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Between Regulatory Fixity and Flexibility in the EU AI Act

Draft paper from January 26th, 2024.

By Stefan Larsson¹, Jockum Hildén² and Kasia Söderlund³.

Abstract

The EU AI Act aims to regulate artificial intelligence (AI) in a way that balances innovation and protection from harms, but faces the challenge of keeping pace with the fast and dynamic development of AI. This paper examines the tension between fixity and flexibility when regulating emerging technologies, drawing on literature on the so-called pacing problem, contrasted by sociolegal theory on the importance of predictability and legal certainty, as a basis to address recent changes in the regulatory AI landscape. Specifically, it analyses how the EU AI Act employs various mechanisms of flexibility, such as i) voluntary measures and codes-of-conduct, ii) delegated and implementing acts, and iii) harmonised standards to cope with the uncertainty and complexity of AI – potentially at the expense of predictability. The study therefore focuses primarily on how the AI Act addresses the emergence of *general-purpose AI* and *generative AI*, to illustrate challenges associated with regulating rapidly developing technologies. In conclusion, the paper argues that while flexibility is unavoidable when drafting law explicitly targeting such a swiftly moving and conceptually blurry field and concept as AI, it also entails trade-offs such as reduced legal predictability, which is concerning since predictability is essential for ensuring trust and legal certainty in the regulatory framework around this set of technologies.

Keywords: *AI Act, the pacing problem, legal certainty, legal flexibility, general purpose AI, delegated acts, harmonised standards*

1. Introduction and Purpose of the Study

Predictability is, on the one hand, since long a commonly emphasised essential feature of law. To uphold the principle of legality and legal certainty, legal scholars such as Alexander Peczenik state, predictability is one of the basic democratic values in and a state governed by legislation.⁴ Legal sociologists like Vilhelm Aubert have expressed that the ability to secure expectations is one of the five main tasks of law.⁵ In brief, the *fixity of norms*, to this school of thought, is key.

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⁴ Peczenik (1995), *Vad är Rätt?* pp. 89–90.

⁵ Aubert (1989, p. 62); see the American judge Richard Posner's description of legal “past-dependence” (2000).

On the other hand, in Europe and the Western world, there is an ongoing and more recent discourse regarding the dynamic between the demands for regulation and the opportunities and risks of technological innovation.⁶ This is often expressed as a *pacing problem*, at times linked to a trend of “future-proofing legislation”,⁷ i.e. there is a difference in the pace of development between regulation and technological innovation, which has led to proposals for more adaptive ways of governance.⁸ Simply put, when innovation is swift and law slow, the argument goes, law has to become more adaptive and anticipatory.⁹ Law, in this theoretical discourse, *needs to be flexible*.

In the case of artificial intelligence (AI), which is in focus for our scrutiny, these dynamics are particularly evident. Even though ethical issues surrounding AI have been widely discussed at least since 2017,¹⁰ and the European Commission's proposal for an AI regulation was published in April 2021,¹¹ a debate surrounding the regulation of AI has been particularly lively since the beginning of 2022. There are two main reasons behind this. First, AI models capable of generating texts, images and sounds – often referred to as generative AI – have reached a level of sophistication where they generate credible human-style expressions. Second, they have become highly accessible in everyday life, creating public awareness and considerable hype. This is perhaps most clearly symbolized by ChatGPT, released by Open AI on 30 November 2022, but it is only the tip of an iceberg of rapid development with major investments by all the major technology companies. Two months after Chat GPT went public, the service had 100 million unique visitors, indicating a speed that simultaneously raises questions about how AI development should be governed, in general, and how the European AI regulation can predictably handle the rapid pace of innovation, specifically.¹²

Concurrently, there have been calls for a moratorium on the development of large language models and a call for increased regulation of AI. Decisions regarding how to regulate AI will have significant consequences for AI development and application for a long time to come.

The *purpose of this paper* is to examine the tension between fixity and flexibility when regulating AI in Europe, by drawing on literature on the pacing problem, contrasted by sociolegal theory on the importance of predictability and legal certainty. Considering the emergence of so-called general-purpose AI and generative AI, we specifically analyse how the EU AI Act employs various mechanisms of flexibility, and analyse to what extent this come at the expense of predictability and legal certainty. The mechanisms of particular relevance are aspects of soft governance, both from the time before as well as *in* the AI Act, the use of delegated and implementing acts within the AI Act, as well as the harmonised standards to be developed. Furthermore, we noted the recently inserted Commission's power to issue decisions in certain cases relating to general purpose AI and the

⁶ Cf. Lyria Bennett Moses (2011) Agents of Change. How the Law ‘Copes’ with Technological Change, Griffith Law Review, 20:4, 763-794, DOI: 10.1080/10383441.2011.10854720; Herkert, J., Marchant, G., & Allenby, B. R. Eds. (2011). The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight: The Pacing Problem. The International Library of Ethics, Law and Technology. Springer. For an analysis of these dynamics in terms of “future-proofing legislation”, see Ranchordás & van ‘t Schip (2020).

⁷ Ranchordás & van ‘t Schip (2020).

⁸ Herkert et al. (2011).

⁹ cf. Nesta (2017).

¹⁰ cf. Jobin et al., 2019; Larsson et al., 2019; Larsson, 2020.

¹¹ COM(2021)206 final, 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.

¹² The Guardian, December 2, 2023.

thresholds for “systemic risks” which too is of interest within this theoretical framework.¹³ These four elements of the AI Act all illustrate, we argue, challenges associated with regulating rapidly developing technologies.

Given the timing of the regulation, that is yet not formally decided by the time of writing this, we base our analysis on a study of the process of developing the AI Act. This means that the material consists of the Commission’s proposal from April 2021, the Council’s from December 2022 and the Parliament’s from June 2023. These are complemented by on the one hand looking back to ethics guidelines and EU strategy on AI, and on the other the provisional agreement reached in the trilogue on December 9th, 2023 as well as the leaked version from January 23rd, 2024.

This contribution proceeds as follows. Section 2 of this article places the study in larger trend of AI governance and adds details to what it is that is on the move in the AI domain. The subsequent Section 3 develops the theoretical discourses mentioned in the introduction on predictability and legal certainty (fixation), on the one hand, and the calls for adaptive and anticipatory (flexibility) law following from a pacing problem, on the other. Section 4 applies this framework to the EU AI Act, and analyses to what extent the legislative or conceptual tools identified in Section 3 are used to achieve the EU lawmaker’s goal of protecting EU residents of harms without hindering innovation. Section 5 addresses the specific challenges that general purpose AI, including generative AI, pose for regulation and how the EU institutions have addressed them.

2. AI as a Moving Target, and Associated Legal Concerns

While ethical and legal concerns have been addressed around implications of AI and autonomous agents since even before the AI concept found its firmer grounding in the 1950s, the ethical concerns have been a topic of particular attention since at least around 2016.¹⁴ This principled development towards AI is also echoed in the EU, via a strategy from 2018,¹⁵ – often focusing on aspects of accountability, transparency and fairness¹⁶ – a coordinated plan¹⁷ the assembly of a high-level expert groups on AI that published Ethics Guidelines for Trustworthy AI¹⁸ with a subsequent White Paper on AI from the EU Commission in 2020.¹⁹

While development of AI capabilities and implemented innovation continuously have been paired with regulatory needs – possible misuses and emerging risks are often emphasised – there has, as

¹³ As per the leaked AI Act version, see below.

¹⁴ Cf. Jobin et al., 2019; Larsson, 2020.

¹⁵ European Commission (2018a). Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions: Artificial Intelligence for Europe, COM(2018) 237 final, Brussels: European Commission.

¹⁶ Cf. Larsson, S. (2019). The socio-legal relevance of artificial intelligence. *Droit et société*, 103(3), 573-593.

¹⁷ European Commission (2018b). Coordinated Plan on Artificial Intelligence (COM(2018) 795 final). See also Larsson, S., Bogusz, C. I., Schwarz, J. A., & Heintz, F. (2020). *Human-Centred AI in the EU: Trustworthiness as a strategic priority in the European Member States*. Stockholm: Fores and European Liberal Forum asbl.

¹⁸ AI HLEG (2019a). Ethics Guidelines for Trustworthy Artificial Intelligence, Brussels: European Commission; see also AI HLEG (2019b). Policy and Investment Recommendations for Trustworthy Artificial Intelligence, Brussels: European Commission.

¹⁹ European Commission (2020a). *White paper. On artificial intelligence — a European approach to excellence and trust*; COM(2021)206 final.

mentioned, been a seemingly strong leap in the field of publicly used language models (LLMs)²⁰ during 2023 (building on the capacity development in LLMs made by the breakthrough with the so-called the transformer architecture in 2017²¹). Although Chat GPT with its public launch in November 2022 stunned the world in terms of how quickly it was adopted by millions of users, it is only the tip of an iceberg of actors developing advanced AI models. It includes language models such as Meta's LLaMa, Google's Bard, Anthropic's chatbot Claude, Hugging Face's BLOOM or Chinese variants such as Huawei's PanGu- Σ or Baidu's Ernie 3.0 Titan.

The development has also prompted a conceptual development of direct relevance for the AI Act. Since the expressions generated by the AI models following from the transformer models began to extend far beyond text and language, a research group at Stanford University's Institute for Human-Centered Artificial Intelligence (HAI) proposed "foundation models" as a concept for models trained on broad sets of data and that can be adapted (e.g. fine-tuned) to a wide range of downstream tasks.²² Interestingly, the report was first published in August 2021, that is after the EU Commission's first proposal for an AI regulation, but the terminology surfaced in the European Parliament's proposal for the AI Act in June 2023. Interestingly, however, the leaked version of the AI Act from January 2024 does not mention the term "foundation models", and includes the concept of "generative AI" under the umbrella of general-purpose AI models²³.

Regardless, the development of these general purpose models and what has become referred to as generative AI has spurred what seems to be a new wave of policy guidelines that stresses the need to govern a set of highlighted challenges. This includes the report on *Initial policy considerations for generative artificial intelligence* from the OECD, concerned with aspects of mis- and disinformation, the lack of transparency when reproducing bias, as well as the more novel challenge of how to handle copyrighted content being used for training of foundation models.²⁴ Similar aspects are brought up by the World Economic Forum²⁵ and the ACM technology policy council.²⁶ Interestingly, the G7 published AI guidelines for a "Hiroshima process" for advanced AI systems²⁷ and a code of conduct for developer organisations in late October 2023, which is the same week that President Biden issued an Executive order on safe, secure and trustworthy artificial intelligence.²⁸ Echoing earlier concerns of automated systems' lack of transparency,²⁹ pointing to the problem of balancing interests in AI

²⁰ Or what may become more commonly called LMMs, that is, multi-modal models, which are likely to be more publicly accessible during 2024.

²¹ Vaswani, A., Shazeer, N., Parmar, N., Uszkoreit, J., Jones, L., Gomez, A. N., ... & Polosukhin, I. (2017). Attention is all you need. *Advances in neural information processing systems*, 30.

²² Bommasani, R., Hudson, D. A., Adeli, E., Altman, R., Arora, S., von Arx, S., ... & Liang, P. (2021). On the opportunities and risks of foundation models. *arXiv preprint arXiv:2108.07258*, p.

²³ See for instance Recital (60c) of the leaked AI Act version: "Large generative AI models are a typical example for a general-purpose AI model, given that they allow for flexible generation of content (such as in the form of text, audio, images or video) that can readily accommodate a wide range of distinctive tasks."

²⁴ OECD (2023) *Initial policy considerations for generative artificial intelligence*, OECD.

²⁵ World Economic Forum (juni 2023) *The Presidio Recommendations on Responsible Generative AI*. White Paper.

²⁶ ACM Technology Policy Council (juni 2023) *Principles for the development, deployment, and use of generative AI technologies*.

²⁷ G7 (30 October 2023). *Hiroshima Process International Guiding Principles for Advanced AI system*.

²⁸ The White House (30 October 2023) *FACT SHEET: President Biden Issues Executive Order on Safe, Secure, and Trustworthy Artificial Intelligence*.

²⁹ Pasquale, F. (2015). *The black box society: The secret algorithms that control money and information*. Harvard University Press.

transparency,³⁰ many of the governance ideas on how to handle concerns of generative AI revolves around transparency and documentation. This is also seen in the parliamentary version of the AI Act from June 2023, that proposed quite extensive transparency obligations for foundation models and development of generative AI systems. Interestingly, a research group at Stanford University assessed the compliance of these proposed transparency obligations for a set of the most relevant large-scale foundation models.³¹ They found that although many providers of foundation models list risks, relatively few disclose the constraints they implement and the impact of those constraints. Few providers in this assessment disclose any information about the copyright status of training data (incl. Open AI's GPT-4, Google's PaLM 2, and Meta's LLaMA), perhaps in part to make claims by rights holders more difficult. They also report inconsistently on carbon dioxide emissions from exercise or their strategies for measuring emissions.

3. Theoretical Framework on Fixity and flexibility in Governance

3.1. Fixity (The Rule of Law)

In much legal thought, there is a strong presence of fixity and predictability as a core essence in law. As mentioned, socio-legal scholars like Vilhelm Aubert³² and Alexander Peczenik³³ stress this. This section of the theoretical framework is mainly meant to serve this argument of predictability as being an essential part of law. Law that is not predictable, one can argue, can only problematically regulate a market. While legal certainty has been discussed at length in the literature and legal doctrine, we mainly focus aspects of predictability, which for example relates to non-retrospective lawmaking, and a certainty of law that is protected under the courts.³⁴

This should not for the analysis of the AI Act below be seen as a binary approach – that a regulation is either predictable or not – but as a continuum along which certain elements in a certain regulation can add to either predictability or less predictable but flexible functions. These various elements should then preferably be compared to both their consequences and the overarching aim of the regulation. We do however analytically use the notions of legal certainty and predictability as signifiers of fixity in law through which we then can compare more novel ideas of flexibility that arguably is needed for handling governance of technological change.

3.2. Flexibility (The Pacing Problem)

Evidently, also traditional civil law systems have elements of flexibility in how they interpret legal statutes in their practice. The fact that the Swedish Contracts Act (1915:218) from 1915 still functions for regulating the expression of intentions and what is to be considered reasonable procedure in concluding contracts is a good example of that, in light of the enormous difference in practices and technologies that have arisen since before the First World War until now. Despite this, the literature calling for even more adaptive types of governance and regulation for certain types of innovative fields has grown over the last few years.³⁵ Analyses have been made on anything from soft governance

³⁰ Larsson, S., & Heintz, F. (2020). Transparency in artificial intelligence. *Internet Policy Review*, 9(2).

³¹ Bommasani, R, Klyman, K, Zhang, D & Liang, P. (juni 2023) "Do Foundation Model Providers Comply with the Draft EU AI Act?" <https://crfm.stanford.edu/2023/06/15/eu-ai-act.html>

³² Aubert (1989).

³³ Peczenik, 1995, pp. 89–90.

³⁴ Cf. Popelier, P. (2000). Legal certainty and principles of proper law making. *Eur. JL Reform*, 2, 321.

³⁵ Cf. Bennett Moses (2011); Herkert et al. (2011);

over emerging technologies,³⁶ experimental regulation,³⁷ sandboxes,³⁸ co-regulation,³⁹ or models on how to “best address familiar forms of legal uncertainty in new sociolegal contexts”.⁴⁰ The last few years, there have been calls for emphasis on foresight or anticipation regulation and governance, for example, through *anticipatory governance*. Anticipatory governance, in the words of Ranchordás and van 't Schip,⁴¹ “places the emphasis on less rigid, less prescriptive instruments and prefers governance instruments that foster collaboration between policymakers and stakeholders, and are forward-looking rather than reactive”. Legal scholar Gregory Mandel, when analysing advancements in biotechnology, nanotechnology, and synthetic biology from a regulatory perspective, states that the “challenge is how to simultaneously leverage a promising technology’s anticipated benefits while guarding against its potential risks, particularly when the potential risks of the technology cannot be suitably understood until the technology develops further”.⁴² This is highly transferable to recent debates on generative AI and the development of the EU AI Act.

There are several ideas in the literature on pacing problems between law and innovation. Different forms of soft regulation, such as voluntary agreements, standardization processes or – something that has become common in the field of AI – principles-based guidelines have been broadly applied as a governance mechanism for emerging technologies. The purpose behind using soft law is to govern actions without the threat of enforcement, and while lacking legal effect, soft laws are intended to have normative significance.⁴³ Importantly, soft law instruments can be drafted more quickly without engaging in lengthy and complicated negotiations over new laws and regulations. However, soft governance mechanisms often interact with ‘hard law’, to the extent that even EU courts take soft laws into account.⁴⁴

While the normative significance of soft governance mechanisms cannot be disregarded, critics of soft law underline that voluntary frameworks lack of enforcement measures might not result in meaningful change, especially if there are economic incentives to disregard such frameworks. However, in some cases, supervisory authorities expect market actors to follow guidelines to demonstrate compliance with legal obligations, which is the case regarding the guidelines issued by the European Banking Authority.⁴⁵

³⁶ Hagemann, R., Huddleston Skees, J., & Thierer, A. (2018). Soft law for hard problems: The governance of emerging technologies in an uncertain future. *Colo. Tech. LJ*, 17, 37.

³⁷ Ranchordás, S. (2014). *Constitutional sunsets and experimental legislation: A comparative perspective*. Cheltenham: Edward Elgar.

³⁸ Ranchordás, S. (2021). Experimental Regulations and Regulatory Sandboxes: Law without Order? *Law and Method* 1–35.

³⁹ Marsden, C. (2022). Platform Law in Europe-Combating Digital Harms Through Co-Regulation. *경제 규제와 법*, 15(1), 34–66.

⁴⁰ Crotoft, Rebecca; och Ard, B.J. 2021. Structuring Techlaw. *Harvard Journal of Law & Technology*, 34(2): 347-417.

⁴¹ Ranchordás & van 't Schip (2020, p. 352).

⁴² Mandel, G. N. (2020). Regulating emerging technologies. In *Emerging Technologies* (pp. 361-378). Routledge, p. 75.

⁴³ Boyle, Alan. “Soft law in international law-making.” *International law* 5 (2014): 119-137.

⁴⁴ Stefan, Oana. “Hybridity before the Court: a Hard Look at Soft Law in the EU Competition and State Aid Case Law”(2012).“ *European Law Review* 37: 49.

⁴⁵ The Swedish Financial Supervisory Authority views EBA Guidelines as its own recommendations, which are not binding, but the regulated entities must follow these recommendations “using all available means”. [Genomförande av de europeiska tillsynsmyndigheternas riktlinjer och rekommendationer \(fi.se\)](https://www.sfi.se/om-sfi/utredningar-och-utskott/2021/2021-01-29-genomforande-av-de-europeiska-tillsynsmyndigheternas-riktlinjer-och-rekommendationer-fi-se)

In practice, soft governance is rarely the polar opposite of hard law, but governance measures exist on a scale ranging from pure self-regulation to top-down enforcement.⁴⁶ While the term ‘co-regulation’ is no longer actively used by the EU institutions,⁴⁷ it is a useful term for referring to self-regulatory mechanisms, such as codes of conduct or certifications, that are either approved by or supervised by supervisory authorities.

3.3. Advantages and Disadvantages of Different types of Flexibility Mechanisms

Our theoretical framework can be summarized by stating that the dynamic between innovation and regulation is both a multifaceted and very decisive field. Regulatory needs to manage both the distribution of opportunities and the countering of risks come with rapid development of potent technologies. On the one hand, the positive aspects can be fostered through a range of adaptive governance approaches, but somewhere along the continuum, flexibility turns into legal unpredictability with potentially significant negative effects – for both market participants and people affected by novel technologies.

4. Flexibility Mechanisms in the EU AI Act

One of the aims of the AI Act is to establish a “robust and flexible legal framework”.⁴⁸ The EU regulator has recognised that the AI Act needs to both provide legal certainty, as well as contain elements which would “enable it to be dynamically adapted as the technology evolves and new concerning situations emerge”.⁴⁹

In this section, we identify and analyse the various mechanisms of flexibility employed by the EU AI Act. Using the theoretical framework above, we evaluate how these mechanisms balance innovation and protection, and address the uncertainty and complexity of AI.

4.1. Soft Governance and European AI regulation

Some of the principled ideas expressed by the AI Act – particularly around transparency – can arguably not be fully understood without including the both global and European development of soft guidelines. This is for two main reasons: 1.) Much of the preparatory work before the Commission’s proposal from 2021 can be traced to the AI strategy and the ethics guidelines developed by the high-level expert group appointed by the Commission. This is also explicit in the AI Act proposals from the Parliament and the Council and the proposed final (leaked) AI Act. 2.) Aspects have been influenced by other organisations’ ways to define key concepts, such as the OECD, whose definition of AI became the final agreed definition of AI in the AI Act.

From a more overarching perspective on the soft governance mechanisms for AI governance, they have in general not been drafted with the purpose of providing more detail on how hard law should be applied to AI. Instead, and in general, guidelines and ethical principles have been drafted by

⁴⁶ Marsden, Christopher T. *Net neutrality: Towards a co-regulatory solution*. Bloomsbury Academic, 2010.

⁴⁷ The term appears to have been phased out after the better regulation communication in 2015, COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS Better regulation for better results - An EU agenda.

⁴⁸ AI Act Explanatory Memorandum, p. 3

⁴⁹ Ibid.

international organisations, states, public authorities and private companies.⁵⁰ However, they have had a normative impact nonetheless.⁵¹ Soft governance in terms of guidelines, often formulated in terms of ethics, has played a significant role in AI development and use over the last seven years.⁵² As mentioned above, a new wave of policy seems to have emerged in 2023 due to generative AI which is likely to have influenced the final stages of the interinstitutional trilogue. As mentioned, the principles and ethical guidelines for AI that have been developed have often focused on the need for better transparency and explainability, issues of accountability, the need for trustworthy applications and the importance of clearly addressing issues of fairness. The notion of a need for transparency to ensure a trustworthy development and implementation of foundation models and generative AI, for example, is evident in the Parliament's AI Act proposal, which served as one of the key points in the negotiations during trilogue, that finally was included in the AI Act.

However, a noteworthy example of soft governance tool used in the AI Act are the voluntary codes of conduct for AI systems other than high-risk, which would cover similar requirements as for high-risk AI systems. Following Article 69 AIA, drawing up of such codes of conduct will be “encouraged” by the AI Office⁵³ and Member States.

4.2. Adaptive Regulation

Delegated and Implementing Acts

An aspect of flexibility is the degree to which law-makers can delegate rulemaking to others, such as granting public authorities the power to issue regulations or ordinances that complement laws. At the EU level, such delegation takes place with reference to Articles 290 and 291 of the Treaty of the Functioning of the European Union (TFEU), granting the European Commission the power to issue delegated and implementing acts. Delegated acts are, per Article 290 TFEU, “non-legislative acts of general application” with the purpose of supplementing or amending certain “non-essential elements of the legislative act”. The legislative act must formally delegate this power to the Commission. Implementing acts, on the other hand, are issued when “uniform conditions for implementing legally binding Union acts are needed”,⁵⁴ and this includes a broader circle of acts than legislative acts.⁵⁵ For instance, the Commission may adopt delegated acts concerning the required technical documentation⁵⁶, and conformity assessment⁵⁷, while the implementing acts may be used by the Commission to adopt common specifications and issue requests to the EU standard-setting bodies (ESOs) to draft harmonised standards. In practice, however, it is difficult to decide whether an act

⁵⁰ Cf. Fjeld, J., Achten, N., Hilligoss, H., Nagy, A., & Srikumar, M. (2020). *Principled artificial intelligence: Mapping consensus in ethical and rights-based approaches to principles for AI*. Berkman Klein Center Research Publication.

⁵¹ Cf. Larsson, S. (2021) “AI in the EU: Ethical Guidelines as a Governance Tool”, in Bakardjieva Engelbrekt, Leijon, Michalski & Oxelheim (eds.) *The European Union and the Technology Shift*. Cham, Switzerland: Palgrave Macmillan.

⁵² See e.g. OECD.AI (2021), powered by EC/OECD (2021), database of national AI policies, accessed on 9/01/2024, <https://oecd.ai>.

⁵³ The leaked final AI Act.

⁵⁴ Article 291 (2) TFEU.

⁵⁵ Spasova, Romyana. (2021). Powers of the European Commission – delegated and implementing acts in practical terms. *ERA Forum* (2021) 22:507–521 <https://doi.org/10.1007/s12027-021-00677-3>.

⁵⁶ Article 11(3) AI Act

⁵⁷ Article 43 AI Act

should be a delegated act or an implementing act, as acts in general will always supplement legislation, although formally only delegated acts should do so.

The procedures leading to their adoption differ, where delegated acts enter into force if no objection has been expressed by the European Parliament or the Council within a time period specified in the legislative act, whereas implementing acts are adopted by the Commission (or, in exceptional cases, the Council) without the involvement of the co-legislators. However, the Member States control the Commission's exercise of implementing powers through comitology procedures. Craig has also raised that the Parliament and the Council will seek to maximize their control by endorsing the acts that grant them the most power to influence the contents of the act – the Council might favour categorising acts as implementing acts because member state representatives may provide detailed input into the measure, whereas the Parliament is more likely to prefer delegated acts as the Parliament has veto power over them.⁵⁸

A perusal of the various proposals for an AI regulation shows that so-called delegated acts and implementation acts seem to play a particularly important role in handling the definition of high-risk AI and for the regulation of multi-purpose AI and foundation models. Through the various proposals from the Commission, the Council and the Parliament, delegated acts seem to have been a way to deal with challenges of fluid concepts and genuine uncertainty. In Article 7 of the leaked final AI Act, the Commission is empowered to, by means of delegated acts, amend the list of techniques and approaches listed in Annex III specifying high-risk AI systems where both of the following conditions are fulfilled: that the AI systems are intended to be used in any of the *areas* listed in points 1 to 8 of Annex III, and that the AI systems “pose a risk of harm to health and safety, or an adverse impact on fundamental rights, and that risk is equivalent to or greater than the risk of harm or of adverse impact posed by the high-risk AI systems already referred to in Annex III. The areas listed in Annex III are the following: biometrics, critical infrastructure, education and vocational training, employment and worker management, access to essential services and benefits, law enforcement, migration and border control, and administration of justice and democratic processes. For example, under the list of employment-related high-risk AI, Annex III lists AI systems that are used for recruitment.

The list in Annex III determines to what extent an entity is covered by the rather arduous requirements in Chapter 2 of the AI Act. Whether or not an AI system is on this list is the difference between light-touch regulation and voluntary compliance and extremely rigorous risk management practices, data governance routines, and technical documentation, with compliance failures leading to administrative fines up to 3 % of the worldwide annual turnover of the company.

Moreover, in the leaked version of the final AI Act, the Commission's power to adopt delegated acts specified in Article 52a (3) is also significant with regard to the classification of general-purpose AI models (GPAI), including generative AI⁵⁹, as posing *systemic risk*. The Commission may amend the minimum thresholds of the so-called FLOPs,⁶⁰ rendering the GPAI be qualified as posing systemic risk (although following Article 52b (2), this presumption may be rebuttable in individual cases). Moreover, the Commission may in the same context supplement the “benchmarks and indicators in

⁵⁸ Craig, p. 675.

⁵⁹ Recital 60c

⁶⁰ Article 52a (2) specifies that the threshold for the classification of a general-purpose AI (including generative AI), as posing "systemic risk" is when the cumulative amount of compute used for its training measured in floating point operations (FLOPs) is greater than 10^{25} .

light of evolving technological developments”, specified in the AI Act, by pointing to the possibility of algorithmic improvements and increased hardware efficiency in the future.

This is of great interest from a legal certainty perspective. How open to future changes can one leave the definition of the object of regulation itself before the legal act becomes “too” unpredictable and legally insecure? From a market perspective, it is reasonable to ask how this may affect the strategies of technology developers that cannot be certain that their application is outside the scope of the high-risk category in a near future even if it currently is. While the Court of Justice of the European Union (CJEU) has ruled on the topic of the choice of legal instrument and essentially confirmed that the legislature is free to choose between the two types of acts as long as it respects the TFEU,⁶¹ the question regarding whether the legislature has in fact given the Commission too much power to determine the scope of a legislative act has not been addressed.

Furthermore, from an EU-legislative point of view it is interesting to scrutinize the boundaries of delegated acts. In a regulation focused on AI, to what extent can the definition of high-risk AI practices in that regulation be understood as a “non-essential element” of this legislation, as framed by Article 290 TFEU? Although it does not seem too likely, a delegation within a legislative act which does not merely grant the Commission to ‘amend and supplement non-essential elements’ would violate EU primary law, and it would be within the CJEU’s competences to annul the AI Act (or parts of it).⁶² Any affected party could, in principle, institute proceedings against the AI Act. The act must be both of direct and individual concern to the applicant.⁶³

Decisions of the Commission

Although the final version of the AI Act has not been officially published, the leaked version includes a new flexible element. The mandate of the Commission as regards the classification of the general-purpose AI (GPAI) model with systemic risk, including generative AI, seems to go beyond the delegated and implementing acts. In accordance with Article 52a (1)(b) of the leaked final AI Act, the Commission is empowered to make a decision in individual cases, which would designate a specific GPAI model as posing a systemic risk, even if it does not meet the cumulative amount of compute specified in Article 52a (2). The Commission has the same competence in cases when it becomes aware of a general-purpose AI model presenting systemic risks, which meets the criteria concerning the amount of FLOPs, and of which it has not been notified (Article 52b (1)). This power of the Commission seems to be a significant novelty in the AI Act, giving the Commission a powerful tool in designating the general-purpose AI models with systemic risks.

4.3. Harmonised Standards

Another important component of the AI Act facilitating its adaptation to the constantly evolving field of AI is the inclusion of *harmonised standards* within the governing framework. In contrast to other international standards (e.g. ISO, IEEE), harmonised standards are supported by the EU legislation and are developed by recognised European standard-setting organisations, namely European Committee for Standardization (CEN), European Committee for Electrotechnical Standardization (CENELEC), and European Telecommunications Standards Institute (ETSI). Unlike delegated and

⁶¹ Merijn Chamon, 'The dividing line between delegated and implementing acts, part two: The Court of Justice settles the issue in *Commission v. Parliament and Council (Visa reciprocity)*', (2015), 52, *Common Market Law Review*, Issue 6, pp. 1617-1633.

⁶² Article 263 of the TFEU. See Case C-378/00, *Commission of the European Communities v European Parliament and Council of the European Union* and Case C-21/94 *European Parliament v Council*.

⁶³ See Case C-486/01 *Front national v European Parliament* and Case C-25/62 *Plaumann v Commission*.

implementing acts characterised above, the primary function of harmonised standards is to provide an example of how the *essential requirements* outlined in the AI Act can be interpreted on a detailed, technical level. Once compliant with the relevant harmonised standards, a high-risk (or general-purpose⁶⁴) AI system carries the *presumption of conformity* with the AI Act. Although adherence to the AI Act harmonised standards will not be mandatory, AI providers are likely to heavily depend on them, as such technical specifications constitute a “safe bet” in interpreting the AI Act in practice.

Following a request of the Commission in 2022, CEN and CENELEC have started the preparatory works on the AI Act harmonised standards, which are expected to be in place by the time the AI Act becomes applicable⁶⁵. The standards will cover such areas as risk management, governance and quality of datasets, transparency and information provisions for users, human oversight, accuracy specifications and conformity assessment⁶⁶.

Although harmonised standards have been generally seen as successful in contributing to the establishment of the EU internal market⁶⁷, the increasing reliance on the technical standards as one of the central governance tools has faced notable criticism. While following EU harmonised standards is voluntary, their widespread adaptation has led to their growing role as substitutes for EU legislation in attaining policy objectives⁶⁸. This raises concerns due to the fact that harmonised standards are developed primarily by industry-driven, private organisations, and their decision-making processes are not transparent for other stakeholders, such as the civil society, SMEs, trade unions and consumer organisations⁶⁹. In the context of AI Act, many aspects of the harmonised standards mentioned above are likely to have a significant impact on fundamental rights⁷⁰ and other EU values⁷¹, which has given rise to further critique⁷². Moreover, given the ambiguous legal status of EU harmonised standards⁷³, the possibility to scrutinise the compatibility of the harmonised standards with binding EU laws by the CJEU remains unclear⁷⁴.

⁶⁴ As per the leaked AI Act version.

⁶⁵ Veale, M., & Borgesius, F. (2021).

⁶⁶ European Commission, Draft standardisation request to the European Standardisation Organisations in support of safe and trustworthy artificial intelligence

⁶⁷ Tovo, C. (2018). Judicial review of harmonized standards: Changing the paradigms of legality and legitimacy of private rulemaking under EU law. *Common Market Law Review*, 55(4), 1187–1216.

<https://doi.org/10.54648/COLA2018096>

Volpato A. (2017). The harmonized standards before the ECJ: James Elliott Construction. *Common Market Law Review*, 54(2), 591–603. <https://doi.org/10.54648/COLA2017036>

⁶⁸ Tovo

⁶⁹ The Commission has recognised this problem and called on the European standardisation organisations to “modernise their governance to fully represent the public interest and interests of SMEs, civil society and users and to facilitate access to standards.” (Commission Communication, 2022, p. 5). ”

⁷⁰ For instance, the rights to privacy, data protection, non-discrimination, human dignity, self-determination, the rights of a fair trial, freedom of expression and consumer protection.

⁷¹ It is noteworthy that in Article 40 (1c) of the leaked AI Act version the standard-setting bodies are encouraged to take into account “existing international standards in the field of AI that are consistent with Union values, fundamental rights and interests, and enhance multi-stakeholder governance ensuring a balanced representation of interests and effective participation of all relevant stakeholders”.

⁷² For instance, Vries, S. de, Kanevskaia, O., & Jager, R. de. (2023).

⁷³ Volpato (2017).

⁷⁴ See the debate concerning the “juridification” of EU harmonised standards, for instance, Volpato A. (2017), Tovo, C. (2018), Schepel, H. (2013), Medzmariashvili M. (2017).

In sum, while harmonised standards may seem somewhat inconspicuous in the AI Act, their role as a governance tool under the AI Act will be pivotal. As Veale notes, the CEN and CENELEC may be arguably seen as the most important actors within the AI Act implementation, even though they are not mentioned in the text.⁷⁵

5. Analysis: Between Regulatory Fixity and Flexibility in the EU AI Act

There is indeed both a long prehistory to what can be called experimental regulations, which can potentially be attractive to both regulators and innovators as they are intended to create a safe environment to foster innovation as there is a trend seen in the literature to govern emerging technologies in more anticipatory or “future-proof” ways.⁷⁶ Part of the expressed aim is to reduce what is sometimes described as a ‘regulatory burden’, improve communication between businesses and regulators, while promoting rapid regulatory decisions without putting consumers or markets at risk. Like Bennet Moses, Ranchordás has noted that innovation, in its more contemporary sense, is a regulatory moving target that does not fit well with traditional and primarily reactive legal frameworks. She has argued for the need to achieve *good timing* of regulatory initiatives in relation to innovation, including through temporary regulation.

The question of timing is certainly one of the key challenges for the EU lawmakers when it comes to AI regulation. On the one hand, many of the flexible elements of the AI Act are part of a broader trend in governance asking for foresight, anticipatory approaches and “future-proof” regulations.⁷⁷ On the other, the swift movements in both the underlying technological capabilities of AI as well as the market structures linked to them a challenge that in a sense forces the hand of the EU lawmakers to add less prescriptive elements to the AI Act. However, by doing so, the lawmakers to some degree push the limits for what is expected of law – particularly with regards to predictability. This seemingly have further implications from not only a legal certainty point of view, but also with regards to the separation of powers and the ideals of democratically supported lawmaking. While principle-based lawmaking can be usefully complemented with case law specifying how abstract legal concepts should be interpreted in practice, the AI Act is rather an example of quite detailed prescriptive rule-making that is in some respects open-ended, leaving key decision-making power to both the Commission and the standards institutions. This is a fraught exercise particularly in the EU, which suffers from what some commentators denote a ‘democratic deficit’.⁷⁸ By granting more definitional power to unelected EU officials the democratic deficit might grow even wider.

For example, the use of standards to be developed for ensuring compliance with high-risk AI alerts attention to democratic participation in setting up the standards. As the compliance instruments of harmonised standards are set to be developed, a question from this point of view would be who and what interests are de facto included in the development of standards.⁷⁹ Similarly, the delegated and implementing acts empower the Commission to both amend and supplement the AI Act, which in

⁷⁵ Veale, M., & Borgesius, F. (2021).

⁷⁶ Cf. Ranchordás & van 't Schip (2020).

⁷⁷ Cf. Ranchordás & van 't Schip (2020).

⁷⁸ Civil society organisations have been critical of extending technical standards to address fundamental rights, arguing that the decision on the degree to which technical standards comply with fundamental rights must be left to the democratic bodies of the EU or Member States, cf. BEUC (2021) *Regulating AI to Protect the Consumer, Position Paper on the AI Act*, 7.10.2021 in particular under 9 at 25, co-authored with ANEC, discussed by Micklitz, H.W. (2023) *The Role of Standards in Future EU Digital Policy Legislation. A Consumer Perspective*. ANEC & BEUC.

⁷⁹ Cf. Veale & Zuiderveen Borgesius (2021);

essence mean that the elected politicians set to represent the electorate are further removed from defining the material scope of the AI Act – arguably an essential element of any regulation.

From the perspective of legal certainty, the AI Act’s flexible elements can even prove challenging for developers and deployers of AI systems. For example, if the Commission indeed will be empowered to make a decision in individual cases, with regards to which specific GPAI models pose a systemic risk, it is hard to see how this discretionary power should align with principles of legal certainty. At worst, it tilts towards what has been discussed as retroactive law-making that of course can pose serious problems from a legal certainty perspective.⁸⁰ At the very least, this mandate to flexibly adapt to technological advancement, risks creating ad hoc classification of risks that are unpredictable.

Furthermore, many of the requirements placed on developers of high-risk AI systems are not easily complied with after an AI system has been developed and shipped – even if the delegated act becomes applicable a year or two after a new system has been listed as “high-risk”. For example, if due consideration was not given to data collection, labelling and general data governance as the AI system was being developed, it can be highly difficult or in some cases even impossible to fulfil the requirements of the AI Act.

While certain components of the AI Act are meant to be “future-proof”, still, the difficulty of designing even such basic legal benchmarks for the fast-developing AI technologies is a challenge. This has been showcased by the emergence of the large language models such as ChatGPT and other generative AI technologies after the legislative process of the AI Act had commenced, and which forced the EU law-makers to introduce substantial changes to the text within a year after the initial AI Act proposal.

The analysis of the AI Act through the lens of fixity/flexibility suggests that the EU lawmakers have attempted to reach a balance between the legal certainty while providing the possibilities to adapt the Regulation to the dynamically evolving landscape of AI technologies. While the fixed elements of the AI Act have been adopted jointly by the Commission, European Parliament and the Council, the flexible components of AI Act are to large extent governed by the Commission (in the form of delegated and implementing acts) and the standard-setting bodies CEN and CENELEC. Moreover, it is noteworthy that the leaked final AI Act includes another flexible element of AI Act in form of the Commission’s power to issue decisions qualifying a GPAI model as posing systemic risks. The impact of soft governance tools in the AI Act, such as voluntary codes of conduct, remains to be seen.

6. Conclusions

This contribution has analysed the AI Act from the perspective of fixity and flexibility, in how sociolegal theories of predictability and legal certainty interact with adaptive and experimental regulation of emerging technologies. The focus here has been on three elements of flexibility – the inclusion of completely voluntary measures, the delegation of definitional power to the Commission in the form of delegated and implementing acts, and the use of harmonised standards to demonstrate conformity with the requirements of the AI Act. We find that the use of delegated and implementing acts risk introducing an element of uncertainty that may pose challenges from a predictability point of view. Further, both delegated/implementing acts and the use of harmonised standards provide non-

Retroactive law, according to Popelier (2000, p. 333) “lays down, for the future, new consequences which are difficult to avoid, even though the facts of the case have already occurred”.

elected officials with additional powers to shape both the requirements of the AI Act as well as how it should be interpreted – a task typically left to the courts.

While the different proposals of the regulation clearly indicate a transition regarding the general purpose AI regulation as a response to innovative developments in the field of AI, the final text is to be seen by the time of making this analysis. The tiered approach to “foundation models”, seen in the provisional agreement in early December 2023 seems to remain but under the umbrella of GPAI, judging from the leaked draft from January 2024. Nevertheless, the EU AI Act expresses a mix of prescriptive and anticipatory law-making in response to a technological field that from a governance perspective is a moving target. There is without doubt a need to further scrutinize the principled implications of introducing rather open-ended “future-proof” elements of technology governance in general, and dimensions of how power shifts through delegated and implementing acts, as well as how issues of representation are handled in the development of harmonised standards.

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References

- ACM Technology Policy Council (June 2023) Principles for the development, deployment, and use of generative AI technologies.
- AI HLEG (2019a). Ethics Guidelines for Trustworthy Artificial Intelligence, Brussels: European Commission.
- AI HLEG (2019b). Policy and Investment Recommendations for Trustworthy Artificial Intelligence, Brussels: European Commission.
- Aubert, V. (1989) *Continuity and Development in Law and Society*. Oslo: Norwegian University Press.
- Bar-Siman-Tov, I. (2018). Temporary legislation, better regulation, and experimentalist governance: An empirical study. *Regulation & Governance*, 12, 192-219.
- BEUC (2021) *Regulating AI to Protect the Consumer, Position Paper on the AI Act*, 7.10.2021, co-authored with ANEC.
- Bommasani, R, Klyman, K, Zhang, D & Liang, P. (June 2023) “Do Foundation Model Providers Comply with the Draft EU AI Act?” <https://crfm.stanford.edu/2023/06/15/eu-ai-act.html>
- Buckley, R. P., Arner, D. W., Veidt, R. & Zetsche, D. A. (2019). Building FinTech ecosystems: Regulatory sandboxes, innovation hubs and beyond. *Washington University Journal of Law and Policy*, 61, 55–56. doi:10.2139/ssrn.3455872.
- Crootof, Rebecca & Ard, B.J. (2021). Structuring Techlaw. *Harvard Journal of Law & Technology*, 34(2): 347-417.

- European Commission (2018a). Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions: Artificial Intelligence for Europe, COM(2018) 237 final, Brussels: European Commission.
- European Commission (2018b). Coordinated Plan on Artificial Intelligence (COM(2018) 795 final).
- European Commission (2020a). *White paper. On artificial intelligence — a European approach to excellence and trust.*
- European Commission (2022a). Draft standardisation request to the European Standardisation Organisations in support of safe and trustworthy artificial intelligence.
<https://ec.europa.eu/docsroom/documents/52376?locale=en>
- European Commission (2022b). Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions: An EU Strategy on Standardisation Setting global standards in support of a resilient, green and digital EU single market, COM(2022) 31 final, Brussels: European Commission
- European Council. (2020). Conclusions on Regulatory Sandboxes and Experimentation Clauses as tools for an innovation-friendly, future-proof and resilient regulatory framework that masters disruptive challenges in the digital age. OJ C 447/1.
- Fjeld, J., Achten, N., Hilligoss, H., Nagy, A., & Srikumar, M. (2020). *Principled artificial intelligence: Mapping consensus in ethical and rights-based approaches to principles for AI.* Berkman Klein Center Research Publication.
- G7 (30 October 2023). Hiroshima Process International Guiding Principles for Advanced AI system.
- G7 (30 October 2023) Hiroshima Process International Code of Conduct for Advanced AI Systems.
- Herkert, J., Marchant, G., & Allenby, B. R. Eds. (2011). *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight: The Pacing Problem.* The International Library of Ethics, Law and Technology. Springer.
- Hagemann, R., Huddleston Skees, J., & Thierer, A. (2018). Soft law for hard problems: The governance of emerging technologies in an uncertain future. *Colo. Tech. LJ*, 17, 37.
- Jobin, A., Ienca, M., & Vayena, E. (2019). The global landscape of AI ethics guidelines. *Nature machine intelligence*, 1(9), 389-399.
- Knight, B. R. & Mitchell, T. E. (2020). The sandbox paradox: Balancing the need to facilitate innovation with the risk of regulatory privilege. *South Carolina Law Review*, 72(2), 445–476.
- Larsson, S. (2019). The socio-legal relevance of artificial intelligence. *Droit et société*, 103(3), 573-593.
- Larsson, S. (2020). On the governance of artificial intelligence through ethics guidelines. *Asian Journal of Law and Society*, 7(3), 437-451.
- Larsson, S. (2021) “AI in the EU: Ethical Guidelines as a Governance Tool”, in Bakardjieva Engelbrekt, Leijon, Michalski & Oxelheim (eds.) *The European Union and the Technology Shift.* Cham, Switzerland: Palgrave Macmillan.

- Larsson, S., Anneroth, M., Felländer, A., Felländer-Tsai, L., Heintz, F., & Ångström, R. C. (2019). Sustainable AI: An inventory of the state of knowledge of ethical, social, and legal challenges related to artificial intelligence.
- Larsson, S., Bogusz, C. I., Schwarz, J. A., & Heintz, F. (2020). *Human-Centred AI in the EU: Trustworthiness as a strategic priority in the European Member States*. Stockholm: Fores and European Liberal Forum asbl.
- Larsson, S., & Heintz, F. (2020). Transparency in artificial intelligence. *Internet Policy Review*, 9(2).
- Lyria Bennett Moses (2011) Agents of Change. How the Law ‘Copes’ with Technological Change, *Griffith Law Review*, 20:4, 763-794, DOI: 10.1080/10383441.2011.10854720
- Mandel, G. N. (2020). Regulating emerging technologies. In *Emerging Technologies* (pp. 361-378). Routledge.
- Marsden, Christopher T. *Net neutrality: Towards a co-regulatory solution*. Bloomsbury Academic, 2010.
- Marsden, C. (2022). Platform Law in Europe-Combating Digital Harms Through Co-Regulation. *경제규제와 법*, 15(1), 34–66.
- Medzmariashvili M. (2017). A Harmonised European (technical) Standard-Provision of EU Law! (Judgment in C-613/14 James Elliott Construction) – European Law Blog. <https://europeanlawblog.eu/2017/01/24/a-harmonised-european-technical-standard-provision-of-eu-law-judgment-in-c-61314-james-elliott-construction/>
- Micklitz, H.W. (2023) *The Role of Standards in Future EU Digital Policy Legislation. A Consumer Perspective*. ANEC & BEUC.
- Nesta (2017). *A Working Model for Anticipatory Regulation*. London: Nesta. https://media.nesta.org.uk/documents/working_model_for_anticipatory_regulation_0.pdf
- OECD (2023) *Initial policy considerations for generative artificial intelligence*, OECD.
- Pasquale, F. (2015). *The black box society: The secret algorithms that control money and information*. Harvard University Press.
- Peczenik, A. (1995) *Vad är rätt? Om demokrati, rättssäkerhet, etik och juridisk argumentation*. Stockholm: Fritzes.
- Popelier, P. (2000). Legal certainty and principles of proper law making. *Eur. JL Reform*, 2, 321.
- Posner, R.A. (2000) Past-Dependency, Pragmatism, and a Critique of History in Adjudication and Legal Scholarship. *67 University of Chicago Law Review* 573.
- Ranchordás, S. (2014). *Constitutional sunsets and experimental legislation: A comparative perspective*. Cheltenham: Edward Elgar.
- Ranchordas, S. (2021). Experimental Regulations and Regulatory Sandboxes: Law without Order? *Law and Method* 1–35.
- Ranchordás, S., & van't Schip, M. (2020). “Future-proofing legislation for the digital age”. In Ranchordás & Roznai, Y. (eds) *Time, Law, and Change. An Interdisciplinary Study*. Hart Publishing.
- Schepel, H. (2013). The New Approach to the New Approach: The Juridification of Harmonized Standards in EU Law. 20–24.

- Vaswani, A., Shazeer, N., Parmar, N., Uszkoreit, J., Jones, L., Gomez, A. N., ... & Polosukhin, I. (2017). Attention is all you need. *Advances in neural information processing systems*, 30.
- Veale, M., & Zuiderveen Borgesius, F. (2021). Demystifying the Draft EU Artificial Intelligence Act — Analysing the good, the bad, and the unclear elements of the proposed approach. *Computer Law Review International*, 22(4), 97–112. <https://doi.org/10.9785/cri-2021-220402>
- The White House (30 October 2023) FACT SHEET: President Biden Issues Executive Order on Safe, Secure, and Trustworthy Artificial Intelligence.
- Tovo, C. (2018). Judicial review of harmonized standards: Changing the paradigms of legality and legitimacy of private rulemaking under EU law. *Common Market Law Review*, 55(4), 1187–1216. <https://doi.org/10.54648/COLA2018096>
- Volpato A. (2017). The harmonized standards before the ECJ: James Elliott Construction. *Common Market Law Review*, 54(2), 591–603. <https://doi.org/10.54648/COLA2017036>
- Vries, S. de, Kanevskaia, O., & Jager, R. de. (2023). Internal Market 3.0: The Old “New Approach” for Harmonising AI Regulation. *European Papers*, 2023 8(2), 583–610. <https://doi.org/10.15166/2499-8249/677>
- World Economic Forum (June 2023) The Presidio Recommendations on Responsible Generative AI. White Paper.