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Assessing the Impact of Artificial Intelligence Systems on Fundamental Rights

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Executive summary

This paper introduces a structured and comprehensive framework for conducting a Fundamental Rights Impact Assessment (FRIA), tailored specifically to address the challenges posed by high-risk Artificial Intelligence (AI) systems, including Generative AI (GenAI). The study is grounded in the obligations set forth by Regulation (EU) 2024/1689, known as the Artificial Intelligence Act (AI Act), which emphasises the necessity of assessing and mitigating risks to fundamental rights. The FRIA bridges the gap between regulatory obligations and practical implementation by providing a structured approach to assess and mitigate risks to fundamental rights.

This paper situates the FRIA as a critical tool mandated by the AI Act for certain high-risk AI systems and proposes a framework to conduct this assessment named FRIAct (Fundamental Rights Impact Assessment AI Act). The analysis proposed in this work positions between the theoretical commitments to fundamental rights protection and their practical operationalisation, providing deployers of AI systems with a replicable approach that aligns with European constitutional values and legal requirements. This approach also applies to GenAI systems, which often involve complex and large-scale implications for individuals and society.

The first part of the paper situates the FRIA within the broader European legal and constitutional framework, emphasising the foundational role of the Charter of Fundamental Rights of the European Union (CFREU). It explores how fundamental rights enshrined in the CFREU shape the obligations of the AI Act. Notably, the Regulation underscores the importance of ensuring that high-risk AI systems, including GenAI, comply with European constitutional values. As a matter of fact, GenAI systems have emerged as transformative technologies capable of reshaping industries, yet they also pose significant challenges. These include risks to privacy, data protection, access to effective remedies, and human dignity, as well as systemic concerns such as misinformation and the erosion of trust in automated systems. The AI Act explicitly extends its regulatory scope to include GenAI, introducing specific safeguards for models with systemic risks. These provisions address the need for enhanced transparency, robust oversight, and proactive risk mitigation in the design, development, and deployment of GenAI systems.

The second part introduces the FRIAct based on a two-pronged approach integrating qualitative and quantitative tools for assessing risks to fundamental rights. The qualitative tool, referred to as the Questionnaire, is designed to gather contextual and operational insights of the AI system,

including its purpose, affected populations, technical characteristics, and the broader societal and ethical implications of its deployment. It evaluates risks producing a Questionnaire Risk Indicator (QRI) that serves as the foundation for further analysis. The Matrix, on the other hand, adds an assessment specifically designed to produce a quantitative output: this purpose is achieved by systematically mapping potential qualitative impacts on specific rights and then attributing a quantitative score to those impacts – this is why we also refer to the Matrix' outcomes as *semi*-quantitative ones. It evaluates risks based on two key dimensions – Severity and Probability of Occurrence – and calculates Impact Significance (IS) scores for each right as outlined in the CFREU. The FRIAct incorporates both the Questionnaire and the Matrix to generate FRIAct Scores, a final output that quantifies the system's overall risk to each fundamental right. Both Questionnaire and Matrix are relevant in the phase of pre-deployment and monitoring. This design ensures flexibility, enabling its application across diverse AI systems and use cases, while maintaining alignment with the AI Act's regulatory requirements.

The final part of the paper applies the FRIAct framework to a practical use case: LoanLens, a high-risk AI system designed for credit scoring of natural persons. LoanLens integrates a traditional Machine Learning System (MLS) with a Generative AI-powered Decision Support System (DSS), creating a hybrid approach that combines structured and unstructured data processing. This section demonstrates how the FRIAct evaluates the system's risks, including transparency, fairness, privacy, and human oversight during the decision-making process. The Questionnaire identifies the system's context, purpose, and operational risks, while the Matrix quantifies its impact on specific fundamental rights, such as privacy, non-discrimination, and human dignity. The case study underscores the importance of robust human oversight, as mandated by Article 14 of the AI Act, and the need for continuous monitoring to address evolving risks throughout the system's lifecycle.

The paper concludes by arguing that the FRIAct framework not only fulfils the compliance requirements of the AI Act but also sets a benchmark for ethical and accountable AI deployment. The FRIAct framework represents a critical step toward embedding fundamental rights at the core of AI. The proposed approach highlights the necessity of collaboration between regulators, AI providers, and deployers to ensure that AI systems not only comply with legal standards but also uphold the societal values enshrined in the CFREU. By providing deployers with a structured approach to assess and manage risks, this framework operationalises fundamental rights protection in a way that is practical, replicable, and adaptable to diverse AI systems.

1. Introduction

The evolution of AI systems, including those embedding GenAI models, have been shaping the transformation of various sectors,[1] from healthcare and finance to social media and education.[2] As these systems become more pervasive, they bring about substantial benefits, including enhanced efficiency, personalised user experiences, and new creative possibilities. However, this transformative potential is accompanied by significant risks to fundamental rights such as privacy, freedom of expression, equality, and human dignity.[3] These risks are not always immediately visible and often involve complex, large-scale repercussions that can affect both individuals and communities. For instance, GenAI models have been linked to issues such as copyright protection,[4] algorithmic bias, data privacy breaches, misinformation, and surveillance concerns, each with far-reaching implications for fundamental rights.[5]

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[1] Generative Artificial Intelligence (GenAI) refers to advanced AI systems that can create new content—such as text, images, audio, or video – based on vast datasets and complex algorithms. Unlike traditional AI systems, which typically perform predefined tasks, GenAI models are capable of producing original content by learning patterns from large datasets, often requiring minimal human intervention. These models are increasingly applied in various domains, including content creation, design, and predictive analysis, and have raised specific concerns around privacy, data security, and intellectual property. Mindy Nunez Duffourc Kollnig Sara Gerke & Konrad, 'Privacy of Personal Data in the Generative AI Data Lifecycle' (*NYU Journal of Intellectual Property & Entertainment Law*, 8 July 2024) <https://jipel.law.nyu.edu/privacy-of-personal-data-in-the-generative-ai-data-lifecycle/> accessed 4 November 2024; Francesco Corea, 'AI Knowledge Map: How to Classify AI Technologies' in Francesco Corea (ed), *An Introduction to Data: Everything You Need to Know About AI, Big Data and Data Science* (Springer International Publishing 2019) <https://doi.org/10.1007/978-3-030-04468-8_4> accessed 10 May 2022; Sandeep Singh Sengar and others, 'Generative Artificial Intelligence: A Systematic Review and Applications' (arXiv, 17 May 2024) <http://arxiv.org/abs/2405.11029> accessed 4 November 2024. For a detailed exploration of GenAI's implications for personal data privacy, European Data protection Board (EDPB), 'Report of the work undertaken by the ChatGPT Taskforce', 23 May 2024; Taner Kuru, 'Lawfulness of the Mass Processing of Publicly Accessible Online Data to Train Large Language Models' [2024] International Data Privacy Law ipae013.

[2] Giovanni De Gregorio, 'The Normative Power of Artificial Intelligence' (2023) 30 Indiana Law Journal; Francesco Paolo Levantino, 'Generative and AI-Powered Oracles: "What Will They Say about You?"' (2023) 51 Computer Law & Security Review 105898; Natali Helberger and Nicholas Diakopoulos, 'ChatGPT and the AI Act' (2023) 12 Internet Policy Review <https://policyreview.info/essay/chatgpt-and-ai-act> accessed 25 May 2023; Claudio Novelli and others, 'Generative AI in EU Law: Liability, Privacy, Intellectual Property, and Cybersecurity' (arXiv, 15 March 2024) <http://arxiv.org/abs/2401.07348> accessed 9 October 2024.

[3] Georgios Feretzakis and Vassilios S Verykios, 'Trustworthy AI: Securing Sensitive Data in Large Language Models' (arXiv, 26 September 2024) <http://arxiv.org/abs/2409.18222> accessed 4 November 2024.

[4] Uri Y Hacohen and Niva Elkin-Koren, 'Copyright Regenerated: Harnessing GenAI to Measure Originality and Copyright Scope' (3 August 2023) <https://papers.ssrn.com/abstract=4530717> accessed 26 February 2024.

[5] Oreste Pollicino, Marco Fasciglione, Giovanni De Gregorio, Federica Paolucci 'Compliance through Assessing Fundamental Rights: Insights at the Intersections of the European AI Act and the Corporate Sustainability Due Diligence Directive' (*MediaLaws*, 30 July 2024) <https://www.medialaws.eu/compliance-through-assessing-fundamental-rights-insights-at-the-intersections-of-the-european-ai-act-and-the-corporate-sustainability-due-diligence-directive/> accessed 4 November 2024.

Against these challenges,[6] the European Union has introduced a horizontal and comprehensive legal framework by enacting the AI Act.[7] This regulation underlines the European intent to consider not only the development of cutting-edge technologies but also safeguarding "health, safety and fundamental rights".[8] As a matter of fact, in its first recitals, the AI Act primarily refers to European values,[9] and the need to respect human dignity, freedom, equality, democracy, the rule of law and fundamental rights, as framed in Art. 2 TUE, and enshrined in the CFREU.

This framework, oriented to the protection of fundamental rights and democratic values, inspires the entire legal framework of the AI Act as driven by a risk-based approach.[10] The regulation identifies different areas of risks corresponding to specific obligations moving from prohibited practices,[11] to systems with high and minimal risks related to the impact on fundamental rights. These obligations also extend to GenAI models, which have been introduced within the scope of the regulation during the political negotiation,[12] as a reaction to the spread of AI applications based on these models and the consequent rising attention of European and national institutions on the

[6] European Commission, White Paper on Artificial Intelligence: a European approach to excellence and trust, 19 February 2020.

[7] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act).

[8] AI Act, Rec. 1-3.

[9] Huw Roberts and others, 'Safeguarding European Values with Digital Sovereignty: An Analysis of Statements and Policies' (2021) 10 Internet Policy Review <https://policyreview.info/articles/analysis/safeguarding-european-values-digital-sovereignty-analysis-statements-and-policies> accessed 26 July 2022; Kim Lane Scheppele, Dimitry Vladimirovich Kochenov and Barbara Grabowska-Moroz, 'EU Values Are Law, after All: Enforcing EU Values through Systemic Infringement Actions by the European Commission and the Member States of the European Union' (2020) 39 Yearbook of European Law 3; Anu Bradford, 'Europe's Digital Constitution' [2023] Verfassungsblog <https://verfassungsblog.de/europes-digital-constitution/> accessed 12 February 2024.

[10] AI Act, Rec. 27. Claudio Novelli and others, 'AI Risk Assessment: A Scenario-Based, Proportional Methodology for the AI Act' (2024) 3 Digital Society 13; Pietro Dunn and Giovanni De Gregorio, 'The European Risk-Based Approaches: Connecting Constitutional Dots in the Digital Age' (2022) 59 Common Market Law Review <https://kluwerlawonline.com/journalarticle/Common+Market+Law+Review/59.2/COLA2022032> accessed 20 May 2022.

[11] Ibid, Art. 5 AI Act.

[12] Nathalie A Smuha and Karen Yeung, 'The European Union's AI Act: Beyond Motherhood and Apple Pie?' (24 June 2024) <https://papers.ssrn.com/abstract=4874852> accessed 14 August 2024.

matter.[13] The AI Act specifically deals with GenAI models by introducing specific safeguards, particularly to those models which fall within the category of systemic risk.[14]

Among the key requirements expressing this constitutional orientation, the AI Act introduces the FRIA. This step requires assessing the risks for fundamental rights coming from the deployment of AI systems, thus increasing the accountability of public and private actors using these technologies. This obligation also includes GenAI models, which, if integrated into AI systems, aim at extending the entire architecture of fundamental rights protection to GenAI systems. By means of regulation, the FRIA is an evaluative process specifically designed for certain systems classified as high-risk by the AI Act.[15] This requirement mandates that organisations deploying such systems undertake a comprehensive assessment to identify, measure, and mitigate potential negative impacts on fundamental rights. The FRIA is intended to prevent abuses and unintended consequences, fostering responsible AI usage that respects fundamental rights at all stages of development and deployment.[16] By introducing FRIA, the AI Act establishes a framework for transparency, accountability, and ethical practices, which are essential for building public trust in AI technologies.

However, despite the relevance of this instrument, there are still no solid approaches to developing a FRIA for AI systems, including those systems based on GenAI models.[17] Although

[13] Italy's SA temporarily banned OpenAI's ChatGPT due to concerns over the unlawful collection and processing of personal data, and the lack of adequate mechanisms to prevent minors from accessing the platform. The case raised questions about how GenAI systems collect, store, and use personal information, especially when operating at such large scales. The Garante ordered OpenAI to implement stronger privacy safeguards and transparency measures, including age verification tools and greater user control over their data. The incident attracted widespread attention, marking the first regulatory action taken against a major GenAI system in Europe. See Italian SA, Measure of 30 March 2023, Register of Measures, No. 112 of 30 March 2023.

[14] Specifically, the AI Act focuses on 'general purpose AI systems', defined by Art. 3, para. 1, no. 63) as "means an AI model, including where such an AI model is trained with a large amount of data using self-supervision at scale, that displays significant generality and is capable of competently performing a wide range of distinct tasks regardless of the way the model is placed on the market and that can be integrated into a variety of downstream systems or applications, except AI models that are used for research, development or prototyping activities before they are placed on the market".

[15] AI Act, Rec. 96, "The aim of the fundamental rights impact assessment is for the deployer to identify the specific risks to the rights of individuals or groups of individuals likely to be affected, identify measures to be taken in the case of a materialisation of those risks. The impact assessment should be performed prior to deploying the high-risk AI system and should be updated when the deployer considers that any of the relevant factors have changed".

[16] Alessandro Mantelero, 'The Fundamental Rights Impact Assessment (FRIA) in the AI Act: Roots, Legal Obligations and Key Elements for a Model Template' <https://iris.polito.it/handle/11583/2991821> accessed 4 September 2024.

[17] In general, Art. 27 of the AI Act gives the competence to develop the template to the AI Office. Efforts towards the development of an explicit methodology made in recent years by different public institutions, including the government of the Netherlands, and the Danish Institute for Human Rights, as well as the Canadian Government. See Government of the Netherlands, 'Fundamental Rights and Algorithms Impact Assessment (FRAIA)', 31 July 2021; Danish Institute for Human Rights, 'Human Rights Impact Assessment and Toolbox', 2020; Government of Canada, 'Algorithmic Impact Assessment tool', <https://www.canada.ca/en/government/system/digital-government/digital-government-innovations/responsible-use-ai/algorithmic-impact-assessment.html>.

research has focused on studying the possible adverse risks caused by such technologies,[18] a generally adopted methodology for assessing the impact of AI systems on fundamental rights is still lacking.[19] Addressing this gap, this paper proposes a structured FRIA framework that organisations can apply to assess the impact of the use of AI systems on fundamental rights. The proposed approach consists of two main components:

- Questionnaire: The open-ended questionnaire gathers context-specific information, examining the unique technical and operational characteristics of the AI system in question. By identifying possible risks inherent in the system's design and application, this analysis serves as the foundational step in assessing its impact on fundamental rights.

- Matrix: The matrix component assigns scores to various rights based on the assessed risk factors, facilitating a numerical assessment of threats to fundamental rights. This matrix incorporates indicators such as the likelihood of adverse outcomes, population exposure, and the severity of impact on each right. In cases where numerical indicators are not feasible, an ordinal scale (e.g., low, medium, high) is employed to ensure a structured evaluation of risks.

Together, these components establish a replicable approach for assessment that enables deployers to systematically evaluate and manage the risks posed by AI systems. This work aims to propose a practical and operational framework to obtain a concrete and reproducible approach to develop the FRIA for high-risk AI systems introduced by the AI Act. By integrating theoretical principles with practical applications, this work seeks to advance responsible AI governance, enabling deployers to navigate the complex interplay between innovation and fundamental rights in the digital age. This

[18] European Commission, 'Study to Support an Impact Assessment of Regulatory Requirements for Artificial Intelligence in Europe', 2021; European Union Agency for Fundamental Rights, 'Getting the future right – Artificial intelligence and fundamental rights' (2020); European Agency for Fundamental Rights, 'Data quality and artificial intelligence – mitigating bias and error to protect fundamental rights', 11 June 2019.

[19] Some proposals have been developed. Allow the referral to a precedent work curated by Samuele Bertaina and others, 'Fundamental Rights and Artificial Intelligence Impact Assessment: A New Quantitative Methodology in the Upcoming Era of AI Act' (2025) 56 Computer Law & Security Review 106101. In this paper, a first methodology for conducting the FRIA has been proposed to underline the importance of accountability and risk based approach. This policy paper represents indeed an evolution of the methodology, which builds a more comprehensive understanding, including also GenAI systems.

It is worth mentioning that has been recently published by the Catalan Data Protection Authority a report which develops an assessment of the impact on fundamental rights in the use of artificial intelligence (called AIDF), in line with what is established in the new Artificial Intelligence Regulation. See DPD, 'FRIA model: Guide and use cases FRIA methodology for AI design and development', 2025.

paper thus serves as a crucial resource for policymakers, AI developers, and stakeholders seeking to integrate a rights-centred approach into the AI lifecycle, promoting the responsible deployment of AI in high-stakes environments.

The assessment procedure aims to provide numerical values, made up of the different evaluation phases, which make it possible to assess the risks coming from the deployments of AI systems. These final risk scores are achieved through the combination of the risk scores resulting from two factors: 1) the completion of a Questionnaire that investigates contextual, processual, and technical aspects of the AI system; 2) the development of a semi-quantitative Matrix assessing possible impacts on fundamental rights.

The first section situates the FRIA within the European legal and constitutional framework, emphasising the pivotal role of the CFREU and the foundational principles of European digital constitutionalism. This section underscores the legal and ethical imperatives for ensuring that AI systems respect and protect fundamental rights such as privacy, non-discrimination, and human dignity. The second section introduces the model for implementing the FRIAct, combining qualitative and quantitative tools. It details a two-pronged approach: a Questionnaire that systematically gathers contextual and technical information to identify potential risks, and a Matrix that evaluates the severity and likelihood of impacts on specific fundamental rights. Together, these tools provide a replicable and adaptable framework for assessing risks and mitigating potential harms resulting from the use of AI systems. The third section illustrates the practical application of the methodology through a case study of a high-risk AI system – LoanLens, a credit-scoring tool combining Machine Learning and GenAI technologies. This example demonstrates the framework's capacity to identify vulnerabilities, quantify risks, and guide mitigation strategies in real-world contexts, ensuring compliance with the AI Act and fostering trust in AI deployment.

2. The European Constitutional Framework and Requirements for FRIA

The expansion of the constitutional narrative in the field of AI is part of a broader trend that started before the spread of AI systems. Since the launch of the Digital Single Market Strategy in 2015, the European Union has moved from a framework dominated by a narrative of digital liberalism to a framework of digital constitutionalism characterised by a larger attention on the

protection of rights and freedoms.[20] The objective is to ensure that the logic of market freedoms does not override reasons of public interest, such as the protection of health, safety, and fundamental rights. At the same time, the European digital constitutional identity has also been based on the need to ensure fundamental freedoms and competition, which have played a foundation role in the EU economic integration process since the beginning, thus making economic freedoms critical to creating a market for AI in Europe.

The obligation to conduct the FRIA introduced by the AI Act falls within this broader framework which has led public and private institutions to increase their accountability in the digital age. Among different trends, Human Rights Impact Assessments (HRIA) have become essential for integrating human rights protections into business processes, following the UN Guiding Principles on Business and Human Rights.[21] Likewise, at the international level, the Council of Europe, through initiatives of the Committee on Artificial Intelligence (CAI), elaborated the Human Rights Democracy and Rule of Law Impact Assessment (HUDERIA),[22] which aimed to establish international AI standards focusing on risk identification, impact assessment, governance evaluation, and continuous mitigation to protect human rights.[23] In the elaboration of the AI Act, precisely under the impulse of the European Parliament, the EU adopted the FRIA as its own impact assessment method, also taking inspiration from the Data Protection Impact Assessment (DPIA) in the General Data Protection Regulation (GDPR).[24]

The FRIA aims to identify risks to safeguard fundamental rights from high-risk AI systems potential impacts.[25] It mandates comprehensive pre-deployment assessments to prevent adverse

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[20] Oreste Pollicino, *Judicial Protection of Fundamental Rights on the Internet: A Road Towards Digital Constitutionalism?* (Bloomsbury Publishing 2021). Giovanni De Gregorio, *Digital Constitutionalism in Europe: Reframing Rights and Powers in the Algorithmic Society* (Cambridge University Press 2022).

[21] United Nations, 'Guiding Principles on Business and Human Rights in the technology sector', 2011.

[22] CAI, Methodology for the Risk and Impact Assessment of Artificial Intelligence Systems from the Point of View of Human Rights, Democracy and the Rule of Law (HUDERIA Methodology) 28 November 2024 https://rm.coe.int/cai-2024-16rev2-methodology-for-the-risk-and-impact-assessment-of-arti/1680b2a09f

[23] For an analysis of the CoE attempts to establish common regulatory principles for AI, see Francesco Paolo Levantino and Federica Paolucci, 'Advancing the Protection of Fundamental Rights Through AI Regulation: How the EU and the Council of Europe Are Shaping the Future' (27 June 2024) SSRN <https://papers.ssrn.com/abstract=4881656>.

[24] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance).

[25] AI Act, Rec. 96: "the impact assessment should identify the deployer's relevant processes in which the high-risk AI system will be used in line with its intended purpose, and should include a description of the period of time and frequency in which the system is intended to be used as well as of specific categories of natural persons and groups who are likely to be affected in the specific context of use. The assessment should also include the identification of specific risks of harm

impacts on fundamental rights, emphasising accountability, transparency, and ethical AI use. Given its strong connection with the European constitutional framework, particularly the protection of fundamental rights, it is crucial to connect the FRIA with the constitutional safeguards towards rights and freedoms in Europe as enshrined in the CFREU.

On these premises, the AI Act refers to European values and the FRIA, it recalls a series of elements related to the application and interpretation of, at least, the CFREU. As introduced in 2000 and then becoming legally binding since the Treaty of Lisbon in 2009, it preserves a wide array of civil, political, economic, and social rights, consolidating the rights derived from the constitutional traditions and international obligations common to the Member States. Nonetheless, from the outset, the European integration project was deeply rooted in the collective vision of shared values such as human dignity, democracy, the rule of law, and respect for human rights.[26] These values, later codified in the Treaties,[27] were envisioned as the foundation for unifying a continent fractured by war and conflict, guiding the Union's evolution toward safeguarding both individual and collective aspirations.

It is worth to be recalled that the fundamental rights protected by the Charter are not absolute.[28] The lack of a strict hierarchy opens to the balancing of different conflicting constitutional interests which "must be considered in relation to their function in society".[29] The process of balancing is primarily connected with the principle of proportionality. According to Article 52 of the Charter, its provisions must be interpreted in a way that does not restrict or adversely affect the essence of rights. Specifically, the CJEU specified that any restriction to the enjoyment of such rights must not constitute an unreasonable, disproportionate and intolerable infringement of them. For example, in the *Schrems* case, the CJEU invalidated an EU decision because it compromised the essence of the

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likely to have an impact on the fundamental rights of those persons or groups. While performing this assessment, the deployer should take into account information relevant to a proper assessment of the impact, including but not limited to the information given by the provider of the high-risk AI system in the instructions for use. In light of the risks identified, deployers should determine measures to be taken in the case of a materialisation of those risks, including for example governance arrangements in that specific context of use, such as arrangements for human oversight according to the instructions of use or, complaint handling and redress procedures, as they could be instrumental in mitigating risks to fundamental rights in concrete use-cases." See, also, Mantelero (n 16).

[26] EU Fact Sheet, 'The protection of EU values', 2025.

[27] Scheppele, Kochenov and Grabowska-Moroz (n 9).

[28] The Charter does not explicitly identify the rights that are absolute. Based on the Charter explanations, the ECHR and the case law of the European courts, it is submitted that human dignity (Article 1 of the Charter) together with the prohibition of torture and inhuman or degrading treatment or punishment (Article 4 of the Charter), are to be considered absolute rights.

[29] C-311/18, *Data Protection Commissioner v Facebook Ireland Ltd, Maximillian Schrems,* ECLI:EU:C:2020:559, para. 172.

right to privacy and the right to judicial protection, setting a precedent that any measure infringing on the essence of a fundamental right is automatically invalid.[30] Thus, the principle of proportionality and the concept of the essence of fundamental rights are critical in protecting these rights, ensuring that limitations are justified, appropriate, and necessary.

Therefore, fundamental rights have become essential in ensuring the legality of actions by public actors within the EU,[31] and their scope has also extended to private actors. Specifically, while Article 51(1) of the Charter does not explicitly state that private individuals have to ensure the protection of fundamental rights established by the Charter, the CJEU has ruled that some rights in the Charter apply directly between individuals, according to the doctrine that recognises the horizontal application of such rights.[32] For instance, the prohibition of discrimination (Article 21) has direct effects on disputes between individuals.[33] Thus, the prominent application of such principles found its way precisely in the digital realm, where the CJEU ruled the existence of horizontal protection of individual's data rights, including de-listing information, in Articles 7 and 8 of the Charter.[34]

Even if aligned with this framework when referring to the protection of European values, however, the AI Act does not fully focus on fundamental rights. Thus, despite some provisions of the AI Act,[35] the Regulation contains few concrete references,[36] which do not provide a comprehensive framework to ensure systematic and adequate verification of fundamental rights violations by specific AI systems. This holds true since the AI Act responds more to a product reliability approach rather than a fundamental rights instrument,[37] as also testified by its legal basis.[38]

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[30] Case 311/18, *supra.*

[31] Case 29/69, *Stauder*, EU:C:1969:57; Case 11/70, *Internationale Handelsgesellschaft*, EU:C:1970:114; Case 4/73, *Nold*, EU:C:1974:51.

[32] C-176/12, *AMS*, 2014, para. 47; C- 414/16, *Egenberger*, 2018, paras 76 and 78; C-569/16 and C-570/16, *Bauer*, 2018, para. 85; C-684/16, *Max-Planck-Gesellschaft zur Förderung der Wissenschaften*, 2018, paras 77–9; C-193/17, Cresco, 2019, 76.

[33] C-43/75, *Gabrielle Defrenne v Société anonyme belge de navigation aérienne Sabena,* 8 April 1976.

[34] Eleni Frantziou, *The Horizontal Effect of Fundamental Rights in the European Union: A Constitutional Analysis* (OUP, 2019); C- 92/ 09 and C- 93/ 09, *Volker und Markus Schecke and Eifert*, 2010, paras 65– 86.

[35] E.g., Recital 1 emphasizes the regulation's aim to promote human-centric, trustworthy AI while ensuring high protection levels for health, safety, and fundamental rights, including democracy, the rule of law, and environmental protection; Recital 5 recognizes the potential risks AI poses to public interests and fundamental rights.

[36] Such as in Articles 13.3(b)(ii) on transparency and user information, and 14.2 on human oversight.

[37] Marco Almada and Nicolas Petit, 'The EU AI Act: a medley of product safety and fundamental rights?,' *EUI, RS.C, Working Paper,* 2023/59, https://hdl.handle.net/1814/75982.

[38] Article 114 TFEU. For a critique on the extensive use of this legal base by the EU for basically any rule that applies to the digital sector, see Erik Longo, 'Grounding Media Freedom in the EU: The Legal Basis of the EMFA' (2025) 7 Rivista italiana di informatica e diritto 14.

Particularly, the lack of individuals' rights and the focus mainly on the categories of deployer and provider symbolised the market approach rather than a fundamental rights-driven one.[39]

In this sense, the FRIA can be considered a compromise to reconcile the internal market dimension with the protection of fundamental rights. The FRIA can be considered a bridge between the realm of AI systems and the protection of fundamental rights based on the principles enshrined in the Charter, thus guiding the interpretation and operationalisation of fundamental rights within the framework of the AI Act. This interconnectedness underscores the importance of a robust compliance system that respects and upholds fundamental rights as a core component of the AI regulatory landscape.

2.1 The FRIA in the AI Act

Article 27 is a crucial provision aimed at ensuring that specific high-risk AI systems are used in ways that respect fundamental rights. The introduction of FRIA in the AI Act stems from the need to balance innovation with risk management, particularly concerning fundamental rights. It represents a significant advancement in the regulatory landscape and sets a precedent for how AI should be managed and monitored, also building on the Ethics Guidelines for Trustworthy AI and on the White Paper on AI, in which it is acknowledged that AI can lead to breaches of fundamental rights, such as freedom of expression, assembly, human dignity, non-discrimination, and privacy. The requirement for a thorough FRIA by both public and selected private entities is a proactive measure to prevent potential abuses and unintended negative consequences of AI deployment.[40]

The AI Act provides few details on how this assessment should be conducted. Precisely, it specifies that it should include usage descriptions, affected groups, potential risks, human oversight measures, and risk mitigation steps.[41] Once the deployer performs the assessment, this should be

[39] On the remedies and their efficacy in the digital sphere, De Gregorio, Giovanni and Demkova, Simona, The Constitutional Right to an Effective Remedy in the Digital Age: A Perspective from Europe (January 31, 2024). In van Oirsouw, Ch., de Poorter, J.; Leijten, I.; van der Schyff, G.; Stremler, M.; de Visser, M. (eds), European Yearbook of Constitutional Law (forthcoming, 2024).

[40] As designated by Art. 27 para. 1, the referral is to "private entities providing public services", as well as, under Annex III, Art. 5, lett. b and c, "AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score, with the exception of AI systems used for the purpose of detecting financial fraud", and "AI systems intended to be used for risk assessment and pricing in relation to natural persons in the case of life and health insurance".

[41] Art. 27, para. 1, lett a-f), and Rec. 96: "The impact assessment should identify the deployer's relevant processes in which the high-risk AI system will be used in line with its intended purpose, and should include a description of the period of time and frequency in which the system is intended to be used as well as of specific categories of natural persons and groups who are likely to be affected in the specific context of use. The assessment should also include the identification of specific risks of harm likely to have an impact on the fundamental rights of those persons or groups".

reported to the market surveillance authority and updated if necessary.[42] Since the AI Act does not provide thorough guidance on how to conduct the assessment, as happened for the DPIA, it will be crucial to consult the guidelines and the templates elaborated by the European Authorities: in the case of the FRIA, the AI Act, assign this competence to the AI Office.[43] Hence, the provision of a standardised template for these assessments by the AI Office is a strategic move to ensure consistency and comprehensiveness in the evaluations. Furthermore, the obligation to report these assessments to the market surveillance authority ensures that there is oversight and that any identified risks are systematically addressed. This approach reflects a broader commitment to integrating ethical considerations into the development and deployment of AI, aligning with the EU's broader agenda of promoting trustworthy AI.[44]

However, the haste with which the FRIA was introduced,[45] its real connection with the rest of the Regulation, which, as mentioned above, has its core in the product safety-based regulation, and the way in which designated private and public actors will have to concretely carry it out are all questions that will have to be answered a year from the entry into force of the AI Act.[46] With the aim of working on compliance before the norm becomes effectively applicable, it is crucial to identify a method, which is the scope of this paper, and to analyse the doubts in the interpretation of the norm.

The AI Act, being first and foremost a regulation oriented to the specific use of a product, better AI, focuses indeed, but not exclusively, on who utilises the product. Providers are tasked with ensuring compliance with essential requirements and undergoing relevant conformity assessments,[47] while certain deployers must adhere to provider instructions and conduct a FRIA prior to deploying high-risk AI systems.[48] Specifically, this obligation applies to three key categories of actors: 1) deployers governed by public law, such as public authorities, like law enforcement using face recognition; 2) private operators providing public services, including education, healthcare, social services, housing, and justice administration;[49] 3) operators deploying high-risk AI systems

[42] Art. 27, para. 3.
[43] Art. 27, para. 5.
[44] Rec. 1 of the AI Act, and Explanatory Memorandum of the Proposal, published by the EU Commission in April 2021.
[45] The FRIA is the result of the EP version of the Regulation, published in June 2023.
[46] The rules relating to 'high risk' systems, as is the case with Art. 27, are set to apply one year after the regulation comes into force: hence, by 1 August 2025.
[47] AI Act, Art. 43.
[48] AI Act, Rec. 96.
[49] Note that even though art. 27 para. 1 is vague in defining this category, Rec. 96 specifies that it is mandated to perform a FRIA also, "services important for individuals that are of public nature may also be provided by private entities. Private entities providing such public services are linked to tasks in the public interest such as in the areas of education, healthcare, social services, housing, administration of justice".

intended for creditworthiness evaluation, credit scoring, or risk assessment and pricing in life and health insurance contexts, as per Annex III AI Act, points 5, lett. b) and c).[50] By mandating FRIAs solely for these actors, the AI Act emphasises the importance of anticipating and mitigating risks to fundamental rights before deploying high-risk AI technologies.

The FRIA must be performed prior to the initial deployment of the high-risk AI system and should be continued during the whole AI life cycle.[51] This entails a thorough evaluation of the system's potential to adversely affect fundamental rights. For this reason, deployers may rely on previously conducted assessments, including those provided by the system's developer, provided the system's context of use remains unchanged.[52] However, should any significant modifications arise during the system's use, such as changes in its purpose, affected populations, or identified risks, the deployer is obligated to update the assessment to reflect the new circumstances.[53]

The assessment, whose completion should be notified to the relevant market surveillance authority, must comprehensively address the following aspects:

- System use and purpose: a detailed description of how the AI system will be integrated into the deployer's processes, ensuring alignment with its intended purpose.
- Operational parameters: an outline of the timeframe and frequency of the system's deployment.
- Affected individuals and groups: an identification of the categories of natural persons and communities likely to be impacted by the system, particularly marginalised or vulnerable groups.

[50] AI Act, Annex III, Art. 5 lett. b) and c), "5. Access to and enjoyment of essential private services and essential public services and benefits: […] (b) AI systems intended to be used to evaluate the creditworthiness of natural persons or establish their credit score, with the exception of AI systems used for the purpose of detecting financial fraud; (c) AI systems intended to be used for risk assessment and pricing in relation to natural persons in the case of life and health insurance".

[51] AI Act, Rec. 96, "Whilst risks related to AI systems can result from the way such systems are designed, risks can as well stem from how such AI systems are used. Deployers of high-risk AI system therefore play a critical role in ensuring that fundamental rights are protected, complementing the obligations of the provider when developing the AI system. Deployers are best placed to understand how the high-risk AI system will be used concretely and can therefore identify potential significant risks that were not foreseen in the development phase, due to a more precise knowledge of the context of use, the persons or groups of persons likely to be affected, including vulnerable groups.".

[52] AI Act, Art. 27 para. 2.

[53] Id.

- Risk analysis: a detailed evaluation of specific risks of harm that may arise from the system's use, with reference to information provided by the developer in compliance with Article 13 of the AI Act.
- Oversight and governance: a description of the human oversight measures that will be implemented, following the developer's guidelines.
- Mitigation measures: strategies to address the materialisation of identified risks, including internal governance mechanisms and accessible complaint procedures.

From the breakdown of the essential requirements, there emerges a potential information asymmetry between deployers and providers: much of the information hereby requested, such as the operational parameters must be shared by the provider with the deployer in order to make the assessment work. As noted by scholars, "providers possess key knowledge about system properties and technical limitations, impacting risk assessments during deployment".[54] Therefore, a crucial element, even though not specifically listed in the AI Act formulation, is indeed that of a collaboration between the provider and the deployer.

Moreover, the success of these assessments relies heavily on the transparency and reliability of the information exchanged. Providers must supply accurate and comprehensive data regarding the design, functionality, and potential risks of the AI systems, enabling deployers to evaluate their societal and rights-based impacts on the concrete context of deployment of the technology. Furthermore, the AI Act does not mention the complex framework of fundamental rights that Member States need to take into account, being all of them also signatories of the European Convention of Human Rights (ECHR).[55] This aspect reflects the need for balancing fundamental rights in European constitutionalism, which does not only come from the constitutional approach of the Charter but also from the ECHR. Additionally, the absence of explicit mention of the criterion through which such rights should be balanced in their application might be a problematic element,[56]

[54] Piergiorgio Chiara and Federico Galli, 'Normative Considerations on Impact Assessments in EU Digital Policy' [2024] MediaLaws <https://www.medialaws.eu/rivista/normative-considerations-on-impact-assessments-in-eu-digital-policy/> accessed 5 September 2024.

[55] Francesco Paolo Levantino and Federica Paolucci, 'Advancing the Protection of Fundamental Rights Through AI Regulation: How the EU and the Council of Europe are Shaping the Future', *SSRN*, 2024.

[56] For instance, the Member States of the EU are also signatories of the European Convention of Human Rights (ECHR) which might create slightly differences in the interpretation of the application of some provisions related to the protection of fundamental rights, as, for instance, stated in ECtHR 30 June 2005, No. 45036/98, *Bosphorus Hava Yolları Turizm ve Ticaret Anonim Şirketi* v *Ireland*.

especially since also private actors must conduct the assessment, as in the context of evaluating the 'creditworthiness' and the 'risk assessment and pricing' in case of insurance.

Likewise, the coordination between the FRIA and other assessments, such as the DPIA, is not fully addressed. This is not only a problem of consistency in legal terms but also a practical one in figuring out who should conduct both a FRIA and a DPIA as an obligation under the GDPR. Accordingly, the AI Act provides that the deployer must conduct the assessment before putting the system into service. Particularly, this ex-ante evaluation is the responsibility of deployers of high-risk systems in situations listed under Article 27 of the AI Act. Moreover, in case the deployer needs to perform a DPIA, the fundamental rights impact assessment referred to shall complement it.[57] Hence, the two compliance measures tend to overlap,[58] creating potential legal uncertainty between the two obligations. This aspect is particularly relevant not only in the cases when a deployer buys the service or the license from the provider, but also when the subject of the deployer and the provider coincide.

This is a significant and potential backlash of the AI Act for at least two reasons: first, the deployer may not participate in the design and development phases, which are carried out by the provider; second, the roles of the deployer and provider under the GDPR might be confused with respect to the different assessment methods. As a matter of fact, the obligation to perform these assessments often falls on the deployer, especially if classified as a 'data controller' under data protection law, making them responsible for conducting the DPIA as well. However, if a provider has significant control over an AI system, such as with foundation models, data protection authorities might classify the provider as a data controller or potentially a joint controller with the deployer. This classification carries additional responsibilities and obligations under data protection laws.[59]

2.2 GenAI, FRIA and Risk Assessment

Together with the focus on creating a safe and fundamental rights-oriented market for AI, the AI Act has introduced, among general rules, also sectorial regulations for some uses or specific systems of AI. The latter is the case of GenAI systems, reflecting their growing importance and widespread

[57] AI Act, Art. 27(4).
[58] Federica Paolucci, 'Shortcomings of the AI Act', *Verfassungsblog*, 14 March 2024.
[59] *Id*.

use. Unlike other AI systems, GenAI systems are characterised by their broad applicability and the substantial impact they can have across various sectors. This has led to a distinct set of rules within the AI Act, aimed at addressing the unique challenges posed by these systems, as introduced by the European Parliament before the trilogue negotiations in June 2023.

GenAI systems are particularly disruptive because of the vast number of parameters used in their training and their versatile nature. For this reason, identifying and applying regulations to GenAI systems is very challenging. These systems can impact a wide range of societal functions, requiring comprehensive regulatory frameworks.

These complexities are also mirrored by the classification adopted by the AI Act. As a matter of fact, the regulation classifies AI systems into different risk levels. However, GenAI models are subject to specific rules outlined in Chapter V, separate from the general risk categorisation in Chapters II-IV. The AI Act aims to provide specific rules for generative AI models, particularly those posing systemic risks, which also apply when these models are integrated in an AI system. As clarified by Rec. 97, "this Regulation provides specific rules for general-purpose AI models and for general-purpose AI models that pose systemic risks, which should apply also when these models are integrated or form part of an AI system. It should be understood that the obligations for the providers of general-purpose AI models should apply once the general-purpose AI models are placed on the market".

Hence, the rules on GenAI distinguish if the system is to be considered as posing a 'systemic risk' or not. Therefore, before continuing this analysis is to be clarified what we mean by systemic risk. Art. 3 no. 65) clarifies that "'systemic risk' means a risk that is specific to the high-impact capabilities of general-purpose AI models, having a significant impact on the Union market due to their reach, or due to actual or reasonably foreseeable negative effects on public health, safety, public security, fundamental rights, or the society as a whole, that can be propagated at scale across the value chain".

In this respect, GenAI models need to be integrated in AI systems in order to become specific-purpose systems and therefore classifiable as high-risk. The obligations for providers of GenAI models apply when these models are placed on the market and continue when integrated into an AI system.[60] These obligations are distinct from those for AI systems and do not apply when the model is used exclusively for internal processes that do not affect individual rights or provide third-party

[60] Rec. 97.

services. However, GenAI models with systemic risks are always subject to the AI Act's obligations due to their potential adverse effects.

However, this definition, highly criticised at a scholarly level,[61] might create some ambiguities with the identification of the obligations specifically for GenAI and the ones set for high-risk systems. Since the AI Act provides a structured framework for overseeing GenAI systems, stressing the importance of specific rules for these versatile and potentially disruptive technologies, the Regulation ensures that GenAI models, when integrated into AI systems, are subject to comprehensive regulatory oversight, reflecting their significant impact on society.

When a GenAI model is to be considered as posing a 'systemic risk', in addition to the obligation of transparency set by Artt. 53 and 54, Art. 55 requests that the providers of such model should: 1) perform evaluations using standardized protocols, including adversarial testing to identify and mitigate systemic risks; 2) assess and mitigate potential systemic risks at the Union level stemming from the model's development, market placement, or usage; 3) document and report serious incidents and corrective measures to the AI Office and relevant national authorities without delay; ensure robust cybersecurity measures for both the AI model and its physical infrastructure.

Specifically, the conformity and mitigation assessment under the AI Act should be conducted to tackle any 'systemic risk'. To understand what the purpose of such analysis is, it is crucial to read Art. 55 para. 1 lett. b) together with the definition of 'systemic risk' provided by Art. 3. Under these lenses, it is possible to understand that conformity assessment under Art. 55 must regard "any actual or reasonably foreseeable negative effects on public health, safety, public security, fundamental rights, or the society as a whole, that can be propagated at scale across the value chain".[62]

However, the FRIA is not a standalone instrument but needs to be complemented by the 'conformity assessment' conducted by the provider to address the effective risks and harms to various categories of people. When concretely possible, it would be ideal for the provider and the deployer to establish a dialogue throughout the AI value chain to evaluate and respond to the "measures to be taken in case of the materialisation of those risks, including the arrangements for

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[61] Philipp Hacker, 'What's Missing from the EU AI Act: Addressing the Four Key Challenges of Large Language Models', VerfassungsBlog, 13 December 2023, https://verfassungsblog.de/whatsmissing-from-the-eu-ai-act/; N.A.Smuha, K. Yeung, "The European Union's AI Act: beyond motherhood and apple pie?", (June 24, 2024), *SSRN*; P. Hacker, A. Engel, and M. Mauer, "Regulating ChatGPT and other large generative AI models", *Proceedings of the 2023 ACM Conference on Fairness, Accountability, and Transparency*, 2023.

[62] See AI Act, Art. 3 no. 65. For a comparison, read A. Mantelero, "The Fundamental Rights Impact Assessment (FRIA) in the AI Act: roots, legal obligations and key elements for a model template", *Computer Science Law Review,* 2024.

internal governance and complaint mechanisms".[63] Without significant collaboration between the provider and the deployer, it would be complex to have a comprehensive view of the risks potentially driven by GenAI. This is crucial not only due to the inherent complexity of these models but also to ensure that risks are managed effectively at both the model and application levels.

Before delving into the framework proposed for conducting a FRIA, it is crucial to situate this assessment within the broader landscape of risk evaluations established by the AI Act. Since several provisions under the AI Act address risk management, including Article 9's Risk Management System (RMS),[64] and Article 43's Conformity Assessment (CA),[65] it is critical to focus on the interplay between the FRIA and the other assessment obligations, as this integration ensures a cohesive approach to compliance.

Essentially, Article 9 establishes a RMS[66] as a core requirement for all high-risk AI systems, emphasising the identification and mitigation of risks to health, safety, and fundamental rights.[67] As mentioned, the FRIA is a targeted assessment specifically applied to certain high-risk AI systems deployed by public bodies, private entities providing public services, or operators involved in high-stakes applications, such as credit scoring or health and life insurance. In contrast, Article 9 applies universally to all high-risk AI systems, covering risks across health, safety, and fundamental rights during the design and development phases.[68]

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[63] AI Act, Article 27 (1) lett. f).

[64] Specifically, as the SRA, article 9 establishes a risk management system that should be performed by the provider. The definition of a risk management system is a process that "specifies how providers of high-risk AI systems must identify, assess and respond to risks", cit. Risto Uuk and others, 'A Taxonomy of Systemic Risks from General-Purpose AI' (Social Science Research Network, 22 November 2024) <https://papers.ssrn.com/abstract=5030173> accessed 3 January 2025.

[65] Whereas article 43's conformity assessment ensures compliance with the AI Act's requirements through external validation "in order to ensure a high level of trustworthiness of high-risk AI systems", as specified by Rec. 132.

[66] The definition of a risk management system is a process that "specifies how providers of high-risk AI systems must identify, assess and respond to risks", cit. Jonas Schuett, 'Risk Management in the Artificial Intelligence Act' (2024) 15 European Journal of Risk Regulation 367.

[67] AI Act, Art. 9, para. 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. It shall comprise the following steps:
(a) the identification and analysis of the known and the reasonably foreseeable risks that the high-risk AI system can pose to health, safety or fundamental rights when the high-risk AI system is used in accordance with its intended purpose;
(b) the estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose, and under conditions of reasonably foreseeable misuse;
(c) the evaluation of other risks possibly arising, based on the analysis of data gathered from the post-market monitoring system referred to in Article 72;
(d) the adoption of appropriate and targeted risk management measures designed to address the risks identified pursuant to point (a)."

[68] AI Act, Rec. 65.

In terms of actors that are responsible for complying with the obligations, the FRIA places responsibility on deployers – entities deploying the AI system in real-world contexts. These deployers must consider risks specific to the operational setting, including impacts on marginalised groups. Conversely, RMS under Article 9 is the obligation of providers that incorporate risk identification and mitigation measures into the system's design, adhering to essential requirements.[69]

Furthermore, the AI Act imposes that providers of GenAI models perform SRA (Systemic Risk Assessment), as mentioned above, focused primarily on the GenAI model itself rather than its specific application.[70] This approach is criticised for addressing hypothetical risks that may never materialise rather than managing concrete risks associated with the AI's actual deployment.[71] Hence, this conformity assessment, tackling also the impact on fundamental rights, must be carried out when GenAI is used in high-risk AI systems or general-purpose models that pose a systemic risk. Hence, while the provider of a GenAI posing a systemic risk must complete a 'conformity assessment' under Article 55, it is important to note that, if the AI is applied for a purpose classified as high-risk under Annex III, the deployer will also be required to perform a FRIA. Thus, a double track of assessment would take place in which, on the one hand, the provider and, on the other hand, the deployer assess the even potential impact of GenAI on fundamental rights.

In a nutshell, the SRA requires providers to conduct adversarial testing, assess systemic risks at the Union level, ensure cybersecurity,[72] and report serious incidents to the AI Office and national authorities. Unlike the FRIA, which is the responsibility of deployers to evaluate the operational context, the SRA places obligations on providers to mitigate risks embedded in the design and development of AI models. This division of responsibilities reflects the complementary roles of these

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[69] AI Act, Art. 9, para. 5, specifies that identifying the essential requirements for performing the risk management system are "(a) elimination or reduction of risks identified and evaluated pursuant to paragraph 2 in as far as technically feasible through adequate design and development of the high-risk AI system; (b) where appropriate, implementation of adequate mitigation and control measures addressing risks that cannot be eliminated; (c) provision of information required pursuant to Article 13 and, where appropriate, training to deployers. With a view to eliminating or reducing risks related to the use of the high-risk AI system, due consideration shall be given to the technical knowledge, experience, education, the training to be expected by the deployer, and the presumable context in which the system is intended to be used".

[70] AI Act, Rec. 114, "The providers of general-purpose AI models presenting systemic risks should be subject, in addition to the obligations provided for providers of general-purpose AI models, to obligations aimed at identifying and mitigating those risks and ensuring an adequate level of cybersecurity protection, regardless of whether it is provided as a standalone model or embedded in an AI system or a product. To achieve those objectives, this Regulation should require providers to perform the necessary model evaluations, in particular prior to its first placing on the market, including conducting and documenting adversarial testing of models, also, as appropriate, through internal or independent external testing".

[71] A. Mantelero, *id.;* P.Hacker, *id.*

[72] AI Act, Rec. 115.

assessments. Furthermore, the FRIA emphasises context-specific evaluations of risks such as data protection breaches, unfair outputs, and human oversight failures. In contrast, the SRA addresses risks related to the performance of the model, requiring standardised evaluation protocols and incident reporting to mitigate vulnerabilities inherent in general-purpose AI.

Hence, the SRA under Article 55 of the AI Act complements the FRIA under Article 27 by addressing different aspects of AI governance. While the FRIA focuses on deployment-specific risks to fundamental rights in high-risk AI systems, the SRA targets systemic risks posed by general-purpose AI models with broad societal impact. Therefore, given the distinction explained above, there might be GenAI which are classified as high-risk under the AI Act, but that are also deemed to pose systemic risks, as underlined by Art. 3 no. 65 of the Regulation. In this case, the provider should perform the SRA, and the deployer will perform a FRIA. Otherwise, if the system is not falling under one of the categories listed by Annex III, only the SRA will be conducted by the provider.[73]

Together, these assessments create a comprehensive regulatory framework, with the SRA ensuring robustness and reliability at the model level and the FRIA addressing deployment-specific risks to fundamental rights. Building on these considerations, the following grid provides a comparative overview of these mechanisms, bridging the legal and technical dimensions of AI governance, and highlighting their roles in a comprehensive regulatory framework that balances innovation with fundamental rights protection.

Table 1 – Confrontation of the AI Act's assessment.

Aspect	*FRIA (Fundamental Rights Impact Assessment)*	*Risk Management System (RMS)*	*Systemic Risk Assessment (SRA)*
Objective	Assess and mitigate the impacts of high-risk AI systems on fundamental rights in specific deployment contexts.	Manage broader risks to health, safety, and fundamental rights during the design and development phases of AI systems.	Assess and mitigate systemic risks of general-purpose AI (GPAI) models at the Union level, including cybersecurity and societal risks.
Legal basis	Article 27 of the AI Act, focusing on fundamental rights as per the CFREU.	Article 9 of the AI Act, requiring a risk management system for all high-risk AI systems.	Article 55 of the AI Act, targeting systemic risks of GPAI models with potential EU-wide impact.

[73] Risto Uuk and others, id.

Actors	Deployers of high-risk AI systems, including public bodies and private entities providing public services.	Providers of high-risk AI systems during the development and design phases.	Providers of general-purpose AI models identified as posing systemic risks.
Timing	Conducted pre-deployment and updated as needed during the lifecycle of the AI system.	Iterative and continuous throughout the AI system lifecycle.	Performed periodically to monitor and address systemic risks.
Methodology	Primarily qualitative; lacks a standardized and unified methodology.	Often based on harmonized standards but focuses on technical design and lifecycle risk management.	Broad evaluation of systemic risks, often lacking specific focus on individual fundamental rights.
Focus on fundamental rights	Directly addresses fundamental rights with a broad focus on CFREU rights but may lack operational depth.	Includes fundamental rights alongside broader risks such as safety and performance.	Addresses fundamental rights indirectly by focusing on systemic-level impacts.
Outcome	Structured report outlining risks to fundamental rights and mitigation measures, submitted to market surveillance authorities.	Ongoing risk management plan ensuring compliance with harmonized standards.	Recommendations to mitigate systemic risks, such as cybersecurity or societal-level harms.

The regulatory landscape of the AI Act reflects a layered approach to managing risks posed by AI systems, particularly high-risk applications. As examined above, each tool serves a specific purpose, from mitigating individual and societal risks to ensuring technical compliance and safeguarding democratic values. While RMS and the SRA primarily concern providers, who focus on the design and development phases, conversely, the FRIA centers on deployers, emphasising the evaluation of risks in the deployment and operational context.

The FRIAct framework integrates these roles into a cohesive dual-phase approach of pre-deployment and post-deployment, ensuring the FRIA remains an active tool throughout the AI system's lifecycle. Essentially, the proposed methodology is designed to align pre-deployment and post-deployment efforts effectively, ensuring a comprehensive evaluation of risks and their mitigation in both design and monitoring phases. This approach bridges the gap between provider-

driven development and deployer-focused implementation, particularly when these entities are distinct. In case the provider and deployer are the same, the process is streamlined internally; however, when separate, FRIAct offers a structured mechanism to align their responsibilities effectively. By fostering collaboration and clearly delineating responsibilities, FRIAct not only enhances compliance with the AI Act but also strengthens its core mission: embedding fundamental rights protection seamlessly across all stages of AI governance.

3. From Theory to Practice: A Proposal for Implementing the FRIA Framework

The FRIA framework, as conceptualised in the AI Act, is designed to systematically evaluate risks to fundamental rights posed by high-risk AI systems. Building on the theoretical foundations of the FRIA, it is necessary to move toward practical implementation. This framework, referred to as the Fundamental Rights Impact Assessment AI Act (FRIAct),[74] adopts a risk-based approach intended to proactively anticipate and mitigate adverse effects on fundamental rights before they occur by adopting a process divided in three main phases:

- Phase 1 – Risk Classification Assessment, Intended Purpose, and Contextual Analysis. Identification whether the system qualifies as high-risk and frames its intended use. This phase is crucial since it provides the foundation for the entire assessment by establishing the context necessary for justifying decisions made in subsequent phases.

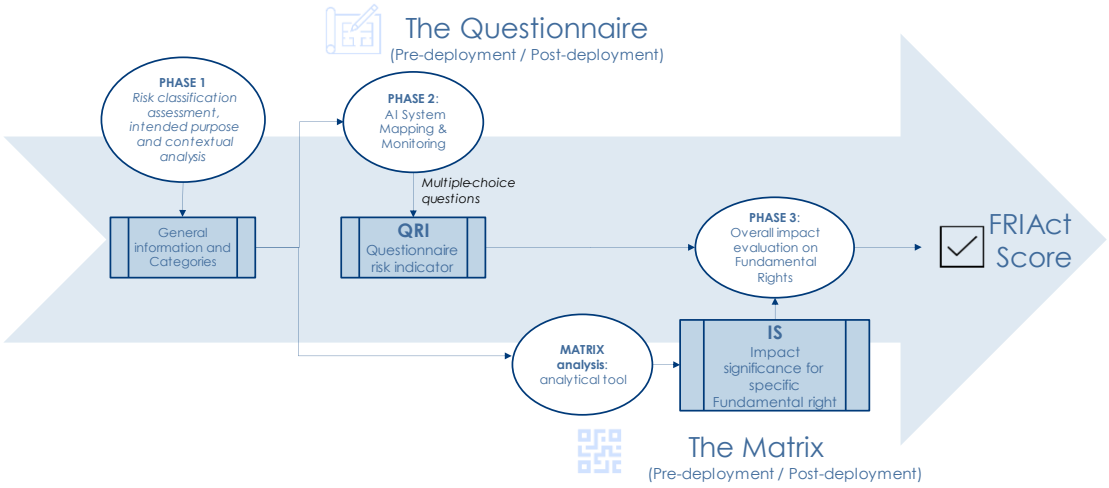
- Phase 2 – AI System Mapping & Monitoring. Examination of technical aspects and production of a Questionnaire Risk Indicator (QRI) that measures risks. The questions in this phase are designed to produce the QRI, a continuous score ranging from 1 (lowest risk) to 10 (highest risk). Each specific answer in this phase is assigned a corresponding risk level, represented as an integer from 1 to 10.[75]

- Phase 3 – Fundamental Rights Impact Evaluation. Synthesis of these findings by integrating the outputs of the Matrix[76] –Impact Significance (IS) scores – into the Questionnaire to calculate the FRIAct Scores, essentially one for each fundamental right analysed, and,

[74] Bertaina and others (n 19).
[75] For each section within Phase 2, a Section Risk Indicator is calculated as the average of the risk levels assigned to the answers within that section, resulting in a continuous score between 1 and 10. The ORI is then determined as the arithmetic average of all Section Risk Indicators across the Questionnaire. However, specific high-risk answers, identified as potential blockers, may override the calculated Section Risk Indicator and compromise the entire assessment.
[76] The combination of QRI with the IS scores will be explained in the following sections.

therefore, defining explicit mitigation measures based on the findings of the analysis, as requested by the AI Act.[77]

Figure 1: A scheme of the assessment process, during which QRI and IS are calculated and then combined in the FRIAct Score. The process consists of two tools (Questionnaire and Matrix) and four Phases.



To achieve this objective, the FRIAct employs a two-pronged approach combining qualitative and quantitative tools: a Questionnaire and a Matrix. The Questionnaire is a qualitative tool structured to collect detailed contextual and technical information about the AI system. It serves as a foundation for understanding the system's purpose, design, and deployment environment, enabling a nuanced identification of risks and potential mitigations. Complementing this, the Matrix assesses the potential impacts on individual fundamental rights by calculating risk scores based on Severity and Probability of Occurrence dimensions, as described in detail in Section 4.2. Together, these tools ensure a comprehensive and reproducible evaluation, bridging theoretical principles with actionable insights for compliance and risk mitigation.

The methodology that has been implemented to perform such an assessment is tailored to adapt across the lifecycle of AI systems, encompassing two critical phases: pre-deployment and ost-deployment. The first assessment is conducted prior to system deployment, providing foundational insights for a 'Go/No-Go' decision. Whereas the post-deployment assessment, carried out

[77] AI act, para. 1, lett. e).

periodically, evaluates the evolving performance and impacts of the system, ensuring ongoing alignment with fundamental rights obligations.[78]

The integration of the Questionnaire and Matrix ensures that FRIAct not only supports compliance with the AI Act but also advances best practices in responsible AI governance. By providing a practical and adaptable framework, FRIAct empowers to safeguard fundamental rights in the use of AI systems. The following sections detail the structure and application of these tools, followed by an in-depth analysis of the Questionnaire and followed by the Matrix, illustrating how they work in tandem to support an effective FRIA process.

3.1 The Questionnaire

The Questionnaire serves as the qualitative foundation of the FRIAct framework, systematically analysing the AI system's design, deployment, and operational context to assess potential impacts on fundamental rights. To ensure adaptability across different stages of the AI system lifecycle, such as the pre-deployment and post-deployment, a specific Questionnaire is carried out during the design stage, while a different Questionnaire is dedicated to assessing the AI system in production - offering a comprehensive assessment process that aligns with the AI Act's requirements. The Questionnaire is organised into three distinct phases, each addressing a critical aspect of the system's evaluation.

The first set of questions acknowledges whether the AI system qualifies as high-risk under Article 6 and Annex III of the AI Act and establishes the broader context of its deployment. Even if an AI system does not fall under the list included in Annex III of the AI Act, and, therefore, is not classified as high-risk, it can potentially impact natural persons significantly. In case the system is perceived to be potentially harming fundamental rights, then the deployer might consider performing the FRIAct in any case.

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[78] A key challenge in developing this methodology was integrating diverse AI technologies, such as Machine Learning, Generative AI, and General-Purpose AI systems, into a cohesive framework. These technologies exhibit varied characteristics and interact differently with their operational environments, and, therefore, this diversity necessitates a flexible and adaptable approach, ensuring that FRIACT can address the wide spectrum of AI applications covered by the AI Act. By accommodating technological and operational differences, FRIACT provides a rational analysis of AI system impacts across varied use cases. For a distinction of the different characteristics of the tecnologies, see Giovanni Sartor, *L'intelligenza artificiale e il diritto* (Giappichelli 2022); Ethem Alpaydın, *Machine Learning* (MIT Press Essential Knowledge series 2016); Ziwei Liu and others, 'Generative Networks' in Stan Z Li, Anil K Jain and Jiankang Deng (eds), *Handbook of Face Recognition* (Springer International Publishing 2024) <https://doi.org/10.1007/978-3-031-43567-6_3> accessed 25 October 2024; Oskar J Gstrein, Noman Haleem and Andrej Zwitter, 'General-Purpose AI Regulation and the European Union AI Act' (2024) 13 Internet Policy Review <https://policyreview.info/articles/analysis/general-purpose-ai-regulation-and-ai-act> accessed 31 December 2024.

Therefore, the objectives of this first phase of the questionnaire are:

- Acknowledge whether the system falls under a certain high-risk category, initiating the obligation to conduct a FRIA.
- Frame the AI system within the scope of its project, detailing its operational purpose and potential societal impact.
- Map the lifecycle of the AI system, including key actors and affected persons.

Key questions of this phase include the understanding of the functionality of the system, the timeline and usage, the affected population, and the risk classification. This phase is crucial to frame the AI system within its lifecycle, identifying key stakeholders and contextual factors that inform technical assessments in later phases.

The second phase consists of several sections, each section containing multiple choice questions to which a risk level is assigned according to the answer selected. In this phase, the Questionnaire evaluates the system's design focusing on key risk factors like fairness, transparency, and human oversight. The risk level assigned to each question is averaged into Specific Risk Indicators for each section, which are then averaged into the Questionnaire Risk Indicator (QRI), which ranges from 1 (low risk) to 10 (high risk). Some questions include a "blocking" answer, which, if selected, immediately halts the assessment. This response signals the need for system modifications, as it highlights design choices that could lead to unacceptable impacts. Table 2 provides an illustrative example of the type of questions addressed during the questionnaire phase of the FRIAct methodology. These questions are structured to ensure a thorough analysis of the AI system's potential impacts on fundamental rights, both before deployment and throughout its operational lifecycle. By addressing key technical, contextual, and legal considerations, this framework's purpose is to facilitate the implementation of a proactive approach to safeguarding fundamental rights in compliance with the AI Act. Thus, the Questionnaire provides essential information about the AI system's purpose, design, operational context, and affected populations, which serves as the foundation for Matrix analysis. For example, as it will be highlighted in Section 4.2, the technical details captured in Phase 2, such as algorithm type, data governance practices may have an impact on the calculation of Probability of Occurrence, while human oversight safeguards may impact the score assigned to Severity.

Then, the QRI summarises the AI system's risk profile across multiple dimensions (e.g., transparency, fairness, oversight). This QRI is directly used to individually weigh the significance of risks calculated through the Matrix, i.e. IS scores. While the Questionnaire contextualises the risks based on operational and technical factors, the Matrix provides numerical IS scores to detail the magnitude and likelihood of impacts on individual rights. Together, these tools offer a comprehensive framework that integrates qualitative insights with quantitative analysis, ensuring robust risk management and compliance under the AI Act. The following grid confronts some examples of the questions for Phase I and Phase II. While Phase I does not lead to obtaining a risk level, Phase II instead contains closed-ended questions with a risk score assigned to each possible answer.

Table 2 – Example of questions in the Questionnaire.

Questions Phase I	
Categories	*Questions*
General Context	Describe the context and the specific purpose of the AI system.
High-Risk Classification	Is the AI system classified as High-risk under article 6 of the AI Act and why?
Affected Groups	Are there any categories of natural persons that can be considered as more vulnerable groups? What are their specific risks?
Questions Phase II	
Technical Deployment	What type of algorithm(s) or model have been used? Please specify your choice and provide detailed examples. - a non-self-learning algorithm in which humans specify the rules the computer must comply to (choose a risk level from 1 to 3) - a System that is entirely or partially based on a self-learning algorithm, where the machine itself is finding patterns in the data (choose a risk level from 4 to 10)
Data and Fairness	Are all input data (from internal and external sources), including third-party training data and data added by the Deployer, governed by data governance and data quality processes?

	- Yes, all, in compliance with GDPR, AIA and IP requirements (risk level 1) - Only partially (e.g., in case a model has been pre-trained by an external provider and there are no warranties about data used). Please specify (choose a risk level between 2 and 10) - No (blocking)
Transparency	Are the components of the AI System and their outputs explainable, interpretable and/or verifiable? - Yes, all the components are designed to be explainable, interpretable and/or verifiable. Describe what techniques are employed (choose a risk level from 1 to 3) - Not all the components of the AI System are explainable, interpretable and/or verifiable. Describe what techniques are employed (choose a risk level from 4 to 10) - No (blocking)
Human Oversight	What is the degree of automated decision-making in the AI system? - The decision is taken by a human being and the AI System provides only an additional layer of information (choose a risk level between 1 and 2) - The decision is made by the application of AI System are only executed after human review or approval (choose a risk level between 3 and 4) - The decision relies on the AI System, but it is possible for a human to override the outcomes (choose a risk level between 5 and 10) - The decision-making process is completely reliant on the AI System, without possibility for overrides (blocking)
Monitoring and Updates	If unfair behavior emerges, will it be possible to intervene to correct it? - Yes, it will be possible to intervene (risk level 1) - No, it has been not possible to correct the unfair behavior (blocking)

3.2 The Matrix

The second element on which the assessment relies is the Matrix, designed to evaluate the potential impact of an AI system on each fundamental right enshrined in the CFREU. By quantifying risks through structured dimensions and scores, the Matrix offers a granular, data-driven analysis of how an AI system might affect individuals and groups. It is built to ensure consistency, reliability, and adaptability throughout the two phases: pre-deployment and post-deployment.

This tool provides a semi-quantitative analysis of potential impacts on fundamental rights as protected and listed by the CFREU. The Matrix produces Impact Significance (IS) scores, which quantify the risk to specific fundamental rights. To ensure reliable results, the data used in the Matrix must: a) extend beyond training datasets (e.g., validation and test datasets) to represent the system's behaviour more comprehensively and reduce overfitting risks; b) be representative of the real population affected by the deployed AI system, as required by Article 10 of the AI Act.

The Matrix is structured to consider up to all 50 rights enshrined in the EU Charter. Each right is evaluated separately to ensure a comprehensive assessment. The result is a distinct IS score for each right, representing the degree to which the AI system impacts that particular right. The compilation of the Matrix for FRIAct has been supplemented by a *vademecum* proposed to enhance clarity and provide structured guidance for evaluating which fundamental rights might be impacted by an AI system. It aims to translate abstract principles of fundamental rights into actionable standards relevant to the AI context. Thus, the *vademecum* includes concise explanations for each right alongside targeted questions that probe the AI system's potential impact. These questions provide a systematic means to assess risks to individual rights. By integrating the *vademecum* into the FRIAct process, the matrix outputs – namely the IS scores – are rendered more precise and contextually relevant. Table 3 shows examples of Articles 1, 7, 8 and 47 as developed and clustered in the *vademecum*. The full version of the *vademecum* is reported as Supplementary Material.

Table 3 – Excerpt from the *vademecum* for the Matrix compilation.

Fundamental Right	*Short Explanation*	*Example Guiding Questions*
Article 1: Human Dignity	Forms the basis of EU values; impacts privacy, equality, and social security.	Does the system respect individuals' autonomy? Does it avoid reinforcing harmful stereotypes or biases?

Article 7: Privacy	Ensures respect for private and family life; critical for gender equality and child protection.	Does the AI system collect personal data responsibly? Does it prevent unauthorized disclosure of private information?
Article 8: Data Protection	Protects data processing fairness and user access to rectification.	How does the system ensure data accuracy? Are processing practices transparent and aligned with GDPR requirements?
Article 47: Fair Trial	Guarantees effective remedies and fair judicial processes.	Does the system provide clear reasoning for its decisions? Are there redress mechanisms for contesting AI outputs?

The Matrix evaluates risks based on two key dimensions: severity,[79] hence the magnitude of the harm; the probability of occurrence,[80] as the likelihood of harm. To better simplify and to encapsulate the broadest picture possible on the potential infringement of fundamental rights, severity is composed of two sub-dimensions:

- Intensity: Measures the magnitude of potential harm, considering worst-case outcomes. It is the conceivable level of harm or damage that could result from a given risk. It considers the most severe possible outcome and classifies the gravity of that outcome based on its impact on a fundamental right.
- Effort of Remediation: The range of measures and resources required to address and potentially reverse any unintended or harmful outcome produced by the AI system.

Likewise, the probability of occurrence can be broken down in:

- Likelihood: The probability that the AI system will produce an error leading to an adverse impact on fundamental rights.
- Robustness: The specific performance indicator of the AI system. This sub-dimension is considered only in the post-deployment Matrix, as it requires post-deployment performance data.

Each sub-dimension is assigned a score on a 1 to 10 scale, in particular:

[79] For the purpose of our analysis, we define severity as *"the extent or degree of harm on the protection of fundamental rights of a natural person or group that could occur if a risk materialize"*.
[80] For the purpose of our analysis, we define the probability of occurrence dimension as *"the likelihood to impact a fundamental right of a natural person or group of people due to the specific AI system performance"*.

- **Intensity**
    - 1–2 (Negligible)

      Harm is minimal and easily mitigated.
    - 3–4 (Moderate)

      Noticeable but generally localized; potential impact remains reversible.
    - 5–6 (Serious)

      Significant effects on an individual's well-being or rights.
    - 7–8 (Severe)

      Major consequences, potentially involving long-term or broad-scale harm.
    - 9–10 (Catastrophic)

      Profound, possibly irreversible impact on a fundamental right.

- **Effort of Remediation**
    - 1–2 (Trivial)

      Corrective actions are minimal; existing resources suffice.
    - 3–4 (Modest)

      Remediation requires moderate effort and some coordination.
    - 5–6 (Substantial)

      Demands notable resource allocation, possibly specialized expertise.
    - 7–8 (High)

      Complex, time-intensive, and may disrupt operations.
    - 9–10 (Nearly Impracticable)

      Extremely difficult or expensive to address, risking feasibility issues.

- **Likelihood**
    - 1–2 (Rare)

      Very low probability; would occur only under exceptional conditions.

- 3–4 (Unlikely)

  Possible but not expected in typical scenarios.

- 5–6 (Moderate)

  Could happen regularly if certain factors align.

- 7–8 (Likely)

  Reasonably anticipated to occur in normal operating conditions.

- 9–10 (Almost Certain)

  Highly probable to occur unless major safeguards are implemented.

Robustness sub-dimension score is obtained using the complementary of the AI system's performance indicator. For example, if the system's accuracy is 80% (scored as 8 out of 10), then the Robustness sub-dimension score is calculated as $10 - 8 = 2$. As such, it is a truly quantitative measure. The scores for sub-dimensions are then combined linearly to calculate:

$$\text{Severity(j)} = \frac{\text{Intensity(j)} + \text{Effort of Remediation(j)}}{2}$$

$$\text{Probability of Occurrence(j)} = \frac{\text{Likelihood(j)} + \text{Robustness(j)}}{2}$$

Where (j) indicates that each dimension is referred to a specific fundamental right.

The IS score for each fundamental right is then obtained as:

$$\text{IS(j)} = \text{Severity(j)} \times \text{Probability of Occurrence(j)}$$

When assessing the risks to the individual rights listed in the CFREU, each right is assigned an IS score, which ranges from 1 to 100, with 1 indicating minimal risk and 100 representing maximum risk. Table 4 is a representation of the Matrix including the first 10 rights of the CFREU.

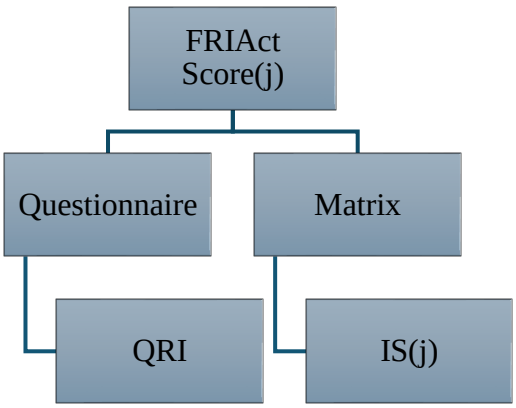
Table – Matrix visual representation.

Fundamental Rights	Art.	Severity			Probability of occurrence (PO)			Impact Significance
		Intensity	Effort of remediation	Severity Level	Likelihood	Robustness	PO Level	
CHAPTER 1: DIGNITY								
Human dignity	1							
Right to life	2							
Right to the integrity of the person	3							
Prohibition of torture and inhuman or degrading treatment or punishment	4							
Prohibition of slavery and forced labour	5							
CHAPTER 2: FREEDOMS								
Right to liberty and security	6							
Respect for private and family life	7							
Protection of personal data	8							
Right to marry and right to found a family	9							
Freedom of thought, conscience and religion	10							

3.3 FRIAct: Integration of Questionnaire and Matrix

The Questionnaire and Matrix are designed to work together as core components of the FRIAct framework, ensuring a comprehensive evaluation of AI systems. While the Questionnaire captures qualitative insights and contextual understanding, the Matrix provides semi-quantitative, rights-specific analysis. The integration of the Questionnaire (QRI) and Matrix (IS) results in the FRIAct Score, which provide actionable insights into the AI system's compliance and areas needing improvement. The third phase synthesizes the QRI scores with the outputs of the Matrix (IS) to calculate the FRIAct Scores for individual fundamental rights.

Figure 2 – Flowchart displaying the relationship between the Questionnaire and the Matrix within the FRIAct framework.



To produce a final, rights-specific, score, we need to combine QRI and IS(j) into a single index. We choose to do that by a weighted sum, where we decide to give more importance to IS(j), since this is the index capturing more granular, rights-specific, features.

The actual weights we are proposing below (30/70) are of course arbitrary, and can be intended as a starting point subject to further refinements and analysis. The same is true for the specific value of the thresholds that we propose, that trigger different actions in response to the assessment.

- **Calculation**: each FRIAct Score is derived using the following formula:

$$\text{FRIAct Score (FR(j))} = 0{,}3 \times \text{QRI(\%)} + 0{,}7 \times \text{IS(j)}$$

Where:

The QRI score is rescaled on a 1 to 100 scale in order to combine it with the IS(j) score; FR(j) refers to the FRIAct score for a specific fundamental right from the CFREU.

The IS(j) is the risk level associated with fundamental right (j) as calculated in the Matrix.

- **Thresholds and Outcomes**:
    - FRIAct Score < 50: The system passes the assessment.
    - FRIAct Score between 50 and 75: The system requires mitigation or monitoring actions before development can proceed.
    - FRIAct Score ≥ 75: The system cannot be developed as planned and must be reevaluated.
- **Mitigation and Reporting**:
    - Any section with a Risk Indicator of 75 or higher must be highlighted and described in detail before closing the assessment.
    - For scores requiring mitigation (50–75), implement the necessary actions and rerun Phases 2 and 3 to verify compliance.

Thus, the integration of the Questionnaire and Matrix culminates in the calculation of FRIAct Scores for each fundamental right. These scores provide actionable insights for deployers and regulators by highlighting specific rights at risk and guiding mitigation strategies. The two instruments are intertwined in every phase. Hence, during the design phase, the Questionnaire identifies potential risks, and the Matrix evaluates projected impacts. Together, they guide system adjustments before deployment. Then, post-deployment, the Questionnaire updates contextual and operational insights, while the Matrix recalculates IS scores using real-world performance data.

The Questionnaire integrates the quantitative part of the FRIAct, gathering contextual and operational data about the AI system, including its intended purpose, affected populations, and technical characteristics. These insights are essential for setting the parameters used in the Matrix. The Questionnaire produces a QRI, summarising the system's overall risk profile. This QRI serves as a baseline for the Matrix by weighting its calculations of the IS scores. The QRI helps align qualitative assessments (e.g., operational context, technical safeguards) with the numerical risk levels calculated in the Matrix. Then, this latter one translates the general risk areas identified in the Questionnaire into precise, measurable impacts on individual fundamental rights.

- Example: if the Questionnaire identifies challenges in data governance, we expect that the Matrix will assign higher Likelihood scores under the Probability of Occurrence dimension, potentially increasing the IS score for rights such as privacy or data protection.

This iterative process ensures that the AI system adapts to evolving risks and maintains compliance throughout its lifecycle. This combination will be further heightened in the case scenario analysis that follows, demonstrating how the Questionnaire and Matrix, even though being interdependent tools that bridge qualitative and quantitative analyses, together ensure a thorough evaluation of AI systems under the FRIAct framework. By leveraging their combined outputs, deployers can proactively address risks to fundamental rights, comply with the AI Act, and foster ethical and responsible AI governance.

3.4 FRIAct Lifecycle

With respect to instructions related to the frequency of the assessment, it is advised to perform the FRIAct in both the two phases for every AI system subject to assessment: once during the pre-deployment phase and periodically thereafter through the post-deployment phase.

Table 5 – Confrontation between pre-deployment and post-deployment phase.

Pre-deployment phase	*Post-deployment phase*
It is recommended to initiate this phase as early as possible in the AI system's lifecycle, before deployment. Early-stage assessments facilitate the development of trustworthy systems by allowing adjustments while software development remains flexible. This can prevent potential infringements on fundamental rights and mitigate financial risks, ensuring the feasibility of deployment strategies.	After deployment, systems should undergo regular reassessments to account for changes in performance and operational contexts. Post-deployment monitoring allows organizations to verify assumptions made during the design phase and adapt to real-world conditions. Monitoring is not merely a verification of initial assumptions; it leverages a broader set of parameters derived from operational performance, providing a more detailed and realistic evaluation. It is suggested to conduct the post-deployment assessment at least every 12 to 18 months, with shorter intervals for cutting-edge technologies or systems that scored high in the FRIAct pre-deployment phase.

The FRIAct is flexible and can be tailored to fit the organisational structure and needs of the deploying entity. It provides a bridge between legal, ethical, technical, and domain-specific considerations, ensuring holistic compliance with the AI Act.

By following this structured, iterative approach, organisations can ensure that their AI systems not only comply with the AI Act but also align with ethical and societal values, safeguarding fundamental rights at every stage of the system's lifecycle. This approach provides a robust mechanism for navigating the complexities of AI governance while fostering trust and accountability.

4. LoanLens: a testing ground use case

The following section illustrates how the FRIAct can be applied to a practical scenario. The use case involves an AI system used for credit scoring, a high-risk area under the AI Act,[81] due to its potential impact on individuals' fundamental rights. This example, while fictitious, is designed to be plausible and representative of real-world applications.

4.1 Overview of the AI system

The AI system that we are considering has the purpose of calculating the credit scoring of natural persons. The prospected scenario consists of a Bank that currently relies on a traditional Machine-Learning System (MLS) to calculate a credit score for individual customers. This system draws on four primary indicators:

1. *A rating derived from 100 creditworthiness variables* - this composite rating is built from a wide array of data points reflecting an individual's financial behavior, such as historical repayment patterns, outstanding debt levels, credit utilization ratios, length of credit history, and other factors that statistically correlate with credit risk;

2. *An early warning system* - this mechanism is designed to continuously monitor customers' activities and external signals that might hint at a decline in creditworthiness. For example, if a pattern of missed payments emerges or there is adverse news about a customer's employer, the early warning system raises alerts. By flagging these signals promptly, the Bank can take proactive measures, such as requesting updated documentation or revising credit limits, to mitigate potential losses;

3. *Transactional or affordability data* - these data reflect the customer's ongoing financial obligations and day-to-day cash flows. Typical examples include monthly spending patterns,

[81] Annex III, 5(b)

recurring bills, salary deposits, and other income streams. By assessing whether the borrower's incoming funds can support their current (and potentially additional) debt, the system can estimate affordability and likelihood of timely repayment;

4. *A metric representing financial wealth* - this indicator provides insight into the customer's broader financial standing, often accounting for assets such as real estate, investment portfolios, or savings. A higher wealth metric generally suggests more capacity to handle debt, while a lower metric may signal limited resources to manage unforeseen financial strains.

Building on this existing infrastructure, the Bank proposes to integrate a conversational Decision Support System (DSS) powered by GenAI.

In practice, the credit score computed by the MLS is fed into the GenAI model along with various unstructured data sources (e.g., documents submitted during the credit application and historical customer profile data). Through a chatbot interface, called LoanLens, a human decision-maker gains a single, centralized access point for receiving credit score outputs and requesting additional analysis and information about customers applying for loans. The AI System's output will be a numerical score ranging from 1 to 100, where 1 is the lowest Credit Score and 100 is the highest achievable score.

To aid quick and consistent decision-making, the Bank categorizes this numerical score using a traffic light threshold framework:

- Red Zone (1–40): High credit risk, possibly requiring additional collateral or higher interest rates.
- Yellow Zone (41–70): Moderate credit risk, suggesting further verification steps or more stringent monitoring.
- Green Zone (71–100): Low credit risk, indicating eligibility for more favorable terms and expedited approval.

The person who makes the final decision on the loan application can rely on the given score or override it, providing a justification that explains the reasons for the disagreement. In this scenario, we assume that the GenAI component is a pre-trained model, developed by an external provider and then fed with purpose-specific data.

The GenAI model complements the MLS by synthesizing additional insights and providing a more user-friendly interface for human decision-makers. Here's how it works:

1. Data flow:
    - The MLS generates a credit score based on its structured input indicators.
    - This credit score, along with unstructured data (e.g., documents submitted during the credit application, historical customer profiles), is fed into the GenAI model.
2. Interface and functionality:
    - LoanLens, the chatbot interface powered by the GenAI engine, acts as a single access point for human decision-makers.
    - LoanLens allows managers to:
        - View the MLS-generated credit score.
        - Request deeper analyses or additional context about a customer's profile.
        - Interact in natural language to extract insights or locate relevant information efficiently.
3. Output:
    - The AI System's output will be a numerical score ranging from 1 to 100, where 1 is the lowest Credit Score and 100 is the highest achievable score.To aid quick and consistent decision-making, the Bank categorizes this numerical score using a traffic light threshold framework:
        - Red Zone (1–40): High credit risk, possibly requiring additional collateral or higher interest rates.
        - Yellow Zone (41–70): Moderate credit risk, suggesting further verification steps or more stringent monitoring.
        - Green Zone (71–100): Low credit risk, indicating eligibility for more favorable terms and expedited approval.
    - Human decision-makers can use this score as a suggestion but retain the authority to override it, providing a justification when doing so.

In this setup, the GenAI component is a pre-trained model provided by an external developer, further refined with purpose-specific data to ensure alignment with the bank's credit scoring needs.

The operational flow of the AI system ensures seamless integration between structured and unstructured data processing. In particular, the GenAI component:

- Utilises natural language prompts to process inputs and generate insights.
- Extracts relevant information from submitted documents, historical data, and credit scores.
- Synthesises this information into a user-friendly format, allowing managers to interact solely with LoanLens for all decision-support needs.

LoanLens simplifies access to layered information in one place, enabling quicker and more informed decision-making. In this sense, the natural language interface eliminates the need for technical expertise, making it accessible to a broader range of users.

A central design feature of this system is its emphasis on human oversight, as mandated by Article 14 of the AI Act. The following mechanisms ensure that human responsibility remains at the forefront:

1. Final decision:
    - LoanLens provides suggestions and information, but all final decisions remain the responsibility of human decision-makers.
    - Decision-makers can override or disregard the output, providing explanations for any discrepancies.
2. Stop mechanism:
    - At any point, LoanLens can be stopped by the user to prevent unintended consequences, satisfying the Article 14(3) of the AI Act requirement for a 'stop button' feature.
3. Risk mitigation:

- By keeping the GenAI system in a supportive, rather than fully autonomous, role, the design minimises potential risks to fundamental rights, such as privacy violations or discrimination.

To ensure reliability and robustness, both the MLS and DSS components are tested rigorously before full deployment. These metrics are essential for compiling the post-deployment Matrix, particularly for assessing the Robustness sub-dimension:

1. MLS Performance:
    - The MLS must achieve a classification accuracy of at least 80% in credit lending decisions during pre-deployment testing.
    - This benchmark ensures the MLS reliably evaluates structured indicators like creditworthiness and financial health.
2. DSS Performance:
    - The DSS must demonstrate at least 90% accuracy in responding to human-posed queries or locating relevant documents within the system.
    - This ensures the DSS provides meaningful, accurate support to decision-makers.
3. Deployment Criteria:
    - The system transitions to production only after both components meet their respective performance thresholds, ensuring a robust foundation for real-world operations.

4.2 The application of the FRIAct

In the following paragraphs we will show the most relevant results of the FRIA assessment conducted for LoanLens. The full Questionnaire is reported as Supplementary Material.

In Phase 1, it is acknowledged LoanLens as a high-risk AI system under Article 6 and Annex III of the AI Act due to its role in determining access to credit, a private service with significant implications for fundamental rights. This classification is critical because credit scoring decisions can affect socioeconomic opportunities, such as housing and employment.

The system impacts two primary groups:

- Individuals applying for loans: These individuals directly rely on the AI-generated credit scores for access to credit services.
- Vulnerable groups: especially younger applicants that may have a 'thin file', i.e., having little or no credit history, and groups of individuals identified by sensitive characteristics potentially subject to algorithmic bias, such as foreigners, women, and persons with disabilities.

This phase establishes the broader context for LoanLens, emphasising its societal relevance and the need for stringent risk assessment.

Phase 2 dives into the technical components of LoanLens, assessing specific risks across key operational dimensions. Each dimension is assigned a Specific Risk Indicator, which contributes to the QRI. The full pre-deployment Questionnaire can be found in Supplementary Material.

1. Deployment Process:
    - LoanLens integrates a non-self-learning MLS and a self-learning GenAI component to process structured and unstructured data.
    - The Risk Level for this dimension is 7.5, reflecting the complexity of combining these technologies and the systemic risks posed by the GenAI component.
    - Alternative, simpler algorithms were considered but deemed insufficient due to lower accuracy, reinforcing the need for this advanced system.
2. Input Data and Fairness:
    - The MLS complies with rigorous data governance standards, mitigating many risks. However, reliance on an external provider for the GenAI component introduces residual risks related to bias and transparency.
    - This results in a Risk Level of 2.4, indicating moderate risk.
3. Transparency:
    - The MLS outputs are explainable and interpretable, while the GenAI's chatbot interface ensures verifiable insights for human decision-makers.
    - This yields a Risk Level of 1.2, reflecting low risk in this area.

4. Human Oversight:
    - The system maintains strong human oversight mechanisms, allowing decision-makers to override or halt the AI's operations, as required by Article 14 of the AI Act.
    - A Risk Level of 1 indicates robust safeguards and minimal risk.
5. Monitoring and Maintenance:
    - LoanLens includes monthly monitoring protocols and emergency update mechanisms to address emerging issues. These processes ensure continued compliance and adaptability.
    - The Risk Level for this dimension is 2.5, representing moderate risk.

Table 6 – Pre-deployment Questionnaire Results

Section	*Risk Indicator (RI)*
Deployment Process	7.5
Input data and Fairness	2.4
Explainability and Transparency	1.2
Performance	4.0
Human Oversight	1.0
Monitoring and Maintenance	2.5
Questionnaire Risk Indicator (QRI)	***3.1***

The Matrix quantifies the system's impact on fundamental rights by evaluating Severity and Probability of Occurrence for each relevant right. Nine rights of the CFREU – Art. 1, Human Dignity, Art. 6 Right to liberty and security, Art. 9 Right to marry and right to found a family, Art. 16 Freedom to conduct a business, Art. 17 Right to property, Art. 25 The rights of the elderly, Art. 26 Integration of persons with disabilities, Art. 33 Family and professional life, Art. 36 Access to services of general economic interest – that have been evaluated by us as potentially impacted by the AI system in this context. Table 7 a visual of the Matrix, calculated on the nine mentioned fundamental rights.

Table 7 – LoanLens pre-deployment Matrix.

Art.	Fundamental Right	Severity			Probability of Occurrence (PO)		IS (%)
		Intensity	Effort of Remediation	Severity Level	Likelihood	PO Level	
1	Human Dignity	10	2	6	1	1	6
6	Right to liberty and security	6	2	4	1	1	4
9	Right to marry and right to found a family	6	2	4	1	1	4
16	Freedom to conduct a business	10	2	6	1	1	6
17	Right to property	10	2	6	1	1	6
25	The rights of the elderly	7	2	4.5	1	1	4.5
26	Integration of persons with disabilities	10	2	6	1	1	6
33	Family and professional life	8	2	5	1	1	5
36	Access to services of general economic interest	10	2	6	1	1	6

Despite high Severity scores for some rights, strong control measures and human oversight safeguards reduce the Probability of Occurrence, keeping overall IS values low.

Before addressing the completion of individual entries, it may be useful to investigate the values for Effort of Remediation and Likelihood. As it is possible to see, the values chosen are always the same: 2 for Effort of Remediation and 1 for Likelihood. These values are determined by the strong presence of the human oversight component. Therefore, we expect that both the effort required to

override an impactful decision and the frequency of such errors occurring will be significantly reduced due to the strong human oversight component.

Upon analyzing Article 1 CFREU, it is possible to notice that an intensity rating of 10/10 has been assigned. This rating reflects our assessment that a wrongful decision to deny a loan would constitute a severe violation of an individual's fundamental right to personal dignity, which we deem to be of the utmost importance. This determination is based on the ethical principle that such decisions, if erroneous, can significantly undermine an individual's sense of agency and personal worth, thus warranting the maximum possible intensity for this particular risk.

Moving to the analysis of Article 6 'right to liberty and security', an intensity of 6/10 has been chosen. This choice is justified by the fact that an erroneous denial of credit could undermine both the security and the freedom of individuals. A slightly above-average intensity was selected because the economic capacity of individuals enables access to essential services that are important for the full enjoyment of personal security and freedom rights.

We followed the same considerations while assessing the impact of the AI systems with regards to Article 9 'right to marry and found a family': we have again chosen an intensity of 6 out of 10. We considered that, for the full enjoyment of the aforementioned Article 9, a proper allocation of loans is necessary. In the case of personal loans, we deemed this article potentially impacted, as it protects the right to be free (and thus 'able') to find a family.

On the other hand, given its close connection to the economic sphere of the individual, we have selected an intensity of 10 out of 10 for the potential impact on the freedom to conduct business (Article 16). Since this freedom is directly linked to the financial situation of the loan applicant, we expect that an erroneous denial of the loan would have the maximum possible impact on the individual's circumstances. The same considerations apply also to article 17 'right to Property'.

The aim of Article 25 is to combat social exclusion and discrimination against the elderly, fostering a society where older individuals are valued as a resource and can live actively and with respect. Based on these considerations, we have assigned an intensity value of 7 out of 10. This decision reflects the potential limitations in exercising this right due to wrongful decisions made by AI systems. Additionally, economic factors may hinder the elderly's ability to participate in activities of interest, thereby undermining the protections outlined in Article 25 of the Charter.

Article 26 CFREU establishes the right to integration for persons with disabilities. Based on considerations related to the socio-economic status of this particularly vulnerable group, an intensity rating of 10 out of 10 has been selected once again. Given the additional costs these individuals must bear to effectively exercise their rights, we anticipate that an unjustified denial of a loan could have the maximum possible impact on this group.

The same considerations made for, among others, Article 16 have been applied to Article 36, which defines the right to access services considered to be of general economic interest. This is due to the nature of the credit requested and the connection between the right enunciated in Article 36 and the economic sphere outlined by this right.

Regarding Article 33 of the Charter, 'family and professional life', an intensity value of 8 out of 10 was assigned. This is due to the following considerations: being wrongly denied a personal loan can lead to the consequence that the balance between work and family life, as protected by Article 33, is significantly undermined. Financial stability results as a core factor in the fulfillment of Article 33.

To conclude the considerations regarding the choices made during the completion of the pre-deployment Matrix, it is important to focus on the IS of the individual articles. As can be seen, the final results are all low scores (ranging from an IS of 4% to an IS of 6%) despite the significantly high intensity values. This is possible due to the design decisions that were made, in addition to the strong human oversight involved in determining the final output. This control is appropriately positioned between the production of the output and the individual potentially impacted by it. Such intermediation allows for quicker detection of errors in the assessment of the loan applicant and ensures the prompt intervention of the designated manager responsible for this task.

Table 8 – Pre-deployment FRIAct Score.

Art.	*QRI (%)*	*IS (%)*	*FRIAct Score (%)*
1	31	6	13.5
6	31	4	12.1
9	31	4	12.1
16	31	6	13.5
17	31	6	13.5
25	31	4.5	12.45

26	31	6	13.5
33	31	5	12.8
36	31	6	13.5

Post-deployment, the Questionnaire incorporates real-world implementation informations. The full post-deplyment Questionnaire can be found in Supplementary Material. Results are shown in the following table:

Table 9 – Post-deployment Questionnaire results.

Section	*Risk Indicator (RI)*
Deployment Process	7.5
Input data and Fairness	2.4
Explainability and Transparency	1.2
Performance	4.0
Human Oversight	1.0
Monitoring and Maintenance	2.5
Ownership and Control	10
Questionnaire Risk Indicator (QRI)	**4.1**

The post-deployment Matrix takes into account also Robustness sub-dimension. Please note that Intensity, Effort of Remediation and Likelihood sub-dimensions are expressed as numerical indicators ranging from 1 to 10, where 1 represents the lowest level and 10 represents the highest level of Intensity, Effort, or Likelihood. By contrast, the Robustness sub-dimension is measured as the inverse of the AI system's performance—thus, to maintain consistency with the 1–10 scale, a score of 1 indicates the highest level of Robustness, and a score of 10 indicates the lowest level of Robustness. For this toy example, as described above, the ML component has to achieve an accuracy of 80% to be effectively deployed, so Robustness indicator is:

Robustness = 10 - Accuracy = 10 - 8 = 2

This adjustment slightly increased IS scores compared to the pre-deployment Matrix, reflecting greater precision in post-deployment evaluations.

Table 10 – Post-deployment Matrix results.

Art.	***Severity***			***Probability of Occurrence***			***IS (%)***
	I	***ER***	***S***	***L***	**R**	**PO**	
1	10	2	6	1	2	1.5	9
6	6	2	4	1	2	1.5	6
9	6	2	4	1	2	1.5	6
16	10	2	6	1	2	1.5	9
17	10	2	6	1	2	1.5	9
25	7	2	4.5	1	2	1.5	6.75
26	10	2	6	1	2	1.5	9
33	8	2	5	1	2	1.5	6.75
36	10	2	6	1	2	1.5	9

Compared to pre-deployment Matrix results, IS indicators resulting from post-deployment Matrix are slightly higher than the ones obtained from the pre-deployment one. Taking into account the actual performance of the AI system led to a very slight worsening of the scores, which were nevertheless extremely low due to the centrality of the designed human oversight component. Post-deployment FRIAct Scores are described in the following table.

Table 11 – Post-deployment FRIAct Scores.

Art.	**QRI (%)**	**IS (%)**	**FRIAct Score (%)**
1	41	9	18.6
6	41	6	16.5
9	41	6	16.5
16	41	9	18.6
17	41	9	18.6
25	41	6.75	17.03
26	41	9	18.6
33	41	6.75	17.03
36	41	9	18.6

Lifecycle adjustments are essential for maintaining compliance. The system is reassessed in cases of significant modifications, such as changes to the GenAI model or new deployment contexts. These

iterative assessments ensure LoanLens evolves responsibly and aligns with the FRIAct framework's standards.

The LoanLens use case highlights the FRIAct framework's ability to integrate the qualitative insights of the Questionnaire with the quantitative approach of the Matrix. By systematically evaluating risks across operational and rights-based dimensions, the framework identifies potential vulnerabilities and guides mitigation strategies. Robust human oversight mechanisms, coupled with continuous monitoring, ensure that the system complies with the AI Act throughout its lifecycle. This approach not only safeguards fundamental rights but also fosters trust and accountability in AI deployment.

5. Conclusion

This paper presents the FRIAct framework as a comprehensive approach for assessing the impact of AI systems on fundamental rights, particularly in compliance with the AI Act. The framework is rooted in the principles enshrined in the CFREU and operationalised through a combination of qualitative and quantitative tools, specifically the Questionnaire and the Matrix. Together, these instruments provide a rigorous structure for evaluating the risks posed by AI systems, particularly high-risk applications such as those involving GenAI and other advanced technologies.

The FRIAct framework is more than a procedural tool. It represents a systematic effort to align AI innovation with European constitutional values. By embedding the assessment of fundamental rights into the lifecycle of AI systems, the framework bridges the gap between the theoretical commitments to rights protection and the practical realities of AI deployment. This approach is crucial in addressing the transformative and sometimes disruptive effects of AI on individuals and society.

The Questionnaire is designed to provide a qualitative understanding of an AI system's context, purpose, and deployment, with a particular focus on identifying risks to fundamental rights. It establishes the framework for evaluating its operational context and the populations it may impact. This qualitative groundwork is complemented by the Matrix, which adds a assessment specifically designed to produce a quantitative output by systematically mapping potential qualitative impacts of the system on specific rights, such as privacy, non-discrimination, and human dignity. The Matrix's numerical outputs, expressed as IS scores, are grounded in measurable dimensions of risk,

including severity and probability of occurrence. This integration of qualitative and quantitative approaches ensures that the framework is both comprehensive and actionable.

The framework's flexibility makes it applicable to a wide range of AI systems, from traditional machine learning models to sophisticated GenAI systems. This adaptability is particularly evident in the LoanLens use case, which demonstrates how the FRIAct framework can be applied to assess the risks associated with a hybrid credit-scoring system that combines structured data analysis with generative AI capabilities. The case study illustrates how the framework addresses challenges such as transparency, human oversight, and fairness, while also emphasising the importance of ongoing monitoring to adapt to changes in system performance and regulatory environments. By incorporating robust safeguards and emphasising the need for human accountability, the framework aligns with the principles of Article 14 of the AI Act, which mandates human oversight of high-risk AI systems.

Another significant contribution of FRIAct is its ability to enhance compliance with the AI Act while fostering public trust in AI systems. The framework's lifecycle approach, encompassing both pre-deployment and post-deployment phases, ensures that risks are not only identified and mitigated during the development of AI systems but also continuously evaluated and managed throughout their operational lifespan. This dynamic risk management process is essential in a rapidly evolving technological landscape, where new risks may emerge as AI systems interact with diverse real-world contexts. The framework's emphasis on inclusivity further ensures that the rights of vulnerable populations, such as the elderly or individuals with disabilities, are carefully considered and protected.

FRIAct also addresses critical gaps in the current regulatory landscape by offering a practical pathway to implement the FRIA obligations under Article 27 of the AI Act. The framework's integration of the Questionnaire and Matrix not only aims to provide a clear approach to risk assessment but also sets a standard for aligning AI practices with broader societal values. This alignment is particularly important in high-stakes applications like credit scoring, where decisions have far-reaching consequences for individuals' access to essential services and economic opportunities.

In addition to its practical utility, FRIAct underscores the importance of fostering a collaborative governance model. The framework highlights the need for greater cooperation between AI

providers and deployers, addressing the information asymmetry that often hampers effective risk management. By ensuring that deployers have access to technical and operational insights provided by AI developers, FRIAct facilitates a more transparent and accountable AI ecosystem. Moreover, the framework emphasises the role of multidisciplinary teams, comprising legal, technical, and ethical experts, in implementing comprehensive assessments. This collaborative approach not only enhances the robustness of the assessment process but also strengthens the organizational capacity to navigate the complex regulatory requirements of the AI Act.

Looking ahead, the FRIAct framework offers a pathway for policymakers, regulators, and organisations to operationalise the principles of ethical and responsible AI. As the EU continues to refine its AI governance structures, frameworks like FRIAct can serve as benchmarks for implementing the AI Act's provisions while ensuring that AI systems respect and uphold fundamental rights. The framework's adaptability, rigorous methodology, and emphasis on lifecycle risk management position it as a critical tool for fostering trust and accountability in AI systems.

In conclusion, the FRIAct framework exemplifies how AI governance can balance innovation with the protection of fundamental rights. By providing a structured, replicable, and context-sensitive approach to risk assessment, the framework not only meets the compliance needs of the AI Act but also contributes to building a rights-centred digital ecosystem.

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