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Regulating AI from Europe: a joint analysis of the AI Act and the Framework Convention on AI

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ABSTRACT

In Summer 2024 two European regulatory instruments in the context of the regulation of artificial intelligence were finalised almost simultaneously. The first was the well-known the EU Regulation laying down harmonised rules on artificial intelligence (the so-called AI Act); the second the lesser known Council of Europe Framework Convention on Artificial Intelligence and Human Rights, Democracy and the Rule of Law. These regulatory instruments have some commonalities, such as their presentation as both 'principle-based' and 'risk-based'. Yet there are also questions to be asked as to how these instruments will interact in practice. These questions are particularly pressing within the global context of the competition for (regulatory) leadership on AI. This article introduces the two new European instruments against this global backdrop and compares them across three central axes: the way in which they define 'AI', the way they deal with the idea of 'risk-based' regulation and the overall structure of the regulatory regimes they envisage.

KEYWORDS European Union; Council of Europe; fundamental rights; artificial intelligence; artificial intelligence regulation; Brussels effect

1. Introduction

In March 2024, only a few days apart, the texts of two major regulatory instruments on the subject of artificial intelligence (AI) were finalised by European international organisations. The first instrument, the Artificial Intelligence Act (Regulation (EU) 2024/1689, hereinafter 'the AI Act'), which entered into force on 1 August 2024,[1] was adopted by the Institutions of the European Union (EU). It is a regulation, binding on all its Member

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[1]Regulation of the European Parliament and of the Council establishing harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain legislative acts of the European Union.

States and aiming to improve the internal market by laying down harmonised rules for trustworthy and human-centric AI in the EU. The second, the Framework Convention on Artificial Intelligence, Human Rights, Democracy and the Rule of Law (hereinafter 'the Framework Convention')[2] is a thematic fundamental rights treaty adopted under the auspices of the Council of Europe, an international organisation which has its seat in Strasbourg.

This development is part of a larger global context, in which Europe is lagging behind the United States and China in terms of research, development and innovation of artificial intelligence. In the words of the European Court of Auditors,

> Despite the EU having a strong AI public research community (the highest number of peer-reviewed scientific publications on AI in the world in 20223), it faces challenges in the global race for AI investment. Private investment in AI has been lower than in other AI-leading regions of the world (the US and China) since 2015[3]

The Regulation and the Framework Convention may be seen as European responses to the tremendous challenge of promoting innovation and competitiveness in AI in a way that is compatible with the protection of fundamental rights and the rule of law.

Both regulatory instruments are the result of a process of legislative, institutional, social, technological and economic debates that date back several years. The rationale for regulating AI is expressed clearly in the first paragraph of the European Commission's White Paper on Artificial Intelligence from February 2020:

> Artificial Intelligence is developing fast. It will change our lives by improving healthcare (e.g. making diagnosis more precise, enabling better prevention of diseases), increasing the efficiency of farming, contributing to climate change mitigation and adaptation, improving the efficiency of production systems through predictive maintenance, increasing the security of Europeans, and in many other ways that we can only begin to imagine. At the same time, Artificial Intelligence (AI) entails a number of potential risks, such as opaque decision-making, gender-based or other kinds of discrimination, intrusion in our private lives or being used for criminal purposes.[4]

The awareness among European policy-makers that we are living in an 'infosphere'[5], and in a global environment composed of interconnected

[2]Council of Europe Framework Convention on Artificial Intelligence and Human Rights, Democracy and the Rule of Law, CETS No. 225.

[3]European Court of Auditors, 'EU Artificial intelligence ambition – Stronger governance and increased, more focused investment essential going forward', Special report 08/2024, 9.

[4]European Commission, White Paper on Artificial Intelligence A European approach to excellence and trust, COM(2020)65 final, 1.

[5]Luciano Floridi, *The Fourth Revolution: How the Infosphere is Reshaping Human Reality* (Oxford: Oxford University Press UK 2014).

informational organisms[6] predates this statement. For instance, in its Statement on artificial intelligence, robotics and 'autonomous' systems of 9 March 2018 the European Group on Ethics in Science and New Technologies had already asked several questions relevant for crafting an appropriate legal answer. For instance, 'how can we make a world with interconnected AI and "autonomous" devices safe and secure and how can we gauge the risks?'. And 'how should our institutions and laws be redesigned to make them serve the welfare of individuals and society and to make society safe for this technology?'[7] In short, how can these powerful technologies be prevented from being used as tools to undermine democratic systems?

In this article we analyse and compare the two aforementioned new regulatory instruments which are meant to be (part of) the answer to questions such as these. At first sight the two have a lot in common. For instance, both instruments refer to a comparable list of principles, reflecting broad consensus within the regulatory community. The Framework Convention counts respect for human dignity and individual autonomy (Article 7), transparency and oversight (Article 8), accountability and responsibility (Article 9) and equality and non-discrimination (Article 10), among the principles each Party has to implement in relation to 'activities within the lifecycle of artificial intelligence systems' (Chapter III). The AI Act references these principles throughout the Act,[8] in particular, when it comes to the operating conditions of high-risk systems. To use the example of the oversight principle, the Act stipulates that these systems have to be 'designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which they are in use' (Article 14 paragraph 1). At the same time, precisely the commonalities, in combination with the almost simultaneous adoption, raises the question of whether these instruments will act in competition with one another or as mutual catalysts for the 'European approach' to the regulation of AI. The goal of this article is to present a first comparison of the two instruments with this question in mind.

To this end, the next Section (2) summarises their history and situates their adoption in a broader international context as a backdrop to a structured analysis of the regulatory approaches in the three subsequent Sections. We selected three axes of comparison: the need to define AI for regulatory

[6]Roger Campione, *La plausibilidad del Derecho en la era de la inteligencia artificial. Filosofía carbónica y filosofía jurídica del Derecho* (Madrid: Dykinson 2020) 13.

[7]European Group on Ethics in Science and New Technologies, Statement on artificial intelligence, robotics and 'autonomous' systems, 9 March 2018, 8.

[8]Inspired by the non-exhaustive set of requirements already suggested by the High-Level Expert Group on AI (AI HLEG) set up by the European Commission in its 2019 Ethics Guidelines for Trustworthy AI, 8 April 2019 <www.europarl.europa.eu/cmsdata/196377/AI%20HLEG_Ethics%20Guidelines%20for%20Trustworthy%20AI.pdf> accessed 29 November 2024. Recital 27 of the AI Act's Preamble references these guidelines and recalls the aforementioned overarching requirements as foundational principles for the AI Act and clarifies their meaning.

purposes (Section 3), the choice for, and the particular meaning of, a risk-based approach (Section 4) and the structure of the overall regulatory regime (Section 5). Before offering conclusion on how the instruments compare across these axes and what that means for their interaction (Section 7), we address the more specific issue of a potential 'Brussels' (or 'Strasbourg') effect of the two regulatory instruments, separately and jointly (Section 6).

2. International and supranational regulatory initiatives

2.1 In the European Union

The EU institutions have been working on a policy around AI for some years. At its meeting on 19 October 2017, the European Council concluded that, in order to successfully build a digital Europe, the EU needs, emerging trends need to be addressed urgently.

> [T]his includes issues such as artificial intelligence and blockchain technologies, while at the same time ensuring a high level of data protection, digital rights and ethical standards. The European Council invites the Commission to put forward a European approach to artificial intelligence by early 2018 and calls on the Commission to put forward the necessary initiatives for strengthening the framework conditions with a view to enable the EU to explore new markets through risk-based radical innovations and to reaffirm the leading role of its industry.[9]

This conclusion marks the start of the particular concern of the EU institutions with regard to the legal regulation of AI, the dual ambition to bolster innovation and technological development and, at the same time, protect fundamental rights and the rule of law already apparent. Several policy statements by the European Commission followed in a short time span.[10] Subsequently, prompted by several European Parliament resolutions on AI in the field of ethics, civil liability and intellectual property rights, in 2021, the Commission put forward a formal legislative proposal.[11]

One stand-out characteristic of this proposal was the definition of AI used, which deviated from the more commonly used OECD definition – that was later on reverted to – by introducing a list of techniques in an annex to the proposed regulation. The choice of definition was one of the several elements to which the Council in its proposed changes, 'to ensure that the definition of AI systems provides sufficiently clear criteria to distinguish them from other

[9]European Council meeting – Conclusions, Brussels, 19 October 2017 <www.consilium.europa.eu/media/21620/19-euco-final-conclusions-en.pdf> accessed 29 November 2024, 7.

[10]European Commission, Communication on a Coordinated Plan on Artificial Intelligence, COM/2018/795 final, Brussels 7 December 2018; European Commission, White Paper on Artificial Intelligence A European approach to excellence and trust, COM(2020)65 final, 1.

[11]European Commission, Proposal for a Regulation of the European Parliament and of the Council establishing harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain legislative acts of the Union was known, COM/2021/206 final, Brussels 21 April 2021.

more classic software systems'.[12] Other proposed amendments included a wider range of prohibited AI practices and changes to the types of application considered 'high risk'. Half a year later, the European Parliament proposed further amendments to the Commission's text,[13] including the following new definition of an AI system: 'a machine-based system designed to operate with varying levels of autonomy and capable, for explicit or implicit purposes, of generating output information – such as predictions, recommendations or decisions—that influences real or virtual environments'. It also proposed to add rules on, what were then still called 'foundational models' ('an AI system model trained on a large volume of data, designed to produce general output information and capable of adapting to a wide variety of different tasks' – later renamed 'general-purpose AI models'), as well as a significant broadening of prohibited practices.

In December 2023, the trilogues between the European Institutions involved (Parliament, Commission, Council) took place to iron out differences on issues such as the scope of the prohibition of the use of real-time remote biometric identification systems in public access spaces. As a result of highly tense, but successful and relatively quick negotiations, the European Parliament's legislative resolution of 13 March 2024 on the 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 was adopted. The final and official version of the AI Act was published in the Official Journal of the EU on 12 July 2024.

2.2 At the Council of Europe

The Council of Europe has 46 Member States and is a more traditional international organisation in the sense that it operates through treaties and conventions, the Convention for the Protection of Human Rights and Fundamental Freedoms being the best known one. This also means that the Framework Convention was viewed from a fundamental rights perspective from the beginning. The Council of Europe, over the years, has commissioned a significant amount of research on algorithms and human rights.[14]

[12] Council of the European Union, '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' (25 November 2022), adopted on 6 December 2022.

[13] 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 – C9-0146/2021–2021/0106(COD)) (Ordinary legislative procedure: first reading).

[14] E.g. Johan Wolswinkel, 'Artificial Intelligence and Administrative Law. Comparative study on administrative law and the use of AI and other algorithmic systems in Administrative Decision-Making in the member States of the Council of Europe' (CoE 2022).

The picture that emerges from this, indicates that AI will affect a large number, if not practically all, of our fundamental rights. The rights affected range from the right to personal liberty to the right to a fair trial and from strongly individualised rights such as the right to privacy and data protection to rights with a collective dimension such as the freedom of expression, the right to information, the right to science and the freedom of assembly and association. The first concrete initiative to turn this approach into regulatory action consisted of a set of basic ethical principles that should be respected when developing and establishing AI applications, including transparency, fairness and fairness, human responsibility for decision-making, security, privacy and data protection, as approved by the Parliamentary Assembly of the Council of Europe on 22 October 2020.[15] It identified the need to create a cross-cutting regulatory framework for AI, with specific principles based on the protection of human rights, democracy and the rule of law and urged the Committee of Ministers to develop a legally binding instrument regulating AI. Subsequently, on 20 May 2022, the Committee of Ministers adopted a cross-cutting approach to artificial intelligence across the various sectors of the Council of Europe, establishing the Committee on Artificial Intelligence (CAI) and entrusting it with the development of a legally binding framework on the development, design and implementation of AI systems, based on the Council of Europe's standards on human rights, democracy and the rule of law. The Committee of Ministers also decided to allow the inclusion in the negotiations of the European Union and interested non-European States that share the values and objectives of the Council of Europe, namely Argentina, Australia, Canada, Costa Rica, the Holy See, Israel, Japan, Mexico, Peru, the United States of America and Uruguay. The Council of Europe involved non-state actors in the negotiations: a total of 68 representatives of civil society and industry participated as observers, intervening together with States and representatives of other international organisations, such as the Organization for Security and Cooperation in Europe (OSCE), the Organization for Economic Cooperation and Development (OECD), the United Nations Educational, Scientific and Cultural Organization (UNESCO) and relevant Council of Europe bodies and committees. The European Union also participated in the negotiations, represented by the European Commission, as well as by representatives of the European Union Agency for Fundamental Rights (FRA) and the European Data Protection Supervisor (EDPS). Although accusations were made that NGOs were excluded from the negotiations, allegedly because the United States refused to share certain information with non-state participants, the

[15]Parliamentary Assembly, Need for democratic governance of artificial intelligence, Resolution 2341 (2020).

Council of Europe justified the process by arguing that the way the draft was developed – discussing it first behind closed doors among state participants and only publishing it and discussing it in plenary afterwards – was in accordance with existing rules and practices.[16] The final result was the aforementioned Framework Convention on Artificial Intelligence, Human Rights, Democracy and the Rule of Law, which was opened for signature during the Conference of Ministers of Justice of the Council of Europe held in Vilnius on 5 September 2024 and has been signed by Andorra, Georgia, Iceland, Norway, Moldova, San Marino, the United Kingdom, Israel, the United States and the European Union.

2.3 Other international initiatives and agreements on the regulation of artificial intelligence

In a context of greater globalisation, the 36 member countries of the OECD, together with Argentina, Brazil, Colombia, Costa Rica, Peru and Romania, signed the OECD Principles on Artificial Intelligence on 22 May 2019 and embraced the OECD definition of an AI system:

> machine-based system that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments. Different AI systems vary in their levels of autonomy and adaptiveness after deployment.[17]

The OECD Principles indicate that AI must be at the service of people and the planet, promoting inclusive growth, sustainable development and well-being. Furthermore, AI systems should be designed in a way that respects the rule of law, human rights, democratic values and diversity, and incorporate appropriate safeguards – for example, by allowing human intervention where necessary – with a view to ensuring a just and equitable society. They should also be governed by transparency and responsible disclosure to ensure that people know when they are interacting with them and can object to the results of that interaction. These systems need to operate robustly, reliably and safely throughout their lifetime, and potential risks should be assessed and managed at all times. Finally, organisations and individuals who develop, deploy, or manage AI systems must be held accountable for their proper functioning in line with the above principles. The OECD recommends that governments facilitate public and private investment in research and development that stimulates innovation in trustworthy AI,

[16]Victoria Hendrickx and Wannes Ooms, 'An interview with KCDS-CiTiP Fellow Jan Kleijssen on the AI Convention of the Council of Europe' (CiTiP, 23 May 2023) <https://lirias.kuleuven.be/retrieve/714817> accessed 29 November 2024.

[17]OECD, Recommendation on Artificial Intelligence (OECD/LEGAL/0449, 2019, amended 2023).

that they foster accessible AI ecosystems with digital technologies and infrastructure, and mechanisms for data and knowledge sharing; developing a policy environment that paves the way for the deployment of reliable AI systems, and that they train people with AI skills and support workers to ensure a fair transition and cooperate in sharing information across countries and sectors, develop standards and ensure responsible management of AI.

A second international initiative worth mentioning is the global agreement reached by the United States, China, the European Union and 26 other countries on 1 and 2 November 2023, to advance scientific cooperation and try to curb the potential 'catastrophic' dangers of AI. The so-called Bletchley Declaration[18] recognises that, in the context of AI, human rights protection, transparency and explainability, equity, accountability, regulation, security, appropriate human oversight, ethics, bias mitigation, privacy, and data protection need to be addressed. To those ends, it was agreed to establish an inclusive international network of scientific research on AI frontier security that encompasses and complements existing and new instances of international collaboration, and to facilitate the provision of the best available science for policymaking and the public good. In addition, and in recognition of the positive transformative potential of AI, and as part of ensuring broader international cooperation on AI, resolve to maintain an inclusive global dialogue involving existing international forums and other relevant initiatives and openly contributing to broader international discussions, and to continue research on AI security at borders to ensure that the benefits of the technology can be used responsibly for the good of all. The Declaration has been unevenly received, mainly because of the voluntary nature of the measures.[19]

3. Defining AI for regulatory purposes

In the short history of AI,[20] various definitions have been proposed which tend to refer to the development of systems that imitate or reproduce human thought and action, act rationally, and interact with the environment. AI aims to synthesise or reproduce human cognitive processes, such as perception, creativity, comprehension, language, or learning.[21] In order to

[18] IThe Bletchley Declaration by Countries Attending the AI Safety Summit (1–2 November 2023) <www.gov.uk/government/publications/ai-safety-summit-2023-the-bletchley-declaration/the-bletchley-declaration-by-countries-attending-the-ai-safety-summit-1-2-november-2023> accessed 29 November 2024.

[19] D. Leslie, C. Ashurst, N.M. González, F. Griffiths, S. Jayadeva, M. Jorgensen, M. Katell, S. Krishna, D. Kwiatkowski, C.I. Martins, S. Mahomed, C. Mougan, S. Pandit, M. Richey, J.W. Sakshaug, S. Vallor, y L. Vilain, 'Frontier AI, Power, and the Public Interest: Who Benefits, Who Decides?' [2024] Harvard Data Science Review (Special Issue 5) <https://doi.org/10.1162/99608f92.4a42495c> accessed 29 November 2024.

[20] The term 'AI' is usually traced back to a workshop held at Dartmouth College in New Hampshire (US) in 1956, the Dartmouth Summer Research Project on Artificial Intelligence.

[21] Stuart Russell and Peter Norvig, *Artificial Intelligence: A Modern Approach* (4th global edition, Pearson 2022).

achieve this, AI uses all the tools at its disposal, including those provided by computing, including algorithms. However, AI systems do not use just any algorithm but preferentially those that 'learn' based on data processing.

The many versions of a definition of AI that have been proposed throughout the legislative history of the AI Act reflect the difficulty of offering a 'definite' definition of AI, especially for legal purposes.[22] The original Commission proposal for an AI Act from 2021 made an attempt to design a definition from scratch as it contained the following wording:

> "artificial intelligence system" (AI system) means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with. (Article 3)

The idea behind this definition was that the list of techniques and approaches would be 'kept up-to–date in the light of market and technological developments through the adoption of delegated acts by the Commission to amend that list',[23] but it was widely considered to be too broad.

As part of the amendments approved by the European Parliament on 14 June 2023, the definition changed to 'a machine-based system that is designed to operate with varying levels of autonomy and that can, for explicit or implicit objectives, generate outputs such as predictions, recommendations, or decisions, that influence physical or virtual environments'.[24] In the text as it was finally adopted, the EU legislator settled on

> a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments. (Article 3 paragraph 1)

Before this provision enters into force on 2 February 2025 the European Commission is expected to publish guidelines to further clarify the meaning and scope of this definition (Article 96).[25]

[22] Wolfgang Hoffmann-Riem, 'Artificial Intelligence as a Challenge for Law and Regulation' in Thomas Wischmeyer and Timo Rademacher (eds.), *Regulating Artificial Intelligence* (Springer International Publishing 2020), 1–29; Ubena John, 'Can Artificial Intelligence be Regulated? Lessons from Legislative Techniques' in *Nordic Yearbook of Law and Informatics 2020–2021 Law in the Era of Artificial Intelligence* (The Swedish Law and Informatics Research Institute 2022), 273–94.

[23] Preamble Commission proposal, Recital 6.

[24] 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 – C9-0146/2021–2021/0106(COD)) (Ordinary legislative procedure: first reading).

[25] The Commission is partly basing these guidelines on the results of a stakeholder survey: <https://ec.europa.eu/eusurvey/runner/Prohibitions-and-Definition-Survey-2024> accessed 29 November 2024.

The Preamble to the AI Act highlights that their ability to infer is a key characteristic of AI systems. This inference refers to 'the process of obtaining the output such as predictions, content, recommendations, or decisions, which can influence physical and virtual environments, and to a capability of AI systems to derive models or algorithms, or both, from inputs or data'.[26] As examples of techniques that enable inference the Preamble mentions 'approaches that learn from data how to achieve certain objectives, and logic- and knowledge-based approaches that infer from encoded knowledge or symbolic representation of the task to be solved'. This is to say that '[t]he capacity of an AI system to infer transcends basic data processing by enabling learning, reasoning or modelling'.[27] The other elements of the definition are either relatively straightforward, such as the term 'machine-based', which refers to the fact that AI systems work through computers, or display a degree of flexibility, such as 'may exhibit adaptiveness' (self-learning capabilities), 'varying levels of autonomy' and 'explicit or implicit objectives'.

This definition substantively, although with slight variations in the exact formulation, coincides with that adopted by the Framework Convention, which defines 'artificial intelligence system' as

> a machine-based system that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations or decisions that may influence physical or virtual environments. Different artificial intelligence systems vary in their levels of autonomy and adaptiveness after deployment[28]

As set out in an explanatory document ('Explanatory Report'), which the CoE published alongside the Convention, this definition of an artificial intelligence system is drawn from the latest revised definition adopted by the OECD on 8 November 2023.[29] Interestingly, the Explanatory Report explicitly mentions that the choice of drafters to use this particular text is significant because of the need to enhance international cooperation on the topic of artificial intelligence and facilitate efforts to harmonise AI governance globally. Harmonising relevant terminology represents an important step in this process. In subsequent paragraph the Explanatory Report stays very close to the text of the Preamble of the AI Act, reflecting close cooperation between the EU and the CoE in the final drafting stages. Both documents include the phrase that 'simpler […] systems that are based on the rules defined solely by natural persons to automatically execute operations' should not be included

[26]Recital 12.
[27]Ibid.
[28]Article 2 Framework Convention.
[29]Explanatory Report to the Council of Europe Framework Convention on Artificial Intelligence and Human Rights, Democracy and the Rule of Law (Vilnius 5 September 2024).

in the definition.[30] The definitions aim contribute to legal accuracy and certainty, whilst allowing for some flexibility to incorporate future developments of the technology. Yet, all elements of the definition, as well as the clarifying phase from the Preamble (in the case of the AI Act) and the Explanatory Report (in the case of the Framework Convention), will need further interpretation and clarification. As far as the AI Act is concerned, to some extent, this has come from the February 2025 Guidelines by the European Commission,[31] for another part – since the first court cases are not expected until some time in the future, at least as far as the higher courts are concerned – the stakeholder community will play some role in this.[32] This process of interpretation and clarification can be expected to play a role in the finetuning of the definition of the Framework Convention, but, naturally, this latter instrument emphasizes that the definition merely provides a common understanding among Parties as to what AI systems are, and Parties may specify it further in their national legal systems.

4. A risk-based approach to AI regulation?

The regulation of AI, as conceived in Europe, albeit not only there, proclaims to rely on a risk-based approach, which adjusts the type of rules and their content to the intensity and scope of risks that AI systems may generate. This approach is connected to the well-known 'precautionary principle', which guides the regulatory activities of the European Union. Although this principle is not explicitly mentioned in the preamble of the AI Act, it is part of two recent resolutions of the European Parliament, which are related to the subject matter at hand. In a resolution from 2017, which focuses on civil law rules on robotics,[33] the European Parliament calls for research activities in the field of robotics to be carried out in accordance with the precautionary principle, anticipating the potential safety impacts of their results and taking appropriate precautions, depending on the level of protection, while promoting progress for the benefit of society, and the environment. In 2020, in a resolution on the ethical aspects of artificial intelligence, robotics and related technologies, the European Parliament states that the precautionary principle should be at the heart of any regulatory framework for artificial intelligence.[34]

[30]Recital 12, Preamble AI Act; Paragraph 24 Explanatory Report.
[31]European Commission, Guidelines on the definition of an artificial intelligence system established by AI Act, Brussels 6 February 2025.
[32]For instance, the NGO Algorithm Audit published the following guidance document: Algorithm Audit, 'Definition of an AI system under the AI Act. Discover the answer by answering three questions: To be or not to be an AI system' <https://algorithmaudit.eu/pdf-files/technical-tools/AIA-Implementation-Tool/20241118_AI_definition_carrousel.pdf> accessed 29 November 2024.
[33]European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL)), par. 7 and 23.
[34]European Parliament resolution of 20 October 2020 with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies (2020/2012(INL)), par 3.

It has been argued that, in short, relying on predefined risk categories, as the AI Act does, cannot amount to true risk-based regulation.[35] Another point of criticism in this regard is that the understanding of 'risk' in the AI Act is simply too limited in scope.[36] Indeed, as the analysis in this Section will show, the EU legislator was faced with a trade-off that was absent from the negotiations about the Framework Convention: the goal to offer clarity to providers of AI systems, an important component of EU product safety legislation, undermined the risk-based approach to some extent.

The AI Act defines risk as the combination of the probability of an occurrence of harm and the severity of that harm (Article 3 paragraph 2). In some cases the risk is deemed unacceptable by the EU legislator, resulting in a ban on AI practices (Chapter II). In other cases, AI systems are characterised as 'high risk' because they are capable of causing harm to the health, safety or fundamental rights of natural persons (Chapter III). They will only be allowed to enter the European market if they comply with certain mandatory requirements. This will be established as part of a conformity assessment procedure based on harmonised standards developed by standard-setting bodies, as is common in legislation which takes the 'New Legislative Framework' approach.[37] The requirements which these standards are meant to operationalise are listed in the AI Act itself. They consist of the following categories: risk management (Article 9), data quality (Article 10), technical documentation (Article 11) and record-keeping (or: 'logging', Article 12), transparency vis-à-vis deployers (Article 13), human oversight (Article 14), and robustness, accuracy and cybersecurity (Article 15).

As for the first category, risk management, it should be emphasized that – in line with the 'value chain approach' which so expressly plays a role in the final text of the AI Act – this concerns a continuous, iterative processthat is planned and run throughout the entire lifecycle of a high-risk AI system (Article 9 paragraph 2). The steps it consists of are subsequently listed:

(a) the identification and analysis of the known and the reasonably foreseeable risks that the high-risk AI system can pose to health, safety or fundamental rights when the high-risk AI system is used in accordance with its intended purpose;

[35]Martin Ebers, 'Truly Risk-based Regulation of Artificial Intelligence How to Implement the EU's AI Act' (2024) *European Journal of Risk Regulation* 4.

[36]Isabel Kusche, 'Possible Harms of Artificial Intelligence and the EU AI Act: Fundamental Rights and Risk' (2024) *Journal of Risk Research*.

[37]Marta Cantero Gamito and Christopher Marsden, 'Artificial Intelligence Co-Regulation? The Role of Standards in the EU AI Act' (2024) 32 *International Journal of Law and Information Technology*; Alessio Tartaro, 'Regulating by Standards: Current Progress and Main Challenges in the Standardization of Artificial Intelligence in Support of the AI Act' [2023] *European Journal of Privacy Law and Technologies* 147.

(b) the estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose, and under conditions of reasonably foreseeable misuse;
(c) the evaluation of other risks possibly arising, based on the analysis of data gathered from the post-market monitoring system referred to in Article 72;
(d) the adoption of appropriate and targeted risk management measures designed to address the risks identified pursuant to point (a).

The Framework Convention also provides for a legal framework for risk and impact management (Article 16), imposing on Parties the obligation to adopt or maintain measures for the identification, assessment, prevention and mitigation of the risks posed by artificial intelligence systems, by considering actual and potential impacts to human rights, democracy and the rule of law. These measures have to be 'graduated and differentiated, as appropriate' and consider the following factors: the context and intended use of artificial intelligence systems, the severity and probability of potential impacts, and the perspectives of relevant stakeholders, in particular persons whose rights may be impacted. They should apply iteratively throughout the activities within the lifecycle of the artificial intelligence system, include monitoring, documentation of risks, actual and potential impacts, and the risk management approach, and require, where appropriate, testing of artificial intelligence systems before making them available for first use and when they are significantly modified. This variety of a 'risk-based approach to AI' differs from the one chosen in the AI Act. For this latter instrument, the choice for product safety regulation, implies the necessity to establish risk categories 'ex ante', in order to be able to construe a mechanism for approval of systems for entrance to the European internal market.[38]

Finally, Parties to the Framework Convention commit to assessing 'the need for a moratorium or ban or other appropriate measures in respect of certain uses of artificial intelligence systems where it considers such uses incompatible with the respect for human rights, the functioning of democracy or the rule of law' (Article 16 paragraph 4). This formulation deviates from the one proposed in the 'zero draft' of the Framework Convention according to which each Party had to have the possibility to impose a ban on harmful AI systems, an obligation which would have been hard to comply with for EU Member States, faced with an AI Act that fully harmonises prohibited AI practices.

[38]For more on the choice for product safety regulation, see Marco Almada and Nico Petit, 'The EU AI Act: A Medley of Product Safety and Fundamental Rights?' (Robert Schuman Centre for Advanced Studies Research Paper 2023/59), 13.

5. The structural differences between the AI Act and the Framework Convention

Both the AI Act and the Framework Convention were drafted and negotiated in a relatively short period of time. This did not prevent the responsible authorities from coordinating the respective processes. In fact, the Committee of Ministers of the Council of Europe decided to allow for the inclusion of the European Union, as represented by the European Commission with delegates from the European Union Agency for Fundamental Rights and the European Data Protection Supervisor, in the negotiations of the Framework Convention. Article 27 paragraph 2 of the Framework Convention acknowledges the special relationship between the two regulatory instruments by stating that

> Parties which are members of the European Union shall, in their mutual relations, apply European Union rules governing the matters within the scope of this Convention without prejudice to the object and purpose of this Convention and without prejudice to its full application with other Parties.

Important structural differences between the two instruments remain though. First of all, the scope of application of the AI Act is regional. It applies to the territory of the European Union, with an extension to 'providers and deployers of AI systems that have their place of establishment or are located in a third country, where the output produced by the AI system is used in the Union' (Article 2 paragraph 1-c) and regardless of the fact that it may generate, as discussed below, a 'Brussels effect'. The Framework Convention has a global reach, both in its nature as a treaty under international law and in its express ambition – the Preamble invokes the

> need to establish, as a matter of priority, a globally applicable legal framework setting out common general principles and rules governing the activities within the lifecycle of artificial intelligence systems that effectively preserves shared values and harnesses the benefits of artificial intelligence for the promotion of these values in a manner conducive to responsible innovation.

The wide geographical scope of the Framework Convention is also apparent in Article 30 paragraph 1, which stipulates that it shall be open for signature by the member States of the Council of Europe, the non-member States which have participated in its elaboration and the European Union.

Secondly, whereas the Regulation, in accordance with Article 288 of the Treaty on the Functioning of the European Union, 'shall be binding in its entirety and directly applicable in all Member States'; the Framework Convention will be binding on the States which sign and ratify it. This difference in legal effect is also apparent in the respective addressees of the regulatory instruments: States for the Framework Convention and (primarily) providers and deployers for the AI Act.

Thirdly, the Regulation consists of lengthy and numerous provisions (a 44-page Preamble, 113 Articles and XIII Annexes), containing detailed norms – to which the harmonised standards and various codes of practice will still be added to complete the EU regulatory framework. The Framework Convention on the other hand is much shorter (a two-page Preamble and 36 Articles) and, of course, less detailed. The Convention itself highlights its 'framework character […], which may be supplemented by further instruments to address specific issues relating to the activities within the lifecycle of artificial intelligence systems' (paragraph 11 of the Preamble).

Fourthly, the AI Act, generally speaking, contains more rules, in the sense of prescriptive norms aimed to regulate concrete practices around AI.[39] The Framework Convention, on the other hand, adopts a more principle-based approach, by imposing obligations which can incorporate different degrees of compliance. For example, the Regulation establishes a series of AI practices that will be prohibited (Article 5) and imposes obligations that must be complied with by providers and deployers (Article 26) of high-risk systems. For its part, the Framework Convention provides (Article 4) that '[e]ach Party shall adopt or maintain measures to ensure that the activities within the lifecycle of artificial intelligence systems are consistent with obligations to protect human rights, as enshrined in applicable international law and in its domestic law'.

Fifthly, and following from the previous difference, the Regulation imposes obligations of means as well as obligations of result while the Framework Convention includes, essentially, obligations of result, leaving it to the States to specify the appropriate measures to achieve them. For example, the Regulation provides that high-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which they are in use (Article 14 paragraph 1). Another example of a norm which entails an obligation of means can be found in Article 20 paragraph 1 AI Act: 'Providers of high-risk AI systems which consider or have reason to consider that a high-risk AI system that they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective actions to bring that system into conformity, to withdraw it, to disable it, or to recall it, as appropriate'. The focus of the Framework Convention on obligations of result is apparent from Article 1 paragraph 2 which stipulates that '[e]ach Party shall adopt or maintain appropriate legislative, administrative or other measures to give effect to the provisions set out in this Convention. These measures shall be graduated and differentiated as

[39]On the preference for rules over ethical guidelines in the final AI Act, see Hannah Ruschemeier and Jascha Bareis, 'Searching for harmonised rules: Understanding the paradigms, provisions and pressing issues in the final EU AI Act' (SSRN 2024).

may be necessary in view of the severity and probability of the occurrence of adverse impacts on human rights, democracy and the rule of law throughout the lifecycle of artificial intelligence systems'. An example of such an obligation may be found in Article 5 paragraph 1 Framework Convention:

> [e]ach Party shall adopt or maintain measures that seek to ensure that artificial intelligence systems are not used to undermine the integrity, independence and effectiveness of democratic institutions and processes, including the principle of the separation of powers, respect for judicial independence and access to justice.

Finally, as a final structural difference, the AI Act contains a system of sanctions. Provisions regarding these sanctions are spread across many Articles. However, the main provision to mention here is Article 99 paragraph 1:

> Member States shall lay down the rules on penalties and other enforcement measures, which may also include warnings and non-monetary measures, applicable to infringements of this Regulation by operators, and shall take all measures necessary to ensure that they are properly and effectively implemented […]. The penalties provided for shall be effective, proportionate and dissuasive.

The article subsequently specifies the amount of administrative fines to be imposed, which are significant.

For its part, the Framework Convention merely provides that '[e]ach Party shall establish or designate one or more effective mechanisms to oversee compliance with the obligations in this Convention' (Article 26 paragraph 1). However, since the Framework Convention is an international treaty, depending on the rules of the national legal system with respect to the application of international law, national courts may declare violations of certain provisions. For many signatories, this will mean that courts or other authorities will have to determine whether the Framework Convention's provisions are precise enough to be considered self-executing. In any case, the Framework Convention will likely function as an interpretative document for the European Court of Human Rights (ECHR),[40] which is not mentioned in the treaty text, which instead provides for a 'Conference of the Parties' as a dispute resolution mechanism (Article 23).

6. A 'Brussels effect' or a 'Strasbourg effect'?

In a well-known article published in 2012,[41] followed by a monograph in 2020,[42] Anu Bradford explained how and why the regulatory output from

[40] Jacques Ziller, 'The Council of Europe Framework Convention on Artificial Intelligence vs. the EU Regulation: Two Quite Different Legal Instruments' (CERIDAP 2/2024), 202.
[41] Anu Bradford, 'The Brussels Effect' (2012) 107 *Northwestern University Law Review* 1.
[42] Anu Bradford, *The Brussels Effect: How the European Union Rules the World* (OUP 2020).

'Brussels', the city home to many of the institutions of the European Union, has penetrated many aspects of economic life inside and outside Europe through the process of 'unilateral regulatory globalisation'. This phenomenon occurs when a state or a supranational organisation is able to externalise its laws and regulations outside its borders through market mechanisms, so without actively imposing them.[43]

The EU's internal market power, coupled with renowned regulatory institutions, obliges foreign companies wishing to participate in that market to adapt their conduct or production to EU standards, which tend to be stricter than in other markets; the alternative is to renounce that market, which does not seem a reasonable option. Bradford explains that multinational companies often have an incentive to standardise their production on a global scale and adhere to a single standard. This turns the EU standard into a global standard: the 'de facto Brussels effect'. Once these export-oriented companies have adjusted their business practices to meet the EU's standards, they often have an incentive to pressure their governments to adopt those same standards in an effort to level the playing field vis-à-vis non-exporting domestic firms: the 'de iure Brussels effect'.[44]

The expectation that the European regulation of AI would generate, in line with what has happened in areas such as privacy and data protection, a 'Brussels effect' of sorts has been floated. However, Bradford herself has been skeptical about this because of the specific nature of AI as an adaptive technology.[45] Marco Almada and Anca Radu, too, question the potential of the AI Act to have real normative impact beyond the EU territory.[46] The consensus in the literature appears to be that in the case of AI regulation the impact of the 'Brussels effect' will be less than in other areas.[47] One important question is how the EU's active efforts to shape alternative instruments, notably the Framework Convention, will play out in this regard. Will the Framework Convention accelerate a potential dissemination of the AI Act as a global standard or, rather, reduce it to the regional instrument it currently is as a 'de iure' matter?

In addition to a 'Brussels effect' one could also speak of a possible 'Strasbourg effect', this city being the seat of the institutions of the Council of Europe. In the case of this treaty, as described above, the European Union

[43] Anu Bradford, 'The Brussels Effect' (2015) 107 *Northwestern University Law Review* 1, 10.
[44] Bradford 2012 (n 41) 7.
[45] Anu Bradford, *Digital Empires. The Global Battle to Regulate Technology* (OUP 2023).
[46] Marco Almada and Anca Radu, 'The Brussels Side-Effect: How the AI Act Can Reduce the Global Reach of EU Policy' (2024) 24 *German Law Journal* 646.
[47] Lily Ballot Jones, Julia Thornton and Daswin De Silva, 'Limitations of Risk-Based Artificial Intelligence Regulation: A Structuration Theory Approach (2025) *Discov Artif Intell* 5, 14; Judith Arnal and Raquel Jorge Ricart, 'Inteligencia artificial (I): menor «efecto Bruselas», las posibles consecuencias desglobalizadoras de un enfoque regulatorio divergente y la importancia de políticas públicas para el empleo' (Real Instituto Elcano 2023), 88; 'The AI Act in perspective', The Tech Brief, podcast 26 January 2024.

and non-European States were included in the negotiations in the process of drafting the Framework Convention (Argentina, Australia, Canada, Costa Rica, the Holy See, Israel, Japan, Mexico, Peru, the United States of America and Uruguay), as well as representatives of other international organisations, such as the Organization for Security and Cooperation in Europe (OSCE), the Organization for Economic Cooperation and Development (OECD) and the United Nations Education Organization, Science and Culture (UNESCO).

Because of the global ambitions of the Framework Convention, and the power that technology companies yield precisely at this level, it is necessary to ensure that the private sector is not completely outside of its scope. The compromise reached in the negotiations is that signatory states can choose between applying CIA standards to private actors directly or, rather, in another way but taking into account the objectives of the Convention (Article 3 – paragraph 1b).

In addition, Article 25 paragraph 1 of the Convention encourages Parties, as appropriate, to assist States not Parties to the Convention to act in accordance with its provisions and to become Parties to the Convention. Article 31 paragraph 1 provides that, after the entry into force of the Framework Convention, the Committee of Ministers of the Council of Europe may, after consulting the Parties and obtaining their unanimous consent, invite any State not a member of the Council of Europe which has not participated in the drafting of the Convention to accede to it by a decision adopted by the majority provided for in Article 20(d) of the Statute of the Council of Europe. Europe, and by unanimity of the representatives of the Parties entitled to sit on the Committee of Ministers. In conclusion, the mechanism of a potential 'Strasbourg effect' will work in a very different way as compared to any possible 'Brussels effect', namely as a framework for collective transnational learning. However, given the last minute efforts to align the AI Act and the Framework Convention as much as possible, the latter will not stand in the way of any 'Brussels effect' or the AI Act – however limited as expert consensus now predicts – either.

7. Concluding remarks

The regulatory instruments introduced in this article will need substantial implementation before it will be possible to answer the larger questions motivating our analysis in a more definitive matter. However, on the basis of our delineated analysis across three selected axes, we are able to draw some first conclusions as to the interaction between the two instruments, as well as their expected combined effects on the global stage. Although the issue of defining AI for legal purposes is still riddled with complications, the alignment of the definition across the two instruments (see Section 3) at

least focuses the debate and offers incentives for concretisation, such as through the European Commission's Guidelines. The observed differences in the meaning of 'risk-based' AI regulation (see Section 4) is to some extent inevitable. The, perhaps counterintuitive, finding that the Framework Convention adheres to a 'truer' form of risk-based regulation may have a positive impact on the EU legislator's alertness to new risks associated with AI systems. The many structural differences (see Section 5) are also unavoidable. However, in this respect, too, the concrete tensions that are bound to arise, for instance when an EU Member State considers that following an AI Act related standard is not sufficient to fulfil the obligations under the Framework Convention, can ultimately serve to improve the legal environment.

The Council of Europe's Framework Convention on AI expressly recognises that its principled approach requires concretisation, and the European Commission has done everything in its power to position the AI Act as a blueprint for this concretisation. At the same time the Framework Convention offers an important self-standing normative contribution to the regulation of AI. For all Parties, it integrates principles of responsible AI into the legal sphere. These legal principles have great potential in the hands of legal actors who can distill specific rules and obligations from them, as has been the case for decades with the principles relating to data protection. In addition, the Framework Convention grants data subjects affected by AI certain procedural rights, such as the right to lodge a complaint to competent authorities (Article 14 paragraph 2). Furthermore, the fact that it is not limited to high-risk AI systems will help a culture of continuous risk assessment, also in EU jurisdictions bound by the AI Act. The fine line between the EU Institutions' desire to position the AI Act as the exclusive means of implementing the Framework Convention[48] and the Framework Convention's basic tenet that signatories will be able to do whatever necessary to address harms and risks associated with AI as they appear, has found expression in Article 27 paragraph 2:

> Parties which are members of the European Union shall, in their mutual relations, apply European Union rules governing the matters within the scope of this Convention without prejudice to the object and purpose of this Convention and without prejudice to its full application with other Parties.

For non-EU Member States, the Framework Convention on AI can play an important role as reference point for domestic regulatory and legal frameworks. And for EU Member States that, the Framework Convention has

[48]Council Decision (EU) 2024/2218 of 28 August 2024 on the signing, on behalf of the European Union, of the Council of Europe Framework Convention on Artificial Intelligence and Human Rights, Democracy and the Rule of Law: 'The Convention is to be implemented in the Union exclusively through Regulation (EU) 2024/1689 and other relevant Union acquis, where applicable'.

the potential to complement and even strengthen the protection of rights, by providing a broader normative framework which on the one hand accepts the AI Act as the primary legal instrument, but on the other invites to keep testing its regulatory choices for their continuing soundness from a fundamental rights perspective.

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