this regard the AI Act disappoints, by recommending, but not requiring, stakeholder engagement in the design, development and implementation of FRIAs.[63]

Indeed, in its analysis of the AI Act a coalition of human rights and social justice groups concluded that 'civil society organisations will not have a direct, legally-binding way to contribute to impact assessments'.[64] Moreover, the long history of ethics-washing by technology companies raises legitimate concerns among human rights advocates regarding the objectivity and comprehensiveness of company-led FRIAs.[65] In addition, the exclusion of law enforcement and migration authorities from certain rules about transparency of data poses further risks, particularly in contexts where governance and oversight of these authorities is weak or where 'the rule of law' is politicised.[66]

The wider context of the ever-evolving AI will also likely pose unprecedented challenges to the implementation of the new EU rules. Notably, lengthy lawmaking procedures make it difficult for the law to keep up with fast-paced technologies such as AI. The first proposal for the AI Act[67] was followed by the launch, in late 2022, of ChatGPT, an open tool using generative AI. Hence, the original proposal for the AI Act was substantially revised by the European Parliament in June 2023 to accommodate for generative AI. There is a risk that the pace of technological development will render FRIAs obsolete before they are implemented. Similarly, there are challenges with the requirement that FRIAs will need to assess the future impacts of an AI system based on current knowledge. This will inevitably carry some margin of error. Given the scale and seriousness of these processes, and the question of whether there is the capacity for transparent and honest self-assessment, the issue of meaningful oversight and governance inevitably arises.

6. AI and Fundamental Rights Violations before the CJEU

Malgieri and Santos critically interrogate the conceptual underpinnings of FRIA, particularly the tension between rights-based and risk-based approaches.[68] They

[63] Available at <https://www.amnesty.eu/wp-content/uploads/2024/04/EUs-AI-Act-fails-to-set-gold-standard-for-human-pdf> accessed 17 June 2025.
[64] Available at <https://www.amnesty.eu/wp-content/uploads/2024/04/EUs-AI-Act-fails-to-set-gold-standard-for-human-pdf> accessed 17 June 2025.
[65] Linda Hogan and Marta Lasek-Markey, 'Towards a Human Rights-Based Approach to Ethical AI Governance in Europe' (2024) 9(6) Philosophies 181.
[66] Available at <https://www.amnesty.eu/wp-content/uploads/2024/04/EUs-AI-Act-fails-to-set-gold-standard-for-human-pdf> accessed 17 June 2025.
[67] Commission, Proposal for a Council and Parliament Regulation Laying down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act) and Amending Certain Union Legislative Acts, COM(2021) 206 final.
[68] Malgieri and Santos (n 36).

argue that while recent EU legislation introduces an approach based on the risk of harm as prevention (and the AI Act is a salient example of this approach), in litigation the CJEU employs an approach that is based on the violation of rights, where harm is not a prerequisite for a violation. The CJEU's assessment typically involves a balancing act employing the principle of proportionality, with specific rights, or multiple specific rights, placed on one end of the scale. However, with regard to fundamental rights enshrined in the CFR, there is a risk that this balancing act might be compromised due to the issues pertaining to direct effect (or lack thereof) of fundamental rights compared to the more straightforward operationalisation of economic priorities such as harmonisation for the internal market.

The CFR's legal effects are limited as only some of its provisions enjoy direct horizontal effect, i.e. they can be relied upon directly, without further implementing measures, by individuals in disputes before domestic courts.[69] In the enforcement of fundamental rights, this is particularly important in the context of direct horizontal effect, i.e. enforceability not only in disputes against the state but also *vis-à-vis* private parties. Importantly, while the nature of activities enumerated in Annex III to the AI Act is such that many deployers of high-risk systems with implications on fundamental rights are going to be public bodies, Annex III AI systems are not exclusively limited to public deployers. Examples of private deployers of high-risk AI systems listed in Annex III include the use of AI in access to essential private services, such as banking or insurance.

Firstly, to be capable of direct effect, a CFR right must fulfil the general conditions for direct effect in EU law and be: 1) clear; 2) precise; and 3) unconditional, i.e. not require any implementing measures, either from the EU or the Member States.[70] Therefore, while this assessment has to be carried out by the CJEU if it is to be definitive, already the analysis of the literal wording of the CFR would lead us to the conclusion that Article 37 CFR pertaining to environmental protection is hardly capable of producing direct effect given that it is phrased as follows:

> A high level of environmental protection and the improvement of the quality of the environment must be integrated into the policies of the Union and ensured in accordance with the principle of sustainable development.

This does not, however, mean that AI deployers can disregard Article 37 CFR, as while the CFR provision is conditional, there is indeed secondary implementing legislation in this area in the form of the above-mentioned Environmental Impact Assessment

[69] Eleni Frantziou, 'The Horizontal Effect of the Charter of Fundamental Rights of the EU: Rediscovering the Reasons for Horizontality' (2015) 21(5) European Law Journal 657; Sacha Prechal, 'Horizontal Direct Effect of the Charter of Fundamental Rights of the EU' (2020) 66 Revista de Derecho Comunitario Europeo 407.

[70] Case 26/62 *Van Gen den Loos*, EU:C:1963:1. See further Sophie Robin-Olivier, 'The Evolution of Direct Effect in the EU: Stocktaking, Problems, Projections' (2014) 12(1) International Journal of Constitutional Law 165.

Directive 2011/92/EU. Thus, this example illustrates the complexity of the regulatory maze that AI deployers will be expected to navigate to conduct a meaningful FRIA.

In contrast, Article 21 CFR guarantees the right to non-discrimination in a sufficiently clear, precise and unconditional way as to produce direct effect, as has been confirmed by the CJEU in a line of case law.[71] The only CFR Articles that have to date been declared by the CJEU as having direct effect in addition to Article 21 CFR are Article 31(2), which guarantees daily and weekly rest periods, as well as Article 47 on the right to an effective remedy. In contrast, Article 27, which protects workers' right to information and consultation, has been excluded by the CJEU from direct effect.[72]

While this distinction alone does not create a hierarchy of fundamental rights[73] and should not, in an ideal world, determine the weight attached to safeguarding various rights, concerns over the lack of enforceability of those CFR rights that are not given direct effect in secondary legislation may potentially leave the affected stakeholders without an adequate remedy. Thus, it could be argued that the harm-based FRIA model, when realised in a meaningful way, including through the lens of intersectionality and vulnerability, might offer a preventative measure that will shield some stakeholders that might otherwise not be in a position to safeguard their interests in situations where the CJEU is reluctant to embrace either intersectionality or vulnerability.

7. Conclusion

The AI Act has established a binding framework for the development and deployment of AI in the EU. While its prohibition of certain uses of AI that are deemed to carry unacceptable risk is of great consequence, the instruments intended to regulate AI systems that are considered high risk require further consideration. Article 27 AI Act establishes the requirement that a comprehensive fundamental rights impact assessment be carried out on AI systems that are categorised as high risk. This will be done via FRIAs.

This paper begins with a legal and ethical analysis of the new legislation and argues that, whereas the AI Act acknowledges that AI will directly impact many fundamental rights protected by the CFR, in fact AI has the potential to directly and indirectly impact all substantive rights included in the CFR. It examines extant, analogous impact assessments, including HRIAs, in order to assess the adequacy of FRIAs to the consequential task of safeguarding the fundamental rights of each person, in the context of high-risk AI systems.

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[71] Case C-414/16 *Vera Egenberger v Evangelisches Werk für Diakonie und Entwicklung e.V.*, EU:C:2018:257; Case C-68/17 *IR v JQ*, EU:C:2018:696.

[72] Case C-176/12 *Association de médiation sociale v Union locale des syndicats CGT and Others*, EU:C:2014:2.

[73] Koen Lenaerts, 'Exploring the Limits of the EU Charter of Fundamental Rights' (2012) 8(3) European Constitutional Law Review 375.

The AI Office has at its disposal methodologies and proposals arising from various projects including the ALIGNER tool for European law enforcement agencies and the B-Tech Project that aims to implement the UNGPs in the context of technology. However, as is argued in this paper, these and other impact assessment models have systemic weaknesses, identified under the headings of: (1) technical; (2) substantive; and (3) political. These must be addressed. The limitations of quantitative measures and technical rationality for assessments that aim to evaluate contextual and intersectional human rights challenges is highlighted, as are the knock-on effects of box-ticking, bureaucratisation and ethics-washing that tend to accompany unsuitable measures.

In addition to the technical limitations, this paper argues that FRIAs to date have functioned with an individualistic and arguably siloed approach to human rights. However, as discussed, AI not only has the potential to compromise multiple fundamental rights of individuals and groups simultaneously, but also the potential to undermine the political framework and supporting institutions (e.g., free press, independent judiciary, etc.) on which the ecosystem of fundamental rights protections depends. Additionally, the political agreement that has permitted those who are bringing AI systems to market to sometimes participate in undertaking the fundamental rights impact assessment suggests that the FRIA model may be compromised by endemic conflicts of interest.

This paper argues that these systemic limitations can and must be addressed if the FRIA is to be adequate to the task for which it is intended. We propose the inclusion of conceptual perspectives from intersectionality and vulnerability theory as a first step to address the most fundamental of these weaknesses. Only if, and when, the fundamental weaknesses of FRIAs are addressed can there be public trust in the AI Act's capacity to secure the ethical deployment of high-risk AI systems.