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The freedom to conduct a business as a driver for AI governance

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ABSTRACT: Artificial Intelligence ('AI') is associated with several risks that need to be contained and mitigated through an appropriate AI governance framework. However, it is also crucial to take into account the opportunities and societal benefits of AI and to consider and respect businesses as key actors in the context of AI. The freedom to conduct a business is a fundamental right enshrined in Article 16 of the Charter of Fundamental Rights of the European Union. It cannot be considered a diminished or functionalised right, nor are companies necessarily a threat to human rights or an obstacle to the pursuit of human-centred governance of AI. As in any scenario of conflict or collision between fundamental rights and interests, a fair balance must be struck between the subjective positions of different stakeholders. Ensuring respect for the freedom to conduct a business safeguards innovation and the flourishing of new opportunities that ultimately benefit citizens and the public interest. In the European Union legal system, AI governance will be shaped by both the 'Artificial Intelligence Act' and novel rules to address liability issues related to AI systems. While its prima facie content is affected by several provisions and obligations, in particular, for providers of high-risk AI systems, the EU legislator does not neglect the freedom to conduct a business. It seeks to provide legal certainty, ensure proportionality and address the special condition of small and medium-sized enterprises and start-ups. However, the rigidity of some provisions and the approach to risk, together with the uncertainty that characterises the normative environment of the AI, leave room for improvement and for further escape valves, with the future application being of particular importance.

KEYWORDS: Artificial intelligence – governance – fundamental rights – freedom to conduct a business.

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1. Introduction

Whatever its precise definition, Artificial Intelligence ('AI') is a *socio-technical* complex and multifaceted reality that can permeate our daily interactions though various means,[1] with an "*unprecedented capacity to reshape individual lives, societies, and the environment*".[2] As some describe it, AI is a "*double-edged sword*" and a "*complex and multi-causal phenomenon*",[3] with effects that can be both beneficial and risky.[4]

In this context, it is fair to say that the *winter of AI* has returned,[5] challenging even the basic assumptions and fundamental principles of entire branches of law.[6]

Indeed, while AI comes with tremendous benefits in different domains and areas of society,[7] there are also emerging obstacles, hazards, uncertainties, and unresolved issues that have prompted proposals and intensified endeavours to attain greater worldwide consensus and standardisation of AI regulation, in light of the limitations of existing laws and regulations.[8]

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[1] As regards the particular challenges of this "infiltration" and the limited personal and material scopes of existing laws, see Elaine Dewhurst, "«In delay there lies no plenty»: overcoming the agebased obstacles, omissions and inconsistencies in the 2008 Proposed Council Directive on Equal Treatment", *UNIO – EU Law Journal*, v. 8, no. 1 (2022): 108, accessed October 29, 2023, doi: https://doi.org/10.21814/unio.8.1.4520.

[2] See, among others, David Leslie et al., "Artificial intelligence, human rights, democracy, and the rule of law: a primer", *Council of Europe and The Alan Turing Institute*, 2021, 14, accessed August 27, 2023, https://rm.coe.int/primer-en-new-cover-pages-coe-english-compressed-2754-7186-0228-v-1/1680a2fd4a, and Huw Roberts et al., "Governing artificial intelligence in China and the European Union: Comparing aims and promoting ethical outcomes", *The Information Society*, v. 39, no. 2 (2023): 79, accessed August 27, 2023, doi: https://doi.org/10.1080/01972243.2022.2124565.

[3] Mônia Clarissa Hennig Leal and Dérique Soares Crestane, "Algorithmic discrimination as a form of structural discrimination: Standards of the Inter-American Court of Human Rights related to vulnerable groups and the challenges to judicial review related to structural injunctions", *UNIO – EU Law Journal*, vol. 9, no. 1 (2023): 39, accessed October 29, 2023, doi: https://revistas.uminho.pt/index.php/unio/article/view/5271.

[4] Stanley Greenstein, "Preserving the rule of law in the era of artificial intelligence (AI)", *Artificial Intelligence and Law*, v. 30 (2022): 307, accessed October 29, 2023, doi: https://doi.org/10.1007/s10506-021-09294-4.

[5] The winter of AI refers to a climate of generalised mistrust that has been replaced by a lot of hype surrounding AI - see Enrico Francesconi, "The winter, the summer and the summer dream of artificial intelligence in law: Presidential address to the 18th International Conference on Artificial Intelligence and Law", *Artificial Intelligence and Law*, v. 30 (2022): 148f, accessed October 29, 2023, doi: https://doi.org/10.1007/s10506-022-09309-8.

[6] With regard to changing tests in copyright laws, see Mark A. Lemley, "How Generative AI Turns Copyright Law on its Head", *SSRN Electronic Journal* (2023): 6f, accessed October 29, 2023, doi: https://dx.doi.org/10.2139/ssrn.4517702. Considering that we are living in the midst of AI spring - John Tasioulas, "The Rule of Algorithm and the Rule of Law", *Vienna Lectures on Legal Philosophy*, *SSRN Electronic Journal* (2023): 1, accessed October 29, 2023, doi: http://dx.doi.org/10.2139/ssrn.4319969.

[7] See Eduardo Gill-Pedro, "Guest note on the proposed EU AI Regulation. The Most Important Legislation Facing Humanity? The Proposed EU Regulation on Artificial Intelligence", *Nordic Journal of European Law*, v. 4, no. 1 (2021): IV, accessed August 27, 2023, doi: https://doi.org/10.36969/njel.v4i1.23473 and Hannah Ruschemeier, "AI as a challenge for legal regulation – the scope of application of the artificial intelligence act proposal", *ERA Forum*, v. 23 (2023): 362, accessed August 27, 2023, doi: https://doi.org/10.1007/s12027-022-00725-6.

[8] As some refer, "*a very large number of non-state bodies have also developed governance tools for AI, including principles, codes of ethics and, notably, models for algorithmic impact assessment*" - Lilian Edwards, "Regulating AI in Europe: four problems and four solutions", *Ada Lovelace Institute* (2022): 4, accessed August 27, 2023, https://www.adalovelaceinstitute.org/wp-content/uploads/2022/03/Expert-opinion-Lilian-Edwards-Regulating-AI-in-Europe.pdf. See also Roberts et al., "Governing artificial intelligence," 79. The "*early movers*" include the European Union, the United Kingdom, the United States of America, Canada,

In the "*race for AI governance*", national, regional, international and supranational organisations,[9] are striving for policies that accurately balance innovation and precaution.[10] In particular, to avoid a pacing problem,[11] a watch and see approach has been replaced by (pro)active frameworks for managing the use, behaviour and risks of AI,[12] under a dual-purpose governance paraphernalia or new paradigm aimed at both addressing the dangers and risks that AI poses, and ensuring its technical robustness and safety.[13]

Nonetheless, the main proposals for the regulation of AI are said to take an (insufficiently) market-driven approach, or to maintain an unbalanced "*trade-off between economic development interest and the protection of fundamental rights*",[14] and they are accused of focusing on promoting innovation and "*the free trade of AI systems*",[15] leaving fundamental rights unprotected.[16]

China and Japan. See Vasiliki Koniakou, "From the «rush to ethics» to the «race for governance» in Artificial Intelligence", *Information Systems Frontiers*, v. 25, no. 1 (2023): 81, accessed August 27, 2023, doi: https://doi.org/10.1007/s10796-022-10300-6. In relation to China, it is important to note that 'Interim Measures for the Management of Generative Artificial Intelligence Services' came into force on August 15, 2023. Subsequently, in October 2023, the National Information Security Standardization Technical Committee released a draft document outlining specific guidelines for identifying problematic generative AI models. See Zeyi Yang, "China has a new plan for judging the safety of generative AI—and it's packed with details", *MIT Technology Review* (October 18, 2023), last accessed October 29, 2023, https://www.technologyreview.com/2023/10/18/1081846/generative-ai-safety-censorship-china/.

[9] Koniakou, "From the «rush to ethics»," 79.

[10] Henrique Sousa Antunes, "Non-Contractual Liability Applicable to Artificial Intelligence: Towards a Corrective Reading of the European Intervention", in *The making of European Private Law: changes and challenges*, ed. Luisa Antoniolli and Paola Iamiceli (University of Trento, 2023 Forthcoming), *SSRN Electronic Journal* (2023): 14f, accessed October 29, 2023, doi: https://dx.doi.org/10.2139/ssrn.4351910, and Inga Ulnicane, "Artificial intelligence in the European Union: Policy, ethics and regulation", in *The Routledge Handbook of European Integrations*, ed. Thomas Hoerber, Gabriel Weber, and Ignazio Cabras (London: Routledge, 2022), 254.

[11] Dominika Harasimiuk and Tomasz Braun, *Regulating Artificial Intelligence Binary Ethics and the Law* (London: Routledge, 2021), 138.

[12] Koniakou, "From the «rush to ethics»," 82. On the Collingridge Dilemma, and the tension between early stages where control is plausible yet lacking in information, and latter stages where there is knowledge, but control has become expensive and slow, see Simon Chesterman, "From Ethics to Law: Why, When, and How to Regulate AI", in *The Handbook of the Ethics of AI*, ed. David J. Gunkel (Edward Elgar Publishing Ltd., Forthcoming), *NUS Law Working Paper No. 2023/014*, *SSRN Electronic Journal* (2023): 6f, accessed October 29, 2023, doi: http://dx.doi.org/10.2139/ssrn.4432941.

[13] In the same vein, speaking of the background of the EU's proposed Artificial Intelligence Act - Rostam J. Neuwirth, *The EU Artificial Intelligence Act: Regulating Subliminal AI Systems* (London: Routledge, 2022), 10.

[14] Claudio Novelli et al., "Taking AI Risks Seriously: a New Assessment Model for the AI Act", *AI & Society*, v. 38, no. 3 (2023): 11, accessed August 27, 2023, doi: https://doi.org/10.1007/s00146-023-01723-z.

[15] David Restrepo Amariles and Pablo Marcello Baquero, "Promises and limits of law for a human-centric artificial intelligence", *Computer Law & Security Review*, v. 48 (105795) (2023): 6, accessed August 27, 2023, doi: https://doi.org/10.1016/j.clsr.2023.105795. See also Roberts et al., "Governing artificial intelligence," 80.

[16] Restrepo Amariles and Marcello Baquero, "Promises and limits," 2 and 8. According to Marco Almada and Nicolas Petit, "The EU AI Act: a medley of product safety and fundamental rights?", *Robert Schuman Centre for Advanced Studies Research Paper No. 2023/59*, *SSRN Electronic Journal* (2023): 18, accessed October 29, 2023, doi: http://dx.doi.org/10.2139/ssrn.4308072, while it is right to state that the AIA will not ensure a sufficient level of fundamental rights protection, it is wrong "*to suggest that this is due to insufficient attention to rights-based demands – and that adding more fundamental rights provisions in the Act is the best solution to the problem.*"

Against all odds, this text seeks to address a particular shortcoming of the existing literature on AI governance, in the belief that it neglects companies as the most common profile of AI developers, producers, importers, distributors or even users or deployers,[17] and in particular as holders of fundamental rights. The text proposes that the freedom to conduct a business is a crucial driver of AI governance. It has the potential to address some of the challenges in implementing AI ethics principles, while also guaranteeing that companies targeted by various frameworks, from product safety and liability, fundamental rights, data protection, privacy and governance and commercial practices, to AI-specific regulations, are not excluded from a fair balancing exercise.[18] In the end, it is also about ensuring the huge potential of AI as an essential tool for the common good.[19]

It is thus argued that a negative or pessimistic vision of AI,[20] combined with biased and sceptical perspectives of AI stakeholders,[21] may lead to the marginalisation of pro-innovation approaches,[22] go against the rule of law and fundamental rights, and diminish them as instruments to curb the potential for abuse and arbitrariness by those in power.[23] Besides participating in the legal community alongside human beings, companies are subject to public powers and increasing laws and regulations as subjects, as a result of which their *status* as holders of fundamental rights cannot be denied in light of a partial reading of their nature, dimension, power, or *goodness*.

While companies tend to be seen as *the powerful* that enjoy subjugating power over human beings, and while businesses' economic or *de facto* power, authority, information and resource advantages, and lobbying efforts[24] are indeed difficult to

[17] According to some, "*digitalisation will most of the time concern legal persons, i.e. (big) corporations*"- Markus Frischhut, *The Ethical Spirit of EU Values* (Springer Cham, Springer International Publishing, 2022), 35.
[18] Ellen Hohma and Christoph Lütge, "From Trustworthy Principles to a Trustworthy Development Process: The Need and Elements of Trusted Development of AI Systems", *AI*, v. 4, no. 4 (2023): 905 and 916, accessed October 29, 2023, doi: https://doi.org/10.3390/ai4040046.
[19] Digital health is an example of the multiple uses and increasing importance of AI, so that risks cannot silence or block its benefits for a common good - health. See Susana Navas Navarro, "Health and Artificial Intelligence in the context of COVID-19 and beyond", *UNIO – EU Law Journal*, v. 7, no. 1 (2021): 33-49, accessed October 29, 2023, doi: https://doi.org/10.21814/unio.7.1.3579. In other areas, AI can also enhance the decision-making process of boards, with varying degrees of autonomy - Iakovina Kindylidi, "Smart Companies: Company & board members liability in the age of AI", *UNIO – EU Law Journal*, v. 6, no. 1 (2020): 115–141, accessed October 29, 2023, doi: https://doi.org/10.21814/unio.6.1.2704.
[20] In fact, "*Pessimistic views of the impact of AI on society are widespread. Public figures including Elon Musk and Stephen Hawking have warned that AI could lead to a handful of companies dominating society, few jobs left for humans, and increasing inequality*" - see Ajay Agrawal, Joshua Gans, and Avi Goldfarb, "Economic policy for artificial intelligence. Innovation Policy and the Economy", *Innovation Policy and the Economy*, v. 19 (2019): 140, accessed August 27, 2023, doi: https://doi.org/10.1086/699935.
[21] That is, for "*organisations and individuals involved in, or affected by, AI systems, directly or indirectly*" – see Organisation for Economic Co-operation and Development, OECD, "Recommendation of the Council on Artificial Intelligence", 2019, 7, accessed August 27, 2023, https://legalinstruments.oecd.org/en/instruments/oecd-legal-0449.
[22] As a pro-innovation approach to AI regulation, reference should be made to the United Kingdom Secretary of State for Science, Innovation and Technology, "A pro-innovation approach to AI regulation", 2023, accessed August 27, 2023, https://www.gov.uk/government/publications/ai-regulation-a-pro-innovation-approach.
[23] Martin Krygier, "What's the Point of the Rule of Law?", *Buffalo Law Review*, v. 67 (2019): 758f, accessed October 29, 2023, https://digitalcommons.law.buffalo.edu/buffalolawreview/vol67/iss3/16.
[24] Roberts et al., "Governing artificial intelligence," 92.

control and monitor,[25] denying their rights or accepting that they can be subject to unfair decisions and adjudication, just because their self-proclaimed commitments to ethical AI as narrative-setters may subsume to *ethics washing*,[26] "*would only relocate the problem, not resolve it*".[27]

In particular, neglecting the bright side of supporting innovation, protecting (small) companies from dominance and incentivising AI developers through IP protection and free competition[28] risks an overly paternalistic and innovation-blocking approach[29] to AI governance, where companies are perceived as threats and confined to the prism of liability in the face of AI risks (from which they tend to benefit). Furthermore, it ignores that, in a community governed by the rule of law and guided by the values of justice and fairness, the sources of power over another person include political authority over corporations as well, which makes "*freedom as antipower*" particularly important (also in their favour).[30]

Of course, the regulation of AI through policies, frameworks, measures and obligations that interfere with the freedom to conduct a business is or may be i) justified or legitimate in the context of various rights and interests to be protected, and ii) necessary in light of the risks that AI poses to fundamental rights.

Nevertheless, understanding the regulation of AI as a "*pressing priority*"[31] does not allow for speed or urgency to be taken in themselves as legitimate grounds for restricting fundamental rights and disproportionately interfering with the *status* of companies. Moreover, the growing demand for ethical and socially oriented AI[32] does not legitimise "*over-regulation, hastily introduced, or ill-premised governance structures*", nor does it allow "*exaggerating not only the risks and opportunities these technologies bear but also the element of novelty and exceptionality*".[33]

The *bright side* of AI, and of companies as forums for the realisation of the rights of others, as well as vehicles for innovation, economic growth and competitiveness in the international arena, must be taken seriously in order to address the considerable degree of uncertainty, or at least novelty, and all the organisational challenges that new governance paradigms may bring to companies.[34]

The impact of regulatory decisions on companies and business activities must be considered in the light of the principle of proportionality and a fair balance between the rights and interests of all AI stakeholders. It is essential (and a prerequisite of a constitutional state based on the rule of law) that AI governance frameworks are kept

[25] Koniakou, "From the «rush to ethics»," 81.
[26] Koniakou, "From the «rush to ethics»," 78.
[27] Pettit, "Freedom," 588.
[28] Axel Walz, "A Holistic Approach to Developing an Innovation-Friendly and Human-Centric AI Society", *IIC - International Review of Intellectual Property and Competition Law*, v. 48 (2017): 759, doi: https://doi.org/10.1007/s40319-017-0636-4.
[29] See Walz, "A Holistic Approach," 758-9.
[30] Philip Pettit, "Freedom as Antipower", *Ethics*, v. 106, no. 3 (1996): 583f, accessed August 27, 2023, doi: http://www.jstor.org/stable/2382272.
[31] Koniakou, "From the «rush to ethics»," 83.
[32] Alessandro Mantelero, *Beyond Data* (The Hague: T.M.C. Asser Press, 2022), 15.
[33] Koniakou, "From the «rush to ethics»," 91.
[34] See, on this topic, Ida M. Enholm, Emmanouil Papagiannidis, Patrick Mikalef, and John Krogstie, "Artificial Intelligence and Business Value: a Literature Review", *Information Systems Frontiers*, v. 24 (2022): 1709, accessed August 27, 2023, doi: https://doi.org/10.1007/s10796-021-10186-w, referring to Alsheibani et al. (2020); Thomas Wischmeyer and Timo Rademacher (eds.), *Regulating Artificial Intelligence* (Springer Cham, Springer International Publishing, 2019), preface §2.

within limits that respect all fundamental rights and the "*right to good governance*",[35] of which companies are also holders.

In other words, a proper balance between under- and over-regulation requires that a focus on the rights of end users and citizens goes hand-in-hand with special attention to the impact of AI governance on the freedom to conduct a business and on the rights of companies.[36] A more balanced and impartial approach will not only recognise the benefits and opportunities of AI for human beings and companies as AI actors,[37] but also consider "*broader, holistic social systems, actors and processes*" relying on AI applications.[38]

Under these circumstances, we contend that an emphasis on fundamental rights is the appropriate foundation for AI governance, as it adequately encompasses both the human and economic aspects. The benefits of fundamental rights are multifarious. First, as they are "*among the foundations and guiding principles of the modern constitutional state and the international community of states*",[39] fundamental rights permeate every regulatory framework, whether legislative or non-legislative, supranational or national. Second, their multidimensionality and multifunctionality, coupled with their broad inclusivity of all participants in a given political community (companies included), leave no doubt as to their capacity to address gaps that are not completely covered by human rights doctrines. Finally, they serve as binding parameters for both public and private actors. On one hand, they constitute benchmarks for the validity of infra-constitutional (or secondary) law (at the origin of constitutional review or annulment proceedings, with specific and binding effects), as well as *status positivus*, requiring the intervention of the State (or a supranational organisation)[40] in a dynamic, positive and prospective manner,[41] namely through legislation, administration or jurisdiction. On the other hand, and of course, they are defensive barriers or rights of defence against private actors and "*the abusive use of AI technologies*".[42]

In the absence of an abstract hierarchy between fundamental rights, it is crucial to examine whether the solutions embodied in AI governance frameworks

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[35] Leslie et al., "Artificial intelligence," 21.

[36] This is all the more pressing in light of the EU's prescriptive and users' rights-based approach, which has already been subject to criticism, precisely for being "*too focused on rigid and potentially innovation-stymieing governance measures*" - Roberts et al., "Governing artificial intelligence," 85.

[37] A subset of stakeholders which is defined as "*those who play an active role in the AI system lifecycle, including organisations and individuals that deploy or operate AI*" – OECD, "Recommendation," 7.

[38] Harasimiuk and Braun, *Regulating Artificial Intelligence*, 57.

[39] Jürgen Schwarze, *Europarecht: Strukturen, Dimensionen und Wandlungen des Rechts der Europäischen Union* (Germany: Nomos, 2012), 428.

[40] Josef Isensee, "Das Grundrecht als Abwehrrecht und als staatliche Schutzpflicht", in *Handbuch des Staatsrechts der Bundesrepublik Deutschland, Band IX: Allgemeine Grundrechtslehren*, ed. Josef Isensee and Paul Kirchhof (Heidelberg: Müller, 2011), 413-567, 415f.

[41] Erhard Denninger, "Staatliche Hilfe zur Grundrechtsausübung durch Verfahren, Organisation und Finanzierung", in *Handbuch des Staatsrechts der Bundesrepublik Deutschland, Band IX: Allgemeine Grundrechtslehren*, ed. Josef Isensee and Paul Kirchhof (Heidelberg: Müller, 2011), 621-662, 621f.

[42] Restrepo Amariles and Marcello Baquero, "Promises and limits," 7. See also Koniakou, "From the «rush to ethics»," 94. Of course, some challenges remain. While the horizontal effect of fundamental rights has been recognised in the EU, some, such as the right to due process and the right to reasoned decisions, have a particular vertical nature whose application on horizontal relationships is actually new. See Restrepo Amariles and Marcello Baquero, "Promises and limits," 9. In any case, the fact that the application of these fundamental rights to private entities is ensured by law (e.g. by a European Union regulation) avoids the problem of a direct horizontal effect of fundamental rights.

and their practical implementation fall within a framework of impartiality and proportionality. In other words, it is important to strike a fair balance between the need to ensure the full potential of AI and "*legal certainty and proportionate regulatory burden for operators*",[43] while addressing its risks and protecting key public interests and fundamental rights.

It is precisely this balanced approach that has led the European Commission to adopt a proposal for a Regulation laying down harmonised rules on Artificial Intelligence on 21 April 2021[44] (hereinafter 'Artificial Intelligence Act' or 'AIA' proposal). The Council adopted its general approach on 6 December 2022[45] ('Council's general approach'), and the European Parliament ('EP') confirmed its position in a plenary vote on 14 June 2023[46] ('EP's amendments' or 'EP position'), the same day the co-legislators held the first political trilogue.[47]

2. Delimitation, focus and sequence

AI regulations are now flourishing in many jurisdictions, with AI policy documents published by more than 60 countries,[48] in a race to regulate AI running parallel to the race to develop it.[49] AI governance is based on shared foundational values[50] and is an issue of global concern that requires that all countries "*have a place on the table*",[51] at least to avoid the risk of global fragmentation.[52] However, differences

[43] Gabriele Mazzini and Salvatore Scalzo, "The Proposal for the Artificial Intelligence Act: Considerations around Some Key Concepts", *SSRN Electronic Journal* (2022): 2, accessed August 27, 2023, doi: http://dx.doi.org/10.2139/ssrn.4098809.

[44] Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union legislative acts, COM/2021/206 final, 2021/0106(COD), Brussels, 21 April 2021, accessed August 27, 2023, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52021PC0206.

[45] Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts - General approach (6 December 2022), ST 15698 2022 INIT Brussels, 6 December 2022, accessed August 27, 2023, http://data.consilium.europa.eu/doc/document/ST-15698-2022-INIT/EN/pdf.

[46] Amendments adopted by the European Parliament on 14 June 2023 on the proposal for a regulation of the European Parliament and of the Council on laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts (COM(2021)0206 – C9-0146/2021 14 June 2023 - Strasbourg – 2021/0106(COD))(1), accessed August 27, 2023, https://www.europarl.europa.eu/doceo/document/TA-9-2023-0236_EN.html.

[47] Informal discussions are currently underway involving all three institutions with regards to the expected release of the final version of the text by the end of 2023. For further context, see also, Marco Almada and Nicolas Petit, "The EU AI Act," 7.

[48] Roberts et al., "Governing artificial intelligence," 79.

[49] Rostam J. Neuwirth, "Prohibited artificial intelligence practices in the proposed EU artificial intelligence act (AIA)", *Computer Law & Security Review*, v. 48 (105798) (2023), accessed August 27, 2023, doi: https://doi.org/10.1016/j.clsr.2023.105798. Also on *SSRN Electronic Journal*, accessed August 27, 2023, doi: https://dx.doi.org/10.2139/ssrn.4261569, 2 (We choose to cite the *open access* version available on *SSRN*).

[50] Roberts et al., "Governing artificial intelligence," 80. Also, Hohma and Lütge, "From Trustworthy Principles," 904. These are transparency, justice, fairness, non-maleficence, responsibility and privacy.

[51] Koniakou, "From the «rush to ethics»," 81.

[52] In this context, international diplomatic efforts are already underway, with the United States of America and the EU dialogue on AI risk management and a voluntary AI code of conduct as evidence of standardisation efforts. See Jonas Schuett, "Risk Management in the Artificial Intelligence Act", *European Journal of Risk Regulation* (2023): 19, accessed August 27, 2023, doi: https://doi.org/10.1017/err.2023.1 and Noha L. Halim and Urs Gasser, "Vectors of AI Governance - Juxtaposing the U.S. Algorithmic Accountability Act of 2022 with The EU Artificial Intelligence Act", *SSRN Electronic*

in legal systems and the wider socio-cultural context behind any particular piece of legislation,[53] make delimitation necessary.

This text builds on the legal order of the European Union ("EU"). First, because of its fundamental rights approach. The EU is the system and jurisdiction whose legal traditions and landscapes the author is more familiar with. In particular, it is necessary to anchor the freedom to conduct a business in existing legal instruments that explicitly recognise its fundamental nature in line with European values and political culture.

The choice of the EU as a proxy is also justified by the promise of the European Commission's proposal for a Regulation laying down harmonised rules on AI, often regarded as: i) "*the flagship piece of legislation when it comes to AI governance*";[54] ii) one of the "*most comprehensive efforts to promote and govern AI*";[55] iii) the "*most influential example of a worldwide trend to complement or replace self-regulation in this domain with legislation*",[56] iv) "*the most prominent and (more) likely-to-be-enacted in the near future*",[57] as well as v) "*arguably indicative of how the future of AI governance might look like when it comes to law*".[58]

As the EU sees itself as a "*global leader in developing and deploying AI technologies*"[59] and a beacon for the world in promoting the European values-based way and human-centred approach to AI, concepts such as *Normative Power Europe* or *Market Power Europe*[60] (not to mention the *Brussels effect*) are advanced to signal its leadership in this field.[61] By contrast, it is also possible that "*significant compliance costs, lack of safe harbours, and legal uncertainty may engender an increasing oligopolisation of an already concentrated market and can both endanger Europe's technological independence and ultimately cost consumers dearly.*"[62]

The purpose of this text is not, however, to scrutinise and criticise the AIA proposal in light of the freedom to conduct a business. On the contrary, it attempts to shed some light on important guiding principles that need to be taken into account in the design, implementation and future consolidation[63] of AI governance frameworks.

Journal (2023): 5, accessed August 27, 2023, doi: http://dx.doi.org/10.2139/ssrn.4476167.

[53] On ethical pluralism' advantages, see Roberts et al., "Governing artificial intelligence," 80. See also Halim and Gasser, "Vectors of AI," 9.

[54] Halim and Gasser, "Vectors of AI," 2.

[55] Among others, see Roberts et al., "Governing artificial intelligence," 79f, for a comparison with China, and Halim and Gasser, "Vectors of AI," 3f and Jakob Mökander, Prathm Juneja, David S. Watson, and Luciano Floridi, "The US Algorithmic Accountability Act of 2022 vs. The EU Artificial Intelligence Act: what can they learn from each other?", *Minds & Machines* v. 32 (2022): 751f, accessed August 27, 2023, doi: https://doi.org/10.1007/s11023-022-09612-y, for a comparison with the state of affairs in the US.

[56] Mökander, Juneja, Watson, and Floridi, "The US Algorithmic Accountability Act," 751-2.

[57] Halim and Gasser, "Vectors of AI," 3.

[58] Halim and Gasser, "Vectors of AI," 5. See also, Gill-Pedro, "Guest note," VI; Koniakou, "From the «rush to ethics»," 82; Mazzini and Scalzo, "The Proposal," 29; Neuwirth, "Prohibited artificial intelligence practices," 2; Ruschemeier, "AI as a challenge," 363, and Schuett, "Risk Management," 1.

[59] Roberts et al., "Governing artificial intelligence," 80.

[60] Ulnicane, "Artificial intelligence," 255.

[61] In this vein, Jon Truby, Rafael D. Brown, Imad A. Ibrahim, and Oriol C. Parellada, "A Sandbox Approach to Regulating High-Risk Artificial Intelligence Applications", *European Journal of Risk Regulation*, v. 13, no. 2 (2022): 270-71, accessed August 27, 2023, doi: https://doi.org/10.1017/err.2021.52, with further references.

[62] Hacker, "AI Regulation in Europe," 6.

[63] For an evolutionary perspective on AI regulation, see Marta Boura, "Inteligência Artificial. Quadro jurídico e reflexões sobre a Proposta de Regulamento de Inteligência Artificial", *Revista Eletrónica de Direito (RED)*, v. 32, no. 3 (2023): 109f, accessed October 29, 2023, https://cij.up.pt//client/files/0000000001/5-marta-boura_2288.pdf.

The AIA proposal is thus, an example of consistency with the fundamental right to conduct a business.

However, while the AIA proposal is considered more closer to market-oriented instruments,[64] being particularly attentive to the position of (economic) operators producing, developing, deploying, or using AI systems, and thus subject to the obligations provided for in the proposed AIA,[65] there is room for improvement. In particular, if approved in its current form, and without the addition of standardisation and practical guidelines for breaking down obligations into specific measures applicable to real-world scenarios,[66] as well as further escape valves, the proposal may not pass a *necessity test*.

It is believed that the restriction of freedom of choice and the interference with possibilities of action, which are typically included in the *prima facie* content of the freedom to conduct a business, cannot be considered legitimate simply because there is a *law*, justified by conflicting rights and interests worthy of protection. Nor can the AIA proposal be presumed to be compatible with fundamental rights and, in particular, with the freedom to conduct a business, just because the legislator states that it "*presents a balanced and proportionate horizontal regulatory approach to AI that is limited to the minimum necessary requirements to address the risks and problems linked to AI, without unduly constraining or hindering technological development or otherwise disproportionately increasing the cost of placing AI solutions on the market*".[67]

By introducing an additional driver - the rights of corporations, as the primary targets of AI legislation - this text seeks to address a particular shortcoming of AI governance doctrine. The text adopts a gradual approach, ultimately culminating in the AIA proposal as a proxy. Incorporating companies and their rights into the desired balance between safeguarding fundamental rights and ensuring the full potential of AI will not introduce harmful entropies. Instead, it is an essential component that contributes to a comprehensive and holistic approach to AI governance frameworks.

In this light, the text is divided into 6 (six) main parts. After these introductory parts (1. Introduction and 2. Delimitation, focus and sequence), we present the main drivers for an AI governance framework in line with fundamental rights and their promise to resolve some of the paradoxes of AI regulation (3. Towards a fundamental rights approach to AI governance). This is followed by a section devoted to the freedom to conduct a business, which briefly analyses its content and specificities in order to ensure that it is perceived as a true fundamental right (4. The freedom to conduct a business as a fundamental right). In the next part (5. The freedom to conduct a business as a driving force and rationale for AI governance), the relationship between AI governance and the freedom to conduct a business is

[64] Marco Almada and Nicolas Petit, "The EU AI Act," 12.

[65] According to some, "*the EU proposal therefore stands within the framework of internal market interests, while protecting fundamental rights. This focus on the market and competition appears to be the main rationale behind regulating an as yet unregulated field, designed to encourage AI investment in the EU*" – Mantelero, *Beyond Data*, 167.

[66] Hohma and Lütge, "From Trustworthy Principles," 918-9. As regards the importance of harmonised standards and specifications, see also Philipp Hacker, "The European AI Liability Directives – Critique of a Half-Hearted Approach and Lessons for the Future", *SSRN Electronic Journal* (2022): 55, accessed October 29, 2023, doi: https://dx.doi.org/10.2139/ssrn.4279796, and Philipp Hacker, "AI Regulation in Europe: From the AI Act to Future Regulatory Challenges ", in *Oxford Handbook of Algorithmic Governance and the Law*, ed. Ifeoma Ajunwa and Jeremias Adams-Prassl (Oxford University Press, 2024, Forthcoming): 13, accessed October 29, 2023, https://arxiv.org/ftp/arxiv/papers/2310/2310.04072.pdf.

[67] See the Explanatory Memorandum that accompanies the AIA proposal, para 1.1.

explored through key guidelines. Such dialogue is then tested against the proposed EU Artificial Intelligence Act in both parts 7 and 8 (7. The pro-business side of the EU proposal, and 8. Improving the proposed Artificial Intelligence Act through the freedom to conduct a business), where the AIA's pro-business side and shortcomings are analysed from the perspective of the freedom to conduct a business. The final division (9. The freedom to conduct a business in the context of AI governance: concluding remarks) summarises some conclusions.

3. Towards a fundamental rights approach to AI governance

AI is undoubtedly a multifaceted reality and phenomenon, disruptive in nature and with unforeseen ethical and social implications. While AI systems and technologies provide a new range of opportunities,[68] they can also negatively impact individuals, groups and society as a whole, through unfair bias and discriminatory decisions and behaviours; access, collection and use of vast amounts of data leading to privacy concerns and panoptic effects; chilling effects on speech and political action through manipulation and fake videos, news and content in social media; monitoring of worker behaviour and algorithmic management.[69] The nature of AI as an all-purpose, transformative widely disruptive, complicated, and still emerging technology[70] and the variety of challenges that it poses to policymakers and individuals, businesses, users, and professionals, are the main reasons for the complex state of its governance.

Striking a balance between fostering the use of AI and innovation, while protecting security and fundamental rights,[71] is a complex task at the origin or several forms of regulation being adopted or tested: from command and control to design-based regulation; from top-down measures to bottom-up initiatives; from hard law to soft law; from horizontal to sectoral regulation; from supranational to industry-based regulation.[72] In short, the colour palette is diverse. All these different approaches are complementary rather than mutually exclusive and fundamental rights can be the glue that holds them all together, given their primacy over *ordinary* frameworks and their expansive nature – from a partial order to a holistic system; from defensive rights to objective guarantees; from individual rights to community values, which in turn develop into sources of subjective rights.[73]

Whatever the concrete path or framework, common principles and key guidelines must be defined, in order to address some of the paradoxes behind AI governance.

First of all, AI is cross-sectoral. As no area of society is immune to the many questions and doubts it raises,[74] a system of a *cabine de regie* may be needed.[75] However,

[68] See Leslie et al., "Artificial intelligence," 14.
[69] We follow closely Leslie et al., "Artificial intelligence," 15-16.
[70] Koniakou, "From the «rush to ethics»," 80, referring to Dafoe (2018), Trajtenberg (2018), and Gruetzemacher and Whittlestone (2022).
[71] See Harasimiuk and Braun, *Regulating Artificial Intelligence*, 93 and Truby, Brown, Ibrahim, and Parellada, "A Sandbox Approach," 273.
[72] Harasimiuk and Braun, *Regulating Artificial Intelligence*, 4. See, also, Koniakou (2023).
[73] Isensee, "Das Grundrecht," 428.
[74] Harasimiuk and Braun, *Regulating Artificial Intelligence*, 3.
[75] Gabriele Mazzini, "A System of Governance for Artificial Intelligence through the Lens of Emerging Intersections between AI and EU Law", in *Digital Revolution – New challenges for Law*, ed. Alberto De Franceschi and Reiner Schulze (München and Baden-Baden: C. H. Beck and Nomos, 2019), 245-298. Also on *SSRN Electronic Journal*, accessed August 27, 2023, https://ssrn.com/abstract=3369266, 55 (We choose to cite the *open access* version available on *SSRN*). On an intersectional approach between legal,

and at the same time, the lack of conceptual and principled *interoperability* makes a multidisciplinary or intersectional approach particularly difficult, as the main drivers of AI governance pursue objectives, follow conceptual frameworks or use tools that are not fully aligned or shared.[76] In other words, the operationalisation of AI governance is blocked by "inter-principle" and "intra-principle" tensions.[77] The clash of different interests and drivers may be tackled by a variable geometry framework, where horizontal (binding and non-binding) approaches are combined with sector-specific principles, standardisation and guidance,[78] with none superseding or excluding the other. In addition, Western values as regards AI ethics (precautionary in nature) can benefit from other visions, as regards the positive potential behind AI.[79]

The second challenge for AI governance arises from the fact that its opportunities and risks are not only global, but also constantly evolving, requiring an *aterritorial*, flexible, and adaptable approach, that is now always compatible with recent tendencies to regulate it as a product. While the suitability of legal frameworks is sometimes put into question,[80] so are soft, light or *non-interventionist* approaches. In particular, while self-regulatory solutions and soft law frameworks have advantages in terms of flexibility and adaptability to specific organisational cultures,[81] they may lack effectiveness, jeopardising equality and introducing a degree of uncertainty that needs to be syndicated through the lens of the Rule of Law.[82] The ability of hard law to provide frameworks with "*growing teeth* "[83] thus justifies a period of belt-tightening for AI stakeholders,[84] at least until the safety and efficacy of AI is proven and tested.[85]

However, and here lies the paradox, it is as important to avoid "*cyber-libertarianism*" and "*excessive privatisation* "[86] of AI governance that relies too much on self-regulation, as it is to avoid rigid and burdensome legal requirements on

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society, economic gender and ethical perspectives, see also, Stamatis Karnouskos, "Symbiosis with artificial intelligence via the prism of law, robots, and society", *Artificial Intelligence and Law*, v. 30 (2022): 95f, accessed October 29, 2023, doi: https://doi.org/10.1007/s10506-021-09289-1.

[76] See, among others, Leslie et al., "Artificial intelligence," 16.

[77] Joris Krijger, "Enter the metrics," 1433.

[78] Leslie et al., "Artificial intelligence," 29.

[79] Nancy S. Jecker and Eisuke Nakazawa, "Bridging East-West Differences in Ethics Guidance for AI and Robotics" *AI* v. 3, no. 3 (2022): 764f, accessed October 29, 2023, doi: https://doi.org/10.3390/ai3030045.

[80] Koniakou, "From the «rush to ethics»," 82.

[81] Leslie et al., "Artificial intelligence," 25. On the importance of alignment between ethical principles and the culture, mission and aims of an organisation in a real-context, see Joris Krijger, "Enter the metrics: critical theory and organizational operationalization of AI ethics", *AI&Society*, v. 37 (2022): 1427-9, accessed October 29, 2023, doi: https://doi.org/10.1007/s00146-021-01256-3.

[82] Koniakou, "From the «rush to ethics»," 79. Some point out that "*the varied approaches taken by organisations following soft law can lead to tokenistic or cosmetic commitments to ethical AI*" - Leslie et al., "Artificial intelligence," 26.

[83] Especially when accompanied by liability regimes. With regard to fault, and two dominant approaches – the "*fault-based liability championed by scholars in the USA and the strict liability of the EU across the Atlantic*", see Truby, Brown, Ibrahim, and Parellada, "A Sandbox Approach," 273 and 275f.

[84] Regine Paul, "The Politics of Regulating Artificial Intelligence Technologies: A Competition State Perspective", *SSRN Electronic Journal* (2022): 1, accessed August 27, 2023, doi: https://dx.doi.org/10.2139/ssrn.4272867. According to the author, "*the arrival of coercive and more concrete regulation by public actors (statutory regulation) over the past five years or so seems to put an end to the 'wild West' phase of disruptive innovation*".

[85] De Almeida, Santos, and Farias, "Artificial Intelligence Regulation," 507.

[86] Koniakou, "From the «rush to ethics»," 90.

companies that could be innovation-blockers.[87] In particular, just as with ethics, law and technology are not mutually exclusionary.[88] On the contrary, *interactive regulatory governance* models may explore the potential for a complementary role from both companies and legislators.[89] To sum up, while self-regulation and soft law may not satisfy the principle of the prohibition of insufficiency, binding rules must in any case be appropriate, consistent with the principle of necessity and be proportionate.[90]

A final challenging issue in AI governance is how to encourage risk-taking that is conducive to innovation, while subjecting AI actors to clear governance and liability frameworks. In other words, it is about how to ensure liability as a counterbalance of the innovation principle.[91] The European Commission appears to be attuned to this matter, as it advanced a "package" of two proposals, outlining the European approach to AI liability.[92] First, there is a novel 'AI Liability Directive', laying down common rules on the disclosure of evidence on high-risk AI systems, and on the burden of proof in the case of non-contractual fault-based civil law claims brought before national courts for damages caused by an AI system.[93] It seeks to facilitate access to information and to alleviate the burden of proof in compensation claims pursued under national fault-based liability regimes in cases where certain AI systems are involved in causing damage. Second, a revision of the Product Liability Directive aims to ensure that when AI systems are defective and cause physical harm, property damage or data loss, it is possible to seek compensation from the AI-system provider or from any manufacturer that integrates an AI system into another product.[94]

While these are important steps, the issue of liability in the AI sector still poses particular problems, starting with the number of actors involved and the uncertainty about who is liable for what,[95] not to mention challenges arising from the fact that

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[87] United Kingdom Secretary of State for Science, Innovation and Technology, "A pro-innovation," 5.

[88] According to Harasimiuk and Braun, *Regulating Artificial Intelligence*, 90, regarding the interaction between law and ethics in the field of AI, ethical principles influence hard law and there is a peaceful coexistence of the two realms of ethics and law. See also Alexandre Veronese, Alessandra Silveira and Amanda Nunes Lopes Espiñeira Lemos, "Artificial intelligence, Digital Single Market and the proposal of a right to fair and reasonable inferences: a legal issue between ethics and techniques", *UNIO – EU Law Journal*, v. 5, no. 2 (2019): 82, accessed October 29, 2023, doi: https://doi.org/10.21814/unio.5.2.2294, arguing that ethics and law are not mutually exclusive regulatory paths.

[89] As regards the obligations of Member States to actively safeguard human rights, democracy, and the rule of law, see Leslie et al., "Artificial intelligence," 29.

[90] Koniakou, "From the «rush to ethics»," 82, with reference to Smuha (2021).

[91] Antunes, "Non-Contractual Liability," 23. According to the author, while the innovation principle "*has determined social acceptance of the risks posed to the community by artificial intelligence systems placed on the market […] it appears incapable of dictating individual acceptance of damage*", 29-30.

[92] On the relationship and key differences between the two proposals, see Hacker, "The European AI Liability Directives," 8f.

[93] See Proposal for a Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive), COM/2022/496 final, 2022/0303(COD), Brussels, 28 September 2022, accessed October 29, 2023, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0496.

[94] See Proposal for a Directive of the European Parliament and of the Council on liability for defective products, COM/2022/495 final, 2022/0302(COD), Brussels, 28 September 2022, accessed October 29, 2023, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0495.

[95] According to Edwards, "Regulating AI in Europe," 6, "*Many AI products are not produced by a single organisation, but involve a complex web of procurement, outsourcing, re-use of data from a variety of sources, etc. This changes the question of who is in scope, and who should be accountable, for different parts of the AI lifecycle. Notably, smaller 'downstream' providers are likely to save time, resources and maintenance obligations by relying heavily on AI services delivered by the large tech firms such as Google, Microsoft and Amazon*".

a certain degree of independence or autonomy of outputs may render the idea of control flawed.[96] All these particularities need to be fully addressed by policymakers.

In the light of all these intricacies, we believe that fundamental rights offer the compromise that the paradoxes of AI require. First, they are inclusive of all AI actors, in particular, legal persons and natural persons. As the EP recognises in its position on the AIA proposal, the rights and freedoms of both natural and legal persons can be seriously undermined by AI systems (see new Recital 84a of the AIA proposal as amended by the EP) and it is essential that companies are recognised as holders of fundamental rights in order to assert their position in the face of all the burdens and the range of obligations that they may face in their capacity as developers, producers, or professional users of AI systems.

As the axiology of fundamental rights goes beyond human dignity and human protection, it encompasses the rights and interests of a wider group of AI stakeholders. To give an example, the freedom to conduct a business is a fundamental right enshrined in the Charter of Fundamental Rights of the European Union ('CFREU' or 'Charter') and is based on the common constitutional traditions of the Member States. As the Charter has the same legal value as the Treaties [Article 6(1) of the Treaty on European Union or 'TEU'], secondary EU law must comply with its provisions, to which it is subordinate.

Second, fundamental rights provide a suitable methodology for balancing conflicting rights and public interests, avoiding an "*overall legal framework ineffective, that is, with rules that are either too stringent or too soft for the actual applications of specific AIs*".[97] As their *dogmatics* is averse to one-size-fits-all and all-or-nothing approaches, it is suited to addressing the specificities of each case and engaging in a process of optimisation.

While this may seem far removed from the model of the AIA proposal, which (despite some criticism)[98] is modelled on EU product safety legislation, some voices are now recognising that *tests* typical of fundamental rights, such as the Alexy proportionality test, may have a role to play in indicating "*whether a risk category is appropriate for an AI under a specific risk scenario or whether it introduces grossly disproportionate limitations and trade-offs for competing values*".[99]

A fundamental rights approach to AI governance requires that any framework take into account the requirements to be respected when there is a conflict or collision between the fundamental rights of different holders, be they human beings or companies as legal persons (see Article 52 CFREU). As a matter of fact, fundamental rights are not absolute or unfettered prerogatives. They may be subject to limitations justified by the need to safeguard other fundamental rights and the public interest. However, they are fundamental precisely because any limitation on their *prima facie* scope or exercise must satisfy a number of requirements listed in Article 52(1) CFREU. These include: i) a justification (a conflicting fundamental right or freedom or a colliding general interest); ii) a legal basis; iii) subordination to the principle of proportionality; and iv) respect for the essence of the right.

The fact that the freedom to conduct a business (or the rights of companies *in genere*) are more likely to be involved in situations of conflict and collision or the specific peculiarity of being practically denied or annihilated (for example, when

[96] Agrawal, Gans, and Goldfarb, "Economic policy," 147-148.
[97] Novelli et al., "Taking AI Risks Seriously," 2.
[98] Marco Almada and Nicolas Petit, "The EU AI Act," 7f.
[99] Novelli et al., "Taking AI Risks Seriously," 3.

the exercise of a certain economic activity or the marketing of a specific product or service is prohibited), does not allow us to depart from Article 52(1) CFREU. As it does not legitimise treating businesses' rights (or corporations themselves) as second tier rights, lacking effectiveness, in particular vis-à-vis public authorities.

Two principles emerge as fundamental in this respect: the principle of proportionality or fair balance (typical of conflicts and collisions between fundamental rights and public interests) and a principle of differentiation or *proportionate equality*, according to which there must be a differentiated approach to different levels of risk as well as to different actors, and that their *difference* must be taken into account in the formulation of regulatory measures.[100] While "*the goal of protecting citizens from the negative impacts of AI systems on human rights, democracy, and the rule of law*"[101] is a legitimate objective and a justified reason for limiting or restricting the freedom to conduct a business as a fundamental right, the obligations imposed on AI developers and other private companies, as well as the prohibitions on their use, "*should be necessary, useful, and proportionate to the goal*".[102]

Since they follow a legal dogmatics that is subject to control and are upheld or supported by a particular legal system, fundamental rights provide a global reference paradigm for truly human-centred AI[103] with *growing teeth*. In particular, they provide effectiveness and *corpus* to the principles discussed in the EU Ethics Guidelines for Trustworthy AI by the High-Level Expert Group on Artificial Intelligence ('AI HLEG'), "*an expert group appointed to advise the European Commission on its AI strategy*",[104] which include: i) human agency and oversight, ii) technical robustness and safety, iii) privacy and data governance, iv) transparency, v) diversity, non-discrimination, and fairness, vi) environmental and social well-being, and vii) accountability.[105]

In summary, fundamental rights are both the *why* and the *what for* of AI governance[106] (although they do not exclude ethics and ethical principles).[107] They

[100] Leslie et al., "Artificial intelligence," 23. While a 'risk-based' approach seems to be present at the Artificial Intelligence Act proposal, some criticise the fact that it "*does not lay down criteria for when AI poses unacceptable risks to society and individuals. It merely designates set lists of what categories of AI systems are deemed 'unacceptable risk' and thus banned from the EU* [...] *and which should be allowed on to market only if certain safeguards are put in place ('essential requirements'), known as 'high-risk' AI* [...] "*These lists are not justified by externally reviewable criteria, and thus can only be regarded as political compromises at one point in time – leaving it difficult-to-impossible to challenge the legal validity of AI systems in principle rather on point of detail*" - Edwards, "Regulating AI in Europe," 11-2.

[101] Leslie et al., "Artificial intelligence," 23.

[102] Leslie et al., "Artificial intelligence," 23.

[103] Mantelero, *Beyond Data*, 83.

[104] Laux, Wachter, and Mittelstadt, "Trustworthy artificial intelligence," 3. See High-Level Expert Group on AI (2019), Ethics Guidelines for Trustworthy Artificial Intelligence, of 8 April 2019. https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai. Accessed 27 Aug 2023.

[105] Ville Vakkuri et al., "How do software companies deal with artificial intelligence ethics? A gap analysis" in *EASE'22: Proceedings of the 26th International Conference on Evaluation and Assessment in Software Engineering* (Gothenburg, Sweden, 2022), 101, accessed August 27, 2023, 100-109, doi: https://doi.org/10.1145/3530019.3530030. They are also included (with some modifications) in the European Parliament's proposed new Article 4a of the AIA proposal, on "*General principles applicable to all AI systems*".

[106] Koniakou, "From the «rush to ethics»," 85.

[107] On this debate, see Koniakou, "From the «rush to ethics»," 84 and Neuwirth, *The EU Artificial Intelligence Act*, 85. On the idea that ethics cannot be replaced by human rights, see Canca (2019). https://cpr.unu.edu/publications/articles/ai-global-governance-human-rights-and-ai-ethics-why-ethics-cannot-be-replaced-by-the-udhr.html. Accessed 27 Aug 2023. Others, for example, argue that it is not necessary to move from ethics to fundamental rights, but rather to move from principles to

are governance principles that underpin, guide and strengthen AI governance.[108] At the same time, they are sufficiently case-sensitive to ensure both a fair balance when AI drivers clash, and a proportionality yardstick. In terms of their effectiveness, fundamental rights solve the problem of how to turn a human rights-focused approach "*into effective tools that can guide AI developers and key AI users, such as municipalities, governments, and private companies*",[109] without separating AI governance from the fundamental values on which it is based, be they fundamental rights, democracy, the rule of law or human dignity,[110] or all of them in interdependence.[111]

AI governance is an interesting laboratory to prove the merits of a fundamental rights approach that takes into account the dimensions of *fundamental rights through*, *in* or *because of companies*. Just think of companies as forums where workers can benefit from AI literacy, education and training in relation to AI [see new Article 4a(2) of the AIA proposal as amended by the EP]. Or companies acting as arbitrators or quasi-judges to resolve conflicts between different fundamental rights [e.g., the right to data protection and the right against negative bias, on Article 10(5) of the AI proposal]. Properly addressing and securing the position of businesses as holders of fundamental rights does not undermine the fundamental rights of individuals or the general interest.

It is now time to take proper account of the fundamental right *par excellence* of private companies.

4. The freedom to conduct a business as a fundamental right

The freedom to conduct a business is a fundamental right. It is not a simple institutional guarantee or a mere principle. It is enshrined (as a fundamental right) in several national constitutions. In the vast majority of European constitutional texts, it is autonomously and explicitly provided for, albeit under different names.[112] Even if it is not autonomously enshrined, it is still provided for alongside neighbouring (economic) freedoms[113] or recognised implicitly or by derivation through the hermeneutics of rules enshrining the freedom of occupation.[114] The

processes – De Almeida, Santos, and Farias, "Artificial Intelligence Regulation," 507 with references.

[108] Koniakou, "From the «rush to ethics»," 72 and 84.

[109] Mantelero, *Beyond Data*, 83.

[110] Roberts et al., "Governing artificial intelligence," 86.

[111] On the interdependence of human rights, democracy and the rule of law, see Leslie et al., "Artificial intelligence," 13.

[112] Examples include Article 26 of the Charter of Fundamental Rights and Basic Freedoms of the Czech Republic, Article 35 of the Constitution of the Slovak Republic of 1992 (revised in 2023), Section 74 of the Danish Constitution Act of 1953, Article 38 of the Spanish Constitution of 1978 (revised in 2011), Article 41 of the Constitution of Romania of 1991 (revised in 2003), Article 31 of the Constitution of the Republic of Estonia of 1992 (revised in 2015), Article 61 of the Constitution of the Portuguese Republic of 1976 (revised in 2005), Article 41 of the Constitution of the Italian Republic of 1947 (revised in 2022) or Article 74 of the Constitution of the Republic of Slovenia of 1991 (revised in 2021).

[113] As in Article 35 of the Constitution of the Grand Duchy of Luxembourg of 1868 (revised in 2023), Section 18 of the Constitution of Finland of 1999 (revised in 2018), Article 25 of the Constitution of the Republic of Cyprus of 1947 (revised in 2022), and Article 6 of the Austrian Basic Law on the General Rights of Citizens.

[114] This is the case of Article 12 of the German Constitution of 1949 (revised in 2022), Article 19 of the Constitution of the Kingdom of the Netherlands of 2018 and Article 65 of the Constitution of the Republic of Poland of 1997 (revised in 2009).

national provisions and the interpretation given to them converge on the reference to the non-absolute character and very limited nature of economic (entrepreneurial) freedom, an interpretation which is also supported by the case law of the Court of Justice of the European Union.[115] This very limited nature can be seen in some national provisions which, with regard to certain fundamental rights and freedoms, give companies and their economic freedom a (generally) less guaranteed regime than the protection afforded to dimensions with an exclusively human referent.[116]

As regards the European Convention on Human Rights ('ECHR'), its silence on the freedom to conduct a business is counterbalanced by a clear concern for the company, the business activity, the risks to which it is exposed and the freedoms of the entrepreneur, in the case law of the European Court of Human Rights ('ECtHR'). Indeed, according to Judge Wojtyczek in the case of *Könyv-Tár Kft and others v. Hungary*,[117] the freedom to conduct a business is an integral part of the European system of legal protection. On the one hand, it is an instrumental right for the enjoyment and protection of other rights enshrined in the ECHR and a vehicle for economic prosperity and the wealth necessary to ensure effective social rights. On the other hand, it is a fundamental right in its own right, which is part of the common heritage and a prerequisite for the political traditions and the ideals of freedom, democracy and the Rule of Law referred to in the preamble to the ECHR.

In order to open up the ECHR to corporations, the ECtHR recognises their legitimacy to bring individual applications as *non-governmental organisations*[118] and recognises them as holders of specific rights, by (re)defining the limits and contours of the rights provided for in the Convention, in light of its stated aim of guaranteeing concrete, effective and *up-to-date* rights, rather than abstract, theoretical, illusory or *crystallised* rights.[119] In addition to Article 1 of Additional Protocol No. 1 to the ECHR on the guarantee of property, which explicitly refers to legal persons,[120] companies are regularly the subject of leading cases on the applicability of Article 8 of the ECHR, thanks to the autonomous and broad notions of private life, home and correspondence,[121] as well as Article 10 of the ECHR, on the freedom of expression

[115] See, in that respect, Judgments CJEU, *Bank Melli Iran*, 21 December 2021, Case C-124/20, EU:C:2021:1035, paras 80-81; *NK (Occupational pensions for managerial staff)*, 24 September 2020, Case C-223/19, EU:C:2020:753, para 88; *Sky Österreich*, 22 January 2013, Case C-283/11, EU:C:2013:28, paras 45-46; *Deutsches Weintor*, 6 September 2012, Case C-544/10, EU:C:2012:526, para 54, and *Spain and Finland v Parliament and Council*, 9 September 2004, Joined Cases C-184/02 and C-223/02, EU:C:2004:497, paras 51-52.

[116] For example, this is the case with the freedom of commercial expression (as a dimension of freedom of enterprise) in Article 23 of the Instrument of Government of 1974, which is part of the Swedish Constitution.

[117] Dissenting Opinion of Judge Wojtyczek in *Könyv-Tár Kft and Others v. Hungary*, no. 21623/13, 16 October 2018.

[118] This was soon the case in *Times Newspaper Ltd., the Sunday Times, and Evans v. the United Kingdom*, no. 6538/74, Commission decision of 21 March 1975, Decisions and Reports (DR) 2, (§1).

[119] The ECHR is qualified as a living instrument, which must be interpreted in the light of present-day conditions – see, mutatis mutandis, *Cossey v. the United Kingdom*, judgment of 27 September 1990, Series A no. 184, 14, § 35 *in fine* and *Société Colas Est and Others v. France*, no. 37971/97, § 41, ECHR 2002-III.

[120] See *Könyv-Tár Kft and Others v. Hungary*, no. 21623/13, 16 October 2018, with reference to *Döring v. Germany* (dec.), no. 37595/97, ECHR 1999-VIII, *Wendenburg and Others v. Germany* (dec.), no. 71630/01, ECHR 2003-II, *Buzescu v. Romania*, no. 61302/00, § 81, 24 May 2005 and *Oklešen and Pokopališko Pogrebne Storitve Leopold Oklešen S.P. v. Slovenia*, no. 35264/04, § 54, 30 November 2010.

[121] See *Satakunnan Markkinapörssi Oy and Satamedia Oy v. Finland* [GC], no. 931/13, 27 June 2017, also

(in which *commercial* freedom of expression is enshrined)[122] and Article 6 of the ECHR on guarantees of due process.[123]

The naturalness of this recognition does not, of course, disregard the special nature of companies, which may be required to exercise a particular degree of care and diligence and to tolerate the risks inherent in economic activity. However, as the landmark case of *Gillan and Quinton v. the United Kingdom*[124] rightly points out, a wider margin of appreciation for public authorities,[125] as in all matters likely to affect fundamental rights (including the freedom to conduct a business and the rights of companies), cannot be interpreted as an unfettered power, as this would be contrary to the rule of law as a fundamental principle of a democratic society. To sum up, even if public authorities may enjoy a wider discretion, the freedoms of corporate subjects also impose limits on public authorities, as well as on injustice and arbitrariness.

While fundamental rights, as guaranteed by the ECHR and as they result from the constitutional traditions common to the Member States, shall constitute general principles of EU law (Article 6(3) of the TEU), the freedom to conduct a business is a fundamental right in the EU system of fundamental rights as well. In particular, Article 16 of the Charter of Fundamental Rights of the European Union explicitly states that, "*the freedom to conduct a business in accordance with Union law and national laws and practices is recognised*". This is a complex right, or an amalgamation of three distinct or autonomous faculties or freedoms: the freedom to carry on a commercial or economic activity,[126] the freedom of contract and the freedom of competition.[127]

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referring to *Niemietz v. Germany*, 16 December 1992, § 29, Series A no. 251 B. See also *Vinci Construction and GTM Génie Civil et Services v. France*, nos. 63629/10 and 60567/10, 2 April 2015, *Naumenko and SIA Rix Shipping v. Latvia*, no. 50805/14, 23 June 2022; *Société Colas Est and Others v. France*, no. 37971/97, ECHR 2002-III; *Buck v. Germany*, no. 41604/98, ECHR 2005-IV; *Sallinen and Others v. Finland*, no. 50882/99, 27 September 2005; *Wieser and Bicos Beteiligungen GmbH v. Austria*, no. 74336/01, ECHR 2007-IV, and *Lindstrand Partners Advokatbyrå AB v. Sweden*, no. 18700/09, 20 December 2016.

[122] *Markt Intern Verlag GmbH and Klaus Beermann v. Germany*, no. 10573/83, judgment of 20 November 1989, Series A no. 165.

[123] *Grande Stevens and Others v. Italy*, nos. 18640/10 and 4 others, 4 March 2014; *A. Menarini Diagnostics S.R.L. v. Italy*, no. 43509/08, 27 September 2011; *Dubus S.A. v. France*, no. 5242/04, 11 June 2009; *Lilly France S.A. v. France* (dec.), no. 53892/00, 3 December 2002; *Didier v. France* (dec.), no. 58188/00, 27 August 2002; *Messier v. France*, no. 25041/07, 30 June 2001; *Guisset v. France*, no. 33933/96, ECHR 2000-IX and *Engel and Others v. the Netherlands*, 8 June 1976, § 82, Series A no. 22.

[124] *Gillan and Quinton v. the United Kingdom*, no. 4158/05, ECHR 2010.

[125] *Bernh Larsen Holding AS and Others v. Norway*, no. 24117/08, § 173, 14 March 2013. As regards the typical risk of commercial and economic activities, see *Čadek and Others v. the Czech Republic*, nos. 31933/08 and 9 others, § 70, 22 November 2012 and *Pine Valley Developments Ltd and Others v. Ireland*, 29 November 1991, § 59, Series A no. 222.

[126] From which some also derive the right to freely pursue a commercial activity in any Member State and the right to a properly functioning and competitive single market - Andrea Usai, "The Freedom to Conduct a Business in the EU, Its Limitations and Its Role in the European Legal Order: A New Engine for Deeper and Stronger Economic, Social, and Political Integration", *German Law Journal*, v. 14, no. 9 (2013): 1887, accessed August 27, 2023, doi: https://doi.org/10.1017/S2071832200002534.

[127] Xavier Groussot, Gunnar T. Petursson, and Justin Pierce, "Weak Right, Strong Court - The Freedom to Conduct Business and the EU Charter of Fundamental Rights", *SSRN Electronic Journal* (2014): 3, accessed August 27, 2023, doi: http://dx.doi.org/10.2139/ssrn.2428181, with the difference that while the first two elements result from the case law of the Court of Justice of the European Union, the protection of competition is supported by the Treaties. On freedom of competition, on the positions that see competition protection as a limit to the freedom of enterprise, and the position that sees it as an instrument to promote the latter - Usai, "The Freedom to Conduct a Business," 1876f. Also on this topic, Stefan Storr, "Das Grundrecht der unternehmerischen Freiheit und öffentliche Unternehmen in der Europäischen Union", in *Festschrift für Walter Berka*, ed. Rudolf

The freedom to conduct a business is a fundamental right that is part of the genetic identity of the European integration project and has a long history in EU law.[128] Indeed, while its importance has been given new impetus by the Lisbon Treaty's explicit commitment to a *social market economy* and by its inclusion in the catalogue of the CFREU,[129] the right to choose and exercise a commercial or economic activity was protected as a "*general principle of Union law*" long before the freedom to conduct a business was explicitly enshrined as a fundamental right in the CFREU.[130] Perhaps, the umbilical connection of the freedom to conduct a business with the construction of the Internal Market, the corresponding freedoms and the prohibition of discrimination could explain the relative recurrence[131] or the agnostic way in which the freedom to conduct a business (a position typically held by non-human subjects - companies) was (early)[132] invoked at an early stage before national courts[133] and recognised as a fundamental right that is neither subordinate[134] nor inferior (to others).

Of course, it is a *special* fundamental right, as its *dual nature* testifies.[135] On the one hand, it is a genuine fundamental right, which aims to guarantee the existential *status* of its holders and to protect their legal sphere by means of a subjective public right.[136] On the other hand, it can (continue to) be seen as an organising principle of the (European) Economic Constitution and is proof of the commitment to a model of the social market economy on which it is based.[137]

Feik and Roland Winkler (Wien: Jan Sramek Verlag, 2013), 220-1 and 224f.

[128] Opinion of Advocate General Cruz Villalón delivered on 19 February 2013 [Judgment *Alemo-Herron and Others*, Case C-426/11], ECLI:EU:C:2013:82, para 48.

[129] Schwarze, *Europarecht*, 429.

[130] Explanation on Article 16 – Freedom to conduct a business in Explanations relating to the Charter of Fundamental Rights, OJ C 303, 14.12.2007, 17–35, accessed August 27, 2023, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32007X1214%2801%29.

[131] See Annual Reports on the Application of the EU Charter of Fundamental Rights, accessed August 27, 2023, https://commission.europa.eu/aid-development-cooperation-fundamental-rights/your-rights-eu/eu-charter-fundamental-rights/application-charter/annual-reports-application-charter_pt.

[132] Peter Oliver, "What Purpose Does Article 16 of the Charter Serve?", in *General Principles of EU Law and European Private Law*, ed. Ulf Bernitz, Xavier Groussot, and Felix Schulyok (Wolters Kluwer, 2013), 281. See also Usai, "The Freedom to Conduct a Business," 1879 and Michelle Everson and Rui C. Gonçalves, "Article 16 -Freedom to Conduct Business", in *The EU Charter of Fundamental Rights: a Commentary*, ed. Steve Peers, Tamara Hervey, Jeff Kenner, and Angela Ward (Hart/Beck, 2021), 466 and 471-2.

[133] On the recognition of a self-executing right for companies of one Member State to invest in another Member State, without being subject to any discrimination, except in a very limited number of cases - Bruno De Witte, "Balancing of Economic Law and Human Rights by the European Court of Justice", in *Human Rights in International Investment Law and Arbitration*, ed. Pierre-Marie Dupuy, Ernst-Ulrich Petersmann, and Francesco Francioni (Oxford: Oxford Academic, 2009), 197. In fact, market freedoms have been structural principles of the European Economic Constitution since its inception - ibidem, 202. Also on this subject, Pieter Van Cleynenbreugel and Xavier Miny, "The Fundamental Economic Freedoms: Constitutionalizing the Internal Market", in *The Idea of Economic Constitution in Europe*, ed. Guillaume Grégoire and Xavier Miny (Brill | Nijhoff, 2022), 263-297.

[134] Its provision alongside civil and political rights in the same Charter supports such a conclusion - Usai, "The Freedom to Conduct a Business," 1869.

[135] *Inter alia*, Everson and Gonçalves, "Article 16," 473.

[136] This is not generally recognised. According to Usai, "The Freedom to Conduct a Business," 1869-70 and, further, 1877, Article 16 of the Charter does not protect the subjective positions of individuals but all the social and economic benefits arising from the free market.

[137] See, in this sense, Everson and Gonçalves, "Article 16," 465. Some, however, dispute the maintenance of the condition of a 'general principle of the Union', from the moment of its consecration as a 'right' in the Charter. On this question, see, in particular, Oliver, "What Purpose," 281f and 295f.

This, of course, has consequences for its determinability, its essential core and its balance with other fundamental rights and public interests. First, a relationship of opposition or apparent confrontation between the economic or market elements and the social principle is used to portray the freedom to conduct a business as the enemy of social policies. Second, the wording of Article 16 contributes to its characterisation as a diminished fundamental right, when it recognises the freedom to conduct a business only "*in accordance with Union law and national laws and practices*". The wording raises some doubts as to whether it is dependent on the legislator or whether it is a diminished or secondary right, with the consequence that it must always take a back seat in order to ensure the realisation of the public interest and other rights and freedoms more closely related to human dignity. Third, the essence of the freedom to conduct a business is particularly complex and controversial,[138] precisely because of its more fluid contours. In particular, the freedom to conduct a business is realised in areas where political, economic and social choices have to be made, involving complex assessments and multiple evaluations by the legislator. Finally, the freedom to conduct a business is also special because it has a specific "*function in society*".[139] We believe that these doubts can be carefully resolved through the dogmatics of fundamental rights.

First, the fact that the freedom to conduct a business is a fundamental right with an enormous potential for conflict with other fundamental rights and principles, and that it impacts on the real European world of socio-economic relations,[140] does not mean that it can be neglected or denied as a fundamental right. Just as fundamental (social) rights are not an obstacle to economic integration,[141] innovation and competitiveness in the context of a market or mixed economy model, neither can the freedom to conduct a business (and other economic freedoms) be seen as an obstacle to the pursuit of social policies or as a threat to the realisation of social rights.

Second, the greater limitation of the freedom to conduct a business does not mean that it is a diminished right or that it is to be exercised in accordance with the decisions of the (ordinary) legislator or secondary EU law.[142] In other words, the fact that the freedom to conduct a business is not an absolute prerogative does not mean that it does not act as a "*a limit on the actions of the Union in its legislative and executive role as well as on the actions of the Member States in their application of European Union law*".[143] Such a view would undermine the primacy of fundamental rights and the CFREU

On the umbilical relationship between freedom of enterprise and the highly competitive social market economy model, see Usai, "The Freedom to Conduct a Business," 1870-71.

[138] Eduardo Gill-Pedro, "Freedom to conduct business in EU law: freedom from interference or freedom from domination?", European journal of legal studies, v. 9, no. 2 (2017): 133, accessed August 27, 2023, doi: https://doi.org/10.1017/S1574019622000153.

[139] Judgment CJEU, NK (Occupational pensions for managerial staff), 24 September 2020, Case C-223/19, EU:C:2020:753, para 88.

[140] Everson and Gonçalves, "Article 16," 483.

[141] Usai, "The Freedom to Conduct a Business," 1879.

[142] In this sense, Eduardo Gill-Pedro, "Whose Freedom is it Anyway? The Fundamental Rights of Companies in EU Law", *European Constitutional Law Review*, v. 18, no. 2 (2022): 191, accessed August 27, 2023, doi: https://doi.org/10.1017/S1574019622000153, considers that requiring companies to comply with certain legal frameworks does not interfere with anyone's human rights. This would only be the case if public authorities could arbitrarily exercise their power over market actors.

[143] Opinion of Advocate General Cruz Villalón delivered on 19 February 2013 [Judgment *Alemo-Herron and Others*, Case C-426/11], ECLI:EU:C:2013:82, para 50.

over the law, whereas this is not a freedom that depends on the law or the will of the legislator. Any denial of its binding nature on the legislator (European or national) must therefore be ruled out.[144] The law that guarantees or affirms the freedom to conduct a business is merely a reflection of the extroversion that characterises the freedom to conduct a business, which also gives the law a prominent role. Whether it is a matter of harmonising conflicting rights, regulating the exercise of rights, or resolving difficult cases that should not be seen in the uncertainty of a theory of *immanent limits*, the law and the freedom to conduct a business are not just enemies.

The more so as the typical holders of the freedom to conduct a business cannot be reduced to the stereotypical image of the *large* company with a dominant or undisputed position in the market, or as a source of danger and threat to the people and the sovereignty of the State. Among the companies concerned there are entities that are no less relevant (at least in quantitative terms), such as small and medium-sized enterprises ('SMEs'), in whose favour the State (*lato sensu*) has to fulfil, in addition to a duty of abstention, positive duties that also derive from the freedom to conduct a business (e.g. with regard to the protection of SMEs, the guarantee of access to the market, competition rules, or support and financing). Put simply, "*not all service providers have the same capacities and resources as YouTube*",[145] and a particular company may be, and often is, "*an important means by which individuals exercise that freedom*".[146] In any case, to equate companies with big, bad and powerful companies would be a mistake similar to denying fundamental rights to a criminal or a bad person, assuming that all people are bad people or that bad people should not be entitled to fundamental rights.

Third, the fluidity of the essence of this right cannot be confused with the denial of such an essential core. Even if it is true that the legislator is allowed a wider margin of action and more extensive possibilities of intervention and interference, and even if it is true that it is important to keep judicial control by the courts within limits that do not impair this margin of appreciation and choice,[147] it is even more important to ensure that every choice, measure or intervention is made in such a way as to remain within the scope of action permitted by fundamental rights. The prima facie content of the freedom, together with the principle of proportionality, provides for the determination of the essence of the right, even if only in concrete scenarios, and even if it cannot be fully determined in advance. Restrictions on the freedom to conduct a business which are not justified by the existence (*in concreto*) of conflicting and colliding rights must be fully and carefully examined, since they may violate the essence of the right.

Finally, with respect to the function of the freedom to conduct a business in society, although there is a risk that it will be misinterpreted in terms of subordination to other fundamental rights or as a mortgage to guarantee the public interest, this is simply the result of the fact that the freedom to conduct a business cannot realise itself without a market in which to compete, sell and

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[144] On the strength of the freedom to conduct a business as a limit, see Usai, "The Freedom to Conduct a Business," 1871.

[145] Opinion of Advocate General Saugmandsgaard Øe delivered on 16 July 2020 [Judgment YouTube, 22 June 2021, Joined Cases C-682/18 and C-683/18], ECLI:EU:C:2020:586, paras 240-242, note 226.

[146] Opinion of Advocate General Saugmandsgaard Øe delivered on 16 July 2020 [Judgment YouTube], paras 240-242, note 226.

[147] On such risk, Gill-Pedro, "Freedom to conduct business," 133-4.

provide services, and without employees, customers, users, consumers and business partners. In other words, the simultaneous intervention of the company, both as *subject* and holder of its own fundamental rights, and as a forum or structure for the realisation of the rights of others and of alien public interests, requires different and more demanding exercises of harmonisation, which cannot be resolved in the light of a bipolar scheme.

The special function of the freedom to conduct a business is the acknowledgement of the fact that companies are important social actors whose activities can benefit society as a whole, as a result of which it does not imply "*either a reduction in the level of protection guaranteed by that right or that it has the status of a principle or of a 'second-class' right*".[148] To the contrary, the impact of a restriction on the freedom to conduct a business is not limited to the company-holder and may actually affect the fundamental rights of others (shareholders, employees, clients or business partners, whether individuals or *other businesses*),[149] in *different ways*. To give an example, while collecting less data could protect the privacy of some users, "*limiting data acquisition can be 'challenging' for machine learning models which are dependent on large amounts of data*",[150] thus diminishing the experience and rights of other users.

In light of the foregoing, it is important to recall that the freedom to conduct a business, like any other fundamental right, cannot be considered in isolation,[151] and must always be considered as a *prima facie* right whose subjective rooting depends on the dialogue with other protected rights and interests protected as fundamental. In other words, the *Tatbestand* (the normative domain) of a right is also always first of all a *potential domain*, which only appears definitive once the concrete existing conditions have been established. However, since there is no hierarchy in the system of fundamental rights,[152] conflicts with the rights of other holders and collisions or clashes with public or general interests or values must be resolved in light of the constitutional and fundamental rights methodology, which is the only one capable of preserving the legislator's room for manoeuvre, while at the same time protecting the freedom to conduct a business from arbitrariness and *free and unfettered* restrictions.

In the legal system of the EU, the *limits of limitations* are provided for in Article 52 of the CFREU. According to this provision, limitations may be imposed on the exercise of the rights and freedoms recognised by the Charter, provided that such limitations: i) are laid down by law (legal basis); ii) respect the very essence of those rights and freedoms; iii) are necessary in accordance with the principle of proportionality; and iv) genuinely meet objectives of general interest recognised by the EU or the need to protect the rights and freedoms of others (justification).

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[148] Opinion of Advocate General Szpunar, delivered on 15 July 2021 [Judgment *Thelen Technopark Berlin*, Case C-261/20], ECLI:EU:C:2021:620, paras 89-90.

[149] See, *inter alia*, Judgements CJEU, *Scarlet Extended*, 24 November 2011, Case C-70/10, ECLI:EU:C:2011:771, para 50 and *Poland v Parliament and Council*, 26 April 2022, Case C-401/19, ECLI:EU:C:2022:297, para 75.

[150] Johann Laux, Sandra Wachter, and Brent Mittelstadt, "Three pathways for standardisation and ethical disclosure by default under the European Union Artificial Intelligence Act", *SSRN Electronic Journal* (2023): 14, accessed August 27, 2023, doi: http://dx.doi.org/10.2139/ssrn.4365079.

[151] It is well established in EU case law that the freedom to conduct a business is not an absolute prerogative, but must be assessed, first, in relation to its function in society – Judgments CJEU, *Polkomtel*, 20 December 2017, Case C-277/16, EU:C:2017:989, para 50, and, secondly, must be balanced against other interests protected by the EU legal order – Judgment CJEU, *Schaible*, 17 October 2013, C-101/12, EU:C:2013:661, para 60, and the rights and freedoms of others – Judgment CJEU, *Sky Österreich*, 22 January 2013, Case C-283/11, EU:C:2013:28, para 48.

[152] Novelli et al., "Taking AI Risks Seriously," 19.

In conclusion, the freedom to conduct a business may be limited. Nevertheless, this does not call into question the fact that it is endowed with a fundamental value. Even if it is subject to more restrictions, the highly restrictive nature of the freedom to conduct a business should not be seen as a *carte blanche* for the legislator. Just as the freedom to conduct a business needs public authorities, society as a whole depends on the freedom to conduct a business, in a *symbiosis* that is often forgotten and must be kept in mind. Any clash between conflicting fundamental rights or the public and general interest (including where the freedom to conduct a business is at stake) must be resolved by means of a balancing test. Recognising and valuing the fundamental nature of the freedom to conduct a business does not risk blocking the activities and duties of States and other political actors, nor does it mean that one right or interest automatically takes precedence over another. The dogmatics of fundamental rights ensure a proper and legal framework that limits and binds political decisions and arbitrariness.

5. The freedom to conduct a business as a driving force and rationale for AI governance

The AI governance landscape has changed recently and will continue to metamorphose in the coming years, being one of the *hot topics* of both the present and the near future. Although there is now a clear trend towards "*ethical governance of AI*",[153] which seeks to avoid or at least mitigate the risks that AI poses to individuals and society, including threats to "*fundamental rights, such as privacy, and to individual and public safety and interests*",[154] many uncertainties remain. First, about what AI means, represents or threatens.[155] Now it is about what can be expected from *AI governance*. AI governance has a say in tomorrow's AI and its impact on society, so the choice between different possible regulatory frameworks is not indifferent to the outcomes and, most importantly, to the companies operating in AI markets. In this context, it is important that: i) the drivers of AI governance are not just about responding to risks and building public trust; ii) AI stakeholders are not limited to humans as customers or end users; and iii) their fundamental rights or the general interest do not justify disproportionate frameworks and burdens that "*may harm efforts to stimulate a competitive AI market*"[156] and ultimately undermine the choices and rights of those same citizens. In other words, "*regulatory choices cannot be justified just by their positive impact on the intended scope – i.e., the protection of fundamental rights – but also by the (difference between) the marginal gains and harms they generate for other values at stake*".[157] We believe that while uncertainty and inconsistency "*can undermine business and consumer confidence in AI, and stifle innovation*",[158] "*clear and consistent regulation can also support business investment and build confidence in innovation*".[159]

[153] It "*covers a set of processes, procedures, cultures, values designed to the highest standards of behaviours, which go beyond the black letter of the law*" - Harasimiuk and Braun, *Regulating Artificial Intelligence*, 138.
[154] Truby, Brown, Ibrahim, and Parellada, "A Sandbox Approach," 273.
[155] This uncertainty is said to be responsible for the phenomenon of the *expertisation of governance*, i.e., the widespread use of expert groups - see Harasimiuk and Braun, *Regulating Artificial Intelligence*, 43.
[156] Roberts et al., "Governing artificial intelligence," 85.
[157] Novelli et al., "Taking AI Risks Seriously," 15.
[158] United Kingdom Secretary of State for Science, Innovation and Technology, "A pro-innovation," 5.
[159] United Kingdom Secretary of State for Science, Innovation and Technology, "A pro-innovation," 5.

The recognition of the freedom to conduct a business as a fundamental right is closely related to AI governance in several ways. On the one hand, the freedom to conduct a business is a *justification for* the adoption of a particular framework or system of AI governance. It is one of the drivers of AI governance, requiring legal certainty and conditions to ensure customer trust, to encourage investment and innovation, and to avoid barriers to the cross-border movement of AI systems. Moreover, in its dimension of *freedom to enter the market* and *develop a particular economic activity*, it requires conditions to ensure contestability, fairness and protection against abusive practices by incumbent operators.

From this point of view, the freedom to conduct a business functions acts as an *optimisation mandate* which obliges public authorities, and in particular the legislator. They must therefore design a framework which, over and above the formal respect for the rights of companies, seeks to ensure the effectiveness of the freedom to conduct a business as a fundamental right with a value in itself (even if it is not exclusively based on human dignity, but on other fundamental values such as the rule of law). Such positive action is made clear in a new Recital 5a proposed by the EP for the AIA, which states that: "*in order to foster the development of AI systems in line with Union values, the Union needs to address the main gaps and barriers blocking the potential of the digital transformation including the shortage of digitally skilled workers, cybersecurity concerns, lack of investment and access to investment, and existing and potential gaps between large companies, SME's and start-ups*".

On the other hand, the freedom to conduct a business is also a *trump card* that cannot be overcome or eliminated by legislators and policymakers. In this dimension, it embodies the defence of companies not to be subject to certain types of unexpected, disproportionate or unreasonable AI frameworks. As we will see, the freedom to conduct a business requires an AI governance framework that is not only *pro-innovation*, but also trustworthy, prospective, predictable, clear, non-contradictory, while remaining adaptable, proportionate, "possible" as what it requires from its subjects, and collaborative. None of this undermines a fundamental rights-based approach to AI governance or the protection of human beings from AI risks.

It is true that the freedom to conduct a business, or at least the rights that companies invoke as producers, developers or deployers of AI, are often treated as obstacles or barriers to achieving a human-centred approach to AI. For example, some argue that "*assuring human centricity would depend on algorithm developing entities, whose rights may be protected by trade secret rules or intellectual property rights*".[160] However, we believe that appropriate rule of law responses require replacing a pessimistic approach with one that is balanced and even-handed enough to recognise that "*AI systems pose very different problems depending on who uses them, where, and for what purpose*".[161]

AI governance and regulation must be designed to "*hold bad actors accountable and allow actors with good intent*",[162] rather than treating them all as *bad actors*. Put simply, the fundamental rights discourse needs to be introduced into AI governance as a whole, without cherry-picking which fundamental rights (or rights holders) should be protected or promoted. Their difference is something that needs to be considered in concrete weighting exercises, not in advance (or in the abstract). Just as concrete is the urgent need to consider the interplay between the hazard drivers of AI and

[160] Harasimiuk and Braun, *Regulating Artificial Intelligence*, 50.
[161] Ruschemeier, "AI as a challenge," 366.
[162] Mökander, Juneja, Watson, and Floridi, "The US Algorithmic Accountability Act," 752.

existing countermeasures (measures that counter or mitigate risks)[163] in order to understand whether a particular risk category and the legal and regulatory burdens associated with it are justified *in concreto*.

Companies will be active players and part of the AI governance system. Their quality as *guardians* of the relationships and interactions between humans and AI technologies and systems is evident in the feasibility study of the Ad Hoc Committee on Artificial Intelligence ('CAHAI'), adopted by its plenary in December 2020,[164] which proposes nine principles and priorities to underpin the governance framework for AI and the design, development, and deployment of AI systems. They translate into concrete rights and fundamental obligations and requirements to be enacted and imposed on AI developers and deployers. Among other obligations, private companies in the AI ecosystem and lifecycle (and depending on their concrete role) will have to: i) "*inform human beings of the fact that they are interacting with an AI system rather than with a human being in any context where confusion could arise*"; ii) comply with data protection rules where AI-enabled manipulation, individualised profiling, and prediction involve the processing of personal data;[165] iii) "*establish human oversight mechanisms that safeguard human autonomy, in a manner that is tailored to the specific risks arising from the context in which the AI system is developed and used*"; iv) "*duly communicate options for redress in a timely manner*"; v) "*take adequate measures to minimise any physical or mental harm to individuals, society, and the environment*"; vi) adopt "*adequate (by design) safety, security, and robustness requirements*" and to comply therewith; vii) "*develop and use AI systems in a sustainable manner, with full respect for applicable environmental protection standards*"; viii) provide adequate notice to users of their "*right to be assisted by a human being whenever using an AI system that can impact their rights or similarly significantly affect them* [...] *and of how to request such assistance*"; ix) comply with traceability and information requirements; x) "*(1) identify, document, and report on potential negative impacts of AI systems on human rights, democracy, and the rule of law; and (2) put in place adequate mitigation measures to ensure responsibility and accountability for any harm caused*".[166]

In addition to these core obligations, companies will most likely be subject to public oversight, be responsible for *due diligence* and *legal compliance* or *accountability checks* (and external audits),[167] and subject to liability (civil or even criminal), where their

[163] Novelli et al., "Taking AI Risks Seriously," 14.

[164] See Ad hoc committee on Artificial Intelligence (CAHAI), "Feasibility study on a legal framework on AI design, development and application based on Council of Europe's standards" (2020), accessed August 27, 2023, https://www.coe.int/en/web/artificial-intelligence/-/the-feasibility-study-on-ai-legal-standards-adopted-by-cahai.

[165] Algorithmic profiling and prediction are of particular concern. For problems of fossilisation, unfalsifiability, pre-emptive intervention and self-fulfilling prophecy, as well as the shortcomings of existing data protection, privacy and discrimination laws, see Hideyuki Matsumi and Daniel J. Solove, "The Prediction Society: Algorithms and the Problems of Forecasting the Future", *GWU Legal Studies Research Paper No. 2023-58, GWU Law School Public Law Research Paper No. 2023-58*, *SSRN Electronic Journal* (2023): 23f, accessed October 29, 2023, doi: http://dx.doi.org/10.2139/ssrn.4453869. On profiling and discrimination by association in particular, see Maria Inês Costa, "The legal concept of discrimination by association: where does it fit into the digital era?", *UNIO – EU Law Journal*, v. 9, no. 1 (2023): 16-28, accessed October 29, 2023, doi: https://doi.org/10.21814/unio.9.1.5206. For more on the shortcomings of data protection laws to provide protection against automated inferences, see Veronese, Silveira and Espiñeira Lemos, "Artificial intelligence," 77.

[166] We closely follow Leslie et al., "Artificial intelligence," 17-22.

[167] Accountability through governance systems is seen as providing overall oversight of the operation of AI and the company behind the system. It is manifested in the industry by "*defining responsibilities and accountability guidelines. Contracts were typically cited as means of establishing accountability for any system, at the start of a project*" - Vakkuri et al., "How do software companies," 103-6.

shield from vexatious suits or the weaponization of disclosure systems cannot be ruled out.[168]

From all of the above, it is appropriate to speak of AI corporate governance or responsibility, or "*corporate digital responsibility*",[169] as a new paradigm with clear implications for corporate governance decisions and structures. For example, "*accountability for the ethical dimensions of decisions associated with the development, deployment and use of AI systems or more broadly with development, deployment and use of any cyber technologies*"[170] may justify the appointment of 'a person in charge of ethical issues related to technologies as well as ethics panels, boards, committees'[171] with the role of monitoring and advising the company's board and management on how to comply with frameworks that call for "*human agency and oversight; technical robustness and safety; privacy and data governance; transparency; diversity, non-discrimination and fairness; societal and environmental well-being and accountability*",[172] with various obligations, requirements and liabilities for companies.

As a *countermeasure*, the freedom to conduct business sets out some general requirements for the governance of AI, regardless of how it looks in practice. Optimising, promoting, guaranteeing and enforcing the freedom to conduct a business requires a clear and proportionate governance framework that companies can participate in, shape and contribute to updating. In other words, a clear, innovation-friendly, and flexible approach to AI regulation that: i) focuses on "*high risk concerns rather than hypothetical or low risks associated with AI*"; and ii) includes "*lighter touch options, such as guidance or voluntary measures*" that ensure "*comprehensive regulatory coverage and flexibility*",[173] iii) where "*liability varies depending on the particular target of a piece of guidance, as well as the regulator's specific powers and jurisdiction*",[174] and iv) where a model of "*adjusted supervisory monitoring that includes participatory dialogue and 'experimental' environments such as regulatory sandboxes and other methods for policies and governance experimentation*"[175] is *the good way forward*, bringing additional benefits such as increased transparency and trust.[176]

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[168] Hacker, "The European AI Liability Directives," 29.

[169] Harasimiuk and Braun, *Regulating Artificial Intelligence*, 87.

[170] Harasimiuk and Braun, *Regulating Artificial Intelligence*, 89.

[171] Harasimiuk and Braun, *Regulating Artificial Intelligence*, 89. According to Eleanore Hickman and Martin Petrin, "Trustworthy AI and Corporate Governance: The EU's Ethics Guidelines for Trustworthy Artificial Intelligence from a Company Law Perspective", European Business Organization Law Review, v. 22 (2021): 599, accessed August 27, 2023, doi: https://doi.org/10.1007/s40804-021-00224-0, businesses "*will face a number of questions in this regard. For example, what should be the division of responsibilities between directors and managers in this area? Should there be specific new roles, such as a 'Chief AI Officer', or a dedicated board committee that focuses on AI? Further, and importantly, to what extent are managers and boards equipped and able to carry out the functions that the Guidelines suggest they assume with regards to AI? At least initially, and until a business has obtained sufficient in-house expertise, it seems that this would necessitate either extensive training and/or reliance on third party expert advisors*".

[172] Harasimiuk and Braun, *Regulating Artificial Intelligence*, 57.

[173] Ceimia, *A Comparative Framework for AI Regulatory Policy* (February 2023): 27-8, accessed August 27, 2023, https://ceimia.org/wp-content/uploads/2023/05/a-comparative-framework-for-ai-regulatory-policy.pdf.

[174] Ceimia, *A Comparative*, 39.

[175] Harasimiuk and Braun, *Regulating Artificial Intelligence*, 139.

[176] Leslie et al., "Artificial intelligence," 30. On the EU approach towards regulatory sandboxes, see Truby, Brown, Ibrahim, and Parellada, "A Sandbox Approach," 284-6. According to these Authors, the EC Proposal's sandbox approach suffers from three important limitations: i) "*the continued imposition of liability under Article 53(4)* [which] *means that the sandbox only provides an exemption from regulatory compliance. While developers should not be allowed to use the sandbox as a shield to liability, imposing the same liability regime on sandbox participation could lead to limiting innovation*"; ii) it "*could create a false perception of safety and compliance in the market*" and iii) it "*could lead to uncertainty and confusion in the market since it is*

To start with proportionality, the obligations imposed on AI actors in relation to AI systems must be proportionate to the risks, taking into account the technical requirements and burdens associated with meeting them. As the EP proposes to add to Recital 42 of the AIA proposal, requirements should be "*objective-driven, fit for purpose, reasonable and effective, without adding undue regulatory burdens or costs on operators*". This means that requirements and obligations must be (strictly) necessary, not go beyond what is necessary to achieve the conflicting right or colliding interest, preferring less stringent measures to more stringent ones, and providing adequate and effective safeguards and guarantees against abuse.[177]

In addition, AI governance frameworks need to recognise that not all companies are the same. Just as AI is a multifaceted reality,[178] so are its players. Both the *differences* between companies (in terms of size, structure, organisation, complexity, resources and activity) and the specific scenarios need to be assessed concretely, avoiding rigid and one-size-fits-all regulatory treatments if this means treating different actors equally[179] or forcing the same (restrictive) solution to be applied to different scenarios. On the contrary, this diversity leaves room for, and may even require, differentiated or tiered regimes that take account of the *difference* and address potential disadvantages for SMEs, as well as measures to support market access, compliance and cost reduction, including regulatory sandboxes and (public and EU) funding. Any different treatment of AI actors in this respect must of course be justified in terms of the idea of *proportionate equality*. This principle raises the bar for what policymakers can decide. While equality requires that access to facilities that may be crucial for the development of an economic activity, of which regulatory sandboxes are an example, must be open, allowing broad and equal access, with any selection criteria being fair (see Article 53a of the AIA proposal as amended by the EP), the idea of treating the same equally and the different differently allows SMEs and start-ups to benefit from priority access and from fee waivers to the extent of their difference (proportionality).

Moving on to legal certainty and predictability, these are also requirements for an AI governance framework that is consistent with the freedom to conduct a business. In addition to avoid chilling effects, legal certainty promotes compliance.[180] There are, however, a number of uncertainties about the AI landscape. Uncertainty starts with the definition of AI as such, as "*a form of conceptual control with significant impacts on the governance discourse*".[181] Uncertainty also remains on how to effectively comply with existing and future laws and specific obligations, with increasing focus on litigation and reputation risks.[182] As uncertainty may be an innovation-blocker,

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not mandatory to, and not necessarily uniform among, EU states".

[177] *Roman Zakharov v. Russia* [GC], no. 47143/06, § 236, ECHR 2015.

[178] Consider general-purpose AI, whose applications are diverse and unpredictable, even to its creators – see Claudio Novelli et al., "Taking AI Risks Seriously: a New Assessment Model for the AI Act", *SSRN Electronic Journal*, 1, accessed August 27, 2023, doi: http://dx.doi.org/10.2139/ssrn.4447964. As regards the use of explanatory techniques to solve the problems of shared responsibility, see Paulo Henrique Padovan, Clarice Marinho Martins and Chris Reed, "Black is the new orange: how to determine AI liability", *Artificial Intelligence and Law*, v. 31 (2023): 134-5, accessed October 29, 2023, doi: https://doi.org/10.1007/s10506-022-09308-9.

[179] Novelli et al., "Taking AI Risks Seriously," 25.

[180] Hacker, "The European AI Liability Directives," 55.

[181] Koniakou, "From the «rush to ethics»," 80 with reference to Larsson (2013, 2020). For an array of definitions, see Enholm, Papagiannidis, Mikalef, and Krogstie, "Artificial Intelligence," 1711f.

[182] See Harasimiuk and Braun, *Regulating Artificial Intelligence*, 92 and Schuett, "Risk Management," 7.

and hamper the social benefits behind AI,[183] legal certainty must also be a driver of regulation.[184]

While the existence of a legal basis (in itself) provides a high degree of certainty and effectiveness, European courts have long required that the law meet certain *quality standards* and provide guarantees against arbitrariness. A clear definition of what is expected and required of each actor is thus imperative. The law that ultimately prescribes an interference with a particular fundamental right should be accessible to the person concerned and foreseeable as to its effects (formulated with sufficient precision to enable its addresses to regulate their conduct accordingly).[185] In this sense, any AI governance framework or system on which a restriction of the freedom to conduct a business is based should be sufficiently clear, accessible, precise and foreseeable in its application and effects. In view of this, regardless of the choice made, companies need to be able to identify the acts or omissions with which they must comply and for which they may be held accountable. In other words, companies need to be reassured that they can continue to operate in the market without being exposed to the harmful and unintended consequences of AI, which can include significant fines and financial losses, in addition to a negative impact on a company's image.[186]

Of course, the complexity and changing nature of the challenges and risks posed by AI will require processes to adapt and update the regulatory framework, which raises the question of whether it is better to ensure legal certainty at the risk of creating regulatory gaps and *false negatives* or *positives*, or whether flexibility should be preferred to certainty. To give an example, while a precise definition of AI[187] is needed, the risk of being overtaken at a pace incompatible with the legislative process makes the concept of "*dynamic regulation*"[188] particularly important.

As with everything, all-or-nothing approaches need to be replaced by a fair balance between the empirical evidence of AI as a *changing reality* and the need to ensure a degree of legal certainty in this regard (especially for those affected by obligations and liability). Any changes to the regulatory framework in which the freedom to conduct a business realises itself must be contained within a predictable framework or complemented by appropriate transitional arrangements. A compromise between the "*the relative stability that law provides for long-term investment*"[189] and the updating that the adoption of delegated acts and periodic mandatory reviews ensure is to be welcomed, especially when those affected by possible changes in the regulatory framework are involved.

This leads us to another requirement of an AI governance framework in line with the freedom to conduct a business: participation and stakeholder engagement. Indeed, despite the central role of public authorities in developing and enforcing AI policy, closer collaboration between policymakers and AI stakeholders "*could encourage*

[183] Leslie et al., "Artificial intelligence," 26.
[184] De Almeida, Santos, and Farias, "Artificial Intelligence Regulation," 506.
[185] *Rotaru v. Romania* [GC], no. 28341/95, § 52, ECHR 2000-V, and *Maestri v. Italy* [GC], no. 39748/98, § 30, ECHR 2004-I.
[186] Enholm, Papagiannidis, Mikalef, and Krogstie, "Artificial Intelligence," 1723-4.
[187] De Almeida, Santos, and Farias, "Artificial Intelligence Regulation," 507.
[188] De Almeida, Santos, and Farias, "Artificial Intelligence Regulation," 507.
[189] Tuomas Mylly, "The New Constitutional Architecture of Intellectual Property", in *Global Intellectual Property Protection and New Constitutionalism: Hedging Exclusive Rights*, ed. Jonathan Griffiths and Tuomas Mylly (Oxford: Oxford University Press, 2021), 54.

innovators to engage proactively with policymakers to co-design the governance ecosystem for their inventions".[190] In other words, for any regulatory framework for AI to be effective, "*close cooperation between all stakeholders, including states, public sector bodies, civil society, and business in order to reflect diverse interests and perspectives*" must be present.[191]

A final requirement relates to investment, support and funding. We agree that "*increasing investment to strengthen basic research and scientific breakthroughs, improve AI research infrastructures, develop AI applications in key sectors, from health to transport, and facilitate the uptake of AI and access to data, is indispensable*".[192] Although this *right to support* or *participation right* ('*Teilhaberecht*') is not a *social right* derived from human dignity, the freedom to conduct a business also implies (financial) support for companies, especially in their production and research and development activities.

None of these requirements threatens a human-centred approach to AI governance. As we will see, the *European way* to AI governance, represented by the AIA proposal, proves that a balanced approach is possible and desirable, even if there is room for improvement. In the next part, we will analyse the AIA proposal, in light of its merits and minor shortcomings when read in light of the freedom to conduct a business.

6. The proposed Artificial Intelligence Act in light of the freedom to conduct a business

Like many other AI governance strategies, the EU legislator behind the AIA proposal wants to maximise the benefits of AI while mitigating its potential risks.[193] The *bright side* of AI is acknowledged in the AIA proposal, which expressly recognises that by "*improving prediction, optimising operations and resource allocation, and personalising digital solutions available for individuals and organisations, the use of artificial intelligence can provide key competitive advantages to companies and support socially and environmentally beneficial outcomes, for example in healthcare, farming, education and training, infrastructure management, energy, transport and logistics, public services, security, justice, resource and energy efficiency, and climate change mitigation and adaptation*" (Recital 3 of the AIA proposal).

However, the EU legislator is also aware that not all of the potential of AI potential is benign,[194] nor are all its actors *role models*. Both companies and "*AI can create risks for individuals and even whole societies. AI can affect fundamental values on which our societies are founded, leading to breaches of fundamental rights of the person*".[195] This means that "*depending on the circumstances regarding its specific application and use, artificial intelligence may generate risks and cause harm to public interests and rights that are protected by Union law. Such harm might be material or immaterial*" (Recital 4 of the AIA proposal).

The hybrid nature of AI is the reason for the *dual purpose* or *twin objective*[196] behind the AIA proposal (see Recital 1), which is now made clearer in the amendment proposed by the EP. In particular, the AIA is intended, i) "*to promote the uptake of human centric and trustworthy artificial intelligence and to ensure a high level of*

[190] Harasimiuk and Braun, *Regulating Artificial Intelligence*, 140.
[191] Leslie et al., "Artificial intelligence," 26. See also Koniakou, "From the «rush to ethics»," 81.
[192] Harasimiuk and Braun, *Regulating Artificial Intelligence*, 20.
[193] Roberts et al., "Governing artificial intelligence," 79. See also the Explanatory Memorandum that accompanies the AIA Proposal.
[194] Gill-Pedro, "Guest note," IV.
[195] Ruschemeier, "AI as a challenge," 362.
[196] Laux, Wachter, and Mittelstadt, "Trustworthy artificial intelligence," 1 and 4.

protection of health, safety, fundamental rights, democracy and rule of law and the environment from harmful effects of artificial intelligence systems in the Union", while ii) "*supporting innovation and improving the functioning of the internal market*" and the EU's global leadership in AI[197] and competitiveness.[198]

This balanced nature inherent in the "*introduction of hard-law mechanisms with room for innovation*"[199] is to be welcomed. Indeed, even those who call for "*structures and governance benchmarks*" that avoid "*turning fundamental values into a box you simply need to click to be on the safe side*"[200] consider that "*it is essential for legislation to strike a balance between protecting society from potential harms and allowing AI technologies to develop and advance for the benefit of society*".[201]

In addition to this balance, the AIA takes a fundamental rights-based approach. It focuses on ensuring fundamental rights and EU values as a guiding framework for '*the types of innovation that are permissible*".[202] Among the fundamental rights that are seen as *requirements* for trustworthy AI and proportionate obligations for all value chain participants are the right to human dignity (Article 1 CFREU), respect for private life and the protection of personal data (Articles 7 and 8 CFREU), non-discrimination (Article 21 CFREU), equality between women and men (Article 23 CFREU), the right to freedom of expression (Article 11 CFREU) and the right to freedom of assembly (Article 12 CFREU), the right to an effective remedy and to a fair trial, the right of defence and the presumption of innocence (Articles 47 and 48 CFREU), the general principle of good administration, as well as the rights of particularly vulnerable groups, such as the workers' rights to fair and just working conditions (Article 31 CFREU), a high level of consumer protection (Article 28 CFREU), the rights of the child (Article 24 CFREU) and the integration of persons with disabilities (Article 26 CFREU). Finally, the right to a high level of environmental protection and the improvement of the quality of the environment (Article 37 CFREU) are specifically addressed in the amendments proposed by the EP.

As regards its scope, the AIA is a holistic and horizontal regulatory approach to AI, "*meaning that it provides rules for all kinds of AI, rather than a vertical approach that focuses only on one specific aspect of AI*".[203] This avoids siloed answers or segmentation of regulatory responses.[204] It is important to note, however, that its horizontal or cross-sectoral nature is not to be confused with the regulation of AI as such, as the AIA will rather regulate the specific uses or applications of AI.[205] In particular, the "*option chosen in the AI Act was to regulate AI systems as products and thus resort to the regulatory principles underpinning EU product legislation*".[206] In other words, and as is typical of EU regulatory law, the AIA presents itself as both market-making and market-regulation.[207]

[197] Roberts et al., "Governing artificial intelligence," 82.
[198] Roberts et al., "Governing artificial intelligence," 82.
[199] Halim and Gasser, "Vectors of AI," 15.
[200] Koniakou, "From the «rush to ethics»," 79.
[201] Koniakou, "From the «rush to ethics»," 80.
[202] Roberts et al., "Governing artificial intelligence," 90.
[203] Neuwirth, "Prohibited artificial intelligence practices," 2.
[204] Koniakou, "From the «rush to ethics»," 80.
[205] Gill-Pedro, "Guest note," IX.
[206] Mazzini and Scalzo, "The Proposal," 3.
[207] Laux, Wachter, and Mittelstadt, "Three Pathways," 4.

The AIA will be a "*risk-based regulation*".[208] The proposal outlines a four-tier framework or "*pyramid of criticality*",[209] which distinguishes between uses of AI that create i) unacceptable, ii) high risk, iii) limited risk, and iv) minimal risk,[210] the latter corresponding to "*the vast majority of all existing AI systems*".[211] "When classifying AI systems according to their risk and deciding whether a particular system should be i) banned, ii) allowed but subject to various restrictions, or iii) allowed only under less burdensome conditions, the EU legislator strikes a balance between the risks and benefits posed by the AI system[212] and "*allocates regulatory burdens to AIs' providers so that the greater the risk posed by AIs, the greater the legal safeguards to minimise it*".[213] As a result, high-risk AI systems are the main target of the proposal, as they will be subject to mandatory requirements before being placed on the Union market, put into service (or used)[214] to ensure that they "*do not pose unacceptable risks to important Union public interests as recognised and protected by Union law*".[215] This tiered and differentiated approach is evidence of the internalisation of proportionality.[216]

While we are confident in the promise of the AIA and the benefits of the *European way* of regulating AI, there are three main issues that need to be addressed in light of the rapid pace of change and innovation, and in addition to the "*difficult fundamental questions about the limited value of strict prohibitions as regulatory instruments for technology and innovation*".[217]

The first is (legal) uncertainty, which "*may undermine the development of AI in Europe*".[218] As some authors acknowledge, even though the Regulation has not yet been adopted, it is important that "*businesses can predict whether their systems will be heavily regulated or not regulated at all and adapt their planning for the coming years*"[219] in order to meet the burden of ensuring that the AI systems they develop, provide, import, distribute or use comply with the requirements' set out in the AIA.[220]

This is all the more important given that private companies that fail to comply with their obligations under the AIA may be subject to administrative, civil and, in some Member States, criminal sanctions and enforcement measures,[221] including provisional measures to i) prohibit or restrict the making available or putting into service of the AI system on the national market, ii) withdraw the AI system from that market, or iii) recall it [e.g. Articles 65(5), 67(2a) and 68(2) of the AIA proposal as amended by the EP]. In light of this, risk identification and

[208] Schuett, "Risk Management," 4. See also Halim and Gasser, "Vectors of AI," 3.
[209] Johanna Chamberlain, "The Risk-Based Approach of the European Union's Proposed Artificial Intelligence Regulation: Some Comments from a Tort Law Perspective", *European Journal of Risk Regulation*, v. 14, no. 1 (2023): 1, accessed August 27, 2023, doi: https://doi.org/10.1017/err.2022.38.
[210] Roberts et al., "Governing artificial intelligence," 82.
[211] Chamberlain, "The Risk-Based Approach," 5.
[212] Chamberlain, "The Risk-Based Approach," 8.
[213] Novelli et al., "Taking AI Risks Seriously," 2.
[214] This results from the amendment by the EP.
[215] Recital 27 of the AIA proposal.
[216] Restrepo Amariles and Marcello Baquero, "Promises and limits," 9.
[217] Neuwirth, "Prohibited artificial intelligence practices," 14.
[218] Norberto N. G. de Andrade and Antonella Zarra, "Artificial Intelligence Act: A Policy Prototyping Experiment: Operationalizing the Requirements for AI Systems – Part I" (2022): 46, accessed August 27, 2023, https://openloop.org/reports/2022/11/Artificial_Intelligence_Act_A_Policy_Prototyping_Experiment_Operationalizing_Reqs_Part1.pdf.
[219] Chamberlain, "The Risk-Based Approach," 5.
[220] Gill-Pedro, "Guest note," IX.
[221] Schuett, "Risk Management," 18. See also Gill-Pedro, "Guest note," IX.

management is particularly important,[222] making guidance and concretisation of what is specifically expected of companies (not just *what*, but *how*) particularly relevant. The EU proposal for an AI Liability Directive is an improvement to be welcomed, as it not only ensures that victims of damage caused by AI obtain equivalent protection to damage caused by products in general, but it also reduces legal uncertainty of businesses regarding their possible exposure to liability, while also preventing the emergence of fragmented AI-specific adaptations of national civil liability rules.[223] However, it alone will not solve the entire problem.

Second, increasing complexity and regulatory or legal overlap threatens the freedom to conduct a business of AI providers, developers, users or deployers (most of which are private companies) and triggers positive duties of the legislator. In particular, "*the AI Act needs to be seen and understood in the context of a plurality of other EU legal frameworks*".[224] Even if these other EU legal frameworks do not regulate AI as such, there is no question that they directly or indirectly impose conditions on and shape the development and use of AI, which may lead to problems of regulatory overlap or inconsistency. In this respect, "*the proposed regulation will add complexity to the European regulatory landscape, and so impose greater burdens on AI developers and manufactures*",[225] which will be added to "*several other acts of EU law, including other pending proposals, which remain fully applicable*".[226]

While the EU legislator seems to be aware of this,[227] avoiding regulatory overlap through a holistic approach under the principles of unity[228] and one-stop-shop,[229] needs to be an ongoing exercise in light of the evolution of EU law and should take into account the requirements of "*better regulation*" (see Article 82a of the AIA proposal as put forward by the EP).

Finally, with regard to proportionality, while it is internalised in specific trade-offs between the benefits of certain AI systems and the risks they pose to fundamental rights, it is important that it is applied not only to the design of legislation, but also to its implementation. Indeed, the AIA proposal undertakes *ex-ante* and preventive harmonisation and proportionality exercises[230] through rigid risk categories that, although legitimate (given the uses at stake), must be accompanied by escape valves[231] to prevent over and under-inclusive legal rules and issues of legal loopholes and overreach.[232] In addition, special attention must be paid to small and medium-sized enterprises, for which policymakers "*should avoid*

[222] Schuett, "Risk Management," 2.
[223] See the Explanatory Memorandum accompanying the Proposal regarding the AI Liability Directive, para 1.
[224] Mazzini and Scalzo, "The Proposal," 29.
[225] Gill-Pedro, "Guest note," IX-X.
[226] Mazzini and Scalzo, "The Proposal," 13f.
[227] E.g., Recital 80 and Articles 9(9) and 29(4) and (5) of the AIA proposal with regard to regulated and supervised financial or credit institutions and the EP amendments to Articles 8(2a), 9(1), 17(1) or 40(1b) on requirements already addressed by Union harmonisation and sectoral law.
[228] See Article 11(2) on technical documentation or Article 48(3) on a single EU declaration of conformity.
[229] See Article 53(6) as amended by the EP as regards a single contact point at Union level to interact with the regulatory sandboxes and to allow stakeholders to raise enquiries with competent authorities, and to seek non-binding guidance.
[230] Novelli et al., "Taking AI Risks Seriously," 11.
[231] Novelli et al., "Taking AI Risks Seriously," 4.
[232] Marco Almada and Nicolas Petit, "The EU AI Act," 13.

raising the barriers to entry into already highly concentrated markets".[233] In light of the above, and while we recognise the complexity that may arise from concrete assessments or *escape valves* such as "*the option for revision of risk management measures based on further circumstances*",[234] we believe this is a lesser evil compared to a strict, rigid and one-size-fits-all approach.

As we will outline, we are not opposed to the AIA proposal. On the contrary, many of its solutions are actually pro-business. However, there is a certain automatism, rigidity and lack of guidance which, apart from the fact that it may not work in practice, could be improved in light of a fundamental rights approach. This could be done by introducing escape valves to ensure fairness in specific cases without affecting the essential core of the proposal.

7. The pro-business side of the EU proposal

The AIA proposal does not neglect the freedom to conduct a business or companies as subjects. Their condition is made clearer in a new Recital 1a proposed by the European Parliament, which states that the AIA should not only facilitate the distribution of the benefits of AI across society and foster innovation, but also protect individuals and companies from the risks of AI. The AIA proposal explicitly recognises that restrictions to this freedom are justified "*to ensure compliance with overriding reasons of public interest such as health, safety, consumer protection and the protection of other fundamental rights ('responsible innovation')*", and not only justified, but also "*proportionate and limited to the minimum necessary to prevent and mitigate serious safety risks and likely infringements of fundamental rights*".[235] In this regard, while some high-risk AI systems will be banned, the essence of the freedom to conduct a business would only be affected if there was no fundamental right or general interest that specifically justified this solution, and if such solution was not necessary to safeguard these rights or interests in light of a fair balance.[236]

The AIA proposal is designed to ensure that even in a highly regulated environment, companies retain some freedom. As the AIA proposal considers AI systems as products, the requirements that high-risk AI systems have to fulfil "*are laid down in the form of high-level objectives, i.e., results to be achieved or hazards to be dealt with*"[237] leaving room for different technical solutions and recognising the freedom of companies to organise themselves internally [e.g., Article 29(2) of the AIA proposal]. While this could be a problem in terms of legal uncertainty, it ensures that even in a highly regulated framework, companies retain some of their freedom to "*choose to put in place the measures which are best adapted to the resources and abilities available to them and which are compatible with the other obligations and challenges which they will encounter in the exercise of their activity*".[238] In addition, the AIA proposal recognises *ad hoc* participation and judicial rights, including the right of companies to appeal

[233] Mökander, Juneja, Watson, and Floridi, "The US Algorithmic Accountability Act," 754.
[234] Novelli et al., "Taking AI Risks Seriously," 1 (*SSRN*).
[235] See the Explanatory Memorandum that accompanies the AIA proposal, para 3.5.
[236] We are, of course, aware that this relative approach seems to confuse the principle of proportionality with the essence of a right. However, as two separate conditions or requirements, they are distinct: proportionality guides the balancing exercise, while the essence of a right provides its limits and additional content to the former as a substantive-procedural principle.
[237] Mazzini and Scalzo, "The Proposal," 6.
[238] Judgment CJEU, *Poland v Parliament and Council*, 26 April 2022, Case C-401/19, ECLI:EU:C:2022:297, para 75.

and to have their case heard by a court, as well as the right to be consulted and to present their views [e.g. Articles 45(1), 47(4), 67(4) and 70(2) as well as Article 68b as proposed by the EP]. This ensures that arbitrariness is subject to control.

The AIA proposal demonstrates that it is possible to achieve a fundamental rights-based approach in which companies and their freedom to conduct a business, on the one hand, and human beings and their rights, on the other, are not mutually exclusive. It increases legal certainty; it rationalises government intervention through clear objectives and priorities; and it ensures sufficient adaptability in terms of updating the list of risky AI.[239]

As for proportionality, it is already present in the tiered regime, where obligations depend on the risk, which means that stricter "*requirements are prescribed for suppliers and users of riskier AIs*" leaving the majority of AI uses free from regulatory burdens.[240] Most of the AIA's requirements, especially for high-risk AI systems, are not only proportionate but also feasible and clear, with concerns about their technical feasibility, particularly from the European Parliament.[241]

To give a few examples, the prohibitions in Article 5 of the AIA proposal are limited to certain harms (physical or physiological in the case of manipulative and exploitative AI systems) and/or targets (public authorities in the case of social scoring practices), not because other harms and targets should not be considered, but because a prohibition would be excessive in relation to them.[242] Regarding the testing procedures to be applied to high-risk AI systems, Article 9(6) of the AIA proposal states that they "*shall be suitable to achieve the intended purpose of the AI system and do not need to go beyond what is necessary to achieve that purpose*". The same applies to the obligation to have a quality management system in place, taking into account the size of the provider's organisation [Article 17(2) of the AIA proposal]. To continue the list of examples, *ex ante* conformity assessment prior to the placing on the market or putting into service shall be carried out in a proportionate manner, avoiding unnecessary burdens on providers and ensuring that the size of an undertaking, the sector in which it operates, its structure and the degree of complexity of the AI system in question are taken into account [Article 30(8) of the AIA proposal]. Moreover, proportionality is also present in the circumstances to be taken into account when setting the amount of administrative fines [Article 71(6) of the AIA proposal]. Finally, the EU legislator has also shown some humility in recognising that preventive balancing exercises cannot always withstand the diversity of concrete circumstances. This is the case when acknowledging that the availability of innovative technologies may sometimes justify the placing on the market or putting into service of AI systems that have not undergone a conformity assessment [Recital 68 and Article 47(1) of the AIA proposal], or when recognising that deep fakes may be underpinned by the freedom of expression and the freedom of the arts and sciences [Article 52(3) of the AIA proposal].

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[239] Novelli et al., "Taking AI Risks Seriously," 9.

[240] Gill-Pedro, "Guest note," X.

[241] See the EP's proposal for a new Article 28b(2)(d) on the obligation for providers of a foundation model to design and develop it with capabilities to measure, where technically feasible, the environmental impact that the deployment and use of the systems may have throughout their lifecycle, and Article 10(1) on quality requirements for datasets. As regards the need to ensure trustworthiness of the development process (and not only of the system requirements), see Hohma and Lütge, "From Trustworthy Principles," 905.

[242] Mazzini and Scalzo, "The Proposal," 24.

For its part, the European Parliament has improved the AIA proposal in several respects, for example by limiting the obligation for AI systems to undergo a new conformity assessment whenever a change occurs that may affect the compliance of the system with the Regulation, or when the intended purpose of the system changes. According to the EP, only "*an unplanned change* [...] *which goes beyond controlled or predetermined changes by the provider including continuous learning and which may create a new unacceptable risk and significantly affect the compliance of the high-risk AI system*" would trigger such an obligation. In addition, updates to the AI system for security reasons should in principle not constitute such a substantial change (Recital 66 as amended).

The AIA proposal also recognises that not all companies are large and powerful. Special consideration is given to small and medium-sized enterprises and start-ups [or small-scale providers and users of AI systems, as such defined in Article 3(3) of the AIA proposal].[243] Specific provisions aim at reducing the regulatory burden, lowering their costs, removing barriers to entry and supporting their activities and compliance (see *inter alia* Recitals 72, 73 and in particular Article 55 of the AIA proposal). In addition to regulatory sandboxes, small-scale providers are specifically targeted with regard to guidance on the implementation of the AIA [Article 59(7) of the AIA proposal], the development of codes of conduct taking into account their specific interests and needs [Article 69(4) of the AIA proposal], and the setting of fines [Article 71(1) of the AIA proposal].

Both the Council and the European Parliament have made proposals and amendments to take even greater account of small and medium-sized enterprises and to strengthen this "*targeted support to SMEs to reduce their costs for ensuring and demonstrating compliance*".[244] With regard to the former, the specific needs of SMEs are taken into account (see Recitals 74 and 76a), in relation to the technical documentation of high-risk systems AI (Article 11); multistakeholder governance and participation [Articles 40 and 56(3)]; derogations for specific operators (Article 55a); guidance on the practical implementation of the AIA (Article 58a), and the maximum level of administrative fines [Article 71(3), (4) and (5)].[245] The same can be said of the amendments adopted by the EP, which underline a special focus on SMEs [Recitals 5, 12a, Article 1(1)(ea)], for example with regard to contractual imbalances that particularly harm them (Recital 60a and Article 28a); the need to establish new dedicated communication channels [Recital 73 and Article 55(1c)]; exemptions and relief from certain obligations (e.g. regarding the new fundamental rights impact assessment to be carried out by deployers of high-risk AI systems before they are put into use – Recital 58a and Article 29a), and in determining the level of fines (Recital 84). The same applies to stakeholder governance [Recitals 61a and 61c and Article 58(2)]; technical documentation [Article 11(1)]; fees for third-party conformity assessment [Article 43(4a)]; free access to regulatory sandboxes (Article 53a), and guidance on the implementation of the AIA [Articles 59(7) and 82b], which appears to be mandatory for the Commission.

[243] A liability shield is also provided for in the liability regimes, this way addressing "*the fear that strict liability would stifle innovation*" – Hacker, "The European AI Liability Directives," 54.
[244] Mökander, Juneja, Watson, and Floridi, "The US Algorithmic Accountability Act," 754.
[245] Where specific reference is made to the Council's General Approach or the European Parliament's position, all the Recitals and Articles referred to can be found on those texts.

Several other provisions reflect the concern to avoid complicated, costly and permanent solutions at the expense of companies.[246] To give an example, there is a presumption of conformity with the requirements of the AIA for high-risk AI systems that comply with harmonised standards and common specifications (Article 40f of the AIA proposal), with the possibility to justify the adoption of other technical solutions (Article 41(4) of the AIA proposal). The same can be said of Article 48(3) of the AIA proposal, which provides that where "*high-risk AI systems are subject to other Union harmonisation legislation which also requires an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all Union legislations applicable to the high-risk AI system*".

Finally, the right to protection of confidential business information and trade secrets, which is not only a general principle of EU law[247] but also inherent in the freedom to conduct a business as a *freedom to compete* or *free competition*, is also explicitly protected (see *inter alia* Articles 70(1)(a) and 72(5) of the AIA proposal). The EP's amendments have been aligned with this right [see Recitals 60, 77b, 78 and 79, and Articles 23(1b), 28(2b) and 64(2), as well as Annex VII, point 4.5] through the duty of professional secrecy of the members or staff of the national supervisory authorities; the obligation to delete all confidential information upon completion of an investigation and, in general, the need for appropriate technical and organisational arrangements or measures to protect trade or business secrets.

Finally, in terms of support and incentives, "*the EU promotes research and development into AI through investment mechanisms, including InvestEU, the Digital Europe programme, the European Investment Fund, and Horizon Europe (the successor of Horizon 2020)*"[248] and is seeking to support companies by providing access to technical expertise, training and innovation services, for example through Digital Innovation Hubs.

In light of all this, it is fair to say that the AIA proposal translates into a "*more holistic framework to AI governance*"[249] that seeks to strike a fair balance between the need to mitigate the risks of AI by limiting the freedom to conduct a business of AI providers and other actors, on the one hand, and the importance of fostering innovation and the competitiveness of the EU's Internal Market by supporting the activities of companies related to the development of AI, on the other. But something more is needed for a fundamental rights-based approach.

8. Improving the proposed Artificial Intelligence Act through the freedom to conduct a business

As noted above, the AIA affects the *prima facie* content of the freedom to conduct a business in a number of ways. In addition to the prohibition of certain particularly harmful AI practices (unacceptable risk), it imposes a number of obligations and requirements on private companies as providers, deployers, users,

[246] See, *inter alia*, Judgment CJEU, *SABAM*, 16 February 2012, Case C-360/10, ECLI:EU:C:2012:85, paras 44-51.
[247] Judgments CJEU, *Interseroh Scrap and Metals Trading*, 29 March 2012, Case C-1/11, EU:C:2012:194, para 43; *Varec*, 14 February 2008, Case C-450/06, EU:C:2008:91, para 49; *SEP v Commission*, 19 May 1994, Case C-36/92 P, EU:C:1994:205, para 37, and *AKZO Chemie and AKZO Chemie UK v Commission*, 24 June 1986, Case C-53/85, EU:C:1986:256, para 28.
[248] Roberts et al., "Governing artificial intelligence," 84.
[249] Halim and Gasser, "Vectors of AI," 6 and 15.

importers, distributors and authorised representatives of AI systems (in particular, if they present what is considered to be a *high risk*). These obligations include registration, transparency and record-keeping requirements, *ex ante* conformity assessment procedures, quality management systems and post-market monitoring systems, and cover both the traditional core content of the freedom to conduct a business (the freedom to pursue and exercise an economic or commercial activity, the freedom of contract and free competition) and other dimensions, such as the freedom of commercial speech (e.g., Article 49 of the AIA proposal on the obligation to affix the CE marking to high-risk AI systems). Even if they comply with all the obligations of the AIA, economic operators responsible for AI systems presenting a (serious) risk may be required to take additional appropriate measures to ensure that the AI system concerned, when placed on the market or put into service, no longer presents that risk [Article 67(1) of the AIA proposal as amended by the EP].

While fundamental rights, proportionality and legal certainty are present in "*the entire structure of the legislative proposal and, more broadly, the most recent pieces of legislation adopted at EU level in the digital context*",[250] "*the EU's strategy has been criticized for being too focused on rigid and potentially innovation-stymieing governance measures*".[251] For our part, and without detracting from its merits, we believe that the EU legislator may have overlooked some important points. While the procedures and requirements of the AIA are legitimate as they serve to realise the fundamental rights of AI end users and to prevent the risks of AI systems in a context of uncertainty, the fundamental rights that are adversely affected (such as the freedom to conduct a business) must also be protected, in particular through appropriate procedural positions.[252] We believe that there is room for improvement in this respect (whether in the text of the proposal, which can be amended to take into account the specificities of each sector,[253] or in the application and enforcement of the AIA).

To begin with, regulating AI systems as products similar to a medical device or a toy may neglect the dynamic and complex, rather than static, nature of AI.[254] AI systems raise difficult normative questions[255] that can only be properly addressed through a fair balancing exercise in a concrete scenario. While conflict and collision scenarios can be resolved in a precautionary manner, thereby increasing legal certainty and avoiding the inherent inequality of concrete cases, balancing and weighting exercises are not all-or-nothing processes that can be fully captured in advance.

In particular, the AIA proposal defines categories of risk in advance, where the rigidity of the risk approach[256] contrasts with the fact that risk assessments "*tend to be highly circumstantial' and 'vary from case to case depending on every fact that is discernible*".[257]

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[250] Novelli et al., "Taking AI Risks Seriously," 10.
[251] Roberts et al., "Governing artificial intelligence," 85.
[252] Denninger, "Staatliche Hilfe," 639.
[253] See Article 84(7b) of the AIA proposal as amended by the EP.
[254] Andrade and Zarra, "Artificial Intelligence Act," 56.
[255] Laux, Wachter, and Mittelstadt, "Three Pathways," 21. Considering that "*what the law and ethics demand in a specific use case of an AI system cannot always be known in advance. It likewise may be subject to principled disagreement over the correct meaning of essentially contested concepts (e.g., fairness, dignity) and thus not resolvable by consensus*" – *ibid*, 9.
[256] Novelli et al., "Taking AI Risks Seriously," 2.
[257] Chamberlain, "The Risk-Based Approach," 3.

We acknowledge that the impossibility of predicting risks and the fact that the effects of AI are "*poorly, not assessable yet or not assessable at all*",[258] complicates predictive risk assessments. And we also recognise that allocating obligations according to risk categories ensures legal certainty and predictability, even for companies as AI actors.

Maintaining certainty in law is essential, yet it must not engender excessive rigidity. The law must be able to adapt to changing circumstances as they unfold.[259] In this context, although banning AI or imposing burdensome regulatory requirements on high-risk AI systems may be legitimate, justifiable and proportionate for specific uses (e.g. social scoring), a proportionality defence may be needed to avoid that the AIA (or any other legislation) is unsustainable for AIs providers or users-deployers.[260] Such a defence could be possible in the context of a ban as a general rule, while allowing companies to present arguments and substantiated evidence to the competent authorities that there is a fair balance of risks and benefits (not only for the company, of course).[261]

In addition, there are circumstances where certain obligations may represent a disproportionate result, in light of the balancing exercise *in concreto*. For example, while human oversight may justify requiring the activation of a *stop* button to halt an AI system in a safe state, there may be cases where human intervention increases risks or negatively affects the performance of the AI system [see Article 14(4)(e) of the AIA proposal as amended by the EP]. Moreover, the more specific the obligations, the less room there is for adaptation and evolutionary guidance. In other words, "*because the AIA dictates more requirements, additional questions are raised on all these requirements. This contrasts with non-prescriptive laws that have a high level of abstraction, where more is left to interpretation in practice*".[262]

What has been said is all the more important in relation to high-risk AI systems. Indeed, in its current form, the proposal may condemn providers and users or deployers of high-risk AI systems to an overly burdensome regulation with no way out. This automaticity leads some voices to advocate a "*proportionality judgement to review risk categories*".[263] Something akin to an efficiency defence would therefore be beneficial and would avoid the loss of opportunity benefits from the use of AI systems, or potential barriers to technological innovation or the densification of barriers to entry.[264] While the risk categories could be maintained in their proportionate tiered regime, the AIA would benefit from the possibility for AI providers and users or deployers to provide evidence of the disproportionate nature of certain obligations in light of their contribution to improving the

[258] Ruschemeier, "AI as a challenge," 364.

[259] *Lindon, Otchakovsky-Laurens and July v. France* [GC], nos. 21279/02 and 36448/02, § 41, ECHR 2007 IV; *Centro Europa 7 S.r.l. and Di Stefano v. Italy* [GC], no. 38433/09, § 141, ECHR 2012 and *Delfi AS v. Estonia* [GC], no. 64569/09, § 121, ECHR 2015.

[260] Novelli et al., "Taking AI Risks Seriously," 10.

[261] On the question of "which competent authorities", it is assumed that the EU level would be best placed to ensure the harmonised application and enforcement of such an escape valve. There is, of course, a risk of too much power being vested in the EU at this level. However, as this would be a mechanism limited to high-risk AI systems, it would be the exception rather than the rule. Moreover, the need to ensure stakeholder participation, to establish legitimacy and transparency, and to avoid 'regulatory capture' would also justify the EU level.

[262] Andrade and Zarra, "Artificial Intelligence Act," 56.

[263] Novelli et al., "Taking AI Risks Seriously," 11.

[264] Novelli et al., "Taking AI Risks Seriously," 15.

production or distribution of AI systems that promote technical or economic progress, while allowing society a fair share of the resulting benefits,[265] without neglecting or violating certain fundamental rights. The EP's position has made some improvements in this respect and its amendments are welcome as they make the categorisation of high risk less automatic.[266] First, the EP has proposed an amendment to require that high-risk systems pose a "*significant risk*" (see Recital 32 as amended by the EP) and has also specified what an assessment of a "*significant risk of harm*" should include, thus pointing to a holistic (and concrete) assessment. Second, a new paragraph 2a is proposed for Article 6, allowing providers falling under one or more of the critical areas and use cases listed in Annex III to submit a reasoned notification to the national supervisory authority if they consider that their AI system does not pose a significant risk and should therefore not be subject to the requirements of Title III, Chapter 2 of the Regulation.

In summary, while the rigidity and automaticity of the AIA proposal and its precautionary approach are legitimate and not necessarily open to criticism, and while the legislator's wider margin of discretion in the face of risk should be preserved, we believe that the AIA will only deliver on its promise to strike a fair balance between mitigating the risks and promoting the opportunities of AI if it is complemented by *escape valves*, some flexibility and guidance in its future application. In particular, the legislator's wider margin of appreciation and the judiciary's tolerance in controlling and supervising the (political) options of the former must not go so far as to neglect the freedom to conduct a business and the rights of private companies as actors within the AIA framework, as this could "*harm efforts to stimulate a competitive AI market*"[267] and "*run the risk of standing without suppliers of these risky yet necessary functions*".[268]

Secondly, there are obligations that are difficult to implement effectively while raising barriers to entry for small companies. Data requirements are a case in point. While they are "*important in ensuring trustworthy AI, the subjective nature of these requirements, and the absoluteness of their wording, which makes them almost impossible to achieve, leads to legal uncertainty, which in turn will have a negative impact on the development of AI in Europe*".[269] Consider, for example, the requirements for the quality of datasets set out in Article 10 of the AIA proposal. According to its paragraph 3, training, validation and test datasets used by high-risk AI systems must be relevant, representative, error-free and complete. While relevance and representativeness may be feasible, the requirements of *error-free* and completeness may be impossible to guarantee, with some already stressing the need to reformulate or translate them into use-case specific quantitative measures.[270] The EP amendment stating that these datasets should be "*appropriately vetted for errors and be as complete as possible in view of the intended purpose*" is an improvement. However, it may still contain some vagueness,[271] which is particularly worrying for SMEs in their early stages, where they are highly dependent on "*venture capitalists, who are often risk-averse with regard to*

[265] See Article 101(3) TFEU by analogy.
[266] Novelli et al., "Taking AI Risks Seriously," 2.
[267] Roberts et al., "Governing artificial intelligence," 85.
[268] Chamberlain, "The Risk-Based Approach," 4.
[269] Andrade and Zarra, "Artificial Intelligence Act," 46.
[270] Andrade and Zarra, "Artificial Intelligence Act," 46 and Hacker, "The European AI Liability Directives," 55.
[271] Andrade and Zarra, "Artificial Intelligence Act," 45.

legal disputes and quickly withdraw funding and support as soon as cases brought against the SMEs in court".[272]

Thirdly, and focusing on the proportionality of the subjective scope of the AIA proposal, it is true that there is a particular concern for SMEs. However, there are still some obligations that while "*medium or large companies might have the in-house capability for risk assessment, startups and smaller sized companies are unlikely to have comparable capabilities*" and have a "*limited 'compliance budget*" which, if used to "*draw up technical documentation might not be the most effective allocation of this budget*".[273] As the EP recognises, "*new medium-sized enterprises may sometimes lack the legal resources and training necessary to ensure proper understanding and compliance with provisions*" (Recital 73 as amended by the EP).

In addition, SMEs may be victims of the lack of democratic legitimacy of standardisation as an instrument of governance[274] and of technical or technocratic bodies[275] whose decisions on technology development and deployment are "*taken behind closed doors*".[276] In light of these two dimensions, the waiver of some specific obligations, as proposed by the Council and the European Parliament, is an opportunity not to be missed. Furthermore, it is crucial to monitor closely how standardisation and support for SMEs are actually ensured in practice. With regard to standardisation in particular, and in order to ensure a level playing field and the competitiveness of undertakings, "*it is necessary to ensure a balanced representation of interests by involving all relevant stakeholders in the development of standards*", as suggested by the EP in Recital 61 of the AIA proposal.

A fourth concern about the AIA proposal is legal certainty. We agree with those who state that, even if enacted into law, the AIA proposal "*appears incomplete without further sectoral regulation or standardization*"[277] as well as guidance and (financial) support. Indeed, while it could be argued that companies know their business model and resources better than anyone else, guidance is essential in the face of all the uncertainties that characterise the normative environment of AI.[278]

First, the definition of high risk according to its *intended use* "*creates legal uncertainty as it is a subjective category related to the provider or user of the AI system*".[279] Second, while the taxonomy of AI actors in Article 3 of the AIA proposal provides legal certainty on the allocation of responsibilities,[280] in practice roles are not always clearly delineated, as there are dynamic, intertwined and collaborative relationships.[281] This leads to the possibility that a provider may be a user when using an AI system for the functioning of its own AI system, and that a user may be a provider when setting requirements for the performance of a particular system.[282] While the EU legislator seems to recognise this in Article 28 of the AIA proposal, further guidance on the circumstances in

[272] Hacker, "AI Regulation in Europe," 5.
[273] Andrade and Zarra, "Artificial Intelligence Act," 41 and 56.
[274] Laux, Wachter, and Mittelstadt, "Three Pathways," 5.
[275] Roberts et al., "Governing artificial intelligence," 85.
[276] Koniakou, "From the «rush to ethics»," 92.
[277] Laux, Wachter, and Mittelstadt, "Trustworthy artificial intelligence," 25. See also Chamberlain, "The Risk-Based Approach," 7.
[278] Laux, Wachter, and Mittelstadt, "Three Pathways," 18.
[279] Ruschemeier, "AI as a challenge," 368.
[280] According to Mazzini and Scalzo, "The Proposal," 4, "*focusing on the key role of the provider in taking responsibility for the compliance of the AI systems ensures legal certainty, notably by avoiding any possible split or dilution of responsibilities across several actors*".
[281] Andrade and Zarra, "Artificial Intelligence Act," 25f.
[282] Andrade and Zarra, "Artificial Intelligence Act," 33.

which a distributor, importer, user (or deployer) or third party is considered to be a supplier (and other exchanges of roles) would be beneficial as to how responsibility is allocated in this respect. Third, a number of obligations are left unspecified as to how providers should comply with them. One example is risk identification, which is part of the risk management system required by Article 9 of the AIA proposal.[283] Given that the "*question of how much effort organisations need to put into identifying new risks involves a difficult trade-off*"[284] and that the balancing of "*risks and benefits involves many empirical uncertainties and difficult normative judgments*",[285] more guidance will be positive and provide legal certainty. Another example concerns technical documentation [Article 11(1) of the AIA proposal and Annex IV], the level of detail and holistic nature of which may not be fully applicable to all AI applications. Some parameters may not even be available to providers before the systems are put into service or tested in a real production environment.[286] Even obligations on transparency and human oversight may require further guidance on how to address the fact that these obligations may have different audiences.[287]

In light of the above, it is important that the AIA is complemented by sufficient, clear and objective metrics to guide the practical implementation of the Regulation. The freedom to conduct a business requires implementing and delegated acts, as well as guidance and clarification on the level of due diligence expected of operators. We believe that stakeholder engagement, metrics, standardisation (complemented by common specifications where it is not possible to provide high quality standards in all areas)[288] and certification can help to create an objective standard of what is considered appropriate behaviour for a market participant.[289] In particular, a constructive and cooperative institutionalised *regulatory dialogue* between the enforcement authorities and the companies concerned (which can take advantage of the benefits and opportunities of digital channels and queries) may not only enable the latter to understand *how* some of the obligations of the AIA can be met, but may indeed be the first step in helping the European Commission to gain insights for more general guidance based on this experience. With a view to updating the regulatory framework, it is important that the appropriate consultations carried out by the European Commission include a balanced selection of stakeholders, among them "*businesses representatives from different sectors and sizes*" (Recital 85 of the AIA proposal as amended by the EP).

In terms of AI literacy, we agree with legal scholars that it is essential that AI designers and developers have adequate ethical training, support, and encouragement to reflect on the fundamental rights implications of AI and to undertake human rights due diligence in the course of their work.[290] This may explain the EP's proposed amendment for a new Article 4b on AI literacy, mandating the Union and Members

[283] Schuett, "Risk Management," 9 and Andrade and Zarra, "Artificial Intelligence Act," 35f.
[284] Schuett, "Risk Management," 10.
[285] Schuett, "Risk Management," 13-4.
[286] Andrade and Zarra, "Artificial Intelligence Act," 48f.
[287] Andrade and Zarra, "Artificial Intelligence Act," 59f. For example, the EP's amendments to Article 52(3) on deep fakes and the obligation to disclose that the content has been artificially generated or manipulated recognise the importance of harmonised standards and specifications in this regard.
[288] Mazzini and Scalzo, "The Proposal," 10.
[289] Andrade and Zarra, "Artificial Intelligence Act," 32.
[290] Koniakou, "From the «rush to ethics»," 93.

States to promote education and training, skills and reskilling programmes for AI providers, deployers and affected persons.

Finally, as far as legal and regulatory overlaps (or contradictions) are concerned, public authorities must act within the framework of the positive duties deriving from the freedom to conduct a business. This means that, in addition to mutual recognition agreements[291] (the importance of which stems from the global nature of AI), the legislator in particular, "*will not only have the task of clarifying the relationship between the various applicable laws and regulations and improving interoperability between them, in terms of legal certainty as well, but it will also have to anticipate and manage possible feedback effects between them*".[292]

All in all, most of AIA's shortcomings demonstrate that its compliance or consistency with fundamental rights will essentially depend on whether and how its provisions are "*implemented and enforced by regulators and industry stakeholders, how the interplay among different bodies of AI relevant norms can be orchestrated, and how well-suited these draft laws are to respond to the evolving landscape of risks and opportunities associated with AI*".[293] For example, if the time-limits for operators to comply with the obligations set out in the AIA (Article 67(2) of the AIA proposal) are set at the discretion of the competent authorities, compliance with the fundamental rights of the target will depend on whether these time-limits are reasonable and take due account of the time and resources needed to implement the specific obligation, while avoiding sanctioning unavoidable non-compliance. Moreover, *ad hoc* references to restrictions on the fundamental rights of AI actors "*where (strictly) necessary*" [e.g., Article 70(4) of the AIA proposal as amended by the EP] will not be sufficient if they are not effectively implemented in full compliance with this principle of proportionality.

As much depends on implementation, high expectations are placed on regulatory sandboxes and test beds, especially when combined with a presumption of conformity with the specific requirements of the AIA, as proposed by the EP (see new paragraph 1g of Article 53 of the AIA proposal as amended by the EP). In fact, regulatory sandboxes can "*allow for more regulatory learning by establishing authorities in a controlled environment to develop better guidance and to identify possible future improvements of the legal framework through the ordinary legislative procedure*" (see Recital 72 of the AIA proposal and Article 53 as amended by the EP and Article 84(7) as regards proposals to amend the Regulation).[294]

While some improvements deserve attention, nothing justifies replacing the AIA with another legal instrument or abandoning hard law. On the contrary, we believe that the AIA proposal and the *European way* of AI governance will overcome minor shortcomings and prove that it is possible to respect and promote companies as holders of fundamental rights.

[291] For example, as regards the acceptance of test results produced by competent conformity assessment bodies, irrespective of the territory in which they are established, where necessary to demonstrate conformity with the applicable requirements of the Regulation (new Recital 65a of the AIA proposal, as amended by the EP).

[292] Halim and Gasser, "Vectors of AI," 12.

[293] Halim and Gasser, "Vectors of AI," 15.

[294] However, even the modalities for the establishment, development, implementation, functioning and supervision of the AI regulatory sandboxes may require a delegated act by the Commission [Article 53a of the AIA proposal as amended by the EP].

9. The freedom to conduct a business in the context of AI governance: concluding remarks

There is no doubt that "*AI will change many aspects of the world we live in, including the way corporations are governed*".[295] Now that the paradigm shift from non-intervention to the adoption of binding legislation is clear, companies will be expected to comply with various obligations and to align their (internal and external) processes with ethical principles and the respect for fundamental rights and public interests. Their governance structure will also be affected by the need to establish human oversight, complaint handling or redress, and stakeholder involvement.[296]

In addition, companies' fundamental rights and their *status subjectionis* to public authorities may be further compromised as a result of the use of AI to investigate, monitor and sanction the use of AI. The AIA proposal, as amended by the EP, would allow national supervisory authorities to conduct unannounced remote inspections of high-risk AI systems and to obtain samples related to high-risk AI systems through remote inspections [see Article 63(3a) and the new Article 14(4) of Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products].[297] As a result, it is fair to say that fundamental procedural rights and rights of defence have never been more in vogue [see the EP's proposal for a new Article 68b and 71(8c) and Article 18 of Regulation (EU) 2019/1020].

Although they are usually perceived as a threat, companies are social actors that engage in relations and are subject to public power in a way that requires the application of fundamental rights. AI is now part of companies' *corporate digital strategy*,[298] helping them to create business value and gain a significant competitive advantage. However, the benefits of AI applications by companies are not limited to the confines of the enterprise, just as "*the introduction of regulatory burdens, or entry barriers, on AIs' providers may weaken technological innovation and, in the case of a radical ban, resulting in the loss of opportunity for the general social interest*".[299] Businesses' activities benefit society, which allows us to conclude that an impartial approach would be preferable to a pessimistic one. This means that while we maintain that companies should not be reduced to vehicles or instruments for the pursuit of the rights and interests of others, the role they play in society is something that, far from legitimising further restrictions, makes the promotion, facilitation and investment in their activities an important and unavoidable dimension of any AI governance framework. As we have tried to show, a human-centred approach to AI is not incompatible with the requirements arising from the need to respect and promote the freedom to conduct a business as what it is: a fundamental right.

Businesses' freedom *par excellence* – the freedom to conduct a business – is a fundamental right expressly provided for in many national constitutions of EU

[295] Hickman and Petrin, "Trustworthy AI," 593.
[296] See for instance the EP's amendment, proposing a new Article 29a of the AIA proposal, on fundamental rights impact assessment for high-risk AI systems.
[297] Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011, PE/45/2019/REV/1, OJ L 169, 25.6.2019, 1-44, accessed August 27, 2023, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32019R1020.
[298] Enholm, Papagiannidis, Mikalef, and Krogstie, "Artificial Intelligence," 1730.
[299] Novelli et al., "Taking AI Risks Seriously," 23.

Member States and especially protected by the case law of the ECtHR, which updates the ECHR scope in light of the Convention as a *living instrument*. In the legal system of the EU the freedom to conduct a business is a complex right with an enormous potential for conflict and collision and with a special function in society. Nevertheless, it is a true fundamental right, anchored in Article 16 of the CFREU. Positive and negative functions can be derived from the freedom to conduct a business. They should be included in the main drivers of a fundamental rights-based AI governance.

A framework for *responsible AI governance*, as "*inextricably associated with responsible and ethical principles being embedded throughout the process of design, deployment, and evaluation*",[300] will mark a new era of AI, where companies not only have to invest financially in technological infrastructure, but also "*be able to govern the necessary resources and have thorough practices and mechanisms for orchestrating and following up on projects from ideation to completion*".[301] In the face of increasing pressure and exposure to risk and liability, companies need to consider and "*enhance their knowledge of the values protected by human rights and how those rights apply to their own actions*".[302] The alignment of companies with responsible frameworks for AI governance may be encouraged by the fact that it can also be a "*a competitive advantage for companies that deal with responsible consumers and partners*".[303] In other words, "*the use of artificial intelligence can provide key competitive advantages to companies and support socially and environmentally beneficial outcomes*" (Recital 3 of the AIA Proposal).

However, in order to ensure cultural change and avoid tick-boxing, it is important that companies can trust the regulatory environment in which they operate. Rules "*should be clear and robust in protecting fundamental rights, supportive of new innovative solutions, and enabling to a European ecosystem of public and private actors creating AI systems in line with Union values*" (Recital 5 of the AIA proposal as amended by the EP). Above all, regardless of the specific choices made in this regard, AI governance frameworks must be fair, respect the position of companies as holders of fundamental rights, and ensure that different rights and interests are reconciled and guaranteed, and that no one is left behind (including companies' rights).

As regards the EU legal order, there are high expectations for the AIA proposal. Although multilateral initiatives should not be downgraded, it can shape the future of AI governance. The AIA proposal takes a business-friendly approach and pays due attention to proportionality, legal certainty and regulatory overlaps. However, there is room for improvement, in particular with regard to its rigidity and the lack of *escape valves*. Regulatory sandboxes, implementing acts and delegated acts can help companies understand how to comply with its provisions, as well as help the EU legislator to improve and update the AIA. In any case, the AIA

[300] Enholm, Papagiannidis, Mikalef, and Krogstie, "Artificial Intelligence," 1726.

[301] Enholm, Papagiannidis, Mikalef, and Krogstie, "Artificial Intelligence," 1726, with reference to Papagiannidis et al. (2021).

[302] De Almeida, Santos, and Farias, "Artificial Intelligence Regulation," 506, referring to Smuha (2020).

[303] Mantelero, *Beyond Data*, 32. According to Jingchen Zhao and Beatriz G. Fariñas, "Artificial Intelligence and Sustainable Decisions", *European Business Organization Law Review*, v. 24 (2023): 9, accessed August 27, 2023, doi: https://doi.org/10.1007/s40804-022-00262-2, "*AI can be applied to enhance the effectiveness and efficiency of CSR programmes. The different roles of AI in this environment open up a world of possibilities for companies and their stakeholders in terms of economic value, enhancement of companies' long-term interests, or improvement in response to social, environmental and human rights challenges*".

proposal is evidence of a fair balance that can be struck between conflicting rights and colliding rights and interests.

Our conclusion is simple. A fundamental rights approach to AI governance must be a goal of general interest, not a top-down imposition. If there is no black or white, right or wrong when it comes to AI governance, the *European way* is certainly on the right track.